

J U N E 2 0 1 8

REPORT TO THE CONGRESS

Medicare and the Health Care Delivery System

MEDpAC Medicare
Payment Advisory
Commission

MEDPAC

Medicare
Payment Advisory
Commission

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program. In addition to advising the Congress on payments to health plans participating in the Medicare Advantage program and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission’s 17 members bring diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts, who typically have backgrounds in economics, health policy, and public health.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. (Meeting transcripts are available at www.medpac.gov.) Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and the Centers for Medicare & Medicaid Services (CMS), health care researchers, health care providers, and beneficiary advocates.

Two reports—issued in March and June each year—are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

REPORT TO THE CONGRESS

Medicare and the
Health Care
Delivery System

MEDPAC Medicare
Payment Advisory
Commission

425 I Street, NW • Suite 701 • Washington, DC 20001
(202) 220-3700 • Fax: (202) 220-3759 • www.medpac.gov



425 I Street, NW • Suite 701
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Francis J. Crosson, M.D., Chairman
Jon Christianson, Ph.D., Vice Chairman
James E. Mathews, Ph.D., Executive Director

June 15, 2018

The Honorable Michael R. Pence
President of the Senate
U.S. Capitol
Washington, DC 20510

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
U.S. Capitol
Room H-232
Washington, DC 20515

Dear Mr. President and Mr. Speaker:

I am pleased to submit the Medicare Payment Advisory Commission's June 2018 *Report to the Congress: Medicare and the Health Care Delivery System*. This report fulfills the Commission's legislative mandate to evaluate Medicare payment issues and to make recommendations to the Congress.

In the 10 chapters of this report, we consider:

- the effects of the Hospital Readmissions Reduction Program.
- using payment to ensure appropriate access to and use of hospital emergency department services.
- rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services.
- paying for sequential stays in a unified prospective payment system for post-acute care.
- encouraging Medicare beneficiaries to use higher quality post-acute care providers.
- issues in Medicare's medical device payment policies.
- applying the Commission's principles for measuring quality to population-based measures and hospital quality incentives.
- recent performance of and long-term issues confronting Medicare accountable care organizations.
- managed care plans for dual-eligible beneficiaries.
- Medicare coverage policy and use of low-value care.

Page 2

I hope you find this report useful as the Congress continues to grapple with the difficult task of controlling the growth of Medicare spending while preserving beneficiaries' access to high-quality care and providing sufficient payment for efficient providers.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive style.

Francis J. Crosson, M.D.

Enclosure

Acknowledgments

This report was prepared with the assistance of many people. Their support was key as the Commission considered policy issues and worked toward consensus.

Despite a heavy workload, staff members of the Centers for Medicare & Medicaid Services and the Department of Health and Human Services were particularly helpful during preparation of the report. We thank Susan Bogasky, Tim Engelhardt, Kate Goodrich, Ryan Howe, Joel Kaiser, Pauline Lapin, Paul Moore, John Pilotte, Suzanne Seagrave, Tiffany Swygert, Tamara Syrek-Jenson, Donald Thompson, and Marie E. Vasbinder.

The Commission also received valuable insights and assistance from others in government, industry, and the research community who generously offered their time and knowledge. They include Peter Bach, Kirstin Blom, Cristina Boccuti, David Certner, Mike Cheek, Mike Chernew, James Cosgrove, Akin Demehin, Al Dobson, Bill Dombi, Laura Dummit, Tom Fise, Greg Fonarow, Erin Giovannetti, Charles Haley, Vivian Ho, Gretchen Jacobson, Joanna Kim, Kathy King, Jennifer Kowalski, Harlan Krumholz, Miriam Laugesen, Christine Aguiar

Lynch, Don May, Sharon McIlrath, Michael McWilliams, Farzad Mostashari, Ann O'Hare, Andrew Ryan, Thomas Ryan, Sherry Smith, Steve Speil, Aaron Tripp, and Carolyn Zollar.

Once again, the programmers at Social and Scientific Systems provided highly capable assistance to Commission staff. In particular, we appreciate the hard work of Michael Brown, Po-Lun Chou, Daksha Damera, Darya Leyzarovich, Sravani Mallela, Sane Maphunghong, Shelley Mullins, Lorena Ortiz, Cindy Saiontz-Martinez, and Susan Tian. In particular, this year, the Commission wishes to acknowledge Mary Beth Spittel, who in 2018 left Social and Scientific Systems after nearly 15 years of service—the full duration of which she managed the Commission's analytic and data support portfolio. She has been an essential partner in the conduct of our work; she will be missed tremendously, and we wish her well in her new endeavors.

Finally, the Commission wishes to thank Hannah Fein, Mary Gawlik, and Melissa Lux for their help in editing and producing this report. ■

Table of contents

Acknowledgments	v
Executive summary	xi
Chapters	
1 Mandated report: The effects of the Hospital Readmissions Reduction Program	3
Background	7
Prior research on the effects of the HRRP	9
Our methodology for evaluating the HRRP effects	12
Results	14
Policy implications	26
2 Using payment to ensure appropriate access to and use of hospital emergency department services	35
Background	39
Rural areas: Maintaining access to emergency department services	46
Urban areas: Incentives have led to an abundance of urban stand-alone EDs	53
Future analyses	58
3 Rebalancing Medicare’s physician fee schedule toward ambulatory evaluation and management services	65
Background on the fee schedule for physician and other health professional services	69
Ambulatory E&M services are underpriced relative to other services	70
An approach to rebalance the fee schedule toward ambulatory E&M services	79
Conclusion	82
4 Paying for sequential stays in a unified prospective payment system for post-acute care	87
Background	91
Challenges with paying for sequential post-acute care stays	91
Summary of the proposed PAC PPS design	92
Definition of sequential PAC stays	93
Characteristics of sequential PAC stays	93
PAC PPS payments need to align with the cost of stays throughout a sequence of post-acute care	98
Defining the beginning and end of stays when treating in place	101
Conclusion	105
5 Encouraging Medicare beneficiaries to use higher quality post-acute care providers	111
Introduction	115
Beneficiaries seeking PAC often have many PAC options that vary substantially in quality	115
Patients referred to PAC need assistance to identify better quality providers	117
Principles for improving hospital discharge planning	121
Approaches for identifying higher quality PAC providers	123
Conclusion	126

6	Issues in Medicare’s medical device payment policies	133
	Introduction	137
	DMEPOS background	137
	Non-CBP DMEPOS products	145
	Policy options to improve the accuracy of Medicare’s payment rates for non-CBP DMEPOS products and protect beneficiaries	153
	Physician-owned distributors	158
	Conclusion	165
7	Applying the Commission’s principles for measuring quality: Population-based measures and hospital quality incentives	175
	Introduction	179
	Applying the Commission’s principles for measuring quality to population-based measures	179
	Applying the Commission’s principles for measuring quality to hospital quality incentives	189
8	Medicare accountable care organization models: Recent performance and long-term issues	211
	Introduction	215
	Background on ACOs	215
	ACO quality and financial performance relative to CMS-designed benchmarks	218
	ACO quality and financial performance results according to other researchers	226
	New tools to allow ACOs to manage care	229
	Long-term issues for Medicare ACOs	230
	Conclusion	237
9	Managed care plans for dual-eligible beneficiaries	243
	Introduction	245
	Background on dual-eligible beneficiaries	245
	Update on the financial alignment demonstration	246
	More states are using Medicaid managed care for dual eligibles	264
	Medicare plans that serve dual eligibles differ in key respects	266
	Potential policies to encourage the development of integrated plans	276
	Conclusion	283
10	Medicare coverage policy and use of low-value care	293
	Primer on Medicare coverage policy	297
	Evidence of low-value care	310
	Tools for addressing low-value care	334
	Conclusion	349
	Appendix A Commissioners’ voting on recommendations	367
	Acronyms	371
	More about MedPAC	
	Commission members	377
	Commissioners’ biographies	379
	Commission staff	383

Executive summary

Executive summary

As part of its mandate from the Congress, each June the Commission reports on refinements to Medicare payment systems and issues affecting the Medicare program, including broader changes in health care delivery and the market for health care services. In the 10 chapters of this report we consider:

- ***The effects of the Hospital Readmissions Reduction Program.*** In this mandated report, we conclude that the Hospital Readmissions Reduction Program contributed to a significant decline in readmission rates without causing a material increase in emergency department (ED) visits or observation stays or an adverse effect on mortality rates.
- ***Using payment to ensure appropriate access to and use of hospital emergency department services.*** To reduce the risk of ED services being undersupplied in rural areas and oversupplied in urban areas, we recommend two changes to Medicare payment for ED services.
- ***Rebalancing Medicare’s physician fee schedule toward ambulatory evaluation and management services.*** We describe a budget-neutral approach to rebalance the fee schedule that would increase payment rates for ambulatory evaluation and management services while reducing payment rates for other services.
- ***Paying for sequential stays in a unified prospective payment system for post-acute care.*** We consider refinements to a unified post-acute care (PAC) prospective payment system, focusing on increasing the accuracy of payment for cases that involve a course of PAC care—that is, sequential stays.
- ***Encouraging Medicare beneficiaries to use higher quality post-acute care providers.*** We discuss increasing the use of higher quality PAC providers. At discharge from an inpatient stay, the selection of a provider within a PAC category can be crucial because the quality of care varies widely among providers.
- ***Issues in Medicare’s medical device payment policies.*** We explore ways to improve Medicare’s payment policies for durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies. We also address how to constrain the risks posed by physician-owned distributors by making them more transparent to beneficiaries, enforcement agencies, and others.
- ***Applying the Commission’s principles for measuring quality: Population-based measures and hospital quality incentives.*** We formalize the Commission’s quality principles and apply them to two population-based outcome measures that may be used to evaluate quality of care for different populations. We also apply the principles to the design of a new hospital quality incentive program that combines measures of hospital outcomes, patient experience, and Medicare spending per beneficiary.
- ***Medicare accountable care organization models: Recent performance and long-term issues.*** We review the current Medicare accountable care organization (ACO) models and look at ACO performance on cost and quality thus far. Based on this review, we raise six issues that are important for two-sided-risk ACOs in the long term.
- ***Managed care plans for dual-eligible beneficiaries.*** We consider three potential policies to encourage the development of plans that integrate care for individuals who receive both Medicare and Medicaid (known as dual-eligible beneficiaries).
- ***Medicare coverage policy and use of low-value care.*** We find that the fee-for-service coverage process does not prevent the use of low-value services and that the use of such services is prevalent in Medicare. We describe six tools that Medicare could consider to reduce the use of low-value care.

Mandated report: The effects of the Hospital Readmissions Reduction Program

To encourage hospitals to reduce preventable readmissions, CMS began to publicly report hospitals’ readmission rates for three conditions in 2009. In 2010, the Congress added a financial incentive to reduce readmission rates when it enacted legislation providing for the Hospital Readmissions Reduction Program (HRRP). At the same time, the Congress funded programs to help hospitals improve care transitions and reduce preventable readmissions. The end goal of reducing hospital readmissions is to relieve Medicare beneficiaries of the burden of returning to the hospital and to relieve taxpayers of the cost of unnecessary readmissions.

In the 21st Century Cures Act of 2016, Congress mandated that the Commission evaluate whether the recent declines in readmission rates were associated with offsetting increases in observation stays and ED visits. In Chapter 1, we first conclude that HRRP did indeed reduce readmission rates. We then consider the question in the mandate and, finally, evaluate whether hospitals that lowered their readmission rates saw an increase in mortality rates.

Hospitals' response to the HRRP has contributed to a large decline in readmissions since 2010, with the greatest declines being in conditions initially covered by the program (acute myocardial infarction (AMI), heart failure, and pneumonia). We measured the change in readmission rates from 2010 to 2016 and found that raw (not risk-adjusted) readmission rates fell by 3.0 percentage points for AMI, 2.2 percentage points for heart failure, and 1.7 percentage points for pneumonia, compared with 0.7 percentage points on average across conditions not covered by the program. Our analyses support the conclusion that the HRRP led to fewer readmissions.

- The rate of decline in *raw* readmission rates for heart failure and pneumonia and in *risk-adjusted* readmission rates for heart failure were faster by a statistically significant amount after HRRP's enactment (2010 to 2016) than in prior years.
- Raw and risk-adjusted readmission rates declined faster, on average, for conditions covered by the program than for other conditions. The difference is statistically significant.

After the reduction in readmission rates, some researchers expressed concerns that the lower rates may have induced an increase in observation stays or ED use. Our analysis found the following:

- Observation stays increased at a slightly faster rate after introduction of the HRRP. However, the increase in observation stays was small and offset only a small share of the reduction in readmissions. Therefore, we conclude that the reduction in readmission rates reflects real changes in practice patterns and not simply a shifting of short-stay admissions into observation stays to avoid readmission penalties. We also found similar rates of increase in observation stays among patients without a recent admission.

- ED visits increased after introduction of the HRRP. However, this increase appears to be due primarily to reasons other than the HRRP.

Some researchers have raised the question of whether efforts to reduce avoidable readmissions have also reduced necessary readmissions, resulting in higher mortality for heart failure patients. We examined readmission and mortality changes from 2010 to 2016. Our measure of mortality includes deaths that occurred during the hospital stay and within 30 days after discharge. We found no evidence to suggest that the readmission policy on net had a negative effect on mortality. To the extent that there was a small effect, our data as a whole suggest the HRRP may have done more to improve than harm mortality rates.

In summary, the HRRP gave hospitals an incentive to reduce inappropriate readmissions. After implementation of the HRRP, readmission rates declined, and our analysis suggests the decline was in part due to the HRRP. Beneficiaries endured fewer readmissions to the hospital, without an increase in risk-adjusted mortality. While the HRRP may have contributed slightly to the secular trend of increasing observation and ED use, the small increases in costs were far outweighed by reduced readmissions costs. (The decline in readmissions across all conditions resulted in net savings to the Medicare program of roughly \$1.5 billion per year.)

Using payment to ensure appropriate access to and use of hospital emergency department services

Medicare's payment policies should foster adequate access to care and encourage efficient delivery of services. Maintaining access to ED services can be a challenge in remote rural areas, where a single hospital may be the sole source of ED care. If that hospital closes, access to emergency care can be lost. In contrast, efficiency can be a challenge in urban areas, where EDs can be in oversupply. New urban stand-alone EDs could result in patients being treated at higher cost EDs rather than lower cost urgent care facilities and physician offices. These facilities also could siphon off lower acuity patients from on-campus hospital-based EDs. To reduce the risk of ED services being undersupplied in rural areas and oversupplied in urban areas, in Chapter 2, we recommend two changes to Medicare payment for ED services.

Maintaining access to ED services can be challenging in isolated rural areas with low population densities.

Hospitals in many isolated rural areas have seen the number of inpatient cases fall dramatically; many hospitals now average less than one inpatient admission per day. However, Medicare will pay a facility for emergency services only if it maintains inpatient services. Therefore, small isolated communities that want an ED must maintain a low-occupancy inpatient department in the hospital.

As an alternative to maintaining empty inpatient beds, the Commission recommends a new payment model that would allow Medicare to pay for emergency services at outpatient-only hospitals in isolated rural areas (more than 35 miles from another ED). Isolated rural full-service hospitals that choose to convert to outpatient-only hospitals would receive the same standard prospective payment rates for ED visits as a full-service hospital. In addition, a set annual payment (common across all outpatient-only hospitals) would be made to help cover the facility's fixed costs.

The new payment option would allow rural communities that cannot support a full-service hospital to maintain access to emergency care in their community while retaining the option to convert back to a full-service hospital if circumstances changed. The recommendation would increase Medicare spending by less than \$50 million per year.

Conversely, an oversupply of EDs can be a problem in urban areas. Urban hospitals can set up stand-alone EDs that bill Medicare as if they are part of the hospital's main ED as long as those EDs are located within 35 miles of the main hospital campus. We refer to these facilities as off-campus EDs (OCEDs). The number of OCEDs has increased rapidly in recent years, particularly in areas with high household incomes. The number of ED visits and the share of visits with high coded severity levels also have increased. Under Medicare's current payment system, providers have an incentive to add new OCEDs rather than urgent care centers, which are paid less than half the hospital ED rates.

Patients who seek care at OCEDs appear to have less complex care needs than those of patients served at on-campus hospital EDs. Ambulance operators typically take trauma, stroke, and heart attack patients to on-campus hospital EDs, which provide trauma services, operating rooms, and inpatient services. OCEDs do not incur the standby costs of these resource-intensive services. While urban OCEDs may provide some services not available at doctors' offices and urgent care centers, we conclude that

Medicare overpays these facilities relative to what is paid to on-campus hospital EDs for more difficult cases.

Medicare currently has two levels of payments for OCEDs. One is for EDs open 24 hours a day, 7 days a week (Type A payment rates), and the other is for EDs open less than 24 hours a day, 7 days a week (Type B payment rates). In 2018, Type B payment rates are roughly 30 percent lower than Type A rates. The Commission recommends that Medicare pay urban OCEDs the Type A payment rates reduced by 30 percent—which would better align payments with costs and make off-campus ED rates similar to Type B rates. An exception would be needed for the one-quarter of urban OCEDs located relatively far (more than six miles) from on-campus EDs and that are more likely to provide unique access to ED services for their local communities (other exceptions could be contemplated when an urban OCED is essential to retain access—for example, if the OCED is the result of its parent hospital closing). Paying these more isolated urban OCEDs the full Type A payment rates would be justified to ensure continued appropriate access to emergency services. This recommendation also would reduce cost sharing for Medicare beneficiaries served at OCEDs close to on-campus EDs. Overall, this policy would reduce the financial incentive to develop new OCEDs and would lower Medicare spending by between \$50 million and \$250 million annually.

Rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services

The Commission is concerned that ambulatory evaluation and management (E&M) services, such as clinician office and hospital outpatient visits, are underpriced in the Medicare fee schedule for physicians and other health professionals ("the fee schedule") relative to other services such as procedures. CMS has made incremental efforts to review potentially mispriced services over the last several years, but there is evidence that certain types of services are still overpriced. CMS's lack of current, accurate, and objective data on clinician work time and practice expenses is a key reason the review process has been inadequate. Under the fee schedule's budget-neutrality rules, the relative prices for ambulatory E&M services are too low because the prices for other services have become artificially high. We call this process "passive devaluation."

In Chapter 3, we describe a budget-neutral approach for rebalancing the fee schedule that would increase payment

rates for ambulatory E&M services while reducing payment rates for other services (e.g., procedures, imaging, and tests). Under this approach, the increased payment rates would apply to ambulatory E&M services provided by all clinicians. For illustration, we modeled the impact of a 10 percent increase in the payment rate for ambulatory E&M services (higher or lower increases could be considered). A 10 percent increase would raise annual spending for ambulatory E&M services by \$2.4 billion. To maintain budget neutrality, payment rates for all other fee schedule services would be reduced by 3.8 percent.

Certain specialties would receive a large increase in their total fee schedule payments (on net) as a result of this change. The three specialties that would receive the highest proportional increases in payments are endocrinology, rheumatology, and family practice. Other specialties—including diagnostic radiology, pathology, physical therapy, and occupational therapy—would experience reductions in their fee schedule payments of about 3.8 percent because they provide very few ambulatory E&M services.

This change would be a one-time adjustment to the fee schedule to address several years of passive devaluation of ambulatory E&M services. Even if this approach is adopted, we urge CMS to accelerate its efforts to improve the accuracy of the fee schedule by developing a better mechanism to identify overpriced services and adjust their payment rates. If successful, these efforts would improve the accuracy of prices for ambulatory E&M and other services going forward and could reduce the need for future significant adjustments to the prices of E&M services. Together, these actions will help reduce the risk of beneficiaries experiencing problems accessing these services and will send a more positive signal to medical students and residents contemplating careers in specialties that provide large shares of these services.

Paying for sequential stays in a unified prospective payment system for post-acute care

Medicare uses separate prospective payment systems (PPSs) to pay for stays in each of the four PAC settings—skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). As a result, Medicare’s fee-for-service (FFS) payments can differ substantially for similar patients treated in different settings. As mandated

by the Congress, in June 2016, the Commission evaluated a prototype design and concluded that it was feasible to design a unified PAC PPS that spans the four settings and bases payments on patient characteristics. In June 2017, the Commission recommended that a unified PAC PPS be implemented beginning in 2021 with a three-year transition and a corresponding alignment of setting-specific regulatory requirements.

In Chapter 4, we consider a refinement to the unified PAC PPS that would increase the accuracy of payment for cases that involve a course of PAC care—that is, sequential stays, which we define as PAC stays within seven days of each other. We evaluate two payment issues related to sequential stays. The first has to do with the way the cost of a stay can vary, depending on where it falls in a sequence of PAC stays. The second involves how to identify, for payment purposes, distinct phases of care for a PAC provider that treats a patient “in place” as care needs evolve rather than refers the patient to another PAC provider. Under the unified PAC PPS, such providers would be financially disadvantaged unless the payment system included a way to trigger payments for different phases of care.

Our analysis of sequential PAC stays found different patterns of costs relative to estimated PAC PPS payments for home health stays and institutional PAC stays. For home health stays, payments under the unified PAC PPS would decrease over the course of a sequence of stays, but the cost of stays would decline more. These results suggest that payments for home health care need a separate downward adjustment for later stays, similar to the adjustment used in the current HHA PPS. By contrast, PAC PPS payments for institutional stays would remain reasonably well aligned with the cost of stays throughout a sequence of care.

However, under its current design, the prototype PAC PPS would not be able to appropriately pay a PAC provider that offered a range of PAC services and was able to treat in place beneficiaries with evolving care needs. For payment purposes, Medicare will need to define when one “stay” or phase of care ends and the next one begins. Otherwise, with only one admission and discharge date, providers would receive only one payment, creating a financial disincentive to treat in place.

Of the approaches we examined, the most promising involves episode-based payments; that is, Medicare would make a single payment for all post-acute care provided

during an episode of PAC. Payment could be made to a hospital, a health system, the PAC provider where the episode starts, an ACO, or a third-party convener that assumes financial risk for the episode. Under this approach, Medicare would not need to define and set payments for subsequent stays because the entity would be paid for the PAC provided during the episode, regardless of how many stays were encompassed.

The Commission will continue to explore episode-based payments over the coming year. Shifting the unit of service from a stay to an episode would change certain incentives (most notably the incentive to initiate subsequent PAC stays), but the most important features of a PAC PPS would remain: correcting the biases of the current PPSs and increasing the equity of payments across all types of stays so that providers have less incentive to selectively admit certain beneficiaries over others. In the meantime, CMS should proceed with implementing a stay-based unified PAC PPS.

Encouraging Medicare beneficiaries to use higher quality post-acute care providers

About 40 percent of Medicare acute inpatient hospital discharges result in use of PAC. Ensuring that the patient is served by the appropriate type of PAC provider is critical, but the selection of a provider within a PAC category can also be crucial because the quality of care varies widely among providers. In Chapter 5, we discuss increasing the use of higher quality PAC providers.

Medicare discharge planning regulations place the responsibility on hospitals for connecting acute hospital inpatients with their options for PAC—including educating beneficiaries about their choices and facilitating access to PAC when necessary. But hospitals are limited in the assistance they can provide. Although they are required to provide beneficiaries who need PAC with a list of nearby SNFs and HHAs, Medicare regulations prohibit hospitals from recommending specific PAC providers.

Beneficiaries report that they value quality of care and that they prefer PAC providers that are close to their home or family. The Improving Medicare Post-Acute Care Transformation Act of 2014 requires hospitals to include quality data when informing beneficiaries about their options, but CMS has yet to finalize the regulations implementing this requirement. Medicare has developed consumer-oriented websites that provide information on the quality of SNFs and HHAs, but many studies

have concluded that these efforts have not significantly increased the use of higher quality PAC providers.

Our analysis of referral patterns of Medicare beneficiaries who were sent to SNFs and HHAs indicates that many beneficiaries had another nearby provider that offered better quality, though not all of the higher quality providers may have had available capacity. For example, over 94 percent of beneficiaries who used HHA or SNF services had at least one provider within a 15-mile radius that was of higher quality than the provider that served them.

Helping beneficiaries to identify better quality PAC providers should be a goal in a reformed discharge planning process, and authorizing hospital discharge planners to recommend specific higher quality PAC providers would further this goal. However, several design decisions would need to be resolved. First, a consistent approach to identifying better quality PAC providers would be needed, and quality standards would need to be transparent for PAC providers and beneficiaries. Second, policies would be needed to safeguard against potential conflicts of interest that could ensue from the authority to recommend specific providers.

Regardless of the approach selected to encourage the use of higher quality PAC providers, beneficiaries should retain freedom of choice. Beneficiaries may have important concerns that are not necessarily reflected in standard quality measures, such as language competency or proximity to family members. These preferences may lead them to select a PAC provider that has lower performance on some quality measures, but additional quality information would allow them to better understand the nature of their options and any trade-offs.

Medicare's options for expanding the authority of discharge planners to recommend higher quality PAC providers range from prescriptive approaches that provide specific metrics or definitions that hospitals must use to more flexible approaches that leave key decisions to discharge planners. A hybrid approach could blend these two methods and specify certain selection criteria that hospitals would need to use while granting hospitals discretion in the application of these criteria.

Issues in Medicare's medical device payment policies

In Chapter 6, we explore two distinct topics related to medical devices. First, we look at ways to improve Medicare's payment policies for durable medical equipment, prosthetic devices, prosthetics, orthotics,

and supplies (DMEPOS). Second, we examine ways to constrain the risks posed by physician-owned distributors (PODs) and to make them more transparent to beneficiaries, enforcement agencies, and others.

Medicare beneficiaries rely on DMEPOS products to treat their illness or injury and to allow them to remain in their homes, as opposed to seeking care in an institutional setting. DMEPOS comprises a large array of products that vary in cost and complexity, ranging from complex power wheelchairs to diabetes testing supplies to knee braces.

Pursuant to a statutory requirement, CMS implemented the DMEPOS Competitive Bidding Program (CBP) to use market competition to set payment rates and limit fraud and abuse, while ensuring beneficiaries retain access to needed DMEPOS products. The CBP began in 2011 with some of the highest cost and highest volume DMEPOS products in nine large urban areas. Over time, the CBP has added products and expanded geographically. The CBP has successfully driven down the cost of DMEPOS products for the Medicare program and beneficiaries. Compared with payment rates in the year before the CBP, Medicare's payment rates for some of the highest expenditure DMEPOS products have fallen by an average of roughly 50 percent.

At the same time, Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow. By 2015, nearly half of all Medicare expenditures on DMEPOS products were for products excluded from the CBP. Medicare pays for these products using a fee schedule that is largely based on supplier charges from 1986 to 1987 (updated for inflation) and undiscounted list prices. Medicare's payment rates for the top 10 non-CBP DMEPOS products in 2015 were a third higher, on average, than private-payer rates for comparable products, and some non-CBP DMEPOS products continue to generate high rates of improper payments and utilization growth and to exhibit patterns of potential fraud and abuse.

To address these issues, additional products that are not currently competitively bid could be moved into the CBP. We also observe that the participation and balance billing rules for DMEPOS products and suppliers could be strengthened to better protect beneficiaries and better align those policies with many other Part B services.

PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-

owners perform on their own patients. PODs have the ability to distort the supply chain for medical devices—potentially resulting in an increase in the volume of surgeries performed on beneficiaries, higher costs for hospitals and the Medicare program, and inappropriate care.

The Commission questions the value PODs produce for the Medicare program and beneficiaries. We suggest several ways in which Medicare and policymakers can constrain the risks posed by PODs. We discuss two specific options to revise the Stark law (which is intended to prohibit physicians from referring Medicare beneficiaries to certain health care facilities in which they have a financial interest) and several key topics for policymakers to consider if such changes are made. While the options likely would limit the use of PODs, some PODs might continue to operate, even if the Stark law were modified. In addition, the Commission supports increasing the transparency of POD-physician relationships by requiring all PODs to report under the Open Payments program, a program designed to shed light on financial ties between physicians and certain industries.

Applying the Commission's principles for measuring quality: Population-based measures and hospital quality incentives

The Commission has recommended that Medicare link payment to the quality of care to reward accountable entities and providers for offering high-quality care to beneficiaries. In Chapter 7, the Commission formalizes a set of principles for measuring quality in the Medicare program. Overall, quality measurement should be patient oriented, encourage coordination, and promote delivery system change. Medicare quality incentive programs should use a small set of population-based measures (e.g., outcomes, patient experience, value) to assess quality of care for populations served by Medicare Advantage (MA) plans, ACOs, FFS in market areas, hospitals, groups of clinicians, and other providers. Medicare quality incentive programs should score these risk-adjusted, population-based measure results against absolute performance thresholds and then use peer grouping to determine payment adjustments based on the provider's quality performance. In Chapter 7, we first apply the Commission's principles to two population-based outcome measures (potentially preventable admissions and home and community days) that may be used to evaluate quality of care for different populations. Next, we apply the principles to the design of a new hospital quality incentive

program that combines measures of hospital outcomes, patient experience, and Medicare spending per beneficiary.

Potentially preventable admissions (PPAs) constitute an important quality measure because hospitalizations for conditions such as diabetes and pneumonia can potentially be preventable if ambulatory care is provided in a timely and effective manner. We calculated the observed rate of PPAs per 1,000 FFS beneficiaries for both chronic and acute conditions. We found that observed (that is, not risk adjusted) PPA rates varied across population groups and across market areas and hospital service areas. This variation signals opportunities to improve the quality of care within areas and the potential to use the measure to compare quality across local health care markets. However, more development is needed to incorporate risk adjustment based on FFS data in the analysis.

The Commission also tested a prototype home and community days (HCDs) measure to assess how well health care markets and organizations that take responsibility for a population keep people alive and out of health care institutions. The HCD measure is defined as 365 days minus the sum of days a beneficiary spends in certain institutional and ambulatory health care settings coupled with mortality days. However, because of the limited variation in HCDs over market areas and the challenges posed by the need to develop appropriate weights for constructing the composite measure, the Commission questions the immediate utility of the HCD measure in its current form to assess market-level FFS performance.

We also examined the potential to create a single quality-based payment program for hospitals to replace the four current hospital payment incentive programs Medicare uses: the Hospital Inpatient Quality Reporting Program, Hospital Readmissions Reduction Program, Hospital-Acquired Condition Reduction Program, and Hospital Value-based Purchasing. The Commission is concerned that these overlapping hospital quality payment and reporting programs create unneeded complexity in the Medicare program.

Ideally, the Congress could redesign the multiple hospital quality payment programs under a single hospital value incentive program (HVIP) that would be patient oriented, encourage coordination across providers and time, and promote change in the delivery system. It also would account for social risk factors by adjusting payment through peer grouping. Based on these principles, we

modeled an HVIP in which quality-based payments are distributed to hospitals organized into 10 peer groups, with awards funded by a payment withhold from all hospitals.

Under our HVIP model, relative to the withhold, about half of hospitals would receive a negative payment adjustment, and about half would receive a positive adjustment. Our peer grouping of hospitals allowed us to examine how hospitals serving large shares of low-income patients perform. We found that, compared with the existing quality payment programs, the HVIP approach makes more equitable payment adjustments among hospitals that serve different populations. Over the next year, the Commission plans to continue to design an HVIP that conforms with our principles for quality measurement. Some topics the Commission will further explore include weighting of measures, withhold values, patient experience measures, and patient safety measures.

Medicare accountable care organization models: Recent performance and long-term issues

Medicare ACOs were created to help moderate the growth in Medicare spending and improve quality of care for beneficiaries by giving providers greater responsibility for costs and quality. In Chapter 8, we first review the current Medicare ACO models and look at their performance on cost and quality. We find that some models—predominantly two-sided models at risk for both savings and losses—are producing small savings relative to the benchmarks set by CMS, and all are maintaining or improving quality. Spending relative to benchmarks is important because it determines which ACOs will receive “shared savings” bonuses. However, some have observed that benchmarks are not necessarily the best measure of what spending would have been in the absence of the ACO and thus may not be a good measure of true program savings. We review the literature on this question and conclude that ACOs may have been saving Medicare 1 percent to 2 percent more than indicated by their performance relative to benchmarks, and that two-sided ACO models appear to save more than one-sided ACO models.

In light of evidence indicating that two-sided ACOs tend to generate greater savings than one-sided ACOs, we consider six issues that need to be resolved if two-sided ACOs are going to be part of the Medicare program in the long term:

- ***Are hospitals viable participants in ACOs?*** We find that, despite the apparent conflict in incentives, hospitals may still want to participate in ACOs because most savings for ACOs to date stem from reduction in the use of post-acute care and not from reductions in inpatient care.
- ***Should asymmetric models be continued?*** Asymmetric models—models with greater opportunities for savings than losses—could be one strategy to help ACOs transition to two-sided risk. The Commission will monitor the current asymmetric ACO models to determine whether aspects of them should be extended.
- ***How should benchmarks be set initially and rebased for subsequent agreement periods?*** The basic ACO model essentially sets benchmarks as a function of historical spending for beneficiaries who would have been attributed to the ACO in the past. In subsequent agreement periods, ACOs must continuously improve over their own past performance to achieve savings, which can create diminishing returns for consistently successful ACOs and potentially discourage long-term participation. We discuss this issue and others related to benchmarking, and then highlight other benchmarking approaches.
- ***Should the 5 percent bonus for clinicians in advanced alternative payment models (A-APMs) be distributed differently to encourage A-APM participation?*** Under current law, clinicians receive a 5 percent bonus on all of their physician fee schedule (PFS) payments if they exceed a threshold level on payments or patients in A-APMs. Moving to a system in which clinicians receive a 5 percent bonus with certainty on their share of PFS payments derived from an A-APM could make the incentive more equitable and encourage participation in two-sided ACOs.
- ***What will be the relationship between specialists and two-sided ACOs?*** We find that currently there are a substantial number of specialists on the participant lists of ACOs. ACOs may include specialists as a way to more effectively coordinate the care of their beneficiaries, and specialists may join ACOs to receive referrals and potentially share in savings.
- ***Are two-sided ACOs a long-term option in the Medicare program?*** Some maintain that ACOs are one way for providers to take greater accountability for

a group of patients and then transition toward taking full accountability as an MA plan. We have found in previous work that ACOs can be the low-cost option in some areas of the country, and their advantage of lower administrative costs could make them a long-term option if benchmarks are set equitably.

Managed care plans for dual-eligible beneficiaries

Individuals who receive both Medicare and Medicaid (known as dual-eligible beneficiaries) often have complex health needs but are at risk of receiving fragmented or low-quality care because of the challenges in obtaining care from two distinct programs. Many observers have argued that the two programs could be better integrated by developing managed care plans that provide both Medicare and Medicaid services. Supporters argue that integrated plans would improve quality and reduce federal and state spending because they would have stronger incentives to coordinate care than either program has when acting on its own. However, these plans have been difficult to develop, and only 8 percent of full-benefit dual-eligible beneficiaries are now enrolled in a plan with a high level of Medicare and Medicaid integration. In Chapter 9, we examine the use of integrated plans and consider three potential policies that would encourage the development of highly integrated plans.

Since 2013, CMS and 10 states have tested the use of integrated Medicare–Medicaid Plans (MMPs) as part of the financial alignment demonstration. There are limited data available on the demonstration’s effects on quality, service use, and cost because the evaluations of the demonstration are taking longer to complete than expected. However, the information available is generally positive. Although the individual demonstrations often have been difficult to implement, enrollment now appears stable (although participation is lower than many expected), and quality appears to be improving.

The demonstration is part of a broader effort by many states to use Medicaid managed care to provide long-term services and supports (LTSS), such as nursing home care and personal care. Between 2004 and 2018, the number of states with managed LTSS programs grew rapidly from 8 to 24, and more states likely will develop similar programs in the future. The growing use of managed care to provide LTSS—which account for most of Medicaid’s spending on dual eligibles—means that, in many states, the development of health plans that provide both Medicare

and Medicaid services is probably the most feasible approach for pursuing closer integration.

Medicare now has four types of plans that serve dual eligibles: the demonstration's MMPs, MA dual-eligible special needs plans (D-SNPs), fully integrated dual-eligible SNPs (FIDE SNPs), and the Program of All-Inclusive Care for the Elderly. There are significant differences among these plans in several key areas, such as their level of integration with Medicaid, ability to use passive enrollment, and payment methodology. In addition, allowing MMPs and D-SNPs to operate in the same market has been problematic in some states because competition between the plans has reduced enrollment in the more highly integrated MMPs. Policy changes to better define the respective roles of each type of plan or consolidate plans in some fashion may be needed.

Three potential policies that would encourage the development of integrated plans are (1) limiting how often dual-eligible beneficiaries can change their coverage, (2) limiting enrollment in D-SNPs to dual eligibles who receive full Medicaid benefits, and (3) expanding the use of passive enrollment, particularly when beneficiaries first qualify for Medicare. Collectively, these policies would improve care coordination and continuity of care, require D-SNPs to focus on the dual eligibles who stand to benefit the most from integrated care, and encourage more dual eligibles to enroll in plans with higher levels of Medicare–Medicaid integration.

Medicare coverage policy and use of low-value care

Some researchers contend that there is substantial use of low-value care—care that has little or no clinical benefit or care in which the risk of harm from the service outweighs its potential benefit—in the Medicare program. Many new services disseminate quickly into routine medical care in FFS Medicare with little or no basis for knowing whether they outperform existing treatments.

In Chapter 10, we review the coverage processes used in FFS Medicare and MA plans and by Part D sponsors. Medicare covers many items and services without the need for an explicit coverage policy. When an explicit coverage policy is required, some services do not show that they are better than existing covered services. Coverage policies often are based on little evidence and usually do not include an explicit consideration of a service's cost-effectiveness or value relative to existing treatment options. As a result, the coverage process does not prevent

the use of low-value services. MA plans are permitted to use tools that are not widely used in FFS Medicare, such as requiring prior authorization to have a service covered and using variable levels of cost sharing. Part D plan sponsors are responsible for creating and managing formularies, which are lists of drugs their plans cover. By contrast, Medicare FFS lacks the flexibility to use formularies for drugs covered by Part B.

Our review of the literature on low-value care reveals that such care is prevalent across FFS Medicare, Medicaid, and commercial insurance plans. Evidence suggests that the amount of low-value care within a geographic area appears to be more a function of local practice patterns than payer type. We analyzed selected low-value services in FFS Medicare using 31 evidence-based measures developed by a team of researchers. In 2014, there were between 34 and 72 instances of low-value care per 100 beneficiaries—depending on whether we used a narrow or broad version of each measure—and annual Medicare spending for these services ranged from \$2.4 billion to \$6.5 billion. The spending estimates are conservative because they do not reflect the downstream cost of low-value services. We also conducted three case studies on care of potentially low value in FFS Medicare: the trend in starting dialysis earlier in the course of chronic kidney disease, proton beam therapy, and H.P. Acthar Gel[®] (a drug covered under Part D).

Last, we identified six tools that Medicare could consider using to address the use of low-value care.

- Expanding prior authorization, which requires providers to obtain approval from a plan or payer before delivering a product or service, could help reduce certain types of low-value care.
- Implementing clinician decision support and provider education could decrease low-value care, and studies show that these tools have reduced inappropriate prescribing of antibiotics.
- Increasing cost sharing for low-value services has the potential to reduce their use. Although Medicare does not currently do so, other health plans and payers have raised cost sharing for targeted low-value services, and an evaluation of one program found that it reduced the use of these services.
- Establishing new payment models that hold providers accountable for the cost and quality of care—such as

ACOs—creates incentives for organizations to reduce low-value services.

- Revisiting coverage determinations on an ongoing basis has the potential to both decrease use of low-value services and result in the development of more rigorous clinical evidence.
- Linking information about the comparative clinical effectiveness and cost-effectiveness of health care

services to FFS coverage and payment policies has the potential to improve the value of Medicare spending. Medicare's coverage process considers, but does not require, comparative clinical effectiveness evidence, and the program's rate-setting processes generally do not consider such evidence. For most items and services, Medicare lacks statutory authority to consider evidence on cost-effectiveness in either the coverage or payment processes. ■

C H A P T E R

1

**Mandated report:
The effects of the
Hospital Readmissions
Reduction Program**

Mandated report: The effects of the Hospital Readmissions Reduction Program

Chapter summary

To encourage hospitals to reduce preventable readmissions, CMS began to publicly report hospital-level readmission rates for acute myocardial infarction (AMI), heart failure, and pneumonia in 2009. In 2010, the Congress added a financial incentive to reduce readmission rates when it enacted legislation providing for the Hospital Readmissions Reduction Program (HRRP). The HRRP reduced Medicare payment rates by up to 3 percent for hospitals with above-average readmission rates for these three conditions. At this same time, the Congress also funded programs to help hospitals improve care transitions and reduce preventable readmissions. The end goal of preventing hospital readmissions is to relieve Medicare beneficiaries of the burden of returning to the hospital and to relieve taxpayers of the cost of unnecessary readmissions.

In recent years, hospital administrators have reported that the HRRP has had a “great impact” on their efforts to reduce readmissions (Joynt et al. 2016). These efforts contributed to a large decline in readmissions since 2010, with the greatest declines in conditions initially covered by the policy (AMI, heart failure, and pneumonia). We measured the change in readmission rates from 2010 to 2016 and found that raw (not risk-adjusted) readmission rates fell by 3.0 percentage points for AMI, 2.2 percentage points for heart failure, 1.7 percentage points for pneumonia, and 0.7 percentage points on average across conditions not covered by the program. To evaluate whether the HRRP led to reduced readmission rates, we conducted a series of longitudinal and

In this chapter

- Background
- Prior research on the effects of the HRRP
- Our methodology for evaluating the HRRP effects
- Results
- Policy implications

cross-sectional analyses of both raw and risk-adjusted readmission rates. Taken as a whole, our analyses suggest that the HRRP did contribute to the decline in readmission rates. The evidence supporting the conclusion that the HRRP led to fewer readmissions includes the following:

- The rate of decline in *raw* readmission rates for heart failure and pneumonia was faster by a statistically significant amount after HRRP's enactment (2010 to 2016) than in prior years.
- The rate of decline in *risk-adjusted* readmission rates for heart failure was faster by a statistically significant amount after the HRRP's enactment (2010 to 2016) than during prior years. Risk-adjusted pneumonia and AMI readmission rates also declined faster during the 2010 to 2016 period compared with prior years. However, the difference is not consistently statistically significant across different methods of testing.
- Raw readmission rates declined faster, on average, for conditions covered by the program (combining all five conditions in effect in 2016) compared with other conditions. The difference is statistically significant.
- Risk-adjusted readmission rates declined slightly faster for HRRP conditions than for non-HRRP conditions. The difference is also statistically significant.
- In addition, a study found that readmission rates declined faster for hospitals covered by the policy than for critical access hospitals not covered by the policy (Ibrahim et al. 2017).

After the reduction in readmission rates, some researchers expressed concerns that reduced readmission rates may have induced an increase in observation stays or emergency department (ED) use. In the 21st Century Cures Act of 2016, the Congress mandated that the Commission evaluate whether the recent declines in readmission rates were associated with offsetting increases in observation stays and emergency room visits. Our analysis found the following:

- Observation stays increased at a slightly faster rate after introduction of the HRRP. However, the increase in observation stays was small and offset only a small share of the reduction in readmissions. Therefore, we conclude that the reduction in readmission rates reflects real changes in practice patterns and not simply a shifting of short-stay admissions into observation stays to avoid readmission penalties. We also found that patients *without* a recent admission had similar rates of increase in observation stays. The broad-based increase in observation use (including for those without a recent admission) could in part reflect the initiation of the recovery audit contractor reviews of admissions starting in 2010. Therefore, we could not determine conclusively whether the small increase in observation stays was due to the HRRP or to other factors.

- ED visits increased after introduction of the HRRP. However, this increase appears to be due primarily to reasons other than the HRRP. To investigate what share might have been driven by the HRRP, we first compared changes in postdischarge ED use for conditions covered by the HRRP and those not covered by the program. The increases in postdischarge ED use were similar for conditions covered by the HRRP (1.9 percent) compared to non-HRRP conditions (2.1 percent). We also compared ED-visit growth for beneficiaries with a recent discharge from a hospital with those growth rates for beneficiaries without a recent hospital discharge. The ED growth rates were approximately equal, and the share of all ED visits that were postdischarge visits was essentially the same in 2010 and 2016 (4.61 percent versus 4.66 percent). Therefore, it appears that the growth in emergency room visits was a broad phenomenon and cannot be primarily attributed to growth in postdischarge ED visits.

Some researchers have raised the question of whether efforts to reduce avoidable readmissions have also reduced necessary readmissions, resulting in higher mortality for heart failure patients. The literature is mixed on this question. One recent study reports a slight nationwide increase in 30-day postdischarge mortality rates for heart failure from 2010 to 2014. The study did not examine in-hospital mortality. Because this period of time coincided with the introduction of the HRRP and because readmission penalties are large relative to mortality penalties in the Medicare program, the study's authors suggested the HRRP may have caused the increase in mortality (Gupta et al. 2017). However, it is not known whether the increase in heart failure mortality reported was caused by the HRRP or other factors, or whether it reflected an increase in patient severity that was not fully reflected by the measure's risk adjustment model. A separate study used the hospital as the unit of analysis and found that reductions in heart failure readmissions were not correlated with increases in heart failure mortality. It concluded that the HRRP did not cause the increase in heart failure mortality from 2010 to 2014 (Dharmarajan et al. 2017).

Using more recent data, we examined readmission and mortality changes from 2010 to 2016. Our measure used a combined inpatient and post-acute mortality. Our findings, which follow, suggest that the HRRP did not negatively affect mortality:

- Although raw rates of heart failure mortality increased (as has been reported), raw rates of pneumonia and AMI mortality decreased rapidly after the HRRP was passed. On average, raw rates of mortality declined across HRRP-covered conditions. In contrast, on average, raw rates of mortality increased across non-HRRP conditions.

- On a risk-adjusted basis, mortality rates declined for all three HRRP-covered conditions from 2010 to 2016. The combination of an increase in the raw rate of heart failure mortality per discharge and a decline in the risk-adjusted rate may be explained by an increase in the severity of illness for those beneficiaries admitted for heart failure. While the reported increase in severity of illness may in part reflect greater coding intensity, we believe some of the increase in reported severity is real given the large decline in admissions per capita and the reduced share of cases that were one-day stays. During the 2010 to 2016 period, initial hospital admissions for heart failure per capita fell by 14 percent, which implies that practice patterns changed to treat the less severely ill patients on an outpatient basis.
- Our hospital-level analysis also found a slight positive correlation between declining readmission rates and declining mortality across all three conditions, meaning that hospitals with larger than average improvements in readmissions also had larger than average improvements in mortality.

Taken together, we find no compelling evidence to suggest that the readmission reduction policy has had a negative effect on mortality. To the extent that there is a small effect, our data as a whole suggest the HRRP may have done more to improve than harm mortality rates.

In summary, the HRRP gave hospitals an incentive to reduce inappropriate readmissions. Readmission rates declined, and our analysis suggests the decline was in part due to the HRRP. Beneficiaries had to endure fewer readmissions to the hospital, and patient mortality did not increase because of the HRRP. While the HRRP may have contributed slightly to the secular trend of increasing observation use and ED use, the small increases in costs were far outweighed by reduced costs of readmissions. The decline in readmissions across all conditions resulted in net savings to the Medicare program of roughly \$1.5 billion per year by 2016. We conclude that the HRRP contributed to a decline in readmission rates without causing a material increase in ED visits, a material increase in observation stays, or a net adverse effect on mortality rates.

While the HRRP has largely been successful, that does not mean that hospitals' financial incentives cannot be improved. In Chapter 7 of this report, we discuss redesigning Medicare's quality improvement programs for hospitals into a single hospital value incentive program that would balance readmission reduction and mortality reduction incentives across conditions, account for patient experience, and adjust penalties to account for the fact that some hospitals serve larger shares of low-income Medicare beneficiaries. The Commission expects to continue to discuss potential changes to hospitals' financial incentives in the Medicare program over the next year. ■

Congressional mandate for this study

The Medicare Payment Advisory Commission shall conduct a study to review overall hospital readmissions described in Section 1886(q)(5)(E) of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)) and

whether such readmissions are related to any changes in outpatient and emergency services furnished. The Commission shall submit to Congress a report on such study in its report to Congress in June 2018. ■

Background

In 2008, the Commission reported on the need for hospitals, physicians, and post-acute care providers to improve care transitions and coordination across settings (Medicare Payment Advisory Commission 2008). One goal of improved care transitions is to reduce preventable readmissions. Unnecessary readmissions can pose risks of iatrogenic infections, medication errors, muscle weakening, and pressure injuries such as decubitus ulcers. According to researchers at the Centers for Disease Control and Prevention, health care–associated infections in hospitals are a significant cause of morbidity and mortality in the United States (Klevens et al. 2007). In addition, the inpatient environment itself can lead to a reduction in elderly patients’ independence as they cope with functional loss that can stem from extended bed rest.

To create an incentive for hospitals to improve care transitions, the Commission’s June 2008 report recommended publicly reporting readmission rates and reducing payment rates to hospitals with relatively high readmission rates (Medicare Payment Advisory Commission 2008). In the following year, CMS started to publicly report hospital-level readmission rates, and a series of articles documented high levels of readmissions to U.S. hospitals and discussed programs to reduce readmission rates (Jack et al. 2009, Jencks et al. 2009, Kanaan 2009). In 2010, the Congress enacted the Patient Protection and Affordable Care Act (PPACA), which provided for the Hospital Readmissions Reduction Program (HRRP). Under this program, hospitals could be penalized (starting in fiscal year 2013) if their readmission rates for certain specified conditions were above the national average.

After enactment of the readmission reduction program, many studies found that readmission rates declined

(Birmingham and Oglesby 2018, Cary et al. 2018, Ibrahim et al. 2017, Medicare Payment Advisory Commission 2016, Zuckerman et al. 2016). While there is a general consensus that readmission rates have declined, some have questioned whether the readmission reduction program has led to increases in substitute modes of care, such as observation stays and emergency department (ED) visits (Himmelstein and Woolhandler 2015). Others have suggested too many readmissions were avoided, resulting in increased mortality.

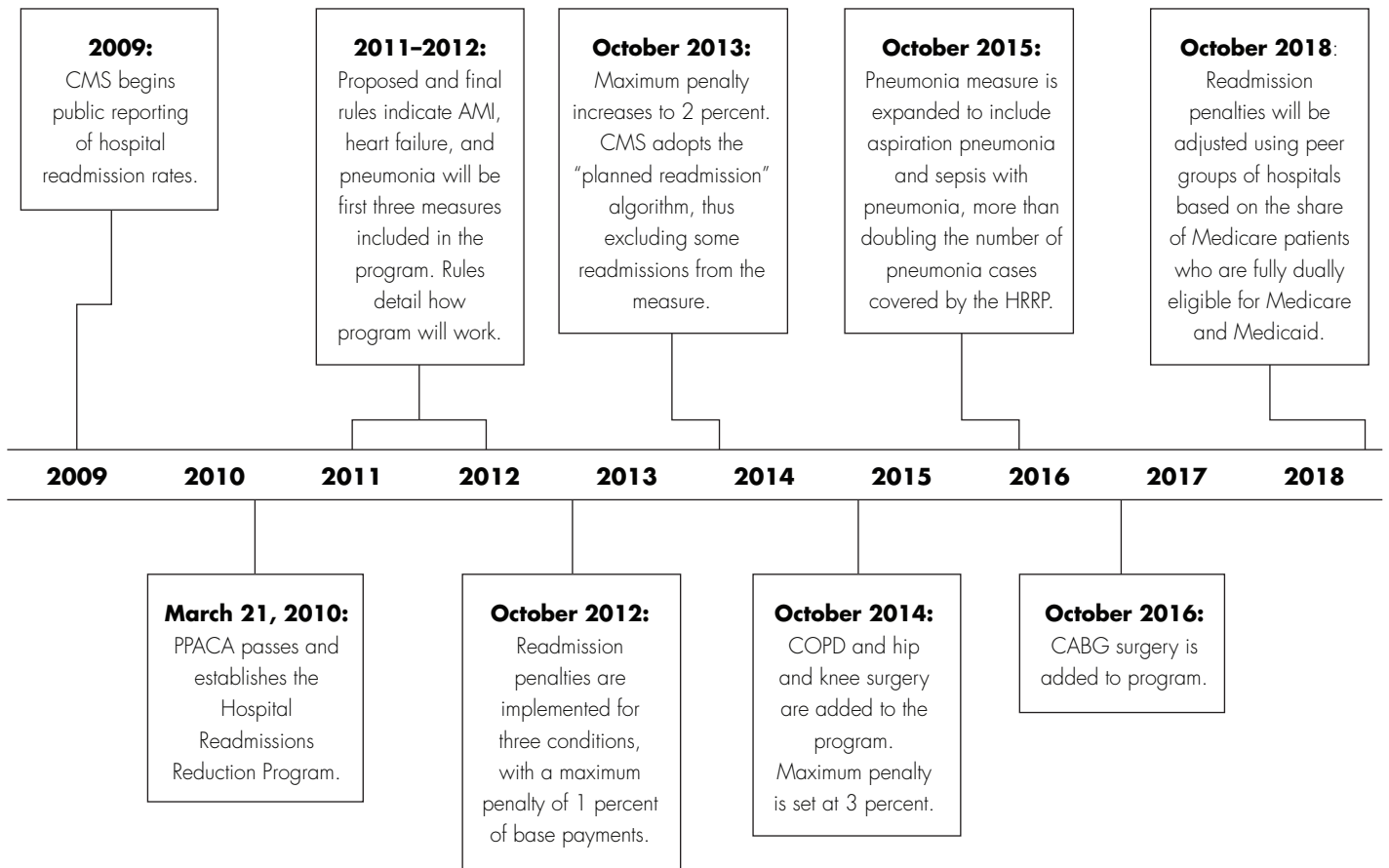
In 2016, the Congress passed the 21st Century Cures Act, which mandated that the Commission examine how the HRRP affected readmissions, observation stays, and ED visits (see text box on the mandate). In response to the mandate, this chapter examines how observation stays and ED use changed after the introduction of the HRRP. We also investigate whether changes in readmission rates are related to changes in mortality rates.

Enactment of and changes to the HRRP

The HRRP was enacted in 2010 and required that Medicare payments to hospitals with above-average risk-adjusted readmission rates be reduced starting in 2013. The 2013 reductions would depend on readmission rates during three previous years (July 2008 to June 2011) for three conditions (heart failure, acute myocardial infarction (AMI), and pneumonia). CMS continues to set penalties for a given year based on readmission performance during the most recent three-year period of data available (e.g., fiscal year 2018 penalties are based on discharges from July 1, 2013, through June 30, 2016). The HRRP was later expanded to include three more conditions (chronic obstructive pulmonary disease (COPD), planned hip and knee replacement surgery, and coronary artery bypass graft (CABG) surgery). A time line of changes to the HRRP is shown in Figure 1-1 (p. 8).

**FIGURE
1-1**

Timeline for the Hospital Readmissions Reduction Program



Note: AMI (acute myocardial infarction), PPACA (Patient Protection and Affordable Care Act of 2010), FY (fiscal year), COPD (chronic obstructive pulmonary disease), CABG (coronary artery bypass graft).

The HRRP caps the maximum penalty for an individual hospital at 3 percent of total base Medicare inpatient operating payments. In fiscal year 2018, 81 percent of hospitals will have payments reduced because of the HRRP. Most of the penalties are small, with 48 percent of those hospitals receiving less than a 0.5 percent penalty. About 6 percent of the penalized hospitals receive the largest penalties (between 2 percent and 3 percent of base payments) for their relatively poor performance. The average penalty is \$217,000 for those hospitals receiving a penalty in 2018. Total penalties are expected to be \$556 million in 2018, or 0.3 percent of hospitals' overall Medicare payments.

CMS computation of risk-adjusted readmission rates

The HRRP measures a hospital's readmission performance using the National Quality Forum–endorsed risk-adjusted 30-day readmission measures for six conditions.¹ Measures are for all-cause readmissions for beneficiaries age 65 or older, with limited exclusions such as planned readmissions for patients with AMI. Risk adjustment is based on the use of hierarchical regression models using selected hierarchical condition categories to adjust for patient characteristics. Conditions are identified based on the principal discharge diagnosis, which is not necessarily

the diagnosis related group (DRG) assigned to the case for payment.² A detailed discussion of how the penalty is computed is included in online Appendix 1-A, available at <http://www.medpac.gov>.

Commission discussions of potential changes to the readmission reduction program

In its June 2013 report to the Congress, the Commission suggested several improvements to the HRRP (Medicare Payment Advisory Commission 2013). The first called for setting a fixed target for readmission rates, so aggregate penalties would go down when industry performance improved. A second suggestion was to fix the current formula by removing the “multiplier,” which sets the readmission penalty equal to a multiple of the price associated with the initial admission. As the policy currently stands, the penalty for each excess readmission is disproportionately large relative to the cost of the readmission. For example, under current law, the penalty for one excess heart failure readmission equals almost 5 times the cost of the initial heart failure admission, and the penalty for one excess hip or knee readmission is over 20 times the cost of an initial admission. Removing the multiplier and setting the penalty equal to the cost of excess readmission would reduce the penalty for a single excess heart failure readmission by about 70 percent and reduce the penalty for a single excess hip/knee readmission by about 95 percent. A discussion of the penalty multiplier is in online Appendix 1-A, available at <http://www.medpac.gov>.

Third, the Commission suggested using an all-condition readmission measure to increase the number of data points and reduce the random variation that single-condition readmission rates face under current policy. The extra savings from shifting to an all-condition measure would fund the cost of removing the multiplier, resulting in budget neutrality. A fourth improvement would be to evaluate hospitals’ readmission rates against rates for peer hospitals with similar shares of low-income patients as a way to adjust penalties for the effects of socioeconomic status. The Congress has acted on only one of these options. The 21st Century Cures Act (Public Law 114–255) includes a provision (Section 15002) requiring the Secretary of the Department of Health and Human Services to adjust readmission penalties using peer groups of hospitals based on the share of Medicare patients who are fully dual-eligible for Medicare and Medicaid starting in fiscal year 2019. Descriptions of the problems each policy option aims to address are shown in the text box (p. 10).

Prior research on the effects of the HRRP

There is general agreement in the literature that readmission rates declined after the passage of the HRRP and that conditions covered under the readmission penalty saw the greatest reduction in readmissions (Medicare Payment Advisory Commission 2016, Zuckerman et al. 2016). A survey of hospital administrators found that most believed the HRRP had a “great impact” on their efforts to reduce readmissions, suggesting that at least part of the reduction in readmissions after the HRRP was due to the program’s incentives (Joynt et al. 2016). Readmission rates have also declined for Medicare Advantage and privately insured patients, suggesting that factors in addition to the HRRP are acting to reduce readmissions or that the effect of the HRRP may have “spilled over” to the Medicare Advantage and private insurer markets (Chen and Grabowski 2017). As we have stated in the past, reductions in readmissions generated more savings for the program than did the readmissions penalties (Medicare Payment Advisory Commission 2015). The more controversial questions involve how the readmissions penalty affects hospitals serving large shares of low-income patients, whether the reduction in readmissions simply reflects a shifting of patients to observation status or ED status, and whether reduced readmissions lead to increased mortality.

Social risk factors and readmission rates

In our initial examination of the readmissions policy, the Commission found that hospitals with larger shares of low-income Medicare patients tended to have systematically higher readmission rates because of individual effects, neighborhood effects, or both (Medicare Payment Advisory Commission 2013). Numerous studies have similar findings (Gu et al. 2014, Hu et al. 2018, Hu et al. 2014, Sheingold et al. 2016). The Office of the Assistant Secretary for Planning and Evaluation, which evaluated social risk factors under the hospital value-based purchasing programs, found that lower income patients did tend to have worse outcomes, but they also found that hospitals serving more lower income patients tended to have worse outcomes even after controlling for patient mix (Office of the Assistant Secretary for Planning and Evaluation 2016). While hospitals serving the poor tend to have higher levels of readmissions, they have also been able to improve readmission rates faster than other hospitals (Salerno et al. 2017).

Policy options previously discussed by the Commission to improve the program

In its June 2013 report to the Congress, the Commission published a chapter on the Hospital Readmissions Reduction Program (HRRP) that discussed how the program was successful in motivating hospitals to reduce readmissions. But we also discussed several problems with the current program and how the HRRP could be revised to work better. Table 1-1 summarizes some of the Commission’s concerns and policy options to address those concerns.

In 2011, the Commission recommended redesigning the Quality Improvement Organization program so that the Secretary could fund time-limited technical assistance directly to providers and communities to help

improve quality of care (Medicare Payment Advisory Commission 2011b). Such a reform could increase the likelihood that providers and communities receive the technical assistance that hospitals deem relevant to their quality improvement efforts. Other sources of federal funding for readmission reduction efforts (such as the Partnership for Patients and Community-Based Care Transitions Program) encourage hospitals to improve care coordination with providers outside the hospital (and thus reduce readmissions) and make other quality improvements. These programs provide funds for external organizations to help support hospitals’ efforts to improve patient outcomes. ■

TABLE 1-1 Readmission policy issues and proposed solutions

Concern	Description of the problem	Proposed solution
Small number of observations	It is difficult to distinguish between random variation and true performance improvement when examining a small number of cases for a small number of conditions.	<ul style="list-style-type: none"> • Use all-condition readmissions. • Continue to use 3 years of data. • Allow hospitals to aggregate performance within a system.
Lack of a fixed target	The readmission rates hospital must achieve to avoid penalties decrease as industry performance improves.	Create a prospective target. The target could be set below current readmission rates to maintain budget neutrality.
Computation of the penalty	The penalty is a multiple of the cost of each excess readmission. As national readmission rates decline, the multiplier increases. Thus, penalties per readmission increase.	Drop the multiplier and set the penalty equal to the cost of excess readmissions. Use all-condition readmissions to offset the cost of removing the multiplier.
Correlation between socioeconomic status and readmission rates	Lower income patients have higher readmission rates.	<ul style="list-style-type: none"> • Report all hospital risk-adjusted rates without an SES adjustment. • Compute targets to determine the penalty for peer groups of hospitals with similar low-income shares (SSI beneficiaries). (<i>The Congress enacted a similar policy that will start in October 2018.</i>)

Note: SES (socioeconomic status), SSI (Supplemental Security Income).

To protect hospitals serving the poor from experiencing disproportionate penalties, the Commission has discussed measuring hospitals’ performance against a peer group

of hospitals with a similar share of low-income patients. Under this construct, the actual readmission scores (unadjusted for social risk factors) would continue to be

reported on Hospital Compare, but the thresholds hospitals would have to meet to avoid readmission penalties would be more lenient for hospitals serving more low-income patients (Medicare Payment Advisory Commission 2013). The Congress mandated that this type of peer grouping be incorporated in the HRRP beginning in October 2018.

Evidence suggests that increased observation care and ED visits are largely due to factors other than the HRRP

Some researchers have contended that the decline in readmissions can be largely attributed to the rapid increase in use of observation, which means that the patient receives care in the hospital but is not formally admitted (Himmelstein and Woolhandler 2015). Their concern is that clinicians are not truly taking steps to improve care and care transitions. The hypothesis is that the number of events requiring a readmission has not truly been reduced, but instead, ED clinicians opt to treat these events by keeping the patients in an outpatient observation status rather than readmitting them. If that hypothesis were the case, the decline in readmissions might result in Medicare program savings but might not reflect any true gains in the quality of care for beneficiaries. However, the Commission's 2016 analysis of the increase in observation stays and decline in readmissions from 2011 to 2013 found that readmission rates declined substantially, even after adjusting for the growth in observation stays (Medicare Payment Advisory Commission 2016). In general, only 20 percent to 25 percent of the readmissions decline could be accounted for by increased use of one-day or longer outpatient observation stays. Moreover, we found that in that 3-year period, growth in the use of 24-hour-plus observation stays occurring within 30 days of discharge from a hospital (22.2 percent) was essentially the same as the overall per capita growth rate in 24-hour-plus observation stays (22.1 percent). Thus, the increased use of observation care was not systematically higher for patients with a prior admission than for the Medicare population overall. Similarly, Zuckerman and colleagues examined data through May 2015 and found “no significant association between changes in observation-service use and changes in readmission rates” after implementation of PPACA (Zuckerman et al. 2016). In accordance with our mandate, we reexamined whether reduced readmissions were associated with increased observation stays or increased ED visits after a hospital discharge. We are not aware of any literature that has examined growth in ED visits after introduction of the HRRP.

Prior studies are inconclusive regarding the relationship between reduced readmissions and increased mortality

A goal of the HRRP is to improve care transitions and coordination between the hospital, physicians, and post-acute care providers. The benefits of reconciling medication before discharge, ensuring postdischarge appointments with primary care physicians, and coordinating care plans with post-acute care providers have been well documented (Coleman et al. 2006, McHugh et al. 2017, Naylor et al. 2011, Zuckerman et al. 2017). To the extent that the HRRP improves care coordination—including reconciling medication before discharge—it should reduce readmissions and reduce (or at least not increase) mortality. However, some have raised concerns that hospitals may avoid appropriate readmissions, possibly by encouraging ED physicians to send patients home rather than readmit them, which could lead to higher mortality and lower readmissions. Another possibility is that the HRRP induces both positive and negative changes in practice patterns, such as better care transitions and medication reconciliation but also the discouragement of readmissions that are medically appropriate.

Two 2017 studies examined changes in heart failure readmissions and mortality from 2008 to 2014. Both studies found that risk-adjusted heart failure mortality during the 30 days after hospital discharge increased slightly from 2010 to 2014 (they ignored in-hospital mortality changes).³ The question is whether that increase in postdischarge mortality is related to the passage of the HRRP or to other factors. The first study, by Dharmarajan and colleagues, examined hospital-level changes in mortality and readmission rates related to AMI, pneumonia, and heart failure (Dharmarajan et al. 2017). The researchers examined Medicare discharges at approximately 3,500 hospitals, including 3 million heart failure discharges, and found a slight positive correlation between changes in mortality and changes in readmissions. This finding indicates that hospitals that reduced readmissions more than average tended to reduce mortality more than average. The magnitude of the correlation for heart failure is small (0.066), but statistically significant. Dharmarajan and colleagues concluded that the increasing rate of postdischarge heart failure mortality was not related to reductions in readmission rates.

The second study, by Gupta and colleagues, which examined a smaller data set and a narrower question, focused only on heart failure mortality (Gupta et al. 2017). The Gupta study looked only at national trends

among heart failure patients using 115,245 discharges over 9 years from a sample of 416 hospitals. Gupta and colleagues found that risk-adjusted mortality rates increased after the readmission reduction program was started. Relative to 2010, they found that one-year raw rates of mortality increased by 3.6 percentage points (from 34.5 to 38.1 percent) and risk-adjusted rates increased by 5 percentage points (from 31.3 percent to 36.3 percent) after the HRRP's passage.⁴ Because the national trend of increasing risk-adjusted mortality coincided with the national trend toward lower readmission rates, the authors conclude that, "if further confirmed, these findings may require reconsideration of the HRRP in HF [heart failure]." Unlike the Dharmarajan study, however, the Gupta study did not conduct a hospital-level analysis to determine whether hospitals with greater readmission reductions also had greater mortality increases.

One concern with the Dharmarajan and Gupta studies is that the 2010 to 2014 time frames they used coincided with a large national drop in initial admissions and a shift in the types of patients treated by the hospitals in the studies' samples. This change in admission patterns could result in a difference in the severity of patients that may not be fully picked up by the risk adjuster (as acknowledged by Dharmarajan and colleagues). The changing patient mix and practice patterns were reflected in the Gupta study by a doubling of hospice use from 2010 to 2014. When Gupta and colleagues removed all hospice patients from their model, the change in 30-day mortality rates after the HRRP's introduction was no longer statistically significant. For one-year mortality, the excess risk of mortality was reduced, but was still slightly positive and remained statistically significant. It is not clear why the HRRP would have a larger effect on one-year mortality than 30-day mortality. An alternative explanation for increasing heart failure mortality is that patient severity could have changed over the 2010 to 2014 period in ways that were not fully accounted for by the risk adjuster (Dharmarajan and Krumholz 2017, Dharmarajan et al. 2017).

A more recent study looked at Medicare's Hospital Compare data to examine changes in mortality for heart failure and AMI from 2009 through 2015 (Chatterjee and Joynt Maddox 2018). This study used Hospital Compare data to show that, on average, AMI mortality fell during the period, but heart failure mortality increased. However, heart failure mortality fell for the subset of hospitals that initially had high heart failure mortality. Unlike the Gupta and Dharmarajan studies, this study examined

mortality for the period during the hospital admission and extending 30 days postdischarge. However, the Hospital Compare risk adjustment method produces data that are not designed for longitudinal comparisons. The risk adjustment method is as follows: "The [risk-standardized mortality measure] is calculated as the ratio of the number of 'predicted' deaths to the number of 'expected' deaths at a given hospital, multiplied by the national observed mortality rate" (QualityNet 2017). Because the ratio of predicted to expected deaths is multiplied by each year's national raw rate of mortality for the year, when reviewed over time, the data are indicative of trends in raw unadjusted mortality rates. Therefore, the Chatterjee study indicates that raw (not risk-adjusted) AMI mortality rates appear to have declined while raw (not risk-adjusted) heart failure mortality rates increased from 2009 through 2015. On average (across baseline poor performers and baseline good performers), the study suggests that raw rates of heart-failure mortality increased slightly. This finding is consistent with the data we show in this chapter. However, as we discuss in the chapter, raw rates of mortality are not fully illustrative of trends in risk-adjusted mortality due to increasing severity of patients admitted for heart failure.

In an epidemiological study, Khera and colleagues reported that one-year mortality following an inpatient admission for heart failure increased slightly from 2010 to 2012 among a 5 percent sample of Medicare patients (Khera et al. 2017). However, that article examined all heart failure cases, including cases that are not subject to the readmissions policy, such as those where heart failure was a secondary diagnosis on admission. In addition, the study ended before the implementation of the HRRP penalties. Thus, the primary article contending that the HRRP may have resulted in an increase in risk-adjusted mortality continues to be the article by Gupta and colleagues. Later in this chapter, we also examine whether lower readmission rates are associated with higher risk-adjusted mortality.

Our methodology for evaluating the HRRP effects

To examine Medicare trends over time (in readmissions, observation stays, ED visits, and mortality), and hospital-specific correlations between readmission and mortality changes (as Dharmarajan and colleagues did), we examined changes in readmissions and mortality

from 2010 to 2016. Our mortality analysis examined changes in mortality during the admission and 30 days postdischarge. As we explain in online Appendix 1-B, available at <http://www.medpac.gov>, we believe looking at the combination of inpatient and postdischarge mortality will reduce problems that can be caused by a shift in the site of mortality (for example, from the inpatient setting to hospice, which may have the effect of increasing postdischarge mortality). We also put our findings in context by discussing other Medicare program changes happening at that time. Changes include the Medicare Recovery Audit Contractor (RAC) Program in 2010 (which started challenging whether hospital short stays were medically necessary) and more intense coding under the Medicare severity–diagnosis related group (MS–DRG) system implemented in 2008. Because these factors coincided with the HRRP, we also conducted a hospital-level analysis. We examined whether changes in readmission rates correlated with changes in mortality rates, as did Dharmarajan and colleagues. If declines in risk-adjusted readmissions are correlated with increases in mortality, that would be of concern. In contrast, if declines in readmission rates are associated with declines in mortality, that would be reassuring. (Online Appendix 1-B, available at <http://www.medpac.gov>, provides more detail on why we have chosen this methodology.) In this report, we show four types of analyses: (1) trends in raw rates of readmission and mortality; (2) trends in risk-adjusted readmissions and mortality (because we expect the severity of admitted patients to be increasing, we expect risk-adjusted readmissions and mortality to fall faster than raw readmissions and mortality); (3) trends in observation stays and ED visits; and (4) a cross-sectional analysis of hospital performance. We examine cross-sectional performance because the time trends for readmissions, observation, ED visits, and mortality may be affected by concurrent policy and coding changes, as discussed in online Appendix 1-B.

Risk adjustment is necessary but imprecise

To evaluate the HRRP’s effects, we started with a population of admissions that are subject to the HRRP incentives. This population was identified using the list of International Classification of Diseases (ninth and tenth revisions) codes that CMS uses to identify eligible cases. We focused our analysis on the five conditions covered by the HRRP through fiscal year 2016: AMI, heart failure, pneumonia, COPD, and planned hip and knee replacement surgery (the latter two conditions were added in 2014).

The population is further limited to beneficiaries at least age 65 who were covered by fee-for-service Medicare (both Part A and Part B) for 12 months before their admission.

Risk adjustment is necessary because the severity of patients admitted to the hospital has been increasing in recent years. While some of the increase in patient risk profiles over time could be because of coding, much of the increased severity of illness appears to be real. One potential cause of a real increase in patient severity is the large decline in admission rates since 2010; declining admission rates may have raised the severity of illness of patients who were admitted. The decline in initial admissions may have been partially caused by the RAC Program that started in 2010—the same year the HRRP was enacted. The RAC Program gave hospitals incentives to keep less severely ill patients who enter the emergency room as observation patients rather than admit those patients into the inpatient system. After introduction of the RAC Program, the share of patients discharged after a one-day stay declined and the share of patients staying longer than one day increased (see online Appendix 1-B, available at <http://www.medpac.gov>). Because patients discharged after only one day tend to be less sick, the one-day stays probably had lower risk of readmission and mortality. As expected, hospitals reported that the risk profile of the admitted patients increased over this time frame. However, some of the increase over time may have been due to changes in coding practices. The changes in coding pressure and RAC pressure differed over time. The changes could be divided into three key periods:

- **2008 to 2010**—In 2008, Medicare introduced MS–DRGs. The new DRGs created greater incentives for complete coding. We and CMS have documented the increased coding that occurred from 2008 to 2010 (Centers for Medicare & Medicaid Services 2012, Medicare Payment Advisory Commission 2011a). For that reason, the more rapid decline in risk-adjusted compared with raw readmission rates during that period may in part reflect coding changes.
- **2010 to 2014**—From the end of 2010 to 2014, hospitals were having the medical necessity of short stays challenged by the RACs, resulting in denial of some payments (see Appendix online Appendix 1-B, available at <http://www.medpac.gov>). During this period, Medicare admissions per capita declined materially, with the largest declines being for one-day stays. This trend suggests that increased severity

of cases during this period was not simply a coding phenomenon, but a real increase in patient complexity.

- **2014 to 2016**—RAC pressure was reduced in 2014. While there continued to be a material decline in medical admissions per capita during this period, the share of cases that were one-day stays actually increased slightly in 2016.

Given the uncertainty about how much of the changes in risk-adjusted readmissions was due to coding, we conducted cross-sectional analyses in addition to the time series analyses to determine whether hospital-level differences in readmission rates over time were related to some combination of hospital-level differences in rates of observation stays, ED use, and mortality after discharge.

Our categorical risk adjustment model

We used a categorical risk adjustment model based on one developed by 3M and used by the Agency for Healthcare Research and Quality to risk adjust mortality rates. In our model, we calculated an expected rate of readmission for a group based on the group's three-year historical average (e.g., 2010 to 2012) rate of readmission. Cases were grouped by base all-patient refined–diagnosis related group (APR–DRG), severity of illness, age, sex, and mental health diagnosis (if any). These classifications allowed us to examine the average rate of readmission for each category—for example, a male age 75 to 84 in base APR–DRG 194 (heart failure) at severity of illness level 3 with no mental health diagnosis. A clinical categorical model is similar to a regression in its approach but with many more interaction terms. For any given base DRG, readmission rates increase with patient severity (and in general increase with age), are higher for men, and are higher again if the patient has a mental health diagnosis. To get a reasonably reliable average readmission rate for each category, we required at least 25 cases in each category. (See online Appendix 1-B, available at <http://www.medpac.gov>, for more details on risk adjustment methods).

Unplanned versus potentially preventable

In our analysis we examined three types of readmissions: all-cause, unplanned, and potentially preventable. We did this to examine whether the rate of change in readmissions is sensitive to type of readmission measure used. All-cause readmissions include all returns (except transfers) to the hospital after a qualifying initial admission. CMS initially

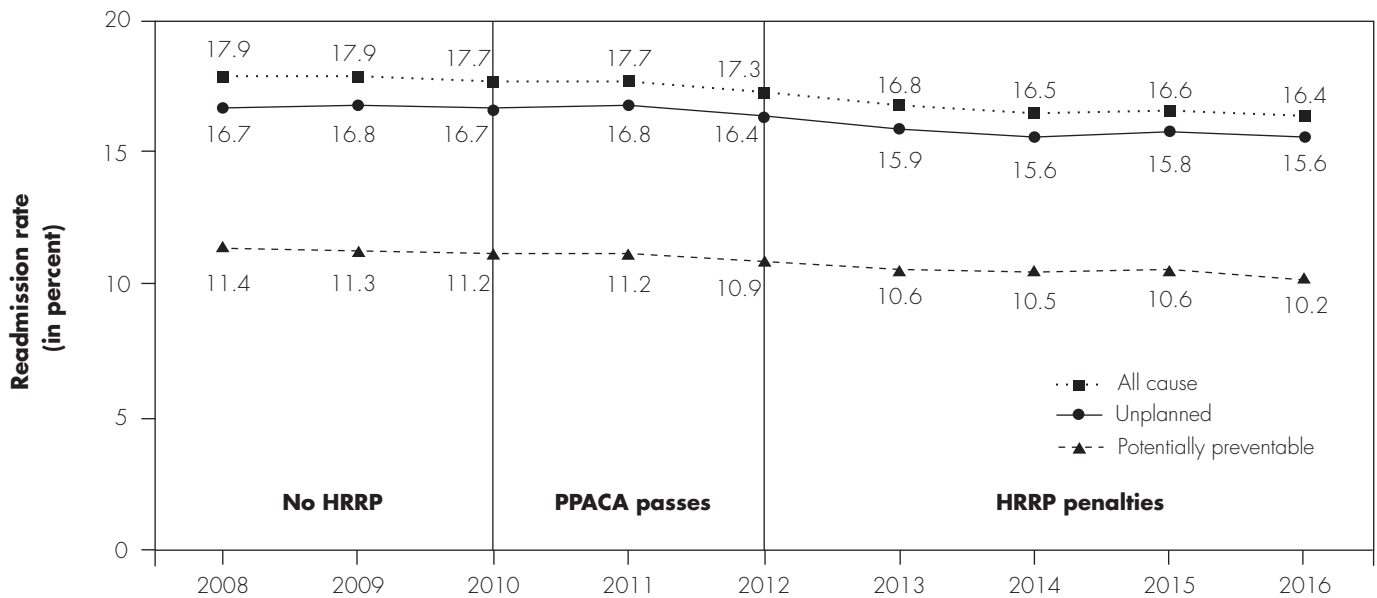
used this approach to track readmissions; however, under the legislation establishing the HRRP, CMS was not supposed to count readmissions that were “unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).” As a result, CMS developed the planned readmission algorithm, which was implemented in the second year of the HRRP. The planned readmission algorithm eliminates readmissions for transplants, maintenance chemotherapy, rehabilitation, and a set of 59 surgical procedures that are generally considered planned. However, if the surgical procedures are accompanied by a selected set of medical diagnoses as the principal discharge diagnosis, the readmission is considered unplanned. We find that only about 5 percent of readmissions are removed with the planned-readmission algorithm.

As a cross-check on the robustness of the unplanned-readmission methodology, we compared trends in unplanned readmissions with an alternative metric of potentially preventable readmissions (PPRs) developed by 3M. The PPR methodology captures readmissions that were clinically related to the prior admission and for which there is a reasonable expectation that it could have been prevented.

Results

Raw all-cause, unplanned, and potentially preventable measures of readmissions all show similar rates of decline

The trends in the raw all-cause, unplanned, and potentially preventable readmission rates from 2008 to 2016 were similar, although the magnitudes differed (Figure 1-2). The unplanned readmission rate was slightly lower than the all-cause rate, which is as expected since the number of exclusions for planned surgeries is relatively small. The PPR rate was about 5 percentage points lower than the unplanned readmission rate. This lower rate is the result of counting only clinically related readmissions that are potentially preventable and not counting subsequent readmissions that are part of a readmission chain.⁵ Over the period examined, the basic trend lines for all of these measures of readmissions were similar, suggesting that using either of the two risk-adjusted measures of readmissions would yield similar results. Historically, the Commission has reported the trend in PPR rates. However, because our mandate is to evaluate the HRRP, we used

FIGURE 1-2**Trends in raw rates of readmission across all conditions, 2008–2016**

Note: HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010).

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

the unplanned readmission rate for this report. Doing so allowed us to examine changes in readmissions, mortality, and service use for the specific population of admissions subject to the HRRP.

The average unplanned readmission rate was flat before the start of the HRRP (16.7 percent in 2008 and in 2010). After the HRRP passed in 2010, the raw unplanned readmission rate declined by an average of 0.15 percentage point per year from 2010 and 2012. After the penalties started to take place in 2013, the rate declined by 0.37 percentage point per year on average for the first two years of the penalties before flattening out from 2014 to 2016.

In the 2010 to 2016 period, raw rates of readmission fell for each condition covered by the HRRP (Figure 1-3, p. 16). Of the conditions initially included in the HRRP, AMI saw the largest decline in raw rates of readmission during that period, falling from 19.0 percent to 15.9 percent. Readmission rates for heart failure also declined, falling from 23.6 percent to 21.4 percent. Pneumonia, the third condition initially covered by the HRRP, also saw a sizable decline, falling 1.7 percentage points. Across conditions not covered by the program, unplanned readmissions

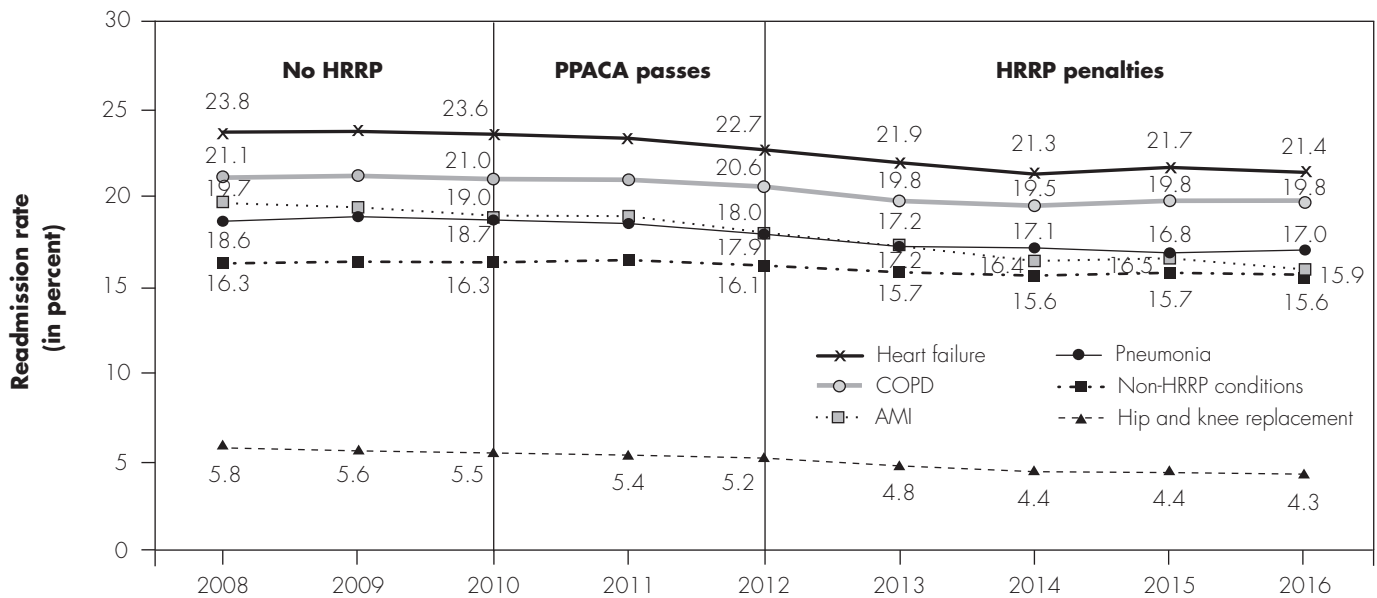
fell at a slower rate than for HRRP conditions, from 16.3 percent to 15.6 percent.⁶

A comparison of pre-HRRP rates of change (2008 to 2010) with rates after the HRRP was introduced (2010 to 2016) shows an accelerated annual rate of decline in raw rates of unplanned readmission: 0.3 percentage point faster on average after 2010 when the Act was passed for the initial three conditions covered by the program. Specifically, we examined readmission rates for all inpatient prospective payment system hospitals with available data from 2010 to 2016. For the 1,819 hospitals with more than 50 heart failure discharges in 2008, 2010, and 2016, the rate of decline in heart failure readmissions was faster after 2010. The difference is statistically significant using a Wilcoxon signed-rank test ($p < 0.01$). Similarly, for the 2,270 hospitals with more than 50 pneumonia discharges, the rate was faster after 2010 ($p < 0.01$). For the 946 hospitals with more than 50 AMI discharges in each year, the rate of decline in AMI readmissions was also greater, but the difference was not statistically significant.

However, raw rates of readmission are not fully illustrative because the mix of cases admitted to hospitals has

FIGURE 1-3

Raw unplanned readmission rates for conditions covered by the HRRP, 2008–2016



Note: HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010), COPD (chronic obstructive pulmonary disease), AMI (acute myocardial infarction). The pneumonia measure reflects the expanded definition used starting in fiscal year 2016, which includes simple pneumonia, aspiration pneumonia, and sepsis with pneumonia as a secondary diagnosis.

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

changed. From 2010 to 2016, Medicare admissions per capita fell by 17 percent, suggesting that the easier cases were no longer being treated on an inpatient basis. Admission rates for the three HRRP-covered conditions also declined substantially: Per capita heart failure admission rates dropped 14 percent, per capita pneumonia rates fell 11 percent, and per capita AMI rates declined 8 percent. A number of factors contributed to this decline in inpatient admissions, including technological improvements, general practice pattern changes, accountable care organizations (ACOs), the impact of RACs denying the necessity of certain admissions, and the “two-midnight” rule that discouraged short-stay admissions.⁷ Many of these policies occurred concurrently with implementation of the HRRP.

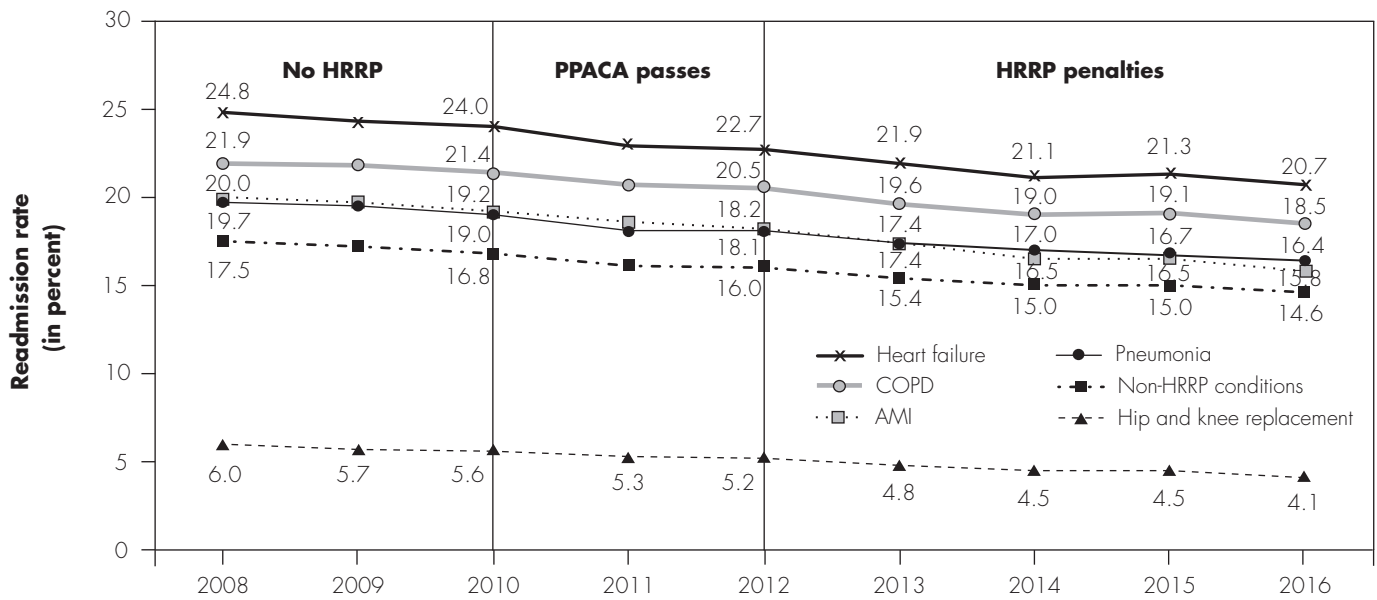
The steep decline in admission rates underscores the importance of adjusting for the change in mix of patients because those admitted after the more restrictive policies would generally have a higher severity of illness with a greater likelihood of being readmitted (that is, higher expected readmission rates).

The decline in risk-adjusted readmission rates was steeper than that in raw readmission rates. Between 2010 and 2016, across non-HRRP conditions, risk-adjusted readmissions fell 2.2 percentage points, from 16.8 percent to 14.6 percent. As shown in Figure 1-4, the declines were even greater for the HRRP-covered conditions as of 2010: heart failure (3.3 percentage points), AMI (3.4 percentage points), and pneumonia (2.6 percentage points). Even the rate of readmissions for hip and knee replacements, which was already low, fell 1.4 percentage points.⁸ The trends in raw readmission rates and the trend in risk-adjusted readmission rates suggest that the HRRP helped to contribute to the reduced hospital readmission rates.

On average, across HRRP conditions, the rate of decline in the risk-adjusted readmission rates was faster after the program’s passage (2010 to 2016) than in the earlier period (2008 to 2010) by about 0.12 percentage point per year. The decline in heart failure readmissions was steeper after 2010 and was statistically significant when measuring the percentage point change or percentage change in heart failure readmission rates.

FIGURE 1-4

Risk-adjusted changes in unplanned readmission rates by condition, 2008–2016



Note: HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010), COPD (chronic obstructive pulmonary disease), AMI (acute myocardial infarction). The pneumonia measure reflects the expanded definition used starting in fiscal year 2016, which includes simple pneumonia, aspiration pneumonia, and sepsis with pneumonia as a secondary diagnosis.

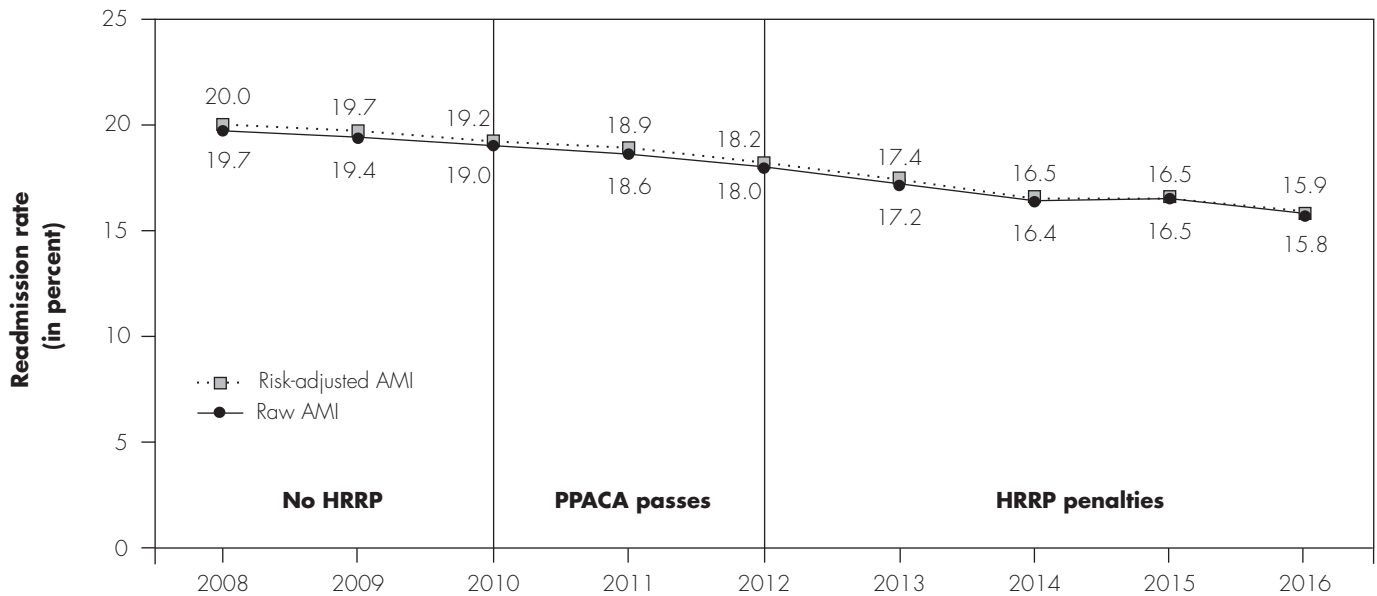
Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

Pneumonia and AMI readmission rates also fell faster after 2010, but the tests for statistical significance were mixed. For pneumonia, if we measure the change in percentage points, the readmission rate fell faster after 2010, but not by a statistically significant amount ($p = 0.70$). However, it was harder to achieve the same percentage point reduction in readmissions in later years because of declining readmission rates. Therefore, we also measured the percentage change in the rate of decline in readmission rates (as opposed to percentage point change). Using this percentage change method, pneumonia readmission rates fell faster after 2010 by a statistically significant amount ($p = 0.04$). Similarly, the risk-adjusted readmission rate for AMI declined 0.1 percentage point per year faster after 2010 on average. The difference is not statistically significant when measuring change in percentage points ($p = 0.22$) but is significant when measuring the percentage change ($p = 0.01$). Therefore, while readmission rates for AMI and pneumonia were falling more rapidly after 2010, the difference is statistically significant only when measuring percentage change.

An interesting finding is that raw readmission rates were generally not declining before 2010, but risk-adjusted rates were declining. The difference could be in part due to increasing complexity of patients, but another possibility is that the introduction of MS-DRGs in 2008 affected the rates. The MS-DRGs may have caused greater increases in coding during the years immediately after their introduction (2008 to 2010), which in turn may have resulted in overstating the decrease in risk-adjusted readmission rates during these years (Centers for Medicare & Medicaid Services 2012, Medicare Payment Advisory Commission 2011a). By 2010, the effect of the new MS-DRGs on coding had largely been built into the system, which could explain the slower growth of coding from 2010 onward.

The decline in readmission rates reflects more than coding changes

To gain some insight into the degree that coding changes affected risk-adjusted rates, we examined raw and risk-adjusted readmission rates for AMI. AMI readmissions are less discretionary than pneumonia or heart failure

FIGURE 1-5**Reduction in AMI readmission rates was not driven by coding, 2008-2016**

Note: AMI (acute myocardial infarction), HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010).

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

readmissions. For example, a readmission that was preceded by a test indicating an ST-elevation myocardial infarction would be seen as less discretionary and less likely to be challenged by the RAC. Therefore, unless coding changed, we would expect profiles of AMI-admitted patients to change relatively little, causing raw and risk-adjusted readmission rates to be similar. However, if coding had driven the change in risk profile, we would have expected even AMI raw and risk-adjusted readmission rates to diverge.

In fact, the risk-adjusted and raw rates for AMI tracked closely after 2010 (Figure 1-5). For this reason, we contend that the increased risk profile in other conditions, such as heart failure and pneumonia, at least partially reflects true differences in the characteristics of admitted patients from 2010 through 2016.

Because the reported characteristics of inpatient admissions have changed, we also examined changes in admissions per capita. For all conditions other than hip and knee replacements, admissions per capita between 2010 and 2016 declined (Figure 1-6). Interestingly, the fall in admission rates for the three initial HRRP-covered

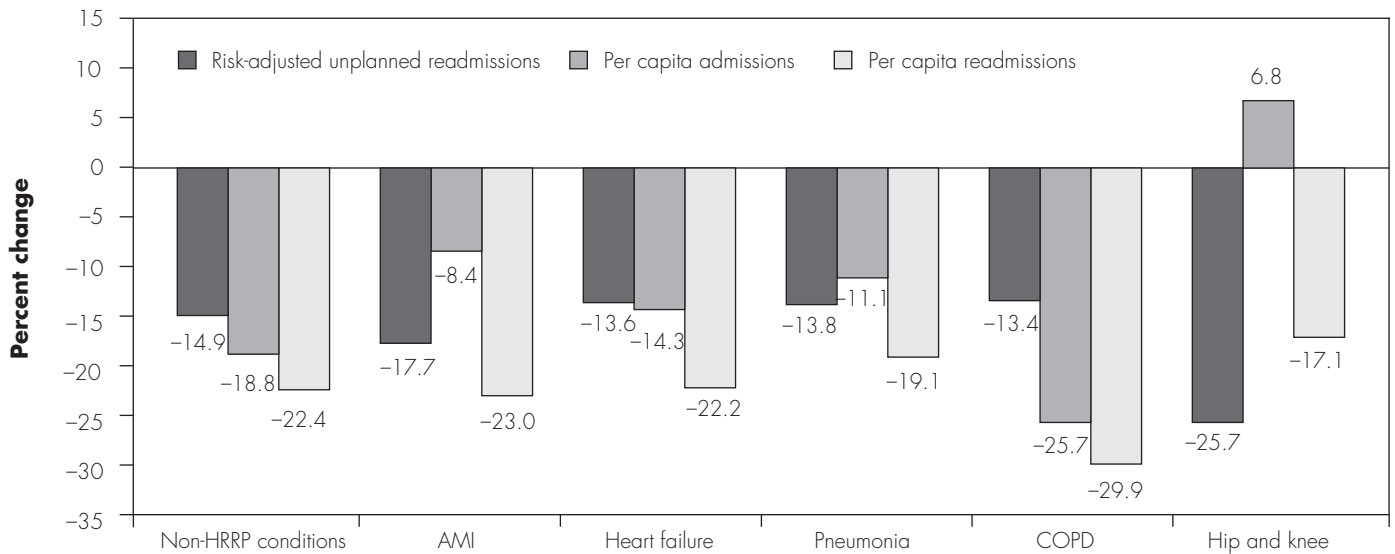
conditions (AMI, heart failure, and pneumonia) was smaller than the decline observed across conditions not covered by the HRRP. If hospitals were avoiding admitting patients in these conditions to potentially circumvent readmission penalties, we would have observed a larger reduction for the HRRP-covered conditions. The combined effect of falling admission rates and decline in readmission rates meant the number of readmissions per Medicare beneficiary (across all beneficiaries) declined by more than 20 percent on average. For example, from 2010 to 2016, heart failure admissions declined by 14.3 percent per capita. Among this smaller number of admissions, readmissions fell by 13.6 percent. The combined effect of fewer admissions and fewer readmissions per admission was a 22.2 percent reduction in heart failure readmissions per capita (Figure 1-6).

Admission rates declined while observation stays and emergency department visits increased

Along with the drop in admission rates, the Medicare program has seen a steady rise in beneficiaries' use of observation stays and EDs (Figure 1-7). These trends in rising observation and ED use started before the HRRP was implemented.

FIGURE 1-6

Percent change in per capita admission and readmission rates, 2010-2016

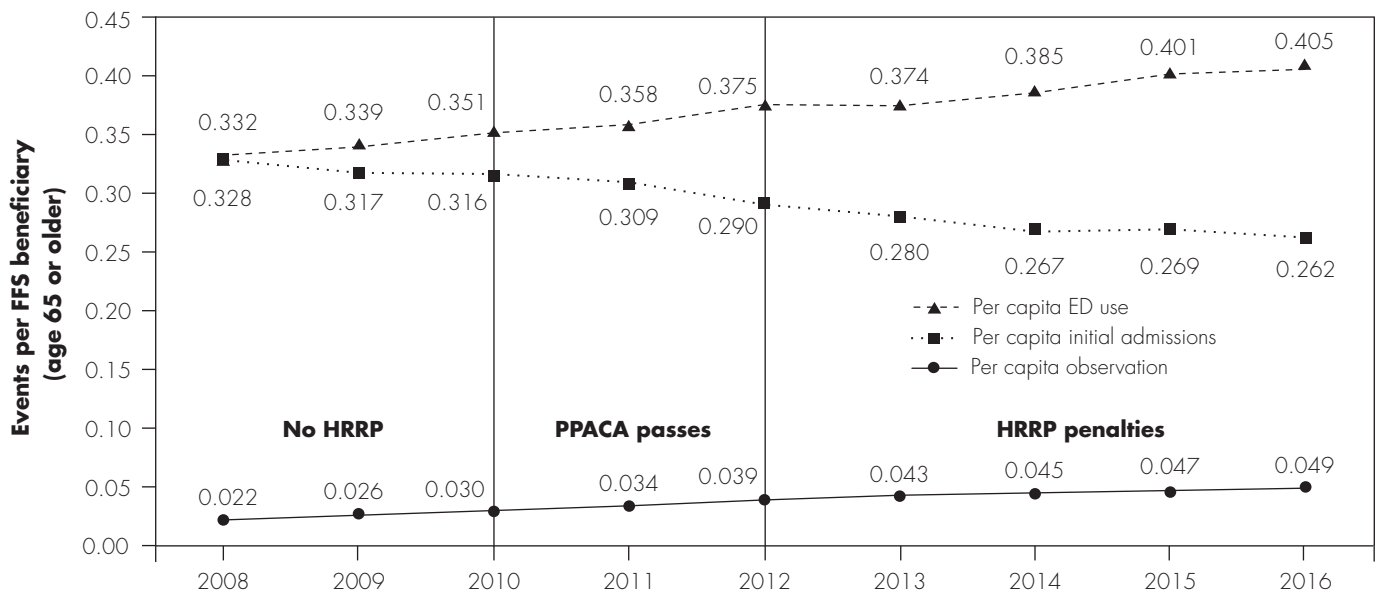


Note: HRRP (Hospital Readmissions Reduction Program), AMI (acute myocardial infarction), COPD (chronic obstructive pulmonary disease). Pneumonia measure reflects the expanded definition used starting in fiscal year 2016, which includes simple pneumonia, aspiration pneumonia, and sepsis with pneumonia as a secondary diagnosis.

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

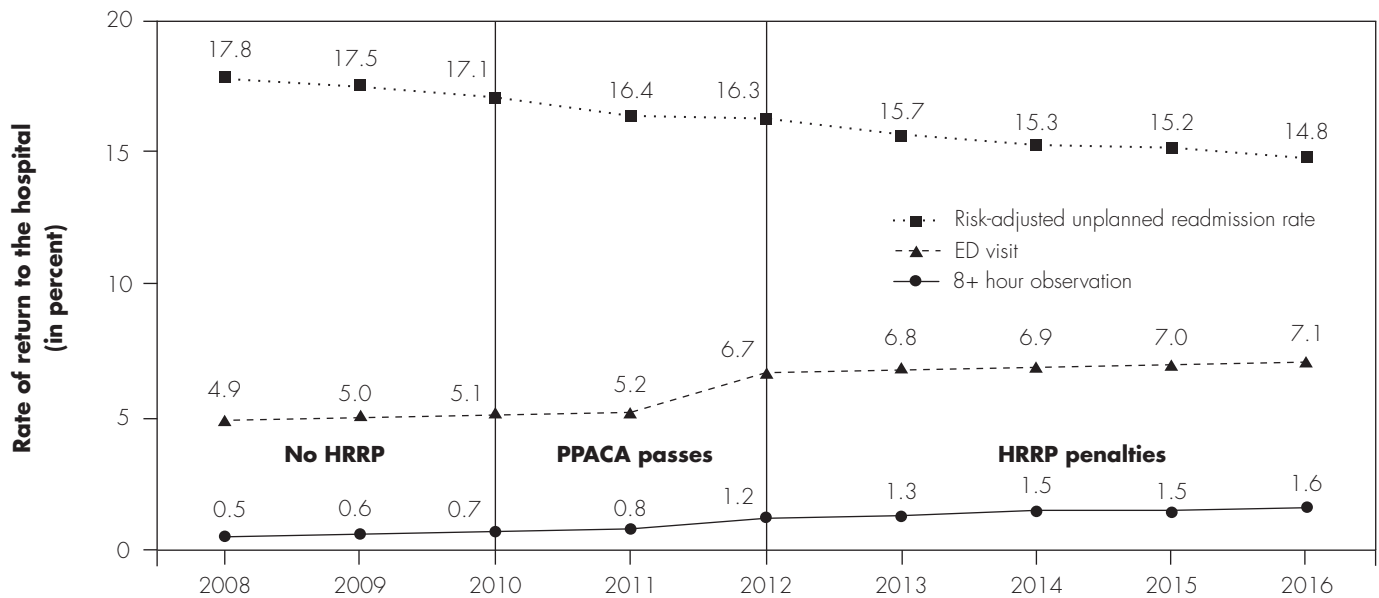
FIGURE 1-7

Per capita admission rates fell, while observation and ED use increased, 2008-2016



Note: ED (emergency department), FFS (fee-for-service), HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010).

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

FIGURE 1-8**Readmissions per discharge declined as observations and ED visits increased, 2008-2016**

Note: ED (emergency department), HRRP (Hospital Readmissions Reduction Program), PPACA (Patient Protection and Affordable Care Act of 2010).

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

Between 2010 and 2016, per capita admission rates (initial admission for qualifying conditions) dropped 17 percent, from 0.316 per capita to 0.262 per capita (Figure 1-7, p. 19). At the same time, however, per capita use of observation care grew 63 percent, from 0.030 per capita to 0.049 per capita. The increase in observation stays may have been partially a response to the RAC audits and two-midnight rule implemented by CMS during this period. Because observation stays increased steadily from 2008 to 2016 (including the period before the RAC incentive), we expect that more than the RAC incentive was at work. Per capita use of ED between 2010 and 2016 also increased, rising 15 percent, from 0.351 visits per capita to 0.405. Almost half of this increase took place from 2010 to 2012. The joint timing of a decline in inpatient admissions with an increase in observation stays and ED visits suggests that there was some substituting of outpatient care for inpatient care. From the Medicare patients' perspective, patients may prefer avoiding a hospital stay if they can achieve an equal or better outcome in an outpatient setting. From the Medicare program's financial perspective, avoiding an inpatient stay helps to reduce program spending since the cost of an observation stay is about 20 percent of the cost

of the average inpatient admission and the cost of an ED visit is about 5 percent of the cost of an inpatient stay.

Observation and ED use increased for both those admitted and those not admitted to the hospital

As readmission rates declined, use of observation and the ED after inpatient stays increased (Figure 1-8). The largest increases occurred in 2012, two years after the HRRP was passed. From 2012 on, the increases in observation and ED use have been more modest.

In 2010, for beneficiaries who were not readmitted, about 0.7 percent of cases were followed by an eight-hour or longer observation stay. By 2016, 1.6 percent of cases were followed by an eight-hour or longer observation stay. In that same period, ED use increased from 5.1 percent of cases to 7.1 percent of cases with a prior admission.

However, this ED growth appears to be broad based and not focused on ED visits after discharge. We compared Medicare beneficiaries' ED-visit growth for those discharged from a hospital and those not discharged from a hospital within the prior 30 days. We found that the

**TABLE
1-2**

Change in risk-adjusted rate of return to the hospital for non-HRRP and HRRP conditions, 2010-2016

Percentage point change in the share of patients returning to the hospital within 30 days categorized as:

	Readmissions	Readmission or observation	Readmission, observation, or ED visit
Non-HRRP admissions	-2.2	-1.5	0.7
HRRP conditions	-2.8	-1.7	0.3
AMI	-3.4	-1.7	0.7
Heart failure	-3.3	-2.1	-0.2
Pneumonia	-2.6	-1.7	0.2
COPD	-2.9	-1.8	0.3
Hip or knee replacement	-1.4	-1.0	0.8

Note: HRRP (Hospital Readmissions Reduction Program), ED (emergency department), AMI (acute myocardial infarction), COPD (chronic obstructive pulmonary disease).

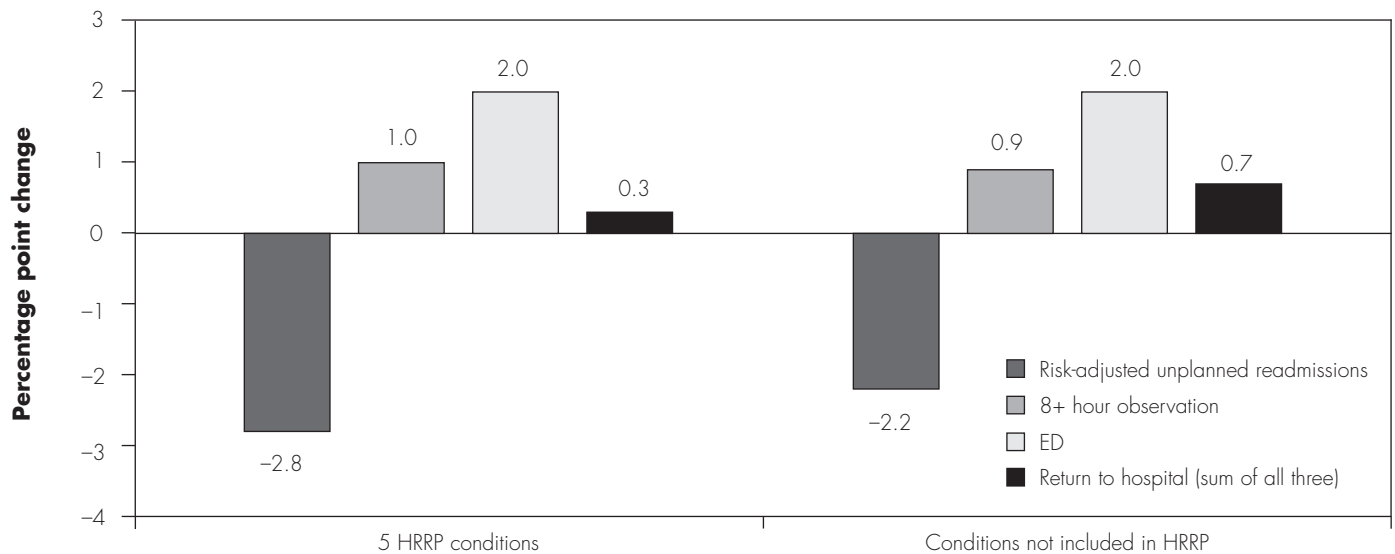
Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

growth rates were similar for the two groups. In fact, the shares of ED visits that were postdischarge visits in 2010 and 2016 were essentially the same (4.61 percent versus 4.66 percent, data not shown). Therefore, it appears that the growth in ED use is a broad phenomenon and cannot be primarily attributed to growth in postdischarge ED visits.

The decline in readmission rates coincided with increases in the rate of observation and the rate of ED use (Figure 1-8). The next question is: To what degree did the increase in observation and ED use offset the decline in readmissions? Looking across conditions not covered by the program, we see a 2.2 percentage point reduction in readmissions (Table 1-2). For those covered by the program, the reduction averaged 2.8 percentage points. At the same time, observation stays rose 1.0 percentage point and ED use within 30 days after discharge, by 2.0 percentage points (data not shown). However, adding together 2.8 percentage point decline in readmissions and the 1.0 percentage point increase in observation stays results in a combined decline of 1.7 percentage points in the sum of inpatient stays and observation stays (Table 1-2). We also saw an increase in ED use within 30 days postdischarge of about 2.1 percentage points (data not shown). The net effect was that the share of Medicare patients returning to the hospital for some type of care (readmission, observation, or ED) within 30 days of

discharge increased by 0.3 percentage point for HRRP conditions and 0.7 point for other conditions. From 2010 to 2016, the change in rates of return to the hospital varied by HRRP condition: AMI returns to the hospital rose, and heart failure returns to the hospital fell.

While the increase in ED and observation use coincided with the decline in readmissions, we cannot conclude that the decrease in readmissions caused the increase in observation visits or ED use. Observation and ED use increased for all Medicare beneficiaries in this time period, not just for those who were admitted to the hospital. For example, from 2010 to 2016, the share of discharges that were followed by an observation visit grew by 1 percentage point. At this same time, the share of all observation stays (including stays by beneficiaries never admitted to a hospital) grew by 1.9 percentage points, meaning observation stays grew faster for patients who had not been admitted. Similarly, the share of beneficiaries with a postdischarge ED visit increased 2.1 percentage points, and the per capita ED use for all Medicare beneficiaries grew by 5.3 percentage points. The faster growth in ED visits and observation stays for those without a recent admission to the hospital allows us to conclude that the readmission policy was not likely the driver behind the ED and observation growth experienced.

FIGURE 1-9**HRRP conditions have unusually large declines in readmissions without unusually large increases in observation or ED stays, 2010–2016**

Note: HRRP (Hospital Readmissions Reduction Program), ED (emergency department), AMI (acute myocardial infarction), COPD (chronic obstructive pulmonary disease). The five HRRP conditions include pneumonia, heart failure, AMI, COPD, and hip and knee replacement. The reasons for returning to the hospital are all measured in events per 100 initial admissions.

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

Small correlations were found between reductions in readmissions and increases in observation and ED visits

In addition to looking at national trends, we examined the data on readmissions, observation stays, and ED visits at the hospital level to determine whether the hospitals with the biggest declines in readmissions also had unusually large increases in observation and ED use rates. In this analysis, we found a small negative correlation coefficient (-0.11) between changes in readmission rates and changes in postdischarge observation use. Similarly, adding changes in observation use and ED visits together, we also found a small negative correlation coefficient (-0.03) with changes in readmission rates, suggesting that hospitals with above-average declines in readmissions did tend to have slightly larger increases in observation and ED use. However, taken together with the data in Figure 1-6 (p. 19) and the national growth rates in observation and ED use for those *without* a recent admission, the data suggest that only a small share of the increase in observation and ED use was related to the HRRP.

Greater readmission declines among HRRP conditions did not trigger greater observation-stay or ED-visit growth

Risk-adjusted readmission rates fell more for conditions covered by the HRRP (i.e., 2.8 percentage points for HRRP conditions versus 2.2 percentage points for non-HRRP conditions) (Figure 1-9).⁹ The difference is modest, suggesting there may be some spillover of behavior from HRRP conditions to non-HRRP conditions. Nevertheless, a hospital-level analysis indicates that the difference between 2.8 and 2.2 percentage points is statistically significant using a Wilcoxon signed-rank test ($p < 0.01$). While the HRRP conditions had bigger reductions in readmissions, changes in observation and ED visits were almost exactly the same for HRRP conditions and other conditions (Figure 1-9). If hospitals were using observation and ED visits to avoid readmission penalties, we would expect to see larger increases for conditions covered by the program, but we did not. Because the greater reduction in readmission rates did not trigger a greater growth in observation stays and ED visits, the

observation and ED-use growth does not appear to be primarily a function of declining readmission rates.

Sensitivity of findings to different methods of statistical testing

Our congressional mandate is to examine whether reductions in readmissions caused an offsetting increase in ED visits and observation stays. Therefore, the method to test for offsetting increases in observation stays and ED visits needed to use a unit of analysis that is comparable across readmissions, ED visits, and observation stays. As a result, Figure 1-9 presents data that are measured as events per 100 stays. The changes in events are equivalent to percentage point changes in readmission, ED-use, and observation rates. When we tested for percentage point differences between HRRP and non-HRRP conditions, we found that the difference (2.8 percentage points vs. 2.2 percentage points) is statistically significant.

However, there is a question of how robust the two findings (that readmission rates for HRRP conditions fell faster than for non-HRRP conditions and the finding that the readmission reductions did not trigger large increases in ED visits and observation stays) are to different methodological approaches. Therefore, we first estimated whether the difference in rate of decline for HRRP conditions and non-HRRP conditions would be statistically significant if we measured change in percentage rather than percentage points. Second, we investigated whether the finding—that greater readmission declines for HRRP conditions did not trigger more ED or observation stays—held for raw (not risk-adjusted) data.

When using percentage changes rather than percentage point changes, we found that the risk-adjusted readmission rate for HRRP conditions declined by 14.9 percent from 2010 to 2016 compared with a 13.0 percent decline for non-HRRP conditions. The difference (1.9 percent) is modest and statistically significant.¹⁰ The fact that the percentage differences are modest could reflect HRRP incentives spilling over into other conditions, coding difference across conditions, and other factors outside of the HRRP such as ACOs' practices also affecting readmission rates (Winblad et al. 2017).

One concern is that the difference (1.9 percent) may be due to greater coding changes for conditions covered by the HRRP. We found no evidence of this concern given that the difference in the change in raw rates of readmission for HRRP and non-HRRP conditions was larger than the risk-adjusted differences. The raw

readmission rate for HRRP conditions declined by 13.2 percent compared with a 4.5 percent decline for non-HRRP conditions. The difference in the rate of decline of raw readmission rates is statistically significant ($p < 0.01$).

Next, we examined whether the decline in raw readmission rates was offset by a raw increase in ED visits or observation stays. As with the risk-adjusted model, the raw change in postdischarge ED use and observation was similar for HRRP conditions and non-HRRP conditions. A version of Figure 1-9 using raw (not risk-adjusted) data is provided in online Appendix 1-C, available at <http://www.medpac.gov>. Looking at the totality of the different tests, there is fairly consistent evidence that the HRRP caused some reduction in readmissions, with most of the tests showing statistical significance. However, given the differences in the magnitude of the effects across different methods of testing for a HRRP effect on readmissions, it is not possible to say what portion of the reduction in readmissions was due to the HRRP and what portion was due to other concurrent factors such as ACOs or changes in coding practices.¹¹

Medicare program costs declined as readmissions declined

The Medicare program's savings from the drop in readmissions was much greater than the increase in payments for the additional observation stays and ED visits. As shown in Table 1-3 (p. 24), the program spent \$1.73 billion less on readmissions in 2016 than it would have if readmissions had occurred at the same rate as in 2010. Even though use of observation and ED visits increased, the effect had a relatively small impact on spending, with observation spending increasing postdischarge by \$167 million and ED spending increasing by \$69 million. The net reduction in spending on readmissions was \$1.49 billion. While it is clear that readmission spending was reduced, it is not clear what share of the reduction was due to the HRRP. Other factors such as ACOs or technological changes may have contributed to the reduction in readmission rates.

Changes in mortality rates and readmissions rates are not highly correlated

We also examined whether there was any relationship between changes in readmissions and changes in mortality, using two prior studies cited earlier as a starting point. Both studies found a slight increase in risk-adjusted heart failure mortality from 2010 through 2014. One study,

**TABLE
1-3**

Changes in costs after the 2010 enactment of the HRRP, 2010–2016

Type of care	Change in the cost of return visits to the hospital (in billions)
Readmissions within 30 days of the initial admission	\$-1.73
Observation stays, initial and postdischarge	0.17
Emergency department visits (without admission), initial and postdischarge	0.07
Net change in spending	-1.49

Note: HRRP (Hospital Readmissions Reduction Program). Reductions in spending on readmissions, observation stays, and emergency use pertain to reductions for all conditions including those not covered by the HRRP. It is not clear the degree to which these reductions are due to the HRRP or other factors.

Source: MedPAC analysis of Medicare claims data.

which conducted a hospital-level analysis regarding the relationship between readmissions and increased mortality, did not find a correlation (Dharmarajan et al. 2017). We repeated the time-trend analysis and the hospital-level correlation analyses with two changes. First, our analysis extended through 2016. Second, we measured mortality as the combination of mortality during the inpatient stay and 30 days after the stay ended. This approach addressed the problem of a possible shift in the location of the mortality due to hospice use increasing during this time period (as discussed in online Appendix 1-B, available at <http://www.medpac.gov>).

We found that, after the HRRP’s introduction, raw rates of mortality materially increased for one of the HRRP conditions (heart failure) but materially declined for two other HRRP-covered conditions (pneumonia and AMI) (Figure 1-10). On average, raw rates of mortality declined for the five HRRP conditions and increased for non-HRRP conditions. The increase in raw rates of mortality for heart failure and non-HRRP conditions may have been related to the decline in initial admissions and increases in the severity level of those admitted. The literature has tended to focus on the one metric where mortality increased (heart failure) rather than the conditions for which mortality declined.

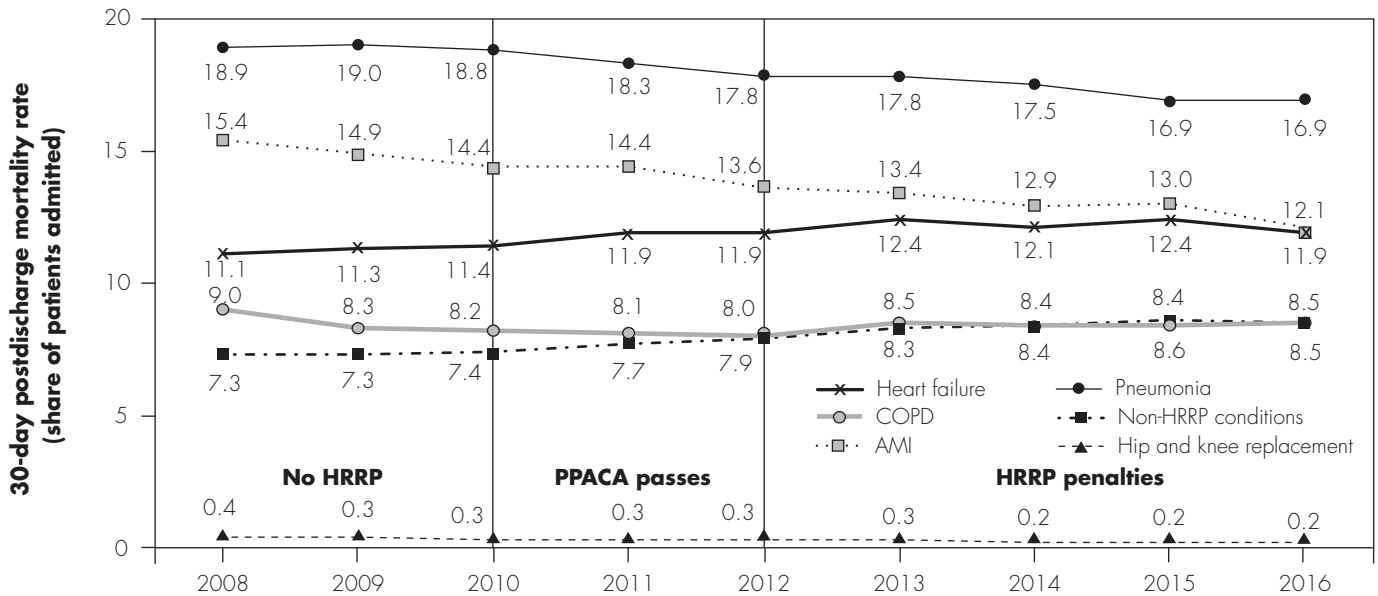
From 2010 to 2016, we found that risk-adjusted mortality rates during the inpatient stay and the following 30 days declined for all conditions (Figure 1-11). While greater coding intensity over time may be responsible for some of the decline in risk-adjusted mortality, we believe that a portion of the decline in mortality is real. We believe

the decline in risk adjusted rates is real due to consistent evidence that the patients admitted in 2016 had a higher risk of mortality than the patients admitted in 2010.

Our finding of declines in risk-adjusted heart failure mortality rests on a finding that the patients admitted in 2016 had a higher risk of mortality than the patients admitted in 2010. From our data, it appears that the large decline in initial heart failure admissions per capita caused the 2016 cohort of heart failure admissions to consist of patients with higher expected mortality than the 2010 cohort of heart failure admissions. In other words, it appears that hospitals were admitting fewer easy cases in 2016. While our categorical model’s finding of higher expected mortality for the 2016 cohort compared with the 2010 cohort could partially be due to greater coding intensity, we also find that patients admitted in 2016 tended to have higher risk scores based on the prior year’s diagnoses, tended to have greater intensive care unit use, and were less likely to be discharged home for self-care than the cohort of patients admitted in 2010.¹² These factors all suggest that the 2016 cohort of heart failure admissions were less healthy than the 2010 cohort. Therefore, our findings of both increasing raw rates of mortality and declining risk-adjusted mortality for heart failure admissions is plausible. These findings do not mean that no clinician ever erroneously failed to admit a patient, or even that the HRRP did not affect the rate of appropriate readmissions. It means only that, on net, care continued to improve during the time the HRRP was in effect. This improvement could indicate that the positive effects of changes in care patterns (better prescription reconciliation,

FIGURE 1-10

Raw 30-day mortality (in-hospital through 30 days postdischarge) rates have risen for some and fallen for other conditions covered by the HRRP

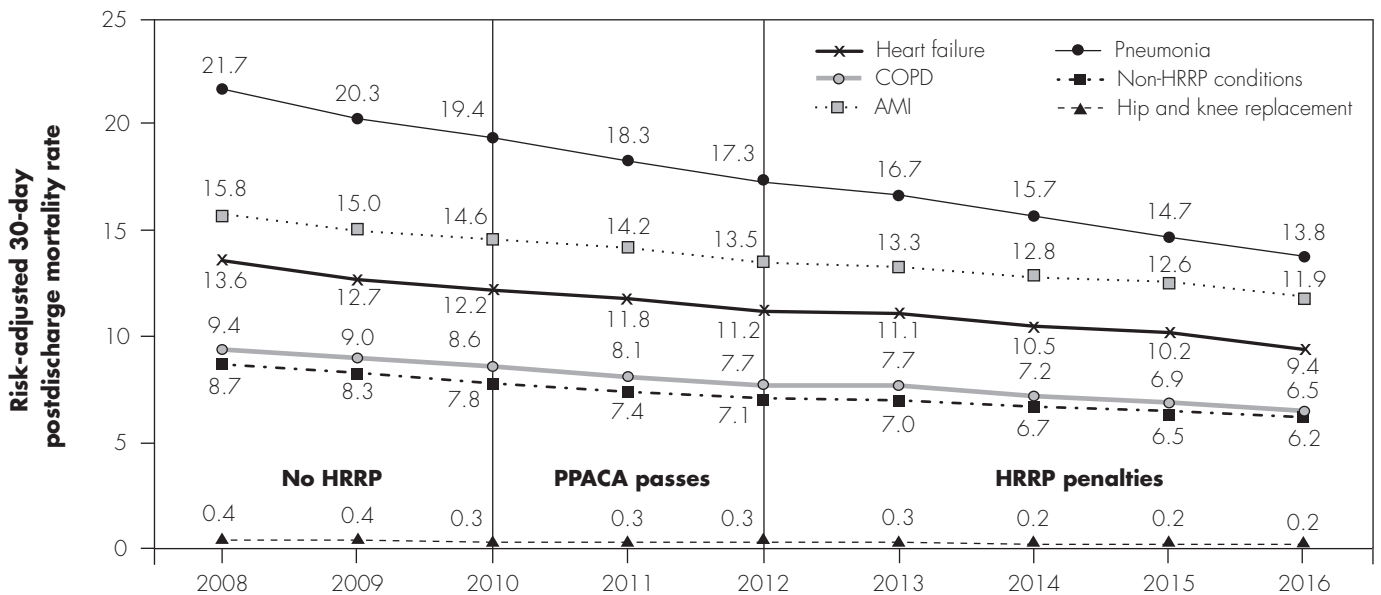


Note: HRRP (Hospital Readmissions Reduction Program), COPD (chronic obstructive pulmonary disease), AMI (acute myocardial infarction), PPACA (Patient Protection and Affordable Care Act of 2010). The pneumonia measure reflects the expanded definition used starting in fiscal year 2016, which includes simple pneumonia, aspiration pneumonia, and sepsis with pneumonia as a secondary diagnosis.

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older, 2008–2016.

FIGURE 1-11

Risk-adjusted mortality (in-hospital through 30 days postdischarge) fell for conditions covered by the HRRP

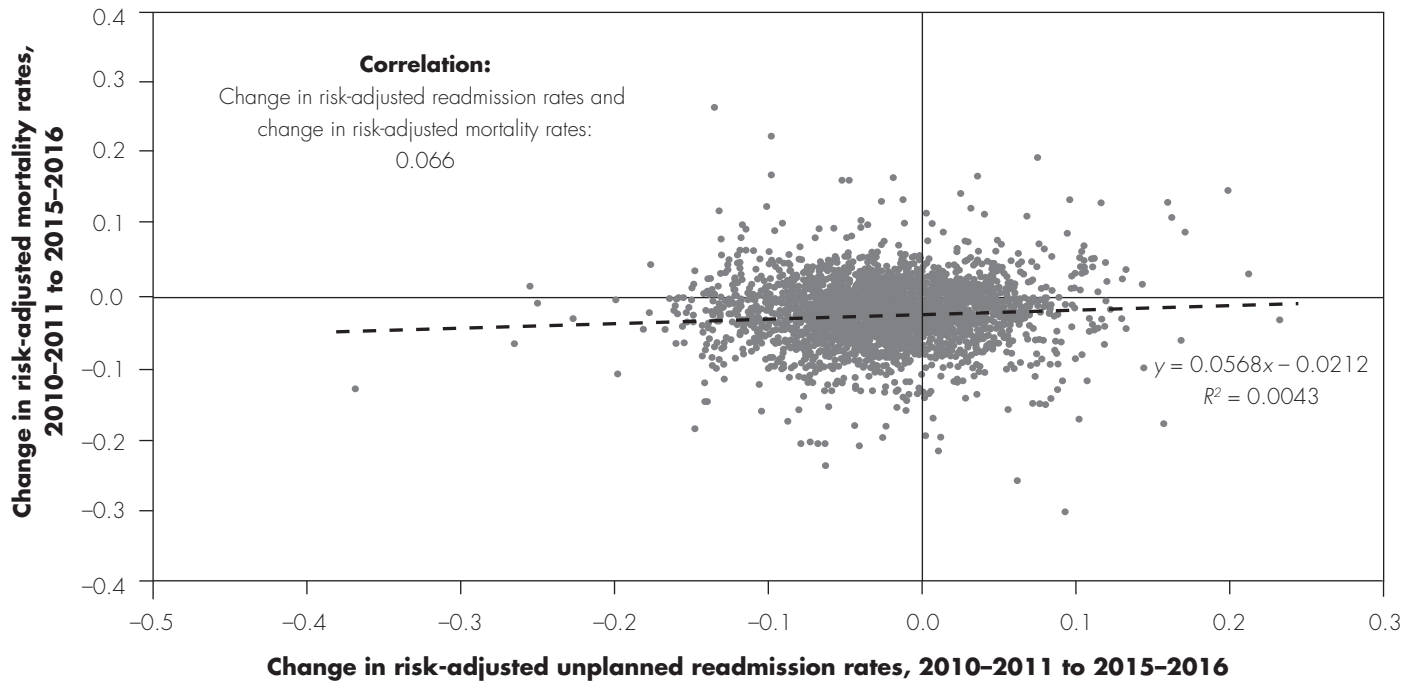


Note: HRRP (Hospital Readmissions Reduction Program), COPD (chronic obstructive pulmonary disease), AMI (acute myocardial infarction), PPACA (Patient Protection and Affordable Care Act of 2010). The pneumonia measure reflects the expanded definition used starting in fiscal year 2016, which includes simple pneumonia, aspiration pneumonia, and sepsis with pneumonia as a secondary diagnosis.

Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older, 2008–2016.

**FIGURE
1-12**

No material relationship between hospital-level changes in heart failure readmission rates and hospital-level changes in mortality



Source: MedPAC analysis of Medicare claims files for Medicare fee-for-service beneficiaries ages 65 or older.

better care transitions, and better coordination with post-acute care providers) may have outweighed any negative changes in care patterns. Our finding for heart failure differs from the earlier two studies, which found a slight increase in risk-adjusted heart failure rates. It could be due to our combination of inpatient and post-acute mortality, differences in risk adjusters, or simply our use of two more years of data. The 2016 data may differ in that the RAC audits had been removed by that time.

Little hospital-level correlation was found between changes in readmission rates and changes in mortality

In addition to looking at national trends—which can be confounded by many concurrent changes—we conducted a hospital-level analysis of the relationship between change in readmission rates and mortality rates over time. As shown in Figure 1-12, we found almost no correlation. The small correlation between changes in readmission rates and changes in mortality rates that we did see was positive, meaning that hospitals that improved their readmission rates more than average tended to also

improve their mortality rates a bit more than average. While statistically significant, the magnitude of the correlation is small (0.066). The correlations for mortality and readmissions for the other four HRRP conditions are also small (and positive), but also statistically significant. Interestingly, the correlation found by the Dharmarajan study, which used a different measure of mortality and different years of data, was the same (0.066) (Dharmarajan et al. 2017).

Policy implications

Readmission rates clearly declined from 2010 to 2016. Given the totality of the evidence and the findings in the literature, it appears that at least some of this reduction was due to the incentives in the HRRP. The exact share that is due to the HRRP and the share due to other factors is difficult to disentangle. The reduction in readmission rates appears to have been achieved without an increase in risk-adjusted mortality or a material increase in spending

on other services. While use of observation care and ED postdischarge increased after the HRRP was introduced, these increases were program wide and likely strongly influenced by other factors such as the RAC audits and two-midnight policy implemented by CMS over this period. While the program has achieved some of its objectives, the program could still be improved. As we discussed in 2013, the program could be expanded to cover all conditions, and the magnitude of the penalty

for each excess readmission could be reduced. This budget-neutral change would create a broader incentive for providers to reduce readmissions and would allow the Medicare program to reduce penalties to a level that is more proportionate to the cost of excess readmissions. In addition, as we discuss in Chapter 7 of this report, the system of hospitals' financial incentives could be adjusted to balance readmission, mortality, and patient experience incentives. ■

Endnotes

- 1 The 30-day measures used for the Hospital Readmissions Reduction Program (HRRP) are essentially the same measure as reported on the Hospital Compare website except that readmissions to Veterans Health Administration hospitals and critical access hospitals are not included. A person who is discharged from a prospective payment system hospital and is later readmitted to a critical access hospital is not considered a readmission for purposes of the HRRP.
- 2 The use of principal discharge diagnosis raises an issue of double counting admissions when the policy was expanded to include chronic obstructive pulmonary disease (COPD) in fiscal year 2015 and coronary artery bypass graft (CABG) surgery in fiscal year 2016. For example, many patients who are admitted to the hospital with a heart attack receive either percutaneous transluminal coronary angioplasty or a CABG during their stay. The principal discharge diagnosis for these patients is usually AMI. Thus, these cases could be counted under both the current AMI readmission measure and the CABG readmission measure.
- 3 During the 2008 to 2014 time frame, heart failure admissions dropped significantly. Dharmarajan and colleagues report a decline in their data set of roughly 16 percent, from 449,135 to 385,222 (Dharmarajan et al. 2017). The cases that may have continued to be admitted may have been the more difficult cases. It is not clear that the risk adjuster would have fully accounted for changes in case mix over time. This issue is discussed further in the online Appendix 1-B, available at <http://www.medpac.gov>.
- 4 Gupta and colleagues found that risk-adjusted mortality rates increased faster than raw mortality rates. This combination of findings implies that the expected rate of mortality decreased, meaning the post-HRRP group had a lower risk of death than the pre-HRRP group. The conclusion that the post-HRRP group had a lower expected one-year mortality is difficult to reconcile with the descriptive statistics stating that the post-HRRP group had an older mean age (80.9 years compared with 80.1 years), was more likely to have had a previous stroke/transient ischemic attack (17.2 percent compared with 15.6 percent), was more likely to be discharged to hospice (4.6 percent compared with 2.5 percent), and less likely to be discharged to home (63.7 percent compared with 69.0 percent) (Gupta et al. 2017). However, the post-HRRP group did have a shorter length of stay: 4.8 days versus 5.4 days for the pre-HRRP group. It is not clear what factors in the Gupta model led to the post-HRRP group being assigned a lower one-year mortality risk.
- 5 While the rates of change in the PPR and HRRP methods are similar, the rates of readmission in the PPR program are generally lower because the PPR methodology excludes more cases (e.g., trauma) and counts a sequence of readmissions as only one readmission. Instead of counting individual readmissions, the PPR approach counts readmission chains, which are defined as sequences of one or more PPRs that are all clinically related to the same initial admission. In calculating PPR rates, readmission chains rather than individual readmissions are used as the numerator. For more information, see: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/08Fallpg75.pdf>.
- 6 We also examined the percentage change (rather than the percentage point change) and again found the raw rate of decline is more than twice as fast for HRRP conditions as non-HRRP conditions (13.2 percent versus 4.5 percent).
- 7 The two-midnight rule specified that CMS would not target admissions that lasted two midnights or longer for medical necessity review. In online Appendix 1-B, available at <http://www.medpac.gov>, we illustrate how the share of heart failure readmissions that were one-day stays fell during the period that the RAC medical necessity reviews of inpatient stays were occurring.
- 8 The percentage point changes do not correspond exactly to the changes shown in Figure 1-4 because the readmission rates in Figure 1-4 were rounded to the nearest one-tenth of a percent.
- 9 The differences in raw rates were even larger (2.4 percentage points for HRRP conditions and 0.7 percentage point for non-HRRP conditions).
- 10 The percentage decline in readmission rates was larger for HRRP conditions using a Wilcoxon signed-rank test ($p < 0.01$).
- 11 Ibrahim and colleagues suggested that about two-thirds of the reduction in risk-adjusted readmission rates was due to patients being coded as being more severely ill, which could reflect true changes in the severity of illness among admitted patients or changes in coding practices (Ibrahim et al. 2017). Only about one-third of the change in readmission rates was not related to coded severity. The study was conducted by comparing inpatient prospective payment system hospitals to critical access hospitals that were not affected by the HRRP. As we discuss in online Appendix 1-B, available at <http://www.medpac.gov>, critical access hospitals are an imperfect comparison group, and the share of the readmissions reduction caused by the more intensive coding practices cannot be precisely estimated. The fact that we also found large changes for raw readmission rates suggests that the effect of coding practices may have been modest (see online Appendix 1-B, available at <http://www.medpac.gov>).

12 The 3M risk of mortality measure we use to examine expected mortality indicates that the severity of illness of heart failure patients increased from 2010 to 2016. However, some of this increase may be due to greater coding rather than truly greater health needs. Therefore, we also examined indicators that are based on patient conditions before admission and indicators that are not dependent on coding. We found that the average hierarchical condition category score for patients admitted with heart failure increased from 2.74 in 2010 to 2.88 in 2012 and to 3.06 in 2016. This means that the diagnoses codes and other factors from the year before admission indicated that 2016 cohort of heart failure patients had higher expected annual healthcare costs (relative to the national average for that year) than the 2010 cohort. To examine factors unrelated to coding, we also examined intensive care unit use. We found the share of heart failure admissions with one or more

days in the intensive care unit increased from 34.3 percent in 2010 to 35.5 percent in 2012 to 35.8 percent in 2016. We also examined discharge destination as another indicator of health that is not dependent on coding. We saw the share of heart failure patients that were discharged home for self-care decreased by 3.9 percentage points from 46.5 percent of patients in 2010 to 42.6 percent of patients in 2016. In contrast, the share discharged to hospice increased by 1.1 percentage points; the share of those discharged to home with home health care increased by 1.8 percentage points; the share discharged to an inpatient rehabilitation facility increased by 0.8 percentage points; and the share discharged to a skilled nursing facility increased by 0.5 percentage points. The coding-based indicators of health and the indicators that are not dependent on coding both point toward the 2016 cohort of patients being less healthy than the 2010 cohort.

References

- Birmingham, L. E., and W. H. Oglesby. 2018. Readmission rates in not-for-profit vs. proprietary hospitals before and after the Hospital Readmission Reduction Program implementation. *BMC Health Services Research* 18, no. 1 (January 19): 31.
- Cary, M. P., Jr., V. Goode, N. Crego, et al. 2018. Hospital readmissions among total hip replacement patients in 2009 and 2014. *Archives of Physical Medicine and Rehabilitation* (January 30).
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2013 rates; hospitals' resident caps for graduate medical education payment purposes; quality reporting requirements for specific providers and for ambulatory surgical centers. Proposed rule. *Federal Register* 77, no. 92 (May 11): 27870–28192.
- Chatterjee, P., and K. E. Joynt Maddox. 2018. U.S. national trends in mortality from acute myocardial infarction and heart failure policy: Success or failure? *JAMA Cardiology* (Published online March 14). <https://jamanetwork.com/journals/jamacardiology/article-abstract/2674715?redirect=true>.
- Chen, M., and D. C. Grabowski. 2017. Hospital Readmissions Reduction Program: Intended and unintended effects. *Medical Care Research and Review* (December 1): 1–18.
- Coleman, E. A., C. Parry, S. Chalmers, et al. 2006. The care transitions intervention: Results of a randomized controlled trial. *Archives of Internal Medicine* 166, no. 17 (September 25): 1822–1828.
- Dharmarajan, K., and H. M. Krumholz. 2017. Consequences of reductions in hospital readmissions: Reply. *Journal of the American Medical Association* 318, no. 19 (November 21): 1934.
- Dharmarajan, K., Y. Wang, Z. Lin, et al. 2017. Association of changing hospital readmission rates with mortality rates after hospital discharge. *Journal of the American Medical Association* 318, no. 3 (July 18): 270–278.
- Gu, Q., L. Koenig, J. Faerber, et al. 2014. The Medicare Hospital Readmissions Reduction Program: Potential unintended consequences for hospitals serving vulnerable populations. *Health Services Research* 49, no. 3 (June): 818–837.
- Gupta, A., L. A. Allen, D. L. Bhatt, et al. 2017. Association of the Hospital Readmissions Reduction Program implementation with readmission and mortality outcomes in heart failure. *JAMA Cardiology* (November 12). <https://jamanetwork.com/journals/jamacardiology/article-abstract/2663213?redirect=true>.
- Himmelstein, D., and S. Woolhandler. 2015. Quality improvement: 'Become good at cheating and you never need to become good at anything else'. *Health Affairs* blog, August 27. <http://healthaffairs.org/blog/2015/08/27/quality-improvement-become-good-at-cheating-and-you-never-need-to-become-good-at-anything-else/>.
- Hu, J., M. D. Gonsahn, and D. R. Nerenz. 2014. Socioeconomic status and readmissions: Evidence from an urban teaching hospital. *Health Affairs* 33, no. 5 (May): 778–785.
- Hu, J., A. J. H. Kind, and D. Nerenz. 2018. Area Deprivation Index predicts readmission risk at an urban teaching hospital. *American Journal of Medical Quality* (January 1): 1–9.
- Ibrahim, A. M., J. B. Dimick, S. S. Sinha, et al. 2017. Association of coded severity with readmission reduction after the Hospital Readmissions Reduction Program. *JAMA Internal Medicine* (November 13). <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663252>.
- Jack, B. W., V. K. Chetty, D. Anthony, et al. 2009. A reengineered hospital discharge program to decrease rehospitalization: A randomized trial. *Annals of Internal Medicine* 150, no. 3 (February 3): 178–187.
- Jencks, S. F., M. V. Williams, and E. A. Coleman. 2009. Rehospitalizations among patients in the Medicare fee-for-service program. *New England Journal of Medicine* 360, no. 14 (April 2): 1418–1428.
- Joynt, K. E., J. E. Figueroa, J. Oray, et al. 2016. Opinions on the Hospital Readmission Reduction Program: Results of a national survey of hospital leaders. *American Journal of Managed Care* 22, no. 8 (August 1): e287–294.
- Kanaan, S. 2009. *Homeward bound: Nine patient-centered programs cut readmissions*. Oakland, CA: California HealthCare Foundation.
- Khera, R., A. Pandey, C. R. Ayers, et al. 2017. Contemporary epidemiology of heart failure in fee-for-service Medicare beneficiaries across healthcare settings. *Circulation: Heart Failure* 10, no. 11 (November): 1–9.
- Klevens, R. M., J. R. Edwards, C. L. Richards, Jr., et al. 2007. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Reports* 122, no. 2 (March–April): 160–166.
- McHugh, J. P., A. Foster, V. Mor, et al. 2017. Reducing hospital readmissions through preferred networks of skilled nursing facilities. *Health Affairs* 36, no. 9 (September 1): 1591–1598.

Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2015. The hospital readmission penalty: How well is it working? MedPAC blog. March 24. <http://www.medpac.gov/-blog-/medpacblog/2015/03/24/the-hospital-readmission-penalty-how-well-is-it-working>.

Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2011a. Comment letter to CMS on the proposed rule entitled: Medicare program; hospital inpatient value-based purchasing program, May 4. http://www.medpac.gov/docs/default-source/comment-letters/06172011_FY12IPPS_MedPAC_COMMENT.pdf?sfvrsn=0.

Medicare Payment Advisory Commission. 2011b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system*. Washington, DC: MedPAC.

Naylor, M. D., L. H. Aiken, E. T. Kurtzman, et al. 2011. The care span: The importance of transitional care in achieving health reform. *Health Affairs* 30, no. 4 (April): 746–754.

Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. 2016. *Report to Congress: Social risk factors and performance under Medicare's value-based purchasing programs*. Washington, DC: ASPE.

QualityNet. 2017. Measure methodology reports. <https://www.qualitynet.org/dcs/ContentServer?cid=1219069855841&pagenam e=QnetPublic%2FPage%2FQnetTier4&c=Page>.

Salerno, A. M., L. I. Horwitz, J. Y. Kwon, et al. 2017. Trends in readmission rates for safety net hospitals and non-safety net hospitals in the era of the US Hospital Readmission Reduction Program: A retrospective time series analysis using Medicare administrative claims data from 2008 to 2015. *BMJ Open* 7, no. 7 (July 13): e016149.

Sheingold, S. H., R. Zuckerman, and A. Shartzter. 2016. Understanding Medicare hospital readmission rates and differing penalties between safety-net and other hospitals. *Health Affairs* 35, no. 1 (January): 124–131.

Winblad, U., V. Mor, J. P. McHugh, et al. 2017. ACO-affiliated hospitals reduced rehospitalizations from skilled nursing facilities faster than other hospitals. *Health Affairs* 36, no. 1 (January 1): 67–73.

Zuckerman, R. B., K. E. Joynt Maddox, S. H. Sheingold, et al. 2017. Effect of a hospital-wide measure on the Readmissions Reduction Program. *New England Journal of Medicine* 377, no. 16 (October 19): 1551–1558.

Zuckerman, R. B., S. H. Sheingold, E. J. Orav, et al. 2016. Readmissions, observation, and the Hospital Readmissions Reduction Program. *New England Journal of Medicine* 374, no. 16 (April 21): 1543–1551.

CHAPTER

2

**Using payment to ensure
appropriate access to and
use of hospital emergency
department services**

R E C O M M E N D A T I O N S

2-1 The Congress should:

- allow isolated rural stand-alone emergency departments (more than 35 miles from another emergency department) to bill standard outpatient prospective payment system facility fees and
- provide such emergency departments with annual payments to assist with fixed costs.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

.....
2-2 The Congress should reduce Type A emergency department payment rates by 30 percent for off-campus stand-alone emergency departments that are within six miles of an on-campus hospital emergency department.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Using payment to ensure appropriate access to and use of hospital emergency department services

Chapter summary

Medicare’s payment policies should foster adequate access to care and encourage efficient delivery of services. Maintaining access to emergency department (ED) services can be a challenge in isolated rural areas, where a single hospital may be the sole source of ED care. If that sole hospital closes, access to emergency care can be lost. In contrast, efficiency can be a challenge in urban areas, where EDs can be in oversupply. New urban stand-alone EDs (medical facilities providing ED services that are located apart from a hospital campus and can be either affiliated or unaffiliated with a hospital) could result in cases shifting from lower cost settings such as urgent care centers and physician offices, which do not provide ED services and are generally not open 24 hours per day, to the higher cost ED setting, which is generally open 24 hours per day. New stand-alone EDs could also siphon off lower acuity (less severely ill) patients from on-campus hospital-based EDs. In this chapter, we recommend two ways to change the way Medicare pays for ED services to reduce the risk of ED services being undersupplied in rural areas and oversupplied in urban areas. Medicare payment rates to isolated rural stand-alone EDs would increase, and payment rates to urban stand-alone EDs close to other sources of emergency care would decrease.

We first review basic information on how Medicare pays for emergency services in rural and urban areas. Second, we outline concerns regarding preserving access to ED services in rural areas, which is a continuation of our

In this chapter

- Background
- Rural areas: Maintaining access to emergency department services
- Urban areas: Incentives have led to an abundance of urban stand-alone EDs
- Future analyses

2016 discussion of rural EDs (Medicare Payment Advisory Commission 2016a). Third, we discuss limiting excess volume of ED services in urban areas, which is an extension of our 2017 discussion of stand-alone urban EDs (Medicare Payment Advisory Commission 2017).

Maintaining access to emergency department services in rural areas

Maintaining access to ED services can be challenging in isolated rural areas with low population densities. In many isolated rural areas, inpatient hospitals' volumes have fallen dramatically, with many hospitals admitting fewer than one patient per day. However, Medicare will pay a facility for emergency services only if it maintains inpatient services. Therefore, small isolated communities that want an ED must maintain a low-occupancy inpatient department in the hospital. In 2016, approximately 130 hospitals averaged less than 1 admission per day (all payers) and were more than 35 miles from other hospitals. EDs at these hospitals serve as important sources of emergency care, but to maintain these isolated EDs, hospitals must maintain their largely empty inpatient beds.

As an alternative to maintaining empty inpatient beds, the Commission is recommending a new payment model that would allow Medicare to pay for emergency services at stand-alone EDs in isolated rural areas (more than 35 miles from another ED). The rural facility would have an ED that is open 24 hours a day, 7 days a week, but would not provide acute inpatient care. The facility could retain other services such as ambulance services and outpatient clinics, and we refer to the combination of the stand-alone ED and its affiliated outpatient services as an outpatient-only hospital. Isolated rural full-service hospitals that choose to convert to outpatient-only hospitals would receive the same standard prospective payment rates for ED visits as a full-service hospital. In addition, a set annual payment (common across all outpatient-only hospitals) would be made to help cover the facility's fixed costs.

The new payment option would allow rural communities that cannot support a full-service hospital a way to maintain access to emergency care in their community, while retaining the option to convert back to a full-service hospital if circumstances change. The recommendation would increase Medicare spending by less than \$50 million per year.

Encouraging efficient delivery of emergency services in urban areas

Urban hospitals can set up stand-alone EDs that bill Medicare as if they are a part of the hospital's main ED as long as they are located within 35 miles of the main hospital campus. We refer to these hospital-affiliated facilities as off-campus EDs (OCEDs). The number of OCEDs has increased rapidly in recent years, particularly

in areas with high household incomes. ED visits overall and their coded severity levels have increased. Under Medicare's payment system for ED visits, providers have incentives to add new OCEDs rather than urgent care centers, which are paid less than half the hospital ED rates.

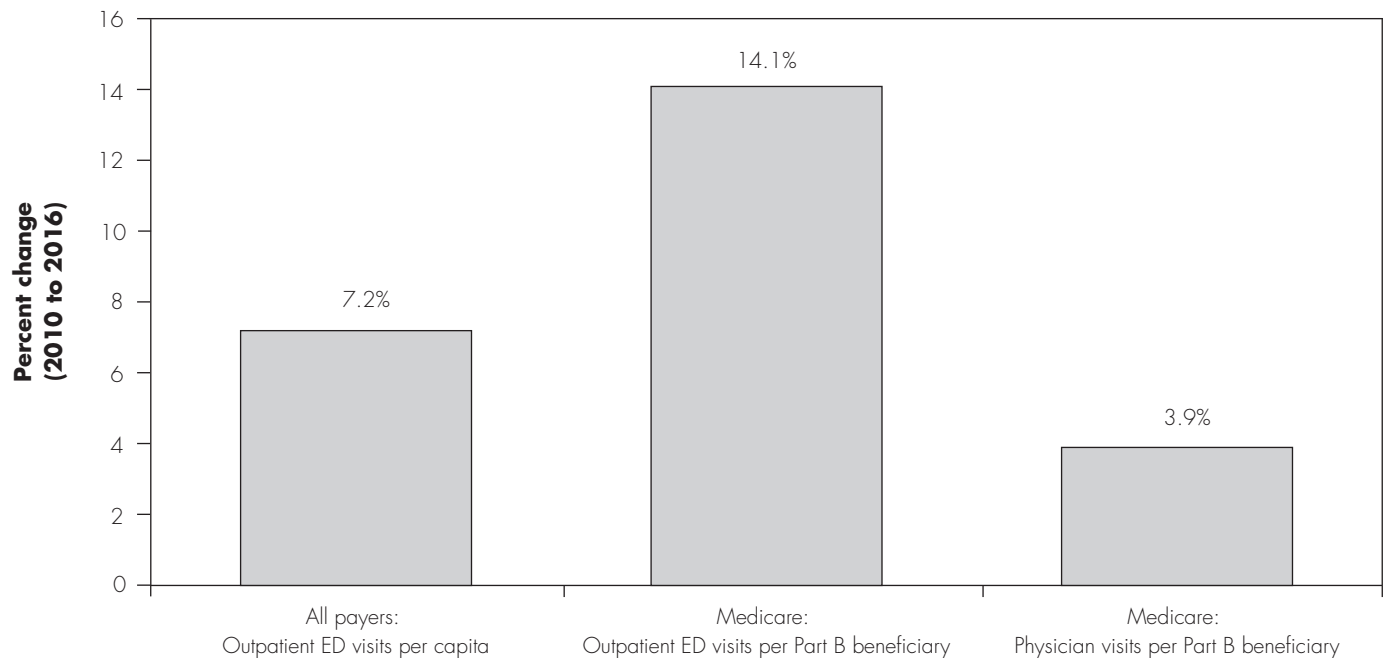
Patients who are served at off-campus EDs appear to have less complex care needs than those of patients served at on-campus hospital EDs. Ambulance operators typically take trauma, stroke, and heart attack patients to on-campus hospital EDs, which provide trauma services, operating rooms, and inpatient services. As a result, off-campus EDs do not incur the standby costs of these resource-intensive services. While urban off-campus EDs may provide some services not available at doctors' offices and urgent care centers, we conclude Medicare overpays these facilities relative to what is paid to on-campus hospital EDs for more difficult cases.

Medicare currently has two levels of payments for OCEDs. One is for EDs open 24 hours a day, 7 days a week (Type A payment rates), and the other is for EDs open less than 24 hours a day, 7 days a week (Type B payment rates). Type B ED rates are lower under the rationale that these facilities have lower standby costs. In 2018, Type B payment rates are roughly 30 percent lower than Type A rates. Evidence from three states indicates that urban OCEDs likely have lower standby costs than on-campus hospital EDs. The Commission is therefore recommending that Medicare pay urban OCEDs the Type A payment rates reduced by 30 percent—which would better align payments with standby costs and make off-campus ED rates similar to Type B rates. An exception would be needed for the one-quarter of OCEDs that are located relatively far (more than six miles) from on-campus EDs and that likely provide unique access to ED services for their local community (other exceptions could be contemplated when an urban OCED is essential to retain access—for example, if the OCED is the result of its parent hospital closing). Paying these more isolated urban OCEDs the full Type A payment rates would be justified to ensure continued appropriate access to emergency services.

The Commission's urban recommendation would better align payment with the standby costs of urban OCEDs in close proximity to on-campus hospital EDs, while maintaining higher payment rates for urban OCEDs that are located farther from on-campus EDs and may provide unique access to ED services. Medicare beneficiaries served at OCEDs close to on-campus EDs would have lower cost sharing, and access to ED services would be preserved in areas where it is most needed. Overall, this policy would reduce the incentive to develop new off-campus EDs and would lower Medicare spending by between \$50 million and \$250 million annually. ■

**FIGURE
2-1**

All-payer and Medicare emergency department visits per capita grew faster than Medicare physician office visits per capita, 2010–2016



Note: ED (emergency department). Outpatient ED visits are those in which the patient was treated in the ED but not admitted to the hospital. ED visits occurring at on-campus hospital EDs and off-campus hospital EDs are both included.

Source: American Hospital Association and Medicare claims data.

Background

Ideally, Medicare payment policies should encourage the appropriate use and efficient delivery of emergency department (ED) services to both rural and urban beneficiaries. Given that ED services can be critically important to supporting the care needs of Medicare beneficiaries, adequate access needs to be maintained in rural and urban areas. In rural areas, the challenge can be to maintain access to a single ED. In contrast, in some urban areas, concern exists about excessive expansion in the number of EDs, which could result in a shift of care from lower cost urgent care centers and physician offices to higher cost EDs. Off-campus EDs (OCEDs)—those EDs located apart from the hospital campus—could then benefit by treating lower cost patients while receiving rates equal to on-campus EDs that treat higher acuity (more severely ill) patients. Private insurers try to manage demand for emergency services by charging higher cost

sharing in EDs and, in some cases, denying payment for services not deemed emergent (Glatter 2017, Livingston 2018). Higher copayments are unlikely to work for fee-for-service (FFS) Medicare given the widespread use of supplemental insurance. In this chapter, we discuss two ways to change the way emergency services are paid. The objectives are to reduce the risk of undersupply in rural areas and oversupply in urban areas.

ED services are most commonly delivered at the roughly 4,500 on-campus hospital EDs that are typically open 24 hours per day, 7 days a week (24/7). However, increasingly, these services are also provided at OCEDs. Between 2010 and 2016, the number of hospital outpatient ED visits (those not resulting in an inpatient hospital stay) nationwide increased by more than 7 percent per capita across all payers (Figure 2-1).¹ Over the same period, Medicare outpatient ED visits per beneficiary increased 14 percent, while Medicare physician office visits per beneficiary increased about 4 percent. Faster

**TABLE
2-1**

Medicare ED visits in the two highest paying levels grew as a share of all Medicare ED visits, 2010–2016

ED payment level	Outpatient ED visits				Change in number of ED visits	Percentage point change in share of ED visits
	2010		2016			
	Number	Share	Number	Share		
Level 1	682,180	4.4%	660,950	3.6%	-21,230	-0.8
Level 2	1,781,920	11.5	1,312,937	7.1	-468,983	-4.4
Level 3	5,103,120	32.8	5,198,704	28.0	95,584	-4.8
Level 4	4,963,920	32.0	6,426,367	34.6	1,462,447	2.6
Level 5	3,004,240	19.3	4,960,439	26.7	1,956,109	7.4
Total	15,535,380	100.0	18,559,397	100.0	3,023,927	0.0

Note: ED (emergency department). ED payment levels are commonly used as a proxy for the severity of patient illness. Level 1 is the lowest paying level, suggesting these are the lowest severity patients. Level 5 is the highest paying level, suggesting these are the highest severity patients. Data include Medicare Type A and Type B ED visits. Outpatient ED visits are those in which the patient was treated in the ED but not admitted to the hospital. ED visits occurring at on-campus hospital EDs and off-campus hospital EDs are both included.

Source: CMS hospital outpatient claims data.

growth at EDs relative to physician office visits suggests some movement of lower severity cases from lower cost physician offices to higher cost ED settings. In 2016, Medicare beneficiaries accounted for 28.4 million ED visits, counting both outpatient ED visits and ED visits that resulted in an inpatient admission (data not shown).

Volume of higher level cases has increased

For payment purposes, Medicare and many other payers require providers to identify ED visits in one of five levels that are based on Current Procedural Terminology (CPT) codes and general descriptions of the service. Between 2010 and 2016, the number of Medicare outpatient ED visits billed at the highest of the five ED levels increased as a share of all Medicare ED visits, climbing from 19.3 percent to 26.7 percent (Table 2-1). By contrast, during the same period, Medicare ED visits coded in the three lowest paying ED levels declined as a share of all Medicare ED visits. For example, as a share of all ED visits, Level 3 ED visits fell from 32.8 percent to 28.0 percent.

Certain factors could account for the more rapid growth of higher level ED services. One possibility is that providers are coding a larger share of ED visits in the higher paying levels, a practice referred to as upcoding. Given the growth in the overall volume of higher level visits (a 2.6 percentage point increase in Level 4 visits and 7.4 percentage point increase in Level 5), it appears that

coding is at least partially responsible for the increased reported severity. Another possibility is that cases formerly admitted to the hospital are now treated on an outpatient basis, increasing the share of higher severity cases. However, the decline in admissions is too small to fully explain the magnitude of the increase in higher level cases seen in EDs. It is unlikely that the growth in higher level ED visits is the result of a real increase in patient severity because the growth in the number of ED visits in Levels 4 and 5 occurred concurrently with growth in total ED visits. That is, the growth in the share of higher intensity visits did not reflect the movement of low-severity cases out of the ED.

Medicare payments for ED services

Medicare beneficiaries who visit EDs generate a physician claim and a hospital outpatient ED claim. Physician claims for ED visits are paid through the Medicare physician fee schedule (PFS). Hospital claims for ED visits that do not result in an inpatient admission are paid through the hospital outpatient prospective payment system (OPPS) or, in the case of ED visits at critical access hospitals (CAHs), under the CAH cost-based payment system.²

The PFS and OPPS both use the five-tiered scale to pay for ED visits. The physician bills Medicare by identifying one of the five ED levels for each case (Table 2-2). The facility

**TABLE
2-2**

Medicare payment rates for ED visits under the Medicare physician fee schedule and hospital outpatient prospective payment system, 2018

OPPS payment amount

ED payment level	Physician fee schedule rate for an OPPS visit	OPPS payment amount	
		Type A (facility open 24 hours per day)	Type B (facility open less than 24 hours per day)
Level 1	\$21.60	\$68.66	\$102.49
Level 2	42.12	124.65	90.82
Level 3	63.00	219.10	157.66
Level 4	119.52	355.53	209.01
Level 5	176.04	520.85	285.88

Note: ED (emergency department), OPPS (outpatient prospective payment system). ED payment levels are commonly used as a proxy for the severity of patient illness. Level 1 is the lowest paying level, suggesting these are the lowest severity patients. Level 5 is the highest paying level, suggesting these are the highest severity patients. The table reflects 2018 Medicare payment rates under the physician fee schedule and OPPS and does not include payments for ancillary services that might be incurred at the time of treatment. ED visits are those in which the patient was treated in the ED but not admitted to the hospital. ED visits occurring at on-campus hospital EDs and off-campus hospital EDs are both included. While Type A rates are on average higher than Type B rates, payment rates for Type B Level 1 ED visits are anomalously higher than Type A Level 1 ED visits.

Source: CMS calendar year 2018 hospital outpatient prospective payment system final rule.

bills under the OPPS, which maintains two sets of rates that depend on the type of facility. Type A rates are used for hospital EDs open 24/7. Type B rates are used for EDs open less than 24/7.³ In 2018, Type B rates are on average roughly 30 percent lower than Type A rates because Type B facilities do not incur the cost of maintaining standby ED staff 24/7. While Type A rates are on average higher than Type B rates, payment rates for Type B Level 1 ED visits are anomalously higher than Type A Level 1 ED visits.⁴ The volume of claims paid under Type B rates is low, accounting for about 1 percent of all Medicare ED claims in 2016.

When a beneficiary visits an ED, the facility bills Medicare for the ED visit and other outpatient services (e.g., imaging and lab services) under the OPPS, and the physician bills Medicare under the PFS. Under a hypothetical example of the most common level billed—a Level 4 ED visit—the Medicare payment rate for a hospital ED open 24/7 is \$356 (not including other outpatient services) and for the physician is \$120, totaling a Medicare payment of \$476 (Figure 2-2, p. 42). If the same patient were treated at a hospital ED open less than 24/7 (that is, a hospital receiving the Type B rate), the Medicare payment to the facility would be \$209 and payment to the physician would be \$120, for a total payment of \$329.

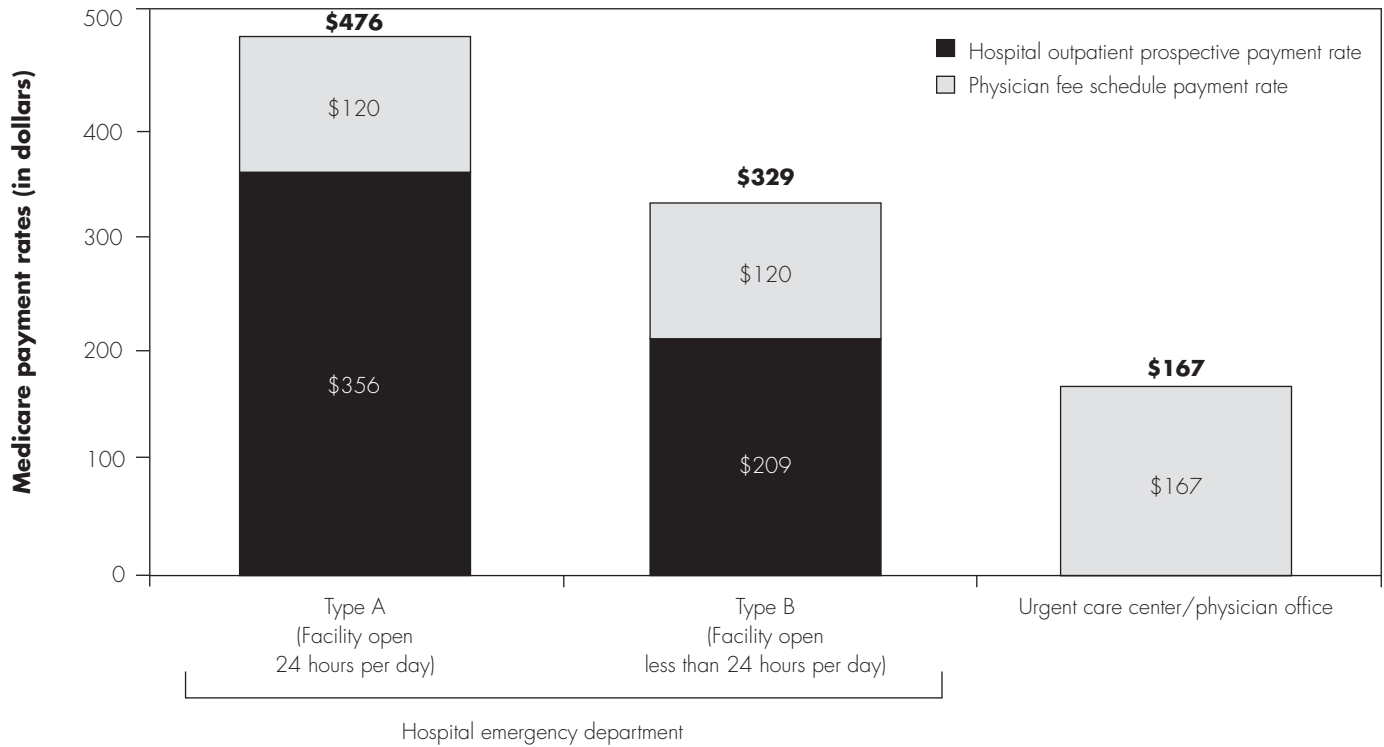
Medicare generally pays lower amounts for services provided at urgent care centers, retail clinics, and physicians’ offices for similar types of patients. New hospital-affiliated urgent care centers, independent urgent care centers, retail clinics, and physician offices are paid the nonfacility PFS rate and are not permitted to bill facility fees for ED services.⁵ Using the same Level 4 example, at one of these non-hospital-affiliated providers, the total Medicare payment would be \$167 to the physician for an evaluation and management (non-ED) visit.

Facilities billing Medicare Type B claims serve lower acuity ED cases

In 2016, about 83 percent of the Medicare Type B claims were in one of the three lowest ED acuity levels (i.e., Levels 1–3; Table 2-3, p. 43). By contrast, only about 38 percent of Type A visits were in one of the three lowest ED acuity levels. This difference may be too large to attribute simply to coding differences at the types of ED facilities and may demonstrate real differences in the acuity of cases treated at Type A and Type B ED facilities. These data suggest that Type B facilities, which in 2016 accounted for 1 percent of all Medicare ED claims, generally serve lower acuity cases than Type A facilities.

**FIGURE
2-2**

Medicare Type A ED payment rates for similar services are higher than Type B ED payment rates and urgent care centers and physician offices payment rates, 2018



Note: ED (emergency department). Hospital outpatient prospective payment rates for Type A and Type B visits reflect Level 4 ED services. The physician fee schedule payment rates for services delivered in hospital emergency departments reflect Level 4 physician ED services. Payment rates for services delivered in urgent care centers and physician offices reflect Level 4 evaluation and management codes for new patients. In addition, the urgent care center/physician office payment of \$167 reflects the rate paid to new urgent care centers or older urgent care centers not affiliated with a hospital, which do not receive a facility fee for outpatient services. Figures have been rounded.

Source: MedPAC analysis of Medicare 2018 hospital outpatient prospective payment system payment rates and physician fee schedule payment rates.

Current Medicare payment policies encourage stand-alone EDs

A growing number of ED facilities are located apart from a hospital campus and are known as stand-alone EDs. There are two types of stand-alone EDs: hospital-affiliated off-campus emergency departments and independent freestanding emergency centers (IFECs).

OCEDs and IFECs generally offer a similar range of services. Both offer ED services 24/7; basic imaging services such as X-rays, computed tomography (CT) scans, and ultrasound; and on-site lab services for basic diagnostic analyses. Neither typically provides trauma services (e.g., care for victims of car accidents or gunshot wounds). They range in size, with larger facilities serving

as many as 100 patients per day and the smallest facilities serving 20 or fewer patients per day. Larger OCEDs and IFECs also can offer MRI and primary care, house physician specialists' offices, and tend to take more ambulance transports than smaller OCEDs and IFECs. They typically have one or more physicians on-site at all times (typically under contract). These facilities often advertise that they are open longer (24 hours per day) than urgent care centers and treat medical conditions such as respiratory distress, infection, orthopedic injuries and fractures, and abdominal pain. A certain degree of overlap exists between the lower acuity cases treated at stand-alone EDs and urgent care centers, signifying that urgent care centers are also important in supporting the care needs of Medicare beneficiaries.

**TABLE
2-3**

Medicare Type B ED claims included a larger share of lower level ED visits than Type A ED claims, 2016

ED payment level	Type A ED visits (facility open 24 hours per day)		Type B ED visits (facility open less than 24 hours per day)	
	Number of visits	Share of visits	Number of visits	Share of visits
Level 1	627,561	3.4%	33,389	18.0%
Level 2	1,262,344	6.9	50,593	27.2
Level 3	5,127,832	27.9	70,872	38.1
Level 4	6,400,141	34.9	26,226	14.1
Level 5	4,955,541	27.0	4,808	2.6
Total	18,373,419	100.0	185,888	100.0

Note: ED (emergency department). Total shares of visits may not total 100 percent due to rounding.

Source: CMS hospital outpatient claims data.

Between 2008 and 2016, the number of OCEDs roughly doubled. In 2017, about 580 stand-alone EDs, including OCEDs and IFECs, were in operation. Two-thirds of these facilities—377 facilities—were OCEDs, located in 35 states and affiliated with more than 300 hospitals. The remaining one-third of stand-alone EDs were IFECs. We have identified about 200 IFECs, operating mostly in Texas but also in Colorado and Minnesota. In Texas, the number of IFECs increased from 0 in June 2010 (when state licensure of IFECs began) to 191 facilities in 2016. The proliferation of IFECs between 2013 and 2017 has been particularly rapid in the Dallas metropolitan area, where the number of state-registered IFECs nearly tripled, from 25 to 73.

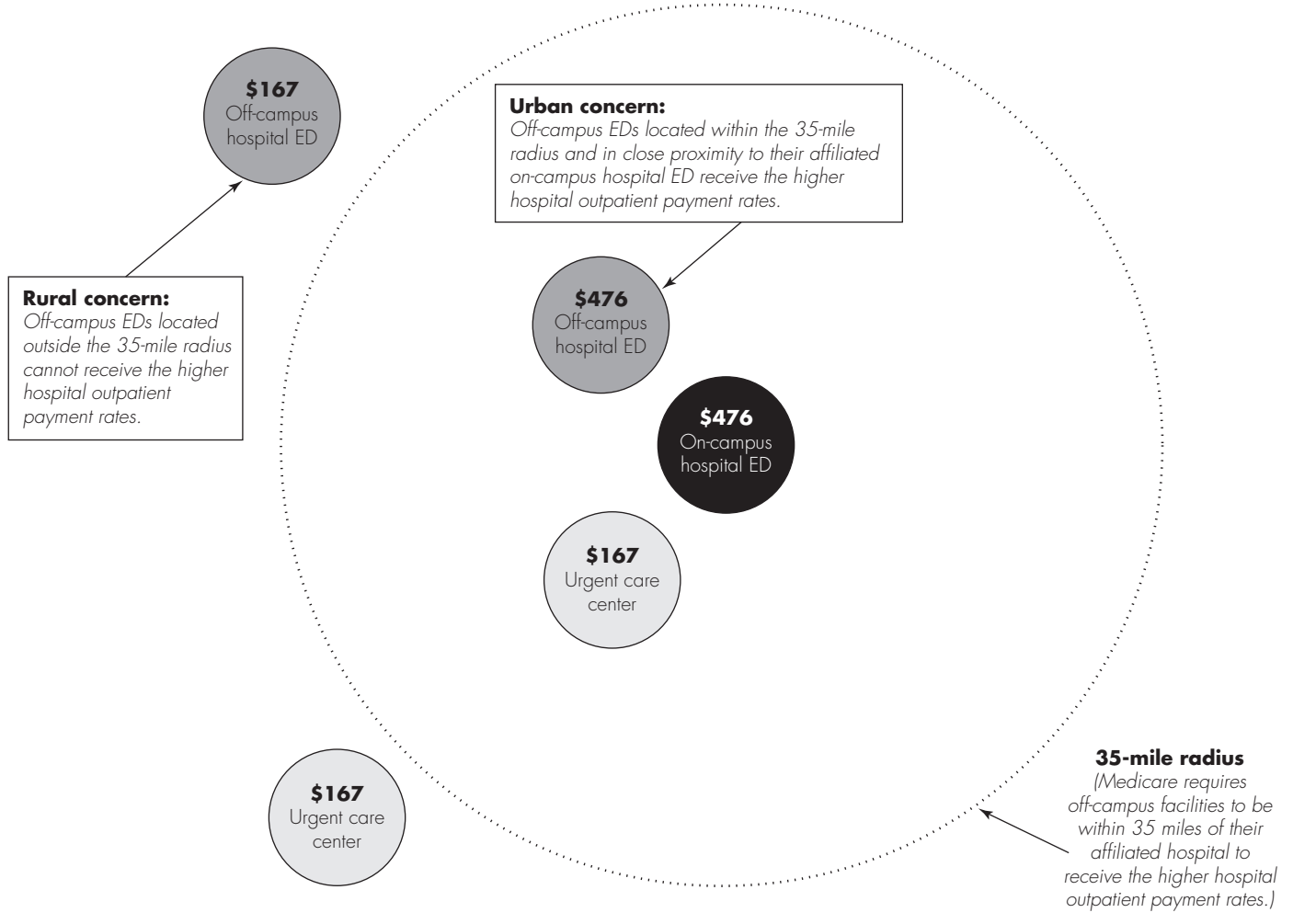
ED services are also provided at micro-hospitals, which are smaller than full-service hospitals and offer a limited range of services. Micro-hospitals focus on the delivery of emergency services and typically have 10 or fewer inpatient beds. Some micro-hospitals also house primary care physician practices, specialty physician practices, and labor and delivery services (Andrews 2016). However, micro-hospitals typically do not offer higher intensity services such as trauma care and intensive care, and patients requiring prolonged care are regularly transferred to larger facilities (Rudavsky 2016). As a result, micro-hospitals likely do not incur the standby costs of full-service hospitals. Nevertheless, micro-hospitals are licensed as independent inpatient hospitals and, as such, can bill Medicare under the OPSP, which pays

substantially more than PFS payment rates. Medicare thus may be overpaying for the ED and outpatient services furnished in micro-hospitals, encouraging their proliferation. About 50 micro-hospitals are open or under development in Arizona, Colorado, Idaho, Missouri, Nevada, Pennsylvania, Oklahoma, and Texas. In addition, the for-profit hospital system Tenet Health stated in its 2018 annual report to shareholders that it currently operates eight micro-hospitals (Morningstar Document Research 2017b). The Commission may conduct future focused research on micro-hospitals.

In addition to EDs, more than 7,000 urgent care centers compete for lower acuity patients.⁶ Urgent care centers provide a broad range of nonemergency services but generally maintain somewhat less service capacity than on-campus hospital EDs. They are typically open less than 24 hours per day; are staffed by physicians, nurses, and physicians’ assistants; and offer relatively limited lab and imaging services. In addition, research suggests that urgent care centers treat lower severity patients than on-campus hospital EDs but that there is overlap between these types of facilities in terms of the types of patients they treat (Baker and Baker 1994, Mehrotra et al. 2009, Thygeson et al. 2008). This overlap occurs among the lowest severity patients. A 2010 study estimated that between 13 percent and 27 percent of cases served in hospitals’ on-campus EDs could be served similarly at urgent care centers or by other providers (Ashwood et al. 2016, Weinick et al. 2010). The severity of patients treated at OCEDs appears

**FIGURE
2-3**

Illustrative example of Medicare ED payment rates by facility type



Note: ED (emergency department). The ED payment amounts displayed are for Level 4 Type A ED visits and for Level 4 office visits at an urgent care center.

to be above that at urgent care centers but lower than that at on-campus hospital EDs. Evaluating how Medicare payment policy influences the treatment location of low-acuity cases at emergency departments may be an area of future Commission research.

Billing for off-campus ED services

OCEDs bill Medicare under the OPPS for a beneficiary's ED visit and any ancillary services (e.g., imaging and lab services), while the clinicians bill under the Medicare PFS. In order to bill Medicare, OCEDs must be deemed off-campus provider-based departments. Provider-based

departments must be in compliance with Medicare and state hospital ED requirements, be financially and clinically integrated with the hospital, be publicized as an affiliate of the hospital, and be located within 35 miles of the main hospital campus (Centers for Medicare & Medicaid Services 2008).⁷ Most private payers pay OCEDs a facility fee and generally consider OCEDs in-network facilities.

If a patient is treated at an OCED, Medicare pays the Type A payment rate as if the patient were at the main hospital campus. As with on-campus EDs, if the patient is transferred from the OCED to the main hospital for

admission, then the ED visit and the ambulance transfer will not be paid separately but, instead, will be deemed part of the cost of the inpatient admission that is bundled into the diagnosis related group payment.

Under current law, hospitals have a financial incentive to build new off-campus EDs and colocate physician offices and specialty clinics within them. The Bipartisan Budget Act of 2015 (BBA of 2015) requires that new “provider-based” clinics owned by hospitals be paid under “the applicable payment system.” The BBA of 2015 did not specify the applicable payment system, but CMS chose a method of paying reduced OPPS rates that are comparable to rates paid in independent physician offices. The BBA of 2015 includes an exception to these reduced OPPS payment rates for any services provided in “dedicated EDs.” This exception, defined in Section 603, requires that both ED and non-ED services (e.g., clinic visits and ancillary services) provided in off-campus EDs be paid the full OPPS payments rates.⁸

The other type of stand-alone ED facility, IFECs, cannot bill Medicare because they are not affiliated with a hospital or considered provider-based facilities by Medicare. Thus, the ED payment policies discussed in this chapter do not address IFECs. Private insurers do not typically contract with IFECs and instead treat them as out-of-network providers. According to several news reports, private insurers are charged significantly higher rates when IFECs are out-of-network facilities, and patients are often left to pay the balance of these charges when claims are denied in part or in full (Rice 2016, Sutherly 2016).

Location of OCEDs can impact Medicare payment rate

Medicare requires provider-based off-campus facilities, such as OCEDs, to be within a 35-mile radius of their affiliated hospitals to receive the higher OPPS payment rates. Figure 2-3 combines the payment rate example used in Figure 2-2 (p. 42) with Medicare’s 35-mile threshold. OCEDs located within a 35-mile radius of their affiliated hospital are paid \$476, the same as an on-campus hospital ED. By contrast, OCEDs located outside of the 35-mile radius are paid \$167 for a comparable service, which is the same as an urgent care center located within or outside the 35-mile radius.

More stand-alone EDs will begin billing Medicare by converting from IFECs to OCEDs

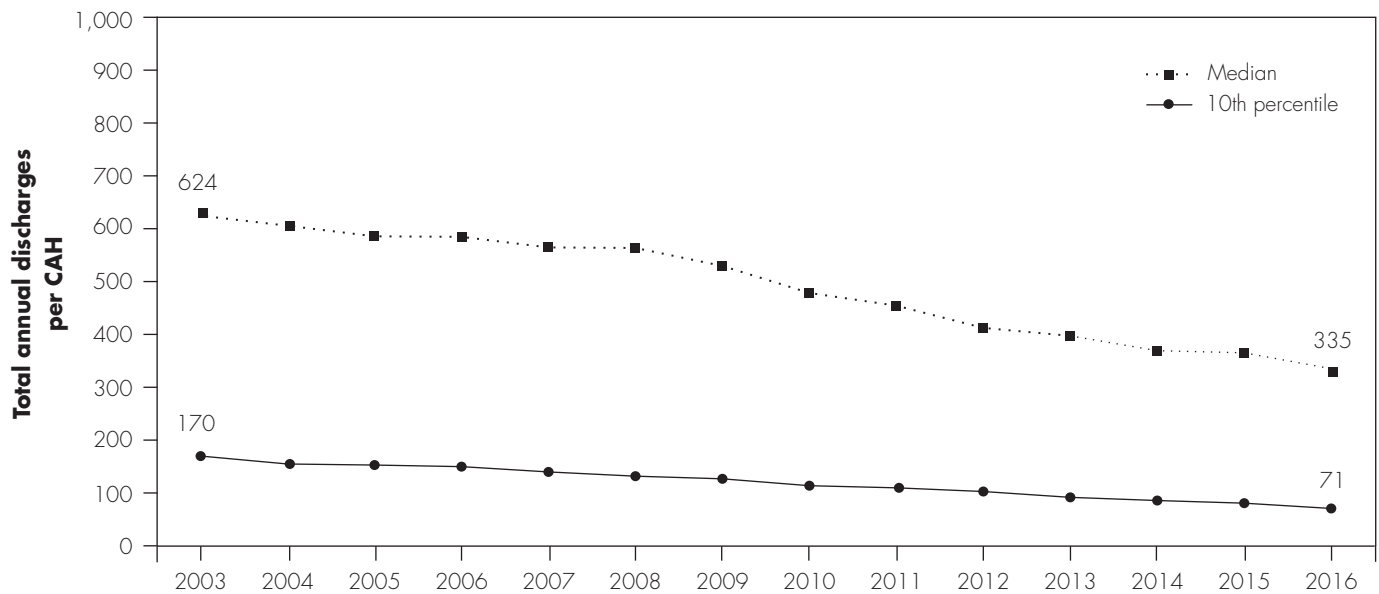
Although Medicare does not pay for services provided in IFECs, many of the 200 IFECs are taking steps to affiliate

with hospitals, effectively converting to new OCEDs, to gain Medicare provider-based status and begin billing Medicare. For example, in recent years, the largest owner of IFECs, Adeptus, modified its business model to partner with hospitals to enable its IFECs to bill Medicare and Medicaid. In Arizona and Ohio, Adeptus partnered with large health systems to build new stand-alone EDs. In Colorado, Adeptus partnered with the University of Colorado Health to build new hospitals with which its existing IFECs could then affiliate. In Texas, Adeptus made two significant changes that enabled their IFECs to begin billing Medicare. First, they began building their own new hospitals (without partnering with a hospital system). Second, Adeptus partnered with hospital system Texas Health Resources, and as a part of the Texas Health Resources agreement, 31 IFECs in Dallas began billing Medicare as OCEDs.

In addition, large for-profit hospital systems are building OCEDs into their business development strategies. In their 2017 annual report to shareholders, Hospital Corporation of America reported that OCEDs are an integral part of their strategy to develop comprehensive health care networks in select communities (Morningstar Document Research 2017a). Community Health Systems also reported that it will use OCEDs to improve market share in certain markets (Community Health Systems 2017). The investment of these large hospital systems in OCEDs suggests the model is viewed as beneficial to the overall success of the system.

Growth in private-payer payment rates also encourages the development of stand-alone EDs

The proliferation of stand-alone EDs is at least in part due to incentives created by commercial insurance contracts to expand ED services. The Health Care Cost Institute reported that the price paid per emergency room visit by private insurers increased by 31 percent from 2012 to 2016 (Health Care Cost Institute 2018). Given the growth in the number of stand-alone EDs during these years, it appears that the providers’ pricing power is sufficient to encourage expansion. Private insurers try to manage demand for emergency services by having higher cost sharing in emergency departments and, in some cases, denying payment for services not deemed emergent. Higher copays are unlikely to work for fee-for-service (FFS) Medicare, given the widespread use of Medicare supplemental insurance. Therefore, other mechanisms for preventing excess use of EDs are needed for the Medicare program.

**FIGURE
2-4****Inpatient use of critical access hospitals declined, 2003–2016**

Note: CAH (critical access hospital).

Source: MedPAC analysis of hospital cost report data from CMS.

Rural areas: Maintaining access to emergency department services

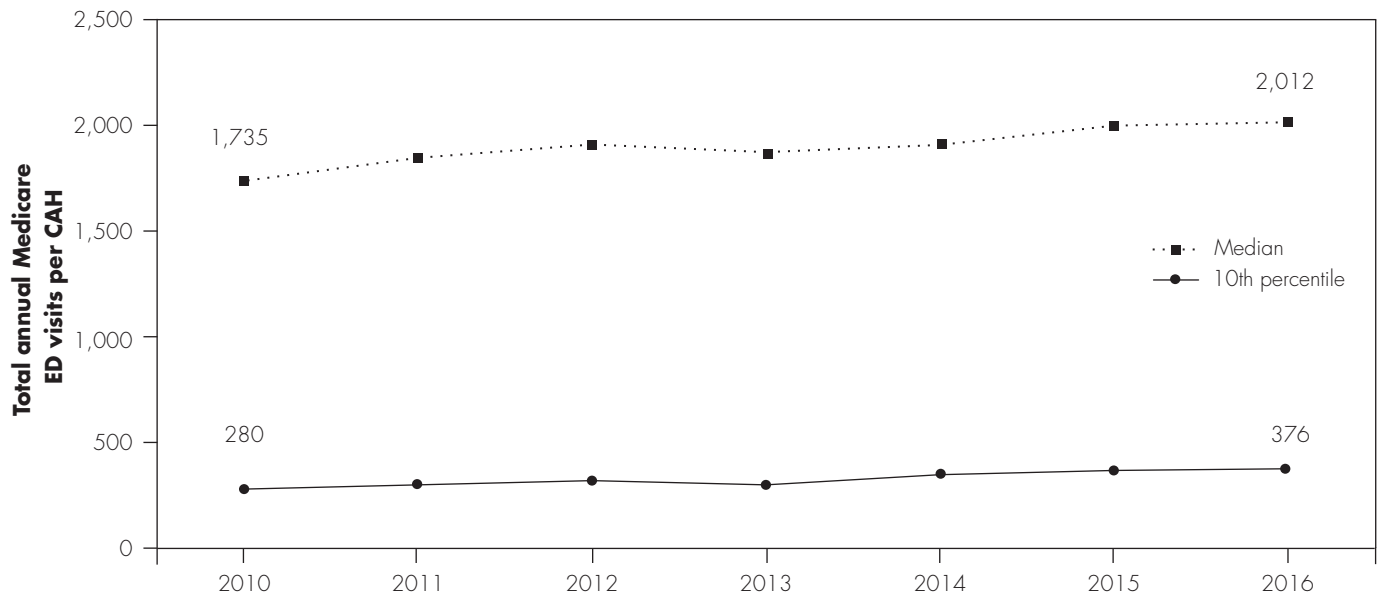
Maintaining emergency access in rural areas is challenging due to declining populations in many rural areas, coupled with a delivery system that is tied to an expensive inpatient delivery model. In addition, rural hospitals are losing volume as rural patients often bypass their local rural hospital for larger (and more distant) rural or urban facilities. In many cases, the bypass occurs even when the services are available locally (Liu et al. 2008, Medicare Payment Advisory Commission 2012, UnitedHealth Center for Health Reform & Modernization 2011). By 2016, the urban hospital occupancy rate was 66 percent compared with 40 percent for all rural hospitals and 31 percent for rural hospitals with fewer than 50 beds (Medicare Payment Advisory Commission 2018). In 2016, approximately 130 hospitals were more than 35 miles from other hospitals and averaged fewer than 1 admission per day (a map is included in online Appendix 2-B, available at <http://www.medpac.gov>). The question is whether emergency services can be provided by these isolated facilities without having to maintain the hospitals'

inpatient facilities, which are operating at a scale that may not be optimal from a quality or cost-of-care standpoint (Medicare Payment Advisory Commission 2016a).

Medicare's existing programs for preserving rural hospitals are inpatient-centric

The Medicare program has several rural payment programs designed to preserve rural hospitals. Most of these programs are inpatient-centric models. The sole community hospital (SCH) program increases inpatient and outpatient payments by about \$900 million per year above inpatient prospective payment system (IPPS) rates to over 300 SCHs. The Medicare-Dependent Hospital (MDH) Program increases inpatient payments by about \$100 million per year above IPPS rates to about 150 rural hospitals. Sixty percent of rural hospitals (1,300) receive cost-based payment through the CAH program. This cost-based payment program increases payments to CAHs by about \$2 billion per year relative to prospective payment system rates for acute care hospitals (Medicare Payment Advisory Commission 2012).

Despite the SCH, MDH, and CAH programs, rural hospital closures have increased in the last three years.

**FIGURE
2-5****The number of Medicare outpatient emergency department visits at critical access hospitals grew, 2010-2016**

Note: ED (emergency department), CAH (critical access hospital).

Source: MedPAC analysis of Medicare outpatient claims data.

Some closures reflect excess capacity, but in other instances, the closed hospitals were the sole providers of emergency services in their area. From 2013 through 2017, 51 rural hospitals closed (67 if we include rural areas of metropolitan counties) (Young 2018).⁹ Among the closures were 22 CAHs. While 28 of the closures were less than 20 miles from the nearest hospital (suggesting there may have been excess capacity in these markets), 21 were 20 to 35 miles from the nearest hospital, and 2 were over 35 miles from the nearest hospital.

The financial challenges faced by CAHs can include declining populations, declining volume of patients with commercial insurance, difficulty recruiting physicians, continued uncompensated care costs, and patients bypassing the local CAH for larger hospitals. In particular, the decline in admissions is difficult for hospitals built on an inpatient payment model. From 2003 to 2016, the median number of annual all-payer discharges among CAHs fell from over 600 to 335, and 10 percent of CAHs had 71 or fewer discharges in 2016 (Figure 2-4). Despite having 25 or fewer beds per CAH, the median CAH

occupancy rate (including post-acute swing-bed patients) between 2006 and 2016 fell from 38 percent to 31 percent.

While hospitals' inpatient volume continues to decline, the use of the emergency services at CAHs increased slightly in recent years (Figure 2-5). This increase suggests the community still values local emergency access. Figure 2-4 and Figure 2-5 together illustrate how CAHs have shifted substantially to outpatient rather than acute inpatient services. In contrast, rural payment models continue to be inpatient-centric.

To maintain access to care in communities where inpatient volume is declining, there is an interest in payment models that are focused on outpatient access rather than maintaining inpatient services (American Hospital Association 2016, Iglehart 2018, Thompson 2015). A key question is whether a rural hospital could cease providing its inpatient services and still generate enough outpatient revenue to maintain an ED. This approach works in some communities, but they are generally rural communities with a fairly high ED volume and payer mixes that

Examples of rural off-campus emergency departments

In August 2017, Commission staff conducted multiple site visits to off-campus emergency departments (OCEDs) located outside of major metropolitan areas. The facilities we visited were located within 35 miles of their parent hospitals and therefore considered OCEDs for the purposes of Medicare billing. The OCEDs were located in communities that experienced hospital closures, often due to low inpatient volumes that led to financial losses; some of the OCEDs were located in the same physical facilities that once housed the closed hospitals. We toured the facilities and spoke with representatives of those facilities, representatives of their parent hospitals, and local emergency medical services (EMS) providers to better understand the challenges associated with operating an OCED in more rural locations and to inform our discussion of potential policy changes.

The representatives with whom we spoke said the cost to run their OCEDs was anywhere from approximately \$3 million to \$5 million a year. Some of these estimates are likely low because they did not include costs such as depreciation or rent and represent efficiencies of belonging to a system. For example, one facility we toured rents its building from the county government for a nominal fee. Its representatives asserted that if the ED had to pay market rates for the building, their costs would be higher. In another instance, the system

to which one OCED belonged centralized many administrative services (e.g., billing, legal services, and contract negotiations) and charged the stand-alone ED a fee. The costs to provide those services would likely have been much higher if the facility had provided them independently. Given these circumstances, the estimates we heard during our site visits were in line with previously published research suggesting a minimum budget of roughly \$5 million per year to operate a rural OCED (Williams et al. 2015).

At each of our site visits, the facility representatives said receiving Medicare's facility payments is critical to ensure the viability of their stand-alone EDs. To demonstrate that point, representatives of the parent hospital of one of the freestanding rural EDs we visited said other struggling inpatient hospitals have contacted them to inquire about converting their facilities to stand-alone EDs. The offers were turned down because none of their own hospitals were within 35 miles of the struggling facilities, which would have made the struggling inpatient hospitals unable to bill as an outpatient department of the larger hospital and receive facility payments from Medicare. The need to receive facility payments for their Medicare patients is particularly acute for rural facilities because more of their patients tend to be covered by Medicare and fewer tend to have private insurance. Some representatives said their stand-alone EDs were not financially viable

(continued next page)

include a large share of privately insured patients. Most conversions of rural hospitals to stand-alone EDs are cases in which the closed hospital is within 35 miles of another hospital and can be deemed an outpatient department of another hospital. That arrangement allows the hospital to obtain facility fees. (See text box for more detail on how this model of rural OCED can work.) In contrast, stand-alone EDs that cannot bill for facility fees are often not financially viable.

Some rural communities have too few ED patients and too few private-pay patients to make the stand-alone

ED model work without additional subsidies. For example, after three rural Georgia hospitals closed, some discussed operating them as stand-alone EDs. However, a committee formed by the state concluded that the stand-alone EDs would not have enough volume to be viable without additional support (Rural Hospital Stabilization Committee 2015). In addition, if a closed hospital is more than 35 miles from another hospital, the hospital cannot operate as a department of another hospital and receive facility fees. This situation is at odds with the objective of preserving access: Isolated communities are the ones that currently cannot receive Medicare's facility fees for

Examples of rural off-campus emergency departments (cont.)

even with Medicare's outpatient prospective payment system Type A ED payment rates and therefore required additional subsidies to remain open. For example, one stand-alone ED initially received a subsidy from the system to which it belonged to remain viable, and one stand-alone ED remained viable only because it was an off-campus department of a critical access hospital that received cost-based reimbursement from Medicare.

The facility representatives said viability also depended on achieving a certain volume of ED visits. They said they generally need 30 to 40 visits per day, or roughly 10,000 to 15,000 visits per year, for a rural off-campus ED to remain sustainable, although they noted that the number of ED visits required to remain viable varies based on factors such as payer mix. For the stand-alone EDs we visited, facility representatives said the vast majority of their patients were walk-ins, as opposed to patients arriving by means of ambulance or helicopter. While representatives said their EDs treat patients with a variety of severity levels—from patients in cardiac arrest to those who need a simple X-ray—they suggested that patients treated at their stand-alone EDs tended to present with less severe injuries or illnesses compared with patients at on-campus EDs.

The EMS providers we interviewed said their staff are familiar with the capabilities of all the local

health care facilities, including stand-alone EDs and hospitals. While patients may request to go to a specific facility, the EMS providers said their staff make recommendations to patients and select the facility for those who are unconscious or otherwise unable to make a decision. For example, the stand-alone EDs we visited were generally bypassed or used only to stabilize patients with ST-elevation myocardial infarctions, a life-threatening type of heart attack during which one of the heart's major arteries is blocked. This dynamic whereby more serious cases routinely bypass stand-alone EDs may be somewhat different for facilities that are farther away from other hospitals because bypassing such facilities means a longer transport than bypassing a stand-alone ED that is located near another hospital. In general, the representatives of systems that operated both rural and urban OCEDs said that patients at rural stand-alone EDs tended to present with more serious injuries or illnesses than those at urban stand-alone EDs because the rural facilities are often a longer distance from other hospitals with an ED than urban stand-alone EDs.

In addition to ED visits, all the facilities we visited had some colocated services and used their equipment for dual purposes. For example, all the facilities we visited rented space to local physicians, including primary care physicians and specialists. Some local residents also used the facilities for nonemergent care, most commonly for imaging and laboratory services.

(continued next page)

OCEDs. These rural facilities may see the only option under current payment policy is to continue as a CAH and receive cost-based payment; however, that is not efficient and may not be financially sustainable.

Extra inpatient payments do not always keep the emergency department doors open

High inpatient payments have not always kept rural hospitals open. In 2016, we conducted an examination of all CAHs that closed in 2014. We found that, before their closure, the seven hospitals received an average of \$500,000 in payments above the comparable prospective

payment system (PPS) payments (Medicare Payment Advisory Commission 2016a). These supplemental payments primarily reflected high rates that CAHs receive for post-acute care.

The extra payments for inpatient care were not sufficient to keep these hospitals open because the extra payments were absorbed by these hospitals' high inpatient costs per day of care. For policymakers, a key question is whether these hospitals could have retained emergency capacity if the Medicare program had directed the supplemental payments toward preserving emergency services rather than subsidizing acute and post-acute inpatient services.

Examples of rural off-campus emergency departments (cont.)

All the EDs we visited offered a range of imaging services, including X-rays, ultrasounds, and computed tomography (CT) scans, and sometimes including additional imaging services such as mammography, nuclear medicine, and magnetic resonance imaging. Because the stand-alone EDs we visited were considered hospital outpatient departments, the facilities received hospital outpatient rates rather than the lower physician office rates for imaging services.

The facility representatives said that rural hospitals traditionally staffed their EDs by relying on community physicians to cover the ED. The use of this model is decreasing because it has become harder to find physicians willing to maintain a community practice plus cover the ED. They said rural EDs are increasingly staffing their EDs with dedicated personnel. All the stand-alone EDs we visited were staffed 24/7 with a physician board-certified in emergency medicine that was contracted through a physician staffing company (e.g., Apollo or EmCare), and some supplemented their physicians with midlevel practitioners during peak hours. Facility representatives said it can be difficult to recruit and retain such personnel to practice in rural areas. They also noted that rural facilities might have to pay such companies subsidies amounting to several hundred thousand dollars per year to recruit physicians to practice in a rural ED. For example, the physician staffing company would receive all the professional billings for the services their physicians perform in the ED plus an additional subsidy from the hospitals. We heard that some rural EDs have faced difficulties financing such subsidies. The representatives noted that

some hospitals were able to avoid paying a subsidy for their ED physicians because the system to which they belonged negotiated a contract for all of the system's EDs, which included urban facilities and facilities with better payer mixes.

Finally, some of the facility representatives said that being part of a larger hospital system was critical to making their stand-alone ED financially viable and more medically capable. According to the representatives, being part of a system helped them decrease costs (e.g., by centralizing nonclinical functions and increasing their purchasing power for drugs and supplies) and increase revenues (e.g., stand-alone EDs benefit from the higher private-payer rates negotiated by the larger system). Clinically, they also mentioned that being part of a system gave their stand-alone EDs better access to physicians by, for instance, allowing the hospital system's employed physicians to rotate through rural areas (e.g., attend a clinic one day a week) and increasing the timeliness of specialist consults through telehealth. All the facilities we visited had some telehealth capabilities. For example, physicians at a more remote stand-alone ED would take a CT scan of a patient who suffered a stroke and project that image on a screen along with a live video of a neurologist who was based at an urban hospital. This approach allowed the ED physician access to the expertise that is often unavailable in rural areas but is critical in determining the appropriate course of treatment, such as whether to administer a clot-busting drug and whether the patient needs to be transported by means of ambulance or helicopter. ■

Limitations on growth of rural OCEDs

To bill as an OCED, a rural ED must be within 35 miles of the main hospital campus. For urban EDs, this requirement is largely not a problem unless a hospital system seeks to open a stand-alone ED in a distant market, but for rural areas, the 35-mile criterion can be a challenge. For example, if a rural hospital wants to set up an ED in a community 10 miles away, it can do so and receive full Type A ED rates. But if the same hospital opened an ED

in response to a closure 40 miles from other hospitals—in a community that truly lacks access to ED services—the hospital setting up that OCED would be paid at physician office rates. The net result is that the Medicare program currently pays more for care in OCEDs that are close to alternative sources of emergency care than it does for EDs that are the only source of ED care. As we discussed in the text box on rural off-campus emergency departments,

these isolated EDs appear to receive more difficult cases than the higher paid OCEDs that are close to a hospital.

A new policy to preserve isolated rural emergency departments

There is a growing interest in trying to preserve access to 24-hour emergency services in rural areas without requiring hospitals to provide inpatient services (American Hospital Association 2016, Iglehart 2018, Morse 2015). Any such policy should achieve three objectives:

- provide a mechanism for preserving emergency access in isolated areas
- not materially increase overall Medicare spending
- improve efficiency of the health care delivery system

Under a proposed rural 24/7 ED model discussed in our June 2016 report, Medicare would pay the Type A outpatient ED rates plus a fixed payment to partially cover overhead services (Medicare Payment Advisory Commission 2016a). This approach would encourage the outpatient facility to focus on ED services, ambulance services, and primary care. The fixed payment could be used to support the rural ED's standby costs and the cost of other services that help preserve access, such as telehealth services. While a few rural PPS hospitals as well as a few rural clinics could convert to a model of an outpatient-only hospital, the providers most likely to convert would be CAHs with very low inpatient volume.

To fund the additional fixed payment without materially increasing overall Medicare spending, Medicare could use the savings generated from discontinuing inpatient payments at the CAHs participating in this model—roughly \$500,000 on average—to fund the fixed payment. A subsidy of this magnitude would represent about 10 percent of the cost of operating a small stand-alone ED.¹⁰ The rationale for this approach is that if standby emergency and primary care capacity are the desired services, then Medicare should subsidize the cost of facilities' standby capacity with an annual fixed payment rather than increased payments per inpatient day. The fixed Medicare payment and the annual local support from the town, hospital district, or county would help maintain emergency access, even in a low-volume environment. See online Appendix 2-A, available at <http://www.medpac.gov>, for a summary of the proposed rural policy.

There may be some rural communities where the population is too low to support a 24/7 ED (even given

the annual subsidy). Our June 2016 report discussed the option of having a clinic open 12 hours a day 365 days a year as an alternative for very low-volume providers (Medicare Payment Advisory Commission 2016a). However, rather than form a new payment model for such facilities, it may make sense for them to be operated as federally qualified health centers (FQHCs). The FQHC program provides federal grant funds and a per visit payment to support stand-alone clinics in rural and urban areas.

All hospitals that convert to an outpatient-only facility would receive equal annual fixed payment amounts. Unlike a cost-based model, hospitals with higher cost structures (often those with more financial resources) would not receive a higher payment. The fixed payment would also not increase with volume because standby ED costs would not materially shift with volume changes, and Medicare would not want to encourage unnecessary ED use. It would also differ from cost-based models because hospitals would no longer have an incentive to offer services for which their costs are not competitive (e.g., post-acute services, MRI services) because additional volume would not lead to increases in supplemental Medicare payments.

If a hospital with inpatient services converted to an outpatient-only facility, we expect that the financing and delivery of care would change as follows:

- Isolated hospitals choosing to eliminate acute inpatient services and accept PPS rates would qualify to receive an annual fixed base payment from Medicare. The inpatient volume would flow to neighboring hospitals, potentially improving the neighboring hospitals' financial viability.
- Given that the fixed payment would be directed to preserving emergency access, some hospitals could convert their hospital beds to skilled nursing facility (SNF) beds for which they would receive SNF PPS rates for the SNF services provided under the existing eligibility rules.
- Converting facilities would make it possible to place a priority on emergency care.
- Outpatient clinics would continue to operate (e.g., FQHCs and freestanding rural health clinics).
- The facilities would have greater flexibility to use telehealth consultations. They would still receive the

hospitals' OPPS telehealth fee, but they could also use the fixed payment to help support telehealth.

- Eliminating services that can be more efficiently delivered in centralized regional facilities (e.g., MRI services) would substantially lower costs relative to the CAH models.

Rural stand-alone EDs could switch back to CAH status

In determining whether or not to participate in the rural outpatient-only hospital model, existing hospital boards would have to decide whether they were willing to discontinue providing inpatient services and convert to outpatient-only hospitals. Discontinuing inpatient services would be a difficult process for rural communities that have long been served by hospitals that focused on inpatient care. To reduce the communities' perceived risk of conversion, Medicare could allow all CAHs that convert to stand-alone EDs the option of converting back to CAH status in the future if the community demographics change so that a full-service hospital is once again needed in the community. Conversion back to a hospital, although rare, is occurring in one of the communities we visited. As discussed in the text box on rural OCEs (pp. 48–50), we visited three communities where the only hospital within 20 miles closed. In two of the three communities, the population of the town grew fairly rapidly after the hospital closed. In both cases, population growth led to opening stand-alone EDs where two hospitals were once located. In one of the communities, the population has continued to grow to the point where the operator of the ED is now going to build a new full-service hospital attached to the stand-alone ED. While we expect this option of converting back to a CAH will be rarely used, it should make the initial decision to convert to a stand-alone ED easier.

To be willing to shift to a stand-alone ED model, small communities' hospital boards may need to better understand the limited economic effect of conversions of hospitals to outpatient-only facilities. While the two communities that grew after hospital closures are anecdotal observations, we are not aware of any research showing the conversion of a hospital to an outpatient-only facility had large economic effects on rural communities.

A converted outpatient facility would also have the option of aligning with its area's larger hospital system to support some functions at the outpatient-only facility. For

example, the larger hospital could help with peer review of physicians, purchasing supplies, and billing for services. Under this option, the new outpatient-only facility could work cooperatively with other health care providers to provide continuity of care across settings.

Who would receive the rural fixed payment to maintain a 24/7 ED?

A facility that eliminated inpatient services (acute and post-acute swing services), accepted outpatient PPS rates, and converted to an outpatient-only facility would receive the fixed payment. To ensure that the funds were used as intended, the facility could be required to use the fixed payment for emergency standby capacity, ambulance service losses, telehealth capacity, and uncompensated care in the ED. The 24/7 ED could be required to be periodically recertified to determine that the facility was still isolated from full-service hospitals and was appropriately spending the annual fixed payments to operate a 24/7 ED. We refer to the combination of the stand-alone ED and its affiliated services (e.g., telehealth, ambulance, clinic services, rehabilitation services) as an outpatient-only hospital.

It is not clear how many providers would choose to convert from a PPS hospital or CAH status to an outpatient hospital under this policy. The decision would in part be determined by the size of the fixed payment and how the program was targeted. The fixed-payment model we discuss is targeted to isolated providers only; *isolated* could be defined as a certain driving distance from other EDs. (See online Appendix 2-B, available at <http://www.medpac.gov>, showing a map of all isolated low-volume hospitals more than 35 miles from another hospital. We use the 35-mile criterion because EDs less than 35 miles from a traditional hospital have the option to become an outpatient department of a neighboring hospital. In addition, the 35-mile criterion is the limit currently used in the SCH and CAH programs.)

Shifting from CAH status to a stand-alone ED would reduce patient cost sharing

Another consideration with regard to CAHs shifting to stand-alone ED status is the degree to which beneficiaries' cost-sharing obligations would decline when hospitals shifted from CAH status to PPS rates. Past Commission work suggests that the Medicare program's share of cost-based payments to CAHs for outpatient services (net of patients' coinsurance liabilities) is roughly equal

to PPS rates (Medicare Payment Advisory Commission 2012). Although the Medicare program would not realize significant program savings from shifting from CAH cost-based rates for outpatient services to PPS rates, beneficiary cost would decline dramatically. The reason is that beneficiaries' coinsurance at CAHs is set at 20 percent of charges, which is roughly 50 percent of the cost-based payment and often close to the full PPS payment rate (Medicare Payment Advisory Commission 2016a, Medicare Payment Advisory Commission 2011). When facilities switch from CAH status to PPS rates under stand-alone ED status, Medicare beneficiaries could see their coinsurance fall by 70 percent or more. For example, if the CAH billed \$700 for a Level 3 ED visit that cost \$350, the beneficiary would owe the CAH 20 percent of \$700 (\$140) in cost sharing. If the facility converted to a stand-alone ED, the payment rate for the service would fall to \$200 and PPS ED coinsurance would be \$40 (71 percent less than CAH coinsurance). However, given the widespread use of Medicare supplemental insurance that shields many FFS Medicare beneficiaries from coinsurance, the benefit for some beneficiaries with medigap policies in rural states would be a small reduction in medigap premiums.

RECOMMENDATION 2 - 1

The Congress should:

- **allow isolated rural stand-alone emergency departments (more than 35 miles from another emergency department) to bill standard outpatient prospective payment system facility fees and**
- **provide such emergency departments with annual payments to assist with fixed costs.**

RATIONALE 2 - 1

Struggling hospitals within 35 miles of another hospital can eliminate inpatient services and reduce their costs by becoming an outpatient department of a neighboring hospital. However, isolated rural facilities more than 35 miles from another hospital do not have an option to convert to a stand-alone emergency department. Therefore, communities that most need an emergency room but cannot support inpatient services also have the fewest payment options. This situation results in stand-alone EDs being financially unviable in most isolated rural markets. Creating a way to pay stand-alone EDs in isolated rural communities will help these areas maintain emergency department capacity. The option would be available to communities more than 35 miles from another hospital

that (1) never had a hospital, (2) had a hospital that closed, or (3) have an open full-service hospital that they want to convert to an outpatient-only facility.

IMPLICATIONS 2 - 1

Spending

- Most rural stand-alone EDs would be former CAHs. Under this recommendation, Medicare would make annual lump sum payments to CAHs that convert to become a rural stand-alone ED and maintain only outpatient services. These payments, if in the range of \$500,000, would be offset by savings from reduced payments for post-acute care (PAC) services as beneficiaries who might have received PAC services at the CAH are shifted to other PAC providers at a lower cost to Medicare. However, a small share of the outpatient-only facilities would be either former PPS hospitals or hospitals that would have closed without the new program. Preserving these hospitals and access to emergency care in these communities will add to program spending. The Congressional Budget Office estimates that the policy would increase spending by less than \$50 million per year.

Beneficiaries and providers

- Rural communities would have a new option for preserving emergency department access without having to maintain expensive inpatient capacity. Medicare beneficiaries would benefit from preserved local access to emergency care and the reduced coinsurance.

Urban areas: Incentives have led to an abundance of urban stand-alone EDs

The number of stand-alone EDs and the share of patient visits taking place in EDs have increased rapidly in recent years. These facilities improve access to services not available at doctors' offices and urgent care centers, but their Medicare payment rates need to be better aligned with the cost of care they provide.

Some researchers believe the growth in ED use may be partially due to patients' lack of access to other providers, changing practice patterns, or patients' desire for more immediate access to care (Gindi et al. 2016, Morganti et al. 2013, Pines et al. 2013). However, the increase in the number of stand-alone EDs and the increase in the volume of ED visits may also partly reflect incentives in

**TABLE
2-4**

Seventy-five percent of urban stand-alone emergency departments are located within 6 miles and a 10-minute drive of the nearest on-campus hospital emergency department, 2018

	Distance to the nearest on-campus hospital ED (in miles)						
	0-2	2-4	4-6	6-8	8-10	10-12	12 or more
Number of stand-alone EDs	23	35	26	13	5	5	5
Share of stand-alone EDs	21%	31%	23%	12%	4%	4%	4%
Cumulative share	21%	52%	75%	87%	91%	96%	100%
Average minutes from the nearest on-campus hospital ED	4.4	8.4	10.3	14.0	14.3	19.8	21.6

Note: ED (emergency department). The five market areas include Charlotte, NC; Cincinnati, OH; Dallas, TX; Denver, CO; and Jacksonville, FL. Components may not sum to totals due to rounding.

Source: MedPAC analysis of the location of hospitals and stand-alone EDs using ArcGIS data software and Google mapping.

both Medicare’s payment system and commercial insurer payment systems (Wilson and Cutler 2014). Recent analysis from three states suggests that stand-alone EDs treat patients who are more similar to patients treated at urgent care centers than patients treated at on-campus hospital EDs. Despite this analysis, under Medicare, OCEDs are paid the same as on-campus hospital EDs, making the OCED model of care financially attractive to hospitals in many markets.

Stand-alone EDs locate in certain markets and higher income zip codes rather than underserved areas

The stand-alone EDs identified in our June 2017 report were concentrated in 20 large metropolitan statistical areas (MSAs) in 2016 and accounted for over 60 percent of all stand-alone EDs.¹¹ These facilities tend to locate in zip codes with higher than average incomes and higher shares of patients with private insurance coverage (Medicare Payment Advisory Commission 2017, Schuur et al. 2016). We found that, in Houston and Denver, about 65 percent of stand-alone EDs were located in zip codes that represented only 35 percent of the city’s population but had an average household income above \$90,000. We found similar patterns in Charlotte, NC; Jacksonville, FL; Oklahoma City, OK; and Seattle, WA (markets without IFECs). Recent research has found that IFECs may be even more likely to locate in high-income areas (Dark et al. 2017). In interviews, stand-alone ED representatives stated that hospitals use stand-alone EDs to capture patient market

share and control patient service use. They also stated that a real estate analysis method—using variables such as the location of other EDs, population growth, household income, and insurance coverage—is used to identify areas with unmet demand for convenient ED services (Adeptus Health Inc. 2016).

Urban stand-alone EDs are in close proximity to on-campus hospital EDs

Our analysis of stand-alone EDs sought to distinguish between urban stand-alone EDs that provide access to urban areas that are relatively isolated from ED services and stand-alone EDs that create redundancies in access because they are in close proximity to existing on-campus hospital EDs. We examined five markets with urban stand-alone EDs (Charlotte, NC; Cincinnati, OH; Dallas, TX; Denver, CO; and Jacksonville, FL) and considered the distance of stand-alone EDs from the nearest on-campus hospital ED, both in driving distance (in miles) and driving time (in minutes). While we measured proximity as the distance to an on-campus hospital ED, policymakers could also opt to measure proximity from the stand-alone EDs to any other ED (on-campus ED or other stand-alone ED).

Overall, our analysis found that stand-alone EDs tend to be located in close proximity to on-campus hospital EDs. In 2018, 75 percent of urban stand-alone EDs in the five markets studied were within six miles of the nearest on-campus hospital ED, and 25 percent were more than six miles from the nearest on-campus hospital ED (Table 2-4).

In addition, using publicly available mapping software, we estimated that, on average, the EDs within 6 miles of the nearest on-campus hospital ED were roughly a 10-minute drive from the nearest on-campus hospital ED. Therefore, a beneficiary living exactly in between a stand-alone ED and an on-campus hospital ED six miles apart would need to travel three miles, or spend five minutes to drive, to the ED nearest their residence.

Patients served at stand-alone EDs in three states have lower acuity than patients at on-campus EDs

Three recent analyses of stand-alone EDs in Texas, Colorado, and Maryland demonstrate that patients served by stand-alone EDs tend to have less complex conditions than patients served by on-campus ED patients, but the prices paid to the stand-alone EDs are typically the same as on-campus EDs. Moreover, the analyses highlight that stand-alone EDs generally do not incur the same standby costs as on-campus EDs.

Texas

A study of commercial insurance claims for enrollees of Blue Cross and Blue Shield of Texas from 2012 to 2015 suggests that stand-alone EDs serve patients who are similar to those served by urgent care centers while being paid rates similar to hospital EDs (Ho et al. 2017). This study found substantial overlap in the type of cases seen at on-campus EDs, off-campus EDs, and urgent care centers, but it also found that on-campus EDs tend to receive the most difficult cases, such as open head or neck wounds. Among the top 20 most common diagnoses treated at each facility type, 12 diagnoses were common to all.¹² Three diagnoses at on-campus hospital EDs were not common to either stand-alone EDs or urgent care centers: kidney stones, nausea and vomiting, and complications of pregnancy. Five of the most common diagnoses at urgent care centers were not common to either stand-alone EDs or on-campus hospital EDs: eye inflammation, flu, other upper respiratory disease, pneumonia, and viral infections. All of the most common diagnoses at stand-alone EDs were also most common to on-campus EDs or urgent care centers. Despite the similarity in cases treated across the three facility types, stand-alone EDs appear to occupy a middle ground between urgent care centers and on-campus EDs with regard to the severity of patients they serve. For example, more acute medical diagnoses such as pregnancy complications and kidney stones and less complicated medical diagnoses such as eye inflammation and viral infections are not common to stand-alone EDs.

This study found that the standby costs of stand-alone EDs fall between the costs of on-campus hospital EDs and urgent care centers (Ho et al. 2017). Stand-alone EDs and on-campus hospital EDs must provide continuous access to emergency clinicians, laboratory services, and imaging services. The cost of meeting these requirements is higher than the costs at urgent care centers, which typically are not open 24/7 and are generally not staffed with physicians specializing in emergency medicine. While the costs of stand-alone EDs are higher than urgent care centers, the authors also contend that their costs are lower than on-campus hospital EDs, in part because stand-alone EDs largely do not maintain the on-call physician capacity for specialists necessary to serve patients with major trauma injuries (e.g., head and neck wounds or gunshot wounds), stroke, and ST-elevation myocardial infarctions. The authors suggest this difference in patient severity is linked to the fact that ambulances preferentially route higher acuity patients to on-campus hospital EDs that maintain operating rooms and overnight inpatient bed capacity. In our interviews with ambulance industry representatives, they confirmed this view, stating that ambulance drivers are instructed to take any potential inpatient admission to an on-campus hospital ED because stand-alone EDs do not have operating rooms or overnight beds. Another study found that ambulance drivers transporting trauma cases typically bypassed an isolated rural stand-alone ED because on-campus hospital EDs were more likely to have trauma care capacity (Lawner et al. 2016).

Colorado

Claims data for privately insured patients in Colorado in 2014 show that most patients served by stand-alone EDs were treated for non-life-threatening conditions, similar to conditions treated at urgent care centers. These data also show that the patients served by stand-alone EDs are somewhat different from those served at on-campus hospital EDs. In July 2016, Colorado's Center for Improving Value in Health Care (CIVHC) compared claims data from nine stand-alone EDs with claims from urgent care centers and on-campus hospital EDs. CIVHC concluded that, among the top 10 conditions for which privately insured patients sought care at stand-alone EDs, 7 were for non-life-threatening conditions. At urgent care centers, all 10 of the top 10 conditions were non-life threatening, whereas at on-campus hospital EDs, only 3 of the top 10 were for non-life-threatening conditions. Between stand-alone EDs and urgent care centers, six of the most common conditions overlapped, and none of them were life threatening. Between stand-alone EDs

and on-campus hospital EDs, four of the most common conditions overlapped, and three were non-life threatening.

Using the same data, CIVHC found that, in 2014, privately insured patients paid higher amounts—exceeding 10 times the amount—for treatment at stand-alone EDs compared with treatment at urgent care centers. For example, in 2014, the average payment amount for an upper respiratory infection (a non-life-threatening condition) at stand-alone EDs was \$1,114, compared with \$124 at urgent care centers. Similar differences existed for other conditions.¹³

Maryland

A 2015 report from the Maryland Health Care Commission (MHCC) concluded that the patients served by three stand-alone EDs generally had lower acuity conditions compared with on-campus EDs (Maryland Health Care Commission 2015). MHCC reported that, in 2014, between 3 percent and 6 percent of patients served by the three stand-alone EDs were later admitted as inpatients to a hospital compared with between 15 percent and 19 percent of patients served at the nearest competing hospital EDs. In addition, at the Maryland stand-alone EDs in two towns, 97 percent and 95 percent of patients, respectively, arrived as walk-ins rather than by ambulance. By contrast, the Emergency Department Benchmarking Alliance and the American College of Emergency Physicians reported that, in 2013, 17 percent of all ED patients nationally arrived at the ED by ambulance (Augustine 2014).

MHCC also concluded that patients served by the three Maryland stand-alone EDs in 2014 were younger, more likely to have private insurance coverage, and had treatment options other than the ED available to them. Compared with all EDs in Maryland, the stand-alone EDs tended to treat a larger share of children and a smaller share of patients older than 41, tended to serve a slightly larger share of privately insured patients, and tended to serve a lower share of Medicare and Medicaid patients.

Required standby capacity of urban stand-alone EDs is less than that of on-campus hospital EDs

Information gathered from site visits to stand-alone EDs and recent research supports ambulance suppliers' statements that stand-alone EDs generally do not maintain the capacity to treat major trauma cases such as major head injuries. Trauma, stroke, and heart attack patients are

more often transported to on-campus hospital EDs where there are backup surgical capabilities, operating rooms, cardiac reperfusion capabilities, and specialized stroke care. Other research has reported ambulances bypassing stand-alone EDs, specifically studies examining the stand-alone ED phenomenon in Maryland (Lawner et al. 2016, Maryland Health Care Commission 2015). Rural EDs that are especially far from other care are the exception; in these areas, ambulances might rely on rural EDs to stabilize trauma patients, and in some cases might use them as a location to begin clot-busting drugs on stroke patients. This exception suggests that isolated off-campus EDs that are a substantial distance from any hospital-based ED can be called on to have a wider range of standby capacity than OCEDs located 10 or 15 minutes from a hospital campus.

Aligning payments to urban stand-alone EDs with the acuity of their patients

The growth in stand-alone EDs in recent years suggests that existing Medicare and private-insurer payment policies encourage providers to treat patients in higher paying settings such as EDs rather than lower paying settings such as urgent care centers. The Commission's position on aligning payment rates across settings is that Medicare should ensure that patients have access to settings that provide the appropriate levels of care and that Medicare should base payment rates on the resources needed to treat patients in the most efficient setting. The concern in the case of stand-alone EDs is that providers seek to gain market share for low-severity conditions that could be treated more efficiently in other settings. For example, some hospitals are building ED facilities or partnering with IFECs to enable them to bill for the higher ED rates, when these conditions could be treated at urgent care centers.

Options for paying urban OCEDs less than full Type A ED rates

To account for the lower standby costs and the lower acuity of patients served at OCEDs, the Commission considered two alternatives to current Type A ED payment rates. The Commission's intent was to better align payment rates with the costs of OCEDs, thereby reducing the incentive to shift lower acuity cases to the ED setting. These two alternative payment rates were intended to lie between the rates of on-campus hospital EDs and urgent care centers.

In public discussion, the Commission initially considered paying OCEDs Type B ED rates because the acuity of

their patients is similar to the mix of patient conditions served at EDs receiving Medicare Type B ED payment rates. However, current Type B payment rates contain an anomalous characteristic that results in payments for Type B Level 1 cases (the lowest level) being higher than Type B Level 2 cases (\$102 for Level 1 cases versus \$91 for Level 2 cases) and higher than Type A Level 1 cases (\$102 for Type B Level 1 cases versus \$69 for Type A Level 1 cases) (Table 2-2, p. 41). This anomaly causes the difference between Type A and Type B payment rates to vary widely across each of the five ED levels.¹⁴ On average, across all five ED service levels, Type B rates are 30 percent lower than Type A rates.

To establish payment rates for OCEDs that lie between those for on-campus hospital EDs and urgent care centers, while reducing payments consistently across the five levels of ED services, Medicare should reduce Type A ED rates by a flat percentage. Reducing the Type A rates by 30 percent would be roughly equivalent to using Type B rates and would avoid the anomaly in the Type B rates. See online Appendix 2-A, available at <http://www.medpac.gov>, for a summary of the proposed urban policy.

Urban stand-alone ED recommendation

Urban OCEDs may provide the benefit of some services that are not available at urgent care centers and doctors' offices, but Medicare appears to be overpaying these facilities relative to what is paid to on-campus hospital EDs that receive more difficult cases. While most urban stand-alone EDs are in close proximity to on-campus hospital EDs, some are located far from on-campus hospital EDs and likely provide unique access to ED services for their local community. Paying these more isolated urban stand-alone EDs higher Type A rates, with no percentage reduction applied, may be justified.

RECOMMENDATION 2-2

The Congress should reduce Type A emergency department payment rates by 30 percent for off-campus stand-alone emergency departments that are within six miles of an on-campus hospital emergency department.

RATIONALE 2-2

The structure of the Medicare payment system for ED services creates incentives for providers to treat lower intensity patients in EDs rather than at urgent care centers, which are paid less than half the Type A payment rates for ED services. The Commission found that urban stand-

alone EDs tend to treat lower intensity patients and incur less standby capacity costs than on-campus hospital EDs because they generally do not maintain services such as trauma care or operating rooms. To better align their payments and costs, Medicare should pay OCEDs at lower rates than on-campus hospital EDs, but at higher rates than urgent care centers.

However, paying the current higher Type A ED payment rates to urban OCEDs that are not in close proximity to on-campus EDs may be justified.¹⁵ These more isolated OCEDs are more likely to be providing their local community with unique access to ED services. The Commission estimates that 25 percent of urban stand-alone EDs are located more than six miles from an on-campus hospital ED, and 75 percent are located within six miles. In response to industry concerns and for operational simplicity, the Commission used a threshold based on the measurement of distance in road miles rather than driving time, and the six-mile threshold appeared to be a natural breaking point in the proximity data. In addition, the Commission found that the 6-mile distance translated into roughly a 10-minute drive. Our six-mile proximity threshold could result in stand-alone EDs locating just beyond the six-mile threshold and in relatively close proximity to other stand-alone EDs. To avoid this dynamic, should the Commission's recommendation be implemented, policymakers might consider an alternative measure of proximity as the distance between the stand-alone ED and any other ED (on campus or stand alone).

The Commission's recommendation to reduce payment rates to OCEDs is intended to align payment rates with the relative costs of OCEDs. Timely congressional action in response to this recommendation would help ensure that hospital systems do not invest significant amounts of capital in OCEDs that are not necessary to ensure appropriate access to emergency care.¹⁶ Our recommendation to reduce payment rates to certain urban OCEDs by 30 percent, making those rates more comparable with Type B payment rates, may reduce the incentive to invest in such facilities.¹⁷ The 30 percent reduction reflects the current best information available, but we note that the Secretary of Health and Human Services could be given the authority to gather additional information on OCEDs' Medicare claims data and OCEDs' costs. This information will enable policymakers to adjust the 30 percent reduction in the future as new information becomes available and the marketplace shifts.

To gather the necessary claims and cost data on OCEDs, policymakers must make two specific administrative changes to hospital-related datasets. First, Medicare will need to identify OCEDs' Medicare claims. In 2016, the Commission recommended that "the Congress should require hospitals to add a modifier on claims for all services provided at off-campus stand-alone ED facilities" (Medicare Payment Advisory Commission 2016b). To date, this recommendation has not been enacted. Second, Medicare will need to require hospitals to report the costs of OCEDs separately on annual hospital cost reports made to CMS. Once OCED claims can be tracked and OCED cost and charge data gathered, CMS could estimate the relative costs of on-campus EDs and OCEDs. At that point, the Secretary could modify the magnitude of the recommended 30 percent reduction to Type A ED payment rates.

The Commission has made a judgment in determining that OCEDs located farther than six miles from an on-campus ED should be paid the full Type A rates. Other, more restrictive options could be considered. One option is to limit the full Type A rates to EDs more than six miles from any ED (including other OCEDs). This option would prevent a clustering of OCEDs. A second option is to impose a moratorium on new OCEDs. A third option is to reduce payment rates for non-ED services at OCEDs, such as paying office visits at affiliated clinics the rate paid to freestanding physician offices. This option would eliminate the exception written into Section 603 of the BBA of 2015, which requires that both ED and non-ED services (e.g., clinic visits and ancillary services) provided in off-campus EDs be paid the higher OPPS rates. The Commission also discussed a less restrictive option, in which OCEDs within six miles of an on-campus ED could continue to receive full Type A ED payment rates if they operated in a location where a hospital closed.

Spending

- Medicare payment rates for the five levels of ED services would each decline by 30 percent for urban off-campus EDs located within six miles of an on-campus hospital ED. Urban off-campus EDs located more than six miles from an on-campus ED would see no change in payment for ED services. The Congressional Budget Office estimates that this policy would result in an overall reduction in Medicare outpatient hospital spending of between \$50 million and \$250 million annually. Over five years, this policy could result in a reduction to Medicare outpatient hospital spending of less than \$1 billion. This reduction represents less than 1 percent of total Medicare outpatient hospital spending.

Beneficiaries and providers

- Medicare beneficiaries served at urban OCEDs located within six miles of an on-campus hospital ED would have lower cost sharing. In addition, this policy would reduce the incentive to develop new OCEDs in close proximity to on-campus hospital EDs. By leaving Medicare payment rates unchanged at urban OCEDs located more than six miles from an on-campus ED, Medicare would continue to ensure access to ED services in areas where they are needed most.
- The implications of this policy for hospitals and hospital systems is that 75 percent of existing urban OCEDs will see a 30 percent decline in payments for ED services. The remaining 25 percent of OCEDs, those located more than six miles from an on-campus ED, will not see a change in payment for ED services.

Future analyses

The Commission has expressed interest in future research concerning the standby costs of different types of EDs and Medicare payment rates for urgent care centers and micro-hospitals. That research could lead to better alignment of payment rates for on-campus hospital EDs, OCEDs, urgent care centers, and micro-hospitals. The objective would be to create incentives for providers to use the appropriate setting to treat patients' needs. ■

Endnotes

- 1 Data separating Medicare and non-Medicare ED use for 2015 and 2016 were not available at the time of publication. Therefore, all-payer data were used to demonstrate the trend in outpatient ED use from 2010 to 2016.
- 2 Hospitals' ED claims that result in a hospital admission are bundled into a diagnosis related group and paid through the inpatient prospective payment system.
- 3 The relative weights placed on Type A payment rates are based on the geometric mean cost of services in Type A EDs relative to the average cost of a clinic visit. The relative weights placed on Type B payment rates are based on the geometric mean cost of services in Type B EDs, which tend to be lower on average.
- 4 The anomaly in which Type B Level 1 ED visits are paid more than Type A Level 1 ED visits is due to the idiosyncratic cost and charge structure of the few hospitals billing Type B rates.
- 5 Older urgent care centers affiliated with a hospital are still permitted to bill hospital OPSS rates, which are on par with what the Type B facilities receive for an ED visit. They were grandfathered under a new site-neutral policy that eliminated facility fees for new hospital-affiliated urgent care centers and physician practices (Medicare Payment Advisory Commission 2016b).
- 6 The number of urgent care centers was obtained from the Urgent Care Association of America's website at <http://www.ucaoa.org/?page=IndustryFAQs#Size%20of%20Industry>.
- 7 Provider-based ED facilities are eligible for Medicare payment if they are in compliance with Medicare's provider-based department regulations, Medicare's conditions of participation, and the requirements of the Emergency Medical Treatment and Active Labor Act.
- 8 Section 603 defines *dedicated EDs* as facilities at which at least one-third of a facility's outpatient visits for the treatment of emergency medical conditions are on an urgent basis without requiring a previously scheduled appointment.
- 9 We generally define *rural* as all areas outside of metropolitan statistical areas (MSAs). This definition of rural includes micropolitan areas. Others have a broader definition of rural areas that includes some small towns within MSAs. For example, others may categorize towns as rural if they are outside the commuting zone of larger cities, even if the county they are located in is considered part of an MSA. Given these different definitions of rural, we present information on hospital closures using both our definition (non-MSA) and the broader definition used by the Federal Office of Rural Health Policy, which incorporate non-MSAs and rural portions of counties within MSAs.
- 10 A few rural facilities currently operate stand-alone EDs with an attached outpatient clinic. A study by the University of North Carolina estimates that the cost of operating a low-volume 24/7 ED facility with an attached outpatient clinic is about \$5 million per year (Williams et al. 2015). Our discussions with rural hospital accountants and administrators of small rural stand-alone EDs support estimates in this range.
- 11 We defined large MSAs as those with 500,000 or more residents in 2015. In 2017, stand-alone EDs were located in 95 MSAs and 35 states.
- 12 The 12 diagnoses common to stand-alone EDs, on-campus hospital EDs, and urgent care centers were abdominal pain, allergic reactions, bronchitis, wounds, connective tissue disease, lower respiratory disease, upper respiratory infections, skin infections, back problems, sprains, superficial injuries, and urinary tract infections.
- 13 Private insurers in Colorado pay stand-alone EDs more for other services associated with non-life-threatening conditions compared with the same services at urgent care centers, including abdominal pain—other specified site (\$5,635 vs. \$151, respectively), bronchitis (\$1,139 vs. \$123, respectively), sinus infection (\$786 vs. \$125, respectively), and open finger wounds (\$1,035 vs. \$134, respectively). These high private-payer payments to stand-alone EDs in Colorado are consistent with data from Blue Cross Blue Shield of Texas (Ho et al. 2017) and with anecdotal reports in the popular press in other states (Kliff 2018).
- 14 The difference between Type A ED payment rates and Type B ED payment rates varies by level of ED service. Type B Level 1 payment rates are 49 percent higher than Type A Level 1 rates. Type B Level 2 payment rates are 27 percent lower than Type A Level 2 rates. Type B Level 3 payment rates are 28 percent lower than Type A Level 3 rates. Type B Level 4 rates are 41 percent lower than Type A Level 4 rates. Type B Level 5 payment rates are 45 percent lower than Type A Level 5 rates.
- 15 Policymakers may identify other situations where higher payments to urban OCEDs are warranted—for example, when an urban OCED is the result of the closure of its parent hospital.
- 16 The Commission's goal of adjusting payment rates to prevent the misallocation of capital based on mispriced services is not new. In earlier years, the Commission recommended

changing the inpatient prospective payment system to prevent overpayment to specialty hospitals treating relatively easier cases (Medicare Payment Advisory Commission 2006, Medicare Payment Advisory Commission 2005).

17 The extent to which the incentive to invest in OCEDs is reduced by a Medicare payment policy change would depend on the share of a given OCED's revenues that are tied to Medicare patient visits.

References

- Adeptus Health Inc. 2016. Form 10-K annual report submitted to the Securities and Exchange Commission. <http://d11ge852tjjqow.cloudfront.net/CIK-0001602367/1421ea7d-761a-4286-a10c-1df276639ca6.pdf?noexit=true>.
- American Hospital Association. 2016. *Task Force on Ensuring Access in Vulnerable Communities*. Chicago, IL: AHA.
- Andrews, M. 2016. Sometimes tiny is just the right size: “Microhospitals” filling some ER needs. *Kaiser Health News*, July 19. <http://khn.org/news/sometimes-tiny-is-just-the-right-size-microhospitals-filling-some-er-needs/>.
- Ashwood, J. S., M. Gaynor, C. M. Setodji, et al. 2016. Retail clinic visits for low-acuity conditions increase utilization and spending. *Health Affairs* 35, no. 3 (March 1): 449–455.
- Augustine, J. 2014. Emergency medical services arrivals, admission rates to the emergency department analyzed. *ACEP Now*, December 17.
- Baker, L. C., and L. S. Baker. 1994. Excess cost of emergency department visits for nonurgent care. *Health Affairs* 13, no. 5 (Winter): 162–171.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Memorandum from the Director of the Survey and Certification Group regarding requirements for provider-based off-campus emergency departments and hospitals that specialize in the provision of emergency services. January 11. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter08-08.pdf>.
- Community Health Systems. 2017. Form 10-K annual report submitted to the Securities and Exchange Commission. February 26.
- Dark, C., Y. Xu, and V. Ho. 2017. Freestanding emergency departments preferentially locate in areas with higher household income. *Health Affairs* 36, no. 10 (October 1): 1712–1719.
- Gindi, R., L. Black, and R. Cohen. 2016. *Reasons for emergency room use among US adults aged 18–64: National health interview survey 2013 and 2014*. National Health Statistics Reports, no. 90. National Center for Health Statistics, Centers for Disease Control and Prevention, Department of Health and Human Services. Hyattsville, MD: NCHS. February 18.
- Glatter, R. 2017. In 3 states, if Anthem thinks you shouldn’t have gone to ER, it won’t pay. *Forbes*, October 16.
- Health Care Cost Institute. 2018. *2016 health care cost and utilization report*. Washington, DC: HCCI.
- Ho, V., L. Metcalfe, C. Dark, et al. 2017. Comparing utilization and costs of care in freestanding emergency departments, hospital emergency departments, and urgent care centers. *Annals of Emergency Medicine* (February 15).
- Iglehart, J. K. 2018. The challenging quest to improve rural health care. *New England Journal of Medicine* 378, no. 5 (February 1): 473–479.
- Kliff, S. 2018. An ER visit, a \$12,000 bill—and a health insurer that wouldn’t pay. *Vox*. January 29.
- Lawner, B. J., J. M. Hirshon, A. C. Comer, et al. 2016. The impact of a freestanding ED on a regional emergency medical services system. *American Journal of Emergency Medicine* 34, no. 8 (August): 1342–1346.
- Liu, J. J., G. Bellamy, B. Barnet, et al. 2008. Bypass of local primary care in rural counties: Effect of patient and community characteristics. *Annals of Family Medicine* 6, no. 2 (March–April): 124–130.
- Livingston, S. 2018. UnitedHealth tightens reins on emergency department reimbursement. *Modern Healthcare*, March 7.
- Maryland Health Care Commission. 2015. *Report on the operations, utilizations, and financial performance of freestanding medical facilities*. Annapolis, MD: MHCC.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016b. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011. *Medicare copayments for critical access hospital outpatient services—2009 update*. Report prepared by staff from RTI International for the Medicare Payment Advisory Commission. Washington, DC: MedPAC.

- Medicare Payment Advisory Commission. 2006. *Report to the Congress: Physician-owned specialty hospitals revisited*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2005. *Report to the Congress: Physician-owned specialty hospitals*. Washington, DC: MedPAC.
- Mehrotra, A., H. Liu, J. L. Adams, et al. 2009. Comparing costs and quality of care at retail clinics with that of other medical settings for 3 common illnesses. *Annals of Internal Medicine* 151, no. 5 (September 1): 321–328.
- Morganti, K., S. Bauhoff, J. Blanchard, et al. 2013. *The evolving role of emergency departments in the United States*. Santa Monica, CA: RAND Corporation.
- Morningstar Document Research. 2017a. HCA Holdings, for 10–K. February 22.
- Morningstar Document Research. 2017b. Tenet Healthcare Corporation, for 10–K. February 27.
- Morse, S. 2015. Kansas plan would convert many rural hospitals into primary health clinics. *HealthCare Finance News*, August 18.
- Pines, J. M., P. M. Mullins, J. K. Cooper, et al. 2013. National trends in emergency department use, care patterns, and quality of care of older adults in the United States. *Journal of the American Geriatrics Society* 61, no. 1 (January): 12–17.
- Rice, S. 2016. Are free-standing emergency rooms helping only the wealthy? *Dallas Morning News*, August 2.
- Rudavsky, S. 2016. St. Vincent to open 4 emergency micro-hospitals. *Indy Star*, August 22.
- Rural Hospital Stabilization Committee, State of Georgia. 2015. *Rural Hospital Stabilization Committee: Final report to the governor*. Atlanta, GA: RHSC. https://gov.georgia.gov/sites/gov.georgia.gov/files/related_files/document/Rural%20Hospital%20Stabilization%20Committee%20Report%20022315%20FINAL.pdf.
- Schuur, J. D., O. Baker, J. Freshman, et al. 2016. Where do freestanding emergency departments choose to locate? A national inventory and geographic analysis in three states. *Annals of Emergency Medicine* (July 12).
- Sutherly, B. 2016. Free-standing emergency departments will drive up costs, some warn. *Columbus Dispatch*, February 29.
- Thompson, B. 2015. Rural Kansas hospitals search for ways to survive. *KHI News Service/Heartland Health Monitor*, June 29. <http://kcur.org/post/rural-kansas-hospitals-search-ways-survive>.
- Thygeson, M., K. A. Van Vorst, M. V. Maciosek, et al. 2008. Use and costs of care in retail clinics versus traditional care sites. *Health Affairs* 27, no. 5 (September–October): 1283–1292.
- UnitedHealth Center for Health Reform & Modernization. 2011. *Modernizing rural health care: Coverage, quality and innovation*. Working paper 6. Minnetonka, MN: UnitedHealth Group.
- Weinick, R. M., R. M. Burns, and A. Mehrotra. 2010. Many emergency department visits could be managed at urgent care centers and retail clinics. *Health Affairs* 29, no. 9 (September): 1630–1636.
- Williams, J. D., P. H. Song, and G. H. Pink. 2015. *Estimated costs of rural freestanding emergency departments*. Findings brief. Chapel Hill, NC: North Carolina Rural Health Research Program, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill.
- Wilson, M., and D. Cutler. 2014. Emergency department profits are likely to continue as the Affordable Care Act expands coverage. *Health Affairs* 33, no. 5 (May): 792–799.
- Young, S. 2018. Personal communication with Sarah Young, Federal Office of Rural Health Policy.

CHAPTER

3

**Rebalancing Medicare's
physician fee schedule toward
ambulatory evaluation and
management services**

Rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services

Chapter summary

Ambulatory evaluation and management (E&M) services, such as office and hospital outpatient visits, are essential for a high-quality, coordinated health care delivery system. These visits enable clinicians to diagnose and manage patients' chronic conditions, treat acute illnesses, develop care plans, coordinate care across providers and settings, and discuss patients' preferences. E&M services are critical for both primary care and specialty care. The Commission is concerned that these services are underpriced in the fee schedule for physicians and other health professionals ("the fee schedule") relative to other services, such as procedures. This mispricing may lead to problems with beneficiary access to these services and, over the longer term, may even influence the pipeline of physicians in specialties that tend to provide a large share of E&M services.

Payment rates in the fee schedule are based on relative weights, called relative value units (RVUs), which account for the amount of work required to provide a service, expenses related to maintaining a practice, and professional liability insurance costs. Work RVUs are based on an assessment of how much time and intensity (e.g., mental effort and technical skill) services require relative to one another. If estimates of time and intensity are not kept up to date, especially for services that experience efficiency improvements, the work RVUs become inaccurate. Because of advances in technology, technique, and clinical practice, efficiency improves more easily for procedures, imaging, and

In this chapter

- Background on the fee schedule for physician and other health professional services
- Ambulatory E&M services are underpriced relative to other services
- An approach to rebalance the fee schedule toward ambulatory E&M services
- Conclusion

tests than for ambulatory E&M services, which are composed largely of activities that require the clinician's time and so do not lend themselves to efficiency gains. When efficiency gains reduce the amount of work needed for a service, the work RVUs for the affected services should decline accordingly. Because the fee schedule is budget neutral, a reduction in the RVUs of these services would raise the RVUs for all other services, such as ambulatory E&M services. Because of problems with the process of reviewing overpriced services, this two-step sequence tends not to occur. Therefore, ambulatory E&M services become passively devalued over time.

CMS, with input from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), has reviewed the work RVUs of many potentially mispriced services since 2009. However, CMS's review has taken several years and has not yet addressed services that account for a substantial share of fee schedule spending. CMS's review is hampered by the lack of current, accurate, and objective data on clinician work time and practice expenses. To estimate clinician work time for specific services, CMS relies on data from surveys conducted by specialty societies that are reviewed by the RUC. We have concerns about these data; for example, the surveys have low response rates and low total number of responses, which raises questions about the representativeness of the results.

To address this problem, the Commission previously recommended that CMS use a streamlined method to regularly collect data from a cohort of efficient practices—including service volume and work time—to establish more accurate work and practice expense RVUs. These data should be used in a “top-down” approach to calculate the amount of time that a physician worked over the course of a week or month and compare it with the time estimates in the fee schedule for all of the services that the physician billed over the same period. If the fee schedule's time estimates exceed the actual time worked, this finding could indicate that the time estimates are too high.

Contractors working for CMS and the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services found that the fee schedule's time estimates for clinician work for a broad range of services—particularly imaging, procedures, and tests—are inflated when compared with ambulatory E&M services. Indeed, errors in some of the fee schedule's time assumptions were very large—multiples of the actual time spent by physicians. For example, the time assumption for MRI of the brain was more than twice as high as the actual time spent by physicians on this service, according to a physician survey. By contrast, the time assumption for three ambulatory E&M services in the survey was about the same as the actual time spent by physicians.

There is also evidence that payment rates for global surgical services—which include the procedure itself and certain services that are provided immediately before and after the procedure—are too high. The global payment rate assumes that the same physician who performs the procedure also provides all the postoperative care, such as E&M visits. However, a study by the RAND Corporation observed that postoperative care is shifting from the physician who performed the procedure to other clinicians, such as hospitalists and nonphysician practitioners, who bill separately for each postoperative visit. This change suggests that physicians who bill for a global surgical service may be receiving payments for postoperative visits that in reality are provided by other clinicians. In addition, the Office of Inspector General reviewed medical records for several types of global surgical services and found that physicians frequently provided fewer E&M visits during the postoperative period than were included in the global payment rate.

There are also major problems with the accuracy of the data used to set practice expense RVUs (practice expense includes the cost of nonphysician clinical and administrative staff, medical equipment and supplies, office rent, and other expenses). First, CMS does not have a comprehensive data source with current information on the prices of medical equipment and supplies; consequently, the price estimates for these items are often outdated. Second, practice expense RVUs are based on data from a survey of total practice costs. Because this survey was conducted in 2007 and 2008, the data are unlikely to reflect current practice costs.

We describe a budget-neutral approach to rebalance the fee schedule that would increase payment rates for ambulatory E&M services while reducing payment rates for other services (e.g., procedures, imaging, and tests). Under this approach, the increased payment rates would apply to ambulatory E&M services provided by all clinicians, regardless of specialty. We modeled the impact of a 10 percent payment rate increase for ambulatory E&M services, although a higher or lower increase could be considered. A 10 percent increase would raise annual spending for ambulatory E&M services by \$2.4 billion. To maintain budget neutrality, payment rates for all other fee schedule services would be reduced by 3.8 percent.

Certain specialties would receive a large increase in their total fee schedule payments (on net) as a result of this change. The three specialties that would receive the highest proportional increase in payments are endocrinology (6.6 percent net increase in fee schedule payments), rheumatology (5.5 percent increase), and family practice (4.9 percent increase). These specialties concentrate on ambulatory E&M services. Several specialties—including diagnostic radiology, pathology, physical therapy, and occupational therapy—would experience reductions in their fee

schedule payments of about 3.8 percent because they provide very few ambulatory E&M services.

This change would be a one-time adjustment to the fee schedule to address several years of passive devaluation of ambulatory E&M services. Even if this approach is adopted, we urge CMS to accelerate its efforts to improve the accuracy of the fee schedule by developing a better mechanism to identify overpriced services and adjust their payment rates. If successful, these efforts would improve the accuracy of prices for ambulatory E&M and other services going forward and could reduce the need for future significant adjustments to the prices of E&M services. ■

Background on the fee schedule for physician and other health professional services

In 2016, Medicare paid about \$70 billion under the fee schedule for physician and other health professional services (“the fee schedule”). The fee schedule contains payment rates for over 7,000 distinct services, classified using the Healthcare Common Procedure Coding System (HCPCS). Payment rates are based on relative weights, called relative value units (RVUs), which account for the amount of work required to provide a service, expenses related to maintaining a practice, and professional liability insurance costs. Collectively, these three components make up the Resource-based Relative Value Scale. Together with the fee schedule’s conversion factor (or base payment amount), the RVUs produce a total payment rate for each service. CMS, with input from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), revises the RVUs for some services each year based on changes in clinical practice, new data, and other factors. In addition, CMS annually sets RVUs for new and revised HCPCS codes.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established a new set of updates for clinicians billing under the fee schedule and repealed the prior framework—the sustainable growth rate (SGR) formula—that set the conversion factor.¹ The SGR was established to limit total fee schedule spending by restraining annual updates when spending exceeded certain parameters. MACRA provided a new framework for updating fee schedule payments. It established two payment paths: one path for clinicians who participate in advanced alternative payment models (A-APMs), such as certain accountable care organization and episode of care models, and another path for other clinicians known as the Merit-based Incentive Payment System (MIPS) (Medicare Payment Advisory Commission 2018). The Commission has recommended that the Congress eliminate MIPS and establish a new voluntary value program in fee-for-service (FFS) Medicare (Medicare Payment Advisory Commission 2018). MACRA established incentive payments for clinicians who participate in A-APMs to encourage them to move toward these models. A-APMs generally require participating entities to assume financial risk for their patients, which encourages providers to

improve care coordination and quality while controlling cost growth.

However, it is still important to ensure the accuracy of fee schedule prices under traditional FFS Medicare because many beneficiaries remain in traditional FFS. In addition, all A-APM models use FFS payment rates as either the basis of payment or the reference price for setting the global or bundled payment amount. Further, the benchmarks used to determine payments to Medicare Advantage plans are based on FFS spending, which reflects fee schedule payment rates. Moreover, many commercial plans use RVUs from the fee schedule to determine their own payment rates for clinicians.

Pricing distortions can influence the mix of services provided by clinicians by encouraging them to focus on services that are relatively more profitable than others, leading to volume increases for the higher profit services. Some of these additional services may represent low-value care, which refers to services that have little or no clinical benefit or care in which the risk of harm from the service outweighs the potential benefit (see Chapter 10 in this report on Medicare coverage policy and use of low-value care). In addition to increasing health care spending, low-value care has the potential to harm patients by exposing them to the risk of injury from inappropriate tests or procedures.

Ambulatory evaluation and management (E&M) services—which we define as office visits, hospital outpatient department visits, visits to patients in certain other settings such as nursing facilities, and home visits—are essential for a high-quality, coordinated health care delivery system. These visits enable clinicians to diagnose and manage patients’ chronic conditions, treat acute illnesses, develop care plans, coordinate care across providers and settings, discuss patient preferences, and engage in shared decision-making with patients. These services are critical for both primary care and specialty care. Therefore, to ensure that clinicians have an incentive to provide ambulatory E&M visits, these services should not be priced too low relative to other services.

In this chapter, we first discuss why ambulatory E&M services tend to be underpriced in the fee schedule and evidence that the prices for other services are inflated. We then suggest an approach to rebalance the fee schedule toward ambulatory E&M services through a one-time price increase for these services that would be funded by reducing payment rates for other services.

Ambulatory E&M services are underpriced relative to other services

When CMS implemented the fee schedule in 1992, one of the main goals was to reduce payment disparities between primary care physicians and specialists (Ginsburg 2012, Laugesen 2016). A large share of services provided by primary care physicians are ambulatory E&M services. From 1991 to 1996 (a period that includes the first five years of the new fee schedule), payment rates for office and hospital outpatient visits grew by 4.3 percent per year and rates for nursing facility/rest home visits increased by 9.4 percent per year (Medicare Payment Advisory Commission 1998). During this period, payment rates for most types of procedures and imaging declined (e.g., rates for cataract lens replacement fell by 6.5 percent per year). However, CMS's review of certain fee schedule services in 1996 and 2001 led to substantially more services receiving higher prices than lower prices (Medicare Payment Advisory Commission 2006b). The budget-neutral nature of the fee schedule means that raising prices for certain services leads to lower prices for others, such as ambulatory E&M services. These issues led the Commission to express concern in 2006 that ambulatory E&M services were underpriced relative to other types of services (Medicare Payment Advisory Commission 2006b).

Using recommendations from the RUC, CMS increased work RVUs for several E&M services in 2007 and 2008, such as office and hospital outpatient visits. In addition, practice expense RVUs for E&M services increased between 2007 and 2013 because CMS adopted new methods and new data to calculate practice expense values (Medicare Payment Advisory Commission 2007, Medicare Payment Advisory Commission 2011b). Since 2013, however, payment rates for office and outpatient visits have changed very little. For example, total RVUs for a Level III office or outpatient visit for an established patient (HCPCS 99213), the most frequently billed office or outpatient visit, declined slightly from 2.14 in 2013 to 2.06 in 2018.² Therefore, the Commission remains concerned that ambulatory E&M services are underpriced relative to other services.

The Commission has made prior recommendations to increase payment rates for ambulatory E&M services provided by certain clinicians (see text box on the Commission's prior recommendations). One of these recommendations—a temporary bonus for certain E&M services provided by designated clinicians—was adopted but expired in 2015.

As services experience efficiency gains, their work RVUs should decline but often do not

Work RVUs for clinician services are based on an assessment of how much time and intensity services require relative to one another. Intensity refers to the mental effort, technical skill, psychological stress, and risk of performing a service. If estimates of time and intensity are not kept up to date, especially for services that experience efficiency improvements, the work RVUs become inaccurate.

Procedures, imaging, and tests are more likely to experience efficiency gains than ambulatory E&M services

Due to advances in technology, technique, and clinical practice, efficiency gains are more likely to occur for procedures, imaging, and tests than for other services. For example, when a new test or procedure is added to the fee schedule, it may be assigned a relatively high work RVU because of the additional time, technical skill, mental effort, and risk associated with performing the service. Over time, however, as clinicians become more familiar with the service and more efficient at performing it, they can complete it faster and with less mental effort, skill, and risk (Medicare Payment Advisory Commission 2006b).

Ambulatory E&M services, by comparison, tend to be labor intensive and so do not lend themselves to efficiency gains (Medicare Payment Advisory Commission 2008). They are composed largely of activities that require the clinician's time, such as taking the patient's history, examining the patient, and engaging in medical decision-making.

Because the time and effort needed to perform procedures, imaging, and tests generally declines over time, clinicians should be able to provide more of these services per day. However, because it is more difficult to achieve efficiency gains for ambulatory E&M services, we can expect lower volume growth for these services. As evidence, the cumulative growth in the volume of E&M services from 2000 to 2016 was much less than the cumulative growth in the volume of tests, imaging, and other procedures (Figure 3-1, p. 72).

Ambulatory E&M services experience passive devaluation over time

Ideally, when efficiency gains reduce the amount of work needed for a service, the work RVUs for the affected services should decline accordingly. Because the fee schedule is budget neutral, a reduction in the RVUs of

Prior Commission recommendations to improve payment for ambulatory E&M services

The Commission has made prior recommendations to increase payment rates for ambulatory evaluation and management (E&M) services provided by certain clinicians relative to other services. In 2008, the Commission recommended that the Congress establish a bonus for designated ambulatory E&M services billed by eligible primary care practitioners (Medicare Payment Advisory Commission 2008). The designated E&M services included office visits, home visits, and visits to patients in certain other settings (e.g., skilled nursing and intermediate care facilities). Eligible primary care practitioners included clinicians whose designated specialty is primary care (e.g., family medicine) and who received at least 60 percent of their fee schedule–allowed charges from ambulatory E&M services.³ To help rebalance the fee schedule, the Commission recommended that spending for the bonus be budget neutral. While the Commission did not recommend a specific amount, we analyzed two levels for the bonus: 5 percent and 10 percent.

In response to this recommendation, the Patient Protection and Affordable Care Act of 2010 created a temporary primary care bonus program called the Primary Care Incentive Payment (PCIP) program. However, the program was not budget neutral and thus required additional funding. The PCIP, which existed from 2011 to 2015, provided a 10 percent bonus payment on fee schedule payments for certain primary care visits provided by eligible primary care practitioners. The PCIP’s definitions for these terms were as follows:

- **Primary care visits** were ambulatory E&M services (e.g., office visits, home visits, and visits in skilled nursing facilities) (Centers for Medicare

& Medicaid Services 2010). E&M services in inpatient hospital settings and emergency departments, annual wellness visits, chronic care management services, and transitional care management services were not considered primary care visits under the PCIP.

- **Primary care providers** included providers with a primary Medicare specialty designation of family practice, internal medicine, pediatrics, geriatrics, nurse practitioner and clinical nurse specialist, and physician assistant and for whom primary care visits accounted for at least 60 percent of allowed charges under the fee schedule.

In 2011, the Commission recommended that the Congress replace the sustainable growth rate (SGR) system with payment updates that would have been higher for certain E&M services billed by eligible primary care practitioners than for other services (Medicare Payment Advisory Commission 2011a). Specifically, the Commission recommended that payment rates for certain E&M services be frozen at their current levels for 10 years and rates for all other services be reduced in each of the first 3 years and then frozen for the subsequent 7 years. Although the SGR was replaced, the Congress did not adopt differential updates for E&M services and other services.

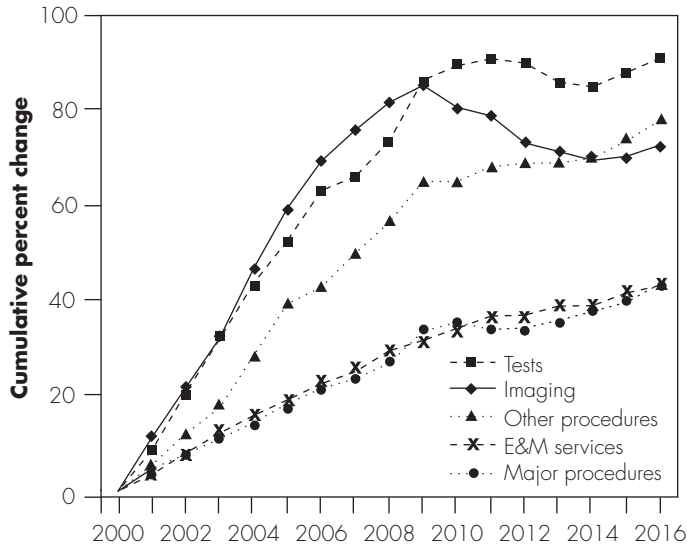
In addition to recommendations specific to the fee schedule, the Commission recommended that the Congress establish a per beneficiary payment for primary care providers to replace the PCIP after it expired at the end of 2015 (Medicare Payment Advisory Commission 2015). The payment would provide funds to support the investment in infrastructure and staff that facilitate care management and care coordination. ■

these services would raise the RVUs for all other services, such as ambulatory E&M services. Because of problems with the process of reviewing mispriced services and the data used to set prices, this two-step sequence tends not

to occur. Therefore, ambulatory E&M services become passively devalued over time. In other words, their relative prices are too low because the prices for other services have become artificially high.

FIGURE 3-1

Cumulative growth in the volume of E&M services per fee-for-service beneficiary was much less than growth in volume of tests, imaging, and other procedures, 2000-2016



Note: E&M (evaluation and management). Volume growth for E&M services from 2009 to 2010 is not directly observable because of a change in payment policy for consultations. To compute cumulative volume growth for E&M services through 2016, we used a growth rate for 2009 to 2010 of 1.85 percent, which is the average of the 2008 to 2009 growth rate of 1.7 percent and the 2010 to 2011 growth rate of 2.0 percent.

Source: MedPAC analysis of claims data for 100 percent of Medicare beneficiaries.

CMS's review of potentially mispriced services has not been sufficient

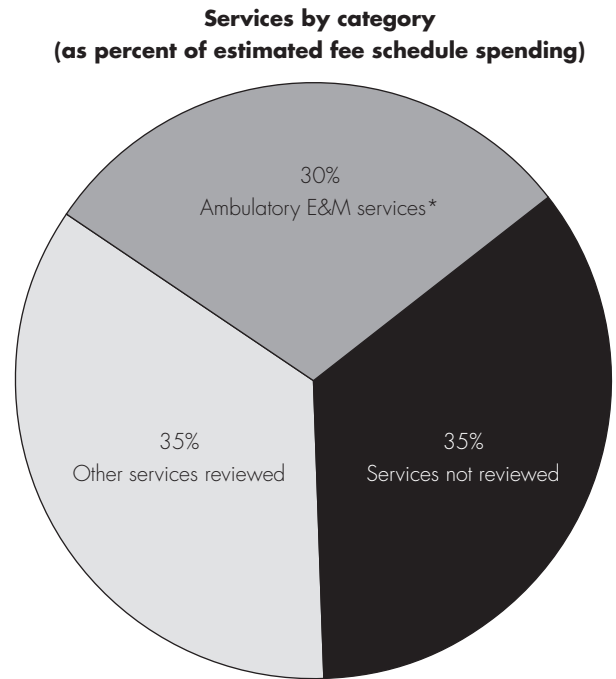
CMS, with assistance from the RUC, has reviewed the work RVUs of many potentially mispriced services since 2009, but has not yet addressed services that account for a substantial share of fee schedule spending.⁴ After a service has been identified as potentially misvalued, it can often take several years for the RUC to develop a recommendation for that service (Government Accountability Office 2015). CMS's review is also hampered by the lack of current, accurate, and objective data on clinician work time and practice expenses. Even among the services for which CMS reduced the work RVUs, the RVUs did not decline as much as the estimated amount of time needed to provide the services.

Although CMS's review of potentially mispriced services began in 2009, the agency has not yet reviewed many

services. Services that have had their work RVUs reviewed since 2009—whether new services, revised services, or services reviewed as potentially mispriced—accounted for 35 percent of fee schedule spending in 2016 (Figure 3-2). Services that have not yet been reviewed accounted for an additional 35 percent of fee schedule spending. If CMS were to review these services, the agency could identify mispriced services and redistribute payments from overpriced to underpriced services. Ambulatory E&M services accounted for the remaining 30 percent of fee schedule spending, and CMS updated the payment rates for many of these services in 2007 and 2008.

FIGURE 3-2

CMS has not yet reviewed the work RVUs of services that accounted for a significant share of fee schedule payments, 2016



Note: RVU (relative value unit), E&M (evaluation and management). Percentages are each category's share of total fee schedule-allowed charges in 2016. Services that had their work RVUs reviewed are those listed in fee schedule final rules for 2009 to 2016 as new, revised, or potentially misvalued or reviewed during the fourth five-year review. Ambulatory E&M services include office visits, home visits, and visits to patients in certain other settings (e.g., nursing facilities).

*CMS increased payment rates for many of these services in 2007 and 2008.

Source: CMS fee schedule final rules and MedPAC analysis of claims data for 100 percent of Medicare beneficiaries.

**TABLE
3-1**

The RUC recommended a decrease in work RVUs for approximately half of the potentially mispriced services for which it reviewed work RVUs, 2009–2017

Work RVUs	Number of services	Percent of services reviewed
No change	647	39%
Increase	210	13
Decrease	<u>795</u>	<u>48</u>
Total	1,652	100

Note: RUC (Relative Value Scale Update Committee), RVU (relative value unit). The RUC examined a total of 2,220 services from 2009 to 2017. Work RVUs were reviewed for 1,652 services, practice expense RVUs (but not work RVUs) were revised for 158 services, and billing codes were deleted for 410 services.

Source: American Medical Association 2017.

CMS and the RUC have identified potentially mispriced services for review. From 2009 to 2017, the RUC recommended lower work RVUs for only half of the potentially mispriced services for which it reviewed work RVUs, a somewhat counterintuitive outcome given that CMS and the RUC identified services for review that were likely to be overpriced (Table 3-1). According to an American Medical Association progress report, the RUC reviewed work RVUs for 1,652 services as of October 2017 (American Medical Association 2017).⁵ The RUC recommended that CMS decrease the work RVUs for 795 services (48 percent) but recommended no change for 647 services (39 percent) and increases for 210 services (13 percent).⁶ The RUC used several screening criteria to identify potentially mispriced services for review, such as services with new technology, surgical procedures that are performed less than half the time in inpatient settings but include inpatient E&M services in their payment rates, services with rapid volume growth, and services that are frequently performed together by the same physician on the same date. These types of services are more likely to be overpriced than underpriced, and thus the majority of services identified with these criteria should have been candidates for RVU reductions. For example, the amount of time required for services that experience rapid volume growth should decline over time as clinicians become more familiar with these services and can perform them faster. Therefore, we would have expected the RUC to have recommended lower work RVUs for more than half of the services they reviewed.

Even among the services for which CMS reduced the work RVUs, the decreases were not consistent with

reductions in the estimated amount of time needed to provide the services. The statute defines the work of clinicians as consisting of the time spent providing a service and the intensity of work effort per unit of time (e.g., mental effort and technical skill). For a number of services, CMS (with input from the RUC) reduced the estimated amount of time that clinicians spend providing these services and the work RVUs for these services. However, CMS did not reduce the work RVUs for these services as much as the time estimates: The agency decreased the time estimates by an average of 18 percent but decreased the work RVUs by an average of 9 percent (Table 3-2). A potential explanation for this disparity is that decreases in time were offset by increases in intensity. In the absence of an increase in intensity, CMS could have reduced work RVUs by the same percentage as the time estimates, thereby making it possible to redistribute more money to other services.

**TABLE
3-2**

Time estimates have decreased more than work RVUs, 2008–2016

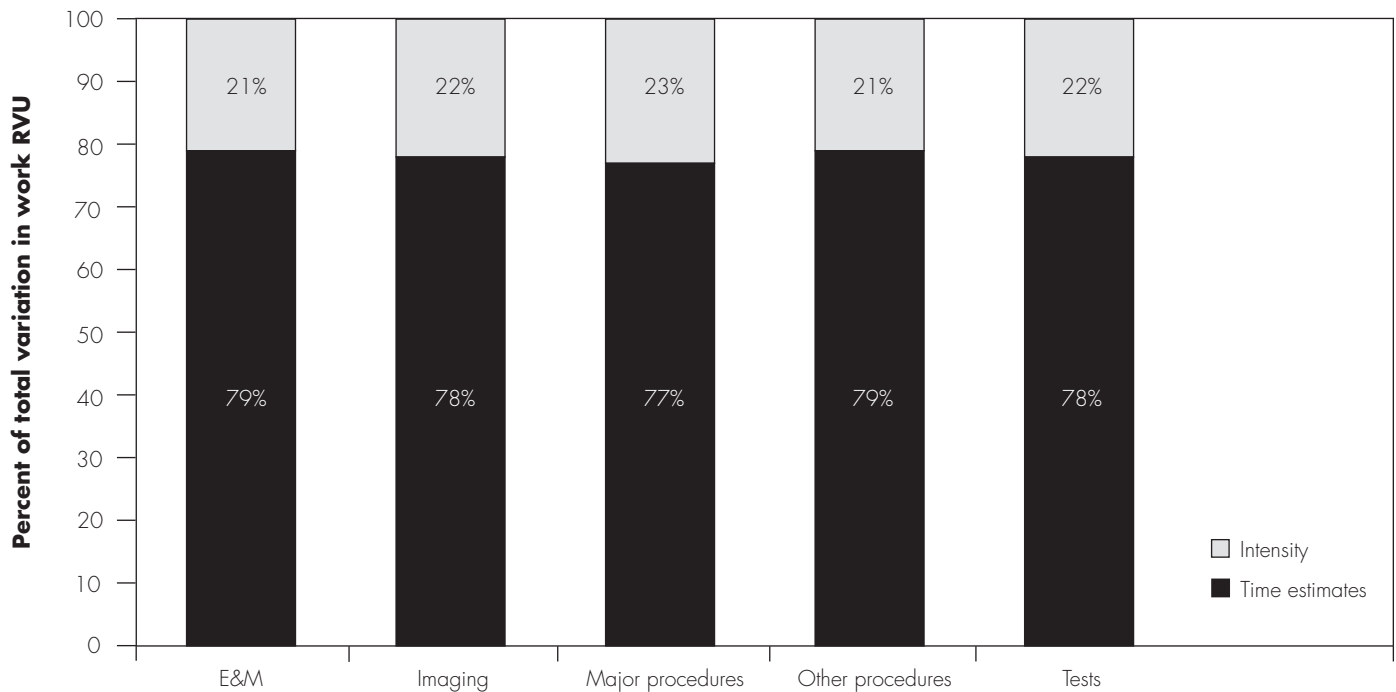
	Average percent change
Time estimates	-18%
Work RVUs	-9

Note: RVU (relative value unit). Table reflects changes to RVUs adopted by CMS. The 607 services evaluated had work RVUs and work-time estimates in 2008 and 2016 and had a decrease in work RVUs, a decrease in the work-time estimate, or both.

Source: MedPAC analysis of physician time and RVU files from CMS.

**FIGURE
3-3**

Fee schedule's time estimates are most important factor in establishing work RVUs, 2017



Note: RVU (relative value unit), E&M (evaluation and management). The percentages for time estimates are from five regression analyses: one for each service type. In these analyses, the log of estimated time was the explanatory variable, and the log of work RVU was the dependent variable. The percentages for intensity are the differences between the estimated time percentages and 100 percent.

Source: MedPAC analysis of time data and work RVUs from CMS.

The data used to price services are inadequate

CMS's lack of comprehensive, current, and objective data on clinician work time and practice expense is a key reason the process for reviewing and revising mispriced services has been inadequate. Clinician work time is a key component of work RVUs. To estimate clinician work time for specific services, CMS relies on data from surveys conducted by specialty societies that are reviewed by the RUC. We have three main concerns about the objectivity and quality of these data. First, the specialty societies that conduct the surveys have a financial stake in the process of setting payment rates. Second, the survey data have weaknesses that include low response rates and low total number of responses, which raises questions about the representativeness of the results. For example, the Government Accountability Office found that, for services

surveyed by specialty societies for payment year 2015, the median response rate to surveys was only 2.2 percent, the median number of responses to surveys was 52, and 23 of 231 surveys had fewer than 30 respondents (Government Accountability Office 2015). Third, the respondents are generally aware of the purpose of the survey (to set payment rates), and therefore their responses may be biased in favor of higher time estimates.

To address this problem, the Commission recommended in 2011 that CMS use a streamlined method to regularly collect data from a cohort of efficient practices—including service volume and work time—to establish more accurate work and practice expense RVUs (Medicare Payment Advisory Commission 2011a). CMS's response has been to contract with researchers to develop models to validate the RVUs. These models attempt to validate the time estimates for services one by one (e.g., through time-and-

motion studies). The Commission's concern has been that this approach is time consuming, costly, and likely to be burdensome for providers and CMS. However, it may be useful for identifying specific services that are potentially misvalued.

The Commission has recommended a different, “top-down” approach to validate the RVUs (Medicare Payment Advisory Commission 2011b). This method looks at the amount of time that a physician worked over the course of a week or month and compares it with the time estimates in the fee schedule for all of the services that the physician billed over the same period. If the fee schedule's time estimates exceed the actual time worked, this finding could indicate that the time estimates are too high. In 2014, a contractor for the Commission explored the feasibility of the top-down approach by collecting data from a small set of physician practices on the services billed by their clinicians and the clinicians' actual hours worked (Medicare Payment Advisory Commission 2015). If CMS used a top-down approach to validate RVUs, it could identify groups of services that are likely overpriced, carefully review those services, and price them more accurately.

Evidence that estimates of clinician work time are inflated

Contractors working for CMS and the Assistant Secretary for Planning and Evaluation (ASPE) in the Department of Health and Human Services have gathered evidence that the fee schedule's time estimates for clinician work are inflated (Merrell et al. 2014, Zuckerman et al. 2016). While there was heterogeneity in the data and methods used by the contractors, the findings were consistent: The time assumptions for a broad range of services in the fee schedule—particularly imaging, procedures, and tests—are inflated when compared with ambulatory E&M services. Indeed, errors in some of the fee schedule's time assumptions were very large—multiples of the actual time spent by physicians. The Commission's position is that the time assumptions—and, therefore, the fee schedule's work RVUs—should be validated and corrected. In the meantime, a budget-neutral payment adjustment would appropriately rebalance the fee schedule toward ambulatory E&M services.

The contractors focused on estimates of the time that it takes clinicians to furnish services to a typical patient. These time assumptions are important because they are highly predictive of the work RVUs. Depending on the

type of service, time explains over 75 percent of the variance in work RVUs (Figure 3-3).

The contractors collected data from diverse sources: administrative data on service volume and physician hours worked, physician surveys, time-and-motion studies, and electronic health records. They analyzed the data using either a top-down approach or a bottom-up approach, which examines each service separately. Although a bottom-up approach is costly, the findings from this method illustrate significant distortions in the time estimates for common services.

Specialties other than primary care had the largest differences between time assumed in the fee schedule and actual time worked

The intent of the project for ASPE was to better understand whether there are systematic differences or errors in the fee schedule's time assumptions across specialties or groups of services. The contractor acquired data from three integrated delivery systems (IDSs): one located in the West, one in the Midwest, and one in the eastern United States (Merrell et al. 2014). To assess the accuracy of the time assumptions from a top-down perspective, the contractor collected administrative data on service volume by physician and billing code. These service volumes were multiplied by the code-specific time assumed in the fee schedule and summed for each physician to calculate “fee schedule time.” Data were also collected on “actual time worked,” calculated based on clinical practice days per year, clinical hours per year, or a full-time equivalent measure, depending on the IDS. The accuracy of the fee schedule's time assumptions was analyzed as the ratio of fee schedule time to actual time worked.⁷

Analyzing the differences between fee schedule time and actual time worked, the contractor concluded that the fee schedule's time assumptions may be distorted for some specialties. Specifically, their findings are consistent with the conclusion that primary care is disadvantaged by the current time assumptions (Table 3-3, p. 76). The median ratio of fee schedule time to actual time worked, when evaluated across all specialties, was 1.35. However, the ratio for radiology was higher, at 2.00; the ratio for cardiology was highest, at 2.08. By contrast, the ratios were lowest for pathology, general surgery, and primary care at 1.14, 1.16, and 1.25, respectively. Primary care specialties tend to concentrate on ambulatory E&M services.

**TABLE
3-3**

Primary care physicians' ratio of fee schedule time to actual time is below the median for all physicians

Specialty	Number of physicians	Median ratio of fee schedule time to actual time
Pathology	31	1.14
General surgery	53	1.16
Primary care	231	1.25
Orthopedic surgery	45	1.35
All other specialties	345	1.36
Radiology	57	2.00
Cardiology	44	2.08
All	806	1.35

Note: "Primary care" includes family medicine and internal medicine. "Fee schedule time" refers to the work time assumed in the fee schedule for the services provided by each physician. "Actual time" refers to the actual time worked by each physician, based on their clinical practice days per year, clinical hours per year, or a full-time equivalent measure.

Source: Merrell et al. 2014.

Findings suggest that the fee schedule's time estimates for services other than ambulatory E&M services are inflated

Two projects that examined each service separately suggest that the fee schedule's time assumptions for services other than ambulatory E&M services are likely too high. One study was a pilot project for CMS on validating the time assumptions for 60 services with data gathered from both electronic health records and direct observation of the care received by individual patients (Zuckerman et al. 2016). The other project, for ASPE, assessed the feasibility of validating the time assumptions for 26 services with data from a survey in which physicians were asked how many minutes they typically spend when furnishing each of the services (Merrell et al. 2014).

Pilot project for CMS The pilot project for CMS included developing empirical measures of physician service time for specific services (Zuckerman et al. 2016). The contractor measured time in one of two ways, depending on the service and data collection site.⁸ First, administrative data were extracted from electronic health records (EHRs) for some services. EHRs include time stamps for each recorded event (e.g., start of a procedure). The contractor calculated the service time in minutes with start and end time stamps, excluding minutes associated with any documented interruptions or pauses. The second

data source was direct observation—project or physician practice staff observing and documenting the time needed to provide services to individual patients. The direct observation data were collected at three sites in different regions of the U.S.: Mid-Atlantic, New England, and Pacific. EHR data were available from two of the sites.

In selecting services for the project, researchers considered a service's risk of being misvalued and its importance to Medicare because of total spending on the service or other policy reasons. Researchers also selected a mix of services that would allow them to test methods in a variety of clinical settings.⁹ The services were of four types: office-based procedures, outpatient department or ambulatory surgical center procedures, inpatient procedures with global periods, and imaging and other test interpretations. E&M services were not included.

In interpreting the results, the contractor concluded that the fee schedule's time assumptions were often high relative to the empirical time captured in their study. For 42 of the 60 services studied, the ratios of fee schedule time to empirical time were over 1.1, based on the data collected (Table 3-4). The largest discrepancies were in imaging and other test interpretations. Electrocardiogram report—the extreme case—had a fee schedule time of 5 minutes but a median study time of only 6 seconds, making the fee schedule time 50 times the actual time observed. Other

imaging and test interpretations had smaller discrepancies, but fee schedule times were still multiples of empirically based medians. Clinical expert reviewers consulted by the contractor attributed the discrepancies to automation and personnel substitution that has become prevalent since CMS and the RUC defined the content of the services and valued them.

Feasibility study for ASPE The contractor for ASPE surveyed physicians in five specialties: cardiology, family medicine, radiology, ophthalmology, and orthopedic surgery (Merrell et al. 2014). Each physician was asked about the time spent providing selected services relevant to their specialty. The 26 services selected—an average of 5 per specialty—were frequently provided, such as echocardiogram, office visits, computed tomography of the abdomen, cataract removal with lens insertion, and knee arthroplasty.¹⁰

A total of 625 physicians participated in the survey. Questionnaires were administered through mixed modes: mail and internet, with telephone prompts performed by interviewers trained to solicit participation. Some of the physicians were from random samples drawn from the American Medical Association Physician Masterfile.¹¹ Others were from multispecialty group practices that agreed to participate. Two of these practices were in the South, three in the West, one in the Midwest, and one in the Mid-Atlantic. The survey was administered from November 2013 through July 2014. Participants were offered a financial incentive to encourage adequate response to the survey. The response rate was 54 percent.

The contractor summarized the survey results as suggesting that, for the majority of the 26 services, the fee schedule’s time assumptions are high. At the time of the study, for example, photocoagulation of the retina had the highest ratio of fee schedule time assumption to median survey time estimate: 3.78. In other words, the fee schedule time assumption was almost four times the survey estimate. The service’s time assumption was 208 minutes, but its median time estimate from the survey was 55 minutes.¹² Another example is MRI of the brain, for which the fee schedule time assumption was more than twice the survey time estimate. By contrast, the ratios for the three ambulatory E&M services in the survey—Level III and Level IV office visits for established patients and Level IV office visit for new patients—were 1.05, 1.00, and 1.00, respectively. Overall, most services (20 of 26) had fee schedule time assumptions that were higher than their median survey time estimates.

**TABLE
3-4**

Ratios of fee schedule time to empirical measures of physician time were over 1.1 for most services reviewed

Ratio of fee schedule time to empirical physician time	Number of services
Under 0.9	8
0.9 to 1.1	10
Over 1.1	42
Total	60

Note: “Fee schedule time” refers to the work time assumed in the fee schedule. “Empirical physician time” is based on data from electronic health records or direct observation of the time needed to provide services to individual patients.

Source: Zuckerman et al. 2016.

To summarize the results by specialty, each physician’s response for a service was categorized as implying that the fee schedule’s time assumption for that service was too high, too low, or about right (Table 3-5, p. 78). Overall, the rate at which physicians said that fee schedule times were too high was almost 58 percent. However, by specialty, the rate ranged from a high of about 72 percent for radiologists to a low of almost 44 percent for family medicine. The rate for family medicine means that the survey participants in this specialty were more likely to say that fee schedule times were too low or about right than they were to say that those times were too high.

Evidence that RVUs for global surgical services are inflated

Currently, the payment rate for many surgical services is a bundled payment that includes the procedure itself and certain services that are provided immediately before and after the procedure; CMS calls this group of services the global package. There are three categories of global billing codes based on the number of postoperative days included in the global package:

- 0-day global codes, which include the procedure and preoperative and postoperative physician services on the day of the procedure;

**TABLE
3-5**

Specialties other than family medicine physicians were more likely to report fee schedule times that were too high

Specialty	Total number of service-level responses	Percent of survey responses that suggest fee schedule time is:		
		Too high	About right	Too low
Family medicine	582	43.8%	10.7%	45.5%
Cardiology	469	50.5	14.9	34.5
Orthopedics	530	59.1	8.1	32.8
Ophthalmology	443	66.1	2.7	31.2
Radiology	496	72.4	3.4	24.2
All	2,520	57.8	8.1	34.1

Note: Fee schedule time was defined as “too high” if the fee schedule time exceeded the survey time estimate by more than 5 percent. “About right” means that the fee schedule time was within 5 percent of the survey time. “Too low” indicates that the fee schedule time was lower than the survey time by more than 5 percent. Each specialty’s shares may not sum to 100 due to rounding.

Source: Merrell et al. 2014.

- 10-day global codes, which include the same services as the 0-day global codes plus physician visits related to the procedure during the 10 days after the procedure; and
- 90-day global codes, which include the same services as the 0-day global codes plus preoperative services furnished one day before the procedure and postoperative services during the 90 days after the procedure.

In general, the Commission supports moving Medicare in the direction of bundled payments to counter the volume incentives intrinsic to FFS Medicare. However, it is essential that the individual services that make up a bundle have accurate values and that there is a mechanism to ensure that the services that are part of the bundle are not paid separately (unbundling). Otherwise, the payment rate for the entire bundle will be inaccurate.

CMS has raised several concerns with the 10-day and 90-day global packages for surgical services (Centers for Medicare & Medicaid Services 2014):

- The number and type of visits needed in the package for a given service are likely to change over time as medical practice and the patient population changes.
- There is a lack of consistency in how the work RVUs for global codes are constructed (e.g., services may have work RVUs that are the sum of each component

of the global package or just a single value for all components of the package).

- The global codes contribute to payment disparities among specialties.
- The global packages are inconsistent with current medical practice (e.g., care has been shifting from individual practitioners to larger practices and teams).

CMS also cited evidence from the Office of Inspector General (OIG) that the RVUs for global codes may not reflect the typical number and level of postoperative visits (Office of Inspector General 2012a, Office of Inspector General 2012b). OIG reviewed a sample of medical records for several types of global surgical codes and counted the number of postoperative E&M visits provided by the physicians. In many cases, OIG found that physicians provided fewer E&M visits during the postoperative period than were included in the payment for the global package. OIG recommended that CMS adjust the number of E&M visits in the global package to reflect the number that are actually provided.

The global payment assumes that the same physician who performs the procedure also provides all the postoperative care. However, a study by the RAND Corporation for CMS observed that postoperative care is shifting from the physician who performed the

procedure to other clinicians, such as hospitalists and nonphysician practitioners, who bill separately for each postoperative visit (Mehrotra et al. 2016). This change suggests that physicians who bill for the global payment may be receiving payments for postoperative care that is provided by other clinicians.

CMS proposed to convert all 10-day global codes to 0-day codes in 2017 and convert all 90-day codes to 0-day codes in 2018. With these changes, providers would bill separately for all preoperative visits and postoperative visits that occur after the day of the procedure. However, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directed CMS to not transition all 10-day and 90-day global codes to 0-day codes. Instead, MACRA mandated that CMS develop and implement a process to gather the necessary data to appropriately value postoperative care. CMS is currently collecting the data.

The available evidence from CMS, OIG, and RAND suggests that 10-day and 90-day global surgical services are overvalued. It may take CMS several years to collect data and revalue these services. In the meantime, a budget-neutral payment adjustment for ambulatory E&M services—excluding the ambulatory E&M services currently considered when valuing global packages—would rebalance the fee schedule toward ambulatory E&M services.

Problems with the accuracy of practice expense RVUs

In addition to the shortcomings with the data used to estimate clinician work time, there are also major problems with the accuracy of the data used to set practice expense RVUs. Practice expense includes the cost of nonphysician clinical and administrative staff, medical equipment and supplies, office rent, and other expenses. First, CMS does not have a comprehensive data source with current information on the prices of medical equipment and supplies; consequently, the price estimates for these items are often outdated (Medicare Payment Advisory Commission 2006a). Second, practice expense RVUs are also based on data from a survey of total practice costs incurred by nearly all specialty groups. Because this survey was conducted in 2007 and 2008, the data are unlikely to reflect current practice costs. CMS has not developed a strategy for updating this information. However, CMS could collect data on total practice costs along with data on service volume and work time from a cohort of efficient practices, as the

Commission recommended in 2011 (Medicare Payment Advisory Commission 2011a).

An approach to rebalance the fee schedule toward ambulatory E&M services

Despite efforts made by CMS and the RUC over the last several years to review potentially mispriced services and adjust their payment rates, there is evidence that certain types of services—such as procedures—are still overpriced. Because the fee schedule is budget neutral, ambulatory E&M services become underpriced through a process of passive devaluation. One approach to rebalance the fee schedule toward ambulatory E&M services is to increase payment rates for these services and to maintain budget neutrality by reducing payment rates for other services (e.g., procedures, imaging, and tests). Because these services are essential for both primary care and specialty care, the higher payment rates should apply to all clinicians who bill for an ambulatory E&M visit, regardless of specialty. This change would be a one-time price adjustment to the fee schedule to address several years of passive devaluation of ambulatory E&M services. This adjustment could be phased in over multiple years to reduce the impact on other services. To reduce the need for future significant price changes and to address the mispricing of individual services, CMS should accelerate its efforts to identify overpriced services and adjust their payment rates. To do so, CMS should regularly collect data from a cohort of efficient practices and use this information to validate payment rates and establish accurate RVUs.

Design issues

A key design issue is which ambulatory services should be included in the payment increase. For the purpose of this approach, we included E&M billing codes for office visits, home visits, and visits to patients in certain non-inpatient hospital settings (nursing facility, domiciliary, rest home, and custodial care). We excluded newer E&M services that were added to the fee schedule in recent years because they have not been subject to several years of passive devaluation. For example, we excluded annual wellness visits (added to the fee schedule in 2011), transitional care management services (added in 2013), and chronic care management services (added in 2015 and 2017). We also considered whether to include

ambulatory psychiatric visits in the payment increase. Like ambulatory E&M services, many ambulatory psychiatric services are time-based services that do not lend themselves to efficiency gains (e.g., HCPCS code 90834 is for a 45-minute psychotherapy visit). However, we excluded them from the payment increase that we model below because the payment rates for most of these services were updated in recent years. Nevertheless, policymakers could consider applying a payment increase to the newer E&M and ambulatory psychiatric services in addition to ambulatory E&M services.

Another important design issue is the size of the payment increase for ambulatory E&M services. Although these services have become passively devalued, we were not able to precisely quantify how much these services are underpriced. We considered an increase in the range of 5 percent to 30 percent. If policymakers decided to make a one-time price adjustment to ambulatory E&M services, they would need to make a policy judgment about the appropriate increase. One precedent to consider is the Primary Care Incentive Payment program, which, from 2011 through 2015, provided a 10 percent bonus for certain E&M visits provided by eligible primary care practitioners (see text box, p. 71). To illustrate the impact of a budget-neutral payment increase for ambulatory E&M services, we modeled a 10 percent increase. However, a smaller or larger adjustment could also be considered. Our model assumes that the increase would apply to both Medicare program payments and beneficiary cost sharing so that cost sharing would continue to equal 20 percent of the total payment amount for a fee schedule service, which is the current policy. As a result, beneficiary cost sharing would increase for ambulatory E&M services but decline for all other services. Total cost sharing across all services would remain about the same.

CMS could increase payment rates for ambulatory E&M services in a budget-neutral manner by raising total RVUs for these services while reducing RVUs for all other services.¹³ Alternatively, CMS could create two different conversion factors: a higher one for ambulatory E&M services and a lower one for all other services.¹⁴ Currently, CMS uses a single conversion factor to calculate payment rates for all fee schedule services. The first approach is consistent with CMS's current method for adjusting practice expense RVUs; if RVUs for some services go up, RVUs for other services decline by a corresponding amount. This approach also makes it simpler to apply the same update to all fee schedule

services because there is a single base payment amount. Moreover, it would increase the reach of the policy beyond Medicare because many commercial plans use the fee schedule's RVUs to determine their payments to clinicians. The second approach would make it easier for policymakers to establish payment updates for ambulatory E&M services that are different from updates for other services in the future. Under either approach, the end result is the same: Clinicians would receive a higher payment rate for ambulatory E&M services and a lower rate for other services. The results of our illustrative model, described below, would be the same under either approach.

Another critical design question is how to offset the increase in fee schedule payments for ambulatory E&M services in a budget-neutral manner. We describe three options:

- an automatic reduction to the prices of new services (after a certain amount of time) and services with high growth rates,
- an extension of the annual numeric target for CMS to reduce the prices of overpriced services, and
- an across-the-board reduction to all fee schedule services other than ambulatory E&M services.

Under the first option for budget neutrality, there would be an automatic adjustment to the prices of new services to ensure that prices declined over time, consistent with the expectation that the amount of time and effort required for new services should decline over time because of advances in technology, technique, and other factors (Medicare Payment Advisory Commission 2006b). Because the payment rates for new services are not updated frequently enough to reflect reductions in time and effort, these services tend to become overpriced. An automatic reduction triggered after a certain number of years would ensure that payment rates did not remain too high. Services that were recently reviewed by the RUC and CMS and had their RVUs reduced could be exempt from an automatic reduction. An automatic reduction could also apply to services that experience high volume growth because the dynamic of learning by doing that applies to new technology should also apply to services that are being provided more frequently. Savings from this automatic reduction could be used to offset increased payments for ambulatory E&M services.

Under the second option for budget neutrality, there would be an extension of the annual numeric target set by the Congress for CMS to reduce the prices of overvalued services. The Congress set this target for a three-year period (2016 through 2018). The target was set at 1 percent of fee schedule spending for 2016 and 0.5 percent for 2017 and 2018. (CMS did not meet the target in any of the three years, which meant that payment rates for all fee schedule services were reduced by the difference between the target and the actual aggregate reduction to the RVUs of overpriced services.) The annual numeric target was based on a Commission recommendation from 2011 (Medicare Payment Advisory Commission 2011a). Under this option, the target would be extended beyond 2018 and the cumulative target amount would be based on the total amount of money to be redistributed to ambulatory E&M services. For example, a cumulative target amount of 4 percent of fee schedule spending could be phased in through an annual 1 percent target over four years. Savings achieved by reducing the prices of overpriced services would be redistributed to ambulatory E&M services.¹⁵ If CMS did not meet the target, payment rates for *all* fee schedule services other than ambulatory E&M services would be reduced by the difference between the target and the actual reduction to the prices of overpriced services. These savings would be redistributed to ambulatory E&M services.

Under the third option, the payment increase for ambulatory E&M services would be offset by an across-the-board payment reduction to all other fee schedule services (procedures, imaging, tests, and other E&M services such as those provided in emergency department and inpatient hospital settings). To fully offset a 10 percent payment increase for ambulatory E&M services, for example, there would need to be a payment decrease of 3.8 percent for all other fee schedule services. These payment changes could be implemented in one year or phased in gradually over multiple years. This estimate assumes that there would be no changes in service volume as a result of the changes in payment rates.

Modeling the net effect of a payment increase for ambulatory E&M services

To illustrate the impact of a budget-neutral payment increase for ambulatory E&M services, we modeled a 10 percent increase that would be offset by a 3.8 percent across-the-board payment reduction to all other fee

schedule services (the third budget-neutrality option described above). Other alternatives could be considered for the size of the payment increase and how to offset the increase. Our model assumes that the payment changes would occur in a single year, but the changes could instead be phased in over multiple years. The net effect of these changes on specialties would vary based on each specialty's mix of ambulatory E&M and other services. Specialties that focus on ambulatory E&M services would receive a net increase in payments, while specialties that mainly provide other services would receive a net decrease, assuming there is no change in volume due to changes in payment rates.

The increased payments for ambulatory E&M services would total \$2.4 billion (based on 2016 data). To determine the total amount of the additional payments for ambulatory E&M services by specialty, we summed the fee schedule payments for ambulatory E&M services in 2016 for each specialty and multiplied this amount by 10 percent. Table 3-6 (p. 82) shows the increase in payments for ambulatory E&M services and the net effect of the 10 percent payment increase for these services and the 3.8 percent reduction to other services, by specialty, for the 20 specialties with the highest share of total fee schedule payments in 2016. Online Appendix 3-A, available at <http://www.medpac.gov>, displays these impacts for all specialties.

Internal medicine and family practice would receive the largest amount of additional payments for ambulatory E&M services (\$435 million and \$378 million, respectively) (Table 3-6, p. 82). The three specialties that would receive the highest percent increase in their total fee schedule payments (on net) are endocrinology (6.6 percent net increase in fee schedule payments), rheumatology (5.5 percent increase), and family practice (4.9 percent increase) (see online Appendix 3-A, available at <http://www.medpac.gov>). These specialties concentrate on ambulatory E&M services. Specialties that perform procedures but also provide a significant number of ambulatory E&M services—such as urology, obstetrics/gynecology, and otolaryngology—would also experience a net increase in fee schedule payments.

Several specialties would experience reductions in their fee schedule payments of 3.8 percent because they provide very few ambulatory E&M services. These specialties include diagnostic radiology, pathology, physical therapy, and occupational therapy (see online Appendix 3-A, available at <http://www.medpac.gov>).

**TABLE
3-6**

Impact of a 10 percent payment rate increase for ambulatory E&M services offset by a 3.8 percent reduction for all other services, for specialties with highest share of total fee schedule payments, 2016

Specialty	Current payments for ambulatory E&M services (in millions)	Amount of payment increase for ambulatory E&M services (in millions)	Share of total payment increase for ambulatory E&M services (across all specialties)	Net change in fee schedule payments as a result of payment increase for ambulatory E&M services and payment reduction for all other services
Family practice	\$3,782	\$378	15.7%	4.9%
Nurse practitioner	1,650	165	6.8	4.1
Hematology/oncology	689	69	2.9	2.8
Physician assistant	824	82	3.4	2.5
Neurology	658	66	2.7	2.0
Urology	745	74	3.1	1.9
Internal medicine	4,349	435	18.0	1.7
Podiatry	744	74	3.1	1.4
Cardiology	1,681	168	7.0	0.3
Pulmonary disease	507	51	2.1	0.2
Gastroenterology	495	49	2.1	0.1
Orthopedic surgery	933	93	3.9	-0.4
Dermatology	841	84	3.5	-0.5
General surgery	341	34	1.4	-1.5
Nephrology	356	36	1.5	-1.6
Ophthalmology	505	50	2.1	-2.6
Emergency medicine	177	18	0.7	-3.1
Radiation oncology	83	8	0.3	-3.2
Diagnostic radiology	14	1	0.1	-3.8
Physical therapy	<1	<1	0.0	-3.8

Note: E&M (evaluation and management). Table includes the 20 specialties with the highest share of total fee schedule payments. "Ambulatory E&M services" includes office visits, home visits, and visits to patients in certain non-inpatient hospital settings (nursing facility, domiciliary, rest home, and custodial care). The payment increase is applied to allowed charges for ambulatory E&M services. Estimates assume there would be no changes in service volume as a result of changes in payment rates. Analysis includes services billable under the fee schedule for physician and other health professional services.

Source: MedPAC analysis of claims data for 100 percent of Medicare beneficiaries, 2016.

Conclusion

We describe an approach to address the problem of passive devaluation of ambulatory E&M services that would rebalance fee schedule payment rates in a budget-neutral manner. It would also help reduce the risk of beneficiaries experiencing problems accessing these services and send a more favorable signal to medical students and residents contemplating careers in specialties that provide a large share of E&M services. Even if this approach is adopted, we urge CMS to accelerate its efforts to improve the accuracy of the data used to calculate payment rates and

the process for reviewing mispriced services. To support these efforts, CMS should regularly collect data from a cohort of efficient practices and use this information to validate the payment rates. Improving the accuracy of prices for ambulatory E&M and other services going forward could reduce the need for future significant adjustments to rebalance the fee schedule. ■

Endnotes

- 1 In this chapter, the term *clinicians* is synonymous with *physicians and other health professionals*.
- 2 These RVUs are the national average nonfacility RVUs.
- 3 The full list of practitioners eligible for the bonus, as recommended by the Commission, was family medicine, internal medicine, geriatric medicine, pediatric medicine, nurse practitioner, and physician assistant.
- 4 When CMS reviews the work RVUs for a code, it also reviews the practice expense RVUs.
- 5 The RUC examined a total of 2,220 services from 2009 to 2017. Work RVUs were reviewed for 1,652 services, practice expense RVUs (but not work RVUs) were revised for 158 services, and billing codes were deleted for 410 services.
- 6 Although CMS has accepted most of the RUC's prior recommendations, we do not have information on whether CMS accepted the recommendations for these specific services.
- 7 The analysis used the fee schedule's payment modifiers (e.g., assistance at surgery) to adjust service volumes.
- 8 Both types of data were based on intraservice time, the largest component of the RUC's time assumptions. Intraservice time includes the time the clinician spends on treatment/therapy and documentation of services. The other two components of the time assumptions are preservice time—preparing to see the patient, reviewing records, and communicating with other professionals—and postservice time—arranging for further services and communicating (written or verbal) with the patient, family, and other professionals.
- 9 Services at risk of being misvalued included those with the fastest growth, substantial changes in practice expenses, and new technologies.
- 10 Physicians in three specialties were asked about time spent providing a Level IV office visit for an established patient (HCPCS 99214): cardiology, family medicine, and orthopedic surgery. Family medicine physicians were also asked about a Level III office visit for an established patient (HCPCS 99213) and a Level IV office visit for a new patient (HCPCS 99204).
- 11 The American Medical Association Physician Masterfile includes current and historical data for more than 1.4 million physicians, residents, and medical students in the United States.
- 12 CMS has since reduced the service's time assumption from 208 minutes to 81 minutes.
- 13 Total RVUs include work, practice expense, and professional liability insurance RVUs.
- 14 There is precedent for a fee schedule with more than one conversion factor. Under the volume performance standard policy that was replaced by the sustainable growth rate formula in 1997, the fee schedule had separate conversion factors for surgical services, primary care services, and other nonsurgical services.
- 15 In extending the target, the Congress would need to specify that the savings would be redistributed only to ambulatory E&M services. Under the target that expires at the end of 2018, savings are redistributed to all fee schedule services.

References

- American Medical Association. 2017. *RUC Relativity Assessment Workgroup progress report*. Updated October 2017. Chicago, IL: AMA.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare program; revisions to payment policies under the physician fee schedule, clinical laboratory fee schedule, access to identifiable data for the Center for Medicare and Medicaid Innovation Models & other revisions to Part B for CY 2015. Proposed rule. *Federal Register* 79, no. 133 (July 11): 40318–40540.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Medicare program; payment policies under the physician fee schedule and other revisions to Part B for CY 2011. Final rule. *Federal Register* 75, no. 228 (November 29): 73169–73860.
- Ginsburg, P. B. 2012. Fee-for-service will remain a feature of major payment reforms, requiring more changes in Medicare physician payment. *Health Affairs* 31, no. 9 (September): 1977–1983.
- Government Accountability Office. 2015. *Medicare physician payment rates: Better data and greater transparency could improve accuracy*. GAO-15-434. Washington, DC: GAO.
- Laugesen, M. J. 2016. *Fixing medical prices: How physicians are paid*. Cambridge, MA: Harvard University Press.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011a. Moving forward from the sustainable growth rate (SGR) system. Letter to the Congress. October 14.
- Medicare Payment Advisory Commission. 2011b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2006a. *Report to the Congress: Increasing the value of Medicare*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2006b. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 1998. *Healthcare spending and the Medicare program: A data book*. Washington, DC: MedPAC.
- Mehrotra, A., C. Gidengil, L. Hilborne, et al. 2016. Developing codes to capture post-operative care. Santa Monica, CA: RAND.
- Merrell, K., C. Schur, T. Oberlander, et al. 2014. *Analysis of physician time use patterns under the Medicare fee schedule*. Report prepared for the Assistant Secretary for Planning and Evaluation. Washington, DC: Social & Scientific Systems and the Urban Institute.
- Office of Inspector General, Department of Health and Human Services. 2012a. *Cardiovascular global surgery fees often did not reflect the number of evaluation and management services provided*. No. A-05-09-00054. Washington, DC: OIG.
- Office of Inspector General, Department of Health and Human Services. 2012b. *Musculoskeletal global surgery fees often did not reflect the number of evaluation and management services provided*. No. A-05-09-00053. Washington, DC: OIG.
- Zuckerman, S., K. Merrell, R. Berenson, et al. 2016. *Collecting empirical physician time data: Piloting an approach for validating work relative value units*. Report prepared for the Centers for Medicare & Medicaid Services. Washington, DC: The Urban Institute.

CHAPTER 4

**Paying for sequential stays in
a unified prospective payment
system for post-acute care**

Paying for sequential stays in a unified prospective payment system for post-acute care

Chapter summary

In 2016, Medicare fee-for-service (FFS) spending on post-acute care (PAC) services—skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs)—totaled \$60 billion. For any condition, Medicare’s FFS payments can differ substantially because Medicare uses separate prospective payment systems (PPSs) to pay for stays in each setting. As mandated by the Congress, in June 2016, the Commission evaluated a prototype design and concluded that it was feasible to design a unified PAC PPS that would establish accurate payments using readily available data. The Commission recommended the necessary features of a PAC PPS that spans the four settings and bases payments on patient characteristics. Our initial work concluded that the design would establish accurate payments for most of the more than 40 patient groups we examined and would increase the equity of payments across conditions. In turn, providers would have less incentive to selectively admit certain types of patients over others. In June 2017, the Commission recommended that a PAC PPS be implemented beginning in 2021 with a three-year transition and a corresponding alignment of setting-specific regulatory requirements.

The Commission continues to work on a unified PAC PPS, considering refinements that would improve the design. These refinements should not delay implementing a PAC PPS or the Commission’s recommendation to improve the equity of PAC payments before the PAC PPS is implemented.

In this chapter

- Background
- Challenges with paying for sequential post-acute care stays
- Summary of the proposed PAC PPS design
- Definition of sequential PAC stays
- Characteristics of sequential PAC stays
- PAC PPS payments need to align with the cost of stays throughout a sequence of post-acute care
- Defining the beginning and end of stays when treating in place
- Conclusion

Refinements focus on increasing the accuracy of payment for cases that involve a course of PAC care—that is, sequential stays—which we define as PAC stays within seven days of each other.

In this chapter, refinements focus on two payment issues related to sequential stays. The first has to do with the way the cost of a stay can vary depending on where it falls in a sequence of PAC stays. The reason is that, throughout a course of care, a beneficiary’s clinical condition is likely to change, so later PAC stays could have different average costs—often lower but sometimes higher—compared with initial PAC stays. As with other FFS payment systems, it will be important under the unified PAC PPS to align payments with the cost of each stay throughout a sequence of stays. If payments and costs are not aligned, providers could have a financial incentive to refer beneficiaries for unnecessary subsequent care or could have difficulty placing beneficiaries who require continued care. A second issue involves how to identify, for payment purposes, distinct levels of care for a PAC provider that treats a patient with evolving care needs “in place” rather than referring the patient to another PAC provider. Under the unified PAC PPS, such providers would be financially disadvantaged unless the payment system included a way to trigger payments for different phases of care.

Of 8.9 million PAC stays in the Commission’s analysis, a majority (64 percent) were solo stays, thus, not part of a sequence of stays. Of the 1.9 million multi-stay sequences, half involved stays in the same setting; the most common of these were back-to-back home health stays. Another third involved beneficiaries who transitioned from more intensive to less intensive settings. The most common of these were SNF and IRF stays followed by home health stays. Far less frequently, beneficiaries transitioned from less intensive to more intensive settings, most commonly from home health care to SNF care.

Our analysis of sequential PAC stays, if paid under our prototype PAC PPS (which adjusts payments based on patient characteristics), found that patterns of costs relative to estimated payments over the course of care differed for home health stays and institutional PAC stays. For home health stays, payments under a unified PAC PPS would decrease over the course of a sequence of stays, but the cost of stays would decline more. As a result, later home health stays in a sequence would be more profitable than earlier stays, with stays that occurred later in longer sequences being the most profitable. These results suggest that payments need to be adjusted downward for later stays, similar to the adjustment used in the current HHA PPS. By contrast, PAC PPS payments for institutional stays would remain reasonably well aligned with the cost of stays throughout a sequence of care. This finding indicates that the PAC risk adjustment adequately captures differences in the cost of

institutional stays throughout a sequence of care, indicating no need for a separate adjustment to payments.

However, under its current design, the prototype PAC PPS would not be able to appropriately pay a PAC provider that offered a range of PAC services and was able to treat in place beneficiaries with evolving care needs (that is, not refer them to another PAC provider), even though such in-place treatment might be optimal for beneficiaries requiring PAC and operationally and administratively easier for providers (assuming the regulatory flexibility to do so). Under current policy, these beneficiaries are typically discharged to a second setting, and Medicare makes two payments for the patient's PAC, one to each provider. Under a PAC PPS, providers will have more flexibility to offer a continuum of services to patients with evolving care needs, but, for payment purposes, Medicare will need to define when one "stay" or phase of care ends and the next one begins. Otherwise, with only one admission and discharge date, providers would receive only one payment, creating a financial disincentive to treat in place.

Of the approaches we examined, the most promising would involve episode-based payments; that is, Medicare would pay for all PAC provided during an episode of care. The episode would include only PAC and would exclude other services furnished during the episode, such as hospital care or physician services. Payments for the episode of PAC would be set prospectively using a unified PAC PPS, with no reconciliation to a target benchmark. Payment for the PAC could be made to a hospital, a health system, the PAC provider where the episode starts, an accountable care organization, or a third-party convener that assumes financial risk for the episode of PAC. Under this approach, Medicare would not need to define and set payments for subsequent stays because the entity would be paid for the PAC provided during the episode, regardless of how many stays, settings, or providers were included. Further, a payment adjuster for later home health stays would not be needed because payments for the episode of PAC would be based on the average cost of the PAC for the full duration of the episode, including lower cost PAC later in the episode.

Though episode-based payments could require an entity receiving payment from Medicare to pay all PAC providers involved in the care, such an arrangement would be necessary only for the small share of sequential stays that involved more than one provider. We expect this share to decline under a PAC PPS as entities evolve to offer a continuum of PAC. Entities would gain valuable experience managing PAC across a continuum before they embarked on assuming more responsibility for caring for beneficiaries. The incentive for entities receiving payment to stint on the

amount or quality of services furnished (to keep costs low) could be countered with value-based purchasing. Episode-based payments would require a certain level of infrastructure for the minority of PAC stays that involve multiple providers, but the Commission contends that the advantages of this approach substantially outweigh its complexities.

The Commission will continue to explore episode-based payments over the coming year. Shifting the unit of service from a stay to an episode would change certain incentives (most notably the incentive to initiate PAC stays), but the most important features of a PAC PPS would remain: correcting the biases of the current PPSs and increasing the equity of payments across all types of stays so that providers have less incentive to selectively admit certain beneficiaries over others. Shifting to an episode-based payment would incorporate these strengths into a bolder approach to a PAC PPS. In the meantime, CMS should proceed with implementing a stay-based unified PAC PPS. ■

Background

Post-acute care (PAC) providers—skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs)—offer important recuperation and rehabilitation services to Medicare beneficiaries.¹ In 2016, Medicare fee-for-service (FFS) spending on these services totaled \$60 billion. However, Medicare’s payments for a similar case treated in different settings can differ substantially, in part because Medicare uses separate prospective payment systems (PPSs) to pay for stays in each setting. Some of the difference in payments reflects the considerably different cost structures and the regulatory and statutory requirements for each setting. At the same time, there is a lack of evidence-based criteria guiding decisions about where patients should receive PAC and how much care they should receive. The only study to compare outcomes across the settings for a broad range of clinical conditions did not find consistent differences in rates of readmission to hospitals or in improvement in mobility or self-care (Gage et al. 2012). These factors contribute to considerable variation in the supply and use of PAC providers across the country. Results from the Center for Medicare & Medicaid Innovation’s Bundled Payments for Care Improvement (BPCI) initiative indicate that, while the use of PAC did not decline, the mix of services shifted away from institutional PAC and toward home health care, indicating that patients in the settings overlap.

Given the overlap among settings for treating similar patients, the Commission has long promoted the idea of moving to a unified system to pay for PAC in FFS Medicare using a PPS that spans the four settings, with payments based on patient characteristics rather than site of service.² As mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT), the Commission, in June 2016, recommended the necessary features of a PAC PPS and considered the implications of moving to such a system (Medicare Payment Advisory Commission 2016). Using readily available data, the Commission’s PAC PPS design accurately predicted the costs of stays for most patient groups. In June 2017, the Commission focused on several implementation issues, including the need for a transition to this new payment system, the level at which to set payments when the system is implemented, and the need for continued monitoring and periodic refinements over time to keep payments aligned with the cost of care (Medicare Payment Advisory Commission 2017). In March 2018,

the Commission recommended that, in anticipation of a transition to a unified PAC PPS, CMS should begin to base payments to providers in each of the PAC sectors on a blend of the sector’s setting-specific relative weights and the unified PAC PPS relative weights. Doing so would begin to improve the equity of payments across conditions (Medicare Payment Advisory Commission 2018).

Challenges with paying for sequential post-acute care stays

The Commission’s initial work on a unified PAC PPS, presented in the June 2016 report to the Congress, considered each PAC stay as an independent event (Medicare Payment Advisory Commission 2016). Yet, many PAC stays are the second or third (or more) in a series of PAC stays, in which patients transition from one setting or provider to another during their course of care. In an FFS payment system like the unified PAC PPS, sequential stays present two potential challenges to payment accuracy. First, throughout a course of care, a beneficiary’s clinical condition is likely to change such that subsequent PAC stays may have different average costs than initial PAC stays. If payments for subsequent stays are too high, providers such as those that are part of a system of care or HHAs that can recertify additional stays have an incentive to refer patients for unnecessary additional PAC stays, which could expose beneficiaries to undue risk and would increase program spending. If payments for subsequent stays are too low, providers could avoid admitting these beneficiaries for necessary additional care.

The second challenge related to sequential stays centers on how to pay institutional providers for treating beneficiaries whose care needs evolve over time.³ Currently, patients treated in institutional settings who need additional PAC typically transition from one setting to another. For payment purposes, each stay has a clearly defined beginning and end, and Medicare pays for each stay separately. As regulatory requirements for institutional PAC settings begin to be aligned under a unified PAC PPS, institutional PAC providers would have the flexibility to offer a continuum of services to beneficiaries who require different levels of care. In such circumstances, however, the “end” of one stay and the “beginning” of another would not be clear. Yet, being able to distinguish between the stays would be important to pay for these services accurately. Otherwise, providers

would have a financial incentive to discharge patients to another PAC provider, exposing beneficiaries to the risks associated with transitions of care.

Summary of the proposed PAC PPS design

Based on its analysis of 8.9 million PAC stays in 2013 and using readily available administrative data, the Commission concluded that a unified PPS is feasible (Medicare Payment Advisory Commission 2016). A PAC PPS design would establish accurate payments using a uniform unit of service (a stay, which, in the case of home health care, is defined as an episode) and a uniform risk adjustment method. The Commission found the following factors to be important predictors of costs that should be considered in the design: the patient's age, disability status, comorbidities (and the number of body systems involved), severity of illness, risk score, cognitive status, and impairments; the primary reason to treat; the length of stay in an intensive care unit during the prior hospital stay (if any); and the use of select high-cost services (such as dialysis and mechanical ventilation).⁴ The design should include an adjustment for stays provided by HHAs because of their much lower costs and for two outlier policies—one for unusually high-cost stays and another for unusually short stays. The Commission examined the accuracy of PAC PPS payments for more than 40 patient groups before concluding that an initial design could be based on readily available data.

The proposed PAC PPS would redistribute payments and narrow the differences in profitability of different types of stays (Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2016). Payments would decrease for rehabilitation care unrelated to patient characteristics (for example, for patients recovering from hip surgery who receive high amounts of rehabilitation therapy services unrelated to their care needs) and increase for medically complex care (for example, patients with comorbidities that involve multiple body systems). Because PAC PPS payments would be based on the average cost of stays across the four settings, the new payment system would also redistribute payments across settings, with payments shifting from the high-cost LTCH and IRF settings to the lower cost settings.

Because payments would be more accurate and equitable, the Commission recommended implementing a PAC PPS

beginning in 2021, which is sooner than the time table for the studies required by IMPACT. In the Act's schedule of required reports on a PAC PPS design, it is unlikely that a new payment system would be proposed before 2024 for implementation at some later date. And while the Act requires recommendations for a design, it does not require the implementation of a PAC PPS.

In 2017, the Commission reported that the level of current PAC payments was high relative to the cost of stays (14 percent higher) and, for that reason, determined that the implementation of the new system should not be budget neutral. In 2017, the Commission recommended, based on its analysis of 2013 PAC stays (with costs and payments updated to 2017), that the Congress direct the Secretary to implement a PAC PPS beginning in 2021, with a three-year transition and payments lowered by 5 percent (absent any prior payment reductions made to any setting's payments). Concurrently, the Secretary should begin to align setting-specific regulatory requirements (Medicare Payment Advisory Commission 2017). The Commission believes that its recommended design could be adopted on this timetable.

In March 2018, the Commission recommended that the Congress direct the Secretary to begin to increase the equity of each PAC setting's PPS payments before implementing the unified PAC PPS. To do so, CMS would base each PAC setting's payments on a blend of the proposed PAC PPS relative weights and the current setting-specific relative weights. Using this blend would redistribute payments in each setting's PPS toward medically complex stays (Medicare Payment Advisory Commission 2018). This approach would also give providers more time to adjust their costs and practices to the incentives of the new payment system.

Medicare has different regulatory requirements for PAC settings, in part to differentiate one level of care from another, even though the conditions they treat overlap. Under the proposed PAC PPS, with payments based on patient characteristics (and not setting), it would be less important to distinguish among types of institutional PAC providers. Furthermore, it would be unreasonable to maintain different regulatory requirements, with varying associated costs, for providers that will be paid the same amount for the same type of patient. Policymakers would need to align the regulatory requirements across the institutional PAC settings by waiving or altering some of the current requirements. The Commission proposed a two-part strategy. In the near term, concurrent with the implementation of the PAC PPS, some of the current

regulatory requirements would be waived or modified, thereby establishing common requirements across institutional settings that help ensure quality of care. In the longer term, CMS could define a common set of requirements for all PAC providers for participation and additional requirements for providers opting to treat patients with specialized care needs, such as those requiring ventilator or severe wound care.

Definition of sequential PAC stays

Although a majority of beneficiaries have just one PAC stay after discharge from the hospital, many beneficiaries have a series of stays before their episode of illness resolves. To examine these stays, we used beneficiary identifiers and admission and discharge dates to link sequences of PAC stays together. This method allowed us to identify common trajectories of PAC use (e.g., a single IRF stay, a SNF stay followed by a home health stay, back-to-back home health stays).

A *sequential PAC stay* refers to care furnished to a beneficiary with short or no gaps in between the stays (see text box, p. 94, defining sequential PAC stays). For our analysis, we defined a sequential stay as one that began within seven days of another PAC use. These rules are rough proxies for clinical relatedness while allowing some flexibility in how quickly home health care can be arranged (changes in institutional PAC setting stays typically involve transferring the beneficiary with no days in between the stays). Sequences include stays in the same setting and in different settings. A “first” stay was defined as having no PAC use within the previous seven days. A SNF stay followed by a home health episode that began within seven days of discharge from the SNF was considered a two-stay sequence. We assigned stays to the following groups based on the dates of the stay:

- Solo (first-and-only) stays consisted of one admission to one PAC provider, with no subsequent care.
- First-of-multiple stays were the first in a sequence of PAC stays.
- Subsequent stays were the second, third, or later in a sequence of PAC.

We aggregated the three institutional-type stays into a single “institutional PAC” group to reflect how a PAC PPS would pay for this care. The PAC PPS would ignore

differences among institutional settings in establishing payments for these providers and would separately adjust payments for home health stays to align payments to the considerably lower costs of this setting.

Characteristics of sequential PAC stays

As background to our analysis of the costs of and payments for sequential stays, we first examined the patterns of PAC (Figure 4-1, p. 95). Of the thousands of multi-stay sequence patterns, the 10 most frequent patterns made up three-quarters of these sequences. Multiple home health stays were the most common. Stay sequences with decreasing intensity were three times as frequent as those with increasing intensity.

Beneficiaries with solo stays differed from those with multi-stay sequences. Among home health stays, beneficiaries with multi-stay sequences were more likely to be dually eligible for Medicare and Medicaid, disabled, and admitted from the community, while beneficiaries with multiple institutional PAC stays were less likely to have those characteristics. Compared with providers of solo home health stays, providers of multi-stay sequences were more likely to be for profit and freestanding. In contrast, institutional PAC providers of multi-stay sequences were more likely to be nonprofit and hospital based compared with providers of solo institutional PAC stays.

Frequency of sequential PAC stays

We identified 5,762 combinations of PAC stays in 2013. About two-thirds (64 percent) of the stays were solo events—that is, consisted of a single stay. Of solo stays, home health stays made up the majority (67 percent), while SNF stays made up 28 percent, IRF stays another 4 percent, and LTCH stays about 1 percent.

About one-third (36 percent) of the combinations involved multiple stays, with beneficiaries transitioning from one PAC setting or provider to another during their course of care. Pairs of PAC stays were the most common multi-stay sequence (see online Appendix 4-A, available at <http://www.medpac.gov>, for information on the 25 most common sequences). Half of the sequential stays were lateral transitions within the same setting. The most frequent of these lateral, same-setting sequences consisted of home health stays only. Beneficiaries who moved from more intensive PAC care to less intensive care made up one-third of multi-stay sequences.⁵ Transitioning from a

Defining sequential PAC stays

Consistent with previous work, characteristics of beneficiaries and stays were assigned based on information from claims, Medicare Advantage risk scores, and the beneficiary enrollment file.

To create sequences of post-acute care (PAC), we began with the 8.9 million PAC stays in 2013 that we used in our previous analysis of the unified PAC prospective payment system (PPS) (Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2016). Beneficiaries with overlapping start and end dates for institutional PAC stays or with duplicate start dates for institutional PAC stays were excluded from the analysis. These exclusions removed 12,479 stays from the analytic file. Home health stays with start and end dates that overlapped with institutional PAC stay dates remained in the analysis because a beneficiary could discontinue a home health care episode and enter into an institutional PAC setting before the end of the 60-day home health episode.

A “first” stay was defined as having no PAC use within the previous seven days. Subsequent stays were defined as stays that began within seven days of another PAC use. Consistent with prior work, we aggregated a beneficiary’s separate skilled nursing facility (SNF) claims to create a stay. Sequences could include any combination of home health or institutional

PAC. Dates were used to establish the sequence and assign stays to a position in the sequence, such as “second stay,” “third stay,” and so on. For example, a second home health stay was second in a sequence (of any length) that included either another home health stay or an institutional PAC stay as the first stay. In our analyses of costs and payments, we examined position and sequence length to separate the effects of sequence length from position in the sequence. Our final analytic sample included 5,334,377 sequences comprising 3,435,192 solo stays and 1,899,185 multi-stay sequences.

Current billing rules govern what constitutes a stay, and our analysis did not redefine stay parameters. Given the separate PPS for each of the four settings, differences exist among settings in how intervening events, such as hospitalizations, define stays. In SNFs, for example, stays interrupted by a hospitalization are considered separately (as two stays), while a single home health episode continues after an intervening hospitalization. An interrupted stay in inpatient rehabilitation facilities and long-term care hospitals can trigger a separate stay, depending on the length of the interruption and the intervening event.⁶ In the future, when a common set of requirements is developed for PAC providers’ participation, billing rules and the treatment of interrupted stays could be defined uniformly. ■

SNF or an IRF to home health care was the most common combination of stays of decreasing PAC intensity. Far less frequently (10 percent of multi-stay sequences), beneficiaries were discharged from a lower level of PAC to a more intensive setting. Presumably, this trajectory reflects a change in care needs of the beneficiary and capabilities of the provider or caregiver at home. Of those, transitions from a home health stay to a SNF stay were the most frequent. The remaining 7 percent of sequences were a mixed pattern of transitions (of increasing and decreasing intensity over the course of care), the most frequent being transitions back and forth between SNFs and HHAs.

Of the thousands of multi-stay sequence patterns, the 10 most frequent made up three-quarters of these sequences.

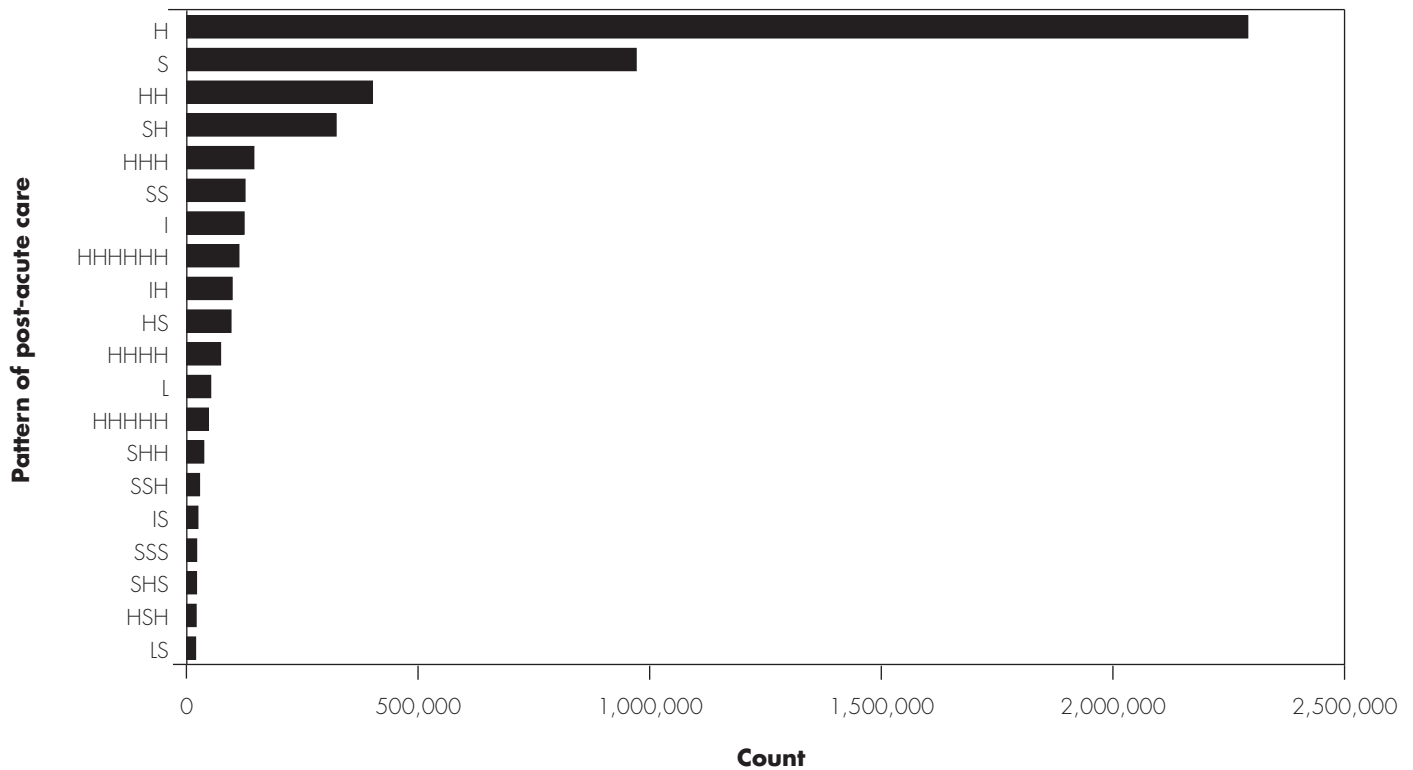
Multiple stays in HHAs were the most common: Sequential home health stays made up 42 percent of all multi-stay sequences, with a pair being the most frequent (21 percent of multi-stay sequences). What appears to be continuous home health care during the year (six or more episodes) made up 7 percent of multi-stay sequences.

Characteristics of solo and multiple home health stays

To assess whether there were differences between beneficiaries with solo home health stays and beneficiaries with multiple stays that included home health stays, we compared the beneficiaries’ characteristics and primary reason for treatment. We compared home health stays that were solo, first of multiple stays, and subsequent stays

**FIGURE
4-1**

The 20 most frequent patterns of post-acute care, 2013



Note: H (stay treated in home health agency), S (stay treated in skilled nursing facility), I (stay treated in inpatient rehabilitation facility), L (stay treated in long-term care hospital). A sequence shows the order and setting of the stays. For example, “LS” refers to a sequence that started with a long-term care hospital stay and was followed by a skilled nursing facility stay. The 8.9 million post-acute care (PAC) stays were provided in 5,334,377 sequences of PAC.

Source: Analysis of 2013 PAC stays conducted for the Commission by the Urban Institute (Wissoker and Garrett 2018).

in a sequence. (Home health stays that were the first of multiple could be followed by PAC stays of any type—including SNF, IRF, and LTCH stays. Subsequent home health stays could be preceded and followed by any type of PAC care.)

Among home health stays, first-of-multiple stays were more likely to be for beneficiaries who were dually eligible, disabled, and admitted from the community compared with solo stays (Table 4-1, p. 96). For example, 73 percent of first-of-multiple home health stays were for beneficiaries who were admitted from the community (thus, 27 percent had a prior hospital stay). In contrast, 55 percent of solo home health stays were admitted from the community (and 45 percent had prior hospital stay). Among subsequent stays, the shares of dually eligible, disabled, and community admissions increased with the

position in the sequence (second stay in a sequence, third stay in a sequence, etc.). The shares of the most frail and chronically critically ill decreased as the position in the sequence increased. There were not large differences between solo home health and first-of-multiple home health stays in the shares of very old (85 years or older), cognitively impaired, beneficiaries with end-stage renal disease, and the least frail (data not shown).

The primary reasons for treatment were similar for solo home health and first-of-multiple home health stays, with two exceptions. A higher share of solo home health stays (10 percent) were for beneficiaries recovering from an orthopedic surgical condition (such as a joint replacement) compared with 2 percent for first of multiple (Table 4-1). Because home health care often follows an institutional stay (in a SNF or IRF) for beneficiaries recovering from

**TABLE
4-1**

Characteristics of beneficiaries with single or multiple PAC stays

Position in sequence	Number of stays	Dual eligible	Disabled	Community admission	Most frail	Chronically critically ill	Multiple body systems	Orthopedic surgery	Cardiovascular medical	Unusually high cost
All	8,877,513	32%	26%	50%	11%	5%	N/A	10%	15%	11%
Home health stays										
Solo	2,290,337	29%	24%	55%	7%	3%	N/A	10%	13%	8%
First of multiple	1,020,688	38	29	73	6	2	N/A	2	19	16
Second	1,388,388	32	26	66	7	3	N/A	9	17	11
Third	581,866	36	30	86	4	1	N/A	1	21	10
Fourth	319,637	39	32	90	4	1	N/A	1	22	10
Fifth	196,815	41	33	92	4	0	N/A	0	22	9
Sixth	125,718	43	34	94	3	0	N/A	0	22	8
Institutional post-acute care stays										
Solo	1,144,855	33%	24%	11%	21%	11%	18%	17%	8%	11%
First of multiple	847,483	24	21	7	21	12	15	25	7	9
Second	479,783	31	24	12	22	8	18	10	11	11
Third	164,420	32	25	15	22	6	19	8	12	11
Fourth	59,590	33	26	15	22	6	21	8	12	11
Fifth	24,018	34	27	15	23	6	23	8	12	12
Sixth	9,255	34	27	15	25	7	23	8	12	15

Note: PAC (post-acute care), N/A (not applicable). "Institutional post-acute care" refers to stays in skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). The table shows the share of stays with the respective characteristic(s). Because each row and column is independent, the rows and columns will not sum to 100 percent. "First-of-multiple" PAC stays are stays discharged to subsequent PAC settings—either home health or institutional PAC. Second, third, fourth, fifth, and sixth stays could be preceded and/or followed by PAC stays of any type, home health or institutional. For example, a third home health stay was third in a sequence of PAC stays, and the sequence could include home health and institutional PAC stays before and after the third stay. Dual-eligible beneficiaries are eligible for Medicare and Medicaid. "Most frail" refers to stays assessed as having most frail patients using the JEN Frailty Index. (The JEN Frailty Index is an algorithm that identifies frail older adults who may be at risk for institutionalization.) "Chronically critically ill" refers to stays for beneficiaries who spent eight or more days in an intensive care or coronary care unit. "Severely ill" refers to stays for patients who were treated in institutional PAC and categorized as severity of illness level 4 during the immediately preceding hospital stay. "Multiple body systems" refers to stays for patients with diagnoses that involved five or more body systems and were treated in institutional PAC settings (thus, "not applicable" in the home health portion of the table). "Unusually high cost" refers to stays that would be included in an outlier pool set at 5 percent for home health stays and 5 percent for institutional PAC stays. About 12,000 stays were excluded from the analysis because the dates on the claims overlapped. Other combinations of visits with seven or more stays in the sequence are not shown.

Source: Analysis of 2013 PAC stays conducted for the Commission by the Urban Institute (Wissoker and Garrett 2018).

orthopedic surgery, the share of second stays for this condition jumps to 9 percent. The share of stays for beneficiaries being treated for a cardiovascular medical condition was higher among first-of-multiple stays compared with solo stays (19 percent vs. 13 percent).

Characteristics of solo and multiple institutional PAC stays

To assess whether there were differences between beneficiaries with solo institutional PAC stays versus beneficiaries with multiple stays that included one or more institutional PAC stays, we compared the beneficiaries' characteristics and primary reason for treatment. We compared institutional solo stays, first-of-multiple sequences, and subsequent stays in a PAC sequence.

(Institutional stays that were the first of multiple could be followed by PAC stays of any type—including SNF, HHA, IRF, and LTCH. Subsequent institutional stays could be preceded and followed by any type of PAC care.)

The patterns for institutional PAC stays were opposite those for home health stays. First-of-multiple stays were less likely than solo stays to be for beneficiaries who were dually eligible, disabled, or admitted from the community. For example, 24 percent of first-of-multiple stays were for dual-eligible beneficiaries compared with 33 percent of solo stays. The frequency of these characteristics increased with the timing of the stay, though differences were small. In multi-stay sequences, indicators of patient complexity (the shares of beneficiaries who were most frail or who had conditions that involved multiple body systems)

**TABLE
4-2**

**Provider characteristics of post-acute care stays,
by position of the stay in a sequence of care**

Position in sequence	Number of stays	Nonprofit	For profit	Hospital based	Freestanding
All	8,877,513	27%	70%	11%	89%
Home health stays					
Solo	2,290,337	36%	61%	14%	86%
First of multiple	1,020,688	21	76	8	92
Second	1,388,388	25	72	9	91
Third	581,866	19	79	7	93
Fourth	319,637	17	81	6	94
Fifth	196,815	16	82	6	94
Sixth	125,718	15	82	5	95
Institutional post-acute care stays					
Solo	1,144,855	28%	67%	11%	89%
First of multiple	847,483	32	63	19	81
Second	479,783	34	71	8	92
Third	164,420	23	73	8	92
Fourth	59,590	22	74	8	92
Fifth	24,018	21	76	8	92
Sixth	9,255	19	76	8	92

Note: "Institutional post-acute care" includes stays in skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). "First-of-multiple" post-acute care (PAC) stays include stays discharged to subsequent PAC—either home health or institutional PAC. Second, third, fourth, fifth, and sixth stays could be preceded and/or followed by PAC stays of any type, home health or institutional. For example, a third home health stay was third in a sequence of PAC stays, and the sequence could include home health and institutional PAC stays before and after the third stay. About 12,000 stays were excluded from the analysis because the dates on the claims overlapped. The 3 percent of stays provided in government providers are not shown.

Source: Analysis of 2013 PAC stays conducted for the Commission by the Urban Institute (Wissoker and Garrett 2018).

increased with the sequence's stay count. For example, 15 percent of first-of-multiple stays had conditions that involved multiple body systems compared with 23 percent of institutional stays that were the fifth and 23 percent that were the sixth in a sequence of PAC stays.

Differences in the clinical reasons for treatment were similar across institutional PAC stays, except that a larger share of first-of-multiple stays compared with solo stays were for beneficiaries recovering from orthopedic surgery (25 percent of first-of-multiple stays vs. 17 percent of solo stays). Stays in longer sequences were for beneficiaries who were generally more medically complex than for beneficiaries with shorter sequences.

Characteristics of providers of solo and multi-stay sequences

In addition to differences in the ownership and type of providers (freestanding and hospital based) treating solo

and multi-stay sequences, differences also were found between home health and institutional PAC stays (Table 4-2). Among home health stays, a larger share of first-of-multiple stays (76 percent) were provided by for-profit agencies compared with solo stays (61 percent), and the share increased for stays later in the sequence, reaching 82 percent of fifth and sixth stays. By type of HHA, a smaller share of solo home health stays (86 percent) were furnished by freestanding HHAs compared with 92 percent of first of multiple and, again, the shares of stays provided by freestanding HHAs increased for later stays, comprising 95 percent of sixth stays.

Differences in ownership and facility type were smaller among institutional PAC stays. Compared with solo institutional PAC stays, first-of-multiple stays were more frequently (32 percent) treated in nonprofit facilities compared with 28 percent of solo stays, and the share of

Estimates of PAC costs and PAC PPS payments

The 8.9 million post-acute care (PAC) stays in 2013 that have been used in previous Commission research on the unified PAC prospective payment system (PPS) were the starting point for this work on sequential stays (Medicare Payment Advisory Commission 2016). To estimate the costs of each stay, information from claims and Medicare cost reports and—as required by the Improving Medicare Post-Acute Care Transformation Act of 2014—data from CMS’s Post-Acute Care Payment Reform Demonstration (PAC-PRD) were used. Therapy and nontherapy costs were estimated using 2013 PAC claims and 2013 Medicare cost reports (see online Appendix 4-A, available at <http://www.medpac.gov>, for a full discussion of the methodology). We took advantage of the unique stay-level information on routine costs collected in the PAC-PRD (and not available elsewhere) to estimate routine costs using a

regression model and applied this model to the 2013 PAC stays. The cost of each stay reflects, in part, the differences in costs across settings.

To estimate payments, the PAC PPS design relies on models that predict the cost of each stay using patient and stay characteristics. The following patient and stay information was used to predict the cost of each stay: patient demographics (e.g., age and disability), primary reason to treat, comorbidities, cognitive status, impairments (e.g., difficulty swallowing and bowel incontinence), measures of severity, and use of special treatments (e.g., ventilator care). We included these factors in the risk adjustment because they captured different dimensions of a patient that could influence the cost of care. The Secretary could consider other dimensions or other measures of the same dimensions in the final design.

(continued next page)

stays treated in nonprofit facilities decreased in later stays. A higher share of first-of-multiple institutional PAC stays were furnished by hospital-based providers (19 percent) compared with solo institutional PAC stays (11 percent), but the mix across later stays was the same.

We did not explore whether providers that are members of vertically integrated systems (with different settings included in their holdings) have different patterns of care. Given a common financial stake, providers with these linkages would have an incentive to refer beneficiaries to subsequent care.

PAC PPS payments need to align with the cost of stays throughout a sequence of post-acute care

Our analysis found that the average cost of stays declined over the course of sequential PAC stays, especially for home health stays (see text box on estimates of PAC

costs and PAC PPS payments). Although estimated PAC PPS payments (which adjust for differences in patient characteristics) for institutional PAC stays would be aligned with the lower average costs of later stays, PAC PPS payments for home health stays would not be. As a result, later home health stays would be increasingly profitable. These findings suggest the need for a payment adjustment for later home health stays similar to the adjustment in the home health PPS. Otherwise, providers will have an incentive to furnish additional stays.

Why costs might vary throughout a sequence of care

It is possible that the average costs of stays differ throughout a sequence as patients’ care needs evolve. Early stays are more likely to include beneficiaries recovering from acute events and receiving services aimed at getting the beneficiaries functioning as independently as possible. Later PAC stays may focus on strengthening beneficiaries and managing chronic conditions, which may require fewer resources. In addition, stays may

Estimates of PAC costs and PAC PPS payments (cont.)

We used Poisson regression models and developed one model to predict the costs of routine and therapy care for stays in the four PAC settings and a separate model to predict nontherapy ancillary (NTA) costs for stays in skilled nursing facilities, independent rehabilitation facilities, and long-term care hospitals. We developed a separate model for NTA services because the home health care benefit does not cover these services. A home health indicator was included in the model to account for this setting's considerably lower costs compared with institutional PAC. Without this adjustment, home health stays would be substantially overpaid and the other PAC providers would be substantially underpaid. The design does not consider differences in costs across institutional settings in establishing payments for stays.

Payments also include two outlier policies—one for unusually high-cost stays and another for unusually short stays. A high-cost outlier policy protects providers from incurring exceptionally large losses from treating

unusually high-cost stays and helps ensure beneficiary access to services. A short-stay policy protects the program and taxpayers from excessive payments that would otherwise be paid for unusually short stays. Instead of being paid a full stay amount, short stays are paid a daily rate for the duration of the stay. (For details of these designs, see the Commission's June 2016 report to the Congress (Medicare Payment Advisory Commission 2016).) Payments were adjusted for budget neutrality so that total payments across the four settings are the same as under the current payment systems.

The payments and costs were updated from 2013 to 2017 (Medicare Payment Advisory Commission 2017). To estimate payments in 2017, payments were updated using each setting's market basket update net of the adjustments made by CMS (e.g., for productivity and any coding adjustments). Costs were updated to 2017 using the average cost increases by PAC setting. ■

have different average costs throughout a sequence if they involve a different mix of settings. Beneficiaries may transition between settings as they no longer meet coverage requirements for a given setting. However, distinctions between the costs of home health care and institutional PAC were already considered in a PAC PPS design, while differences across institutional PAC settings are intentionally not factored into payments (payments are “site neutral”). Therefore, the cost differences due to setting should not be a factor in evaluating whether payments require further adjustment.

The average cost of stays declines throughout a sequence of care

The average cost of home health and institutional PAC stays declined throughout a course of care. For home health stays, the average cost of last stays in the sequence was considerably lower than the cost of a first stay in the sequence (Table 4-3, p. 100). For example, in two-stay sequences, the cost of the first stay averaged \$2,699 compared with \$2,278 for the second stay (16 percent lower

than the first). In a five-stay home health sequence, the average cost of the fifth stay was 26 percent lower than the first stay (\$1,896 compared with \$2,574 for the first stay). Beneficiary characteristics are unlikely to explain these large cost differences, which is consistent with findings from extensive work conducted for the Commission on the cost of home health episodes (Wissoker and Garrett 2015) (see online Appendix 4-A, available at <http://www.medpac.gov>, for more information). That work found that clinical characteristics explain little of the variation in costs across episodes. If payments are not aligned to the declining cost of stays, later stays will be increasingly profitable and create an incentive for HHAs to furnish additional stays.

The average cost of institutional PAC stays generally declined throughout a sequence, though the pattern was a little more variable and the differences were smaller compared with home health stays. Except for the two-stay sequence, the costs of later stays were between 7 percent and 12 percent lower than first-stay costs. Compared with later stays, first-stay costs were higher in part because they involved a costlier mix of settings (with higher

**TABLE
4-3**

Average costs of stays generally decline over a sequence of care

Position in sequence	Sequence length (number of stays)					
	1 stay	2 stays	3 stays	4 stays	5 stays	6 stays
Home health stays						
First	\$2,190*	\$2,699	\$2,611	\$2,592	\$2,574	\$2,174
Second		2,278	2,565	2,430	2,356	2,056
Third			2,087	2,343	2,226	1,986
Fourth				1,982	2,204	1,982
Fifth					1,896	1,979
Sixth						1,790
Institutional post-acute care stays						
First	\$14,245*	\$13,948	\$15,191	\$16,097	\$16,740	\$17,506
Second		14,318	14,334	14,785	15,162	16,147
Third			14,100	14,821	15,205	15,966
Fourth				14,287	15,052	15,784
Fifth					14,677	16,016
Sixth						16,246

Note: Second, third, fourth, fifth, and sixth home health stays could be preceded and followed by post-acute care (PAC) stays of any type—including skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) stays. Second, third, fourth, fifth, and sixth institutional stays could be preceded and followed by PAC stays of any type—including SNF, home health, IRF, and LTCH. For example, a third home health stay was third in a sequence of PAC stays, and the sequence could include home health and institutional PAC stays before and after the third stay.
*The first stay in a one-stay sequence is a solo stay.

Source: Analysis of 2013 PAC stays conducted for the Commission by the Urban Institute (Wissoker and Garrett 2018).

shares of stays in IRFs: 21 percent of first-of-multiple stays compared with 10 percent of fifth stays (data not shown)). If risk adjustment does not adequately capture the differences in patient complexity throughout the sequence, later stays will be less profitable, and providers of subsequent stays could be discouraged from admitting these beneficiaries, creating placement problems for beneficiaries with extended PAC needs.

Profitability would increase throughout a sequence of home health care but remain relatively uniform for institutional PAC stays

We found that payments estimated by our prototype PAC PPS design for home health stays were not evenly aligned with these stays’ declining costs, so that later stays were considerably more profitable than earlier stays (Table 4-4). PAC PPS payments are risk adjusted for differences in patient characteristics (see text box on estimates of costs and payments, pp. 98–99). For example, in a three-stay

sequence, payments for the first stay would be 5 percent higher than the average cost (a payment-to-cost ratio (PCR) of 1.05), but payments for the third stay would be 24 percent higher than costs (PCR = 1.24). The pattern of increasing profitability was consistent across sequences, and later stays in longer sequences were more profitable compared with earlier stays. For example, the PCR for the last stay in the two-stay sequence was 1.16 but increased to 1.41 for the last stay in a six-stay sequence. Ideally, differences in the cost of stays would be captured by the case-mix adjusters. However, the higher profitability for later home health stays suggests the need for an adjustment to payments based on the timing of the stay to more closely align payments with costs. Otherwise, HHAs could generate additional profits by recertifying beneficiaries for additional home health care, assuming the beneficiary continued to meet coverage rules. Such a refinement of the PAC PPS would be consistent with the current payment system for HHAs that lowers payments

**TABLE
4-4**

Under our proposed PAC PPS, payment-to-cost ratios would increase for later home health stays but would be relatively uniform for institutional PAC stays

Position in sequence	Sequence length (number of stays)					
	1 stay	2 stays	3 stays	4 stays	5 stays	6 stays
Home health stays						
First	1.16*	1.01	1.05	1.06	1.07	1.22
Second		1.16	1.08	1.13	1.16	1.22
Third			1.24	1.16	1.21	1.31
Fourth				1.29	1.22	1.31
Fifth					1.34	1.31
Sixth						1.41
Institutional post-acute care stays						
First	1.14*	1.17	1.12	1.10	1.08	1.05
Second		1.13	1.14	1.12	1.12	1.08
Third			1.14	1.11	1.10	1.07
Fourth				1.14	1.11	1.08
Fifth					1.13	1.08
Sixth						1.06

Note: PAC (post-acute care), PPS (prospective payment system). The ratio of payments to costs is a measure of profitability. Payments are estimated PAC PPS payments. Institutional post-acute care includes stays in skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). Second, third, fourth, fifth, and sixth home health (HH) stays could be preceded and followed by PAC stays of any type—including SNF, IRF, and LTCH stays. Second, third, fourth, fifth, and sixth institutional stays could be preceded and followed by PAC stays of any type—including SNF, HH, IRF, and LTCH. For example, a third home health stay was third in a sequence of PAC stays, and the sequence could include home health and institutional PAC stays before and after the third stay.
*The first stay in a one-stay sequence is a solo stay.

Source: Analysis of 2013 PAC stays conducted for the Commission by the Urban Institute (Wissoker and Garrett 2018).

for third and later episodes of home health care. The changes to the HHA PPS proposed by CMS in 2017 also include a large adjustment for subsequent stays to reflect the lower average resource use for these episodes (for example, a 39 percent reduction for later stays admitted from the community) (Centers for Medicare & Medicaid Services 2017).

In contrast, PPS payments for institutional PAC stays would be more consistently aligned with the cost of stays throughout sequences, with much smaller variation in the profitability across stays in a sequence. Although the profitability of stays would generally increase for later stays, the patterns would be more uneven and the differences would be much smaller. For example, the PAC PPS payments for three-stay sequences would range from 12 percent to 14 percent higher than the average cost of stays (payment-to-cost ratio of 1.12 to 1.14). For five-stay sequences, the PCR would range from 1.08 for the first stay to 1.13 for the fifth stay. While profitability would

be lower for institutional PAC stays, they would remain well above the cost of stays. The results for institutional PAC stays indicate that the risk adjustment included in the proposed PAC PPS design would do a reasonable job capturing the differences in patients’ characteristics across stays in a sequence. An additional payment adjustment based on the order of the stay in a sequence of care is not needed for institutional PAC stays.

Defining the beginning and end of stays when treating in place

Under a unified PAC PPS with modified regulatory requirements, some providers may choose to treat a broader range of patients than they can under current policies, opting to treat “in place” patients who require changing levels of care during an episode of illness rather

**FIGURE
4-2**

Comparison of the number of stays under the proposed PAC PPS design when institutional PAC providers refer beneficiaries to another provider and when they opt to treat in place

There would be two stays when a beneficiary is referred to a second provider for additional care.

When a beneficiary is treated in place by the same provider under the proposed PAC PPS, there would be one stay unless a second stay is established for the second phase of care.



Note: PAC (post-acute care), PPS (prospective payment system).

than refer them to another provider. A patient could remain at the same facility and receive intensive services for the early portion of care and less intensive services as recovery progresses. IRFs and LTCHs could opt to treat patients with less intensive care needs (as opposed to transferring them to SNFs), while SNFs could opt to offer services that previously had been furnished by IRFs and LTCHs. Reducing the number of handoffs between providers would lower the risk of poor transitions.

Defining a stay is straightforward when a beneficiary is discharged from one provider and admitted to another; the stay begins at admission to the first PAC provider and ends when discharged to the second (or when discharged home for home health care) (Figure 4-2). Sequential home health care stays are also easy to identify because the unit of service is 60 days, with another home health stay triggered on day 61 of service. In both cases, Medicare makes two payments, one for each stay.

For institutional PAC providers furnishing a continuum of care, the end of one stay and the beginning of another would be less clear. CMS will need a way to distinguish between the different phases of care. Otherwise, with one admission and one discharge, a provider opting to treat in place would receive one payment that may not be sufficient to cover the costs of an extended phase of PAC. Providers that treat in place would then be at a financial disadvantage compared with providers that refer the beneficiary to another level of care. Yet, if treating in place would offer comparable care and reduce the risk of

untoward outcomes from a poor transfer, providers opting to treat in place should not be discouraged.

Define a stay based on time

One approach to defining the beginning and end of stays when treating in place would be to use a fixed period of time—a threshold—to define when the first stay ends.⁷ A provider would be paid a PAC PPS amount for the initial stay, but if the stay reaches a certain length, providers would conduct a new assessment and would receive a separate payment based on it. This method would be similar to the day-based definition of home health episodes (currently 60 days, but the Balanced Budget Act of 2018 changes this period to 30-day episodes beginning in 2020). A day-based definition of a stay could be considered for all stays, not just those furnished by providers treating in place.

The advantage of an approach based on length of stay is that it would be clear and relatively simple to administer. The large downside is that it would encourage PAC providers to extend stays beyond the pre-set threshold to establish a subsequent stay and receive an additional payment. Providers' likely response to this financial incentive would increase the share of stays that extend beyond the threshold. Medicare's experience with thresholds illustrates how providers typically adjust their practices in response to thresholds (e.g., HHAs and SNFs have been known to provide additional therapy visits or minutes—respectively—to qualify for higher case-mix

payments and LTCHs to extend stays beyond the short-stay outlier threshold to qualify for full payment).

Strategies to counter the incentive to increase the volume of subsequent stays

Because providers would have an incentive to extend care past a threshold to generate subsequent stays, CMS would need to undertake multiple activities to guard against uncontrolled volume increases. First, it would need to use a relatively long unit of service that would encompass the majority of stays. Second, it would need to develop a short-stay outlier policy, which would weaken the incentive to extend initial stays to garner payment for a second stay. That is, providers would have to extend a stay beyond the day threshold to a number exceeding the short-stay outlier cut-off for the stay to qualify for another full payment. Third, recertification by a beneficiary's physician could be required for the PAC provider to receive an additional payment. Under such a policy, the physician would be required to review the plan of care, attest to the continued need for PAC, and estimate how much longer services would be required, as is done for recertification for home health episodes. Finally, a value-based purchasing program that included a measure of resource use, such as Medicare spending per beneficiary, could also counter the incentive to generate volume since the added spending would count against the provider's performance.

CMS would need to monitor the frequency of subsequent PAC and examine providers with aberrant patterns. Inevitable differences in stay-level profitability, even if small, could make certain practice patterns more attractive. For example, a large increase in subsequent PAC could indicate that providers are delaying care until after the stays are complete, thereby obtaining full payments for stays and lowering their costs or taking undue advantage of the ability to treat in place to generate an additional stay. Periodic reevaluation of the alignment of payments and costs would indicate whether the Secretary needed to revise the PAC PPS. The Commission previously recommended that the Congress grant the Secretary the authority to revise and rebase the PAC PPS over time to keep payments aligned with the cost of care (Medicare Payment Advisory Commission 2017).

While it would be feasible to design and implement these counter-incentive strategies, Medicare's experience with them suggests that they would not be effective. Many of these strategies are currently in place but have not deterred the provision of PAC of questionable value.

Change the unit of service to an episode of post-acute care

Another approach would circumvent the multiple issues raised by sequential stays by shifting the unit of service from a stay to an episode of PAC. The episode would include only PAC and would exclude other services. This approach differs in a couple of ways from the "virtual" bundled payment the Center for Medicare & Medicaid Innovation (CMMI) is testing with the Bundled Payments for Care Improvement (BPCI) initiative. Under the BPCI, Medicare continues to make FFS payments to each provider, with retrospective reconciliation between total actual spending and a benchmark amount. The entity is at risk for the cost of all services furnished during the episode, including any hospital care, additional PAC, physician services, and ancillary services. The approach that the Commission will explore is narrower in concept. The unit of service for the PAC PPS would include all PAC for an episode of care, but no other services. Medicare could make one payment to an entity to cover all PAC within the episode. There would be no benchmarks or reconciliation.

If the unit of service for the PAC PPS were an episode of PAC, Medicare would not need to define and set payments for subsequent stays because the entity would be paid for all PAC services provided during the episode, regardless of how many stays that included. Further, a payment adjuster for later home health stays would not be needed because payments for the episode would be based on the average cost of the PAC for the full duration of the episode, including lower cost care toward the end.

An episode-based payment would require one entity to be financially at risk for the entire episode of care. The entity could be the first PAC provider, a health care system, a hospital, an accountable care organization (ACO), a physician group practice, or a third-party convener. This entity would need to have the infrastructure to receive a lump-sum payment from Medicare and, in turn, make payments to any "downstream" PAC provider furnishing care during the episode. If the first PAC provider is the entity at risk, it could opt to furnish all PAC for the episode or refer the beneficiary to another PAC provider that it would pay. Given current practice patterns, we estimate that a minority of episodes (about 18 percent) would involve paying more than one provider, and we would expect this share to decline substantially under a PAC PPS as providers opt to offer a continuum of PAC.⁸

Episode-based payments for providers choosing to treat beneficiaries in place underscores the need to align Medicare coverage rules and beneficiary cost-sharing requirements across PAC settings. For example, a prior hospital stay of three days is currently required for SNF coverage but not for HHA, IRF, or LTCH services. As distinctions between particular institutional settings blur and providers opt to offer a broader mix of services, it would make sense to have one set of coverage rules. Likewise, beneficiary cost-sharing requirements currently vary by setting. Standardized cost sharing would enable beneficiaries to select PAC based on their care needs and preferences rather than on financial considerations.

Advantages of episode-based payments

Using episodes as the unit of care would have numerous advantages. First, an episode-based payment would overcome the distortions inherent in volume-driven FFS payment. Providers would have an incentive to furnish a mix of services to meet a beneficiary's care needs over the entire PAC episode rather than to furnish more stays. Results from CMMI's BPCI initiative indicate participants lowered their use of PAC, which may translate to fewer sequential stays (Lewin Group 2017).

If providers opted to treat in place rather than transfer beneficiaries to another provider, there would be fewer handoffs between providers, and beneficiaries would be less likely to experience poorly coordinated care. Having one entity responsible for payment could also improve care coordination among providers. Entities would be incentivized to improve their follow-up care and use case managers to oversee the PAC, strategies used by some ACOs, bundled payment conveners, and Medicare Advantage plans. In this case, beneficiaries and their families would have a better idea of whom to contact with questions and concerns, thus overcoming a common criticism of FFS care.

Episode-based payment should, in no way, limit a beneficiary's choice of PAC provider. Because the entity in charge could seek to influence a beneficiary's decision about where to get their PAC, Medicare would need to ensure that information given to beneficiaries to aid their decision making did not limit their choice to poor-quality providers.

Another advantage of episode-based payments is that they would align the incentives of PAC providers with those of alternative payment models (such as ACOs and bundled payments) that encourage low-cost, high-quality care. For

those providers not already participating in alternative payment models, an episode approach would give them valuable experience managing beneficiaries across a continuum of care. For them, episode-based payment would represent a stepping stone to accepting more risk, which will be required under broader payment reforms.

As practice patterns change under episode-based payments, CMS would need to periodically evaluate whether payments continue to be aligned with the cost of care and adjust payments as needed. The Commission previously recommended that the Congress grant the Secretary the authority to revise and rebase the PAC PPS over time to keep payments aligned with the cost of care.

Disadvantages of episode-based payments

There are three potential downsides to episode-based payments. First, providers would have a financial incentive to furnish fewer services than medically appropriate or provide lower quality care if it lowered their costs. The potential for providers to stint on care is inherent in any prospective payment system. Second, with more dollars at stake, episode-based payments could encourage more episodes, resulting in increased program spending. However, the risk of more episodes would be lower than the risk of unnecessary subsequent stays because the decision to use PAC would be made by the beneficiary's physician in consultation with discharge planning staff (as it is now), whereas, under the length of stay approach, the decision to generate additional stays would be made by the PAC provider. Last, an episode-based payment would require the entity at risk to have the infrastructure needed to pay multiple providers. Although episodes that involve multiple providers represent the minority of episodes, some PAC providers would not be ready to accept this level of financial risk or have the administrative infrastructure to set and make payments to other providers. The Commission maintains that the administrative complexities of this approach are far outweighed by the advantages of episode-based payment.

Strategies to counter the potential disadvantages of episode-based payments

To counter these disadvantages, CMS would need to monitor the frequency of PAC use and examine entities with aberrant utilization patterns. Given the financial incentives of the current payment systems to furnish unnecessary therapy care, changes from current practice would not necessarily signal a worrisome trend. To discourage unnecessary episodes, physicians could

be required to attest to the need for PAC. Value-based purchasing that included a measure of resource use could deter providers from delaying care until after the episode window. One such measure, the Medicare spending per beneficiary–PAC, identifies spending during the PAC stay plus 30 days after discharge. To detect stinting, a value-based policy would also need to include quality measures, such as rates of potentially avoidable (or ambulatory care–sensitive) readmissions and emergency room visits. It could also consider measures of care coordination, such as the number of days between hospital discharge and the first physician visit or the number of transitions while the beneficiary is away from her residence.

Conclusion

An episode-based PPS would discourage the provision of unnecessary PAC stays and would ready providers for

alternative payment models that require them to assume more risk. The Commission will explore this approach over the coming year. In the meanwhile, CMS should proceed with implementing a stay-based unified PAC PPS. While shifting the unit of service from a stay to an episode would change certain incentives (most notably the incentive to generate unnecessary PAC stays), the most important features of a PAC PPS would remain: correcting the biases of the current PPSs and increasing the equity of payments across all types of stays so that providers have less incentive to selectively admit certain beneficiaries over others. A shift to an episode-based payment should, in no way, be interpreted as a temporary retreat from a PAC PPS. Rather, building on these basic features of a PAC PPS, the Commission will explore bolder approaches that focus providers’ efforts on considering beneficiaries’ PAC needs throughout the duration of a PAC episode. ■

Endnotes

- 1 We refer to all care furnished in home health agencies, inpatient rehabilitation facilities, and long-term care hospitals as “post-acute care,” even though some of the beneficiaries were admitted from the community. The chapter includes community admissions in all of its work on the unified PAC prospective payment system.
- 2 In this chapter, we examine PAC use by FFS beneficiaries. We do not include PAC use by beneficiaries enrolled in Medicare Advantage.
- 3 Subsequent care in HHAs does not present the same problem because each stay is clearly defined by the 60-day episode.
- 4 The predictors and their relative importance in estimating payments under a PAC PPS were published in 2016 in a report prepared for the Commission by researchers at the Urban Institute (Wissoker and Garrett 2016).
- 5 The intensity of the setting is based on the following hierarchy: LTCHs were considered the most intensive, followed by IRFs, then SNFs, and the least intensive was home health care.
- 6 Current billing rules establish definitions of stays. In a home health stay, an intervening hospital or institutional PAC stay that occurs entirely during a home health care episode does not change the counting of the 60 days that define an episode and does not establish separate episodes for the care before and after the intervening stay. For SNF stays, an intervening hospital or PAC stay establishes separate SNF stays, one before the intervening event and another after. In IRFs, the duration of the interruption (for a hospital or other PAC stay) and whether the beneficiary returns to the same facility establishes whether the original IRF stay continues after the intervention. If the intervening event is three days or less and the beneficiary returns to the same facility, the original IRF stay continues. If the intervening event is longer than three days or the beneficiary goes to a different facility after the intervening event, there are two IRF stays—one before the event and another after the event. In LTCHs, the duration of the interruption and whether the beneficiary returns to the same LTCH define whether a separate stay is established. An LTCH stay is counted as one if the intervening stay is in an acute hospital and shorter than 10 days, in an IRF and is shorter than 28 days, or in a SNF and is shorter than 46 days. If the intervening stay is longer than those limits or if the beneficiary is transferred to a different LTCH, there are two LTCH stays.
- 7 The Commission considered another approach that would define stays using a phase of care. As care needs evolved, a provider would on paper “discharge” the beneficiary from the first phase and “admit” her to the second phase, triggering two payments. It was not clear whether criteria could differentiate a new phase of care from normal disease progression or healing without the criteria being easily manipulated by providers. The difficulty of designing and monitoring this approach seemed unworkable.
- 8 The estimate is based on the share of stay combinations that are solo (64 percent) and the share of sequences that include lateral stays (18 percent), neither of which would involve paying different providers. Our data suggest that most lateral stays involve the same provider and that most are back-to-back home health stays. Lateral institutional PAC stays are most likely for stays interrupted by a hospitalization that triggered a new PAC stay. Far less frequently, beneficiaries change PAC providers for any number of reasons, including proximity to family or dissatisfaction with the initial provider.

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare and Medicaid programs; CY 2018 home health prospective payment system rate update and proposed CY 2019 case-mix adjustment methodology refinements; home health value-based purchasing model; and home health quality reporting requirements. Final rule. *Federal Register* 82, no. 214 (November 7): 51676–51752.

Gage, B., M. Morley, L. Smith, et al. 2012. *Post-Acute Care Payment Reform Demonstration: Final report, volume 1 of 4*. Prepared under contract to the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS.

Lewin Group. 2017. *CMS Bundled Payments for Care Improvement Initiative models 2-4: Year 3 evaluation & monitoring annual report*. Report prepared by the Lewin Group for the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS. <https://downloads.cms.gov/files/cmimi/bpci-models2-4yr3evalrpt.pdf>.

Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Wissoker, D., and B. Garrett. 2018. *Characteristics, costs, and payments for stays within a sequence of post-acute care*. Washington, DC: The Urban Institute.

Wissoker, D., and B. Garrett. 2016. *Designing a unified prospective payment system for post-acute care*. Washington, DC: Medicare Payment Advisory Commission.

Wissoker, D., and B. Garrett. 2015. *Simulation and analysis of an alternative Medicare home health payment system not based on number of therapy visits*. Washington, DC: The Urban Institute.

CHAPTER

5

**Encouraging Medicare
beneficiaries to use
higher quality
post-acute care providers**

Encouraging Medicare beneficiaries to use higher quality post-acute care providers

Chapter summary

About 40 percent of Medicare acute inpatient hospital discharges result in use of post-acute care (PAC), which includes four provider types: skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities, and long-term care hospitals. Ensuring that the patient is served by the appropriate type of PAC provider is critical, but the selection of a provider *within* a PAC category can be crucial because the quality of care varies widely among providers. Increasing the use of higher quality PAC providers is particularly important as CMS implements value-based payment reforms, such as the Hospital Readmissions Reduction Program (HRRP), hospital value-based purchasing programs, and accountable care organizations (ACOs), which hold providers accountable for the expenditures related to readmissions during a PAC stay.

Beneficiaries report that they value quality of care and that they prefer PAC providers that are close to their home or family. Medicare discharge planning regulations place responsibility with hospitals for connecting inpatient acute care hospital patients with their options for PAC, including educating beneficiaries about their choices and facilitating access to PAC when necessary. Medicare regulations also require that hospitals consider patient preferences and guarantee beneficiary freedom of choice in selecting PAC providers, but hospitals are limited in the assistance they can provide. Though they are required to provide beneficiaries who need PAC with a list of nearby

In this chapter

- Introduction
- Beneficiaries seeking PAC often have many PAC options that vary substantially in quality
- Patients referred to PAC need assistance to identify better quality providers
- Principles for improving hospital discharge planning
- Approaches for identifying higher quality PAC providers
- Conclusion

SNFs and HHAs, Medicare regulations prohibit hospitals from recommending specific PAC providers. The Improving Medicare Post-Acute Care Transformation Act of 2014 requires hospitals to include quality data when informing beneficiaries about their options, but CMS has yet to finalize the regulations implementing this requirement. CMS has developed consumer-oriented websites that provide information on the quality of SNFs and HHAs, but many studies have concluded that these efforts have not significantly increased the use of higher quality PAC providers, possibly because beneficiaries are not always made aware of the data.

The Commission's analysis of referral patterns of Medicare beneficiaries who were sent to SNFs and HHAs indicates that, for many beneficiaries, another nearby provider offered better quality care, though not all of the higher quality providers may have had available capacity. For example, over 94 percent of beneficiaries who used HHA or SNF services had at least one provider within a 15-mile radius that had higher performance on a composite quality indicator than the provider they selected. About 70 percent of beneficiaries who received HHA services had 5 or more other HHAs within a 15-mile radius that offered better quality than their original provider, while almost half of SNF users had 5 or more options with better quality.

Helping beneficiaries to identify better quality PAC providers should be a goal in a reformed discharge planning process, and authorizing hospital discharge planners to recommend specific higher quality PAC providers would further this goal. However, several design decisions would need to be resolved. First, a consistent approach to identifying better quality PAC providers would be needed, and quality standards would need to be transparent for PAC providers and beneficiaries. Second, policies would be needed to safeguard against potential conflicts of interest that could ensue from the authority to recommend specific providers. Finally, the criteria to determine what defines a quality provider would need to account for variations in quality across markets since the number of higher quality providers available in any market will depend on how quality is defined.

Regardless of the approach selected to encourage the use of higher quality PAC providers, beneficiaries should retain freedom of choice. Beneficiaries may have important concerns that are not necessarily reflected in standard quality measures, such as language competency or proximity to family members. These preferences may lead them to select a PAC provider that has lower performance on some quality measures, but additional quality information would allow them to better understand the nature of their options and any trade-offs.

Medicare's options for expanding the authority of discharge planners to recommend higher quality PAC providers could include prescriptive approaches that provide specific metrics or definitions that hospitals must use or more flexible approaches that leave key decisions to discharge planners. A hybrid approach could specify certain selection criteria hospitals would need to use while granting hospitals discretion in the application of these criteria.

In a flexible approach, hospitals would be responsible for defining the criteria they would use for identifying higher quality PAC providers. Hospitals would select quality measures, collect data from PAC providers or other sources of information, and set the performance levels that PAC providers have to meet. CMS could require that hospitals establish formal vetting processes for setting the criteria and reviewing PAC provider performance to provide some degree of transparency for beneficiaries and PAC providers. This option would allow hospitals to use criteria they believe best meet the needs of their patient populations and reflect the availability of PAC providers in their local markets. However, it could be confusing for beneficiaries and PAC providers in a market area to have different hospitals use different quality definitions. In addition, this option could be administratively complex for CMS to oversee.

In a prescriptive approach, CMS would select the quality measures, set the performance levels, identify and notify hospitals and PAC providers, and update the measures as new data became available. Hospitals would be required to notify beneficiaries of the PAC providers that are designated as higher quality. This option would ensure consistent standards of quality and would be less burdensome for hospitals. However, the number of PAC providers designated as high quality would vary across markets. Beneficiaries could find it difficult to select a higher quality provider in areas with limited supply.

In a variation of the prescriptive approach, CMS could rate providers on a composite measure that captures various aspects of PAC quality. In each market, discharge planners could highlight the PAC providers that are higher rated and have available capacity. This approach would account for the variation in quality across markets and provide more flexibility to discharge planners. ■

Introduction

While many delivery system reform options highlight the importance of placing patients in the appropriate type of post-acute care (PAC)—skilled nursing facility (SNF), home health agency (HHA), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH)—the selection of a *particular* PAC provider from among several of any given type can also be crucial for the clinical outcome and expenditures of an episode of care. Beneficiaries seeking posthospital care, particularly those patients referred to SNFs and HHAs, frequently have many agencies or nursing facilities operating in their markets. CMS has implemented some initiatives to help beneficiaries identify better PAC providers, but these efforts may not be adequate.

Encouraging beneficiaries to use higher quality providers is also important because PAC services are costly and frequently used in traditional fee-for-service (FFS) Medicare. In 2015, about 40 percent of hospital discharges resulted in the use of PAC services, and Medicare spending on PAC totaled about 10 percent of all FFS expenditures—over \$60 billion. PAC providers vary in the quality of care they provide, as we have reported annually in our analyses of Medicare payment adequacy (Medicare Payment Advisory Commission 2018). Lower quality providers have higher rates of complications such as rehospitalizations and emergency services use, resulting in worse health outcomes for beneficiaries and further driving up Medicare spending. Policies that encourage the selection of higher quality providers could yield better quality of care and lower Medicare spending and beneficiary cost sharing.

Medicare discharge planning regulations place responsibility with hospitals for connecting inpatient acute hospital patients with their options for PAC, including educating beneficiaries about their choices and providing referrals when necessary. These regulations are designed not only to ease the burden for arranging posthospital care for beneficiaries but also to guarantee beneficiary freedom of choice in selecting PAC providers. In fact, current regulations do not permit discharge planners to recommend specific PAC providers to beneficiaries.

Increasing the use of higher quality PAC providers is particularly important as CMS implements value-based payment reforms that hold hospitals accountable for the expenditures and outcomes related to PAC (Table 5-1,

p. 116). For example, under the Hospital Readmissions Reduction Program (HRRP), the quality of the PAC providers selected by a hospital's patients could affect whether the hospital receives a reward or penalty. Other models, such as accountable care organizations (ACOs) and payment bundles that include inpatient hospital care and PAC, can create even more explicit links between hospitals' financial incentives and the use of higher quality PAC providers. Because Medicare's current discharge planning regulations have not been substantially revised in over 20 years, opportunities exist to update them to better serve beneficiaries and advance delivery system reform.

Beneficiaries seeking PAC often have many PAC options that vary substantially in quality

Though the supply of PAC providers varies widely across the country, most beneficiaries have a number of PAC providers in their local area. Most areas have at least one, if not many, SNFs and HHAs participating in Medicare. For example, 86 percent of beneficiaries had five or more HHAs operating in their zip code of residence in 2016 (Medicare Payment Advisory Commission 2018). The supply of IRFs and LTCHs is more concentrated. In practice, most hospitals refer to many SNF and HHA providers. For example, one study found that, in 2008, the average hospital referred patients needing PAC services to 23 HHAs and 34 SNFs (Lau et al. 2014). Two recent studies have found that readmission rates generally decrease when a hospital's PAC discharges are concentrated with a select number of providers, so referring to a wider range of providers than necessary may increase readmission rates (Rahman et al. 2013, Schoenfeld et al. 2016). While factors in addition to supply, such as distance from a beneficiary's residence, bed availability, and any special clinical needs, can constrain a beneficiary's options, the substantial supply of providers in many areas indicates that beneficiaries usually have a number of nearby options in selecting a PAC provider.

Selecting among providers in markets with a robust supply is complicated by the variation in quality among PAC providers. For example, the Commission found the following in analyses of PAC providers:

- Among SNFs, potentially avoidable rehospitalization rates for the first 30 days of a stay averaged 20.2 percent for the lowest performing quartile of facilities

**TABLE
5-1**

Medicare initiatives that place hospitals at financial risk for readmissions from PAC

	Initiative	Participation	Financial incentive to prevent readmissions
Inpatient hospital value-based purchasing program	VBP incentive that pays hospitals bonuses or imposes penalties based on their performance	Mandatory for all PPS hospitals	Payment determination is in part based on a measure of spending in the 30-day postdischarge period.
Hospital Readmissions Reduction Program	Penalty for hospitals that exceed expected rate of readmission for six conditions	Mandatory for all PPS hospitals	The program includes a financial penalty for hospitals with higher than expected readmissions.
Comprehensive Care for Joint Replacement	Creates an incentive that holds hospitals accountable for cost and quality of the inpatient acute care services and 90 days of postdischarge care for joint replacement patients	Mandatory for all hospitals in 67 selected urban areas (CMS intends to reduce to 34 areas in 2018)	Hospitals in the CCJR program can receive a bonus or penalty depending on their aggregate spending in the payment bundle. Lowering readmissions from PAC helps keep spending below target.
Bundled Payments for Care Improvement	Includes a model that allows hospitals to select a bundle that includes the inpatient stay plus PAC and all related services up to 90 days after discharge; the beneficiary's condition must be 1 or more of 48 diagnostic groups	Voluntary	Participants in the BPCI initiative can receive bonus payments if they keep spending below a target based on prior utilization.
Accountable care organizations (Next Generation or Medicare Shared Savings Program)	Hospitals can participate in ACOs with other stakeholders to share financial risk and collaborate to improve care; not all ACOs include a hospital	Voluntary	Incentives vary depending on the program. Hospitals that lower readmissions relative to their target will have lower spending and better quality, which will influence whether they receive penalties or bonuses.

Note: PAC (post-acute care), VBP (value-based purchasing), PPS (prospective payment system), CCJR (Comprehensive Care for Joint Replacement), BPCI (Bundled Payments for Care Improvement), ACO (accountable care organization).

Source: MedPAC analysis.

compared with 8.4 percent for the highest performing quartile in 2015 (Medicare Payment Advisory Commission 2017).

- Among HHAs, rates of hospitalization during or within the 30 days after home health care in 2014 varied from 17.5 percent for the agency at the 25th percentile compared with 30.1 percent for the agency at the 75th percentile.
- Among IRFs, the share of patients discharged to a SNF in 2015 almost doubled between the providers at the 25th percentile and the 75th percentile of the

range of performance (Medicare Payment Advisory Commission 2017).

These examples illustrate the importance of selecting a quality provider since the choice of provider can have implications for the quality of care received. Beneficiaries served by lower quality providers could experience additional hospital stays, have more difficulty recovering from the acute condition that required their hospitalization, and may have adverse long-term health outcomes (e.g., not recovering to a premorbid level of walking or other form of physical function).

Patients referred to PAC need assistance to identify better quality providers

Patients selecting an HHA or SNF after a hospitalization report that they value quality and a provider that is close to the beneficiary's residence, but several factors complicate the challenge for beneficiaries to make informed choices (BearingPoint 2003, Sefcik et al. 2016, Shugarman and Brown 2006). Reports of patient experience suggest that many beneficiaries who need PAC do not understand the basic nature of the services, particularly those who have no prior experience with posthospital care (BearingPoint 2003, Coleman et al. 2005, Shugarman and Brown 2006). Some patients report being unaware they have a choice of provider, despite Medicare's requirements for making them aware of their options (Baier et al. 2015).

The hospital stay can be a confusing period when beneficiaries and their families are focused on the patient's acute health problem that led to admission, and they may not recognize, or may be slow to realize, that the beneficiary will require posthospital care. While provider-level quality information is available for beneficiaries, some studies suggest that patients are not always aware of it and can find the information difficult to understand (Castle et al. 2009, Harris and Beeuwkes-Buntin 2008). In addition, the decision to discharge a beneficiary can come suddenly. In one study, 30 percent of patients reported being discharged with less than a day's notice (Horwitz et al. 2013). The selection of a PAC provider may need to happen swiftly. With these pressures, it can be challenging, without significant assistance, for many beneficiaries to identify the highest quality provider available.

Medicare's discharge planning policies are intended to facilitate choice and access to PAC

Under Medicare's conditions of participation (COPs), hospitals are responsible for evaluating their patients' postdischarge needs, educating beneficiaries about those needs, and, if necessary, arranging transfers to the selected postdischarge provider. The hospital discharge planner is required to solicit patient preferences for postdischarge care and consider the practicability of the patient returning to home when presenting PAC options.

Medicare statute and the hospital discharge planning COPs are intended to protect beneficiary choice in the selection of PAC providers. As they have with other

Medicare providers, beneficiaries have a "basic freedom of choice" to select any PAC provider participating in the program (though PAC providers do not have an obligation to accept any patient that is referred). In addition, the Medicare statute defining discharge planning indicates that a hospital "may not specify or otherwise limit" the PAC providers made available to beneficiaries. (Medicare Advantage allows plans to establish their own networks; these plans' enrollees must select a provider that is in their plan's network.) The Balanced Budget Act of 1997 also requires that hospitals provide a list of HHAs or SNFs that are near the beneficiary's residence for patients identified as needing these services. The list is not required to include quality or performance information. In practice, many discharge planners are cautious about providing advice to beneficiaries because they do not want to be seen as limiting patient choice (Baier et al. 2015, Tyler et al. 2017).

Providing PAC quality information has had limited success in shifting volume to higher quality providers

Medicare has made provider-level PAC quality measures available for PAC providers through components of the Medicare.gov website.¹ For each of the four settings, consumers may search for providers by zip code, and the website provides a list of participating providers, quality measures, and other information describing the provider. The website includes 23 quality measures for SNFs and 21 quality measures for HHAs. The information is updated quarterly. Consumers search the SNF data about 158,000 times a month; the HHA data, about 33,000 times a month.

The information provided through Medicare.gov—such as staffing ratios, quality measures for short-stay patients, compliance survey results, and services offered—can be useful to beneficiaries but also has some limitations for patients seeking PAC. The measures generally cover broad categories of patients, so there is no ability to examine quality for specific conditions, such as outcomes for a facility's poststroke or other rehabilitation patients. The site also does not identify facilities that provide specialized treatments such as ventilator care.

In recent years, Medicare has added a star rating system to make the quality reports under Nursing Home Compare and Home Health Compare easier to interpret. Under this system, Medicare computes a composite measure for SNFs and HHAs that summarizes performance on several

individual quality measures. The value of the composite measure is used to rate providers: The highest scoring providers receive 5 stars, and the lowest receive 1 star. The quality measures in the SNF and HHA star rating systems include patients receiving PAC, but many of the measures also pertain to long-term care or community-admitted patients. Because the rating's measures are not specific to the PAC population, their utility for posthospital patients may be limited.

The evidence suggests that Medicare's Nursing Home Compare and Home Health Compare data have minimal impact in motivating beneficiaries to choose higher quality providers. Studies have assessed whether patient selection of HHAs and SNFs changed after Medicare.gov data were made available to consumers. One study found that most SNF patients did not appear to select higher quality providers after the Medicare.gov data were released to consumers, while another found that the data had a small impact (an increase of less than 1 percent of a facility's volume) when there was a large difference in the quality of available providers (Werner et al. 2012, Werner et al. 2011). A review of the impact of the HHA data available through Medicare.gov also found minimal impact: On average, the best performing agencies might have increased their market share by less than 1 percent (Jung et al. 2016). The lack of impact is consistent with studies of the use of information about quality for consumers in other settings. Reviews of the health services literature have found that, while provider quality information can be useful for consumers, it has had limited or minimal success in getting beneficiaries to select higher quality providers (Goncalves-Bradley et al. 2016, Harris and Beeuwkes-Buntin 2008, Hussey et al. 2014). The limited impact of these data may indicate that patients are often unaware of this information or that they have limited or no access to online services when hospitalized. Patients who are hospitalized may be too distracted or sick to conduct detailed research about their PAC provider options, and a beneficiary's family member or other caregiver may also have difficulty finding and using this information.

Beneficiaries seek assistance from trusted intermediaries for selection of a PAC provider

In practice, beneficiaries report soliciting the views of physicians, family members, or other associates to recommend a PAC provider (Advisory Board Company 2016, Harris and Beeuwkes-Buntin 2008, Shugarman and Brown 2006). Beneficiaries generally view this information as more valuable than comparative quality

data available through sources like Medicare.gov (Advisory Board Company 2016, Harris and Beeuwkes-Buntin 2008, Sefcik et al. 2016). However, some patients find that physicians vary in their knowledge of the quality of posthospital care (Burke et al. 2017, Colwell 2017).

Hospital discharge planners might be a natural source of recommendations since their principal responsibilities should make them familiar with the PAC options in an area. However, Medicare discharge planning rules do not permit them to recommend specific PAC providers. In addition, a lack of knowledge about PAC quality may limit their ability to provide useful information to beneficiaries. A 2004 survey of discharge planners found that, while 63 percent of planners were aware of the PAC quality data that Medicare makes available, only 38 percent reported using it (Castle 2009). A more recent analysis found that discharge planners are not always aware of comparative quality data on PAC providers or do not believe that PAC providers differ significantly in quality (Baier et al. 2015). Discharge planners' awareness may have increased since 2004, but the survey suggests that a significant share may not use quality data even if they are aware of it.

Concern about protecting patient choice reportedly also makes some discharge planners cautious in the assistance they provide, even when patients ask for their opinions (Baier et al. 2015). Hospital and health system representatives have been concerned that COPs do not adequately define permissible educational activities that respect the beneficiary's freedom to select a PAC provider (Kahn 2015, Thompson 2016). In practice, this lack of definition means that some discharge planners see providing more tailored information, such as highlighting PAC providers that have agreed to collaborate with the hospital, as part of their assistance responsibilities. In contrast, others report being unwilling because they believe it violates Medicare's freedom of choice requirements (Baier et al. 2015, Tyler et al. 2017). For many patients, especially those who lack family contacts or a physician prepared to advise on PAC, the hesitancy of a discharge planner to provide additional assistance could be problematic since there may not be other medical professionals in a better position to help beneficiaries consider their options.

IMPACT mandates hospitals' use of quality information, but implementation status is unclear

In 2014, the Improving Medicare Post-Acute Care Transformation Act (IMPACT) required changes to the

discharge planning COPs to mandate that hospitals “take into account quality, resource use, and other measures . . . in the discharge planning process.” CMS proposed regulations in 2015 to put this mandate into effect but never finalized the regulation. The proposed rule also would have required that beneficiaries referred to IRFs or LTCHs be given a list of nearby providers, similar to the current requirement for SNFs and HHAs. These policies had the potential to strengthen patient choice by explicitly permitting hospitals to provide and explain quality data to beneficiaries during the discharge planning process. However, the expanded use of quality information did not address some concerns about current discharge planning regulations. Hospital representatives wanted the rule to be more explicit that a discharge planner could recommend a PAC provider to a beneficiary (Kahn 2015, Thompson 2016).

The proposed regulation would have required hospitals to share with beneficiaries the cross-sector PAC measures of quality that CMS was required to develop under IMPACT.² Since the measures were not expected to be ready before the regulation’s expected implementation, the rule suggested that hospitals use other sources of quality information such as the data on SNFs and HHAs found on Medicare.gov. The regulations implementing IMPACT requirements were never finalized, and CMS has offered no information about future actions on the proposed rule.

While CMS has made data available to beneficiaries through Medicare.gov, there is no regulatory requirement that hospitals inform patients about these data. If discharge planners do not inform beneficiaries, beneficiaries would have to know about publicly reported measures from their own research. Finding and understanding this information may be challenging for beneficiaries who have been recently hospitalized or who are unfamiliar with online information.

Patient choice under Medicare’s delivery system reform efforts

CMS has also had to consider how to address beneficiary choice of PAC in some of its delivery system reform models. Many of these initiatives are intended to encourage partnerships or collaboration among providers to improve care, such as encouraging PAC providers and hospitals to coordinate transitional care or quality improvement efforts. The high cost of readmissions from posthospital care in many episodes suggests that the quality of PAC providers significantly affects the success

of these models. Participant hospitals and ACOs have an incentive to encourage the use of better PAC providers.

In most reform models, CMS has not changed or waived any existing discharge planning requirements, and hospitals continue to be subject to the current regulations. Hospitals and health systems participating in these efforts have indicated that they seek to encourage the use of preferred PAC providers by educating beneficiaries about PAC choices and highlighting the supplemental services available in their reform model. For example, in the Bundled Payments for Care Improvement (BPCI) initiative, hospitals can indicate that they have identified preferred PAC providers with which they collaborate; beneficiaries selecting one of these providers can receive additional services, such as a transitional care nurse that will follow the patient across settings. While some hospitals report success with encouraging beneficiaries to use preferred providers, no studies have directly assessed the impact of these efforts (Hargrave et al. 2014).

Another approach to the PAC selection issue is found in the Comprehensive Care for Joint Replacement (CCJR) program. CMS provides hospitals participating in the CCJR program with the authority to recommend preferred PAC providers but leaves the beneficiary’s right to select the PAC provider unchanged. In effect, hospitals can recommend a provider, but beneficiaries are not obligated to use it. While the CCJR program has been active since 2016, no studies of the impact on patient choice of PAC provider have been released.

Hospitals have developed preferred PAC provider networks to lower readmission rates

The changes in payment policy resulting from the Patient Protection and Affordable Care of 2010 (PPACA) led many hospitals to establish partnerships with PAC providers to perform well under the new policies regarding hospital readmission rates. In recognition of these new incentives, hospitals established PAC networks with select providers to strengthen their connections with posthospital care. While some hospitals created these networks because of their participation in programs like BPCI or ACOs, all prospective payment system hospitals had an incentive to scrutinize PAC quality because patients readmitted from these settings could affect their payments under the HRRP and hospital value-based purchasing programs. Initial efforts were reportedly focused on SNF networks, though some organizations reported developing networks for the

other provider types. These networks are widespread and likely to increase in number. A 2016 survey of Premier Health hospitals found that 56 percent had established a formal or informal PAC network and that 32 percent were developing a network (Compton-Phillips and Mohta 2016).

To establish a network, hospitals generally release a solicitation for PAC providers to indicate interest and to collect information about PAC providers' ability to meet criteria on a variety of metrics. Hospitals are free to establish their metrics, which can include quality measures, clinical capabilities, performance on licensing and accreditation surveys, compliance history, physician staff affiliation, and geographic coverage in the hospital's service area. Frequently, a major consideration is the volume of patients a PAC provider currently receives from a hospital. Focusing the network on higher volume PAC providers ensures that any quality improvement efforts are targeted to the PAC providers that serve a significant share of a hospital's patients. These networks are arrangements between the hospital and the PAC providers, and beneficiaries are not required to select a PAC provider in the hospital's network. Once the networks are established, the hospital and PAC providers can collaborate on quality improvement activities such as establishing new clinical protocols and case reviews.

Hospitals with preferred networks use voluntary approaches to promote preferred PAC providers to beneficiaries, such as beneficiary education about the quality of preferred providers or the offer of transitional care nurses that follow patients through their episode of care (Hargrave et al. 2014). For example, one provider established an online tool that allowed beneficiaries to search the preferred providers by geographic location and quality performance. Though some hospitals reported success in encouraging beneficiaries to select preferred PAC providers, they also reported that discharge planners could be reluctant to highlight network providers because they were concerned about violating patient choice requirements or disrupting current referral patterns (Hargrave et al. 2014). Hospital representatives indicated that changing the practices of hospital discharge planners continued to be a challenge.

Beneficiaries who use PAC often have a higher quality provider nearby

A review of the referral patterns of Medicare beneficiaries that were sent to SNFs and HHAs provides an illustration of current policies and practices. In 2015, about 1.8

million beneficiaries were referred to a SNF and about 2.2 million beneficiaries were referred to an HHA after a hospitalization. To understand the options available to these beneficiaries, the Commission compared the quality of the 5 closest providers within a 15-mile radius of a beneficiary's home zip code with the quality of the provider from which the beneficiary received service.³ Each provider within the radius was rated using a composite score that included two quality measures: one for adverse events such as hospitalization and a second for improvement in functional ability such as walking.⁴ Over 94 percent of beneficiaries who used HHA services had at least one provider within a 15-mile radius that had a higher quality score than the provider from which they received services (Table 5-2).⁵ Similarly, about 84 percent of beneficiaries who used SNF services had at least one better provider within a 15-mile radius of their residence. Many beneficiaries lived in an area with multiple options, though they were disproportionately located in urban areas. About 70 percent of beneficiaries who received HHA services had five or more other HHAs that offered better quality than their selected provider, while almost half of SNF users had five or more options with better quality. Beneficiaries who used SNF services and resided in rural areas typically had fewer options: Only 9.9 percent had 5 or more SNFs in the 15-mile radius.

The magnitude of the quality difference between the higher performing nearby providers and the provider selected was substantial in many cases. For example, for beneficiaries with one better provider nearby, the geographically closest better SNF had a rate of rehospitalization 3 percentage points lower on average. The average difference between the selected provider and the higher quality providers nearby increased with market size. For example, for beneficiaries with five nearby providers with better quality, the average rehospitalization rate for the better nearby SNFs was 15 percentage points lower than the selected hospital's rate.

There are some limitations to this analysis. First, the analysis does not measure whether SNFs had available capacity at the time a beneficiary was discharged from the hospital. Second, CMS does not report data on quality for smaller providers. The absence of data for small providers may be acute for the rates observed in rural areas because these providers tend to have lower patient volume than urban providers. In addition, the rural rates for the availability of SNFs could be affected because critical access hospitals are not required to report quality data for the swing beds they operate.

**TABLE
5-2**

Many beneficiaries had higher quality PAC options nearby, 2015

Number of higher quality providers available within 15-mile radius

	0 (No better options)	1	2	3	4	5 or more	Total
Share of beneficiaries with higher quality options nearby:							
Skilled nursing facility patients	14.7%	12.2%	9.8%	8.3%	8.2%	46.8%	100%
Home health patients	5.5	5.7	6.0	5.9	7.4	69.5	100

Note: PAC (post-acute care). Beneficiary and provider locations were measured using zip code centroids. A provider’s location had to be within 15 miles of the beneficiary’s zip code.

Source: Medicare Provider and Review skilled nursing facility file 2015, home health standard analytic file 2015, and Medicare Beneficiary Summary File 2015.

These results suggest that a significant share of beneficiaries had a nearby HHA or SNF that offered better quality. While several factors such as available capacity, clinical needs, or patient preference could affect where a beneficiary is served, it is also clear that the current hospital discharge planning process can limit efforts to refer patients to better performing PAC providers.

Principles for improving hospital discharge planning

Helping beneficiaries to identify better quality PAC providers should be a goal in a reformed discharge planning process, and authorizing hospital discharge planners to recommend specific PAC providers would further this goal. However, several design decisions would need to be resolved. First, a clear approach to identifying better quality PAC providers would be needed, and quality standards would need to be transparent for PAC providers and beneficiaries. Second, policies would be needed to safeguard against potential conflicts of interest that could ensue from the authority to recommend specific providers. Finally, the criteria to determine what defined a quality provider would need to account for variations in quality across markets because the number of a market’s higher quality providers will depend on how quality is defined.

CMS would need to consider whether it should limit the PAC providers a hospital can recommend to those that

meet specific quality levels (e.g., top third nationwide) or give hospitals the authority to flag the best of the PAC providers in their local markets available at discharge. A more prescriptive approach would focus attention on PAC providers that are higher overall performers. However, if these providers were not available or unable to take a patient, the advice a discharge planner could provide would be limited. Setting a less restrictive policy that allows hospital discharge planners to recommend the higher performing of available providers could address this issue, but the quality of recommended providers could be more variable.

CMS has developed a significant quantity of measures for its various quality reporting programs (Table 5-3, p. 122). The selection of a subset of these measures that were of shared importance to beneficiaries and the program could serve as criteria for identifying better PAC providers. These measures would need to minimize bias due to shortcomings in risk adjustment or industry coding practices. Outcome measures that focused on high-cost events would be appropriate, as would more easily verifiable quality measures such as claims-based measures of rehospitalization or emergency department use. Other outcomes such as functional gain are important but are more difficult to verify because they rely solely on provider assessment practices. In identifying higher quality providers, CMS should avoid selecting measures that could be vulnerable to manipulation. Finally, a revised policy could allow hospitals to supplement Medicare’s core measures with other information. Beneficiaries would

**TABLE
5-3****Selected PAC quality measures available through Medicare quality programs**

Setting	Examples of measures available
Skilled nursing facilities	Share of short-stay residents who: <ul style="list-style-type: none">• were rehospitalized after a nursing home admission• had an outpatient emergency department visit• were successfully discharged to the community• received antipsychotic medication for the first time
Home health agencies	Share of patients experiencing: <ul style="list-style-type: none">• acute care hospitalizations• emergency department use without hospitalization• rehospitalization during the first 30 days of home health care• emergency department use without hospital readmission during the first 30 days of home health
Inpatient rehabilitation facilities	All-cause unplanned 30-day post-IRF discharge readmission measure
Cross-sector measures <i>(not yet implemented in all sectors)</i>	Discharge to community Medicare spending per beneficiary Potentially preventable 30-day postdischarge readmission measure

Note: PAC (post-acute care), IRF (inpatient rehabilitation facility). Includes certain measures from Skilled Nursing Home Compare and Home Health Compare websites. IRF and long-term care hospital measures are from Medicare's quality reporting programs for these settings.

Source: Information on Nursing Home Compare, IRF quality reporting measures, and LTCH quality reporting measures from CMS.

be free, but not obligated, to weigh both the core measures and any supplemental information when selecting their PAC provider.

Medicare's five-star rating systems for SNFs and HHAs reflect its current approach to a composite measure of quality for PAC providers, but it would likely need some modifications to serve as a measure in a revised discharge planning policy. Both systems use a number of process measures, which may give providers a better rating for measures that do not necessarily improve outcomes. The five-star measures do not focus solely on Medicare PAC patients. Both systems also include measures of functional improvement that can be sensitive to provider coding practices. A revised star-rating system that focuses on post-acute services and claims-based outcomes measures would address these shortcomings.

Beneficiaries must retain their freedom to choose a PAC provider under a revised discharge planning process. Beneficiary preferences would be incorporated in the options a discharge planner presented, as current

requirements encourage (Center for Medicare Advocacy 2016, Coalition to Preserve Rehabilitation 2016). Beneficiaries could have concerns that are not necessarily reflected in standard quality measures, such as language competency or proximity to family members. Their preferences could lead them to select a PAC provider that has lower performance on some quality measures, but additional quality information would allow them to understand the nature of their options and any trade-offs.

PAC provider capacity, in addition to patient decision-making, will also affect the ability of any quality information to shift beneficiaries to higher quality PAC providers. The supply of higher quality PAC capacity is finite. Facilities vary in the services they offer, and, consequently, beneficiaries requiring specialized or higher cost services may have even fewer options. These factors can limit the ability to shift beneficiaries to PAC providers with higher quality. Optimally, any additional authority for hospital discharge planners would allow them to identify, when possible, the higher performing PAC providers among those with available capacity at discharge.

Additional assistance selecting providers could be even more important if CMS implements a unified payment system for PAC. Under such a system, providers could have the option to consolidate separate PAC operations into a single PAC facility. Quality metrics could be used to explain the clinical services and goals of care a patient can expect from particular PAC providers. Improved quality information about the new category of providers, along with the discharge planner's ability to highlight the better performing ones, would make it easier for beneficiaries to choose among the options in a PAC PPS.

Improving discharge planning should also complement other efforts to improve value in Medicare. Hospitals have a financial incentive to encourage beneficiaries to use the PAC providers with which they collaborate under payment reforms such as ACOs and bundling programs. However, if the new authority limited the PAC provider options to only those that met the Medicare-selected quality metrics, hospitals could find that some of their referral partners were not highly rated under these terms. In these instances, hospitals would have to weigh how to respond. They could encourage these providers to improve quality, provide supplemental information to beneficiaries that emphasizes these providers' other merits (such as meeting other facets of quality not measured by Medicare or providing supplemental services like transitional care nurses), or opt to collaborate with different PAC providers.

Developing quality measures that capture the full gamut of beneficiaries' preferences could be challenging. Medicare already has many clinical quality measures, but beneficiaries may have other preferences such as facility condition, staff cultural or linguistic competencies, and facility amenities such as dining and recreation options. Developing these additional indicators would dilute a focus on clinical outcomes, and, in some cases, it could be impractical or impossible to develop useful measures for preferences that are more subjective (e.g., facility décor or staff demeanor). A more practical approach could be for CMS to focus on a core set of measures that focus on outcomes that matter for the beneficiary and the program and allow hospitals to supplement these measures with other information when they deem it relevant to beneficiary preferences. As mentioned earlier, many beneficiaries want hospital discharge planners or other clinicians to recommend a facility. Such a recommendation should respect patient preferences, and a revised discharge planning policy should not overload beneficiaries with more information than they can process during an acute health crisis.

Approaches for identifying higher quality PAC providers

Medicare's options for helping hospitals select appropriate PAC providers at the point of patient discharge range from flexible (leaving key decisions about selecting beneficiaries' PAC providers to hospital discharge planners) to prescriptive (setting specific metrics or other criteria that define a PAC provider as high quality and limiting a hospital's selection of PAC providers to those meeting this definition) (Table 5-4, p. 124). A hybrid approach could specify certain quality criteria hospitals must use while granting hospitals discretion in the use of these criteria. Table 5-4 illustrates two hypothetical policy options, one more flexible, the other more prescriptive.

Illustrative example of a flexible approach

Under a flexible approach, hospitals would be responsible for defining the criteria they would use to identify higher quality PAC providers. A hospital would be responsible for selecting quality measures, collecting data from PAC providers, and setting the performance levels that PAC providers would have to meet to be recommended by the hospital. CMS could require that hospitals establish formal vetting processes for setting the criteria and reviewing PAC provider performance to provide some degree of transparency for beneficiaries and PAC providers. Hospitals could be required to make their criteria and selection process available for public review.

The advantage of this approach is that it provides hospitals with the freedom to establish the criteria that they believe best reflect the needs of their patients and to tailor those criteria to the available supply of providers. Some hospitals have conducted similar processes to identify PAC referral partners for ACOs and bundled payment initiatives, for instance. Metrics could be set to identify the best of the local PAC providers, regardless of how they compared with national levels. As many programs make hospitals accountable for readmissions, hospitals would have a significant incentive to work with higher quality providers.

Flexibility would permit hospitals to select the quality measures they deem appropriate and could include compliance history and selected quality measures. If some measures did not adequately control for differences in patient mix, hospitals could also opt to use judgments of a PAC provider's clinical reputation among hospital medical staff. On the one hand, flexibility could permit

**TABLE
5-4**

Illustrative examples of policies for revising discharge planning

	Option 1: Hospitals have flexibility to write own standards	Option 2: Medicare sets standards to define higher quality PAC providers
Medicare’s role	<ul style="list-style-type: none"> Medicare COPs require hospitals to define criteria. 	<ul style="list-style-type: none"> Medicare designates providers that can be recommended (e.g., must be at least three or four stars, better CAHPS® score).
Use of quality measures	<ul style="list-style-type: none"> Hospitals select measures, allowing for innovation and experimentation. 	<ul style="list-style-type: none"> Medicare sets hospitals’ selection criteria.
Regulatory safeguards	<p>There would need to be:</p> <ul style="list-style-type: none"> safeguards to prevent financial conflicts of interest; disclosure of conflict of interest/ownership/collaboration; and CMS approval of individual hospitals’ criteria and monitoring of proper application. 	<ul style="list-style-type: none"> Likely, the same safeguards stated in Option 1 would be needed, but standards for recommending PAC providers would be clearer.
Beneficiary implications	<ul style="list-style-type: none"> Beneficiaries would receive recommendations that reflect quality of PAC care in the market. It could be confusing to have multiple definitions across hospitals. 	<ul style="list-style-type: none"> A single set of standards across hospitals would make reasoning behind selected PAC providers more transparent to beneficiaries. The quality of PAC providers selected would be more consistent.
PAC provider implications	<ul style="list-style-type: none"> Providers would have to consider multiple definitions if working with many hospitals, potentially with different measures for each setting. Designation as a higher quality provider could vary among hospitals and across geographic markets. 	<ul style="list-style-type: none"> A single set of standards would result in consistent designation. There would be consistency across markets as to which providers qualify as higher quality.
Advantages	<ul style="list-style-type: none"> Flexibility in the definition of quality would allow hospitals to develop patient-centered definitions and require them to scrutinize referral partners. Approaches could reflect local PAC markets’ capacity and scope of offerings. 	<ul style="list-style-type: none"> A single definition of “quality” would provide clear standards for PAC providers, consistent treatment under policy. The implementation burden on hospitals would be lighter. Enforcement would be less complex. CMS would need to ensure that hospitals observe sanctioned criteria when recommending PAC providers.
Disadvantages	<ul style="list-style-type: none"> There would be a greater burden on hospitals to implement and maintain standards and on CMS to verify and audit standards and their application. Multiple definitions of higher quality providers could be confusing for beneficiaries and PAC providers. 	<ul style="list-style-type: none"> If there were a single standard, the number of designated providers would vary across areas.

Note: PAC (post-acute care), COP (condition of participation), CAHPS® (Consumer Assessment of Healthcare Providers and Systems®).

Source: MedPAC analysis.

the development of more patient-centered standards based on a hospital’s clinical expertise. On the other hand, the quality of PAC providers selected and recommended to beneficiaries could vary as a result. In addition,

hospitals would have the burden of developing criteria for identifying higher quality PAC providers.

Both beneficiaries and PAC providers could find this policy confusing since there would be no consistent

standards for designating a provider as higher quality. PAC providers would be subject to different definitions of quality among hospitals and could find it difficult to satisfy the multiple and potentially conflicting definitions. A single PAC provider could have different quality designations among the hospitals in the PAC provider's market, qualifying as a higher quality provider with some hospitals but not others. Medicare has been moving in the opposite direction, toward efforts to develop standardized cross-sector measures of PAC quality that facilitate comparisons; the use of unique measures by hospitals could increase the reporting burden on PAC providers.

Another disadvantage of this more flexible approach is that it would be more challenging for CMS to oversee. Ensuring that hospitals were not creating inappropriate business or financial relationships that encouraged undue favoritism or inappropriate PAC volume would require some oversight by CMS. Ensuring that collaboration among hospitals and PAC providers is aimed at improving outcomes and not cooperating in ways that inefficiently increase Medicare spending would be important. A broad range of permissible policies would make it challenging to identify when a hospital's practices created unacceptable risk for fraud, waste, and abuse. CMS might find it difficult to conduct a uniform and efficient review process if each hospital followed a unique approach.

Illustrative example of a prescriptive approach

Under a more prescriptive approach, CMS could establish quality metrics for designating PAC providers as higher quality. Under this approach, CMS would select the measures, set the performance levels, identify and notify hospitals and PAC providers, and update the measures as new data became available. Hospitals would be required to notify beneficiaries of the PAC providers designated as higher quality.

Establishing a single standard would make the program easier for beneficiaries and PAC providers to understand. Beneficiaries would likely better understand why the recommended providers were selected, which might make them more inclined to use higher quality PAC providers. There would be more consistency in the quality of care available to beneficiaries from designated providers because the standards applied by Medicare would be identical across markets. The administrative burden on hospitals would be lower relative to the more flexible option, though CMS would have more responsibility. Since the standards are set by CMS, this approach does not

have the same vulnerabilities to fraud, waste, and abuse that are present in the flexible approach.

The quality measures available vary among PAC settings, but CMS could, in most cases, start with measures of efficiency and quality that are used in the pay-for-reporting and value-based purchasing programs for PAC providers. CMS might focus on hospital readmissions, discharge to community, and other measures that reflect high-cost and high-consequence events. CMS is developing cross-sector measures of PAC quality, including readmissions, and these measures could be used when they become available.

CMS would have to consider how to set the performance levels to qualify as a higher quality PAC provider, such as setting a benchmark for rehospitalization from a SNF or HHA to be specified as higher performing. Setting a single national benchmark would have the advantage of simplicity and consistency, but because the quality of PAC providers varies across regions, some regions would have more providers that qualified for selection and other regions would have fewer.

For example, a national benchmark could be set defining higher quality SNFs as those in the bottom third (lowest) on rehospitalization rates. With this benchmark, 114 core-based statistical areas (CBSAs) would have only 1 or 2 SNFs that qualified as higher quality, while 39 CBSAs would have 20 or more SNFs that qualified. A lower performance benchmark (i.e., a higher rate of readmissions as the criteria) could be specified that would increase supply in some markets, but doing so would degrade the acceptable level of quality in all markets nationwide, even in areas that did not need more providers.

Alternatively, a prescriptive approach could establish a definition that uses both national and local standards. For example, the definition could be a two-step test: the first would designate providers that are in the lowest third of the nationwide distribution for readmission rates, and the second would qualify any providers in the lowest third relative to other providers in their local market area. This combination approach could result in a more even supply of designated higher quality providers across markets but would result in designations that varied from region to region. For example, across urban areas, the average rate of readmissions for SNFs varied in 2014 from 11 percent to 21 percent.⁶ Even if beneficiaries used only providers deemed "high quality" in their areas, the quality of care received would vary across markets. Further, PAC providers with the same level of performance could receive different designations depending on their market.

In a variation of this option, CMS could rate providers on a composite measure that captured different aspects of PAC quality. Within each market, discharge planners could highlight the PAC providers that are more highly rated and have available capacity. This approach would account for the variation in quality across markets and provide more flexibility to discharge planners.

Another approach would be for CMS to create a core set of metrics but permit hospitals to supplement this information with their own measures. Medicare’s measures could reflect outcomes important to patients and the program, such as rates of readmission and discharge to the community, and CMS could require that this information be reported to beneficiaries. Hospitals could have the option to include additional information they also deem important, and discharge planners could be charged with helping beneficiaries understand the different indicators.

Hybrid approaches combining elements of flexible and prescriptive frameworks

Policymakers could combine elements of the two approaches to balance or mitigate the disadvantages of each approach. For example, policymakers could begin with the flexible framework but require hospitals to select quality measures that meet certain standards or are already in use in the program. Alternatively, Medicare could leave the exact measures open for determination but

require that PAC providers achieve certain performance levels (e.g., top third of providers) on selected measures to be designated as a higher quality PAC provider. If policymakers favored the more prescriptive approach, CMS could provide a standardized definition that includes a quality rating of PAC in a market. The hospital could observe how the supplemental data revised the rating of PAC providers, with the better PAC providers receiving the designation as higher performing. Determining the appropriate balance would benefit from experimentation, and CMS could pilot policies that varied the degree of flexibility and regulatory specificity—for example, by geographic region.

Conclusion

Medicare policy currently places a premium on protecting beneficiary choice of PAC provider, but it does not encourage beneficiaries to use higher quality PAC providers. Any new policy should seek to ease or simplify the burden on beneficiaries, many of whom already report that discharge planning can be a difficult and confusing period. Efforts to provide additional information should not overwhelm beneficiaries and should ensure that patient preferences for PAC are recognized. ■

Endnotes

- 1 Medicare provides information through Nursing Home Compare, Home Health Compare, Inpatient Rehabilitation Facility Compare, and the Long-Term Care Hospital Compare websites available at Medicare.gov.
- 2 IMPACT requires CMS to develop quality measures for resource use, hospital readmission, and discharge to community for PAC providers.
- 3 The measure of distance was based on zip codes. For each beneficiary, we identified the zip codes with a geographic center within 15 miles of the center of the beneficiary's residential zip code. The five closest providers were identified and rated based on the quality measures.
- 4 The measures for skilled nursing facilities included all-cause readmissions during the SNF stay and improvement in mobility; the HHA measures included hospitalization during the HHA stay and improvement in walking at discharge. Providers within a 15-mile radius of the beneficiary were rated from high to low on these measures, with the two measures weighted evenly.
- 5 We included only providers with a complete set of quality measures data in this analysis.
- 6 This finding pertains to core-based statistical areas with 10 or more SNFs that had adequate data for computation of the readmission rate.

References

- Advisory Board Company. 2016. What consumers want: Understanding post-acute patients and families. Infographic. <https://www.advisory.com/research/post-acute-care-collaborative/members/multimedia/infographics/2016/what-consumers-want-from-post-acute-care>.
- Baier, R. R., A. Wysocki, S. Gravenstein, et al. 2015. A qualitative study of choosing home health care after hospitalization: The unintended consequences of ‘patient choice’ requirements. *Journal of General Internal Medicine* 30, no. 5 (May): 634–640.
- BearingPoint. 2003. *Consumer testing of Home Health Compare website prototype*. Report prepared for the Centers for Medicare & Medicaid Services by BearingPoint. McLean, VA: BearingPoint.
- Burke, R. E., E. Cumbler, E. A. Coleman, et al. 2017. Post-acute care reform: Implications and opportunities for hospitalists. *Journal of Hospital Medicine* 12, no. 1 (January): 46–51.
- Castle, N. G. 2009. The Nursing Home Compare report card: Consumers’ use and understanding. *Journal of Aging & Social Policy* 21, no. 2 (April–June): 187–208.
- Castle, N. G., J. Engberg, J. Lave, et al. 2009. Factors associated with increasing nursing home closures. *Health Services Research* 44, no. 3 (June): 1088–1109.
- Center for Medicare Advocacy. 2016. Letter to CMS regarding the proposed rule entitled, “Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies,” January 4.
- Coalition to Preserve Rehabilitation. 2016. Letter to CMS regarding the proposed rule entitled, “Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies,” January 4.
- Coleman, E. A., E. Mahoney, and C. Parry. 2005. Assessing the quality of preparation for posthospital care from the patient’s perspective: The care transitions measure. *Medical Care* 43, no. 3 (March): 246–255.
- Colwell, J. 2017. Perfecting post-acute care. *ACP Hospitalist*, April. <https://acphospitalist.org/archives/2016/04/post-acute-care.htm>.
- Compton-Phillips, A., and N. Mohta. 2016. Strengthening the Post-Acute Care Connection. *NEJM Catalyst*. <http://catalyst.nejm.org/strengthening-post-acute-care-connection/>.
- Goncalves-Bradley, D. C., N. A. Lannin, L. M. Clemson, et al. 2016. Discharge planning from hospital. *Cochrane Database Systematic Review*, no. 1 (Jan 27): CD000313.
- Hargrave, E., K. Quirk, and D. Weinstein. 2014. *Private sector approaches to managing post-acute care*. A study conducted by staff from NORC at the University of Chicago and Georgetown University for the Medicare Payment Advisory Commission. Washington, DC: MedPAC.
- Harris, K., and M. Beeuwkes-Buntin. 2008. *Choosing a health care provider*. Synthesis report. Princeton, NJ: Robert Wood Johnson Foundation.
- Horwitz, L. I., J. P. Moriarty, C. Chen, et al. 2013. Quality of discharge practices and patient understanding at an academic medical center. *JAMA Internal Medicine* 173, no. 18 (October 14): 1715–1722.
- Hussey, P. S., H. S. Luft, and P. McNamara. 2014. Public reporting of provider performance at a crossroads in the United States: Summary of current barriers and recommendations on how to move forward. *Medical Care Research and Review* 71, no. 5 supplement (October): 5S–16S.
- Jung, J. K., B. Wu, H. Kim, et al. 2016. The effect of publicized quality information on home health agency choice. *Medical Care Research and Review* 73, no. 6 (December): 703–723.
- Kahn, C. 2015. Comment letter by the Federation of American Hospitals on CMS’s proposed rule entitled, “Medicare Program; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies” (CMS 3317–P). December 21.
- Lau, C., A. Alpert, P. Huckfeldt, et al. 2014. Post-acute referral patterns for hospitals and implications for bundled payment initiatives. *Healthcare* 2, no. 3 (September): 190–195.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Rahman, M., A. D. Foster, D. C. Grabowski, et al. 2013. Effect of hospital-SNF referral linkages on rehospitalization. *Health Services Research* (October 17): 1–22.
- Schoenfeld, A. J., X. Zhang, D. C. Grabowski, et al. 2016. Hospital-skilled nursing facility referral linkage reduces readmission rates among Medicare patients receiving major surgery. *Surgery* 159, no. 5 (May): 1461–1468.

Sefcik, J. S., R. H. Nock, E. J. Flores, et al. 2016. Patient preferences for information on post-acute care services. *Research in Gerontological Nursing* 9, no. 4 (July 1): 175–182.

Shugarman, L., and J. Brown. 2006. *Nursing home selection: How do consumers choose? Volume I: Findings from focus groups of consumers and information intermediaries*. Report prepared for the Department of Health and Human Services by the RAND Corporation. Washington, DC: Department of Health and Human Services.

Thompson, A. 2016. Comment letter by the American Hospital Association on CMS's proposed rule entitled, "Medicare Program; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies" (CMS 3317–P). December 21.

Tyler, D. A., E. A. Gadbois, J. P. McHugh, et al. 2017. Patients are not given quality-of-care data about skilled nursing facilities when discharged from hospitals. *Health Affairs* 36, no. 8 (August 1): 1385–1391.

Werner, R. M., R. T. Konetzka, E. A. Stuart, et al. 2011. Changes in patient sorting to nursing homes under public reporting: Improved patient matching or provider gaming? *Health Services Research* 46, no. 2 (April): 555–571.

Werner, R. M., E. C. Norton, R. T. Konetzka, et al. 2012. Do consumers respond to publicly reported quality information? Evidence from nursing homes. *Journal of Health Economics* 31, no. 1 (January): 50–61.

CHAPTER

6

**Issues in Medicare's medical
device payment policies**

Issues in Medicare's medical device payment policies

Chapter summary

This chapter explores two distinct topics related to medical devices. First, we explore ways to improve Medicare's payment policies for durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS). Second, we explore ways to constrain the risks posed by physician-owned distributors (PODs) and to make them more transparent to beneficiaries, enforcement agencies, and others.

Medicare's DMEPOS payment policies

Medicare beneficiaries rely on DMEPOS products to treat their illness or injury and to allow them to remain in their homes, as opposed to seeking care in an institutional setting. DMEPOS as a category comprises a large number of products that vary in cost and complexity, ranging from complex power wheelchairs to diabetes testing supplies to knee braces.

Pursuant to a statutory requirement, CMS implemented the DMEPOS Competitive Bidding Program (CBP) to use market competition to set payment rates and limit fraud and abuse while ensuring beneficiaries retain access to needed DMEPOS products. The CBP began in 2011 in nine large urban areas and was focused on the highest cost and highest volume items with the largest potential for savings. Over time, the CBP has added products and expanded geographically. As of 2016, Medicare's payment rates for DMEPOS products included in the CBP are set either directly through bidding

In this chapter

- Introduction
- DMEPOS background
- Non-CBP DMEPOS products
- Policy options to improve the accuracy of Medicare's payment rates for non-CBP DMEPOS products and protect beneficiaries
- Physician-owned distributors
- Conclusion

or indirectly by administratively setting prices at least partially based on CBP information in areas where the CBP has not been implemented (e.g., rural areas). The CBP has successfully driven down the cost of DMEPOS products for Medicare and beneficiaries. Compared with payment rates in the year before the CBP, Medicare's payment rates for some of the highest expenditure DMEPOS products have fallen by an average of roughly 50 percent. CMS initially estimated that the CBP would save over \$42 billion in the first 10 years of the program—\$25 billion in savings for the program and \$17 billion in savings for beneficiaries.

At the same time, Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow. By 2015, nearly half of all Medicare expenditures on DMEPOS products were for products excluded from the CBP. Medicare pays for these products using a fee schedule that is largely based on supplier charges from 1986 to 1987 (updated for inflation) and undiscounted list prices. Medicare's payment rates for the top 10 non-CBP DMEPOS products in 2015 were a third higher, on average, than private-payer rates for comparable products, and some non-CBP DMEPOS products continue to generate high rates of improper payments, experience high utilization growth, and exhibit patterns of potential fraud and abuse.

To address these issues, some additional products that are not currently competitively bid could be moved into the CBP. We also observe that the participation and balance billing rules for DMEPOS products and suppliers could be strengthened to better protect beneficiaries and to better align those policies with many other Part B services.

Physician-owned distributors

PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. PODs have the ability to distort the supply chain for medical devices—potentially resulting in an increase in the volume of surgeries performed on beneficiaries, higher costs for hospitals and the Medicare program, and inappropriate care.

The Commission questions the value PODs produce for the Medicare program and beneficiaries. We suggest several ways in which Medicare and policymakers can constrain the risks posed by PODs. We discuss two specific options to revise the Stark law, which is intended to prohibit physicians from referring Medicare beneficiaries to certain health care facilities in which they have a financial interest, and several key topics for policymakers to consider if such changes are made. While the options would likely limit the use of PODs, some PODs might continue to operate even if the Stark law was modified. In addition, the Commission supports

increasing the transparency of POD-physician relationships by requiring all PODs to report under the Open Payments program, a program designed to shed light on financial ties between physicians and certain industries. ■

Introduction

Medicare beneficiaries rely on durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) to treat their illness or injury and to allow them to remain in their homes, as opposed to seeking care in an institutional setting. This chapter provides an overview of Medicare's Competitive Bidding Program (CBP) for DMEPOS products and of Medicare's payment methods for DMEPOS products that are excluded from the CBP. The chapter describes payment policy changes that could be made to improve the accuracy of Medicare's payments for DMEPOS products, to protect beneficiaries, and to enhance program integrity.

This chapter also includes a discussion of issues surrounding physician-owned distributors (PODs), which allow physicians to profit from the sale of medical devices they use. PODs, which have historically been concentrated in the market for implantable medical devices, create an incentive for physicians to base their decisions, such as whether to operate on a patient and which instrumentation to use, on financial rather than clinical considerations. To better protect beneficiaries and the Medicare program, this chapter discusses revisions to the Stark law to limit the use of PODs.

DMEPOS background

DMEPOS, as a category, comprises a wide range of products. Durable medical equipment (DME) comprises products that serve a medical purpose, can withstand repeated use, are generally not useful in the absence of an illness or injury, and are appropriate for use in the home (e.g., wheelchairs). Supplies that are necessary for the effective use of DME are also covered under the DME benefit (e.g., oxygen in oxygen tanks). Prosthetic devices replace all or part of an internal body organ or function (e.g., colostomy bags and parenteral and enteral nutrition). Prosthetics include artificial legs, arms, and eyes. Orthotic devices are defined as providing rigid or semi-rigid support for weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body (e.g., leg, arm, back, and neck braces). Other DMEPOS items include surgical dressings and therapeutic shoes and inserts for beneficiaries with diabetes.

DMEPOS spending overview

Medicare sets the payment rates for many DMEPOS products through the CBP. Products excluded from the CBP are primarily paid on a fee schedule basis. The trends in Medicare spending for these two broad categories of products substantially diverged over the last several years.

Medicare expenditures on DMEPOS products included in the CBP have decreased considerably over time. From 2010 to 2015, Medicare expenditures for products included in the CBP fell from \$7.5 billion to \$4.4 billion, a decrease of 42 percent.¹ Expenditures for certain types of products in the CBP declined even faster. For example, between 2010 and 2015, Medicare expenditures on diabetes testing supplies (e.g., blood glucose test strips) fell from \$1.6 billion to \$0.3 billion, a decrease of 79 percent (Table 6-1, p. 138).

Over the same time period, Medicare expenditures on DMEPOS products not included in the CBP continued to increase. Between 2010 and 2015, expenditures for these products grew from \$3.3 billion to \$4.0 billion, a total increase of 23 percent.² Because of the decrease in spending on CBP products and the increase in spending on non-CBP products, the share of total Medicare DMEPOS spending attributable to non-CBP products has increased rapidly. In 2010, non-CBP products represented about 30 percent of Medicare DMEPOS spending; by 2015, non-CBP products accounted for nearly half (48 percent) of all spending.

At the beginning of the program, CMS expected the CBP's overall savings to Medicare and beneficiaries to be more than \$42 billion over the first 10 years. This estimate included \$25 billion in savings for the Medicare program and \$17 billion in savings for beneficiaries, as a result of lower coinsurance payments and the downward effect on premiums (Centers for Medicare & Medicaid Services 2012).

History of DMEPOS payment methods

Before implementing the CBP in 2011, CMS paid for nearly all DMEPOS products on a fee schedule basis. Fee schedule payment rates were largely based on supplier charges from July 1986 through June 1987 and on information such as unadjusted list prices for products introduced after this time period.³ Before 2011, annual payment rate adjustments were generally between zero percent and the consumer price index for all urban consumers (CPI-U). Since 2011, payment rates have

**TABLE
6-1**

Medicare expenditures on CBP products fell while expenditures on non-CBP products increased, 2010–2015

	Total Medicare expenditures (in billions of dollars)		
	2010	2015	Percent change
CBP products (total)	\$7.5	\$4.4	–42%
DMEPOS other than diabetes testing supplies	5.9	4.0	–31
Diabetes testing supplies	1.6	0.3	–79
Non-CBP products	3.3	4.0	23

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies). Figures in table are rounded and include beneficiary spending. If a product was included in any CBP round through 2017, it is included in the CBP product categories in both 2010 and 2015. The totals for CBP products include spending in both competitive bidding areas and non-competitive bidding areas.

Source: MedPAC analysis of 2010 and 2015 Physician/Supplier Procedure Summary file and Competitive Bidding Implementation Contractor’s Healthcare Common Procedure Coding System code lists.

annually been increased by the CPI–U, reduced by the change in economy-wide productivity (Social Security Act Section 1834 (a)(14)(L)). Historically, fee schedule rates were not updated to reflect technological improvements, such as efficiency gains in manufacturing, or changes in market conditions.

As a result of setting payment rates based on supplier charges and largely updating payment rates for inflation over time, many DMEPOS products had become substantially overpriced before the CBP. The Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published numerous reports detailing products for which Medicare’s DMEPOS payment rates were higher, often by significant amounts, compared with what suppliers paid to purchase products from manufacturers, what suppliers paid to purchase products from wholesalers, list prices on suppliers’ websites, payment rates of private payers, and payment rates of other government purchasers (Office of Inspector General 2009, Office of Inspector General 2005, Office of Inspector General 2004, Government Accountability Office 1997). For example, based on the 2006 median Medicare fee schedule amount, a 2006 OIG report found that Medicare paid \$7,215 for 36 months’ rental of oxygen concentrators that cost \$587, on average, to purchase (Office of Inspector General 2006).

Excessively high payment rates increased expenditures and likely encouraged inappropriate utilization. After analyzing

2010 and 2011 claims for diabetes testing supplies, OIG found that \$425 million in Medicare-allowed claims had characteristics of questionable billing, such as claims billed by suppliers who had an unusually high share of beneficiaries who received their diabetic testing supplies at perfectly regular intervals (which suggests suppliers automatically provided refills as opposed to beneficiaries specifically requesting refills, which is required by Medicare) (Office of Inspector General 2013a). In another instance, OIG found that 80 percent of claims for power wheelchairs supplied to beneficiaries in the first half of 2007 did not meet Medicare requirements (Office of Inspector General 2011).

The Balanced Budget Act of 1997 instructed the Secretary of HHS to conduct a competitive bidding demonstration for DMEPOS. CMS conducted demonstrations in Polk County, FL (1999 to 2002), and San Antonio, TX (2000 to 2002), that collectively reduced Medicare expenditures for the subject DMEPOS products by 19 percent, or \$9.4 million—\$7.5 million in savings for the Medicare program and \$1.9 million in savings for beneficiaries. The demonstrations had little overall impact on beneficiary access (Karon et al. 2003).

After the successful demonstrations, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to establish competitive bidding for certain DMEPOS products. The MMA also expressly prohibited certain DMEPOS

products such as Class III devices from being included in competitive bidding.⁴ The law required CMS to implement the CBP in 10 of the largest metropolitan statistical areas (MSAs) initially and expand to additional areas thereafter. The law also gave the Secretary the authority to phase in competitive bidding among the highest cost and highest volume items or those with the largest savings potential.

CMS implemented CBP Round 1 in 2008, but the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) canceled all the contracts two weeks after the program began and instructed CMS to rebid the round. Because the CBP was expected to produce savings for Medicare and beneficiaries, the DMEPOS industry agreed to a 9.5 percent payment reduction for all items that were to be included in the CBP in exchange for delaying the CBP.

In 2011, CMS implemented CBP Round 1 rebid for nine product categories in nine MSAs, referred to as competitive bidding areas (CBAs). This round of the CBP was referred to as a “rebid” because it largely covered the same areas and products as the original Round 1 that was canceled by MIPPA.⁵ Since 2011, CMS has conducted two additional rounds of competitions (i.e., “recompetes”) in the same nine Round 1 MSAs. These rounds are referred to as “Round 1 recompute” and “Round 1 2017.” As required by statute, CMS also conducted competitions in 90 additional MSAs beginning in July 2013, referred to as “Round 2” and “Round 2 recompute.” Finally, CMS implemented the National Mail-Order Program for diabetes testing supplies (e.g., blood glucose test strips) in July 2013.⁶ As the name implies, this competition covers the entire country, including both urban and rural areas, but applies only to diabetes testing supplies purchased on a mail-order basis (which include supplies shipped or delivered to a beneficiary’s home, regardless of the method of delivery). As of 2018, two CBP rounds are active (Round 1 2017 and Round 2 recompute) that together operate in 99 large MSAs, and the National Mail-Order Program recompute for diabetes testing supplies is also active (Figure 6-1, p. 140).

CMS also uses pricing information from the CBP to adjust fee schedule payment rates for areas and channels not directly covered by the CBP. Pursuant to the American Taxpayer Relief Act of 2012, CMS sets the payment rates for non-mail-order diabetes testing supplies equal to the payment rate determined through the National Mail-Order Program beginning July 2013. Additionally, as required

by the Patient Protection and Affordable Care Act of 2010, CMS began in 2016 to use pricing information from the CBP to adjust the fee schedule payment rates in non-CBAs for DMEPOS items included in the CBP. DMEPOS items that are not included in the CBP, regardless of whether a beneficiary lives in a CBA or non-CBA, are still paid largely on a fee schedule basis.

Suppliers who furnish DMEPOS products included in the CBP must accept assignment (42 CFR § 414.408 (c)). For DMEPOS products not included in the CBP and CBP products used by beneficiaries who live outside a CBA, assignment is generally not mandatory. As a result, DMEPOS suppliers do not have to accept Medicare’s fee schedule rate as payment in full and may balance bill beneficiaries (i.e., bill beneficiaries for the difference between the fee schedule rate and what the supplier decides to charge for a given product). In contrast to other Part B services, there is currently no limit on balance billing for DMEPOS products. For example, physicians may balance bill only up to 115 percent of the allowed amount under the physician fee schedule.

Further, Medicare’s current payment policies do not encourage DMEPOS suppliers to enroll as participating suppliers. Participating suppliers accept assignment on all Medicare claims during the year, whereas nonparticipating suppliers are able to accept or reject assignment on a claim-by-claim basis. Under the physician fee schedule, Medicare reduces the allowed amount to 95 percent of the fee schedule rate for all nonparticipating providers, even if a particular claim is paid on an assignment basis. In contrast, no such payment reduction exists for nonparticipating DMEPOS suppliers.

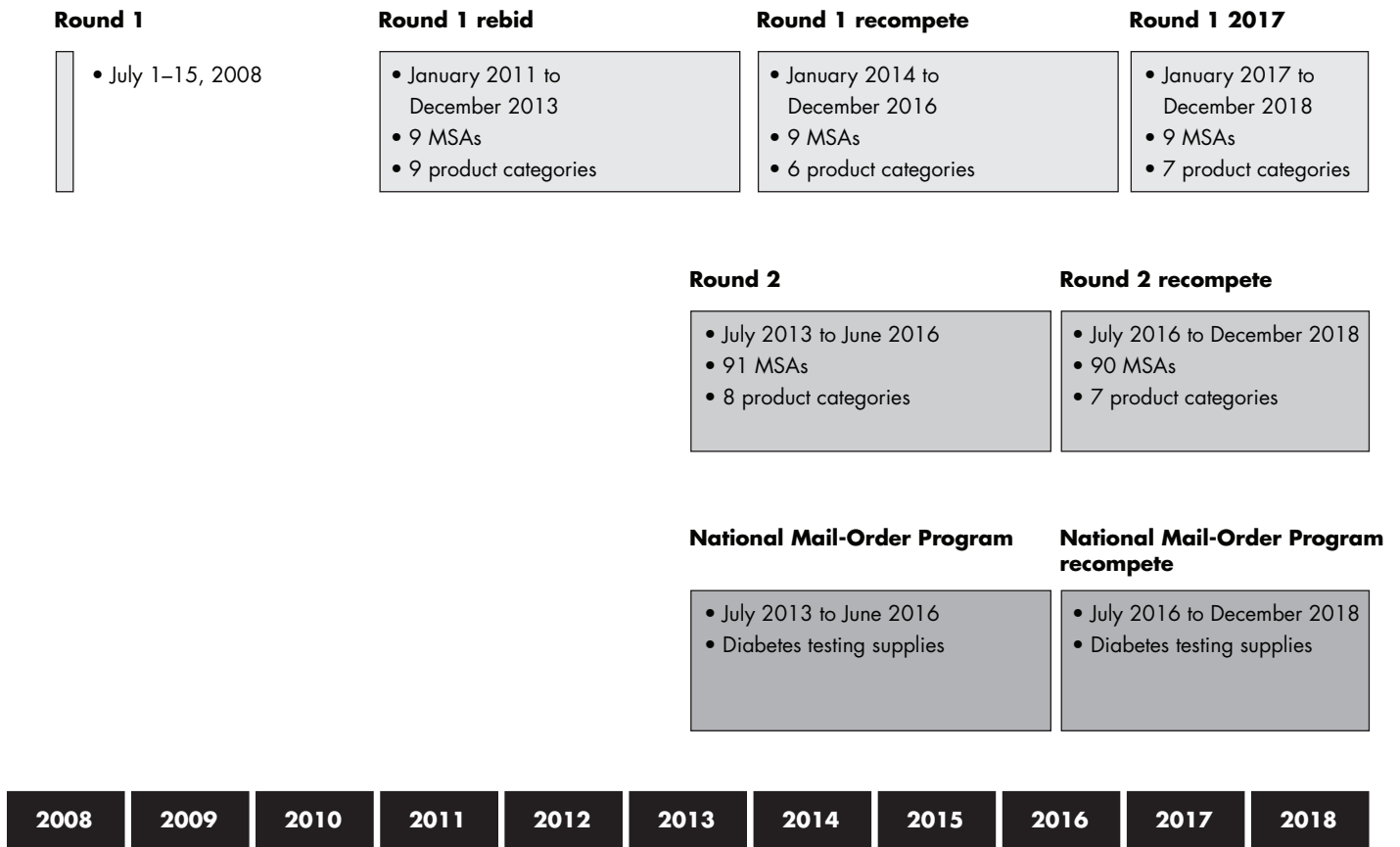
CBP structure

Suppliers are required to meet certain eligibility requirements to be considered for a contract under the CBP. For example, eligible suppliers are required to:

- be enrolled in Medicare and in good standing;
- be accredited by a CMS-approved accrediting organization;
- meet applicable state licensing requirements; and
- submit certain financial documents, including the suppliers’ most recent tax return, financial statements, and credit report (Competitive Bidding Implementation Contractor 2014b).

**FIGURE
6-1**

Time line of DMEPOS Competitive Bidding Program rounds, 2008–2018



Note: DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), MSA (metropolitan statistical area). Round 2 recomplete covers the same geographic areas that were included in Round 2. However, as a result of the Office of Management and Budget’s updates to the original 91 Round 2 MSAs, there are 90 MSAs for Round 2 recomplete. The specific DMEPOS items included in a product category may change between rounds.

Source: Government Accountability Office and CMS.

Eligible suppliers submit bids for one or more product categories in one or more CBAs. For example, a supplier could bid on the standard mobility product category in the Pittsburgh, PA, CBA. Product categories can comprise a number of individual products and can vary greatly in scope. For example, the standard mobility product category in CBP Round 1 2017 includes over 150 different Healthcare Common Procedure Coding System (HCPCS) codes, ranging from walkers to power and manual wheelchairs (Competitive Bidding Implementation Contractor 2017). Other product categories include fewer products. For example, in the same round, the

negative pressure wound therapy pump product category includes only three HCPCS codes (Competitive Bidding Implementation Contractor 2017).

CMS requires bids to be bona fide. To meet this criterion, suppliers should include in their bid the cost to purchase the item, overhead, and profit. Suppliers may be asked to submit a rationale and documentation to verify that they can furnish an item for the bid amount. For example, to prove that their bids are bona fide and that they can supply the products at the price stipulated in their bid, suppliers may be required to submit manufacturer

invoices, receipts (including retail sales receipts), manufacturer price lists, and signed written quotes. If an amount for any one of a bid's products is determined not to be bona fide, then the supplier's entire bid for the product category and CBA is rejected (Competitive Bidding Implementation Contractor 2014a).

In their bids, suppliers indicate the volume of a product they can provide in a given CBA and the price at which they are willing to supply the product. To select winning bids, composite bids are first constructed for each product category. To construct a composite bid, the price that each supplier provides in its bid is multiplied by a weight for each product. The weight for a product is based on the utilization of that item compared with other items within the product category based on historic Medicare claims (Centers for Medicare & Medicaid Services 2007).

Once the suppliers' composite bids are calculated, they are arrayed from least to most expensive. Winning suppliers are then selected, starting with the lowest cost bid, until the "pivotal bid" is reached. The pivotal bid is the lowest composite bid for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category (42 CFR § 414.402). All suppliers with composite bids at or below the pivotal bid are offered contracts.

After the winning composite bids are selected, payment rates are determined from among those bids. While winning bids are selected on a composite basis, payment rates are set at the individual HCPCS code level. Specifically, the payment rate for each HCPCS code—referred to as the single payment amount (SPA)—is derived from the median of all winning suppliers' bids for that specific item. The CBP ensures savings to the Medicare program and beneficiaries by requiring that the SPA for any product cannot exceed the fee schedule rate for the same product.

After CMS selects the winning composite bids and calculates SPAs, the agency offers contracts to the winning suppliers. Suppliers are not required to accept contract offers; that is, the bids are nonbinding.⁷ If suppliers accept a contract, they are referred to as contract suppliers. Beneficiaries living in CBAs must get DMEPOS products included in the CBP through contract suppliers, with a few exceptions.⁸

Except for the National Mail-Order Program and cases without a sufficient number of eligible suppliers, CMS

awards at least five contracts per product category and CBA (42 CFR § 414.414 (h)). Accordingly, CMS caps the share of the product category the agency expects a bidder to supply at a maximum of 20 percent of a given market's potential demand. For example, if a supplier's bid indicated that it could supply 70 percent of the demand for a given product category, CMS disregards the 70 percent and assumes that the supplier can supply only 20 percent of the market for the purposes of establishing the pivotal bid. Once contracts are awarded and suppliers begin serving beneficiaries, suppliers are not limited to any specific market share—that is, suppliers are free to compete with other suppliers that won contracts to supply as much of the market as possible.

CMS is also required by statute to ensure that small suppliers have an opportunity to participate in the CBP. To that end, CMS set a target for 30 percent of suppliers under the CBP to be small suppliers. CMS defines small suppliers as those with annual gross revenues of \$3.5 million or less, including Medicare and non-Medicare revenue (42 CFR § 414.402). If fewer than 30 percent of suppliers at or below the pivotal bid are small suppliers, then CMS offers contracts to small suppliers whose composite bids were above the pivotal bid in ascending order based on the proximity of each small supplier's composite bid to the pivotal bid. CMS continues making these offers until 30 percent of the suppliers are small suppliers or until there are no more small suppliers who submitted composite bids for the product category (42 CFR § 414.414 (g)(1)).

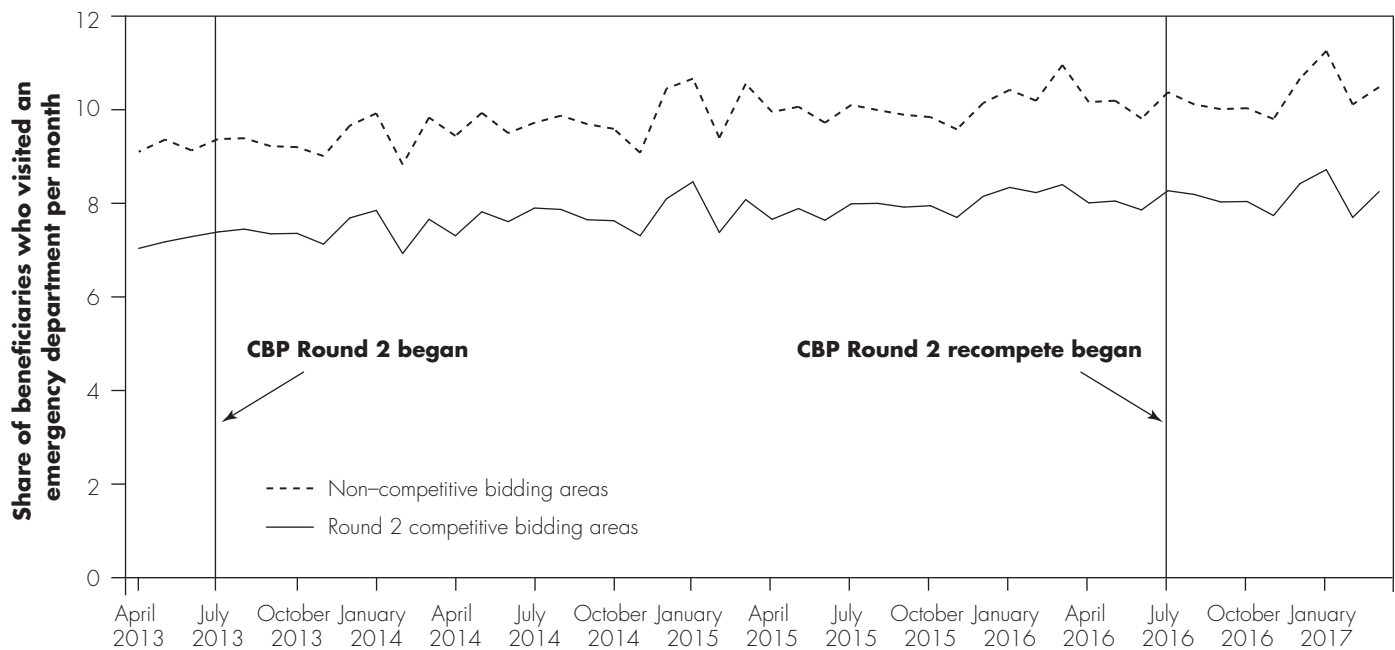
Subsequent to the awarding of contracts, CMS also has the discretion to award additional contracts if the agency determines that more suppliers are needed to meet beneficiary demand. To do so, CMS refers to the original arrayed list of composite bids for a product category and offers contracts to suppliers whose composite bids were closest to the pivotal bid. These additional contracts are offered on the same terms and conditions as those awarded to other winning suppliers (42 CFR § 414.414 (i)(1)).

Health status monitoring

Concurrent with the implementation of the CBP, CMS instituted a real-time claims monitoring system that is designed to analyze changes in several key secondary indicators of beneficiary access to medically necessary DMEPOS products—mortality rates, monthly hospital admission rates, monthly emergency room rates, monthly physician visit rates, monthly skilled nursing facility

**FIGURE
6-2**

Emergency department use among beneficiaries likely to need home oxygen was lower in Round 2 competitive bidding areas compared with non-competitive bidding areas (West region)



Note: CBP (Competitive Bidding Program).

Source: CMS health status monitoring data, March 2017 update.

admission rates, average monthly days in a hospital, and average monthly days in a skilled nursing facility.⁹ CMS analyzes these data for each product category and CBA for multiple cohorts of beneficiaries—all fee-for-service (FFS) beneficiaries, beneficiaries who have a claim for one of the CBP products in a given time period, and beneficiaries who are likely to use one of the CBP products on the basis of related health conditions (Centers for Medicare & Medicaid Services 2017b). These data are analyzed multiple times each month using an algorithm designed to identify potential changes in health outcomes (Government Accountability Office 2016). If potential problems are identified in utilization or outcome changes, CMS discusses them internally and has the ability to follow up to determine the specific cause. For example, CMS’s monitoring revealed declines in the use of mail-order blood glucose test strips and continuous positive airway pressure (CPAP) device supplies in certain Round 1 CBAs, so CMS conducted 300 calls to beneficiaries who stopped using the supplies after the CBP was implemented. CMS found that, in virtually

every case, the beneficiary reported having more than enough supplies on hand, often multiple months’ worth, which suggests that beneficiaries had historically received excessive replacement supplies before they were medically necessary (Wilson 2012). Based on the results of the monitoring system, CMS has said that no negative changes in beneficiary health outcomes have resulted from the CBP (Centers for Medicare & Medicaid Services 2017b).

CMS publicly posts aggregated data from its health status monitoring program. In the public data, the results are aggregated by region—Midwest, Northeast, South, and West. The data are also stratified by whether a beneficiary lives in one of the CBP Round 1 areas, Round 2 areas, or a non-CBA. For example, Figure 6-2, using the publicly available data, shows the trend in the share of Medicare FFS beneficiaries who visited an emergency department in each month from April 2013 through March 2017 and had a diagnosis in claims data indicating a potential need for home oxygen (e.g., chronic obstructive pulmonary disease). The data in the figure are limited to beneficiaries

who lived in the West region and are stratified by whether a beneficiary lived in a Round 2 CBA or a non-CBA. The figure reveals several patterns. First, the use of health care services varies across geographic areas, likely for reasons beyond the CBP. In this case, emergency department use was actually lower in CBAs compared with non-CBAs, a trend that also held in the other three geographic regions.¹⁰ Second, there appeared to be a secular trend of higher emergency department use; that is, emergency department use appeared to be increasing for all beneficiaries during the period from 2013 to 2017. In fact, the Commission has documented that emergency department use had been growing for the Medicare population even before the implementation of the CBP (See Chapter 1 of this report). Given these observations, Figure 6-2 does not suggest that a major increase in emergency department utilization occurred among beneficiaries likely to need home oxygen in the months after either of the CBP Round 2 competitions began.

Price and utilization changes under the CBP

The payment rates for DMEPOS products have declined substantially since the CBP's implementation. Among the 25 highest expenditure DMEPOS products included in the CBP (based on 2015 Medicare expenditures), the median payment rate decrease was 53 percent from 2010 (the year before the CBP began) to the most current CBP round, which is CBP Round 1 2017 for most products. Among these 25 products, price declines ranged from 25 percent for certain standard power wheelchairs (HCPCS code K0823) to 75 percent for blood glucose test strips (HCPCS code A4253) (Table 6-2, p. 144).

Utilization of DMEPOS products included in the CBP declined more in CBAs compared with non-CBAs after the implementation of competitive bidding. In a 2016 report, GAO analyzed the change in the number of beneficiaries utilizing a particular product and number of items received in the year before and after the implementation of CBP Round 2 in July 2013. GAO found that the number of beneficiaries receiving a product included in CBP Round 2 declined by 17 percent in CBAs compared with 6 percent in non-CBAs (Government Accountability Office 2016).¹¹ The utilization changes varied substantially among the eight product categories included in CBP Round 2. Seven of eight product categories saw declines in the number of beneficiaries receiving products after the CBP was implemented, and most of the declines were larger than the declines for the same products in non-CBAs. For example, the

number of beneficiaries receiving hospital beds declined 37 percent for CBAs and 28 percent for non-CBAs after CBP Round 2 was implemented (Government Accountability Office 2016). For one product category—CPAPs—both the number of beneficiaries and items received increased in both CBAs and non-CBAs after implementation of CBP Round 2. Specifically, after CBP Round 2 was implemented, the number of CPAP items received in CBAs increased by 25 percent compared with a 17 percent increase in non-CBAs (Government Accountability Office 2016).

Critiques of the CBP

The DMEPOS industry, economists, and others have criticized the CBP. The criticisms generally fall into three categories—criticisms of the CBP's structure, how CBP information is used to adjust fee schedule payment rates in non-CBAs, and the structure of the health status monitoring program. Regarding the CBP's structure, the four main critiques are that:

- the bids are nonbinding (i.e., a supplier can win a bid and then reject the contract);
- SPAs are set using the median price of all winning bids as opposed to the price of the pivotal bid (i.e., the market-clearing price);
- composite bids are used; and
- the program lacks transparency (167 Concerned Auction Experts on Medicare Competitive Bidding Program 2010).

Critics of the CBP contend that these issues, especially the first two, will have several negative consequences. First, they suggest that using nonbinding bids encourages “low-ball” bids whereby suppliers bid at unreasonably low rates to ensure that they are offered a contract. Then, after the SPAs are announced, the low-ball bidders can decline the contract. Second, using the median of winning bids to set SPAs results in half of winning bidders being offered contracts at prices less than their bids, which could result in many suppliers rejecting contracts or supplying products at a loss.¹² In addition, critics suggest that using the median of winning bids further encourages low-ball bids, since a low bid increases the chances of a supplier being offered a contract but has a modest effect on the SPA. In total, critics of the CBP believe that these design issues will lead to supply shortages, as suppliers refuse to offer unprofitable products, and a deterioration in the quality

**TABLE
6-2**

Change in Medicare payment rates from 2010 to current round of CBP for 25 highest expenditure DMEPOS products included in the CBP

HCPCS code	Description	Total Medicare expenditures (in millions) (2015)	Median Medicare fee schedule payment rate (2010)	Median competitive bidding single payment amount (2017)	Percent change in payment rate
E1390	Oxygen concentrator	\$1,216	\$173	\$79	-55%
A4253	Blood glucose test strips	311	33	8	-75
E0601	Continuous positive airway pressure (CPAP) device	205	101	42	-58
A7030	Full face mask used with positive airway pressure device	151	171	90	-47
A7034	Nasal interface used with positive airway pressure device	128	106	56	-47
E2402	Negative pressure wound therapy electrical pump	112	1,553	659	-58
A7031	Face mask interface, replacement for full face mask	94	63	34	-46
E0431	Portable gaseous oxygen system	91	29	17	-40
E0260	Hospital bed, semi-electric, with any type side rails, with mattress	89	127	60	-53
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface (e.g., facial mask)	85	232	109	-53
A7032	Cushion for use on nasal mask interface, replacement only	82	37	19	-47
B4035	Enteral feeding supply kit	78	11	5	-53
E0562	Humidifier, heated, used with positive airway pressure device	76	273	140	-49
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface (e.g., facial mask)	66	581	276	-53
K0823	Power wheelchair, group 2 standard, captain's chair, patient weight capacity up to and including 300 pounds	57	364	273	-25
B4152	Enteral formula, nutritionally complete, calorically dense	53	0.54	0.30	-44
E0143	Walker, folding, wheeled, adjustable or fixed height	52	109	48	-56
A7033	Pillow for use on nasal cannula type interface, replacement only	50	26	16	-39
A7035	Headgear used with positive airway pressure device	48	36	18	-50
A7037	Tubing used with positive airway pressure device	46	37	12	-68
K0001	Standard wheelchair	45	56	26	-54
E0570	Nebulizer, with compressor	43	17	7	-56
B4154	Enteral formula, nutritionally complete, for special metabolic needs	43	1.18	0.68	-42
B4150	Enteral formula, nutritionally complete	42	0.65	0.37	-43
A7038	Filter, disposable, used with positive airway pressure device	38	4.83	2.00	-59

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System). Numbers may be rounded. The unit of payment for the payment rates listed in the table varies (e.g., per month, per device, etc.). Some HCPCS code descriptions are shortened for brevity. All CBP prices were based on Round 1 2017 single payment amounts except A4253, which was based on the National Mail-Order Program recompute. Fee schedule rates for 2010 were calculated as a median of the state-level payment amounts except enteral nutrition codes, which were based on a national fee schedule. HCPCS codes E1007, A4221, and E0784 were excluded from this table because they were excluded from the current rounds of competitive bidding (Round 2 recompute and Round 1 2017).

Source: MedPAC analysis of CBP single payment amounts, 2015 Physician/Supplier Procedure Summary file, and DMEPOS and parenteral and enteral nutrition fee schedules.

of products, as suppliers engage in a “race to the bottom” to offer only the cheapest products to beneficiaries (167 Concerned Auction Experts on Medicare Competitive Bidding Program 2010).¹³ If beneficiaries cannot access

needed DMEPOS products, CBP critics contend that Medicare costs might actually increase as beneficiaries seek care in more expensive settings (e.g., hospitals) (Crampton et al. 2015).

The DMEPOS industry has also criticized the use of information from the CBP to set prices in non-CBAs. Non-CBAs generally consist of small and moderate-size urban areas and rural areas. The primary criticism is that applying CBP rates to non-CBAs is inappropriate because the CBP's design flaws result in prices that are artificially low. Critics also contend that suppliers in non-CBAs cannot accept CBP payment rates because they cannot serve the volume of beneficiaries that suppliers in CBAs do because CBAs have higher populations and the number of suppliers in CBAs is limited based on the number of contracts awarded. Finally, critics suggest that the cost to supply DMEPOS products can be higher in rural areas (e.g., higher costs to deliver products in more remote locations) (American Association for Homecare 2017).

Critics of the CBP have alternately criticized CMS's health status monitoring program but then also used the program's data to suggest that beneficiaries living in CBAs are negatively affected by the CBP. One criticism is that not all beneficiaries who might need DMEPOS products are tracked because of relatively short look-back periods used to identify beneficiaries as having a specific diagnosis (Lewis 2012). For example, CMS tracks outcomes for beneficiaries with diabetes to ensure diabetics have sufficient access to diabetes testing supplies, which are included in the National Mail-Order Program. CMS defines diabetics by searching through FFS claims for four months—the month for which the outcome is measured and three previous months. Critics contend that this four-month look-back period is insufficient because many diabetics might not have generated a claim in the previous four months. Other criticisms of the health status monitoring program include the lack of transparency, unsteady cohorts (i.e., the beneficiaries tracked by CMS change over time), and lack of a matched control group (National Minority Quality Forum 2015). While some stakeholders have criticized CMS's health status monitoring program as inadequate, other industry representatives have asserted that these same data contradict the agency's claims of no negative health outcomes related to the CBP. For example, industry representatives have pointed to the increase in emergency department use among diabetics to suggest that diabetics do not have sufficient access to diabetes testing supplies. However, we have seen emergency department use increase among both beneficiaries with diabetes and those without diabetes. Also, as we note in the readmissions chapter (Chapter 1) in this report, emergency department

use had been growing for the Medicare population before the implementation of the CBP, so increasing emergency department use appears to be a secular trend with many likely contributing factors beyond the CBP.

Non-CBP DMEPOS products

In 2015, non-CBP products represented \$4 billion in Medicare spending, nearly half of all Medicare spending on DMEPOS. Unlike products under the CBP, payment rates for non-CBP products are not routinely evaluated for accuracy, and the payment rate for many products continues to be based on historical supplier charges. As a result, some non-CBP products are likely mispriced. As was seen before CMS instituted the CBP in 2011, mispriced DMEPOS products can lead to rapid growth in expenditures, inappropriately high utilization, and potential fraud and abuse.

There are a large number of non-CBP DMEPOS products, but spending is concentrated among relatively few of them. While the number of products varies over time, Medicare paid suppliers for roughly 1,500 non-CBP DMEPOS products in each year from 2010 through 2015, compared with about 400 DMEPOS products that have ever been included in the CBP. Average spending per product is lower for non-CBP DMEPOS products compared with CBP products, reflecting the fact that CMS included higher expenditure DMEPOS products in the CBP first. Notwithstanding the lower average, a relatively small number of non-CBP products have substantial expenditures associated with them and account for a disproportionate share of the total non-CBP DMEPOS spending. For example, the top 25 products in spending represented about half of the \$4 billion in non-CBP DMEPOS spending in 2015 (Table 6-3, p. 146).

Rapid growth in expenditures for non-CBP DMEPOS products

In contrast to the rapid decline in spending for products included in the CBP, Medicare spending on non-CBP products has grown. Since the implementation of competitive bidding, non-CBP DMEPOS products have more commonly experienced rapid growth in expenditures compared with CBP products. For example, among all DMEPOS products with at least \$10 million in expenditures in 2015, 9 of the 10 products with the fastest growth in expenditures from 2014 to 2015 were

**TABLE
6-3**

The 25 highest expenditure non-competitively bid DMEPOS products, 2015

HCPCS code	Total Medicare expenditures (in millions)	Product description
E0464	\$343	Pressure support ventilator used with non-invasive interface (e.g., mask)
K0606	179	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type
A4351	133	Intermittent urinary catheter, straight tip
L0650	114	Lumbar-sacral orthosis, off-the-shelf
L1833	105	Knee orthosis, off-the-shelf
A4352	103	Intermittent urinary catheter, curved tip
E0748	97	Osteogenesis stimulator, electrical, non-invasive, spinal applications
B4197	90	Parenteral nutrition solution, 74 to 100 grams of protein
A5500	76	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe
E0463	69	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)
L0648	63	Lumbar-sacral orthosis, off-the-shelf
A5513	54	For diabetics only, multiple density insert, custom fabricated
A4353	54	Intermittent urinary catheter, with insertion supplies
L5673	53	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated
A5512	50	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, prefabricated
L5301	47	Below knee, molded socket, shin, SACH foot, endoskeletal system
K0861	43	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds
B4199	42	Parenteral nutrition solution, over 100 grams of protein
L0637	41	Lumbar-sacral orthosis, prefabricated item that has been customized to fit a specific patient by an individual with expertise
L5856	40	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s)
A6021	39	Collagen dressing, sterile, size 16 sq. in. or less
L5700	38	Replacement, socket, below knee, molded to patient model
B4193	38	Parenteral nutrition solution, 52 to 73 grams of protein
A4407	35	Ostomy skin barrier, with flange, extended wear, with built-in convexity, 4x4 inches or smaller
E0483	31	High frequency chest wall oscillation air-pulse generator system

Note: DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), SACH (solid ankle cushion heel). Expenditures are rounded and include beneficiary cost sharing. Some HCPCS code descriptions are shortened for brevity.

Source: MedPAC analysis of 2015 Physician/Supplier Procedure Summary file.

non-CBP products, with the lone CBP product being tubing commonly used in conjunction with CPAP devices (A4604). Among the 25 highest expenditure non-CBP DMEPOS products, Medicare spending from 2014 to 2015 grew 21 percent. Several non-CBP products grew even faster than this average, such as back braces (see text box on off-the-shelf orthotics).¹⁴

The growth in expenditures for these products is largely due to growth in utilization; the increases in payment rates and number of Part B FFS beneficiaries between 2014 and 2015 were modest.¹⁵ These large, one-year growth rates were also not likely driven by changes in beneficiary health, given that the relative health status of the Medicare population is unlikely to change substantially over such a

Rapid growth and potentially inappropriate utilization of off-the-shelf orthotics

Broadly, the orthotics market can be separated into three segments—off-the-shelf, custom-fitted, and custom-fabricated products. Off-the-shelf orthotics are prefabricated products that require minimal self-adjustment for appropriate use (42 CFR § 414.402). Custom-fitted orthotics are also prefabricated but require substantial modification by a certified orthotist or someone with equivalent training. Custom-fabricated orthotics are the most individualized type of orthotic and are individually fabricated for the patient.

Medicare spending on off-the-shelf orthotics has grown rapidly in the last several years. From 2014 to 2016, Medicare expenditures on off-the-shelf orthotics roughly doubled, from \$255 million to \$547 million. There are currently over 50 off-the-shelf products payable by Medicare, but spending is concentrated on relatively few products. For example, in 2016, spending for one back brace product (Healthcare Common Procedure Coding System code L0650) was \$190 million and for one knee brace product (L1833) was \$107 million. Expenditures for these two codes also grew rapidly. From 2014 to 2016, Medicare expenditures for the back brace product grew by 311 percent (from \$46 million to \$190 million), while expenditures for the knee brace product grew by 81 percent (from \$59 million to \$107 million).

Given the rapid growth in expenditures for off-the-shelf orthotics, we examined in greater depth one type of prefabricated back brace with high Medicare spending for signs of inappropriate utilization.¹⁶ We identified several patterns involving physicians and suppliers suggesting that a meaningful portion of the increased use of off-the-shelf orthotics since 2014 could represent supplier-induced demand or even potential fraud and abuse.

- ***A limited number of physicians ordered a disproportionate share of back braces.*** In 2016, over 50,000 physicians ordered at least one of the back braces we examined for a Medicare fee-for-service (FFS) beneficiary. However, only 25 physicians ordered 20 percent of all such braces in 2016.
- ***Physicians ordered braces for beneficiaries without billing Medicare for other services.*** The 25 top-ordering physicians ordered back braces for roughly 38,000 FFS beneficiaries in 2016. These physicians billed Medicare for other physician services, such as an office visit or surgical procedure, for less than 1 percent of these beneficiaries. In contrast, we randomly sampled roughly 500 physicians who ordered at least one back brace in 2016 but were not among the top 100 physicians in terms of back braces ordered and found that the physician who ordered the brace also billed a physician service for the same beneficiary over 80 percent of the time.
- ***Physicians ordered braces for beneficiaries from across the country.*** Many top-ordering physicians ordered back braces for beneficiaries from across the country. For example, in 2016, one physician ordered at least 100 of the back braces we studied for beneficiaries who resided in 9 geographically distant states—California, Connecticut, Florida, Indiana, Maryland, Massachusetts, New York, Ohio, and Virginia.
- ***Top-ordering physicians have a history of disciplinary actions.*** Of the 12 physicians who ordered the highest number of back braces in 2016, we identified 9, or 75 percent, who had previously been disciplined by at least one state medical board or were under investigation when their medical license expired. In contrast, in 2015, less than 0.5 percent of the general population of physicians was sanctioned by a state medical board.¹⁷ Among the top-ordering physicians, the severity of the actions that triggered state medical boards to act ranged from submitting false or misleading information on their medical license applications to participating in inappropriate referral schemes. For example, one top-ordering physician was put on probation for participating in a referral scheme in which she was paid \$30 per patient to speak with patients over the phone and then write prescriptions for pharmaceuticals.

(continued next page)

Rapid growth and potentially inappropriate utilization of off-the-shelf orthotics (cont.)

- **Suppliers were concentrated in Florida.** Roughly 7 percent of Medicare FFS beneficiaries reside in Florida. However, roughly 30 percent of the spending increase from 2014 to 2016 on the back brace product we studied was attributable to suppliers located in Florida. Suppliers located in Florida have a history of elevated rates of fraud and abuse.
- **Suppliers—especially new ones—drove the increase in expenditures.** In 2016, suppliers of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) furnished two-thirds of the back braces we studied, while physicians, physical therapists, and orthotists furnished most of the remaining third. From 2014 to 2016, DMEPOS suppliers accounted for over 80 percent of the growth in Medicare expenditures on the back brace products we studied, while the growth attributable to physicians, physical therapists, and orthotists was much smaller. Among the 25 suppliers with the highest Medicare expenditures for the back brace product we studied in 2016, 18 of them did not bill Medicare for those products in 2014.

The physicians who are driving the increasing utilization appear to be ordering braces for beneficiaries with whom they have a limited

relationship (based on their lack of Medicare claims and the geographic distance between the physicians and beneficiaries) from suppliers who often ship their products to beneficiaries (based on the geographic distance between suppliers and beneficiaries). Based on a review of several telehealth companies' websites and other public documents, we found that several of the top back brace-ordering physicians were employed by telehealth companies. All of this information appears to be consistent with the existence of supplier-funded telehealth arrangements that some industry analysts have warned could violate the anti-kickback statute (Baird 2016). Under one type of such arrangement, a supplier pays a lead-generation company to recruit Medicare beneficiaries who might want a back brace (e.g., through television advertising); the lead-generation company pays a telehealth company; the telehealth company pays a physician to conduct a telehealth visit with beneficiaries; the physician orders back braces; and suppliers ship the braces to beneficiaries and bill Medicare. This nexus of relationships between certain physicians, telehealth companies, lead-generation companies, and suppliers who predominantly mail orthoses to their customers appears to be driven more by financial considerations than by clinical ones. Independent of including orthoses in the Competitive Bidding Program, policymakers may want to consider policies designed to limit such practices. ■

short time period. Given these facts, some of the growth in utilization could be supplier induced and represent potentially inappropriate utilization.

Improper payment rates and potential fraud and abuse

In addition to rapid expenditure growth, many non-CBP DMEPOS products tend to have high improper payment rates, and some have been involved in cases of fraud and abuse over the last several years.

While all payments made as a result of fraud are considered “improper payments,” not all improper

payments are fraudulent. In fact, improper payments typically do not involve fraud. Rather, insufficient documentation errors caused the vast majority (80.4 percent) of improper payments for DMEPOS in 2016 (Centers for Medicare & Medicaid Services 2016d). Claims are placed into this category when the documentation submitted is inadequate to support payment for the services billed. For example, a few of the more common missing pieces of documentation for DMEPOS products include an order form for the product, a certificate of medical necessity, and a physician evaluation (Centers for Medicare & Medicaid Services 2016d). Even

though improper payments are predominantly not related to fraud, such high rates of improper payments make it difficult to determine whether all DMEPOS utilization is appropriate.

Compared with other Part B services, DMEPOS products are prone to high improper payment rates.¹⁸ As part of its Comprehensive Error Rate Testing (CERT), CMS found the improper payment rate for all DMEPOS products to be 46.3 percent compared with 11.7 percent for all other Part B services in 2016 (Centers for Medicare & Medicaid Services 2016d). Several categories of non-CBP DMEPOS products had improper payment rates above the already high DMEPOS average. For example, shoes designed to be worn by diabetics had an improper payment rate of 64.0 percent, and surgical dressings had an improper payment rate of 84.3 percent (Centers for Medicare & Medicaid Services 2016d). In addition to the CERT report, DME Medicare administrative contractors (MACs) have also initiated targeted service-specific prepayment reviews (Centers for Medicare & Medicaid Services 2017d). The results of these service-specific reviews generally substantiate the CERT findings that DMEPOS products are prone to high improper payment rates. For example, from January through April 2017, one MAC found that the potential improper payment rate was 89 percent or higher for several non-CBP DMEPOS products—parenteral nutrition (Healthcare Common Procedure Coding System code B4197), diabetic shoes (A5500), off-the-shelf back braces (L0650), and off-the-shelf knee braces (L1833) (Noridian Healthcare Solutions 2017a, Noridian Healthcare Solutions 2017b, Noridian Healthcare Solutions 2017c, Noridian Healthcare Solutions 2017d). The text box (p. 151) describes some policy options, beyond competitive bidding, to reduce potentially inappropriate utilization of DMEPOS products.

While documented cases of fraud are far less common than improper payments, there have been several documented fraud cases involving non-CBP DMEPOS products in recent years. One high-profile case of fraud and abuse involved bone growth stimulators. Bone growth stimulators, or osteogenesis stimulators, are used to promote bone healing in difficult-to-heal fractures or fusions by applying electrical or ultrasonic current to the site of the fracture or fusion. As part of a settlement announced in December 2012, the government detailed how one large manufacturer of bone growth stimulators obstructed a federal audit and manipulated certificates of medical necessity, including having its employees fill out the entire form and forging physician signatures

(Department of Justice 2012). The case also saw several company employees (including company officers ranking as high as a vice president of sales) and providers plead guilty to or be convicted of charges including paying kickbacks to induce providers to prescribe the company's products, falsifying beneficiary medical records to fraudulently induce Medicare to pay for the company's bone growth stimulators, and making a false statement to a grand jury (Department of Justice 2014, Department of Justice 2012).

Potentially excessive payment rates

Excessive payment rates can lead to inappropriately high utilization and expenditure growth and encourage potential fraud and abuse. To examine whether any of the highest expenditure non-CBP DMEPOS products had excessive payment rates, we evaluated Medicare's payment rates for the 10 highest expenditure non-CBP DMEPOS products in 2015. To do so, we reviewed CMS's payment policy changes since 2015 (if any) that were made to address overpriced products and compared Medicare's payment rates with private-payer rates and direct-purchase prices for two orthoses. The results suggest that Medicare is substantially overpaying for many non-CBP DMEPOS products.

Comparison to private-payer rates

To compare Medicare rates with private-payer rates, we first determined the median Medicare payment rate for each non-CBP DMEPOS product because payment rates can vary by state. We then calculated the median payment rate from a private-payer database.¹⁹ Finally, we compared these two rates to determine the difference and the amount Medicare and beneficiaries would have saved if Medicare had paid for the DMEPOS product at the median private-payer rate in 2015.

The median Medicare payment rate was higher than the comparable private-payer rate in 2015 for 9 of the top 10 non-CBP DMEPOS products. For those nine products, we found Medicare's median payment rates were 18 percent to 57 percent higher than median private-payer rates. In dollars, Medicare's median payment rates ranged from \$0.60 higher per item for one type of catheter to over \$1,100 higher per item for one type of bone growth stimulator (Table 6-4, p. 150).

For two ventilator products, we found Medicare's payment rates were higher than private-payer rates in 2015, but CMS lowered the payment rates in 2016. (For

**TABLE
6-4**

Comparison of private-payer rates to Medicare rates for the 10 highest expenditure non-CBP DMEPOS products, 2015

HCPCS code	Product description	Median private payer rate	Median Medicare fee schedule rate	Percentage more (or less) Medicare paid relative to private-payer rate	Potential savings if Medicare paid median private-payer rate (in millions)
E0464	Pressure support ventilator used with non-invasive interface (e.g., mask)	\$1,153	\$1,561	35%	\$89
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	2,945	2,795	(5)	N/A
A4351	Intermittent urinary catheter, straight tip	1.33	1.93	45	41
L0650	Lumbar-sacral orthosis, off-the-shelf	877	1,130	29	25
L1833	Knee orthosis, off-the-shelf	436	650	49	34
A4352	Intermittent urinary catheter, curved tip	4.55	7.13	57	37
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications	3,191	4,318	35	25
B4197	Parenteral nutrition solution, 74 to 100 grams of protein—premix	260	322	24	17
A5500	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe	60	71	18	11
E0463	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)	1,125	1,561	39	19

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). Some of the figures are rounded. Because of data limitations, we were unable to determine the specific month of the capped rental period for K0606 in the private-payer data, which can affect the payment rate. Given this limitation and the fact that most Medicare beneficiaries use K0606 for three or fewer months, all private claims for K0606 were assumed to be from the first three months, which means that the private-payer rate in the above table is likely a lower bound in terms of comparing the rate to the Medicare payment rate for the first three months.

Source: MedPAC analysis of 2015 MarketScan Commercial Claims and Encounters Database; 2015 Medicare durable medical equipment and parenteral and enteral nutrition fee schedules; and 2015 Physician/Supplier Procedure Summary File.

more information, see the text box on payment rates for ventilators, p. 152.) For one product, a wearable automatic external defibrillator (AED), the Medicare and private-payer rates were relatively comparable. For the remaining seven products, roughly \$192 million dollars would have been saved in 2015 if Medicare paid the median private-payer rate for all such products—approximately \$154 million in savings for the Medicare program and \$38 million in savings for beneficiaries.

Medicare could likely save substantially more than \$192 million per year if non-CBP DMEPOS products' payment rates were set more appropriately, for two reasons. First, private-payer rates for some products outside the top 10 non-CBP DMEPOS products are lower compared with Medicare's payment rates. Second, in some instances,

Medicare could likely achieve a lower payment rate compared with private-payer rates; that is, private-payer rates likely represent an upper bound on appropriate Medicare DMEPOS payment rates.

Medicare's payment rates for some non-CBP DMEPOS products outside the top 10 highest expenditure products are higher than private-payer rates. For example, the two off-the-shelf orthotic codes included in Table 6-4 represented approximately \$218 million of the \$433 million in Medicare expenditures on off-the-shelf orthotics in 2015. For the remaining off-the-shelf orthotic codes with at least \$1 million in Medicare expenditures in 2015, we found that Medicare's payment rates ranged from 20 percent to 50 percent higher compared with private-payer rates and that Medicare would have saved an additional

Efforts to reduce potentially inappropriate utilization

In addition to implementing the competitive bidding program (CBP), CMS over the last several years has implemented broader initiatives that could reduce the rate of potentially inappropriate utilization, such as taking additional steps to identify aberrant or suspicious billing patterns among all Medicare fee-for-service claims before making payments and implementing new safeguards to better screen existing and new Medicare suppliers (Government Accountability Office 2016). Some have suggested expanding certain efforts to cover a broader range of products. Three examples of initiatives that could be expanded include:

- **Prior authorization.** Prior authorization is a process through which suppliers request a preliminary determination from CMS that a product is covered before submitting an actual claim. One advantage of prior authorization is that it stops many improper payments before they are made, instead of trying to recoup payments after they are made. CMS currently maintains a list of durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) products that could be subject to prior authorization, referred to as the “master list.” To be added to the master list, products must have an average fee schedule purchase price of \$1,000 or greater, or an average rental fee schedule of \$100 or greater (adjusted annually for inflation), and have been identified by the Office of Inspector General, Government Accountability Office, or CMS as susceptible to high rates of fraud, unnecessary utilization, or improper payments (42 CFR § 414.234).²⁰ From among the products on the master list, CMS has required prior authorization nationally for two power wheelchair products (Healthcare Common Procedure Coding System (HCPCS) codes K0856 and K0861) since July 2017. Separate from the national prior authorization process for these two codes, CMS has been running the Prior Authorization of Power Mobility Devices Demonstration since 2012. For the original seven states included in the demonstration, Medicare expenditures fell from roughly \$12 million per month to \$3 million per month one year after implementation and remained relatively steady thereafter (Centers for Medicare & Medicaid Services 2015c). Because prior authorization disproportionately affects suppliers who furnish products inappropriately, such a process could help reduce improper payment rates.
- **Face-to-face visits.** CMS requires face-to-face visits for some DMEPOS items, such as certain hospital beds, but not for others (e.g., knee or back braces).²¹ To meet the requirement, a physician, physician assistant, nurse practitioner, or a clinical nurse specialist must have had a face-to-face encounter with the beneficiary on the date the DMEPOS item was ordered or within six months before such date (42 CFR § 410.38(g)). The intent of requiring a face-to-face visit for certain items is to ensure that a beneficiary needs a particular DMEPOS product, based on a needs assessment conducted by a physician or other practitioner, before a product is dispensed.
- **Pricing, Data Analysis, and Coding (PDAC) contractor letters.** Among other duties, the PDAC contractor provides coding guidance to manufacturers on the proper use of HCPCS codes. Manufacturers submit a product to the PDAC contractor, and within 90 days the contractor issues a coding verification letter that delineates the HCPCS code(s) under which a product is billable. Some DMEPOS items already require a PDAC letter before suppliers can bill for them while others do not. Requiring PDAC letters for a broader array of items could represent a modest step to help limit “upcoding”—that is, suppliers furnishing a relatively inexpensive product and then submitting a claim for a more expensive product. ■

\$55 million in 2015 if Medicare’s payment rates were equal to the median private-payer rate of the comparable product.²² Other families of products, including bone growth stimulators, catheters, parenteral nutrition, and

diabetic shoes/inserts, also have products not included in Table 6-4 for which Medicare could have achieved additional savings if Medicare’s payment rates were lowered to private-payer rates.

CMS revised the payment rates for ventilators in 2016

In 2015, 2 of the 10 highest expenditure durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) products excluded from Medicare's Competitive Bidding Program (CBP) were ventilators (Healthcare Common Procedure Coding System (HCPCS) codes E0464 and E0463). Billing for these products grew rapidly from 2010 through 2015. For example, Medicare expenditures for noninvasive pressure support ventilators (E0464) grew from \$9 million to \$343 million over that time period, an average annual growth rate of 107 percent. In a 2016 report, the Office of Inspector General noted that the rise in ventilator billing was related to a change in technology that allowed the same machine to function as a ventilator, continuous positive airway pressure (CPAP) device, or respiratory assist device (RAD) (Office of Inspector General 2016). Compared with ventilators, CPAPs and RADs are used to treat lower acuity patients.

Beginning in 2016, CMS changed the way it paid for ventilators by collapsing five ventilator HCPCS codes into two codes (Centers for Medicare & Medicaid Services 2015b). Specifically, in 2015, CMS was paying for five ventilator HCPCS codes using two different

methodologies. Since being added to the fee schedule in 2005, the payment rates for E0464 and E0463 were based on manufacturer suggested retail prices; these codes were intended to represent specific types of ventilators, such as those used by pediatric patients. In contrast, the payment rates for the older ventilator codes were based on supplier charges from 1986 to 1987. The latter payment method resulted in substantially lower payment rates. As evidence of abuse related to the newer, higher paid codes (E0464 and E0463) mounted, CMS, beginning in 2016, used its authority to base DMEPOS payment rates on 1986–1987 supplier charges for all ventilators. Between 2015 and 2016, this change resulted in the median monthly rental rate for products historically billed under E0464 and E0463 going from \$1,561 to \$1,055, a reduction of 32 percent.

While the change reduced overpayments, it is unclear whether the new payment rates represent appropriate prices. Specifically, the payment rates are still based on supplier charges that are 30 years old, updated over time for inflation. CMS proposed including noninvasive pressure support ventilators in CBP Round 1 2017 but removed the product before the round began. ■

While private payers might have negotiated payment rates that were lower than Medicare for products excluded from the CBP, private-payer rates might not represent the best price that Medicare could achieve. Recent research suggests that average CBP Round 1 rebid payment rates were 8.1 percent lower than commercial prices for several common DMEPOS products (Newman et al. 2017). Further, Medicare's payment rates generally continued to fall in subsequent CBP rounds. To further illustrate the point that private-payer rates likely represent an upper bound on Medicare rates, we looked at the direct-purchase price—that is, the price at which beneficiaries could purchase a DMEPOS product outside of insurance coverage—for two off-the-shelf orthotic codes.

Direct-purchase price for off-the-shelf orthotic codes

To identify specific products (e.g., manufacturer and model) that could be billed under the off-the-shelf orthotic

codes—L0650 (back brace) and L1833 (knee brace)—we identified what products were certified as payable under those two HCPCS codes through CMS's Pricing, Data Analysis, and Coding contractor. We then selected several approved products and conducted an internet search to determine the prices at which these products could be directly purchased. For the off-the-shelf back brace, the median private-payer rate in 2015 was \$877; we found multiple products eligible to be billed under that HCPCS code that could be purchased for less than \$250. For the off-the-shelf knee brace, the median private-payer rate in 2015 was \$436; we found multiple products eligible to be billed under that HCPCS code that could be purchased for less than \$150.

A large number of braces can be billed under each of these HCPCS codes we examined. The limited number of examples we examined were not designed to be statistically representative, and other braces

that are billable under these HCPCS codes could be substantially more expensive. However, previous OIG work substantiates our finding. Specifically, in 2012, OIG reported that, for one type of back brace, Medicare paid an average of \$919 compared with an average of \$191 paid by suppliers to acquire the braces (Office of Inspector General 2012). Furthermore, the magnitude of the differences between the private-payer rates and the direct-purchase prices suggest that the private-payer rates, while already below Medicare's rates, do not necessarily represent the lowest payment rates that Medicare could potentially obtain.

Policy options to improve the accuracy of Medicare's payment rates for non-CBP DMEPOS products and protect beneficiaries

Shifting additional products into the CBP

The Commission supports shifting additional DMEPOS products from being paid on a fee schedule basis to being included in the CBP. Medicare's reliance on outdated and inflated pricing information (e.g., 30-year-old supplier charges and unadjusted list prices) to set payment rates for non-competitively bid DMEPOS products results in excessive payment rates. Setting payment rates too high also creates incentives for higher volume, financially burdens beneficiaries and taxpayers, and encourages fraud and abuse. Shifting more products into the CBP is consistent with the Commission's long-held support of payment accuracy in FFS payment systems. Payment rates should be high enough to ensure beneficiary access to needed products and low enough to encourage efficient provision of those products.

The CBP has been operating for over seven years and has effectively reduced excessive payment rates, reduced the financial burden on beneficiaries and taxpayers, and been an important tool to combat fraud and abuse. CMS's health status monitoring program has helped ensure beneficiaries maintain access to needed DMEPOS items and is more advanced than outcomes monitoring in many other sectors.

CMS currently has the authority to include some additional products in the CBP. Examples of such products include chest wall oscillation devices, ventilators, and off-the-shelf orthotics.

However, CMS is statutorily prohibited from including other groups of products in the CBP. Many of these products are likely good candidates for the CBP because multiple suppliers furnish the products, and Medicare's payment rates appear to be substantially higher than private-payer rates. For example, CMS is statutorily prohibited from including parenteral nutrition in the CBP, despite the fact that we found Medicare's payment rate for the highest expenditure parenteral nutrition product was 24 percent higher compared with private-payer rates in 2015, and the agency already has substantial experience successfully bidding out a similar product—enteral nutrition. In another case, Medicare's payment rate for the highest expenditure bone growth stimulator product is even higher relative to private payers—roughly 35 percent higher—but CMS is prohibited from including such products in the CBP because they are Class III devices.²³

For a third group of products, CMS's authority is unclear or additional legislative authority would likely be beneficial. In the case of ostomy, tracheostomy, and urological supplies (e.g., catheters), we found two products for which Medicare's payment rates were 45 percent and 57 percent higher than private-payer rates. CMS has stated that it has the authority to include certain medical supplies in the CBP (Centers for Medicare & Medicaid Services 2007). However, compared with other products, the legal authority to do so appears to be less clear. An explicit grant of authority could accelerate the inclusion of these products into the CBP and protect the agency from potential legal challenges. In the case of orthotics, CMS has the authority to include only off-the-shelf products in the CBP. Including only off-the-shelf orthotics in the CBP would likely lower costs and reduce inappropriate unitization. However, including a broader array of orthoses in the CBP would likely better protect Medicare by eliminating the incentive that suppliers would have to shift utilization from off-the-shelf products to more customizable products. For example, if only off-the-shelf orthotics were included in the CBP, some suppliers who did not win a contract might simply switch to billing for more custom-fitted braces, which are prefabricated products that require substantial modification by a trained practitioner. This behavior would be especially likely, given that many prefabricated products are approved to be billed under two codes—an off-the-shelf code if no customization is done and a custom-fitted code if the device is customized. We have found that, in the past, suppliers have rapidly shifted the types of products they bill for based on the incentives they face (see text box on back braces, p. 154).

Suppliers can rapidly shift utilization between off-the-shelf and custom-fitted back braces

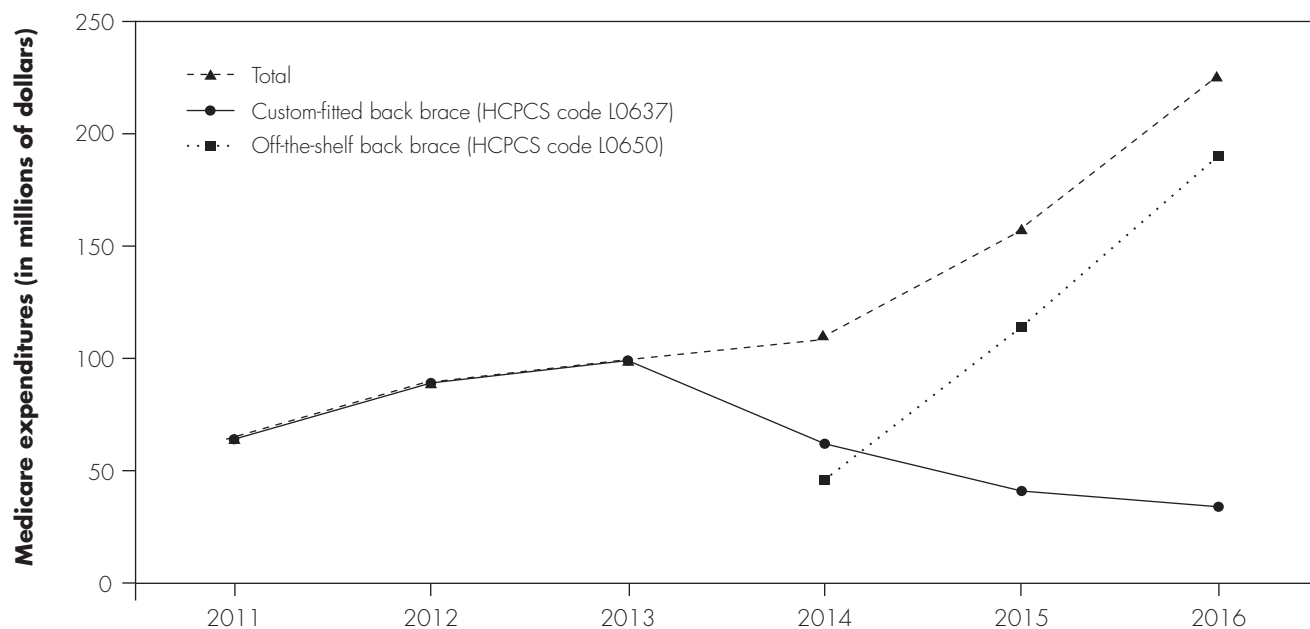
In 2014, CMS split many orthotic Healthcare Common Procedure Coding System (HCPCS) codes into two separate codes—one for off-the-shelf products (prefabricated products that require minimal self-adjustment) and another for custom-fitted products (prefabricated products that require substantial modification by a trained practitioner). For example, CMS split a back brace product into L0650 (an off-the-shelf product) and L0637 (a custom-fitted product). The payment rates for the new codes are the same, but suppliers that bill for custom-fitted products are subjected to additional quality requirements (e.g., Appendix C of the DMEPOS Quality Standards) (Centers for Medicare & Medicaid Services 2016c).

Therefore, suppliers currently have an incentive to furnish off-the-shelf instead of custom-fitted products.

Suppliers quickly responded to this incentive. In the three years following this coding change, Medicare spending for the off-the-shelf back brace increased rapidly, while spending for the custom-fitted brace decreased rapidly. Specifically, from 2014 to 2016, Medicare's expenditures for the off-the-shelf back brace increased by over 300 percent (\$46 million to \$190 million) compared with a decrease of nearly 50 percent for the custom-fitted back brace (\$62 million to \$34 million) over the same time period (Figure 6-3). This example suggests that suppliers can rapidly shift utilization between off-the-shelf and custom-fitted orthoses. ■

FIGURE 6-3

Suppliers rapidly shifted to billing for off-the-shelf back braces following a 2014 coding change



Note: HCPCS (Healthcare Common Procedure Coding System).

Source: MedPAC analysis of Medicare fee-for-service durable medical equipment claims.

If the Congress grants CMS additional authority, then requiring a date by which the products must be incorporated into the CBP could be helpful, but flexibility regarding the manner in which the products are

incorporated is likely important. In the past, the Congress has mandated that CMS make changes to the CBP by certain dates, which, to some extent, protects the agency from industry pressure to delay the program. The deadline

should reflect the level of effort required by CMS. For instance, the agency would need to design any special rules for the new product categories, solicit industry feedback, and incorporate the new products into its health status monitoring program. To expedite the inclusion of new products, the agency could be given the flexibility to phase in bidding in a small number of areas or bid out the new products only in a limited number of areas and use that information to adjust the fee schedule in the rest of the country.

As the agency has done in the past, CMS could consider allowing physicians and other providers, such as hospitals, to furnish CBP products to their own patients at the single payment amount without bidding or being contract suppliers. To further encourage continuity of care, policymakers could also consider allowing hospitals to furnish certain products to their patients without undergoing a DMEPOS accreditation process, similar to the accreditation exemptions currently allowed for physicians and other suppliers.²⁴ While allowing noncontract suppliers to provide DMEPOS products could drive down the value of winning a contract and result in higher single payment amounts, they could also allow for greater convenience and continuity of care for beneficiaries. We found that physicians, hospitals, physical therapists, and orthotists furnished a minority of the off-the-shelf back brace product we studied and are not driving the increase in utilization and expenditures for such products. Therefore, for the back braces we examined, exempting such providers would likely increase continuity of care without substantially affecting the operation of the CBP. CMS could also monitor the implementation of such policies to make sure that the exceptions were not abused.

DMEPOS products that are not good candidates for the CBP

Regardless of CMS's authority to add certain products to the CBP, some DMEPOS products are not good candidates for inclusion in the CBP. Two such types of products are those with small Medicare FFS markets and those without a sufficient number of suppliers to produce lower prices through competition.²⁵

First, even if there is sufficient competition, DMEPOS products with a small Medicare FFS market could be excluded from the CBP. The principle underlying this notion is that the administrative costs of incorporating products into the CBP should not exceed the potential savings.²⁶ Second, the CBP relies on competition among suppliers to produce lower payment rates. If insufficient

competition exists, the CBP will not produce savings, but CMS will still incur the administrative costs of including such products in the CBP. Table 6-5 (p. 156) provides some basic information on the competitiveness of the 25 highest expenditure non-CBP DMEPOS products in 2015, using Medicare FFS claims.

As the results in Table 6-5 indicate, in 2015, wearable AEDs (HCPCS code K0606) did not have sufficient competition to include them in the CBP. From 2010 to 2016, Medicare FFS expenditures on wearable AEDs totaled \$760 million and grew at an average annual rate of 42 percent per year, reaching \$204 million in 2016 alone. Medicare's payment rate for wearable AEDs is likely excessive as a result of basing the rate on the undiscounted manufacturer suggested retail price of the only company who manufactured the product (see text box on wearable AEDs, p. 157, for more information).

Allowing manufacturers or suppliers, and especially those who face little competition, to functionally set Medicare's payment rates for their own products and then largely increase those rates by inflation over time leads to excessive payment rates. Given the fact that large payment declines have occurred when products are added to the CBP, policymakers could consider directing CMS to reduce the payment rates for wearable AEDs and other products that are excluded from the CBP and that meet certain other criteria, such as rapid utilization growth, that indicate a potentially mispriced product. Future Commission work could also further examine how to more rationally set fee schedule rates for DMEPOS products when including them in the CBP is not practical.

Limiting balance billing and encouraging supplier participation to protect beneficiaries

Another policy option for policymakers to consider is changing Medicare's assignment and participation rules for DMEPOS products and suppliers to better protect beneficiaries. Unlike many other suppliers, DMEPOS suppliers are generally not required to accept Medicare's payment rate as payment in full (i.e., assignment is not mandatory) outside of CBP products furnished to beneficiaries who reside in CBAs, and there is no limit on balance billing (i.e., billing beneficiaries beyond the standard 20 percent coinsurance) when assignment is not mandatory.²⁷ Also, DMEPOS suppliers do not face the 5 percent payment reduction that physicians do when they enroll as nonparticipating (a status that allows physicians and other suppliers to bill unassigned on a claim-by-claim basis).²⁸ As a result, DMEPOS suppliers are far more

**TABLE
6-5**

Number of companies supplying products varied among the 25 highest expenditure non-CBP DMEPOS products in 2015

HCPCS code	Product description	Number of companies		Share of product's allowed charges accounted for by top three companies
		All	With at least 1 percent of product's allowed charges	
E0464	Pressure support ventilator used with non-invasive interface (e.g., mask)	633	11	44%
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	1	1	100
A4351	Intermittent urinary catheter, straight tip	3,086	15	43
L0650	Lumbar-sacral orthosis, off-the-shelf	1,073	23	15
L1833	Knee orthosis, off-the-shelf	1,402	19	33
A4352	Intermittent urinary catheter, curved tip	1,492	16	45
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications	137	4	87
B4197	Parenteral nutrition solution, 74 to 100 grams of protein	345	19	27
A5500	For diabetics only, fitting, custom preparation and supply of off-the-shelf depth-inlay shoe	8,861	4	6
E0463	Pressure support ventilator used with invasive interface (e.g., tracheostomy tube)	402	15	20
L0648	Lumbar-sacral orthosis, off-the-shelf	1,307	17	16
A5513	For diabetics only, multiple density insert, custom fabricated	5,413	7	9
A4353	Intermittent urinary catheter, with insertion supplies	937	17	31
L5673	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated	1,267	4	23
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees fahrenheit or higher, prefabricated	6,816	2	4
L5301	Below knee, molded socket, shin, SACH foot, endoskeletal system	1,176	3	23
K0861	Power wheelchair, group 3 standard, multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds	501	15	29
B4199	Parenteral nutrition solution, over 100 grams of protein	249	21	27
L0637	Lumbar-sacral orthosis, prefabricated item that has been customized to fit a specific patient by an individual with expertise	1,913	10	6
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s)	444	8	27
A6021	Collagen dressing, sterile, size 16 sq. in. or less	656	11	48
L5700	Replacement, socket, below knee, molded to patient model	1,102	4	23
B4193	Parenteral nutrition solution, 52 to 73 grams of protein	268	13	32
A4407	Ostomy skin barrier, with flange, extended wear, with built-in convexity, 4x4 inches or smaller	2,114	10	49
E0483	High frequency chest wall oscillation air-pulse generator system	96	3	93

Note: CBP (Competitive Bidding Program), DMEPOS (durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies), HCPCS (Healthcare Common Procedure Coding System), SACH (solid ankle cushion heel). We define "companies" as unique tax ID numbers.

Source: 2015 durable medical equipment 100 percent standard analytic file.

Rapid expenditure growth and high Medicare payment rates for wearable AEDs

The wearable automatic external defibrillator (AED) was approved by the Food and Drug Administration in 2001 and is designed for patients at risk of sudden cardiac death who are not immediate candidates for an implantable cardioverter-defibrillator (ICD), such as patients at risk of sudden cardiac death but who have an active infection or whose clinical condition continues to improve (and therefore might not need an ICD) (Piccini et al. 2016). While technologically similar to nonwearable AEDs, wearable AEDs have the clinical advantage of not needing another individual present to initiate defibrillation.

Between 2010 and 2016, Medicare expenditures for wearable AEDs increased from approximately \$25 million to \$204 million, an average annual growth rate of 42 percent. Wearable AEDs are capped rental items, meaning that Medicare pays a monthly fee for beneficiaries to rent the product from a supplier for up to 13 months. If the beneficiary uses the device for less than 13 months, the device is returned to the supplier; if the beneficiary uses the device for 13 months, ownership is transferred to the beneficiary. In 2018, Medicare's payment rate for a wearable AED is about \$2,800 per month for the first 3 months and about \$2,100 for months 4 through 13. Given Medicare's formula for determining the monthly payment rates for capped rental items (i.e., the payment rate for the first month is 10 percent of the purchase price), Medicare's implied purchase price for a wearable AED is over \$28,000 in 2018.

The implied purchase price for wearable AEDs is substantially higher compared with direct-purchase prices of nonwearable AEDs. Specifically, nonwearable AEDs can commonly be purchased directly for \$1,500 to \$2,000 (American Heart Association 2017). Thus, Medicare's implied purchase price for a wearable AED is roughly 15 times higher than the purchase price of a nonwearable AED.

While a reasonable payment rate for wearable AEDs is likely based on a price somewhat higher than the purchase price of nonwearable AEDs (e.g., to account for the additional functionality, the cost of refurbishing the device between beneficiary rentals, etc.), several facts—beyond the magnitude of the price difference between wearable and nonwearable AEDs—suggest that Medicare's payment rate is potentially excessive. First, Medicare's payment rate is based on the undiscounted manufacturer suggested retail price of the only company that manufactured the product (Centers for Medicare & Medicaid Services 2006). The lack of competition means the sole manufacturer had an opportunity to set a price as high as possible. Second, the manufacturer's own data, submitted as part of the Healthcare Common Procedure Coding System code assignment process, suggested the median manufacturing cost was under \$8,000 in 2003 (Centers for Medicare & Medicaid Services 2006). Medicare's \$28,000 implied purchase price far exceeds that figure and leads to high gross profit margins. For example, for the fiscal year ending in October 2011, the gross profit margin for wearable AEDs appears to be greater than 50 percent (Zoll Medical Corporation 2011).²⁹ ■

likely to enroll as nonparticipating suppliers compared with other providers. For example, in 2016, more than 60 percent of DMEPOS claim lines were submitted by nonparticipating suppliers. In contrast, less than 5 percent of physicians generally enroll as nonparticipating (Boccuti 2016).

Historically, DMEPOS assignment rates have remained high despite the fact that suppliers have commonly enrolled as nonparticipating suppliers (and therefore have the ability to bill on an unassigned basis). One

explanation could be that payment rates have generally been adequate or excessive, so suppliers that routinely balance billed beneficiaries would have likely lost business to other DMEPOS suppliers that could profitably furnish the products on an assignment basis. As payment rates for DMEPOS products are reduced to more appropriate levels and less efficient suppliers drop out of the market, the remaining DMEPOS suppliers could try to account for some of their lost revenues by balance billing beneficiaries.

Therefore, while nonparticipating suppliers have largely not exercised their ability to bill on a nonassigned basis, the large pool of nonparticipating suppliers poses a risk to Medicare beneficiaries should these suppliers begin to balance bill in response to falling payment rates. To mitigate that risk and to better align DMEPOS policies with the rest of Medicare, policymakers could consider capping balance billing and reducing the allowed fee schedule amount by 5 percent for nonparticipating DMEPOS suppliers. The balance billing cap could be set equal to the physician fee schedule cap—115 percent—or somewhat higher (e.g., 125 percent) to the extent policymakers want to allow for added flexibility.

Physician-owned distributors

Physician-owned distributors (PODs) allow physicians to profit from the sale of medical devices they use. Specifically, PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. The primary concern with PODs is that such entities create an incentive for physicians to base their preferences, such as whether to operate on a patient and which instrumentation to use, on financial rather than clinical considerations.

PODs have historically been concentrated in the market for implantable medical devices (IMDs), and the spinal implant market in particular.³⁰ The IMD market is particularly fertile ground for PODs for several reasons. First, hospitals typically purchase IMDs, so any higher costs associated with POD-supplied devices are not borne by the physician-owners. Second, physicians have traditionally had significant influence on hospitals' purchasing decisions, so they can help channel hospitals' device purchases to their PODs. According to a 2013 OIG report, 94 percent of hospitals that purchased from PODs reported that surgeon preference influenced their decision to purchase from PODs (Office of Inspector General 2013c). Hospitals have historically been willing to accommodate such preferences due to physicians' ability to control patient referrals and the profitability of surgical lines of business.

Types of PODs

PODs are commonly structured using one of three models—a distributor, manufacturer, or group purchasing organization (GPO) model:

- **Distributor model.** IMD manufacturers traditionally sell and distribute their products directly to hospitals. Under the distributor model, PODs operate as intermediaries between device manufacturers and hospitals; that is, a device manufacturer sells a device to a POD, and the POD resells the device to a hospital at a higher price.
- **Manufacturer model.** Under the manufacturer model, PODs typically sell devices that another company manufactures on their behalf. For example, a manufacturer POD might obtain a Food and Drug Administration clearance to market a relatively simple device, such as a surgical screw, and outsource its production to a contract manufacturer.
- **GPO model.** Under this model, physicians reportedly form a POD to aggregate their purchasing power and get bulk discounts from manufacturers. However, given the small size of PODs, it is unclear the amount of negotiating leverage such entities would have with manufacturers relative to the hospital itself or other, larger GPOs.

Prevalence of PODs and their impact on Medicare

Relatively little is known about the current prevalence of PODs. OIG found that PODs supplied spinal devices for nearly one in five spinal fusion surgeries billed to Medicare in 2011 and that roughly a third of hospitals purchased such devices from PODs in the same year (Office of Inspector General 2013c).^{31,32} While these data suggest that the use of PODs was relatively widespread as of 2011, OIG released a special fraud alert in 2013, calling PODs “inherently suspect” under the anti-kickback statute (AKS) (Office of Inspector General 2013b). The special fraud alert caused some hospitals to reevaluate whether purchasing devices from PODs was worth the legal risk, and some ceased doing business with PODs. However, industry stakeholders have suggested that, while the special fraud alert slowed the spread of PODs, many PODs continue to operate, and a 2016 report from the Senate Finance Committee found PODs were operating in 43 states as of December 2015 (U.S. Senate Committee on Finance 2016).

Even though Medicare does not directly pay for most IMDs, PODs raise several concerns for the Medicare program and beneficiaries:

- **Increased volume.** Physicians who own PODs have an incentive to refer more patients for surgery because more surgeries result in more devices used. For some

spinal conditions, appropriate treatments can range from physical therapy to intensive surgical procedures, so physician-induced demand could be a larger issue in this area compared with areas in which clinical guidelines are more prescriptive.

- **Increased intensity.** Physicians who own PODs have an incentive to use more devices in a given case or refer patients for more intense procedures that require more devices.
- **Inappropriate care.** PODs' financial incentives could encourage physicians to refer patients for surgery inappropriately, and, because they have a financial interest in choosing devices that their PODs sell, to use devices of inferior quality or that are not best suited for a procedure (U.S. Senate Committee on Finance 2016).
- **Higher device costs.** PODs profit from selling or arranging for the sale of devices at the highest possible price. Higher device prices put pressure on hospital margins and can contribute to calls for higher reimbursements from Medicare.

Data from OIG and an example from a POD prosecuted by the Department of Justice substantiate some of the concerns about PODs. Specifically, OIG found the following:

- The rate of spinal surgery grew faster among hospitals that began purchasing devices from PODs compared with all hospitals (16 percent vs. 5 percent, respectively).
- The rate of spinal fusions—a subset of spinal surgeries that are more likely to use devices—grew faster among hospitals that acquired devices from PODs compared with all hospitals (21 percent vs. 9 percent, respectively).
- None of the six types of spinal devices examined was less costly per unit when purchased through a POD, and one—spinal plates—cost \$845 more on average when supplied by a POD (\$2,475 vs. \$1,630) (Office of Inspector General 2013c).³³

One example of a POD's financial incentives warping clinical judgment involves a series of cases brought by the Department of Justice against Dr. Aria Sabit, a POD in which Sabit was an investor (Apex Medical Technologies), and others (e.g., Reliance Medical Systems). Sabit was allegedly paid an average of \$17,000 per month by the

POD in which he invested over the course of more than two years (United States of America vs. Reliance Medical Systems et al. 2014). Three other physician-owners are alleged to have received similar or higher monthly payments from their PODs (United States of America vs. Reliance Medical Systems et al. 2014). In one of these cases, Sabit pled guilty and was sentenced in 2017 (Department of Justice 2017). In connection with his guilty plea, Sabit admitted the following:

- The financial incentives provided to him by his POD caused him to use more spinal implant devices than were medically necessary to treat his patients in order to generate more sales revenue for his POD, which resulted in serious bodily injury to his patients.
- The money he made from using his POD's spinal implant devices motivated him either to refer patients for unnecessary spine surgeries or for more complex procedures that they did not need (Department of Justice 2017).

Application of the anti-kickback statute and Stark law to PODs

Two federal laws are critical to determine the legality of a POD—the AKS and the Stark law. The AKS generally makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of federal health care program enrollees for the furnishing or arranging for the furnishing of items or services reimbursable by federal health care programs. In the case of PODs, the kickback would be the payment physicians receive from their POD for arranging for the furnishing of the POD's devices purchased by hospitals for use on the physician's patients. To violate the AKS, a person or entity must offer, pay, solicit, or receive remuneration to induce the referral with knowledge that the conduct is wrongful—that is, the government must prove intent.

OIG has suggested that PODs are “inherently suspect” under the AKS, and some industry stakeholders echo that sentiment. However, other industry stakeholders suggest that PODs may be structured to avoid violating the AKS. In practice, government prosecutions of PODs on AKS grounds have been limited. Government enforcement actions against PODs may be rare at least partly because the AKS requires proof of intent, which can be difficult to prove in court. The limited number of prosecutions and the difficulty in proving AKS cases suggest that the Stark law may need to be revised to more effectively limit the use of PODs.

The Stark law is intended to prohibit physicians from referring Medicare beneficiaries to certain health care facilities in which they have a financial interest. Specifically, the Stark law (1) prohibits a physician from making referrals for designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare for those referred DHS, unless an exception applies. This prohibition is based on the premise that physicians have a conflict of interest in such situations because they have significant influence over patient referrals and directly profit from referring their patients to facilities in which they have a financial interest. Opponents of PODs suggest that the incentives inherent in PODs violate the intent of the Stark law and may also often violate the letter of the law (AdvaMed 2016). CMS has also said that PODs may run afoul of the Stark law (Centers for Medicare & Medicaid Services 2008b). However, others believe that PODs can be structured to comply with the Stark law, and, to our knowledge, no POD has yet been prosecuted based on a violation of the Stark law.

The principal sanction for violating the Stark law is denial of payment for any claims involving DHS arising from a prohibited referral. (Knowing violations of the Stark law can also trigger civil monetary penalties and False Claims Act liabilities.) Unlike the AKS, the government does not need to prove intent; instead, parties are strictly liable for Stark law violations, even inadvertent ones.

A wide range of services are considered DHS, including clinical laboratory services, radiology services, and physical therapy services. Importantly for the application of the Stark law to PODs, IMDs are not DHS, but hospital inpatient and outpatient services are. Generally, a “DHS entity” is any person or entity that performs DHS or bills Medicare for DHS. For example, in the case of a physician who refers his or her patient to receive spinal fusion as a hospital inpatient procedure, the DHS is the inpatient facility service, and the DHS entity is the hospital. Even if a POD sold the devices used in the fusion to the hospital, the POD is not a DHS entity because it neither performs nor bills Medicare for the DHS.

Broadly, the Stark law defines two types of financial relationships—ownership/investment arrangements and compensation arrangements. Either type of relationship may be direct, meaning the relationship is between the DHS entity and physician, or indirect, meaning there is

some intervening entity between the DHS entity and the physician. Establishing that a financial relationship exists and the type of relationship is important in applying the Stark law and determining whether an exception applies because some exceptions apply to only one type of financial relationship.

An ownership relationship means that a physician has an ownership or investment interest in a DHS entity (e.g., a physician who owns a clinical laboratory). There are relatively few ownership exceptions, and some believe that the application of the Stark law to ownership/investment relationships has been relatively effective in reducing physician investment in DHS entities and straightforward to regulate compared with compensation arrangements. However, PODs are not DHS entities, so the Stark law does not prohibit physician ownership or investment in PODs.

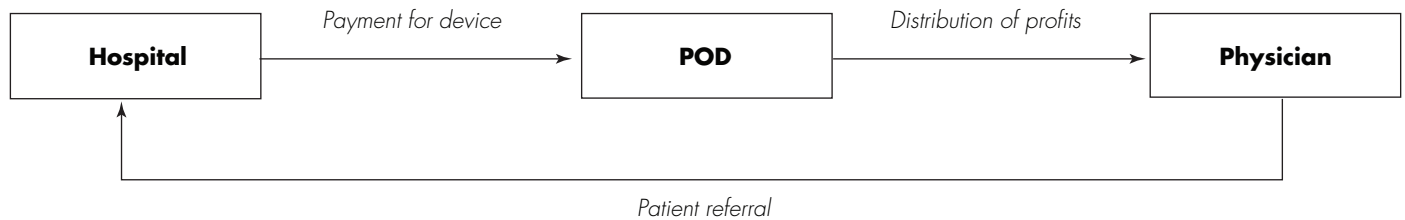
The second type of financial relationship is a compensation arrangement between a DHS entity and a referring physician. Again, compensation arrangements can be either direct or indirect. Because PODs are not DHS entities, financial arrangements between PODs and physicians do not typically create direct compensation arrangements.

The inclusion of indirect compensation arrangements in the Stark law is intended to prevent DHS entities and physicians from circumventing the Stark law by channeling an otherwise prohibited arrangement through other entities. To be categorized as an indirect compensation arrangement for the purposes of the Stark law, three conditions must be met:

- There must be an unbroken chain of financial arrangements between a DHS entity and the referring physician.
- The referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship (e.g., the POD) that varies with the volume or value of referrals generated by the referring physician for the entity furnishing the DHS (e.g., the hospital).
- The entity furnishing the DHS (e.g., the hospital) knows or recklessly disregards evidence that the referring physician receives aggregate compensation that varies with the volume or value of referrals to the DHS entity.

**FIGURE
6-4**

Illustrative example of an indirect compensation relationship between a hospital and a physician-owner of a POD



Note: POD (physician-owned distributor).

Source: MedPAC analysis of Stark law and POD–physician relationships.

For PODs, the unbroken chain often consists of the physician’s ownership interest in the POD and the POD’s sale of devices to a hospital (Figure 6-4). In general, the referring physician’s aggregate compensation from a POD should vary with the volume or value of referrals generated. For example, a physician’s return on investment is often a portion of the POD profits, which in turn takes into account sales of devices used by the physician in procedures he or she referred to the hospital. Given that devices often cost hospitals thousands of dollars per case, hospitals should be aware that referring physicians who own PODs increase their payments from PODs as the number of referrals increase. Therefore, PODs selling medical devices to a hospital where physician-owners use the devices in their inpatient or outpatient surgeries appears to create an indirect compensation arrangement between the referring physician and the hospital.

Once a financial relationship between a physician and a DHS entity is established, that physician is prohibited from referring Medicare beneficiaries to the DHS entity unless an exception applies. While there are many exceptions for direct compensation arrangements, there is only one for indirect compensation arrangements. The indirect compensation exception has the following key elements:

- the compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;

- the compensation arrangement does not violate the AKS;
- the compensation received by the referring physician from the entity with which he or she has a direct financial relationship must be fair market value; and
- the compensation received by the physician from the entity with which he or she has a direct financial relationship does not take into account the volume or value of referrals by the referring physician for the entity furnishing the DHS.

Meeting the first requirement appears to be perfunctory. As for the second, most PODs that avoid suspect characteristics appear to not violate the AKS or, at least, have not been prosecuted for doing so. With respect to the third element, the compensation received by the referring physician from a POD will generally be at fair market value if the devices sold by the POD are sold at competitive prices. While this provision might prevent substantially aberrant pricing, the price paid for the same device often varies substantially from one hospital to another, so there is likely substantial leeway in how PODs price their devices while still meeting the fair market value test. Regarding the last element, the payments physicians receive from their PODs do vary based on their referrals to the hospital. PODs would therefore appear to fail the last criterion needed to qualify for the indirect compensation exception. However, the compensation can be deemed not to take into account referrals so long as it complies with the “per unit of service” rule.

The “per unit of service” rule states that unit-based compensation is deemed not to take into account the volume or value of referrals if the compensation per unit is fair market value and does not vary during the course of the arrangement in any manner that takes into account referrals of DHS.³⁴ For example, if a hospital agrees to pay a POD \$1,000 per pedicle screw over the course of a year, such an arrangement should meet the “per unit of service” rule so long as \$1,000 is a fair market price for a pedicle screw and the \$1,000 price does not increase or decrease based on referral patterns.

Potential revisions to the Stark law

The Commission questions the value PODs produce for the Medicare program and beneficiaries. The conflict of interest that PODs create is the type of problem the Stark law was designed to solve—providers’ self-interest unduly influencing medical decisions. Unlike the AKS (which has proved ill equipped to limit the use of PODs), the Stark law does not require the government to prove intent for a violation to have occurred. The goal of any change to the Stark law would not be to ban PODs per se, but rather to prohibit physician self-referral involving PODs (i.e., to limit the use of PODs).

While there are several ways the Stark law could be revised to limit the use of PODs, the Commission has discussed two specific revisions: (1) eliminating the application of the “per unit of service” rule to PODs and (2) making PODs DHS entities.

The “per unit of service” rule appears to be key in allowing self-referral involving PODs that would otherwise violate the Stark law. Referring physicians commonly receive *aggregate* compensation from their PODs that varies with the volume or value of referrals to hospitals. Such compensation creates an indirect compensation arrangement for the purposes of the Stark law and would normally result in a prohibition of POD owners referring patients for surgeries in which their PODs supplied the devices. However, the “per unit of service” rule deems such arrangements to not take into account the volume or value of physician referrals if the *per unit* compensation is fair market value and does not vary during the course of the arrangement based on referral patterns. Therefore, the only reason referrals in such arrangements appear to be legal under the Stark law is due to the “per unit of service” rule, and, as a consequence, eliminating the rule’s application to PODs would prohibit physicians from referring their patients for surgeries in which their PODs supplied the devices, unless another exception applied.

There is a precedent for making such a change. In 2008, CMS revisited the “per unit of service” rule as it applied to space and equipment leases. The revised rule prohibited physicians from renting an imaging machine, for instance, on a per unit or “per click” basis to a hospital (i.e., the physician gets paid every time the machine is used) and then referring their patients to use that imaging machine. CMS said that such arrangements create the incentive for overutilization; provide the incentive for the physician lessor to refer patients to the lessee of the physician’s space or equipment (rather than to entities that may employ a different, and possibly more appropriate, treatment modality); and may foster anticompetitive behavior because entities (e.g., hospitals) may enter into such agreements due to fears of losing the physician lessor’s referrals (Centers for Medicare & Medicaid Services 2008a).

In defending its proposal to no longer allow “per click” equipment and space leases, CMS said that the agency monitors financial arrangements in the health care industry and revises its regulatory decisions as evidence of abuse or overutilization changes. Therefore, eliminating the application of the “per unit of service” rule to PODs could be seen as a logical extension of CMS’s regulatory history of modifying the application of the rule as evidence of potential abuse presents. Also, as was the case for the 2008 revision, CMS could possibly make such a change without any new legislative authority.

The second potential revision to the Stark law entails classifying PODs as DHS entities. Under such a change, physicians who have an ownership stake in PODs would have an ownership stake in a DHS entity and would therefore be prohibited from referring their patients for services that use devices supplied by their PODs, unless another exception applied. For example, there is an ownership exception for an entity that furnishes at least 75 percent of its DHS to residents of rural areas. Therefore, if PODs were reclassified as DHS entities, the rural exception would need to be amended to limit the use of PODs in rural areas.

Reclassifying PODs as DHS entities would be a departure from how CMS currently defines a DHS entity and would, therefore, require some additional accommodations. For example, the principal penalty for a Stark law violation is nonpayment of a claim, and given that PODs do not submit claims to Medicare, specific rules stipulating how PODs, hospitals, or both would be held accountable for Stark law violations involving PODs would likely

be needed. Furthermore, CMS will likely require new legislative authority to classify PODs as DHS entities.

If the Stark law is amended, policymakers would face several decisions to adapt the law to limit the use of PODs, including defining a POD, considering whether additional exceptions to protect device innovation are warranted, and implementing any changes.

Defining a POD

The Stark law currently does not define PODs. Therefore, a definition of PODs would need to be added to the Stark law. To ensure that the definition of PODs captures as many PODs as possible (and as few non-POD entities as possible), the definition should include characteristics that are common to all PODs, include characteristics as distinct as possible from non-POD entities, cover all three types of known POD models (distributor, GPO, and manufacturer), and be flexible enough to cover idiosyncratic design features that do not alter the basic incentives of PODs.

The core of any POD definition should be an entity that receives revenue from selling medical devices ordered by a physician-owner for use in procedures performed by a physician-owner. To ensure that the definition applies to all known POD models, language could be explicitly added to include PODs that do not directly sell devices or that do so through contractual relationships. Using these two criteria, a basic definition of a POD could be an entity that receives any of its revenue from selling or arranging for the sale (including through contractual arrangements such as group purchasing organization contracts) of medical devices ordered by a physician-owner for use in procedures performed by a physician-owner.

In response to prior legislative changes such as the establishment of the Open Payments program, PODs have reportedly changed their structure while maintaining the fundamental incentives embodied in PODs (U.S. Senate Committee on Finance 2016). Language could be added to the definition of a POD to ensure that superficial variations in ownership and payment structures do not preclude a POD from being characterized as such. To that end, a POD owner could be defined as a physician who has an ownership or investment interest in a POD, including ownership or investment through agents, trusts, partnerships, limited liability companies, corporations, unincorporated associations, or any other entity. Further, the type of payment a POD owner receives—a commission, return on investment, profit sharing, profit distribution, or any other type of remuneration—should

not allow an entity to avoid being categorized as a POD, so long as the entity's fundamental structure remains unchanged.

To avoid being classified as a POD or being regulated by the Stark law, some physician-owners could try to channel money through immediate family members, become POD employees, or engage in other referral schemes. For the purposes of defining a POD-owner, an immediate family member of the physician-owner should be included in the definition of a physician-owner.³⁵ To prevent PODs from converting their physician-owners to employees to avoid regulation, language could be added to the POD definition to clarify that PODs include entities that generate revenue from selling medical devices ordered by a physician who is an owner, employee, or contractor for use in procedures performed by such physician. To prevent referral schemes that might be designed to circumvent any POD restrictions, language could also be added to the POD definition, although the legality of some of these schemes is likely already questionable under current law.³⁶

Device innovation

While some believe that limiting the use of PODs could inhibit medical device innovation, the Commission concludes that innovation in the medical device market would be largely unaffected by such changes.

Limiting the use of PODs through the Stark law would not prohibit physician investment in companies developing new medical devices. Rather, limiting the use of PODs would prohibit Medicare payment for cases where a physician performs surgery using a device supplied by a company in which the referring physician has a financial interest. Some stakeholders believe that this limitation reduces the ability of physicians to profit from their inventions, and, therefore, additional exceptions should be added to the Stark law preserving physicians' abilities to self-refer.³⁷

The Commission concludes that no additional exceptions are needed to protect innovation in the medical device market for several reasons. First, current Stark regulations protect investment interests in companies that are listed on public exchanges and that have a net value of over \$75 million. This provision recognizes that physician ownership in large entities is unlikely to create an inappropriate incentive to refer patients for services because the physician's impact is likely to be attenuated. A similar clause could be added to any new POD provisions.³⁸ Second, the Commission believes physicians

would still be able to profit from contributing significant intellectual capital to the development of medical devices if the use of PODs were limited. The Commission argues that a device is unlikely to be innovative if the only manner in which physicians profit from it is through using it themselves. If a device does represent an actual advancement, other providers will use the device, and the physician who contributed to the invention of the device would continue to profit. Finally, the Commission notes that physicians contributed to medical device innovation before the proliferation of PODs (and will continue to do so if the use of PODs is limited) and that physicians have many nonfinancial incentives to continue innovating.

Implementation issues

The Stark law is intended to be self-implementing to a large degree. The potential for significant Medicare disallowances provides a strong incentive for hospitals to police their arrangements with physicians. As a consequence, many hospitals have implemented conflict-of-interest policies, especially with regard to physician relationships with hospital vendors. If the Stark law were changed to limit the use of PODs, hospitals would likely adopt similar policies to protect against Stark law and additional False Claims Act liabilities by demonstrating they took reasonable measures to comply. To the extent active enforcement is needed, most Stark law cases that are brought by the government are initiated by whistleblowers.

Even if the Stark law is changed to limit the use of PODs, some PODs could continue to exist. First, the Stark law predominantly applies to FFS Medicare, so any new restrictions would not apply to all payers. For example, the Stark law contains an exception for services provided to Medicare Advantage enrollees (42 CFR § 411.355 (c)). Second, while most PODs sell to hospitals, others may sell to non-DHS entities (e.g., ambulatory surgical centers).³⁹ Such sales are not encumbered by the Stark law. Finally, PODs could adapt to the new regulations in some unforeseen manner that would allow them to continue operating. For example, after CMS prohibited per click arrangements for space and equipment leases, some entities began leasing based on a block of time (e.g., renting an MRI machine for a day per week) rather than per use.

Improving transparency of POD–physician relationships

The Commission maintains that the financial relationships between physicians and PODs should be more transparent.

Absent changes in the Stark law, additional transparency could still help beneficiaries make informed decisions and help enforcement agencies, payers, and others better understand the effect of PODs. Also, enhanced transparency could be useful even if Stark law changes are made, given that some PODs could continue to exist.

Under the Open Payments program, manufacturers of drugs, devices, biologics, and supplies are required to annually report to CMS information about certain payments and other transfers of value to physicians and teaching hospitals. GPOs must also report payments and transfers of value to physicians who have an ownership or investment interest. In addition, manufacturers and GPOs are required to report ownership or investment interests that physicians or their immediate family members have in their companies (Medicare Payment Advisory Commission 2017). The intent of the Open Payments program is to shed light on industry ties to providers.

The statute that forms the basis of the Open Payments program does not explicitly mention PODs. However, PODs that fall within the definition of an applicable manufacturer or GPO must report. In its 2013 final rule establishing the Open Payments program, CMS stated that it intended to capture as many PODs as possible in the Open Payments program, but not every POD model may be covered by the program (Centers for Medicare & Medicaid Services 2013). For example, PODs that sell or arrange for the sale of devices to only one hospital may not fit the definition of an applicable GPO and may therefore not be required to report.

In addition, some PODs that are likely covered by the program are failing to report. For example, a 2016 report from the Senate Finance Committee found that many PODs identified by the Committee staff did not appear in the Open Payments data. The report concluded that there were serious gaps in the reporting of POD arrangements under the Open Payments program (U.S. Senate Committee on Finance 2016).⁴⁰

Likely as a result of the incomplete requirement for PODs to report under the Open Payments program and underreporting by covered PODs, very few PODs appear in Open Payments data. For example, using the 2015 Open Payments data (which were released in January 2017), the Commission found that only 8 PODs reported general payments to physicians, and only 16 PODs reported physician ownership (Medicare Payment Advisory Commission 2017).

To address this lack of reporting, the Commission supports requiring all PODs to report under the Open Payments program. When reporting under the Open Payments program, PODs should identify as a POD, as opposed to another type of entity that is required to report. Improving the specificity of the data could improve their utility to policymakers, oversight agencies, researchers, hospitals, and others.

Conclusion

The Commission believes that Medicare can improve its payment policies for both DMEPOS products and IMDs. For DMEPOS products, the CBP has effectively used market competition to reduce payment rates and limit fraud and abuse for over seven years. Medicare could include additional products in the CBP, while at the same

time continuing to ensure beneficiaries maintain access to needed products. In addition, policymakers should also consider making Medicare's DMEPOS payment policies consistent with those of other Part B suppliers and clinicians by capping balance billing and giving suppliers an incentive to enroll as participating suppliers.

Because Medicare does not directly pay for most IMDs, the Commission focused on policy changes to better align the incentives between physicians (who refer beneficiaries for procedures in which IMDs are used) and hospitals (who predominantly pay for IMDs). The Commission supports limiting the use of PODs because they encourage physicians to use more and more-expensive devices without providing countervailing benefits. The Stark law could be modified to achieve that goal, and the Commission discussed two such options, although other viable approaches likely exist. ■

Endnotes

- 1 In this report, we define DMEPOS using Berenson-Eggers Type of Service categories D1A, D1B, D1C, D1D, D1E, D1F, and O1C, with certain exclusions. These categories exclude drugs used in conjunction with DME; we excluded such drugs because their payment rates are set in a manner different from other DMEPOS items.
- 2 Over the same time period, the number of Medicare FFS beneficiaries enrolled in Part B increased by roughly 3 percent (Boards of Trustees 2017).
- 3 For more information on how supplier charges were used to set fee schedule rates, see 42 CFR § 405.502. The time period from which supplier charges were used to set payment rates may vary by payment class. Payment rates for products introduced after that initial time period are set using a gap-filling process that relies on, among other sources, unadjusted list prices.
- 4 The Food and Drug Administration classifies medical devices based on the risks associated with the device. Devices are classified into one of three categories—Class I, Class II, and Class III. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control.
- 5 There were some differences between the CBP Round 1 and Round 1 rebid. For example, a CBA in Puerto Rico was excluded from the CBP Round 1 rebid.
- 6 Mail-order diabetes testing supplies were originally included in the Round 1 rebid. However, Round 1 rebid contracts for mail-order diabetes testing supplies ended on December 31, 2012, and the supplies were included in the National Mail-Order Program as of July 2013.
- 7 For future CBP rounds, suppliers will have to obtain bid surety bonds of \$50,000 for each CBA. If a supplier rejects a contract and its composite bid for the product category was at or below the median composite bid rate for all suppliers included in the calculation of the single payment amounts, then the supplier will forfeit the bid surety bond (42 CFR § 414.412(h)). This provision was intended to prevent “low ball” bidders who bid unreasonably low (to ensure they are offered a contract) and then accept or reject the contract after the payment rates are known.
- 8 One exception is that beneficiaries may continue to receive certain products from grandfathered suppliers.
- 9 CMS also employs other tools to ensure beneficiary access to needed DMEPOS items under the CBP, including monitoring inquiries to 1-800-MEDICARE, conducting secret shopping calls to DMEPOS suppliers, and conducting beneficiary satisfaction surveys.
- 10 For other product categories or outcome measures, the differences across geographic areas varies. For example, hospital admission rates among beneficiaries with a potential need for home oxygen tended to be higher in CBAs than non-CBAs, both before and after CBP Round 2 was implemented.
- 11 Of the 15 areas with the largest declines in utilization after CBP Round 2 was implemented, 12 were in Texas or California. CMS officials have said that the relatively large decreases in California and Texas were likely because these states historically had high rates of potential fraud and abuse (Government Accountability Office 2016).
- 12 In practice, CMS has reported high contract acceptance rates. For example, suppliers accepted 92 percent of contracts offered in CBP Round 1 2017 (Centers for Medicare & Medicaid Services 2016b).
- 13 As part of its ongoing work to evaluate the CBP, OIG found that CBP Round 2 did not appear to disrupt beneficiary access to CPAP/respiratory assist devices (RADs) (Office of Inspector General 2017). The report was inconclusive about whether access to CPAP/RAD supplies was disrupted.
- 14 Some of the growth in off-the-shelf orthotic codes appears to be attributable to CMS splitting existing codes into two in 2014 (one for the off-the-shelf version and another for the custom-fitted version).
- 15 In 2015, the payment rate increase was 1.5 percent (Centers for Medicare & Medicaid Services 2015a). From 2014 to 2015, the number of Part B FFS beneficiaries increased from roughly 33.2 million to 33.3 million, or 0.25 percent (Boards of Trustees 2017).
- 16 Specifically, we examined the utilization and expenditures for a prefabricated back brace when it was dispensed as an off-the-shelf brace (L0650) or a custom-fitted brace (L0637). Analyzing the combined figures allowed us to determine net increases in utilization and spending, as many suppliers began billing for L0650 instead of L0637 beginning in 2014.
- 17 Specifically, the Federation of State Medical Boards reported that only 4,091 out of 931,921 licensed physicians in the United States were disciplined by a state medical board in 2015 (Federation of State Medical Boards 2016).

- 18 An improper payment is any payment made in error or in an incorrect amount; to an ineligible recipient; for ineligible goods or services; for goods or services not received; that duplicates a payment; that does not account for credit for applicable discounts; without supporting documentation; or for services where documentation is missing or not available (Centers for Medicare & Medicaid Services 2016d).
- 19 The MarketScan Commercial Claims and Encounters Database captures person-specific utilization and expenditures in the outpatient and other settings for active employees, early retirees, COBRA continuees, and dependents insured by employer-sponsored plans.
- 20 Implementing prior authorization involves added administrative costs. Therefore, limiting prior authorization to DMEPOS products above a certain dollar value could help ensure the process results in savings for the Medicare program.
- 21 CMS has largely suspended enforcement of this requirement even for many DMEPOS products that are required to have a face-to-face visit.
- 22 For this analysis, we examined an additional 20 HCPCS codes. (One code with over \$1 million in Medicare expenditures was excluded because of an insufficient number of private-payer claims.)
- 23 CMS is also statutorily prohibited from including inhalation drugs in the CBP and, per the 21st Century Cures legislation, infusion drugs used in conjunction with DME.
- 24 Such an exemption would apply to hospitals, not hospital-owned DMEPOS suppliers or DMEPOS suppliers that are only affiliated with a hospital.
- 25 Other products beyond these two categories might also not be ideal candidates for inclusion in the CBP. For example, many industry representatives have suggested that highly customized products should not be included in the CBP. The Commission could consider this topic in the future.
- 26 At the HCPCS level, there are many non-CBP DMEPOS products with relatively low expenditures. In determining whether a market is large enough to justify inclusion in the CBP, families of HCPCS codes should be considered because any given HCPCS code might have low expenditures, but a related family of products that suppliers often provide together could be large enough to justify inclusion.
- 27 Similar to other suppliers, DMEPOS suppliers are prohibited from balance billing beneficiaries dually eligible for Medicare and Medicaid.
- 28 Assignment is mandatory for many Medicare providers. For example, clinical diagnostic laboratory services, services of nurse practitioners, ambulatory surgical center services, and several other categories of services are required to be billed on an assignment basis under current Medicare payment rules (Centers for Medicare & Medicaid Services 2017c).
- 29 The company that manufactures wearable AEDs (among other products) reported an increase in gross margins between 2010 and 2011 from 54 percent to 57 percent. Part of this increase was attributable to the higher margin wearable-AED business being a larger share of the company's overall sales in 2011 compared with 2010 (Zoll Medical Corporation 2011). Therefore, to contribute to increasing the overall gross margins up to 57 percent, the gross margin for wearable AEDs was likely above 50 percent. In 2012, the company that manufactures wearable AEDs was acquired by the Asahi Kasei Corporation, making access to more recent financial information regarding wearable AEDs more difficult to ascertain (Zoll Medical Corporation 2012).
- 30 Some are concerned that PODs could spread to other types of implants, prosthetics, or orthotics (U.S. Senate Committee on Finance 2016).
- 31 Surgeries can involve multiple devices. If at least one POD-supplied device was used in a surgery, OIG counted that surgery as using a POD-supplied device.
- 32 Among hospitals that purchased spinal devices from PODs, OIG found that approximately three-quarters purchased spinal devices from PODs that manufacture their own devices: 40 percent of hospitals bought only from PODs that manufacture their own devices, 19 percent of hospitals bought only from PODs that buy devices from other entities, 36 percent of hospitals bought from both types of PODs, and 5 percent of hospitals were unclear whether PODs they bought from manufactured their own devices (Office of Inspector General 2013c).
- 33 The OIG study did not substantiate all the concerns that have been expressed regarding PODs. For example, the study found that surgeries in which devices were acquired through PODs involved fewer devices on average (12.3 vs. 14.2 when not acquired through PODs). Also, OIG's findings were mixed with regard to the complexity of surgeries at hospitals that acquired devices through PODs and those that did not.
- 34 See 42 CFR § 411.354(d)(2) and (d)(3) for a description of the unit-based special rules on compensation.

- 35 The concept of a physician’s immediate family member is used throughout the Stark law and means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild (42 CFR § 411.351).
- 36 For example, the Stark definition of *referrals* reaches referrals by others at a physician’s direction or control and could encompass such arrangements. In addition, there is a civil monetary penalty for circumvention schemes that could apply.
- 37 For example, self-referral could be allowed if PODs generated a certain share of their business (e.g., 60 percent) from non-self-referrals or for products for which a physician holds a patent.
- 38 Under such a provision, physicians would be allowed to refer their patients for surgery in which their POD supplied the devices so long as the net value of the POD was \$75 million or more. We believe that few, if any, PODs would currently meet this threshold, based on conversations with industry.
- 39 To the extent a physician has an ownership stake in an ambulatory surgical center (ASC), his or her incentive to use POD-supplied devices may be attenuated. Physicians that have an ownership stake in ASCs have an incentive to negotiate the lowest price for their devices because the ASC’s profits are the difference between the ASC facility payment and the costs (including device costs) to perform the surgery.
- 40 Applicable manufacturers and GPOs that fail to report required information are subject to civil monetary penalties of up to \$1,150,000 annually—up to \$10,000 per instance of nonreporting (up to an annual maximum of \$150,000) and up to \$100,000 per knowing instance of nonreporting (up to an annual max of \$1,000,000) (42 CFR § 403.912). In the agency’s 2016 and 2017 annual reports to the Congress on the Open Payments program, CMS said it did not impose any civil monetary penalties in program years 2014 or 2015 (Centers for Medicare & Medicaid Services 2017a, Centers for Medicare & Medicaid Services 2016a).

References

- 167 Concerned Auction Experts on Medicare Competitive Bidding Program. 2010. Letter to the Honorable Pete Stark. September 26.
- AdvaMed. 2016. Letter to the Honorable Orrin Hatch and Honorable Kevin Brady. Potential revisions to the physician self-referral law (“Stark law”). February 5.
- American Association for Homecare. 2017. DMEPOS adjusted fee methodology for non-bid areas: Stakeholder input on Section 16008 of the 21st Century Cures Act. <https://www.aahomecare.org/uploads/Document-Library/bf4ad1bc565732d3d6ccbca989cdf09.pdf>.
- American Heart Association. 2017. CPR & first aid emergency cardiovascular care: AED programs Q and A. http://cpr.heart.org/AHA/ECC/CPRAndECC/Programs/AEDImplementation/UCM_475254_AED-Programs-Q-A.jsp#How%20much%20does%20an%20AED%20cost.
- Baird, J. 2016. Avoid sham telehealth arrangements. Medtrade. <https://www.medtrade.com/news/general-healthcare/Avoid-Sham-Telehealth-Arrangements/>.
- Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2017. *2017 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds*. Washington, DC: Boards of Trustees.
- Boccuti, C. 2016. *Paying a visit to the doctor: Current financial protections for Medicare patients when receiving physician services*. Issue brief. Menlo Park, CA: The Kaiser Family Foundation.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017a. *Annual report to Congress on the Open Payments program*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017b. *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program health status monitoring: Summary of findings thru the second quarter of 2017*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017c. *Medicare claims processing manual*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017d. Verifying potential errors and taking corrective actions. In *Medicare Program Integrity Manual*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016a. *Annual report to Congress on the Open Payments program*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016b. CMS awards contracts for the DMEPOS Competitive Bidding Program Round 1 2017. Fact sheet. November 1. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-01-2.html>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016c. DMEPOS quality standards. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/DMEPOS-Qual-Stand-Booklet-ICN905709TextOnly.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016d. Medicare fee-for-service 2016 improper payments report. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports.html>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. *Calendar year (CY) 2015 update for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) fee schedule*. MLN Matters no. MM8999. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. Internal Healthcare Common Procedure Coding System (HCPCS) decision regarding codes for ventilators. <https://web.archive.org/web/20150610042556/http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/Internal-Coding-Decisions.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015c. Medicare prior authorization of power mobility devices demonstration status update. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/PMDDemoOctoberStatusUpdate10142015.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. Medicare, Medicaid, Children’s Health Insurance Programs; transparency reports and reporting of physician ownership or investment interests. Final rule. *Federal Register* 78, no. 27 (February 8): 9458–9528.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Next steps for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program. Fact sheet. April 17. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2012-Fact-sheets-items/2012-04-17.html>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008a. Medicare program; changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; payments for graduate medical education in certain emergency situations; changes to disclosure of physician ownership in hospitals and physician self-referral rules; updates to the long-term care prospective payment system; updates to certain IPPS-excluded hospitals; and collection of information regarding financial relationships between hospitals. Final rule. *Federal Register* 73, no. 161 (August 19): 48433–49084.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008b. Medicare program; proposed changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; proposed changes to disclosure of physician ownership in hospitals and physician self-referral rules; proposed collection of information regarding financial relationships between hospitals and physicians. *Federal Register* 73, no. 84 (April 30): 23528–23938.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2007. Medicare program; competitive acquisition for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other issues. Final rule. *Federal Register* 72, no. 68 (April 10): 17991–18090.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2006. *Pricing workbook for K0606 automatic external defibrillator—garment type*. Baltimore, MD: CMS.

Competitive Bidding Implementation Contractor. 2017. Product categories: Round 1 2017 HCPCS codes. [https://dmecompetitivebid.com/Palmetto/Cbicrd12017.Nsf/files/14_HCPCS_Excel.xls/\\$File/14_HCPCS_Excel.xls](https://dmecompetitivebid.com/Palmetto/Cbicrd12017.Nsf/files/14_HCPCS_Excel.xls/$File/14_HCPCS_Excel.xls).

Competitive Bidding Implementation Contractor. 2014a. Requirement to submit a bona fide bid. [https://www.dmecompetitivebid.com/Palmetto/Cbicrd2Recompete.Nsf/files/23_Fact_Sheet_Requirement_to_Submit_a_Bona_Fide_Bid.pdf/\\$File/23_Fact_Sheet_Requirement_to_Submit_a_Bona_Fide_Bid.pdf](https://www.dmecompetitivebid.com/Palmetto/Cbicrd2Recompete.Nsf/files/23_Fact_Sheet_Requirement_to_Submit_a_Bona_Fide_Bid.pdf/$File/23_Fact_Sheet_Requirement_to_Submit_a_Bona_Fide_Bid.pdf).

Competitive Bidding Implementation Contractor. 2014b. Round 2 recompetes & national mail-order recompetes request for bids (RFB). [http://www.dmecompetitivebid.com/Palmetto/Cbicrd2Recompete.Nsf/files/R2RC_Request_for_Bids_RFB.pdf/\\$File/R2RC_Request_for_Bids_RFB.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2Recompete.Nsf/files/R2RC_Request_for_Bids_RFB.pdf/$File/R2RC_Request_for_Bids_RFB.pdf).

Crampton, P., S. Ellermeyer, and B. Katzman. 2015. Designed to fail: The Medicare auction for durable medical equipment. *Economic Inquiry* 36, no. 1 (January): 469–485.

Department of Justice. 2017. Detroit-area neurosurgeon sentenced to 235 months in prison for role in \$2.8 million health care fraud scheme. News release. January 9. <https://www.justice.gov/opa/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud>.

Department of Justice. 2014. Virginia doctor convicted on perjury charges in Orthofix investigation. News release. January 15. <https://www.justice.gov/usao-ma/pr/virginia-doctor-convicted-perjury-charges-orthofix-investigation>.

Department of Justice. 2012. Orthofix, Inc. sentenced for illegal promotion of bone growth stimulators: Company to pay almost \$8 million in criminal penalties; \$42 million recovered in joint criminal/civil resolution. News release. December 20. <https://www.justice.gov/archives/usao/ma/news/2012/December/OrthofixsentPR.html>.

Federation of State Medical Boards. 2016. U.S. medical regulatory trends and actions. https://www.fsmb.org/Media/Default/PDF/FSMB/Publications/us_medical_regulatory_trends_actions.pdf.

Government Accountability Office. 2016. *CMS's Round 2 durable medical equipment and national mail-order diabetes testing supplies competitive bidding programs*. Washington, DC: GAO.

Government Accountability Office. 1997. *Medicare: Comparison of Medicare and VA payment rates for home oxygen*. Washington, DC: GAO.

Karon, S., T. Hoerger, R. Lindrooth, et al. 2003. *Evaluation of Medicare's competitive bidding demonstration for DMEPOS: Final evaluation report*. Prepared under contract to the Centers for Medicare & Medicaid Services. Report prepared for the Medicare Payment Advisory Commission. Research Triangle Park, NC: RTI International. June.

Lewis, A. 2012. Letter from the Disease Management Purchasing Consortium International to Secretary Sebelius regarding the methodology of the Health Status Monitoring data used by CMS. August 6. <http://www.cramton.umd.edu/papers2010-2014/lewis-letter-to-secretary-sebelius-6-aug-2012.pdf>.

Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

National Minority Quality Forum. 2015. *Centers for Medicare & Medicaid Services Competitive Bidding Program: Assessment of impact on beneficiary acquisition of diabetes-testing supplies and durable medical equipment prosthetics orthotics and supplies—associated health outcomes*. Washington, DC: NMQF. <http://www.nmqf.org/wp-content/uploads/2015/11/National-Minority-Quality-Forum-Report-on-CMS-Competitive-Bidding-Program.pdf>.

Newman, D., E. Barrette, and K. McGraves-Lloyd. 2017. Medicare Competitive Bidding Program realized price savings for durable medical equipment purchases. *Health Affairs* 36, no. 8 (August 1): 1367–1375.

Noridian Healthcare Solutions. 2017a. Knee orthoses (HCPCS L1832, L1833) quarterly results of service specific prepayment review. <https://med.noridianmedicare.com/web/jadme/cert-review/mr/complex-notifications-results/knee-orthoses-hcpcs-l1832-l1833-quarterly-results-of-service-specific-prepayment-review>.

Noridian Healthcare Solutions. 2017b. Parenteral nutrition (HCPCS B4197, B4199) quarterly results of service specific prepayment review. <https://med.noridianmedicare.com/web/jadme/cert-review/mr/complex-notifications-results/parenteral-nutrition-hcpcs-b4197-b4199-quarterly-results-of-service-specific-prepayment-review>.

Noridian Healthcare Solutions. 2017c. Spinal orthoses (HCPCS L0648, L0650) quarterly results of service specific prepayment review. <https://med.noridianmedicare.com/web/jadme/cert-review/mr/complex-notifications-results/spinal-orthoses-l0648-l0650-quarterly-results-of-service-specific-prepayment-review>.

Noridian Healthcare Solutions. 2017d. Therapeutic shoes (HCPCS A5500) quarterly results of service specific prepayment review. <https://med.noridianmedicare.com/web/jadme/cert-review/mr/complex-notifications-results/therapeutic-shoes-hcpcs-a5500-quarterly-results-of-service-specific-prepayment-review>.

Office of Inspector General, Department of Health and Human Services. 2017. *Round 2 competitive bidding for CPAP/RAD: Disrupted access unlikely for devices, inconclusive for supplies*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2016. *Escalating Medicare billing for ventilators raises concerns*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2013a. *Inappropriate and questionable Medicare billing for diabetes test strips*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2013b. Special fraud alert: Physician-owned entities. March 26. https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/pod_special_fraud_alert.pdf.

Office of Inspector General, Department of Health and Human Services. 2013c. *Spinal devices supplied by physician-owned distributors: Overview of prevalence and use*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2012. *Medicare supplier acquisition costs for L0631 back orthoses*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2011. *Most power wheelchairs in the Medicare program did not meet medical necessity guidelines*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2009. *Comparison of prices for negative pressure wound therapy pumps*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2006. *Medicare home oxygen equipment: Cost and servicing*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2005. *Medicare and FEHB payment rates for home oxygen equipment*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2004. *A comparison of prices for power wheelchairs in the Medicare program*. Washington, DC: OIG.

Piccini, J. P., L. A. Allen, P. J. Kudenchuk, et al. 2016. Wearable cardioverter-defibrillator therapy for the prevention of sudden cardiac death: A science advisory from the American Heart Association. *Circulation* 133, no. 17 (April 26): 1715–1727.

U.S. House of Representatives. 2013. American Taxpayer Relief Act of 2012. 112th Cong., 2nd sess., H.R. 8.

U.S. House of Representatives. 2010. Patient Protection and Affordable Care Act. 111th Cong., 2nd sess., H.R. 3590.

U.S. House of Representatives. 2003. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. 108th Cong., 1st sess., H.R. 1.

U.S. House of Representatives. 1997. Balanced Budget Act of 1997. 105th Cong., 1st sess., H.R. 2015.

U.S. Senate Committee on Finance. 2016. *Physician owned distributorships: An update on key issues and areas of congressional concern*. A Senate Finance Committee majority staff report. Washington, DC: Government Printing Office.

United States of America vs. Reliance Medical Systems et al. 2014. United States of America vs. Reliance Medical Systems LLC; Apex Medical Technologies LLC; Kronos Spinal Technologies LLC; Bret Berry; John Hoffman; Adam Pike; and Aria O. Sabit, M.D. United States District Court (Central District of California) Civ. Action No. 14–6979.

Wilson, L. 2012. Testimony by Laurence Wilson, Director of the Chronic Care Policy Group, Centers for Medicare & Medicaid Services. Medicare Durable Medical Equipment Competitive Bidding Program, before the Committee on Ways and Means Subcommittee on Health, U.S. House. 112th Congress, 2nd sess. May 9.

Zoll Medical Corporation. 2012. Asahi Kasei completes acquisition of Zoll. <https://www.zoll.com/news-releases/2012/04/26/asahi-kasei-completes-zoll-acquisition>.

Zoll Medical Corporation. 2011. Form 10–K submitted to the Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/887568/000119312511321014/d221219d10k.htm#tx221219_6.

C H A P T E R

7

**Applying the
Commission's principles for
measuring quality:
Population-based measures
and hospital quality incentives**

Applying the Commission's principles for measuring quality: Population-based measures and hospital quality incentives

Chapter summary

The Commission has recommended that Medicare link payment to quality of care to reward accountable entities and providers for offering high-quality care to beneficiaries. The Commission has recently formalized a set of principles for measuring quality in the Medicare program. Overall, quality measurement should be patient oriented, encourage coordination, and promote delivery system change. Medicare quality incentive programs should use a small set of outcomes, patient experience, and value measures to assess the quality of care across different populations, such as beneficiaries enrolled in Medicare Advantage (MA) plans, accountable care organizations (ACOs), and fee-for-service (FFS) in defined market areas, as well as those cared for by specified hospitals, groups of clinicians, and other providers. Applying the Commission's principles, Medicare quality incentive programs should score these risk-adjusted, population-based measure results against absolute performance thresholds and then use peer grouping to determine payment adjustments based on the provider's quality performance. In this chapter, we first apply the Commission's principles to two population-based outcome measures (potentially preventable admissions and home and community days (formerly known as "healthy days at home")) that may be used to evaluate quality of care for different populations. Next, we apply the principles to the design of a new hospital quality incentive program that combines measures of hospital outcomes, patient experience, and Medicare spending per beneficiary.

In this chapter

- Introduction
- Applying the Commission's principles for measuring quality to population-based measures
- Applying the Commission's principles for measuring quality to hospital quality incentives

Applying the Commission's principles for measuring quality to population-based measures

We analyzed the utility of two population-based measure concepts to assess the quality of FFS care at market-area levels (e.g., geographic areas representing local health care market areas) and whether there is enough variation in performance to allow comparisons of FFS quality of care across market areas.

Potentially preventable admissions

Potentially preventable admissions (PPAs) constitute an important quality measure because hospitalizations for conditions such as diabetes and pneumonia can potentially be preventable if ambulatory care is provided in a timely and effective manner. To build on the Commission's work testing the measurement of PPAs in FFS Medicare and across Medicare payment models, we applied a quality measure developed for MA to FFS administrative claims data.

We calculated the observed rate of PPAs per 1,000 FFS beneficiaries for both chronic (e.g., diabetes) and acute (e.g., bacterial pneumonia) conditions. We found that observed (that is, not risk-adjusted) PPA rates varied across population groups (e.g., age, sex, Medicaid eligibility) and across two different definitions of market areas. This variation signals opportunities to improve the quality of care within areas and the potential to use the measure to compare quality across local health care markets. However, more development is needed to incorporate risk adjustment based on FFS data in the analysis.

Home and community days

The Commission tested a prototype home and community days (HCDs) measure to assess how well health care markets and organizations that take responsibility for a population keep people alive and out of health care institutions. The HCD measure is defined as 365 days minus the sum of (1) the number of days in the year that a beneficiary spends in certain institutional (e.g., hospital, skilled nursing facility) and ambulatory (e.g., emergency department) health care settings and (2) the number of mortality days (i.e., the number of days in the year that a beneficiary was not living, if any).

We calculated risk-adjusted HCDs from 2013 to 2015 for two populations of FFS beneficiaries (all beneficiaries 65 years and older and beneficiaries 65 years and older with two or more chronic conditions). In 2015, the adjusted HCD rate for beneficiaries 65 years and older was 351 days compared with 328 days for beneficiaries 65 years and older with 2 or more chronic conditions. We also compared the distribution of mean, risk-adjusted HCDs by MedPAC-defined market areas and hospital service areas. For the group of all beneficiaries 65

years and older, the difference in HCDs was only 3 days between high- and low-performing market areas; the difference was only 9 days for the group with 2 or more chronic conditions. However, because of the limited variation in HCDs over market areas and the challenges posed by the need to develop appropriate weights for constructing the composite measure, the Commission questions the immediate utility of the HCD measure in its current form to assess market-level FFS performance.

The Commission has continued interest in developing claims-calculated, population-based outcome measures. Ideas for population-based measures include “mean time between failure” (e.g., mean time between hospitalizations), successful community discharge, home-to-home transition time, end-of-life care and burdensome transitions, and low-value care.

Applying the Commission’s principles for measuring quality to hospital quality incentives

We also examined the potential to create a single quality-based payment program for hospitals in light of Medicare’s experience with four hospital payment incentive programs: the Hospital Inpatient Quality Reporting Program, Hospital Readmissions Reduction Program, Hospital-Acquired Condition Reduction Program (HACRP), and Hospital Value-based Purchasing (VBP) Program. The Commission’s and others’ main concerns about these programs are that (1) there are too many overlapping hospital quality payment and reporting programs, which creates unneeded complexity in the Medicare program; (2) all-condition measures are more appropriate to measure the performance of hospitals rather than the condition-specific readmissions and mortality measures currently used; (3) the existing programs include process measures and measures not consistently reported by providers; and (4) some of the programs score hospitals using “tournament models” (providers are scored relative to one another) rather than on clear, absolute, and prospectively set performance targets.

Ideally, the Congress could redesign the multiple hospital quality payment programs under a single hospital value incentive program (HVIP) that would be patient oriented, encourage coordination across providers and time, and promote change in the delivery system. Although CMS likely has the authority to make some of our suggested changes to hospital quality payment without congressional action (e.g., improving public reporting), other key reforms would require statutory changes.

The Commission asserts that the Medicare program should consider differences in providers’ patient populations—which affect providers’ performance on quality measures, including social risk factors—and that Medicare should account for

social risk factors in quality programs by adjusting payment through peer grouping. Applying these principles, we modeled an HVIP in which quality-based payments are distributed to hospitals organized under 10 peer groups based on the share of fully dual-eligible beneficiaries treated. (Fully dual-eligible beneficiaries are covered by both Medicare and Medicaid, and so we use this population category as a proxy for low income as a social risk factor.) In our model, the HVIP is budget neutral, with awards funded by a payment withhold from all hospitals. Our HVIP model uses a 2 percent withhold, which is the same as the existing VBP program uses, but policymakers could raise or lower the withhold amount.

Under our HVIP model, relative to the 2 percent withhold, about half of hospitals would receive a negative payment adjustment, and about half would receive a positive adjustment. Most hospitals rewarded under the existing programs would continue to receive rewards, and hospitals currently incurring penalties would continue to do so. Our peer grouping of hospitals allowed us to examine how hospitals serving large shares of low-income patients perform. We found that, compared with the existing quality payment programs, the HVIP approach makes payment adjustments among hospitals that serve different populations more equitable. Over the next year, the Commission plans to continue to refine a design for an HVIP that conforms with our principles for quality measurement. Some topics the Commission will further explore include weighting of measures, withhold values, patient experience measures, and patient safety measures. ■

Introduction

The Commission contends that Medicare payments should not be made without consideration of the quality of care delivered to beneficiaries. The Congress has enacted quality reporting programs for almost all of the major fee-for-service (FFS) provider types and for Medicare Advantage (MA) and Part D plans, and it has mandated pay-for-performance (which Medicare refers to as value-based purchasing) for hospitals, dialysis facilities, physicians, accountable care organizations (ACOs), and skilled nursing facilities. Over the past several years, the Commission has expressed concern that Medicare's quality measurement programs are "overbuilt," relying on too many clinical process measures that are, at best, weakly correlated with health outcomes of importance to beneficiaries and the program. Relying on a large number of process measures can reinforce payment incentives in FFS to overprovide and overuse measured services. Process measures are also burdensome for providers to report, while yielding limited information to support clinical improvement. Although CMS has been shifting away from process to outcome measures in some of the Medicare quality programs, more work is needed to align the quality measurement systems with the Commission's principles for measuring quality (see text box, p. 180).

Applying quality measurement principles across populations

In the June 2014 and 2015 reports to the Congress, the Commission put forth a concept for an alternative to Medicare's current system for measuring the quality of care provided to beneficiaries (Medicare Payment Advisory Commission 2015a, Medicare Payment Advisory Commission 2014). This alternative led to the development of the Commission's principles on quality measurement—in particular, encouraging providers to work across the delivery system. Under this alternative policy, Medicare quality incentive programs would use a small set of outcomes, patient experience, and value measures to assess the quality of care across different populations, such as beneficiaries enrolled in Medicare Advantage (MA) plans, accountable care organizations (ACOs), and fee-for-service (FFS) in defined market areas, as well as those cared for by specified hospitals, groups of clinicians, and other providers. Medicare can link quality performance to payment using such measures to create incentives for MA plans, ACOs, and providers to offer high-quality care

to beneficiaries. Based on the Commission's principles, Medicare quality incentive programs for these accountable entities should score risk-adjusted measure results against absolute performance thresholds and then use peer grouping to adjust payment based on performance. Medicare's use of the same set of measures and scoring framework across populations could also promote other payers (e.g., Medicaid and commercial) using the same systems, which could reduce the burden providers face in tracking a diverse number of quality measures and methodologies across payers.

In this chapter, we first apply the Commission's alternative policy and principles to test the use of two population-based outcome measures (potentially preventable admissions (PPAs) and home and community days (HCDs) (formerly known as "healthy days at home")) to evaluate FFS quality of care and beneficiary access to health care in local health care market areas. We wanted to test the use of the measures for the FFS population in health care markets before applying the measures to other populations. Next, we apply the Commission's principles to the design of a new hospital quality payment program that uses current hospital outcome, patient experience, and Medicare spending per beneficiary measures.

Applying the Commission's principles for measuring quality to population-based measures

This chapter presents our analysis of two claims-based, population-based measures: PPAs and HCDs. Our analyses are meant to test whether the two measures can be used to evaluate quality of care for FFS beneficiaries and compare performance across local health care market areas, before applying the measures to other populations.

Potentially preventable admissions

Hospital stays can pose risks to patients, particularly the elderly. Adverse events represent a prominent risk, including iatrogenic infections, medication errors, device failures, and pressure injuries such as decubitus ulcers. According to researchers at the Centers for Disease Control and Prevention (CDC), on any given day, approximately 1 in 25 U.S. patients contracts at least one infection during the course of hospital care

The Commission's principles for measuring quality in the Medicare program

The Commission has recently formalized a set of principles for measuring quality in the Medicare program, principles that we apply in developing quality measures, modeling the design or redesign of quality incentive (or value-based purchasing) programs, and commenting on CMS proposals for quality measurement. Over recent years, the Commission has articulated elements of these principles in its policy development process, but we now present them in a complete framework for evaluating Medicare's approaches to assessing quality of care. The Commission's principles are as follows:

- Quality measurement should be patient oriented, encourage coordination across providers and time, and promote relevant change in the nature of the delivery system.
- Quality measurement should not be unduly burdensome for providers.
- Medicare quality programs should include population-based measures such as outcomes, patient experience, and value (e.g., Medicare spending per beneficiary, measures of services that have little or no clinical benefit). Providers may choose to use more granular measures to manage their own quality improvement.
- Medicare quality programs should give rewards based on clear, absolute, and prospectively set performance targets (as opposed to "tournament models," under which providers are scored relative to one another).

- The Medicare program should take into account, as necessary, differences in a provider's patient population, including social risk factors. Because adjusting measure results for social risk factors can mask disparities in clinical performance, Medicare should account for social risk factors by directly adjusting payment through peer grouping.
- Medicare should target technical assistance resources to low-performing providers.
- Medicare should support research and data collection to reduce measurement bias, including, for example, the effects of social risk factors.

The Commission also maintains that the goal of improved care should extend to all patients, regardless of health status, income, and race. Recognizing that those expectations are more likely to be met if they are combined with additional resources to accelerate a provider's ability to address particularly challenging care delivery environments, the Commission recommended in June 2011 that the Quality Improvement Organization Program be fundamentally restructured and that funding be reprogrammed to give providers and communities more choices in who assists them in quality improvement activities and flexibility in how resources can be used. (Medicare Payment Advisory Commission 2011). The Commission also recommended that Medicare make technical assistance to low-performing providers and community initiatives a high priority as a strategy to complement payment policy and address persistent health care disparities. ■

(Centers for Disease Control and Prevention 2016b). In addition, the inpatient environment itself can lead to a reduction in elderly patients' independence as they cope with functional loss that can stem from extended bed rest (Covinsky et al. 2011). Furthermore, the hospital environment often hinders discussion about treatment options.

Hospitalizations due to conditions such as diabetes and pneumonia are potentially preventable if ambulatory

care is provided in a timely and effective manner.¹ PPAs can fall into five categories: system related (e.g., unavailability of services), physician related (e.g., suboptimal monitoring), medical (e.g., medication side effects), patient related (e.g., delay in seeking help), and social (e.g., lack of social support) (Freund et al. 2013). Evidence also suggests that effective primary care is associated with lower PPAs (Gao et al. 2014). The patient may have required acute-level services at the time he or

she sought care, but the need for the admission might have been avoided with appropriate ambulatory care and coordination activities.

Rates of PPAs calculated through administrative claims data can reflect the quality of the care provided under payment models and by providers in a local market area (that is, a defined population). High-quality MA plans in a local market area should be able to manage beneficiary, hospital, and physician relations to coordinate care and provide appropriate access (Wholey et al. 2003). High-quality ACOs should also be able to manage relationships to improve care. For example, ACOs can provide tools and data to clinicians about patients with chronic ambulatory care-sensitive conditions (such as diabetes and asthma) so they can appropriately monitor, coordinate, and follow up with patients and reduce avoidable hospitalizations. FFS clinicians can also play a role in affecting admissions in the ambulatory care area they serve by effectively coordinating with other providers and offering adequate access to beneficiaries. For example, a clinician's availability for appointments can affect how well a patient's chronic conditions are managed and whether a patient's acute conditions (such as pneumonia) can be identified and treated outside of the hospital in a timely manner (Davies et al. 2009).

The Commission's prior work on measuring PPAs

In our June 2014 and 2015 reports to the Congress, the Commission included PPAs for inpatient hospital care as a population-based measure concept for evaluating quality in a market area (Medicare Payment Advisory Commission 2015a, Medicare Payment Advisory Commission 2014). Over the years, we have used two existing measure specifications to define the concept of "potentially preventable" and measure FFS rates accordingly. In the March 2017 report to the Congress, we presented national rates and variation by market areas using a definition of PPAs developed by 3M (Medicare Payment Advisory Commission 2017). During the Commission's November 2016 meeting, the Commission expressed concern that the 3MTM measure was not available in the public domain and that providers could find the measure definitions overly complicated. In recent March reports to the Congress, we also published CMS-reported rates of hospitalizations based on the Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicator (PQI) specifications for three individual ambulatory care-sensitive conditions (diabetes, congestive heart failure (CHF), and bacterial pneumonia).

Calculating potentially preventable admissions in the FFS population

To further test the concept of measuring PPAs for FFS beneficiaries and to compare performance across market areas, we used a 2018 measure specification developed by AHRQ and adopted with permission by the National Committee for Quality Assurance (NCQA). The measure specification is publicly available as part of NCQA's Healthcare Effectiveness Data and Information Set[®] (HEDIS[®]), and the measure is written for the Medicare population, specifically for MA plans to report.² In the summer of 2018, MA plans will report measure results to CMS using the 2018 measure specification (collected by NCQA), along with other quality measures that are used to calculate star ratings.³ Thus, in the future, we may have the ability to use one PPA measure specification to compare performance across MA, FFS, and ACOs nationally and within markets.

The HEDIS (MA) PPA measure represents the observed rate of PPAs and the risk-adjusted ratio of observed-to-expected potentially preventable admissions. PPAs are calculated for chronic conditions (e.g., diabetes) and acute conditions (e.g., pneumonia).^{4,5} (Although we chose to analyze this measure specification for FFS, we are not endorsing any approach to measuring PPAs. We are simply exploring the use of PPAs as a population-based measure of ambulatory care.) Comparing FFS and MA plan quality performance in a local area is a future goal of this work, so we did not make changes to the HEDIS specification in order to permit "apples-to-apples" comparisons among Medicare payment models. Our analysis examines PPAs for Medicare FFS beneficiaries ages 67 and older because the HEDIS specification requires two years of beneficiary enrollment in the MA plan. In future analyses, we could apply the measure to different populations, including the under-age 67 population. We did not calculate risk-adjusted numbers of expected discharges because the regression model NCQA uses to calculate the expected results is based on the risk profiles of a sample of MA beneficiaries. Since MA plan populations and the coding intensity of diagnoses differ from FFS, we would need to develop FFS-based risk weights to calculate expected results. We therefore focused our analysis on the observed rate of unadjusted PPAs per 1,000 beneficiaries ages 67 and older. We also focused on national results and not results at the market level because unadjusted results would not capture any underlying differences in market-area population characteristics.

**TABLE
7-1**

PPAs per 1,000 FFS beneficiaries ages 67 and older vary by population group, 2016

	PPA rate per 1,000 FFS beneficiaries		
	Acute conditions	Chronic conditions	Total
Age groups			
67–74	8.4	12.0	20.3
75–84	17.0	20.0	37.0
85+	34.3	31.3	65.6
Sex			
Male	13.2	17.6	30.9
Female	17.0	17.8	34.8
Medicaid eligibility			
Fully dual eligible	32.2	34.0	66.1
Partially dual eligible	22.4	33.3	55.7
Non-dual eligible (Medicare only)	13.3	15.5	28.7
Total	15.3	17.7	33.1

Note: PPA (potentially preventable admission), FFS (fee-for-service). To evaluate the utility of measuring PPAs for FFS beneficiaries, we calculated the observed (not risk-adjusted) rates of admissions tied to acute (e.g., pneumonia), chronic (e.g., diabetes) and total (acute plus chronic) conditions. Rates presented are the number of PPAs divided by the number of beneficiaries in the qualifying population, multiplied by 1,000. The qualifying population is the same across the acute and chronic categories. Beneficiaries who died in the measurement year are excluded. Fully dual-eligible beneficiaries qualify for a full range of Medicaid benefits, and partially dual-eligible beneficiaries qualify for Medicaid payment of the Medicare premium and perhaps the cost sharing for Medicare services.

Source: MedPAC analysis of 2016 Medicare claims data.

We found that it is feasible to calculate unadjusted, observed PPAs for FFS beneficiaries nationally and for two different geographic area levels representing local health care markets (MedPAC-defined market areas designed to match insurance markets served by private plans and Dartmouth-defined hospital service areas (HSAs), which are collections of zip codes that represent a local market area whose residents receive most of their inpatient care from the hospitals in that area). We also found variation by population groups (e.g., age, sex, Medicaid eligibility) and by market area, which signals both opportunities to improve quality performance within areas and the measure’s potential for comparing quality across local health care markets.

In the future, the Commission could develop a risk adjustment model to calculate FFS and ACO expected PPA rates and compare market-area risk-adjusted PPAs. The risk adjustment model would need to ensure that the PPA measure primarily reflects an organization’s or area’s quality of care rather than underlying differences in patient severity. Using the MA PPA measure as an example, we can test risk adjustment using age, sex, and disease

severity based on CMS’s hierarchical condition categories (CMS–HCCs) because we have access to these FFS data. In the future, if the PPA measure is considered for a Medicare quality payment program, we can test the use of peer grouping to account for differences in the social risk factors of populations. The Commission continues to encourage CMS to support research and data collection to improve our ability to take into account social risk factors.

Qualifying population The qualifying population for the PPA measure is all FFS beneficiaries who meet the following criteria: are ages 67 years and older at the end of the measurement year, are alive at the end of the measurement year, are continuously enrolled in Part A and Part B for the measurement year and the previous year with no months of MA enrollment, and have used no hospice services in the measurement year. For the 2016 measurement year, the population of FFS beneficiaries who met those criteria was about 22.5 million nationwide.

Beneficiaries with three or more discharges in the measurement year were considered outliers and removed from the qualifying population and observed event

**TABLE
7-2**

Distribution of PPAs per 1,000 FFS beneficiaries ages 67 and older varies by local health care market area, 2016

PPA rate per 1,000 FFS beneficiaries

	Acute conditions	Chronic conditions	Total
National mean	15.3	17.7	33.1
10th percentile (highest performing)	10.4	11.1	22.4
50th (median)	16.2	17.8	34.9
90th (lowest performing)	24.3	24.9	48.7
Ratio of 90th to 10th percentile	2.3	2.2	2.2

Note: PPA (potentially preventable admission), FFS (fee-for-service). To evaluate the utility of measuring PPAs for FFS beneficiaries, we calculated the observed (not risk-adjusted) rates of admissions tied to acute (e.g., pneumonia), chronic (e.g., diabetes) and total (acute plus chronic) conditions. Rates presented are the number of PPAs divided by the number of beneficiaries in the qualifying population, multiplied by 1,000. The qualifying population is the same across the acute and chronic categories. Beneficiaries who died in the measurement year are excluded. There are over 1,200 MedPAC-defined market areas designed to match insurance markets served by private plans. The average qualifying population in each market area is about 19,000 beneficiaries.

Source: MedPAC analysis of 2016 fee-for-service Medicare claims data.

counts. Almost 57,000 outlier beneficiaries were removed from our measure calculation (about 75 percent had hospitalizations tied to chronic conditions vs. acute primary diagnoses).

PPAs by chronic and acute conditions As with the MA plan PPA measure, we calculated the number of inpatient admissions and observation stays tied to the beneficiaries in the qualifying population (both are observed events). The observed events include admissions with the primary diagnosis of the following *chronic* conditions: diabetes (short-term and long-term complications, uncontrolled diabetes, lower extremity amputation among patients with diabetes); chronic obstructive pulmonary disease (COPD); asthma; hypertension; and heart failure. Observed events also include admissions tied to beneficiaries with the primary diagnosis of the following *acute* conditions: bacterial pneumonia, urinary tract infection, cellulitis, and pressure ulcers. We calculated a total number of PPAs (chronic plus acute).

National PPAs results In 2016, PPAs accounted for about 8 percent of FFS Medicare hospital admissions.⁶ Nationally, there were 15.3 acute-condition-related PPAs per 1,000 FFS beneficiaries and 17.7 chronic-condition-related PPAs per 1,000 FFS beneficiaries, for a total of 33.1 PPAs per 1,000 FFS beneficiaries (Table 7-1).

In 2016, older Medicare beneficiaries had higher PPA rates for both acute and chronic conditions. Female

beneficiaries had higher PPA rates than men for acute conditions and about the same PPA rate as men for chronic conditions. Both fully (i.e., receive full range of Medicaid benefits) and partially (i.e., Medicaid pays Medicare premium and may also pay the cost sharing for Medicare services) dual-eligible beneficiaries had higher PPA rates for both acute and chronic conditions compared with non-dual-eligible (Medicare-only) beneficiaries. These patterns are consistent with CMS-produced results using selected AHRQ PQIs and with our prior work using the 3M PPA measure.

The pattern of higher PPA rates for the dual-eligible population is also expected when comparing admission rates that are not risk adjusted for population characteristics. For example, the fully dual-eligible population is older than the partially dual-eligible population, which may explain the fully dual-eligible population’s higher rate of PPAs. In future analyses of PPA rates, we will consider the effect of dual eligibility on the PPA results.

Distribution of PPAs in local health care market areas

Differences in PPA results across local health care markets can help distinguish differences in quality compared with a national mean and across market areas. We calculated PPA rates for acute and chronic conditions and total PPAs per 1,000 FFS beneficiaries in the 1,200 MedPAC market areas that the Commission recommends for MA payment and quality reporting (Table 7-2). We found that

total observed (not risk-adjusted) PPA rates varied across market areas, with the market area in the 90th percentile of PPA rates having a rate that was 2.2 times the market area in the 10th percentile. The magnitude of difference between the market areas in the 90th and 10th percentiles of observed PPA rates for acute conditions and chronic conditions individually was similar to that for the total PPA rate.

To model rates at a more narrowly defined health care market level (that is, the Dartmouth-defined hospital service areas (HSAs)), we calculated PPA rates for acute and chronic conditions and total PPA rates per 1,000 FFS beneficiaries in the roughly 3,400 HSAs. An HSA is a collection of zip codes that represents a local market area whose residents receive most of their inpatient care from the hospitals in that area. As with the larger MedPAC market areas presented in Table 7-2, PPA rates varied across HSAs, with HSAs in the 90th percentile of PPA rates exceeding HSAs in the 10th percentile of PPA rates by 2.1 times (data not shown). PPA rates for acute conditions had slightly more variation compared with PPA rates for chronic conditions.

Home and community days measure

The Commission tested a “home and community days” (HCDs) quality measure to assess how well health care organizations keep people healthy and out of health care institutions.⁷ We chose to focus on the number of days per year that beneficiaries did not receive institutionalized medical care (such as days during which a beneficiary did not have an inpatient stay) and mortality days. An alternative to the measure could include days in which beneficiaries had any interaction with the health system (i.e., days in which Medicare covered any medically necessary service such as a physician office visit or an inpatient stay (Medicare Part A and Part B)).

High-quality MA plans and ACOs are designed to manage beneficiary, hospital, and physician relations to coordinate care and provide appropriate access to keep people out of health care institutions. For example, ACOs can provide tools and data to physicians about patients with ambulatory care-sensitive conditions (such as diabetes and asthma) so that they can appropriately monitor, coordinate, and follow up with patients and reduce inpatient stays. FFS clinicians can also play a role in affecting HCDs in their ambulatory care area by effectively coordinating with other providers and offering adequate access to beneficiaries.

Commission staff worked with a team from the Harvard School of Public Health to develop a prototype HCD measure. As described in the June 2015 report to the Congress, an HCD measure using Medicare claims data may be a meaningful gauge for comparing differences in health status across populations and be less complicated than other measures for beneficiaries, policymakers, and other stakeholders to understand (Medicare Payment Advisory Commission 2015a).

CMS is actively developing a quality measure for Medicare and Medicaid health plans and long-term services and support populations based on the Commission’s HCD measure. CMS may submit the measure, currently named “days in the community,” for endorsement by the National Quality Forum. Also, in 2016, the National Bureau of Economic Research released a working paper, *Healthy-time Measures of Health Outcomes and Healthcare Quality*, that describes some conceptual and empirical foundations of “healthy-time” measures of health care quality. Their analysis features the Commission’s developing HCD measure and similar measures from other organizations.⁸ The authors concluded that “the basic premises underlying this [the Commission’s] measure’s definition are conceptually sound and intuitively appealing; its use as a patient-centered outcome or care-quality indicator holds promise” (Burns and Mullahy 2016).

Calculating home and community days

The Commission’s HCD measure, for the purposes of this chapter, pertains to FFS Medicare beneficiaries 65 years and older, excluding those enrolled in MA for any part of the year and those not enrolled in Medicare FFS continuously throughout the year. For the HCD measure we modeled, we focused on beneficiary interactions with more serious health care that is covered by Medicare and on mortality. We defined this measure algorithmically as follows:

$$\text{HCDs} = 365 \text{ days} - (\text{days in short-term acute care hospital} + \text{days in inpatient rehabilitation facility} + \text{days in long-term care hospital} + \text{days in inpatient psychiatric facility} + \text{days in skilled nursing facility} + \text{days in observation status} + \text{days of emergency department use} + \text{mortality days})$$

For each FFS beneficiary, we calculated his or her total number of mortality days, which is defined by the number of days remaining in the calendar year after the date of death. For example, a beneficiary who did not die during

the year would have no mortality days. A beneficiary who died on December 28 would have three mortality days for the year. Inpatient, observation, skilled nursing facility (SNF), inpatient psychiatry, inpatient rehabilitation, and long-term care hospital days were defined as the total number of days per year the beneficiary spent in each of these respective settings. For the purposes of this analysis, we weighted HCD components equally, but policymakers interested in developing this measure further could give the components different weights based on some prioritization that takes into account interests shared by the Medicare program and its beneficiaries.

We did not subtract home health visit days in calculating a beneficiary's HCDs. Home health represents a midpoint at which the patient is at home but is still in need of health care services. In some health care markets, home health visits are used to prevent or limit use of other, more expensive services—in particular, inpatient and SNF care. Subtracting home health visit days from the HCD measure could therefore penalize these markets and providers unfairly. Documented overuse of home health care could make a case for subtracting home health visits from the HCD measure. For instance, the Office of Inspector General (OIG) has recently identified 27 geographic areas as “hotspots” for characteristics commonly found in OIG-investigated cases of home health fraud, so, in some markets, penalizing home health use could be an appropriate approach (Office of Inspector General 2016). Yet even with these potential differences in home health use by market area, from the beneficiary's perspective, home health visits are likely more desirable than the use of other health care services that would lower HCDs, a circumstance that argues for not subtracting home health visit days from the HCD measure.

Risk adjustment modeling

A critical step in the development of the HCD measure is to test appropriate risk adjustment models. Such models should ensure that the HCD measure primarily reflects an organization's or area's quality of care rather than underlying differences in patient severity. Using linear regression, we developed a model that included variables readily available in FFS claims data and used in other quality measures: age, sex, disease burden determined from HCCs, and market-fixed effects (e.g., local characteristics).⁹

We found that disease burden had the greatest impact on HCDs. The diseases or conditions that had the most effect

on HCDs were respiratory arrest, nephritis, extensive third-degree burns, seizure disorders and convulsions, and coma/brain compression/anoxic damage (all statistically significant). Our analysis found that HCDs decrease with age. Men had slightly more HCDs than women.

Effect of dual-eligibility status We also tested the effects that social risk factors could have on the risk adjustment model. In a separate regression model, we included race and dual eligibility (defined by a beneficiary having both Medicare and Medicaid coverage for at least one month of a year). (Dual eligibility may be a proxy for low income.) When included as a variable, dual-eligibility status had some impact on HCDs (regression coefficient = -7.76) (i.e., dual-eligible status corresponds with fewer HCDs). Coefficients for race were not significant. When we compared the explanatory power (R^2) of a risk adjustment model with age, sex, disease burden, and market-fixed effects with a model that included those variables plus dual-eligibility status, there was no difference in the explanatory power of the models (both $R^2 = 0.32$).

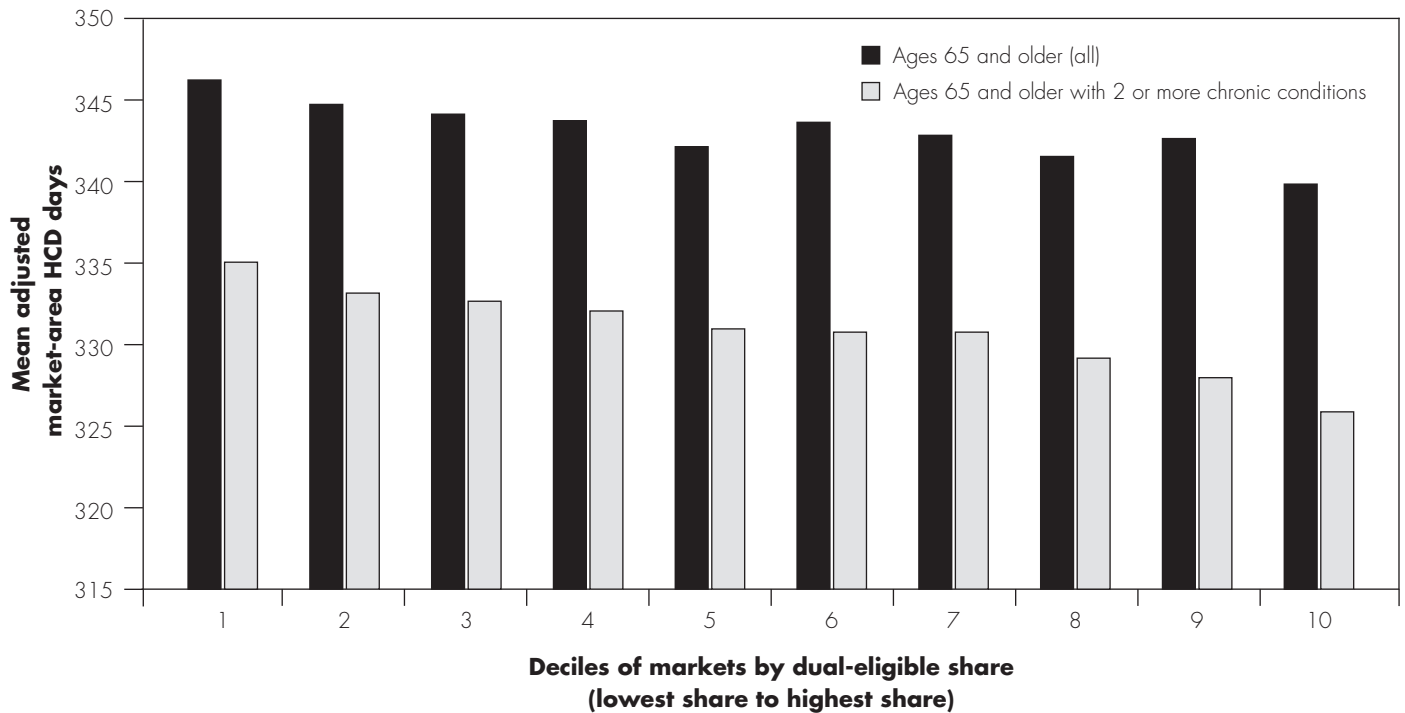
Since dual eligibility seemed to have some impact for individual beneficiaries but not on the overall model's explanatory power, we investigated the impact of dual-eligibility on market-area performance.¹⁰ We examined how market performance varies among high-share versus low-share dual-eligible markets and found that mean HCDs decline with increasing deciles of dual-eligible share, although the relationship is not constant (Figure 7-1, p. 186). Among all beneficiaries ages 65 and older, markets in the top decile of dual-eligible share—in which more than 37 percent of beneficiaries were Medicaid eligible—had, on average, about 4 fewer HCDs compared with markets in the bottom decile of dual-eligible share (in which over 9 percent of beneficiaries were dual eligible). Among beneficiaries ages 65 and older with 2 or more chronic conditions, markets in the top decile of dual-eligible share had, on average, about 6 fewer HCDs compared with markets in the bottom decile of dual-eligible shares.¹¹

We found that mortality days tended to be somewhat higher in markets with high dual-eligibility shares, resulting in a lower average number of HCDs, although the differences were small. Inpatient and SNF days were stable across the deciles of markets.

If CMS opted to use HCDs to compare quality across market areas or providers, the Secretary should be

**FIGURE
7-1**

Mean adjusted home and community days are slightly lower in local health care market areas with higher shares of dual-eligible beneficiaries, 2015



Note: Home and community days (HCDs) are adjusted for age, sex, and disease burden. There are over 1,200 MedPAC-defined market areas, designed to match insurance markets served by private plans. Deciles of markets were created based on the share of Medicare beneficiaries who were partially dual eligible for Medicare and Medicaid at any point in the year. Partially dual-eligible beneficiaries qualify for Medicaid payment of the Medicare premium and perhaps the cost sharing for Medicare services. Markets in Decile 1 have the lowest share of partially dual-eligible beneficiaries (9.4 percent), while markets in Decile 10 have the highest share of Medicaid-eligible beneficiaries (37.3 percent). The scale of the y-axis was chosen to highlight the differences in HCDs across market areas.

Source: Analysis of fee-for-service Medicare claims data, 2015.

cognizant of differences that correlate with dual eligibility. However, the Commission does not support the inclusion of dual-eligibility status in a risk adjustment model because doing so would mask disparities in clinical performance. Rather, Medicare should account for social risk factors by directly adjusting payment through peer grouping. The Commission continues to encourage the Secretary to support research and data collection to improve Medicare's ability to account for the effect of social risk factors on health outcomes.

Adjusted HCDs in local health care market areas

To understand HCDs for Medicare beneficiaries of different health status in different market areas over time, we calculated mean, risk-adjusted HCDs for the two different geographic area levels representing local health care markets that we used in the PPA analysis (MedPAC-

defined market areas designed to match insurance markets served by private plans and Dartmouth-defined HSAs, which are collections of zip codes that represent a local market area whose residents receive most of their inpatient care from the hospitals in that area). We calculated HCDs in each MedPAC-defined market area and HSA using 3 years of FFS Medicare data (2013 to 2015) for 2 populations: (1) all beneficiaries 65 years and older and (2) beneficiaries 65 years and older with at least 2 chronic conditions. There were at that time about 27.3 million beneficiaries 65 years and older, and about 7.7 million of those had at least two chronic conditions.

As expected, we found that Medicare beneficiaries with greater chronic-condition burden had fewer HCDs (Table 7-3). In 2015, the adjusted HCD rate for beneficiaries 65 years and older was 351 days compared with 328 days for beneficiaries 65 years and older with 2 or more chronic

**TABLE
7-3**

Mean adjusted home and community days for FFS beneficiaries were stable from 2013 to 2015

Home and community days

	2013	2014	2015
All beneficiaries 65 years and older	351	351	351
Beneficiaries 65 years and older with 2 or more chronic conditions	331	332	328

Note: FFS (fee-for-service). Home and community days are adjusted for age, sex, disease burden, and market-fixed effects. There are over 1,200 MedPAC-defined market areas, which are designed to match insurance markets served by private plans.

Source: Analysis of FFS Medicare claims data, 2013–2015.

conditions (a difference of 23 days). From 2013 to 2015, the results for beneficiaries 65 years and older were stable (351 days in each year), but the average HCDs declined slightly over the three years for beneficiaries with 2 or more chronic conditions (from 331 to 328 days).

For both population groups, the components of the HCD algorithm with the biggest impact on a market area’s HCDs were mortality days, SNF days, and inpatient days (Table 7-4). For beneficiaries 65 years and older, the components were stable over time. There was somewhat more change from 2013 to 2015 in the HCD components for the beneficiaries 65 years and older with 2 or more chronic conditions. In the 2013 to 2015 period, the mortality days for that population increased by about 2.3

days; SNF days slightly increased over the three years (from 6.2 days to 6.6 days).¹²

Distribution of adjusted HCDs in local health care market areas

Because our goal was to compare FFS quality across health care markets and across different populations, we looked for variation in HCD measure results across both MedPAC-defined market areas and HSAs. We calculated the distribution of HCDs for all beneficiaries 65 years and older and for beneficiaries 65 years and older with 2 or more chronic conditions across MedPAC-defined market areas (Table 7-5, p. 188). The distribution among MedPAC-defined market-area HCDs for both populations was very small. The difference between the 90th and

**TABLE
7-4**

Home and community day components were stable from 2013 to 2015

Component (days)	All beneficiaries 65 years and older			Beneficiaries 65 years and older with 2 or more chronic conditions		
	2013	2014	2015	2013	2014	2015
Mortality	9.8	9.4	9.7	21.4	20.5	23.7
Skilled nursing facility	2.1	2.1	2.0	6.2	6.0	6.6
Inpatient	1.6	1.5	1.5	4.7	4.5	4.8

Note: Components are part of the home and community days (HCDs) calculation and represent mortality days and/or days in which beneficiaries have interactions with more serious health care. Mortality, skilled nursing facility, and inpatient days have the biggest impact on a market area’s HCDs. HCDs are adjusted for age, sex, disease burden, and market-fixed effects. There are 1,200 MedPAC-defined market areas designed to match insurance markets served by private plans.

Source: Analysis of fee-for-service Medicare claims data, 2013–2015.

**TABLE
7-5**

Distribution of home and community days did not vary across local health care market areas, 2015

Home and community days

	All beneficiaries 65 years and older	Beneficiaries 65 years and older with 2 or more chronic conditions
National mean	351	328
10th percentile (lowest performing)	349	323
50th (median)	351	328
90th (highest performing)	352	332
Ratio of 90th to 10th percentile	1.01	1.03

Note: Home and community days are adjusted for age, sex, disease burden, and market-fixed effects. There are over 1,200 MedPAC-defined market areas designed to match insurance markets served by private plans.

Source: Analysis of fee-for-service Medicare claims data, 2015.

10th percentile MedPAC-defined market areas (of 1,200 MedPAC-defined market areas) for beneficiaries 65 years and older was only 3 days. The difference between the 90th and 10th percentile MedPAC-defined market areas for beneficiaries 65 years and older with 2 or more chronic conditions was only 9 days. For both populations, the highest performing MedPAC-defined market area’s HCDs were always almost equal that of the lowest performing MedPAC-defined market area’s HCDs. We found similar results when calculating HCDs for the more narrowly defined HSAs (data not shown).

With so little variation across local market areas and the challenges posed by the need to develop appropriate weights for constructing the composite measure, the Commission questions the immediate utility of the HCD measure in its current form to assess market-level FFS performance.

Future work on population-based quality measures

The Commission and policymakers may explore the following claims-calculated, population-based measures to assess Medicare quality for different defined populations (e.g., FFS populations associated with local market areas and beneficiaries served by MA plans, ACOs, hospitals, post-acute care (PAC) providers, or groups of clinicians). These measures are in line with the Commission’s quality measurement principles to use population-based outcome measures that are patient-oriented, encourage coordination, and promote delivery system change.

- **Mean time between failure**—“Mean time between failure” is a commonly used engineering measure of predicted elapsed time between inherent failures of a mechanical or electronic system during normal system operation. Policymakers could consider how to apply this concept to measure quality of care for Medicare beneficiaries (for example, how many days between serious health care interactions (e.g., mean time between hospitalizations) for Medicare beneficiaries).
- **Successful community discharge**—The Improving Medicare Post-Acute Care Transformation Act of 2014 mandated that CMS develop quality measures for PAC providers. Responding to this mandate, CMS has developed measures for each PAC setting that assess whether PAC providers successfully discharge beneficiaries to the community (e.g., rate of beneficiaries discharged to the community who do not have an unplanned admission to a hospital within a set period of time). The Commission also currently calculates rates of discharge to the community for some individual PAC settings. Policymakers could consider measuring successful community discharge across all PAC providers for different populations.
- **Home-to-home transition time**—Home-to-home transition time is a measure that adds time spent in a PAC facility to time spent in the hospital to capture the full span of a hospitalization episode (Barnett et al.

2017). This measure is patient centered since patients are interested in when they can return home from all institutional care. Policymakers could explore the use of this measure to assess the home-to-home transition times for different populations.

- **End-of-life care and burdensome transitions**—Research has shown that a growing number of older adults in the United States are dying at home, but many continue to face multiple health care transitions to different care sites and receive aggressive inpatient care in their final days (Teno et al. 2013). Policymakers can consider developing a quality measure that assesses potentially burdensome transitions in the last days or weeks of life.
- **Low-value care**—For several years, the Commission has expressed concern that beneficiaries are receiving low-value care, or care that has little or no clinical benefit and that can potentially harm them (Medicare Payment Advisory Commission 2017, Medicare Payment Advisory Commission 2015b) (see also Chapter 10 in this report). The Commission has examined national FFS population rates for certain services and procedures that are considered low value. Policymakers should continue to explore measures of low-value care for different populations.

Applying the Commission’s principles for measuring quality to hospital quality incentives

The Commission contends that Medicare payments should not be made without consideration of the quality of care delivered to beneficiaries and has recently formalized a set of principles for quality measurement in the Medicare program. For several years, the Medicare program has provided hospitals with incentive payments based on the quality of care they give to FFS beneficiaries (see text box on current hospital quality and value payment programs, pp. 190–191). The quality of hospital care has been improving over the years, which is partly due to these programs. However, the hospital industry has raised concerns that the designs of these programs are complex, overlap, and send different performance signals to hospitals. In addition, aspects of the programs do not align with the Commission’s principles for measuring quality in the Medicare program.

Issues with current hospital quality and value programs

The Commission has four main concerns about the design of the current hospital quality programs. The first is that too many overlapping hospital quality payment and reporting programs create unneeded complexity for hospitals and the Medicare program itself (Medicare Payment Advisory Commission 2016a, Medicare Payment Advisory Commission 2016b). Some of the quality measures are scored in multiple programs. For fiscal years (FYs) 2020 and 2021, CMS has proposed to remove much of the duplication in quality measures across programs. For example, CMS would continue to use the hospital-acquired infection measures to assess performance in the Hospital-Acquired Conditions Reduction Program (HACRP) but would remove these measures from the Inpatient Quality Reporting Program (IQRP) and Hospital Value-based Purchasing (VBP) Program (Centers for Medicare & Medicaid Services 2018b).

Second, the Commission believes that all-condition mortality and readmissions measures are more appropriate to measure hospitals’ performance, rather than the condition-specific (e.g., acute myocardial infarction) measures that are scored in the IQRP, VBP Program, and Hospital Readmissions Reduction Program (HRRP). Using all-condition measures would increase the number of observations and reduce the random variation that single-condition readmission rates face under current policy (Medicare Payment Advisory Commission 2013).

Third, the IQRP includes process measures that are not tied to outcomes and are burdensome to report (e.g., fibrinolytic therapy received within 30 minutes of hospital arrival). Also, providers may not be consistent in how they report some of the measures included in the IQRP, VBP Program, and HACRP (e.g., chart-abstracted measures and hospital-acquired infections). For FYs 2020 and 2021, CMS has proposed removing some chart-abstracted process measures, such as median time from emergency department (ED) arrival to ED departure for admitted ED patients, from the IQRP because the data collection and reporting costs outweigh the benefit of their continued use (Centers for Medicare & Medicaid Services 2018b).

Fourth, the VBP Program, HRRP, and HACRP score hospitals using “tournament models” (i.e., providers are scored relative to one another), not on clear, absolute, and prospectively set performance targets. For example, the HACRP’s statutory design penalizes 25 percent of hospitals every year, even if all hospitals significantly reduce their HAC rates. The Commission’s principles for quality measurement encourage Medicare quality programs to use fixed targets.

Current hospital quality and value payment programs

The Medicare program adjusts hospital payment based on four quality payment programs.

One program adjusts payment based on whether a hospital reports quality measure results, and three programs adjust payment based on quality performance. Although not tied to payment, CMS's public reporting of hospital quality performance on the Hospital Compare website, including their star ratings, is another avenue for comparing acute care hospitals.

Reporting

The Hospital Inpatient Quality Reporting Program (IQRP) has been in place since fiscal year 2009 and is built on the preceding voluntary Hospital Quality Initiative. The IQRP reduces a hospital's annual market basket (the measure of inflation in costs of goods and services used by hospitals in treating Medicare patients) update by 2.0 percent if it does not successfully report quality measure data. In fiscal year 2018, nearly all inpatient hospitals met the IQRP requirement and will receive the full annual market basket update.

There are 61 quality measures in the fiscal year 2020 program (based on coverage year 2018 performance). Hospitals report about half of those measures to CMS (e.g., patient experience surveys, health care-associated infections, medical record-abstracted measures such as average number of minutes before outpatients with chest pain or possible heart attack got an electrocardiogram, use of safe surgery checklist), while the other half are claims-based outcome (e.g., readmissions) or cost measures that CMS calculates. (CMS has proposed to remove 39 measures from the IQRP for fiscal years 2020 and 2021 (Centers for Medicare & Medicaid Services 2018b).)

Incentives for higher quality

Three programs adjust hospital payment based on how the hospital performs on quality results: the Hospital Readmissions Reduction Program (HRRP), the Hospital-Acquired Conditions Reduction Program (HACRP), and the Hospital Value-based Purchasing (VBP) Program.

Hospital Readmissions Reduction Program The HRRP was implemented in fiscal year 2013.¹³ As a part of this program, hospitals that have excess Medicare readmissions over a three-year period for selected conditions have their inpatient prospective payment system (IPPS) payments reduced. In fiscal year 2018, the readmissions policy applies to six conditions (acute myocardial infarction (AMI), heart failure, pneumonia, chronic obstructive pulmonary disease, total hip and knee arthroplasty, and coronary artery bypass graft surgery). In 2018, the payment penalty is capped at 3 percent of a hospital's base diagnosis related group (DRG) payments per year. In 2018, about 80 percent of hospitals will have payments reduced because of higher than average readmissions for at least one condition. Total penalties will be about \$556 million in 2018, or 0.5 percent of Medicare's total IPPS payments. Research has shown that readmission rates for AMI, heart failure, and pneumonia decreased more rapidly after the HRRP began and that improvement was most marked for hospitals with the lowest pre-HRRP performance (Wasfy et al. 2017).

Hospital-Acquired Conditions Reduction Program The HACRP was effective beginning in fiscal year 2015. Hospitals are ranked on their total rate of preventable conditions in two categories: (1) claims-calculated patient safety indicators such as pressure ulcer and sepsis

(continued next page)

Redesigning Medicare's hospital quality and value payment programs

There is an opportunity to redesign Medicare's hospital quality payment programs as one hospital value incentive

program (HVIP) that would be patient oriented, encourage coordination across providers and time, and promote change in the delivery system. Since current hospital quality programs are defined in statute, the Congress

Current hospital quality and value payment programs (cont.)

rates and (2) hospital-reported health care–associated infections such as surgical site infections and catheter-associated urinary tract infections. The 25 percent of hospitals with the highest rates of preventable conditions (poorest performers) receive a 1 percent reduction to all inpatient payments. In 2017, the HACRP reduced payment to 742 hospitals, with penalties totaling roughly \$370 million (Medicare Payment Advisory Commission 2017). Before the start of the HACRP, hospitals had been successful in reducing the number of hospital-acquired conditions (HACs). An Agency for Healthcare Research and Quality (AHRQ) study reported that, from 2010 to 2015, HACs per discharge declined by 21 percent, an estimated 125,000 fewer patients died in the hospital as a result of the reduction in HACs, and an estimated \$28 billion in health care costs was saved (Agency for Healthcare Research and Quality 2016).

Hospital Value-based Purchasing Program The Hospital VBP Program was implemented in fiscal year 2013. As required by law, the program is budget neutral; that is, the total pool of withheld payments (currently equal to 2 percent of base inpatient DRG payments) must be redistributed to hospitals based on their performance on the VBP Program’s quality measures. In 2018, the VBP Program increases payments to about 50 percent of IPSS hospitals and decreases payments to 42 percent of them. Hospitals earn back anywhere from 17 percent to 200 percent of their withheld payments. For roughly a third of these hospitals, the change in payments under the program was small, less than 0.25 percent of base payments.

The program uses a combination of measures from four quality domains to score hospitals on quality (the measures are also part of the IQRP): (1) 25 percent of the score is based on patient experience of care surveys; (2) 25 percent is based on patient safety, using a composite patient safety measure

(AHRQ’s patient safety indicator (PSI) 90) and data on six health care–associated infections; (3) 25 percent is based on efficiency, using a 30-day Medicare spending per beneficiary measure; and (4) 25 percent is based on clinical care, tied to 30-day mortality for three conditions—AMI, heart failure, and pneumonia).^{14,15} The VBP Program gives a hospital credit for achievement (relative to other hospitals) and improvement (relative to its own baseline performance).

Public reporting of quality performance

Although not tied directly to payment, Medicare reports certain quality results to consumers and providers on CMS’s Hospital Compare website. The website shows a hospital’s results for given measure categories alongside the state and national averages for the measure. The displayed measures are from the IQRP, HRRP, HACRP, and VBP programs as well as results from hospital outpatient facilities (e.g., imaging efficiency). The measure categories include (1) survey of patient’s experiences; (2) timely and effective care (i.e., cataract surgery care, heart attack care, emergency department care); (3) complications and deaths (e.g., health care–associated infections); (4) hospital returns; (5) use of medical imaging; and (6) payment and value of care (e.g., Medicare spending per beneficiary). The Hospital Compare website also presents a summary star rating (up to 5 stars) for the patient experience category and another star rating that combines individual clinical, patient experience, and efficiency measures from the VBP Program, HRRP, and the Hospital Compare website. The Commission has commented to CMS that the overall star rating system creates unneeded complexity in the Medicare program because it creates a new system of measures and scoring methodology for CMS to administer and for hospitals to track (Medicare Payment Advisory Commission 2016a). ■

would need to create the new HVIP and eliminate the current programs in legislation. We believe that CMS has the authority to make some of our suggested changes to hospital quality payment without congressional

action (e.g., improving public reporting.)¹⁶ The HVIP is intended to replace quality programs that affect FFS hospital payment. However, in line with the Commission’s principles, the HVIP measures and scoring methodology

should align across Medicare accountable entities and providers, including hospitals. MA plans, ACOs, and hospitals should be held accountable to a small set of population-based measures, scored against absolute thresholds, and have their payments adjusted through peer grouping. Medicare's use of the same set of measures and scoring framework across different populations could also promote multipayer alignment.

Design

The Medicare program should not pay hospitals and other providers for reporting quality measures, but should pay based on performance on these measures. Virtually all hospitals currently meet the IQRP reporting requirements and receive their full payment update, arguing for the need to retire the IQRP. The Congress could also consider removing payment incentives tied to Medicare quality reporting programs in other sectors where pay-for-performance programs have been implemented (e.g., skilled nursing facilities).

For simplicity, hospitals should have their payment adjusted based on performance on quality and cost measures in a single program instead of three separate programs. The HRRP and VBP programs should be combined into one HVIP. The HACRP, which scores patient safety measures such as infection rates, should also be retired as a hospital payment adjustment (see p. 194 for more discussion of patient safety).

Like the VBP Program, an HVIP would translate quality measure performance to payment and redistribute a budgeted amount to hospitals based on their performance. We would expect the new program to be budget neutral to the HRRP and HACRP, which, based on our analysis, reduce Medicare payment by 0.5 percent.

Public reporting of quality results can drive quality improvement by fostering competition among providers and allowing providers to better identify opportunities for improvement. We believe that CMS could incorporate an HVIP into the public reporting of quality results on Hospital Compare or other websites. CMS could report results as a consumer-friendly summary quality score (e.g., a star rating). For beneficiaries interested in more detailed quality results, CMS could also report all available patient experience measures (e.g., communication, cleanliness), some condition-specific outcomes (e.g., pneumonia readmissions, heart failure mortality), and HAC results.

Under an HVIP, the Medicare program would continue to provide hospitals with quality feedback reports to help them understand their performance on the claims-based measures. Reports could include benchmark and other comparative information so that hospitals could take action to improve their results. Even though an HVIP would score all-condition measures, CMS could consider providing hospitals with condition-specific results (e.g., acute myocardial infarction mortality) calculated by claims data for hospitals to use for their own quality improvement.

Measures

Based on our quality measurement principles, we propose an HVIP that would include four largely CMS-calculated or CMS-administered quality measures: mortality, readmissions, Medicare spending per beneficiary (MSPB), and patients' overall rating of the hospital.¹⁷ These risk-adjusted measures are included in the existing hospital quality programs and thus are known to hospitals. (We envision that, as risk adjustment models evolve, they will be incorporated into the HVIP measures.) Providers could choose to use other granular quality measures to manage their own quality improvement, but these would not factor into Medicare payment.

Readmissions Hospital readmission, for any reason, is disruptive to patients and caregivers and costly to the health care system, and it puts patients at additional risk of hospital-acquired infections and complications. Readmissions are also a major source of patient and family stress and may contribute substantially to loss of functional ability, particularly in older patients. Measuring and adjusting payments based on a hospital's readmission rates holds the hospital accountable for ensuring that beneficiaries have the discharge information they need and encourages hospitals to coordinate with other providers. Since the implementation of the HRRP, hospitals have taken action and improved readmission rates. The readmission measure is also important to and understandable by the beneficiary and can be calculated through claims data.

In our HVIP model, we scored hospitals on their unplanned, risk-adjusted rates of readmissions within 30 days of discharge for all conditions using Medicare claims. Using an all-cause readmission measure (rather than the six conditions used in the HRRP) increases the number of observations and reduces random variation.

Our model also used three years of claims data (2014 through 2016) to increase the number of observations.

Mortality Mortality during or soon after a hospital stay (e.g., within 30 days) is an important outcome measure, and it encourages hospitals to coordinate with post-acute care providers. Like the readmission measure, this outcome measure can be determined with a high degree of accuracy through claims. As suggested with the readmissions measure, an all-condition mortality measure would hold hospitals more accountable than condition-specific measures. Our HVIP model used an all-condition, risk-adjusted measure of mortality during the hospital stay and 30 days after discharge, and we used three years of data (2014 to 2016) to increase the number of observations. (The measure excludes patients who are in hospice care before admission.)

Medicare spending per beneficiary MSPB is a claims-based value measure that we propose be included in an HVIP. This measure rewards efficient, effective hospital care, not volume of services, and reduces delivery system fragmentation. By pairing the spending measure with mortality and readmissions, hospitals have an incentive to maintain episode quality while reducing episode costs. The measure shows whether Medicare spends more, less, or about the same per Medicare patient treated at a specific hospital compared with how much Medicare spends on comparable patients nationally. Our model used the MSPB values CMS currently produces for the VBP Program, which are price-standardized, risk-adjusted episodes that include all Medicare Part A and Part B claims paid during the period from 3 days before an inpatient hospital admission through 30 days after discharge. The model used the MSPB values calculated with three years of data (2014 to 2016).

Patients' overall rating of the hospital The Hospital Consumer Assessment of Healthcare Providers and Systems[®] (HCAHPS[®]) is a national standardized survey instrument and data collection methodology for measuring patients' perspectives on their care during a recent hospital stay.¹⁸ The survey allows Medicare, hospitals, beneficiaries, and others to make objective and meaningful comparisons of hospitals. Since 2006, CMS and hospitals have worked with third-party survey vendors to collect survey results from a random sample of each hospital's adult inpatient discharges. The survey results are used to calculate 10 core measures of patient experience: (1) communication with nurses,

(2) communication with doctors, (3) responsiveness of hospital staff, (4) communication about medicines, (5) cleanliness of hospital environment, (6) quietness of hospital environment, (7) discharge information, (8) care transition, (9) overall rating, and (10) whether the beneficiary would recommend the hospital to others. (Hospitals can add their own survey items to the core survey.) The HCAHPS measures are scored in the VBP Program; they are publicly reported on Hospital Compare and as part of the star rating system.

Based on the Commission's principles, a new HVIP ideally includes population-based patient experience measures. High-quality hospitals and physicians appear to focus not only on technical excellence but also on how patients perceive their care (Chatterjee et al. 2015). When patients have a better experience, they are more likely to adhere to treatments, return for follow-up appointments, and engage with the health care system by seeking appropriate care (Safran et al. 1998).

For simplicity, we modeled the HVIP using a single overall hospital rating measure (i.e., share of patients who gave their hospital a rating of 9 or 10 on a scale from 0 (lowest) to 10 (highest)) instead of a combination of the 10 HCAHPS measures. The overall hospital rating measure is strongly or moderately related to the other quality measures (e.g., communication with nurses correlation (r) = 0.64; care transition correlation (r) = 0.48), so by scoring a hospital's overall rating, we likely capture the other measures (Centers for Medicare & Medicaid Services 2017). Also, a hospital's performance on some of the other HCAHPS measures, such as discharge information and care transitions, would be detected in the readmissions, mortality, and MSPB measures. Alternatively, the HVIP could use a unique composite measure based on a subset of the HCAHPS measures that are meaningful to both beneficiaries and providers such as measures of communication with nurses, communication with doctors, responsiveness of staff, and discharge information.

To be scored on the overall hospital quality rating measure, hospitals would need to administer the entire core HCAHPS survey and would receive a score of zero for that measure if they did not. Hospitals could continue to monitor the other HCAHPS measures and use them to manage their own quality improvement. CMS could also continue to publicly report multiple HCAHPS measures on Hospital Compare.

Patient safety Our HVIP model adjusts a hospital's payment based on its performance on four measures that are part of the existing hospital quality payment programs. We also support a Medicare-influenced system to improve patient safety outside of an HVIP. But because of concerns with the accuracy of some patient safety data, we do not propose inclusion of patient safety measures in the HVIP model at this time. Under the HVIP, hospitals should continue to have incentives to improve patient safety because doing so could potentially affect performance on the four HVIP measures (e.g., readmissions due to hospital-acquired infections).

As part of the IQRP, HACRP, and VBP programs, hospitals are scored on five self-reported hospital care-acquired infection rates, such as catheter-associated urinary tract infections. Hospitals use their own claims and medical records to report their infection rates through the CDC's National Health Safety Network (NHSN).¹⁹ The NHSN provides hospitals, states, and regions with comparative data needed to identify problem areas and measure local and national progress on prevention efforts. The monitoring and evaluation of infection rates through Medicare's programs and other national initiatives such as the Partnership for Patients have improved infection rates.

Over the years, there have been anecdotal reports of some hospitals' intentional misreporting of infection data—for example, clinicians ordering diagnostic tests in the absence of clinical symptoms to potentially identify infections present on admission so they are not considered hospital acquired (Centers for Disease Control and Prevention 2016a). The CDC and CMS have reported that there is no evidence such behaviors are widespread and have released guidance on the importance of adherence to the NHSN protocol, definitions, and criteria to ensure the reliability and comparability of the data. However, there are concerns that some hospitals are better than others at reporting infections and other patient safety issues (Calderwood et al. 2017). Also, even though there are specific definitions and criteria to capture the infection data, hospital infection control specialists have to make judgment calls about how to catalog infections, which makes part of the reporting subjective.

The IQRP, HACRP, and VBP programs also include a claims-based composite measure of 10 underlying patient safety indicators (PSIs), PSI 90, which signals potential in-hospital complications and adverse events and procedures, including pressure ulcers, iatrogenic pneumonia, postoperative sepsis, postoperative pulmonary embolism,

and accidental punctures or lacerations.²⁰ The use of the PSI 90 measure in pay-for-performance programs has been criticized for several reasons, including surveillance bias (e.g., hospitals with higher rates of postoperative blood clots were often the hospitals that were most vigilant in screening patients for them) and concerns about the accuracy of this measure in identifying meaningful unintentional cases of injury (Rajaram et al. 2015). AHRQ has recently updated the PSI 90 measure to address some of these concerns, and hospitals will begin to report on the revised measure this year. At this time, we do not propose to include the measure in the new payment program, but we will continue to monitor the measure's performance.

Hospital-acquired conditions are an important measure of patient safety, but since the only way currently to monitor a hospital's infection rate is through self-reported information, we propose that the current measures of infection rates not be part of a new HVIP. Rather, we suggest that hospitals be required as a Medicare condition of participation (COP) to report accurate infection rates to the NHSN and that hospitals continue to work with the CDC to monitor and evaluate opportunities to lower infection rates. (CMS could exempt small and rural hospitals that may not have sufficient patient numbers to warrant reporting to the NHSN.) This requirement can be built into the existing infection control COPs requiring hospitals to have a designated infection control officer, a hospital-wide quality assessment and performance improvement program, and training programs to address problems identified by the infection control officer (Centers for Medicare & Medicaid Services 2012). The Secretary should continue to publicly report infection rates (currently found on Hospital Compare) and investigate providers with high rates. Consistent with our principles, we also encourage CMS to support research and data collection to improve patient safety measures for potential inclusion in the HVIP.

Scoring methodology

Scoring under an HVIP should provide incentives for hospitals to improve the quality and efficiency of their care. To maintain the independence and importance of each of the four measures, our model treats each measure as an equally weighted, separate domain, consistent with the VBP Program methodology. Each of the 4 measures is worth 10 points for a total of 40 possible HVIP points. This model is illustrative; policymakers could give the components different weights based on the priorities of the Medicare program and its beneficiaries.²¹

**TABLE
7-6**

Illustration of point system to score performance on measures under our potential HVIP model

	Risk-adjusted readmissions rates (lower is better)	Risk-adjusted mortality rates (lower is better)	Relative Medicare spending per beneficiary (lower than 1 is better)	Patients' overall rating of hospital (higher is better)
0 points	20% or above	15% or above	1.16 or above	53% or below
2 points	18%	13%	1.09	60%
4 points	16%	11%	1.02	67%
6 points	14%	9%	0.95	73%
8 points	12%	7%	0.88	80%
10 points	10% or below	5% or below	0.82 or below	87% or above

Note: HVIP (hospital value incentive program). Each measure in the HVIP is continuously scored from 0 to 10 points, and only a subset of points is displayed here. Lower rates are better for readmissions, mortality, and Medicare spending per beneficiary (MSPB), and they receive more HVIP points. The MSPB value is based on the hospital's spending compared with the national mean. "Patients' overall rating of hospital" is the share of Hospital Consumer Assessment of Healthcare Providers and Systems® survey respondents who gave the hospital an overall rating of 9 or 10 on a 10-point scale.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

Converting measure performance to HVIP points (score)

One of the Commission's principles is that Medicare quality programs should reward providers based on clear, absolute, and prospectively set performance targets rather than score providers relative to one another. Prospective targets allow providers to know in advance what outcomes they must achieve to avoid penalties and achieve rewards; they also allow the industry as a whole to be rewarded if all providers improve. In addition, rewards should be distributed based on a continuous scale (i.e., without payment "cliffs"), so that hospitals with similar performance will receive similar financial rewards. In our example, hospitals earn points for their performance on quality metrics based on a continuous scale, starting at 0 points and gradually increasing to 10 points. The continuous scale stretches over almost the whole distribution of performance, giving even top-performing hospitals an incentive to continue to improve.

In our HVIP model, each measure has a continuous performance-to-points scale based on the 2nd percentile of hospital performance (0 points) to the 98th percentile of hospital performance (10 points), which is based on the hospitals in our data set. This scale—from the 2nd percentile to 98th percentile—is meant to represent empirically derived scores that available evidence suggests can be achieved by an optimally performing hospital (Safran et al. 2007). Although scoring is continuous, hospitals would know in advance what performance

targets (or "gates") they needed to reach to achieve a certain point level for each measure. Table 7-6 presents a subset of the scale of points associated with performance targets in our HVIP model.

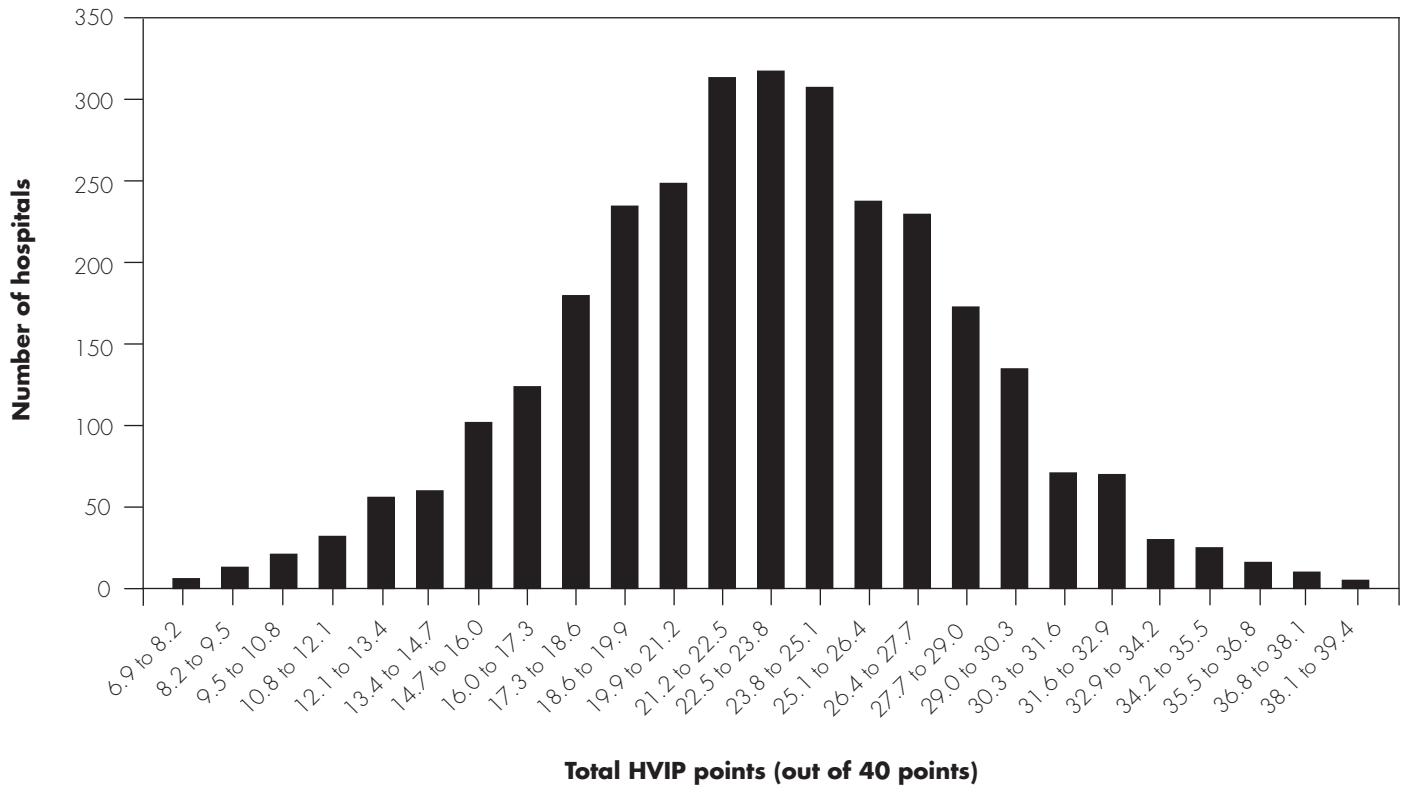
Following is an example of converting measure performance to points using the continuous performance-to-points scale highlighted in Table 7-6: Hospital A has a risk-adjusted readmissions rate of 15 percent (earns 5 points), risk-adjusted mortality rate of 7 percent (earns 8 points), Medicare spending per beneficiary value of 0.96 (earns 5.9 points), and overall patient experience rating of 79 percent (earns 7.8 points). Hospital A receives a total of 26.7 of 40 possible HVIP points.

Each hospital's total quality performance score, which would be used to determine its HVIP payment adjustment, would have a maximum of 40 points. In our HVIP model, each hospital has a total number of points based on its performance against our continuous performance-to-points scale (Table 7-6). The 3,021 hospitals included in our sample had a nearly normal distribution of total quality performance scores under our HVIP model (Figure 7-2, p. 196).²²

In our HVIP model, the average total HVIP score point total for all hospitals was 22.9 points (Table 7-7, p. 197). On average, mortality contributed 7 of those points because more hospitals perform better on this measure

**FIGURE
7-2**

Hospitals have a nearly normal distribution of total quality performance under the potential HVIP



Note: HVIP (hospital value incentive program). Hospitals receive 0 to 40 total HVIP points based on their performance on four equally weighted measures (readmissions, mortality, Medicare spending per beneficiary, and patients’ overall rating of hospital). There are 3,021 hospitals included in our HVIP model.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

compared with readmissions, MSPB, and overall patient experience rating, which each contributed about 5 points to the total score. In addition, there were some differences in total HVIP scores based on hospital characteristics. For example, in our model, major teaching hospitals had a lower average total HVIP score compared with nonteaching hospitals (21.2 points compared with 23.2 points, respectively). This difference is partially because major teaching hospitals have worse readmission rates and therefore fewer points in that domain of the HVIP scoring model (3.8 points for teaching hospitals compared with 5.5 points for nonteaching hospitals).

Converting HVIP points to payment adjustments using peer grouping In measuring providers’ performance on quality measures, the Commission contends that Medicare should take into account, as necessary, differences in

providers’ populations, including social risk factors. However, adjusting measure results for social risk factors can mask disparities in clinical performance, so Medicare should adjust performance payments through peer grouping rather than through performance score adjustments. (In peer grouping, each provider is compared with its “peers”—defined as providers with a similar patient mix.)²³ The Commission also believes that Medicare should target technical assistance resources to low-performing providers and should support research and data collection to reduce measurement bias, including, for example, the effects of social risk factors.

Based on these principles, our HVIP model distributes quality-based payments to hospitals classified in 10 peer groups. Each peer group has about the same number of hospitals (in our model, about 300 hospitals), and

**TABLE
7-7**

Illustrative total HVIP points by hospital characteristics

Hospital group	Number of hospitals	Average:				
		Total HVIP points (score)	Readmissions points	Mortality score	MSPB score	Patients' overall rating of hospital
All hospitals	3,021	22.9	5.3	7.0	5.1	5.5
Hospital size						
Large urban	1,209	22.2	4.8	7.6	4.5	5.3
Other urban	1,065	23.8	5.7	7.2	5.2	5.7
Rural	747	22.9	5.5	5.9	6.1	5.4
Teaching status						
Major teaching	300	21.2	3.8	7.8	4.7	4.9
Other teaching	764	22.9	5.2	7.6	4.9	5.3
Nonteaching	1,957	23.2	5.5	6.7	5.3	5.6
Ownership						
Nonprofit	1,826	23.9	5.5	6.8	5.3	5.7
For profit	754	21.1	4.8	7.4	4.4	5.1
Government	441	22.1	5.2	6.1	5.5	5.3
DSH						
No DSH	410	25.8	6.1	7.2	5.5	7.1
Moderate to low DSH	1,897	23.2	5.5	6.9	5.3	5.5
High DSH	665	20.3	4.2	7.3	4.5	4.3

Note: HVIP (hospital value incentive program), MSPB (Medicare spending per beneficiary), DSH (disproportionate share). Hospitals receive up to a total of 40 points based on their performance on four equally weighted measures (up to 10 points each): risk-adjusted, unplanned readmissions; risk-adjusted 30-day postdischarge mortality; MSPB; and patients' overall rating of hospital. "Patients' overall rating of hospital" is the share of Hospital Consumer Assessment of Healthcare Providers and Systems® survey respondents that gave the hospital an overall rating of 9 or 10 on 10-point scale. "High DSH" hospitals have higher proportions of low-income patients compared to "no DSH" hospitals. There are 49 hospitals with unknown DSH status.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

hospitals are assigned to peer groups based on their share of Medicare patients who are fully dual-eligible beneficiaries—that is, who also fully qualify for Medicaid, which can be a proxy for low income. (In fiscal 2019, the HRRP will use five peer groups based on the hospital's share of Medicare patients who are fully dual-eligible beneficiaries.) Since our HVIP model is designed to be budget neutral, each peer group has, in essence, a budget based on a 2 percent payment withhold from each of the peer group's hospitals. This budget is redistributed to the peer group's hospitals based on their HVIP points. The 2 percent withhold is the same as the withhold in the existing VBP Program, but policymakers could raise or lower that amount.

In our HVIP model, we followed five steps to convert performance points to payment adjustments using currently available hospital quality and payment data. (See text box, pp. 202–203, describing the process used in our HVIP model to convert each hospital's HVIP points to a quality-based payment adjustment.) Overall, we found that it was feasible to compute incentive payments that support the Commission's HVIP's goals.

After scoring each hospital on the same continuous performance-to-points scale, we divided the 3,021 hospitals in our HVIP sample into 10 equal-sized peer groups based on the hospitals' shares of fully dual-eligible Medicare patients (text box Steps 1 and 2, p. 202). The

**TABLE
7-8**

Illustration of hospital payment adjustments using peer groups under potential HVIP model

Peer group	Average:		Peer group budget based on 2 percent withhold of hospitals' base IPPS payments (in millions)	Percentage adjustment to base IPPS payments per HVIP point
	Share of fully dual-eligible beneficiaries	Total HVIP points		
1 (lowest share of fully dual-eligible beneficiaries)	6.5%	26.4	\$211.8	0.08%
2	10.8	24.5	228.2	0.08
3	13.1	23.9	274.9	0.08
4	15.2	23.7	227.8	0.08
5	17.2	23.7	208.6	0.08
6	19.3	22.6	216.4	0.09
7	22.1	22.6	165.8	0.09
8	25.3	22.3	169.5	0.09
9	30.5	21.2	179.5	0.09
10 (highest share of fully dual-eligible beneficiaries)	48.3	18.3	148.3	0.10

Note: HVIP (hospital value incentive program), IPPS (inpatient prospective payment system). There are about 300 hospitals in each of the 10 hospital peer groups. Peer groups are assigned based on the share of the hospital's Medicare patients who are fully dual eligible for Medicare and Medicaid for a majority of the year. Fully dual-eligible beneficiaries qualify for a full range of Medicaid benefits.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

average share of these beneficiaries per hospital in each peer group ranged from less than 7 percent (Peer Group 1) to about 48 percent (Peer Group 10) (Table 7-8). The average total HVIP points hospitals received in each peer group ranged from 26.4 (Peer Group 1) to 18.3 (Peer Group 10). Peer Group 10 had fewer total HVIP points mainly because of higher average readmissions and lower overall patient ratings compared with Peer Group 1 hospitals. Although, on average, Peer Group 10's point total was lower, some hospitals in the peer group were high performers and received more HVIP points than the average hospital.

For each peer group, we calculated a budget of expected HVIP payments to the group's hospitals based on a 2 percent withhold of base inpatient prospective payment system (IPPS) payments from each of the group's hospitals (text box Step 3, p. 202). Under our model, a total of \$2.03 billion is distributed to hospitals based on their HVIP points. The budget for each peer group ranges from about \$275 million (Peer Group 3) to about \$148 million (Peer Group 10) (Table 7-8). Inherent in the peer group budgets are the number of discharges for the peer group's hospitals, so the budget is smaller for those peer groups that have hospitals with fewer discharges and thus

smaller IPPS base payments to be used in the withhold calculation.

For each peer group, we also calculated the percentage adjustment to payments per point, which converts total HVIP points to dollars and results in spending the 2 percent withhold for each group (text box Step 4, p. 202). The percentage adjustments to payments per point range from 0.08 percent (Peer Group 1) to 0.10 percent (Peer Group 10) (Table 7-8). In other words, high-performing hospitals in Peer Group 10 have the potential to earn a slightly higher payment adjustment per performance point compared with the other groups because the percentage adjustment to payments per point for Peer Group 10 is higher than the other groups.

We calculated each hospital's HVIP-based payment adjustment using its total HVIP points and its peer group's conversion factor for points-to-payment adjustment (text box Step 5, p. 202). In our HVIP model, small differences exist between the peer groups' ranges of payment adjustments. In general, a hospital's payment adjustment could range from -1.4 percent to 1.6 percent based on the hospital's base IPPS payment after accounting for their 2 percent withhold (Table 7-9). (By design, no hospital can

**TABLE
7-9**

Illustrative HVIP payment adjustments by hospital peer groups

Peer group	Average withhold of total base IPPS payments	Range of HVIP payment adjustments	
		After withhold	Relative to withhold
1 (lowest share of fully dual-eligible beneficiaries)	2%	-1.1% to + 1.1%	44% to 156%
2	2	-1.1 to + 1.1	47 to 155
3	2	-1.2 to + 1.0	38 to 149
4	2	-1.1 to + 0.9	44 to 146
5	2	-1.2 to + 1.1	40 to 152
6	2	-1.1 to + 1.0	45 to 152
7	2	-1.3 to + 1.1	37 to 154
8	2	-1.4 to + 1.3	31 to 163
9	2	-1.3 to + 1.2	37 to 158
10 (highest share of fully dual-eligible beneficiaries)	2	-1.3 to + 1.6	37 to 180

Note: HVIP (hospital value incentive program), IPPS (inpatient prospective payment system). There are about 300 hospitals in each of the 10 hospital peer groups. Peer groups are assigned based on the share of the hospital's Medicare patients who are fully dual eligible for Medicare and Medicaid for a majority of the year. Fully dual-eligible beneficiaries qualify for a full range of Medicaid benefits. The average HVIP adjustments after the withhold is zero by design.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

lose more than its 2 percent withhold.) Thus, hospitals can recover between 31 percent and 180 percent of their 2 percent withhold.

Under our model, about half of the hospitals (1,510) would receive a penalty and about half (1,511 hospitals) would receive a reward. About 11 percent of hospitals (367) would receive a reward more than 1.5 times the withhold. About 12 percent (365) would receive a penalty of less than one-half of the withhold.

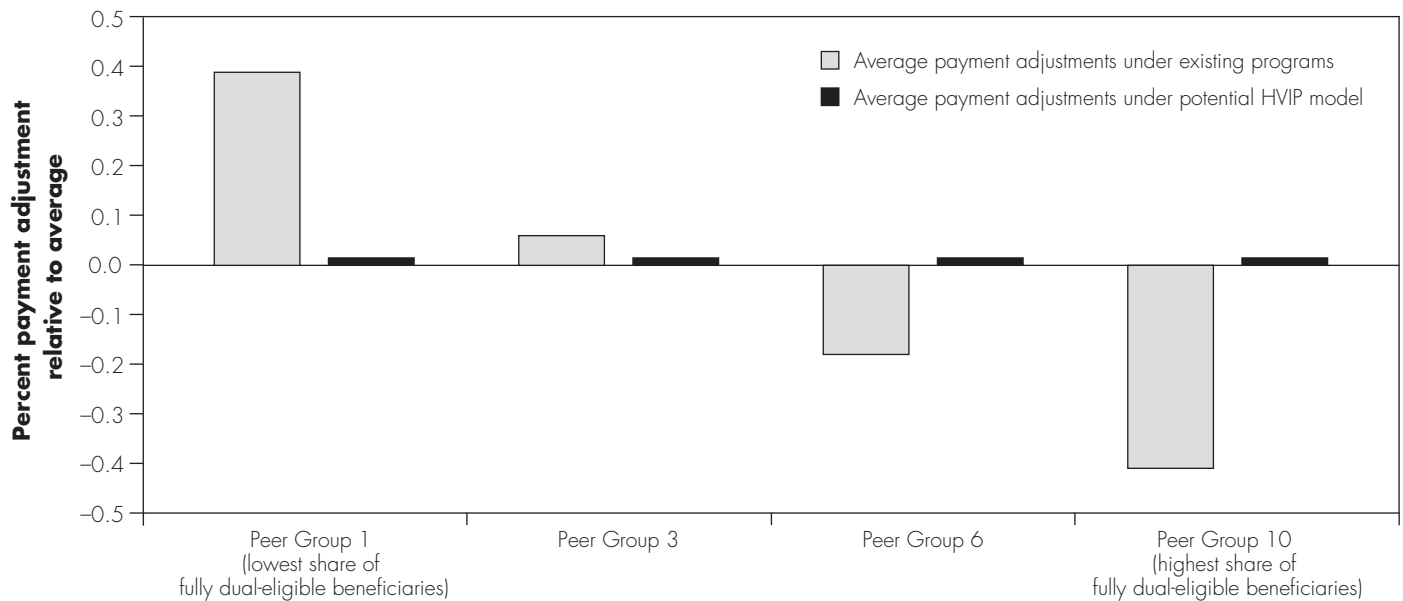
Comparison of HVIP model to existing hospital quality programs

To understand differences between hospital performance in the existing programs and our HVIP model, we assigned hospitals to quartiles based on their total performance in the existing programs and then quartiles based on their performance under the HVIP model. About a quarter of hospitals were in the same performance quartile under the existing programs and the HVIP model. Three-quarters of hospitals were in the same or within one performance quartile under the existing program and the HVIP model. At the extremes, 2 percent (61 hospitals) were poor performers in the existing programs but were

top performers in the HVIP model. About 1 percent (34 hospitals) were top performers in the existing programs but were poor performers in the HVIP model. The HACRP appeared to play a role in this trend (i.e., some hospitals were poor performers in the existing programs because they received a HAC penalty but did well under the HVIP model.) This supports our concerns with potential misreporting of hospital infection data in a program that uses a tournament model rather than fixed targets.

Effect of peer grouping on reducing disparities among hospitals

Our HVIP model uses a small set of measures, a continuous performance-to-points scale, and converts those points to payment adjustments relative to groups of hospitals that serve similar shares of fully dual-eligible populations (hospital peer groups). Since one goal of an HVIP is to adjust payments to account for differences in social risk factors, we examined how hospitals serving large shares of low-income patients perform.²⁴ Figure 7-3 (p. 200) compares the existing quality payment program adjustments with the HVIP model's payment adjustments by peer group. All the HVIP adjustments are zero relative to the average within each peer group since

**FIGURE
7-3****Compared with existing quality payment programs, the potential HVIP makes payment adjustments more equitable for hospitals grouped by share of fully dual-eligible beneficiaries**

Note: HVIP (hospital value incentive program). The existing quality programs include the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition Reduction Program (HACRP), and Hospital Value-based Purchasing (VBP) Program. The HRRP and HACRP are penalties, and the VBP Program is budget neutral. To make the existing programs and HVIP comparable, we included a budget-neutrality adjustment in the existing programs' adjustment. The budget-neutrality adjustment is the overall existing program adjustment divided by overall base payments (0.93 percent). The average HVIP adjustment is the sum of each hospital's HVIP adjustment after the withhold divided by the sum of each hospital's base payment. The HVIP is budget neutral. Peer groups are assigned based on the share of the hospital's Medicare patients who are fully dual eligible for Medicare and Medicaid for a majority of the year. Fully dual-eligible beneficiaries qualify for the full range of Medicaid benefits.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

the adjustments are budget neutral within each peer group. Under the existing programs, Peer Group 1 (lowest share of fully dual-eligible beneficiaries) hospitals receive a 0.39 percent positive adjustment while Peer Group 10 (highest share of fully dual-eligible beneficiaries) hospitals receive a -0.41 percent adjustment. Thus, compared with the existing quality payment programs, the HVIP approach makes payment adjustments among hospitals that serve different populations more equitable.

We can also see this effect in Figure 7-4, which compares existing and HVIP model payment adjustments for different groups of hospitals according to their disproportionate share (DSH) hospital status (which can also be considered a proxy for low-income status). Under the existing quality programs, non-DSH hospitals receive, on average, a 0.42 percent positive adjustment; under an

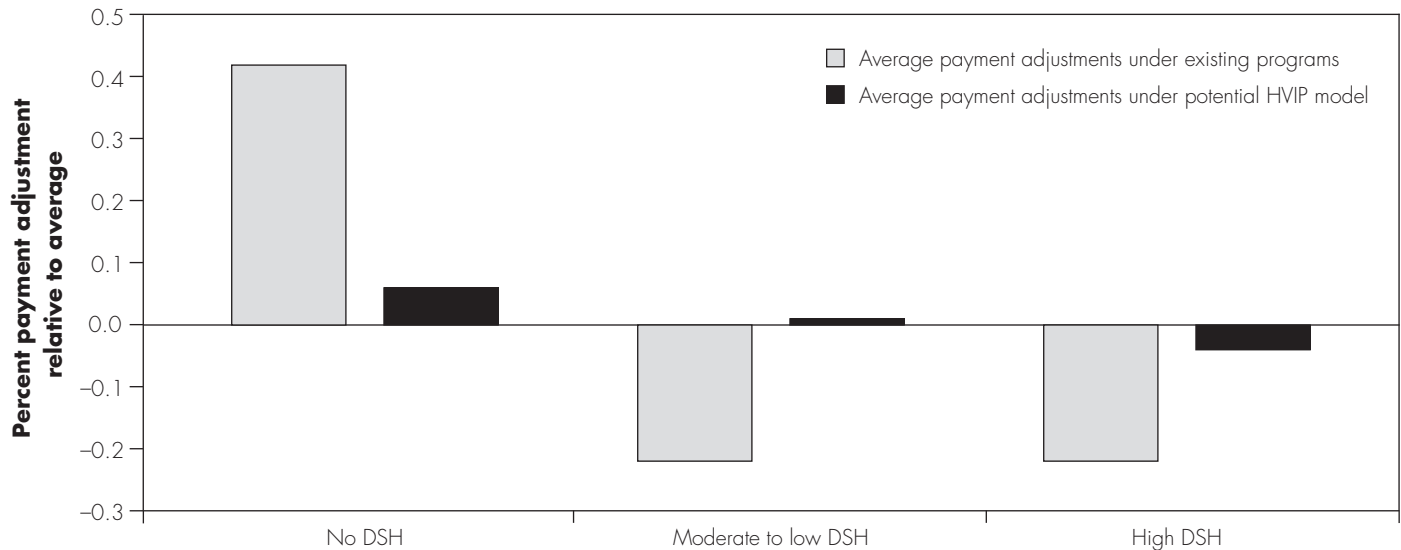
HVIP program, they would receive a smaller positive adjustment—on average, 0.06 percent. Under the existing programs, the high-DSH hospitals receive, on average, a -0.22 percent adjustment; under an HVIP program, that adjustment would rise to an average of -0.04 percent.

Conclusion

A single quality payment program for hospitals, such as our HVIP model, would be simpler to administer and would produce more equitable results compared with the existing quality payment programs. The HVIP, as a single program, would eliminate the complexity of overlapping program requirements, focus on outcomes, and promote the coordination of care. It would also align with the Commission's principles for quality measurement, in particular, by setting absolute value targets and using

**FIGURE
7-4**

Compared with existing quality payment programs, the potential HVIP makes payment adjustments more equitable for hospitals grouped by DSH status



Note: HVIP (hospital value incentive program), DSH (disproportionate share hospital). The existing quality programs include the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition Reduction Program (HACRP), and Hospital Value-based Purchasing (VBP) Program. The HRRP and HACRP are penalties, and the VBP Program is budget neutral. To make the existing programs and HVIP comparable, we included a budget-neutrality adjustment in the existing programs' adjustment. The budget-neutrality adjustment is the overall existing program adjustment divided by overall base payments (0.93 percent). The average HVIP adjustment is the sum of each hospital's HVIP adjustment after the withhold divided by the sum of each hospital's base payment. The HVIP is budget neutral.

Source: MedPAC analysis of Medicare fee-for-service hospital quality data, 2014–2016.

peer grouping to account for differences in provider populations. Under peer grouping in our HVIP model, differences in payment adjustments were reduced among providers serving populations of varying social risk factors.

Over the next year, the Commission plans to continue to refine a design for an HVIP consistent with our principles for quality measurement. Some topics the Commission will further explore include weighting of measures, withhold values, patient experience measures, and patient safety measures. ■

Steps to convert hospital value incentive program points to payment adjustments using peer grouping

Our hospital value incentive program (HVIP) model distributes quality-based payments to hospitals classified in 10 peer groups. Each peer group has about the same number of hospitals, and hospitals are assigned to peer groups based on their share of Medicare patients who are fully dual-eligible beneficiaries—that is, who also fully qualify for Medicaid, which can be a proxy for low income. Since our HVIP model is designed to be budget neutral, each peer group has, in essence, a budget based on a 2 percent payment withhold from each of the peer group’s hospitals. This budget is redistributed to the peer group’s hospitals based on their quality performance.

We followed five steps to convert each hospital’s quality measure performance to a payment adjustment that provides rewards or penalties.

Step 1: Convert each hospital’s performance on quality measures to total HVIP points based on a continuous performance-to-points scale. (Every hospital is scored on the same scale.)

Step 2: Divide hospitals into 10 equal-sized peer groups based on the hospital population’s share of fully dual-eligible patients.

Step 3: For each peer group, create a budget of expected HVIP payments to hospitals, based on a 2 percent withhold from each of the hospitals in the peer group (e.g., 2 percent of each hospital’s base inpatient prospective payment system (IPPS) payments).

Step 4: For each peer group, calculate the percentage adjustment to payment per HVIP point, which converts total HVIP points to dollars and results in spending the group’s budget defined in Step 3.

Percentage adjustment to payments per point = HVIP budget for peer group / (sum (each hospital’s base IPPS payments × hospital’s total HVIP points))

Step 5: Compute each hospital’s adjustment for the coming year based on past performance and their peer group’s percentage adjustment to payment per HVIP point.

Hospital’s HVIP-based adjustment = percentage adjustment to payments per point × hospital’s total HVIP points

Multiply the hospital’s HVIP-based adjustment by the hospital’s withhold of IPPS payments to yield the payment adjustment in dollars.

(continued next page)

Steps to convert hospital value incentive program points to payment adjustments using peer grouping (cont.)

Table 7-10 below describes an example of converting HVIP points to payment adjustments using peer grouping. First, we convert each hospital's quality measure performance to total HVIP points based on the continuous performance-to-points scale (Step 1). As seen at the top of the table, Hospital 1 has higher total HVIP performance with 40 points compared with Hospital 2's 30 points. We assume two hospitals were assigned to a peer group because of a similar share of fully dual-eligible beneficiaries (Step 2). We withhold 2 percent of each of the hospital's total base IPPS payments (Step 3). Since Hospital 1 has fewer discharges, its 2 percent withhold is less than Hospital 2's withhold. As shown in the middle of the table, the total HVIP bonus pool to be redistributed

for the peer group is a sum of the two hospital's withholds (or \$1.3 million). We then calculate the percentage adjustment to payments per point for the peer group, which converts total HVIP points to dollars and results in spending the entire \$1.3 million budget (Step 4). For every HVIP point that a hospital in the peer group earns, it can receive a 0.065 percent payment adjustment per point. Based on the hospital's HVIP performance and the peer group's percentage adjustment to payments per point, Hospital 1 will earn a payment adjustment of 2.6 percent, which is equal to \$130,000 (or a reward of \$30,000 greater than the hospital's withhold) (Step 5). Because Hospital 2 had lower HVIP points, it will have a \$30,000 penalty. ■

**TABLE
7-10**

Example of converting HVIP points to payment adjustments for a peer group's hospitals

	Hospital 1 (500 discharges)	Hospital 2 (5,000 discharges)
HVIP points (Step 1)	40	30
Total base IPPS payments	\$5,000,000	\$60,000,000
2 percent withhold of IPPS payments	\$100,000	\$1,200,000
Total HVIP budget for peer group (Step 3)	\$1,300,000	
Percentage adjustment to payments per point (Step 4)	0.065% adjustment per point	
Hospital HVIP-based adjustment (Step 5)	2.60% (\$130,000)	1.95% (\$1,170,000)
Reward or penalty relative to 2 percent withhold	+0.60% (+\$30,000)	-0.05% (-\$30,000)

Note: HVIP (hospital value incentive program), IPPS (inpatient prospective payment system). This example assumes the peer group has two hospitals (Step 2).

Endnotes

- 1 For clarity and consistency with the Commission’s past work, we use the term *potentially preventable admissions* throughout the chapter. The literature and industry also refer to the measure concept as *avoidable hospitalizations*, *ambulatory care–sensitive condition hospitalizations*, and *hospitalizations for potentially preventable complications*.
- 2 HEDIS is a registered trademark of NCQA. The HEDIS potentially preventable admissions measure is called “hospitalizations for potentially preventable complications.”
- 3 CMS has proposed to retain this measure as a 2019 MA Plan Finder display page measure. The agency has also signaled its intent to move the measure to the star rating program in 2022 (Centers for Medicare & Medicaid Services 2018a).
- 4 The expected-discharges value is the predicted number of hospitalizations based on the age, sex, and comorbidities (i.e., hierarchical condition categories (HCCs)) of the eligible population of beneficiaries.
- 5 The measure uses discharges rather than admissions because patients who die in the hospital are not included in the measure. For consistency, we use the term *potentially preventable admissions*.
- 6 Eight percent represents 740,000 potentially preventable admissions out of 9.5 million admissions.
- 7 The Commission has previously referred to this measure as “healthy days at home.” The measure’s new name does not presume that beneficiaries are healthy just because they are at home and is more explicitly inclusive of beneficiaries who may be living in long-term care facilities.
- 8 For example, the Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) study uses a days alive and out of the hospital measure during the six months after the randomized use of pulmonary artery catheters for patients with congestive heart failure.
- 9 Because our goal is to calculate market-specific estimates of HCDs and ultimately compare payment models across and within market areas, we used a fixed-effect model that includes an indicator variable for each of the markets in the regression model to better estimate the age, sex, and HCC covariates.
- 10 *Market areas* refers to the over 1,200 MedPAC-defined market areas used in the PPA analysis.
- 11 The HCD measure includes beneficiaries ages 65 years and older, while the PPA measure was specified for beneficiaries ages 67 years and older. The PPA measure focuses on admissions tied to five chronic conditions. For the HCD calculations, chronic conditions are identified from a set of 15 (acute myocardial infarction/ischemic heart disease, CHF, specified heart arrhythmias, dementia, hematologic disease, lung disease, psychiatric disease, chronic kidney disease, endocrine disease, vascular disease, neuromuscular disease, diabetes, cancer, liver disease, stroke). The conditions were chosen based on the combination of high prevalence and mortality as well as associated health care spending.
- 12 One possible explanation for the increase in mortality days in 2015 is the very severe flu season from October 2014 to March 2015. Beneficiaries who died in the January to March portion of the 2014 to 2015 flu season would have fewer HCDs because they had more mortality days subtracted from the 365 calendar days of 2015. Beneficiaries who died in the October to December portion of the 2014 to 2015 flu season would have more HCDs because they had fewer mortality days subtracted from the 365 calendar days of 2014.
- 13 The Commission recommended a readmissions reduction program in our 2008 report to the Congress (Medicare Payment Advisory Commission 2008). Our June 2018 report to the Congress also includes a study mandated by the 21st Century Cures Act of 2016 that examines whether changes in readmission rates under the HRRP are related to any changes in outpatient and emergency services furnished.
- 14 The PSI 90 measure is a composite of eight patient safety measures: PSI 03 (pressure ulcer); PSI 06 (iatrogenic pneumothorax); PSI 07 (central venous catheter–related bloodstream infections); PSI 08 (postoperative hip fracture); PSI 12 (perioperative pulmonary embolism or deep vein thrombosis); PSI 13 (postoperative sepsis); PSI 14 (postoperative wound dehiscence); and PSI 15 (accidental puncture or laceration).
- 15 In 2018, 2 process-of-care measures were dropped from the VBP Program, and the 1 remaining process-of-care measure, PC–01 (elective delivery before 39 weeks), was moved to the patient safety domain; this measure’s weight increased from 20 percent to 25 percent. CMS has proposed removing the PC–01 measure from the VBP Program (Centers for Medicare and Medicaid Services 2018b).

- 16 The IQRP was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and updated by the Patient Protection and Affordable Care Act of 2010 (PPACA). The HRRP, VBP Program, and HACRP are mandated in PPACA.
- 17 CMS calculates claims-based mortality, readmissions, and MSPB measures. CMS oversees the Hospital Consumer Assessment of Healthcare Providers and Systems® patient experience survey (including certifying survey vendors and developing standardized data collection and sampling protocols). Hospitals work with a survey vendor or follow the standardized protocols themselves to collect and report the core and supplemental experience data from their patients.
- 18 CAHPS® is a registered trademark of AHRQ, a U.S. government agency.
- 19 NHSN is operated by the Centers for Disease Control and Prevention. It is the nation's most widely used health care-associated infection tracking system. Acute care hospitals, long-term care hospitals, dialysis facilities, inpatient rehabilitation facilities, and other facility types report data to NHSN.
- 20 This PSI 90 composite measure was created by AHRQ to help hospitals measure adverse events and address their own quality improvement efforts.
- 21 In some current Medicare quality payment programs, CMS uses differential measure weighting to prioritize outcome measures over process measures. For example, the MA star rating program assigns outcome and intermediate outcome measures a weight of 3, patient experience and access measures a weight of 1.5, and process measures a weight of 1.
- 22 We included only hospitals paid through the inpatient prospective payment system. Because we wanted to model the scoring of all four measures, we did not include hospitals with no publicly reported HCAHPS data or MSPB data (from CMS) or risk-adjusted mortality or readmissions value of 0 or missing. A policy question is how to score missing values—for example, when a hospital's population is too small for HCAHPS. Another policy question is whether and how to include critical access hospitals, which may have numbers too small for valid measurement.
- 23 Based on suggestions from the Commission and the recent requirement legislated in the 21st Century Cures Act of 2016, CMS is implementing a peer-group scoring model, using five peer groups, in the HRRP. Others have tested and found that the peer-grouping approach adequately accounts for differences among providers serving populations with social risk factors (Office of the Assistant Secretary for Planning and Evaluation 2016, Samson et al. 2018).
- 24 We compared the amount of quality payment adjustments in existing programs with the HVIP model payment adjustments by hospital characteristics (e.g., size, teaching status) (see Table 7-A1 in online Appendix 7-A, available at <http://www.medpac.gov>). To make the existing programs and HVIP comparable, we included a budget-neutrality adjustment for the existing program adjustment calculation.

References

- Agency for Healthcare Research and Quality. 2016. *National scorecard on rates of hospital-acquired conditions 2010 to 2015: Interim data from national efforts to make health care safer*. Rockville, MD: AHRQ. <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html>.
- Barnett, M. L., D. C. Grabowski, and A. Mehrotra. 2017. Home-to-home time: Measuring what matters to patients and payers. *New England Journal of Medicine* 377, no. 1 (July 6): 4–6.
- Burns, M., and J. Mullahy. 2016. *Healthy-time measures of health outcomes and healthcare quality*. NBER working paper no. 22562. Cambridge, MA: National Bureau of Economic Research.
- Calderwood, M. S., S. S. Huang, V. Keller, et al. 2017. Variable case detection and many unreported cases of surgical-site infection following colon surgery and abdominal hysterectomy in a statewide validation. *Infection Control and Hospital Epidemiology* 38, no. 9 (September): 1091–1097.
- Centers for Disease Control and Prevention. 2016a. Adherence to the Centers for Disease Control and Prevention’s (CDC’s) infection definitions and criteria is needed to ensure accuracy, completeness, and comparability of infection information. <https://www.cdc.gov/nhsn/cms/cms-reporting.html>.
- Centers for Disease Control and Prevention. 2016b. *National and state healthcare-associated infections progress report*. Atlanta, GA: CDC.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018a. Advance notice of methodological changes for calendar year (CY) 2019 for Medicare Advantage capitation rates, Part C and Part D payment policies and 2019 draft call letter. February 1. <https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/downloads/advance2018.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018b. Fiscal year (FY) 2019 Medicare hospital inpatient prospective payment system (IPPS) and long term acute care hospital (LTCH) prospective payment system proposed rule, and request for information. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-24.html>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. HCAHPS patient-level correlations table. <http://www.hcahponline.org/globalassets/hcahps/summary-analyses/patient-level/july-2015--june-2016-discharges.pdf>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare program; reform of hospital and critical access hospital conditions of participation. Final rule. *Federal Register* 77, no. 95 (May 16): 29034–29076.
- Chatterjee, P., T. C. Tsai, and A. K. Jha. 2015. Delivering value by focusing on patient experience. *American Journal of Managed Care* 21, no. 10 (October): 735–737.
- Covinsky, K. E., E. Pierluissi, and C. B. Johnston. 2011. Hospitalization-associated disability: “She was probably able to ambulate, but I’m not sure.” *Journal of the American Medical Association* 306, no. 16 (October 26): 1782–1793.
- Davies, S. M., K. M. McDonald, E. Schmidt, et al. 2009. *Expanding use of the Prevention Quality Indicators: Report of Clinical Expert Review Panel*. Report prepared for the Agency for Healthcare Research and Quality. Rockville, MD: AHRQ.
- Freund, T., S. M. Campbell, S. Geissler, et al. 2013. Strategies for reducing potentially avoidable hospitalizations for ambulatory care-sensitive conditions. *Annals of Family Medicine* 11, no. 4 (July–August): 363–370.
- Gao, J., E. Moran, Y. F. Li, et al. 2014. Predicting potentially avoidable hospitalizations. *Medical Care* 52, no. 2 (February): 164–171.
- Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016a. Letter to the Acting Administrator of the Centers for Medicare and Medicaid Services regarding the hospital star rating system. September 22.
- Medicare Payment Advisory Commission. 2016b. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2015a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2015b. The use of low-value care in Medicare is substantial. *The MedPAC Blog*, May 21. <http://www.medpac.gov/blog-/medpacblog/2015/05/21/use-of-low-value-care-in-medicare-is-substantial>.
- Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

- Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system*. Washington, DC: MedPAC.
- Office of Inspector General, Department of Health and Human Services. 2016. *Nationwide analysis of common characteristics in OIG home health fraud cases*. Washington, DC: OIG.
- Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. 2016. *Report to Congress: Social risk factors and performance under Medicare's value-based purchasing programs*. Washington, DC: ASPE.
- Rajaram, R., C. Barnard, and K. Y. Bilimoria. 2015. Concerns about using the Patient Safety Indicator–90 composite in pay-for-performance programs. *Journal of the American Medical Association* 313, no. 9 (March 3): 897–898.
- Safran, D. G., M. Anastario, H. P. Rodriguez, et al. 2007. Evaluating the potential for an empirically-derived standard of performance excellence in ambulatory patient experience measures. Pre-publication draft.
- Safran, D. G., D. A. Taira, W. H. Rogers, et al. 1998. Linking primary care performance to outcomes of care. *Journal of Family Practice* 47, no. 3 (September): 213–220.
- Samson, L. W., L. M. Chen, A. M. Epstein, et al. 2018. Dually enrolled beneficiaries have higher episode costs on the Medicare Spending Per Beneficiary measure. *Health Affairs* 37, no. 1 (January): 86–94.
- Teno, J. M., P. L. Gozalo, J. P. Bynum, et al. 2013. Change in end-of-life care for Medicare beneficiaries: site of death, place of care, and health care transitions in 2000, 2005, and 2009. *Journal of the American Medical Association* 309, no. 5 (February 6): 470–477.
- Wasfy, J. H., C. M. Zigler, C. Choirat, et al. 2017. Readmission rates after passage of the Hospital Readmissions Reduction Program: A pre-post analysis. *Annals of Internal Medicine* 166, no. 5 (March 7): 324–331.
- Wholey, D. R., J. B. Christianson, M. Finch, et al. 2003. Evaluating health plan quality 1: A conceptual model. *American Journal of Managed Care* 9 spec. no. 2 (June): SP53–64.

CHAPTER

8

**Medicare accountable care
organization models:
Recent performance and
long-term issues**

Medicare accountable care organization models: Recent performance and long-term issues

Chapter summary

Medicare accountable care organizations (ACOs) were created to help moderate the growth in Medicare spending and improve quality of care for beneficiaries by giving providers greater responsibility for costs and quality. In reviewing current Medicare ACO models, we found that some models—predominantly those at risk for both savings and losses (two-sided risk)—have produced small savings relative to their benchmarks set by CMS, and all have maintained or improved quality. Spending relative to benchmarks is important because it determines which ACOs will receive “shared savings” bonuses. However, some have raised the point that benchmarks are not necessarily the best measure of what spending would have been in the absence of the ACO and thus may not be a good measure of true program savings. From our review of the literature on this question, we conclude that ACOs may have saved Medicare from 1 percent to 2 percent more than indicated by their performance relative to benchmarks and that two-sided ACO models appear to save more than one-sided ACO models.

In light of evidence regarding two-sided ACOs and savings, we identified issues that need to be resolved if two-sided ACOs are going to be part of the Medicare program in the long term:

- *Are hospitals a viable participant in ACOs?* Hospitals could be important participants in ACOs, especially given their ability to supply the capital needed to take on two-sided risk. But, while ACOs may want to constrain

In this chapter

- Introduction
- Background on ACOs
- ACO quality and financial performance relative to CMS-designed benchmarks
- ACO quality and financial performance results according to other researchers
- New tools to allow ACOs to manage care
- Long-term issues for Medicare ACOs
- Conclusion

unnecessary service use (e.g., unnecessary hospital admissions) to generate savings, hospitals may have conflicting incentives to admit patients to increase their fee-for-service (FFS) revenue. We find that hospitals may still want to participate in ACOs despite the apparent conflict in incentives around inpatient hospital care primarily because most ACO savings to date stem from reductions in the use of post-acute care and not from reductions in inpatient care.

- ***Should asymmetric models be continued?*** Asymmetric models—models with greater opportunities for savings than losses—could be one strategy to help ACOs transition to two-sided risk. For example, the new Track 1+ ACO model has two asymmetries. First, the shared savings rate is 50 percent (i.e., if actual spending is less than expected spending (the benchmark), then ACOs get half of the savings and Medicare keeps the other half), while the shared loss rate is 30 percent. Second, the loss cap is lower than the savings cap. Because potential gains to ACOs are greater than potential losses, this asymmetric relationship could result in a cost for the Medicare program. Currently, CMS’s Track 1+ model is a demonstration, and savings are not required under CMS’s demonstration and waiver authority. If Track 1+ were incorporated into permanent Medicare law, the costs may need to be offset if performance is essentially random. If it is demonstrated that ACOs are modifying their behavior from what they would have done if not in ACOs and are reducing spending, then this issue will not arise. The Commission will continue to monitor the Track 1+ model to determine whether aspects of it should be extended to other ACO models to encourage uptake of two-sided risk.
- ***How should benchmarks be set initially and then rebased for subsequent agreement periods?*** The basic ACO model essentially sets benchmarks as a function of historical spending for beneficiaries who would have been attributed to the ACO in the past. If ACOs reduce the level of spending or keep spending growth below the trend in FFS spending, they share in savings. If the same approach were taken in subsequent agreement periods, then ACOs would have to continuously improve over their own past performance to achieve savings, which could create diminishing returns for consistently successful ACOs and potentially discourage long-term participation. In some models, benchmarks are now being rebased using a blend of regional and historical spending. There are additional concerns related to the current benchmark methodology (e.g., the impact of beneficiaries moving in and out of the ACO), and we discuss several approaches to address these issues.

- ***Should the 5 percent bonus for clinicians in advanced alternative payment models (A-APMs) be distributed differently to encourage A-APM participation?*** Under current law, clinicians receive a 5 percent bonus on all of their physician fee schedule (PFS) payments if they exceed an annual threshold level for payments or patients in A-APMs. (One-sided ACOs do not qualify as A-APMs, and thus clinicians in them do not receive the bonus.) This A-APM provision could discourage clinicians from participating in ACOs because they would be uncertain about whether they would exceed the threshold. Moving to a system in which clinicians receive a 5 percent bonus with certainty on their share of PFS payments derived from an A-APM could make the incentive more equitable and encourage participation in two-sided ACOs.
- ***What will be the relationship between specialists and two-sided ACOs?*** Currently, a substantial number of specialists are on the participation lists of ACOs. ACOs may want to include specialists as a way to coordinate the care of their beneficiaries more effectively, and specialists may be incentivized to join ACOs to receive referrals and potentially share in savings. Moving forward, specialty-focused ACO models may also be an option for increasing specialist participation.
- ***Are two-sided ACOs a long-term option in the Medicare program?*** Some maintain that ACOs are one way for providers to take greater accountability for a group of patients and then transition toward taking full accountability as a Medicare Advantage (MA) plan. If ACOs are regarded only as a transition step toward becoming an MA plan, then it may discourage participation in the ACO model. We have found in previous work that ACOs can be the low-cost option in some areas of the country, and their advantage of lower administrative costs could keep them as a long-term option, if benchmarks are set equitably.

Given the early success and popularity of the ACO model, the above issues should be considered if Medicare's ACOs are to continue in the long term. ■

Introduction

The Commission has long maintained that Medicare should encourage clinicians to improve the quality of care, overall health, and costs of care for a population of patients. In the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Congress provided an incentive for clinicians to join advanced alternative payment models (A-APMs), which were predicated on putting an entity responsible for meeting quality goals for a defined patient population at financial risk for Medicare spending. In response, the Medicare program deemed certain models to be A-APMs, created several A-APMs, and is currently developing new ones. The Commission has developed principles for A-APMs and commented on which A-APMs best meet those principles (Medicare Payment Advisory Commission 2016a). In general, accountable care organization (ACO) models at two-sided risk—that is, at risk for losses if spending exceeds benchmarks and sharing savings if spending is lower than benchmarks—seem to be the models that best meet the Commission’s principles because they encourage clinicians to be responsible for the quality and cost of care for a defined population of Medicare beneficiaries.

The Commission has determined that the balance of incentives in MACRA between clinicians in A-APMs and those not in A-APMs needs to be rethought. We recommended in our March 2018 report to the Congress that the current Merit-based Incentive Payment System (MIPS)—which pertains to all fee-for-service (FFS) clinicians not in A-APMs unless excluded—be eliminated and replaced with a voluntary value program that would encourage clinicians to elect to be measured for cost and quality purposes as a voluntary group (Medicare Payment Advisory Commission 2018). This recommendation was intended, in part, to prepare clinicians to eventually move to A-APMs.

If it is important for clinicians to move to A-APMs, and if two-sided-risk ACOs are the model most in keeping with the Commission’s principles for A-APMs, then it is important to understand performance on cost and quality and what issues need to be resolved for two-sided ACOs to be a long-term part of the Medicare program.

Background on ACOs

Medicare ACOs began in 2012 and have grown rapidly since then to care for about one-third of Medicare FFS beneficiaries. In Medicare, ACOs are groups of health care providers that have agreed to be held accountable for the cost (that is, spending in Medicare Part A and Part B) and quality of care for a defined group of Medicare beneficiaries. Generally, the goals of ACOs are to lower costs, increase quality of care and patient experience, and improve provider accountability for the cost and quality of care provided to their patients. Theoretically, ACOs could generate savings by substituting lower cost services for higher cost services (e.g., substituting outpatient services for inpatient services) or reducing low- or no-value services. If ACOs achieve their goals, they are rewarded with shared savings.

There are three main concepts in ACO programs:

- **Attribution**—Beneficiaries are primarily attributed to ACOs based on their use of services.¹ Prospective attribution occurs when beneficiaries are assigned to an ACO at the start of the performance year (based on their prior year usage); retrospective attribution occurs when a beneficiary is attributed at the end of the year (based on their current year usage). Unlike Medicare Advantage (MA) plans, beneficiaries attributed to ACOs can use whatever providers they choose.
- **Composition of the ACO**—An ACO’s providers do not have to provide all services for a beneficiary, although they are responsible for total Part A and Part B spending. The essential requirement is that the providers as a group have enough beneficiaries attributed to them to meet the minimum requirement for their model. ACOs can be clinician-only or can include providers such as hospitals and skilled nursing facilities (SNFs).
- **Benchmarks**—The goals of ACOs are assessed using a set of quality measures (see online Appendix 8-A, available at <http://www.medpac.gov>, for the list of measures) and spending benchmarks. The spending benchmark is an estimate of Part A and Part B spending for an ACO’s beneficiaries in a given year. If spending for an ACO’s beneficiaries—including health care services provided outside the ACO—is below the benchmark, then the ACO is eligible to earn

**TABLE
8-1**

Characteristics of the MSSP ACO tracks

	Attribution	Risk arrangement	Maximum shared savings or loss rate ^a	Cap on earned: ^b	
				Savings	Losses
Track 1	Retrospective ^c	One sided	50%	10%	0%
Track 2	Retrospective ^c	Two sided	60%	15%	10%
Track 3	Prospective	Two sided	75%	20%	15%

Note: MSSP (Medicare Shared Savings Program), ACO (accountable care organization).

^aThe actual shared savings/loss rate could change depending on the ACO's quality score (e.g., an ACO that scores poorly on quality would receive a smaller shared savings amount than if it had earned a high quality score).

^bThe amount an ACO can share in savings (or repay in shared losses) is capped as a percentage of the benchmark.

^cThese tracks have preliminary prospective attribution and then retrospective attribution for final reconciliation.

Source: Centers for Medicare & Medicaid Services 2017c.

a “shared savings” payment. If spending is above the benchmark, then the ACO may be financially liable for shared losses. One-sided-risk arrangements are those in which ACOs can earn shared savings but are not responsible for losses; two-sided-risk arrangements are those in which ACOs can earn savings and are responsible for shared losses. The amount of shared savings an ACO is eligible to earn varies by program.

Overview of Medicare’s ACO programs

The first Medicare ACOs began at the start of 2012 as part of the Pioneer ACO Model, which was a demonstration that ended in 2016. Midway through 2012, the first cohort of ACOs belonging to the Medicare Shared Savings Program (MSSP)—a permanent ACO program created by the Congress—began. Medicare’s ACO programs have grown quickly since their beginning in 2012, both through additional demonstrations and expansion of the MSSP. With the passage of MACRA in 2015, the Congress created stronger incentives for providers to move into A-APMs and, therefore, ACOs. The Commission has been supportive of ACOs since the beginning, especially two-sided risk ACOs that best fit our A-APM principles.

Medicare currently has three ACO programs that have been in operation since 2016 (or earlier), including the MSSP, the Next Generation (NextGen) ACO model, and the ESRD (End-Stage Renal Disease) Seamless Care Organizations (ESCOs). At the start of 2018, CMS introduced two new ACO models: the Track 1+ ACO Model and the Vermont All-Payer ACO Model.

Medicare Shared Savings Program

The MSSP was established in the Patient Protection and Affordable Care Act of 2010 (PPACA) and is a permanent part of the Medicare program. It currently consists of three ACO tracks: Track 1, Track 2, and Track 3. Table 8-1 summarizes the main differences between each ACO track.

MSSP ACOs are allowed to participate as a Track 1 ACO—which is a one-sided track—for only two three-year agreement periods.² This stipulation provides a transition period for ACOs to prepare to take on risk as they move to two-sided-risk models (e.g., Track 2 or Track 3). (Because they are two-sided, Track 2 and Track 3 qualify as A-APMs and clinicians in them can be eligible for the 5 percent bonus on their fee schedule revenue as established in MACRA.) Furthermore, even beyond the shared savings/loss rate, there are model-specific limits on how much an ACO can earn in savings or pay in losses. These savings and loss limits vary for each model. For instance, Track 1 shared savings payments are capped at 10 percent of benchmark. Track 2 shared savings are capped at 15 percent of benchmark, while losses are capped at 10 percent of benchmark. For Track 3, shared savings are capped at 20 percent of benchmark, while losses are capped at 15 percent of benchmark.

Next Generation ACO Model

NextGen is a demonstration that began in 2016 and was based in part on the previous Pioneer ACO Model.

NextGen is a two-sided-risk, prospective-attribution demonstration run by the CMS's Center for Medicare & Medicaid Innovation (CMMI). For the 2017 and 2018 performance years, NextGen qualifies as an A-APM. NextGen ACOs can choose their level of shared savings and losses and can opt to share at either 80 percent or 100 percent of savings and losses. Both shared savings and losses are capped at 15 percent of the ACO's benchmark. Additionally, NextGen ACOs receive some regulatory flexibility because of their level of assumed risk. This flexibility includes waivers to expand the use of telehealth and to waive the three-day hospital stay rule before using a SNF.

ESRD Seamless Care Organizations

An ESCO is a disease-specific ACO model that applies to ESRD beneficiaries utilizing chronic dialysis services. ESCOs began in 2016 as a demonstration and are run by CMMI. Beneficiaries are assigned to ESCOs on a "first touch" basis, meaning that the first time an ESRD beneficiary utilizes an ESCO dialysis facility, he or she will be prospectively assigned to that ESCO. ESCOs are split into two tracks based on their size. Large dialysis organizations (LDOs) are organizations with 200 or more dialysis facilities, while non-large dialysis organizations (non-LDOs) are those with fewer than 200 dialysis facilities. In ESCOs, LDOs are automatically at two-sided risk, while non-LDOs have the option to be at one-sided risk or two-sided risk. For the 2017 and 2018 performance years, LDOs and non-LDOs at two-sided risk can qualify as A-APMs. For their first performance year, the shared savings/loss rate for LDOs is a maximum of 70 percent, and it is 75 percent in their second and future performance years; the limit on shared losses is equal to the shared loss rate for the year (e.g., 75 percent). Non-LDOs have a shared savings rate of 50 percent, with a limit on savings of 5 percent of benchmark.

Track 1+

Track 1+ is an asymmetric, two-sided-risk model with prospective attribution that began in 2018. It is a demonstration through CMS's CMMI authority and is jointly run with CMS's MSSP office. ACOs that join Track 1+ are eligible to earn up to 50 percent in shared savings, but because it is an asymmetric risk model, they are responsible for only 30 percent of shared losses. Additionally, the savings and loss limits vary based on ACO composition as follows:

- **Hospital Track 1+ ACOs**—Losses are capped at 4 percent of the ACO's benchmark.
- **Clinician-only Track 1+ ACOs³**—Losses are capped at 8 percent of ACO-participant FFS revenue. This model differs from the other ACO models because it sets a limit relative to FFS revenue instead of the ACO's benchmark, which is notable because FFS revenue tends to be much lower than the total Part A and Part B benchmark. In general, this loss threshold of 8 percent is lower (and thus more attractive) to ACOs than the benchmark standard.

While ACOs with hospitals may have less incentive to join the Track 1+ demonstration because they are not eligible for the lower risk limit based on FFS revenue, about half of the Track 1+ ACOs list hospitals as participating providers, indicating broad interest in the model. Savings for both types of Track 1+ ACO are limited to 10 percent of benchmark.

Vermont All-Payer Model

The other new ACO model in 2018, the Vermont All-Payer ACO Model demonstration, brings together Vermont's largest payers—Medicare, Medicaid, and commercial insurers—under one ACO model focused on health care value and quality. There is one ACO in the model, OneCare Vermont, with model specifics (e.g., benchmark methodology) varying slightly for each payer. The overall goals of the model, however, are similar across payers and are Vermont specific. In 2018, OneCare Vermont is responsible for 122,000 individuals across payers and has 10 participating hospitals from different systems across the state (D'Ambrosio 2017).⁴

Similar to other ACO models, providers participating in the Vermont All-Payer Model have the potential to earn shared savings and a quality bonus payment but are also accountable for shared losses. Because the model's providers assume risk for the patient population, the model qualifies as an A-APM for the 2018 performance year. Specific goals for the model include attributing to the ACO, by 2022, 90 percent of the state's Medicare beneficiaries (and 70 percent of all Vermont-insured residents) and limiting Medicare per capita expenditure growth to 0.1 to 0.2 percentage points below projected national Medicare growth. The model also includes 21 quality measures that focus on 3 areas prioritized by Vermont: reducing deaths due to substance use disorders and suicides, reducing prevalence and morbidity due to

**TABLE
8-2**

The number of Medicare ACOs increased from 2017 to 2018

	Number of ACOs		Assigned beneficiaries
	2017	2018	
MSSP (total)	480	506	10.5 million
Track 1	438	460	N/A
Track 2	6	8	N/A
Track 3	36	38	N/A
Track 1+	0*	55	N/A
Next Generation	45	58**	1.4 million
ESCOs	37	37	16,085
Total	562	656	N/A

Note: ACO (accountable care organization), MSSP (Medicare Shared Savings Program), N/A (not available), ESCO (ESRD [End-Stage Renal Disease] Seamless Care Organization). Count of assigned beneficiaries is based on the most recent data available; the total MSSP count is from 2018, the Next Generation count is from 2017, and the ESCO count is from 2016.

*Track 1+ started in 2018.

**At the start of 2018, there were 58 participating Next Generation ACOs. According to CMS's website, there are currently only 51 Next Generation ACOs, meaning that 7 ACOs appear to have dropped from the program. The Vermont All-Payer ACO model is included in the Next Generation count (even though it is a separate model) because, for 2018, OneCare Vermont is considered a Next Generation ACO.

Source: "Side-by-Side Comparison: Medicare Accountable Care Organization (ACO) Models" from the Kaiser Family Foundation; MSSP 2018 Fast Facts from CMS.

chronic conditions, and increasing access to primary care (Green Mountain Care Board 2018).

The only ACO in the model, OneCare Vermont, has been a Medicare ACO since 2013, first as an MSSP Track 1 ACO from 2013 to 2017. Starting in 2018, it transitioned into a NextGen ACO. In 2016, actual spending was above the benchmark, and OneCare Vermont generated losses of 4.6 percent relative to the benchmark. Vermont previously had other Medicare ACOs operating in the state, including the Track 1 ACO Community Health Accountable Care LLC, which had spending 16.9 percent above its benchmark in 2016 and is not a Medicare ACO in 2018.

Although the Vermont All-Payer ACO demonstration is a one-state model, it could be a starting point for all-payer models in other states. It could show, for example, the utility of having most of a provider's patient population in one payment model with one set of quality indicators. We will monitor developments.

Number of participating ACOs in 2018

In 2018, there are 656 Medicare ACOs (Table 8-2 shows the number of ACOs by program). Together, these ACOs

are now responsible for almost one-third of the Medicare FFS population.

ACOs are available in all 50 states (and the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam), although not in all areas of every state. MSSP Track 1, a one-sided model, is still the predominant model, accounting for nearly three-quarters of Medicare ACOs. However, MSSP Track 1 does not qualify as an A-APM; thus, most MSSP ACOs are not A-APMs.⁵ Track 1+, which qualifies as an A-APM, is in its first year and already has 55 ACOs. It is interesting to note that many ACOs include hospitals as participants, even though the financial incentives for hospitals and ACOs may appear to be in conflict. We discuss this apparent contradiction later in this chapter.

ACO quality and financial performance relative to CMS-designed benchmarks

This section summarizes the quality and financial performance of the ACO programs active in Medicare

in 2016, the latest performance data available at this time. Financial performance is discussed relative to the CMS benchmarks for each program. In the next section, we discuss estimates from the literature on financial performance relative to the counterfactual—that is, what spending would have been if the ACO did not exist. Benchmarks and counterfactuals differ because benchmarks are designed to fulfill policy goals—for example, to encourage clinicians to participate in ACOs or to increase equity across the country. Therefore, “savings” relative to benchmarks will not be the best estimate of program savings relative to the counterfactual. The latter is in some ways the better estimate of whether ACOs are saving the Medicare program money. But “savings” relative to the benchmarks is how the ACOs will determine whether they want to stay in the program; thus, CMS-computed “savings” are also important.

MSSP ACOs

The MSSP was established by PPACA and is a permanent part of the Medicare program. The first MSSP ACOs started in April 2012, and the program has grown rapidly to 506 ACOs as of 2018. The program currently consists of three tracks, each with its own savings and loss specifications: Track 1, Track 2, and Track 3.

MSSP ACOs generally perform well on quality metrics

MSSP, Pioneer, and the NextGen programs use the same set of measures to calculate an annual quality score for each ACO. The measure set in 2016 included 31 process and outcome measures covering the following 4 quality domains: patient experience measures (e.g., getting timely care), care coordination and patient safety (e.g., readmissions, screening for risk of falls), preventive health (e.g., influenza immunization), and at-risk populations (e.g., depression remission at 12 months). (See online Appendix 8-A, available at <http://www.medpac.gov>, for the full list of ACO quality measures.) The measures are reported through a combination of claims and administrative data, a CMS-provided web interface designed for capturing ACO-reported clinical quality measure data, and the ACO Consumer Assessment of Health Care Providers and Systems[®] patient experience survey.

In each ACO’s first performance year, the quality score is based only on whether the ACO completely and accurately reported quality data. In the ACO’s second and

future years, the ACO’s quality score is based on how the ACO performed relative to a prospective national FFS benchmark. In the MSSP program, ACOs with higher quality scores receive greater shared savings bonuses.

In 2016, only 4 of the MSSP Track 1 ACOs (1 percent of 438 ACOs) did not meet the quality standard because they did not report a complete set of data. (One of those ACOs dropped out in 2017.) All 22 of the ACOs participating in Track 2 or Track 3 met the quality standard. MSSP quality scores are high, with average quality scores of 93 percent for Track 1, 94 percent for Track 2, and 96 percent for Track 3.

We reviewed changes over time in some of the patient experience and population-based outcome measures that the Commission supports. The MSSP ACOs on average had strong patient experience results and high-performing readmission results from 2012 to 2016, with little change in results between years.

MSSP performance relative to benchmarks (relative savings)

Summarized financial results for the MSSP ACOs from 2013 to 2016 are shown in Table 8-3 (p. 220). The total benchmark amount for the MSSP ACOs is shown in the first row (e.g., \$81,377 million in 2016). The second row is the total amount of actual Part A and Part B Medicare spending for beneficiaries attributed to the MSSP ACOs (e.g., \$80,725 million in 2016). “Relative savings” are defined as the difference between the benchmark and the actual spending. In 2016, for example, Medicare spent \$652 million less than the benchmark in total, although some ACOs spent more than their benchmark and some less. Relative savings, by this definition, were less than 1 percent of the benchmark in each year, although this number is slowly increasing. Medicare then paid ACOs that saved enough to entitle them to share in savings (listed as “paid to ACOs” in the table), which is shown as a negative number in the next row, for example, –\$701 million in 2016. Some ACOs that were in Track 2 and Track 3, which are two-sided models, had actual spending greater than their benchmark and had to share that loss with Medicare. They paid Medicare the amount shown in the next row (“paid back to CMS”), for example, \$9 million in 2016. The net amount is the sum of relative savings, the amount paid to ACOs as shared savings, and the amount paid back to Medicare by ACOs as shared losses. For 2016, this net amount was –\$39 million.

**TABLE
8-3****Summary financial results of MSSP ACOs relative to benchmarks**

	2013		2014		2015		2016	
	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent
Benchmark	\$42,499	100.0%	\$52,885	100.0%	\$73,298	100.0%	\$81,377	100.0%
Actual Part A and Part B spending	<u>42,265</u>	<u>99.5</u>	<u>52,594</u>	<u>99.0</u>	<u>72,868</u>	<u>99.4</u>	<u>80,725</u>	<u>99.2</u>
Relative savings	234	0.5	291	0.6	429	0.6	652	0.8
Paid to ACOs	-316	-0.7	-341	-0.6	-646	-0.9	-701	-0.9
Paid back to CMS	<u>4</u>	<u>0.0</u>	<u>0</u>	<u>0.0</u>	<u>0</u>	<u>0.0</u>	<u>9</u>	<u>0.0</u>
Net	-78	-0.1	-50	-0.1	-216	-0.3	-39	-0.1

Note: MSSP (Medicare Shared Savings Program), ACO (accountable care organization). The number of ACOs was 220 for 2013, 333 for 2014, 392 for 2015, and 432 for 2016. There were originally 433 MSSP ACOs in 2016, but CMS reported data for only 432 ACOs. "Relative savings" is defined as the difference between the benchmark and the actual spending. "Net" is the sum of relative savings and amounts paid to ACOs and paid back to CMS. Components may not sum to totals due to rounding.

Source: MedPAC analysis of CMS MSSP ACO public use files.

It may not seem logical that shared savings payments to ACOs can exceed total relative savings, and they cannot for any individual ACO. However, under the Track 1 MSSP model's one-sided risk, if actual payments exceed the benchmark, the ACO does not share losses with Medicare—

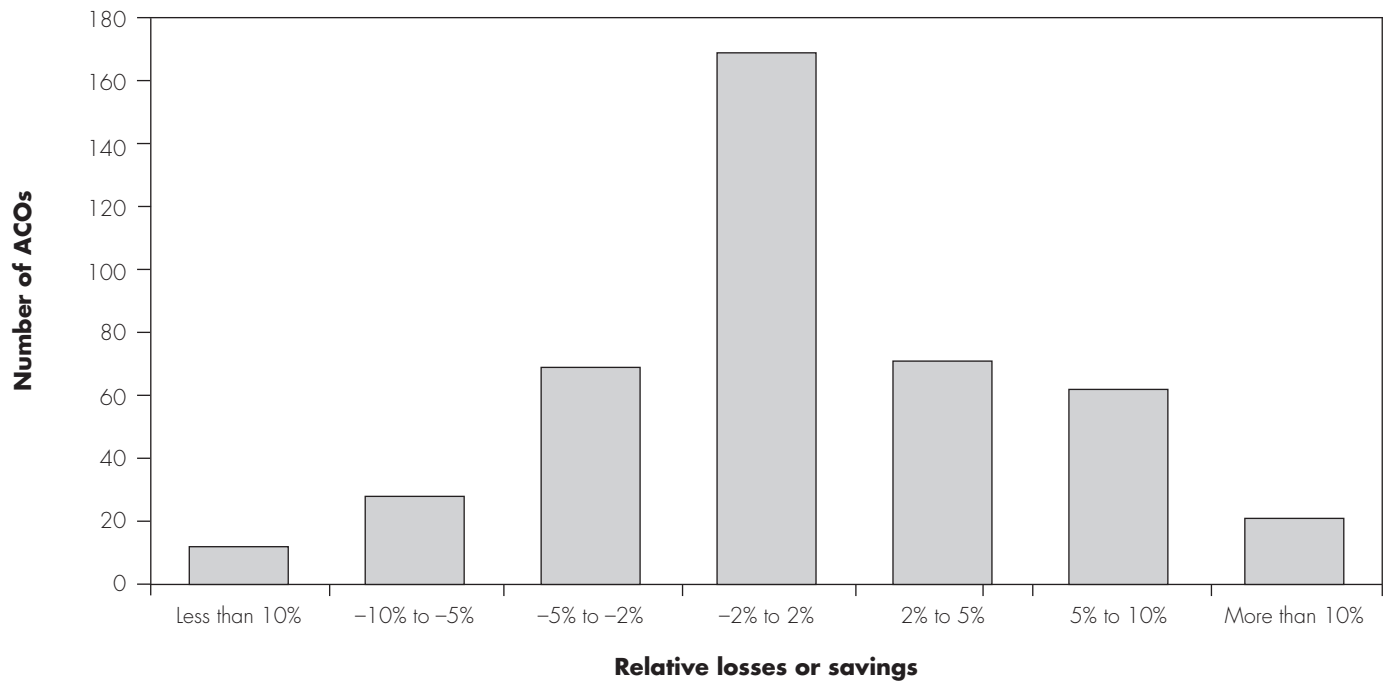
all losses are borne by the program. For example, under this model, if one ACO had savings of \$1 million and the other had losses of \$1 million, Medicare would pay shared savings of \$500,000 to the first and collect nothing from the second; thus, relative savings would be zero and the shared

**TABLE
8-4****Summary financial results of MSSP ACOs relative to benchmarks, by track, 2016**

	One-sided model		Two-sided models			
	Track 1		Track 2		Track 3	
	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent
Benchmark	\$76,718	100.0%	\$688	100.0%	\$3,971	100.0%
Actual Part A and Part B spending	<u>76,177</u>	<u>99.3</u>	<u>647</u>	<u>93.9</u>	<u>3,901</u>	<u>98.3</u>
Relative savings	541	0.7	42	6.1	69	1.7
Paid to ACOs	-613	-0.8	-23	-3.4	-64	-1.6
Paid back to CMS	<u>0</u>	<u>0.0</u>	<u>0</u>	<u>0.0</u>	<u>9</u>	<u>0.2</u>
Net	-72	-0.1	18	2.7	14	0.4

Note: MSSP (Medicare Shared Savings Program), ACO (accountable care organization). In 2016, the number of ACOs was 410 in Track 1, 6 in Track 2, and 16 in Track 3. There were originally 433 MSSP ACOs in 2016, but CMS reported data for only 432 ACOs. "Relative savings" is defined as the difference between the benchmark and the actual spending. "Net" is the sum of relative savings and amounts paid to ACOs and paid back to CMS. Components may not sum to totals due to rounding.

Source: MedPAC analysis of CMS MSSP ACO public use files.

FIGURE 8-1**Distribution of MSSP ACO savings and losses, 2016**

Note: MSSP (Medicare Shared Savings Program), ACO (accountable care organization).

Source: MedPAC analysis of CMS MSSP ACO public use files.

savings payments would be \$500,000. On net, the program would have paid out \$500,000 more than the amount predicted by the benchmarks, and we would assess that result as a net relative loss to the Medicare program.

The difference between one-sided and two-sided models is illustrated in Table 8-4, which shows the performance in 2016 of the ACOs in Track 1, the one-sided model, and the ACOs in Track 2 and Track 3, the two-sided models.

For Track 1 ACOs, the amount paid to ACOs in shared savings bonuses (\$613 million) exceeded the amount saved relative to the benchmarks (\$541 million), resulting in spending by the program exceeding expectations by \$72 million. In contrast, because Track 2 and Track 3 ACOs share in losses, these ACOs produced net savings for the Medicare program in 2016 relative to the benchmark (2.7 percent and 0.4 percent, respectively). All Track 2 ACOs generated savings relative to the benchmark, and 69 percent of Track 3 ACOs generated savings (11 of 16 ACOs).

There is variation in reported relative savings or losses across MSSP ACOs. Much of the savings and losses could be the result of random variation. As shown in Figure 8-1, 169 of the 432 of ACOs (almost 40 percent) had savings or losses of 2 percent or less. However, some had significantly greater savings or losses. Among the 83 ACOs with reported savings of over 5 percent, most are located in areas of high service use. For example, 20 of these ACOs with savings over 5 percent served beneficiaries in Florida, and 12 served beneficiaries in Texas. These data are not surprising in light of our 2016 report finding that a market's historical level of service use is the best predictor of reported ACO savings (Medicare Payment Advisory Commission 2016d). That analysis and its findings are discussed briefly below.

Factors contributing to MSSP ACO performance

Using 2014 data, we analyzed the contribution of three selected factors that might contribute to ACO performance relative to benchmarks: ACO type (hospital based, primary care based, or multispecialty practice based); size of the

**TABLE
8-5**

ACOs with the highest price-adjusted benchmarks were more likely to generate net savings to Medicare based on CMS's benchmarks, 2016

Quintile	Price-adjusted mean per capita ACO benchmark	Percent of ACOs:		As a share of quintile's benchmark:	
		Achieving savings relative to benchmark	Receiving shared savings	Shared savings payments	Net savings to Medicare based on CMS's benchmarks
1 (lowest price-adjusted benchmark)	\$7,911	38.0%	11.4%	0.2%	-1.3%
2	8,933	40.5	19.0	0.3	-1.5
3	9,733	55.7	22.8	0.4	-0.1
4	10,511	60.8	40.5	1.1	0.4
5 (highest price-adjusted benchmark)	13,160	77.2	59.5	2.3	2.0

Note: ACO (accountable care organization), MSSP (Medicare Shared Savings Program). Benchmarks in the second column have been price adjusted using CMS county-level standardized prices from 2015. Savings presented in the other columns are based on CMS's benchmarks. The last column is the net of relative savings minus the amount paid to ACOs as shared savings, plus the amount paid back to CMS as shared losses. Data exclude 38 ACOs serving beneficiaries in multiple states that do not share a border (e.g., an ACO serving beneficiaries in both New York and California).

Source: MedPAC analysis of CMS MSSP ACO public use file.

ACO; and the historical level of service use in the ACO's markets. Because these variables are all correlated to some degree, we evaluated them in a multivariate model. We used service use rather than spending because spending includes service use and price. Service use (relative to the national average) is something that the ACO could theoretically control; price is outside of the ACO's control and is instead a result of Medicare payment policy. The common practice of assuming that the ACO's benchmark is a good proxy for service use is a poor assumption. Our analysis found that:

- historical service use in the area where an ACO's beneficiaries live is the factor that best explains savings relative to benchmark performance for ACOs;
- ACO size (10,000 or fewer beneficiaries) and southern location also have some statistically significant explanatory value; and
- the ACO's size may have a larger effect on its odds of financial success than its type—that is, whether the ACO is formed around a primary care practice, multispecialty practice, or hospital.

Using 2016 performance data, we find there continues to be a relationship between service use and MSSP performance (Table 8-5). We price adjusted the 2016 ACO benchmarks to approximate historical service use (that is, we removed regional pricing differences in the

benchmarks) and separated the ACOs into quintiles based on the price-adjusted benchmarks.⁶ In Table 8-5, those ACOs with the highest price-adjusted benchmarks are in the fifth quintile, while those with the lowest price-adjusted benchmarks are in the first quintile. When prices are standardized, we found that ACOs with the highest price-adjusted benchmarks—indicating higher levels of historical service use—were more likely to achieve savings relative to the benchmark and earn shared savings payments. Furthermore, ACOs with higher price-adjusted benchmarks were more likely to generate net relative savings for the program.

These results are not surprising. ACOs with benchmarks exhibiting high historical service use tend to have more service use to reduce; thus, they have more opportunities to generate savings. This tendency is highlighted by results for ACOs in the highest quintile of price-adjusted benchmarks (approximated service use): Over 77 percent of these high-use ACOs achieved savings relative to their benchmarks, and almost 60 percent received a shared savings payment. In contrast, only about 11 percent of ACOs with the lowest level of price-adjusted benchmark received shared savings. Similarly, shared savings payments were 2.3 percent of the benchmark for ACOs with the highest benchmarks, and the implied net relative savings for the program (total savings minus shared savings payments to ACOs) was 2.0 percent. The program lost 1.3 percent of the benchmark for ACOs with the

**TABLE
8-6**

Summary financial results of Pioneer ACOs relative to benchmarks

	2012		2013		2014		2015		2016	
	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent	Dollars (in millions)	Percent
Benchmark	\$7,598	100.0%	\$7,142	100.0%	\$6,931	100.0%	\$5,490	100.0%	\$3,381	100.0%
Actual Part A and Part B spending	<u>7,507</u>	<u>98.8</u>	<u>7,046</u>	<u>98.7</u>	<u>6,811</u>	<u>98.0</u>	<u>5,453</u>	<u>99.3</u>	<u>3,320</u>	<u>98.2</u>
Relative savings	91	1.2	96	1.4	120	1.7	37	0.7	61	1.8
Paid to ACOs	-77	-1.0	-68	-1.0	-82	-1.2	-34	-0.6	-37	-1.1
Paid back to CMS	<u>2.5</u>	<u>0.0</u>	<u>11</u>	<u>0.2</u>	<u>9</u>	<u>0.1</u>	<u>2</u>	<u>0.0</u>	<u>0</u>	<u>0.0</u>
Net	16	0.2	39	0.6	47	0.7	5	0.1	24	0.7

Note: ACO (accountable care organization). The number of Pioneer ACOs was 32 for 2012, 23 for 2013, 20 for 2014, 12 for 2015, and 8 for 2016. "Relative savings" is defined as the difference between the benchmark and the actual spending. "Net" is the sum of relative savings and amounts paid to ACOs and paid back to CMS. Components may not sum to totals due to rounding.

Source: MedPAC analysis of CMS Pioneer ACO quality and financial results, performance years 1-5.

lowest benchmarks. Although, within each quintile, some ACOs achieved savings and others incurred losses relative to their benchmark, the general trend was that ACOs' relative savings were positively correlated with higher service use.

Pioneer ACOs generally performed well on cost and quality metrics

The Pioneer ACO demonstration was the first ACO design tested in Medicare, and it was focused on organizations that had some experience in taking risk. It started with 32 ACOs in 2012 and continued through 2016. No ACOs were allowed to join the demonstration after it started, but participating ACOs were allowed to leave, so the number of ACOs decreased as time went on; by the final year of the program, only eight ACOs remained. The Pioneer demonstration was judged to be successful in controlling cost and increasing quality by the CMS Office of the Actuary and was certified for expansion. Many of the lessons learned in the Pioneer demonstration (e.g., prospective attribution and allowing ACOs to share in a larger portion of savings) were used when designing the Next Generation ACO program and Track 3 of the MSSP.

Pioneer quality

In the Pioneer program, an ACO's quality score determined its savings/losses sharing rate. In 2016, all

Pioneer ACOs met the quality reporting requirement. Like the MSSP ACOs, they also had high quality scores, ranging from 89 percent to 96 percent. We reviewed changes over time in some of the patient experience and population-based outcome measures that the Commission supports. The eight ACOs that participated in all five years of the Pioneer program had consistently high patient experience results. On average, these Pioneer ACOs showed some meaningful improvement in two measures: health promotion and education (improvement of almost 5 percent) and health/functional status (3 percent improvement). All but one of the ACOs improved their hospital readmissions rates.

Pioneer performance relative to benchmarks (relative savings)

In the final year of the demonstration, there were 8 remaining Pioneer ACOs serving nearly 270,000 beneficiaries. Those remaining ACOs generated savings relative to their benchmarks, with a net relative savings of \$24 million in 2016 (Table 8-6).

The relative savings percentage, with and without taking into account shared savings, increased over the first three years, followed by lower savings in the fourth year. Two factors may partially account for this trend. First, ACOs that stayed in the program tended to be more successful

**TABLE
8-7****Summary financial results of Next Generation ACOs relative to benchmarks, 2016****2016**

	Dollars (in millions)	Percent
Benchmark	\$5,149	100.0%
Actual Part A and Part B spending	<u>5,101</u>	<u>99.1</u>
Relative savings	48	0.9
Paid to ACOs	-58	-1.1
Paid back to CMS	<u>20</u>	<u>0.4</u>
Net	10	0.2
Discount	53	1.0
Total relative savings	63	1.2

Note: ACO (accountable care organization). There were 18 Next Generation (NextGen) ACOs in 2016. "Relative savings" is defined as the difference between the benchmark and the actual spending. Benchmarks for NextGen ACOs are constructed with a built-in discount—an ACO-specific decrease to the benchmark—to ensure savings for the program. "Net" is the sum of relative savings and amounts paid to ACOs and paid back to CMS.

Source: MedPAC analysis of CMS Next Generation ACO quality and financial results, performance year 1.

than those that left. Hence, relative savings appeared to increase in subsequent years as the unsuccessful ACOs dropped out. Second, the decrease in relative savings in 2015 was likely due to the benchmarks being rebased. Rebasing takes into account any success achieved in the previous years. If relative savings were achieved in the first three years, the rebased benchmark will decrease before trending, making it more difficult to achieve relative savings in future years. This issue of how much rebasing should take into account ACOs' past success in controlling spending is discussed later in the chapter.

In 2016, four more ACOs left the Pioneer demonstration, and the remaining ACOs generated relative savings. This result is partly because these ACOs' per capita benchmark between 2015 and 2016 increased significantly. Four ACOs had an increase of 10 percent or more. Even so, after subtracting shared savings paid to the ACOs, the Medicare program saw net relative savings of less than 1 percent of the benchmark.

Next Generation ACOs have performed well on cost and quality metrics

The three program performance years for the Next Generation (NextGen) demonstration are 2016 to 2018, with an option for ACOs to extend their participation for

an additional two years. The NextGen demonstration qualifies as an A-APM. It has a few differences that distinguish it from the MSSP and Pioneer demonstrations, including higher risk sharing, new benchmark methodology, multiple payment models, and beneficiary engagement tools. The text box on the NextGen demonstration (pp. 226–227) summarizes these provisions.

Performance of NextGen ACOs (relative savings)

There were 18 NextGen ACOs in performance year (PY) 1 (2016); Table 8-7 shows summary financial results for 2016. Actual spending was less than the aggregate benchmark, resulting in relative savings of \$48 million (0.9 percent). After taking into account payments for shared savings and losses, there was net relative savings of \$10 million (0.2 percent). However, the benchmarks for NextGen ACOs are constructed with a built-in discount—an ACO-specific decrease to the benchmark—to ensure savings for the program (see the text box on the NextGen demonstration, pp. 226–227, for more information on the discount). Taking into account the discount, the demonstration saved \$63 million (1.2 percent) relative to the benchmark.

The ACOs varied in performance. Eleven NextGen ACOs had savings ranging from 0.1 percent to 4.1 percent, and

**TABLE
8-8**

Summary financial results of ESRD Seamless Care Organizations relative to benchmarks, 2016

2016

	Dollars (in millions)	Percent
Benchmark	\$1,415	100.0%
Actual Part A and Part B spending	<u>1,340</u>	<u>94.7</u>
Relative savings	75	5.3
Paid to ESCOs	-51	-3.6
Paid back to CMS	<u>0</u>	<u>0</u>
Net	24	1.7

Note: ESCO (ESRD (End-Stage Renal Disease) Seamless Care Organization). There were 13 ESCOs in 2016. "Relative savings" is defined as the difference between the benchmark and the actual spending. "Net" is the sum of relative savings and amounts paid to ESCOs and paid back to CMS.

Source: MedPAC analysis of CMS ESCO quality and financial results, Performance Year 1.

the other seven had losses ranging from 0.1 percent to 2.6 percent. Because 2016 was the first year of the NextGen ACOs, any ACO that fully and accurately reported quality data received a 100 percent score for quality; all NextGen ACOs received 100 percent in 2016.

ESRD Seamless Care Organizations

As part of the Comprehensive ESRD Care (CEC) Model, nephrologists, dialysis clinics, and other providers can join together to create ESCOs, which are ACO-like models for the ESRD population. Similar to other ACO models, ESCOs are responsible for their attributed population's quality and financial outcomes, with larger ESCOs liable for shared losses.

ESCOs have performed well on cost metrics (relative savings) and average on quality metrics

There were 13 ESCOs in PY1 (2016). All 13 produced savings relative to their benchmarks, with 12 ESCOs producing enough savings to earn shared savings payments. These shared savings payments ranged from \$1 million to \$12 million. Quality in PY1 was essentially pay for reporting, so all ESCOs that completely and accurately reported quality data received a quality score of 100 percent. In total, the demonstration saved 1.7 percent relative to the benchmark (Table 8-8).

ESCOs are a good test case for ACOs. The population is well defined and has a chronic condition that dominates their care. Most beneficiaries on dialysis are treated at a dialysis facility three times a week and see their nephrologist at least monthly. Thus, the ESCO has many opportunities to communicate with its patients and coordinate their care, and attribution should be clear.

ESCO quality

The measure set for the CEC currently includes 11 process measures (e.g., advance care plan, influenza immunization), 1 outcome measure (i.e., standardized mortality ratio), and 6 patient experience measures based on the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems[®] survey. In the first year of the program, all 13 ESCOs received full credit for the quality score because they completely and accurately reported data to calculate quality measure results. Analysis of the 2016 results recently released by CMS shows that the ESCOs' patient experience results are around the national average for dialysis facilities (e.g., rating of kidney doctors, rating of dialysis center).

Beginning in the second year of the program (2017), each ESCO earns quality points on a sliding scale based on its performance compared with a national benchmark or its improvement from its previous year results. The

Next Generation ACO demonstration: Key provisions

The Next Generation (NextGen) accountable care organization (ACO) demonstration builds on CMS's experience with previous ACOs but has a few differences, including higher risk sharing, new benchmark methodology, and new beneficiary engagement tools.

Risk sharing

The NextGen program allows for higher risk sharing for ACOs; Arrangement A allows ACOs a shared savings (or loss) rate of up to 80 percent, and Arrangement B ACOs can have a sharing rate of up to 100 percent. Savings and losses are shared at first dollar instead of requiring an ACO to exceed a minimum savings or loss rate. There is also a limit on shared savings or losses for the ACO: 15 percent of the benchmark.

Benchmarks

The prospective benchmark calculation for the NextGen ACOs differs from Pioneer and Medicare

Shared Savings Program ACOs and is intended to promote savings, better reward ACOs that are already efficient, and provide certainty as to the benchmark at the beginning of the year.⁷ Benchmarks for the first three performance years are calculated based on historical expenditures as in the other ACO programs, but the baseline for calculating the benchmark will come from one year of data (2014) instead of three years of data. The baseline 2014 expenditure data will then be trended based on regional projections for the current year and risk adjusted. After trending and risk adjustment, the benchmark is discounted; the discount can be thought of as an automatic decrease to the benchmark, making it slightly more difficult to generate savings. The size of the discount differs for each ACO because the discount is adjusted to take into account both a national and regional efficiency ratio. ACOs that are more efficient than their market or the nation will receive a more favorable (smaller) discount to their benchmark. The intent of this approach is to rectify previous benchmarking methods that in some sense penalized already efficient providers.

(continued next page)

total points earned for each measure is multiplied by the measure weight and summed to produce the ESCO total quality score, which is used to determine the ESCO's eligibility for shared savings. Data are not yet available for 2017.

ACO quality and financial performance results according to other researchers

In this section, we discuss estimates from the literature of how much ACOs have saved the Medicare program. Each study's estimate depended on the choice of counterfactual, meaning the study's estimation of what spending would have been for the beneficiaries attributed to ACOs in the absence of the ACO. The studies often used a comparison group to determine the counterfactual. Because the studies' counterfactuals differ from the ACOs'

benchmarks, the estimated savings in the various studies differ from the relative-savings computations that are used when CMS distributes shared savings. We discuss how various savings estimates compare with the savings CMS has computed using administratively set ACO benchmarks.

Savings relative to benchmarks and other estimates of savings can differ

Savings relative to CMS-constructed benchmarks and other estimates of ACO savings can differ because CMS constructs benchmarks to fulfill certain policy goals. For example, in our early work on ACOs, we maintained that the appropriate trend for the benchmark should be the national increase in FFS spending stated in absolute dollar terms and that the benchmark should be stated in standardized dollars (Medicare Payment Advisory Commission 2009). The rationale for that design was that an area that had historically low service use would see a relatively large trend increase, and one that had

Next Generation ACO demonstration: Key provisions (cont.)

In addition to the prospective benchmark calculation, NextGen ACOs also have the opportunity to choose one of four ways to receive payment from CMS: standard fee-for-service (FFS), FFS and infrastructure payments, population-based payment (PBP), and (starting the second year) partial capitation. Under the FFS and infrastructure option, ACOs receive their usual FFS payments and an additional payment to be put toward infrastructure. At the end of the year, these infrastructure payments are subtracted from the savings an ACO would receive or are added to the loss amount an ACO owes. The PBP option reduces FFS claims by a percentage and then pays ACOs this reduction in per beneficiary per month (PBPM) payments. ACOs then receive both PBPM payments and reduced FFS payments. In the final option, partial capitation, CMS estimates expenditures for a given ACO on a PBPM basis, and then participating ACOs receive PBPM payments at the start of each month that cover the expected cost of ACO-aligned providers. Choosing the partial capitation option places responsibility on

ACOs to pay claims for services provided by ACO participants that have written agreements with the ACO. CMS will continue to pay claims to other providers and reconcile payments with the NextGen ACO's target after the year is complete.

Beneficiary engagement

NextGen ACOs are designed to focus on greater beneficiary engagement by allowing beneficiaries to align themselves with the ACO and providing incentives for using ACO services. Incentives can include reward payments to beneficiaries for using ACO-affiliated providers and allowing a more flexible Medicare benefit, such as covering skilled nursing facility stays without a prior three-day hospitalization. Beneficiaries will be able to align with an ACO by filling out a form that confirms that they use a specific provider or practice. This voluntary alignment process began in 2016, and beneficiaries who submitted an alignment form were added to the prospective list of beneficiaries starting in performance year 2 (2017). ■

historically high service use would receive a relatively low trend increase. Thus, our option would not reward areas of the country with already high service use. Actual policy kept the national trend, but spending was not stated in standardized dollars. In other words, the trended benchmark was not designed to necessarily best predict spending for an area's beneficiaries but rather to meet the goal of being equitable across the country. While CMS's benchmark is designed to fulfill certain policy goals, other groups have used other methods to provide an alternative assessment of whether ACOs save Medicare money. These alternative assessments use a counterfactual—that is, what spending on the beneficiaries in the ACO would have been in the absence of the ACO—to estimate savings.

Savings estimates in literature (program savings)

To determine what spending would have been for beneficiaries in the absence of an ACO, most studies relied on comparing changes in ACO spending with changes in

spending for a control group. For instance, one study used a 20 percent sample of beneficiaries to compare changes in spending for beneficiaries in ACOs with changes in spending for a group of beneficiaries served by non-ACO providers in ACO service areas (McWilliams et al. 2016). Under this scenario, McWilliams estimated that MSSP net savings in 2014—including bonus payments paid to ACOs—were \$287 million, or 0.7 percent of spending for ACO beneficiaries (McWilliams 2016a, McWilliams 2016b).

Using the same methodology to analyze the performance of Pioneer ACOs, McWilliams and colleagues estimated that Pioneer ACOs saved \$118 million (1.2 percent of spending for ACO beneficiaries) relative to expected spending in their first year (2012), or \$42 million (0.3 percent of spending) when bonus payments paid to ACOs are subtracted from total savings (McWilliams et al. 2015).

L & M Policy Research, the group CMS contracted with to formally evaluate the Pioneer ACO program, estimated

\$280 million (3.7 percent of spending) in savings for the first year of the Pioneer ACO program (L & M Policy Research 2015, Nyweide et al. 2015, Office of the Actuary 2015).⁸ The comparison group in L & M's analysis included all "FFS Medicare beneficiaries who are not aligned or assigned to a Medicare ACO in the Pioneer ACO's local, or 'near' market."⁹ This analysis did not restrict the comparison group to ACO-attributable FFS beneficiaries. Thus, savings might be overstated because, to be attributable to an ACO, beneficiaries had to have a primary care visit. FFS beneficiaries who did not have a primary care visit in the baseline year were only in the control group, not in the ACO. The problem is that these individuals tend to have low baseline spending and high spending growth, which could have made the comparison group appear to grow faster than it would have if it included only ACO-attributable beneficiaries.

Another analysis examined the combined performance of both MSSP and Pioneer ACOs in 2012 and 2013. It created a control group by utilizing "a random 40% sample . . . of continuously enrolled fee-for-service beneficiaries with at least 1 evaluation and management visit in a calendar year" (Colla et al. 2016). That analysis found that, together, MSSP and Pioneer ACOs saved approximately \$592 million (about 1.1 percent of the benchmark) in 2013.

When CMS' Office of the Actuary (OACT) certified that expanding the Pioneer ACO Model would reduce spending for the program, it conducted a market-level analysis (Office of the Actuary 2015). OACT's analysis compared FFS spending growth in markets with heavy MSSP and Pioneer penetration with markets that had few ACOs. For markets with low rates of ACO penetration, FFS per capita spending decreased by 0.3 percent from 2011 to 2014, whereas for markets with high rates of MSSP ACOs, per capita spending decreased 1.2 percent, and in markets with high rates of Pioneer ACOs, it decreased by 2.1 percent. OACT's findings that FFS spending growth decreased more in Pioneer ACO markets, taken in conjunction with Pioneer ACOs' ability to save money relative to their benchmarks and L & M's positive evaluation results, led OACT to certify that Pioneer ACOs were successful in reducing spending.

Given the CMS benchmarking analyses, studies in the literature, and the work by OACT, it appears the ACO programs have generated savings estimated in the 0 percent to 2 percent range. ACOs also generally appear

to improve the quality of care received while generating savings (Government Accountability Office 2015, Office of Inspector General 2017, Pham et al. 2014). While these savings may appear modest, they are more than most care coordination demonstrations have achieved, including the most recent Comprehensive Primary Care initiative (Dale et al. 2016, Nelson 2012).

Spillover estimates

In addition to the direct savings from reduced spending on beneficiaries in ACOs, indirect savings of two kinds (spillover and reduced MA benchmarks) are also possible, according to researchers. McWilliams's (2016) research on MSSP ACOs considers potential additional savings accrued through spillover effects. Under this theory, ACO providers furnish better coordinated care to all their patients, thus "spilling over" to their non-ACO FFS beneficiaries. The magnitude of the spillover effect is expected to be modest and has not been tested empirically. Another indirect benefit could result from reduced MA benchmarks over time, as a county's FFS spending on which MA benchmarks are based is reduced. This effect presupposes savings from ACOs. In fact, spending in some counties with MSSP ACOs could have increased, particularly if shared savings payments are included as FFS spending, and could result in an increase in MA benchmarks, although the magnitude would probably be small in either direction.

Sources of savings

Research shows that how ACOs generate savings does not necessarily align with preconceptions. Early in the development of ACOs, some speculated that savings would accrue through better coordinated care and subsequent reductions in unnecessary inpatient capacity, tests, imaging services, and post-acute care (PAC) use (Fisher et al. 2007). Data from the Alternative Quality Contracts (AQC), a commercial predecessor to Medicare's ACOs, indicated that savings could be generated through these avenues, specifically by decreasing utilization of procedures, imaging, and tests and by referring patients to less expensive providers (Song et al. 2014). While AQCs were successful in these areas, Medicare ACOs—especially those in the MSSP—have largely created savings by decreasing PAC utilization. A recent study by McWilliams and colleagues found that, while MSSP ACOs were scaling back inpatient capacity slightly, they were generating a higher proportion of their savings by decreasing PAC

utilization—specifically SNF use (McWilliams et al. 2017b). Pioneer ACOs likewise reduced PAC utilization to generate savings, in addition to having lower rates of inpatient stays, imaging, tests, and procedures, similar to the AOCs (L & M Policy Research 2015, McWilliams et al. 2014).

Additionally, while many expected ACOs to focus on coordinating care for high-risk patients to save money, a recent study found that those savings have yet to occur in the MSSP program. When comparing ACO savings in 2014 for high-risk and low-risk patients, savings between the two groups were relatively similar for the cohort of ACOs that began in 2012 (McWilliams et al. 2017a). For ACOs that entered the program in 2013, more savings were accrued for low-risk patients than high-risk patients. Furthermore, the study found MSSP ACOs did not reduce hospitalizations for ambulatory care-sensitive conditions.

New tools to allow ACOs to manage care

While the ACO program has grown in numbers of ACOs and beneficiaries, it continues to evolve. The recently passed Bipartisan Budget Act of 2018 (BBA of 2018) included several changes to Medicare’s ACO programs, including incentives for beneficiaries to see ACO providers, use of telehealth, and beneficiary assignment. Many of these changes are consistent with past Commission positions on ACOs. These changes are expected to make the program more attractive to providers by enhancing the tools they have to improve quality and reduce costs.

ACO Beneficiary Incentive Program

Starting no later than 2020, the Secretary is to establish an ACO Beneficiary Incentive Program, which would allow ACOs to pay beneficiaries up to \$20 for each qualifying primary care visit with an ACO provider. ACOs will have to apply to run such a program, which will be available only to two-sided-risk ACOs. Incentive payments will not factor into an ACO’s benchmark, and incentive payments could be funded through previous shared savings payments. The Commission has previously supported giving ACOs more options for incentivizing beneficiaries to use their ACO providers so that ACOs have more leverage in coordinating their beneficiaries’ care (Medicare Payment Advisory Commission 2014b).

Telehealth

The BBA of 2018 expanded the use of telehealth for two-sided-risk ACOs with prospective attribution. Under the BBA of 2018, qualifying ACOs are no longer subject to a geographic limitation on the telehealth originating site and are allowed to use the beneficiary’s residence as an originating site. Currently, some ACO demonstrations allow for expanded use of telehealth (e.g., NextGen), but ACOs are required to submit a waiver to utilize the benefit. In its recent telehealth discussions, the Commission has supported the expanded use of telehealth for risk-bearing ACOs because the ACOs are at risk for cost (unlike providers in traditional FFS) (Medicare Payment Advisory Commission 2018).

Expanded prospective attribution

ACOs in retrospective attribution models (i.e., MSSP Track 1 and Track 2) beginning or renewing their agreements on January 1, 2020, and beyond can choose to have their beneficiaries assigned prospectively. The Commission has long been in support of prospective attribution because it gives providers more certainty at the start of the performance year about which beneficiaries are in their ACOs and allows for better coordination of care throughout the year (Medicare Payment Advisory Commission 2015a, Medicare Payment Advisory Commission 2014a). However, benchmarks for ACOs changing attribution will need to be recomputed to reflect the beneficiaries in the baseline who would have been attributed under prospective attribution versus retrospective attribution.

Attribution based on voluntary identification by beneficiaries

According to the BBA, the Secretary will also establish a process by which beneficiaries will be informed of their option to voluntarily identify a principal primary care provider. If the designated primary care provider participates in an ACO, the beneficiary will be automatically attributed to that ACO. A similar process is already in place for the MSSP. Currently, beneficiaries can log on to MyMedicare.gov and designate a clinician as their “primary clinician” who is responsible for coordinating their overall care (Centers for Medicare & Medicaid Services 2017a). Clinicians in ACOs have some latitude to encourage beneficiaries to designate them as their primary clinician. However, to date it appears that few beneficiaries are being aligned under this mechanism.

Long-term issues for Medicare ACOs

Medicare ACOs were created to help moderate the growth in Medicare spending and improve quality of care for beneficiaries by giving providers greater responsibility for costs and quality. ACOs have grown rapidly (about a third of Medicare FFS beneficiaries are now in ACOs), and several new initiatives have been designed to expand ACOs. Performance to date shows high quality being maintained, some savings relative to benchmarks, and slightly greater savings relative to what Medicare spending would have been without ACOs. However, several issues confront Medicare ACOs—particularly as they transition to models with two-sided risk—that will need to be resolved for the program to be successful in reaching its goals.

Because two-sided risk models are more likely to result in savings for the Medicare program, the following questions arise: Can hospitals and ACOs viably coexist and, if so, what does that mean for ACOs moving to two-sided risk? Should asymmetric models be continued even if they present the risk of excess spending for Medicare? What approaches to setting benchmarks should be used? What method should be used to distribute the 5 percent bonus for clinicians participating in A-APMs? What relationship will specialists have with ACOs? Are ACOs a path to MA plans or are they an end in themselves?

Are hospitals a viable participant in ACOs?

In general, hospitals have greater financial resources than most clinician groups, which can make accepting downside risk easier for an ACO with a hospital participant than an ACO without one. In fact, about half of risk-bearing MSSP ACOs (Track 1+, Track 2, and Track 3) list hospitals as participating providers. Thus, it may be important for hospital-based ACOs to thrive to make two-sided ACO models more available.

There is a concern, however, that hospitals may be reluctant to reduce service volumes to meet ACO spending targets because they do not want to reduce their own FFS revenue. However, the data show that ACOs with hospitals can meet spending targets. We examine how they are meeting spending targets and conclude that hospital-based ACOs may continue to be part of the ACO landscape into the future.

Conflict between hospital and ACO incentives

It may at first appear that the incentives for ACOs and hospitals conflict. In an FFS payment environment,

a hospital has an incentive to increase the volume of Medicare admissions as long as the payment for an additional patient exceeds that patient's variable cost and the hospital has excess capacity. (In our March 2018 report, we found that the average hospital occupancy rate was 66 percent and that variable costs were 8 percent less than Medicare payments. Therefore, most hospitals have an incentive to increase the volume of Medicare admissions (Medicare Payment Advisory Commission 2018).) At the same time, ACOs have an incentive to keep Medicare spending for their attributed beneficiaries below a target amount—their benchmark. If they do so, they can share savings with Medicare. One way to reduce or constrain spending is to reduce inpatient admissions. Thus, it would appear that the incentives for hospitals and ACOs are in conflict.

While ACOs may eventually have some effect on admissions, it appears to date that ACOs have not caused a large reduction in inpatient admissions, despite rhetoric to the contrary. We examined changes in inpatient admissions and considered why the trends should not be surprising. Assuming trends continue, opportunities for cooperation between ACOs and hospitals may exist, and concerns about the conflicting incentive may be less germane.

Reducing post-acute care (not inpatient care) is the primary source of ACO savings

In interviews we conducted in 2012 and 2013, many ACO leaders expected to generate savings by reducing the volume of inpatient care. In particular, physician leaders of ACOs saw the hospital as a key driver of spending, and reducing unnecessary hospital admissions as a key source of savings. However, a review of the literature finds that reducing PAC has been a much bigger source of ACO savings than reducing inpatient admissions (McWilliams et al. 2017a, McWilliams et al. 2017b). Similarly, the AQC program, a commercial ACO program, did not generate significant reductions in inpatient facility fees or inpatient professional fees (Song et al. 2014). In contrast, AQC savings were generated by reducing spending on outpatient facility fees and professional fees—often by shifting services to lower priced providers (Song et al. 2012). Thus, decreased hospital revenues from the actions of ACOs may be due to a shift of outpatient services to lower priced settings rather than a decline in the number of admissions. The finding that ACOs do not cause big reductions in inpatient spending is consistent with the following three findings.

First, in FFS Medicare, inpatient service use varies little by region (Medicare Payment Advisory Commission 2017b). Our analysis of claims data from 2014 found that across 484 market areas, inpatient use for market areas at the 90th percentile of use was 1.16 times that for market areas in the 10th percentile of use. In contrast, PAC use for market areas at the 90th percentile of use was 1.88 times that of market areas in the 10th percentile of use. Across all markets, the ratio of the maximum to minimum service use was 1.49 for inpatient and 5.66 for PAC use. This finding suggests ACOs would have a greater opportunity for savings by reducing spending on PAC services in high-use areas than by reducing spending on inpatient services.

Second, we found that admission and revenue growth vary by hospital, but ACOs and MA plans are not the driving forces. To see whether ACOs and MA plans have had a material effect on hospital volumes in recent years, we examined whether county-level ACO penetration in 2015, MA penetration in 2015, and growth in MA penetration from 2011 to 2015 were associated with reductions in either all-payer admissions or revenue at hospitals from 2012 to 2016. We also tested to see whether hospitals that were in an ACO tended to have lower volume or revenue growth.¹⁰ We add in MA penetration because, if MA penetration does not materially affect hospital inpatient volume, then there is little reason to expect ACOs to materially affect hospital inpatient volume.

Our test consisted of a linear regression in which we controlled for, among other things, population growth and hospitals' size. The level of ACO penetration, MA penetration, growth in MA penetration, and whether the hospital participated in an ACO all failed to have a statistically significant effect on the change in a hospital's total admissions or total revenue. While hospitals in markets with ACOs and growing MA penetration saw small declines in inpatient use, it was not higher than in the average market. This finding suggests either that MA plans and ACOs have a limited impact on Medicare inpatient admissions or that hospitals are able to replace lost Medicare admissions with other patients. In contrast, population and hospital size were highly significant. For each 1 percent increase in population, hospital admissions increased by 0.8 percent. We also found that smaller hospitals tended to lose discharges faster than larger hospitals. The net finding, that admission and revenue growth vary by hospital, but ACOs and MA plans are not the driving forces, suggests that hospitals can coexist with MA plans and ACOs.

Third, another way to examine whether MA plans significantly reduce inpatient use is by analyzing their bids for self-reported spending on inpatient care. We find that MA plans and FFS Medicare devote similar shares of their overall spending to inpatient care. This finding suggests that MA plans do not reduce inpatient care to a larger degree than they reduce other services on average, which differs from data from 20 or 30 years ago. There is some evidence that HMOs historically had 35 percent to 40 percent fewer admissions per capita than indemnity plans or Medicare FFS (Duggan et al. 2018, Newhouse 1993). However, those studies used data from 2003 or earlier. Since that time, FFS discharges per capita have fallen by about 25 percent, making reductions from the lower FFS baseline more difficult. ACOs, which have fewer tools than MA plans to control admissions, should not be expected to achieve greater reduction than MA plans.

In light of these findings, it appears that the greatest opportunity for ACOs to control spending is in post-acute care, not inpatient care. While ACOs may eventually lead to small reductions in inpatient use, we have not seen evidence to date that they materially affect hospital revenue.

Should asymmetric models be continued?

One way to encourage ACOs to take on risk is to make the models asymmetrical—that is, to make the share of savings greater than the share of losses or to put higher caps on savings than on losses. A policy question is whether such models should be a temporary path to increase ACO participation in these models (and give clinicians an opportunity to participate in A-APMs) or be a permanent part of the program.

For example, the Track 1+ model has two asymmetries. First, the model has a shared savings rate of 50 percent and a shared loss rate of 30 percent. Second, the loss cap is lower than the savings cap for all types of Track 1+ ACOs. There are two choices for the loss cap, both of which are less than the 10 percent of the benchmark cap on gains. The first choice is 4 percent of the benchmark; the second is 8 percent of the Medicare FFS revenue for the ACO participants. This choice is limited to ACOs whose only participants are clinicians or clinicians plus a small rural hospital. This amount will also be much less than 10 percent of the benchmark.¹¹

This design gives Track 1+ ACOs certain advantages over ACOs in the Track 1 model, despite the downside risk in Track 1+ not present in Track 1. In Track 1+, providers are at risk for losses, but the ACOs' clinicians are eligible

for the 5 percent incentive on their physician fee schedule (PFS) payments because these ACOs are considered A-APMs. The 5 percent incentive considerably ameliorates the risk of being in Track 1+ because the maximum risk in Track 1+ for ACOs with only clinicians as participants is 8 percent of their FFS Medicare revenue. If they automatically get a 5 percent bonus, risk is essentially limited to 3 percent of Medicare FFS revenue. If the ACO is likely to break even—that is, has a roughly equal probability of showing a loss or a gain—we calculate that the clinicians would see more financial advantage in Track 1+ than in Track 1. A recent analysis by Avalere found that, in aggregate, MSSP ACOs would have fared better in 2016 by \$966 million if they had all been in Track 1+ rather than Track 1 (Avalere Health 2018).

By statute, CMS can introduce other MSSP models as part of permanent Medicare law if those models are estimated not to increase Medicare spending relative to the Track 1 model (CMS has done so for the Track 2 and Track 3 models). However, Track 1+ is a demonstration under the authority of CMS’s Center for Medicare & Medicaid Innovation (CMMI), not an additional MSSP model. Therefore, the Track 1+ model does not have to meet that requirement, and ACOs can join even if the model increases spending.¹² If Track 1+ were incorporated into permanent Medicare law, the costs would have to be offset.

It appears that Track 1+ could put the Medicare program at risk of financial loss if Track 1+ ACOs’ losses relative to the benchmark are greater than ACOs’ relative savings because of the model’s asymmetries. If Track 1+ were incorporated into permanent Medicare law, the costs may need to be offset if performance is essentially random. If it is demonstrated that ACOs are modifying their behavior from what they would have done if not in ACOs and reducing spending, then this issue will not arise. Currently, ACOs can be in Track 1+ for only one three-year agreement period. Policymakers must decide whether the asymmetries in Track 1+ are appropriate and whether the model is a success; if it is a success, policymakers will need to decide whether aspects of the model should be extended to other ACO models (or CMS should continue the Track 1+ model).

Whether Track 1+ will cost Medicare more relative to what spending would otherwise have been or relative to Track 1 will depend on the ACOs’ performance. Because of the possibility of sharing in losses, clinicians in Track 1+ could be more likely to succeed at controlling spending

than in Track 1 or in unconstrained FFS and could indeed save money for the program while possibly increasing quality. It seems to be a popular model thus far; in 2018, 55 ACOs entered the Track 1+ model. Therefore, it will likely increase the availability of A-APMs for clinicians to join. Whether the increased availability of A-APMs is worth the possible increased cost to the program is an important policy question. The Commission will track the progress of the Track 1+ model over the next few years to see whether the model is saving or costing the Medicare program relative to Track 1 and FFS Medicare.

How should benchmarks be set initially and rebased for subsequent agreement periods?

One of the most important policy questions when designing ACO and MA payment policy is how to set the benchmarks. The goal of a benchmark for an individual ACO is to create incentives to encourage the ACO’s providers to increase quality while restraining overall Part A and Part B spending. However, a benchmark that accomplishes that goal may not be the best estimate of what spending for those beneficiaries would have been in the absence of the ACO. We need to know the latter to ensure that, at the national level, the ACO program is reducing Medicare spending over the long term while improving quality or at least keeping it constant. Thus, to determine whether an ACO program is “working,” we need to know whether it is creating useful incentives at the individual ACO level and savings at the national level.

Two approaches to setting benchmarks

Generically, there are two approaches to setting benchmarks in Medicare: regional benchmarks, as used in the MA program, or historical spending, as used in the ACO programs. For example, in MA plans, the benchmark is set based on five years of historical FFS spending in each county, adjusted for the beneficiaries’ hierarchical condition category (HCC) coding scores. This approach creates incentives for MA plans to devote resources to coding, and the result has been more coding in MA plans than in FFS Medicare. (Under this coding incentive, MA beneficiaries appear to be getting sicker quicker compared with beneficiaries in FFS Medicare, whose providers—paid differently from MA plans—lack the same incentive to code their patients at the greater intensity levels.) In addition, coding practices across MA plans vary widely. We have made recommendations to address MA’s higher level of coding in aggregate and the variation by plan (Medicare Payment Advisory Commission 2016c).

In part to get around the dependence on risk adjustment using HCC scores, ACOs were built on a model that looks at historical spending for a fixed group of people or a fixed group practice and examines how spending for the ACO's beneficiary population changes from one year to the next. This approach incorporated the assumption that the population of beneficiaries and providers in each ACO would be relatively stable. However, the "churn," or movement of beneficiaries (and, in some cases, providers) in and out of ACOs, has been larger than anticipated, with one study finding only 66 percent were consistently assigned over two years and about 20 percent of beneficiaries left the ACO each year (McWilliams et al. 2014). Although changes in provider participation are dealt with by recalculating baseline spending, churn in attributed beneficiaries could be an issue for benchmarking if those who lose ACO alignment have systematically different characteristics from those coming into alignment. For example, those leaving the ACO could be very high cost and those entering could be very low cost, in which case the ACO's benchmark would need to be refined.

Population dynamics

In a preliminary analysis, we compared a control population with MSSP ACO-aligned beneficiaries located in the same metropolitan areas. We found that beneficiaries attributed to MSSP ACOs for two consecutive years had spending growth about 3 percent lower than beneficiaries who were not in an ACO in either year. We also found that beneficiaries who were attributed in the first year and lost attribution to the ACO in the second year (and thus were in an ACO for only one year) had spending growth that was even further below the control group. Conversely, those who were attributed to an ACO in the second year and not in the first had much higher spending growth than the control group. That is, the people who lose alignment to the ACO have low spending growth, and those who join have high spending growth. (We also found that MSSP ACOs do not appear to materially affect end-of-life spending.) Savings estimates for MSSP ACOs should be evaluated taking these findings into account.

There are several potential explanations for these findings. For example, a beneficiary may become sick, see an ACO clinician repeatedly, and have increased spending. Because the plurality of care will now be with an ACO clinician, this case could result in the beneficiary being aligned with the ACO when she otherwise would not have been, and it would be consistent with findings in our preliminary analysis. At the same time, beneficiaries who stop seeing clinicians because their principal condition improves

may have lower spending and lose attribution to their ACO because their plurality of care is no longer with the ACO clinician. This scenario is also consistent with our findings. A consistent relationship between service use and attribution (or loss of attribution) could be an issue. One way to limit the effect of attribution on changes in spending is to use prospective attribution. Under prospective attribution, the year of data used to attribute an individual differs from the performance year data used to evaluate spending relative to the benchmark. Therefore, an episode of illness that results in a beneficiary being attributed to an ACO will be in a previous year and thus in the benchmark.

This preliminary analysis suggests that, although MSSP ACOs are to some extent controlling the spending growth for beneficiaries who are continuously attributed, there is a tendency for ACOs to have beneficiaries leaving who have lower growth in spending and beneficiaries joining who have higher growth in spending. Attribution is related to service use, which could be a source of concern when setting benchmarks or estimating savings.

Rebasing benchmarks

In our February 2015 comment letter on the MSSP ACO proposed rule, we noted a basic conflict in the benchmark-setting mechanism and in the dynamics of rebasing (Medicare Payment Advisory Commission 2015b). (Rebasing is the process of setting ACO benchmarks at the start of each three-year agreement period subsequent to the first period.)

On the one hand, if benchmarks are rebased strictly on the historical experience of the ACO's patients, the benchmark will incorporate the efficiencies the ACO has realized in the first three years and further improvements will be difficult to achieve. If an ACO were in the program for repeated periods, this increased difficulty could make it less desirable for an ACO to continue with the program. Such a result does not seem equitable for an ACO that has improved its efficiency—particularly if its benchmark to begin with was below the level of ambient FFS spending in its region.

On the other hand, one could set benchmarks using an approach similar to that for MA plans (HCC-adjusted local FFS spending). A regional benchmark could be calculated using FFS spending, and that amount multiplied by the HCC score for each attributed beneficiary would be summed to calculate the ACO's benchmark. However, under such an approach, ACOs would be able to calculate

their benchmarks in advance, and only ACOs that are already below their regional benchmark would participate. ACOs that had spending above the regional average would not participate because they would likely have actual spending above their benchmark. Thus, efficient ACOs would likely receive a shared savings bonus for doing what they would have done anyway, and inefficient ACOs that needed an incentive to control spending would not participate. The result would likely cost the Medicare program more and not improve quality appreciably. In addition, if HCC scores were used in benchmarking, some of the same issues that have been well documented in MA would arise—with the variability in coding intensity across practices and the incentives to spend more money on coding being the most problematic.

One approach to this challenge is to blend historical experience and the regional average when rebasing benchmarks. This approach is now being taken in MSSP when benchmarks are rebased every three years. Essentially, the average of the ACO's risk-adjusted expenditures over the past three years is compared with the FFS region's risk-adjusted expenditure average. If the ACO's per capita risk-adjusted expenditures are higher than the regional average, the benchmark is reduced toward the regional average; if the ACO's expenditures are lower, the benchmark is raised toward the average. This approach rewards ACOs whose original benchmarks (i.e., the benchmarks at the start of the three-year agreement period) were below the regional average, penalizes those with original benchmarks above the regional average, and compresses rebased benchmarks in a market toward the regional average (Centers for Medicare & Medicaid Services 2017b).

The NextGen program has initially taken a different approach to accounting for efficiencies and regional variation. NextGen ACO benchmarks incorporate a discount to the historical spending for an ACO's beneficiaries. That discount varies in size from 0.5 percent to 4.5 percent. A larger discount reduces the benchmark more than a smaller discount. The size of the discount varies based on the ACO's efficiency relative to FFS spending in its region and relative to the national average of FFS spending. ACOs that are efficient in comparison with their region get a smaller discount, as do ACOs in a region that is efficient compared with the national average. Over time, however, the NextGen program will also face pressure to blend benchmarks to avoid a downward spiral in benchmark levels.

The blending in MSSP rebasing and the NextGen discount adjustment are both attempts to deal with the issue of setting benchmarks that are equitable while still creating incentives for savings at the ACO level and trying to ensure that Medicare program spending does not increase. Efforts should continue to monitor whether ACO programs overall are saving money while maintaining or improving quality. It is important to remember that benchmarks will always incorporate policy goals, such as increasing equity across the nation or encouraging participation in two-sided-risk ACOs, and will not—and are not intended to—represent the best counterfactual to ACO participation.

Should the 5 percent bonus for clinicians in A-APMs be distributed differently to encourage A-APM participation?

One step to encourage clinicians to continue to expand their participation in meaningful payment reform models would be to make their eligibility for the 5 percent A-APM incentive more certain. Under current policy, clinicians who participate in an A-APM can qualify for a 5 percent A-APM incentive payment established in MACRA. The incentive payment is applied to all of a clinician's PFS revenue from the prior year. But to qualify for the incentive payment, the clinician must meet either the threshold for share of revenue derived through an A-APM or for share of patients coming through the A-APM. The numerical threshold for share of revenue is set in statute and increases over time. In 2019 and 2020, to be eligible for the 5 percent incentive, clinicians must have at least 25 percent of their PFS revenue in an A-APM, 50 percent in 2021 and 2022, and 75 percent in 2023 and later. The "patient count" thresholds are set by CMS. CMS has set lower thresholds for the patient count option of 20 percent in 2019 and 2020, 35 percent in 2021 and 2022, and 50 percent in 2023 and later. This lower threshold appears to enable a larger share of participating clinicians to qualify for the bonus.

In addition, there is an "all-payer" option starting in 2021, which requires CMS to determine what share of a clinician's revenue or patients is coming through A-APM-like arrangements for other payers. CMS has started the process of collecting information for the all-payer option. In the 2019 advanced notice for MA plans, CMS proposed collecting from MA plan sponsors lists of clinicians and the contracts those clinicians hold with MA plans that qualify as A-APM-like contracts.¹³

In our June 2017 report to the Congress, we described a way to simplify the incentive award process (Medicare

Payment Advisory Commission 2017a). The proposal was to eliminate the threshold calculation and instead apply the 5 percent A-APM incentive payment only to the clinician's PFS revenue derived from an A-APM (instead of to all of a clinician's PFS revenue). This proposal would greatly simplify the system and make it more equitable. For example, under the current system, clinicians with 24.9 percent of their revenue coming through an A-APM get no bonus, and clinicians with 25.0 percent of their revenue coming through the A-APM get a 5 percent incentive bonus on all of their PFS revenue. The proposed system would eliminate such payment "cliffs" or discontinuities. Instead, under our proposed refinement, the bonus would be certain because the incentive would depend solely on the clinician's revenue coming through the A-APM, whatever that level may be. (Additionally, such a refinement would help avoid uncertainty for clinicians who would be concerned they could lose the incentive payment as the threshold rises from 25, to 50, to 75 percent in later years.)

A benefit of this policy is that the patient count and all-payer options would no longer be necessary and could be eliminated because, under this revised design, the bonus is applied only to the share of revenue coming through the A-APM. Under the current all-payer option, CMS must calculate the clinicians' total revenue from all payers and determine what share came through A-APM-like contracts. That determination could represent a large administrative burden on all parties and intrusion of the government into the business relationship between MA plans and clinicians.

Whether the proposed approach would result in more or less spending is not clear. On the one hand, more clinicians would be eligible for some payment (e.g., in 2019 and 2020, all those with less than 25 percent of revenue through the A-APM). On the other hand, the actual payments for some clinicians would be lower; for example, a clinician with 30 percent of revenue through an A-APM would get a 5 percent payment adjustment on 30 percent of PFS revenue, not on 100 percent of PFS revenue. How these changes balance out would need to be estimated.¹⁴

What relationship will specialists have with ACOs?

Another concern is that specialists are not perceived to have a role in ACOs because attribution to ACOs is predominantly dependent on primary care visits, and

thus specialists are not required for an ACO to meet the minimum number of attributed beneficiaries. Also, some could be concerned that specialists would attract high-need patients to the ACO, thereby increasing its costs. However, if the patients are high cost to begin with and are thus in the historical baseline, the ACO's benchmark will reflect those higher costs. In fact, one could argue that those beneficiaries may be the ones who could most benefit from the better care coordination that the ACO is designed to provide.

Our analysis of the 2016 MSSP ACO public use file indicates that about 60 percent of ACO-participating physicians are specialists.¹⁵ Being on the participant list does not mean that a physician will share in savings or help manage the ACO. Each individual ACO has the latitude to decide on the relationship of the physician to the ACO as to who shares savings and how much.

ACOs may have an incentive to involve specialists because specialists who practice in a conservative, cost-effective style and avoid unnecessary testing and procedures could help control costs and increase the quality of care for beneficiaries attributed to the ACO. At the same time, participating in an ACO could be attractive to specialists. Participating in the ACO would give the specialist access to a patient's claims history and possibly alert the specialist when the patient was admitted to a hospital or visited an emergency room. Thus, the specialist might be able to better coordinate patient care. (In the case of two-sided-risk ACOs that are A-APMs, specialists also could be eligible for the 5 percent A-APM bonus on their PFS revenues.) Specialists could also receive more referrals from the ACO's primary care clinicians if they had a relationship with the ACO. This arrangement could prove mutually beneficial to both primary care clinicians and specialists.

Furthermore, there could be a role for specialty-focused ACOs. For instance, the success of ESCOs—a specialty-focused ACO model—indicates that specialty providers could develop their own ACO-like models, which could be done by submitting a proposal to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). If accepted by the PTAC, the model could be recommended to the Secretary as a potential new demonstration for CMMI, creating even more opportunities for specialists to participate in ACO-like models. The Commission will monitor the relationships between specialists and ACOs as the ACO models continue to evolve, and we will examine whether it is possible to ascertain the level of participation

in ACOs by specialists and whether the degree of specialists' participation affects ACOs' performance.

Are ACOs only a transition step to MA?

The ACO program is large, continues to expand, and continues to evolve. However, some suggest that MA plans are the more efficient model and that, eventually, ACOs should evolve into MA plans. As a matter of policy, the question is whether all ACOs should be encouraged to become MA plans or whether there are circumstances in which it is better for ACOs to remain ACOs (Medicare Payment Advisory Commission 2016b).

In the past, the Commission has discussed how no one model is the low-cost model in all parts of the country (Medicare Payment Advisory Commission 2014c). In some markets, the tools that MA plans have to manage service use result in substantial savings. In other markets, ACOs or FFS is the lower cost model. For analytical purposes, that report synchronized the benchmarks at 100 percent of FFS spending for all three models. In fact, in 2018 we estimate MA benchmarks (including quality bonuses) will average 107 percent of FFS spending.

One particularly important factor is that, although MA plans have more tools to control service use, they also have higher administrative costs. Data from the major insurance companies indicate that, on average, administrative costs in MA plans are approximately \$1,300 per beneficiary. Among those costs are costs for marketing, both directly to beneficiaries and through brokers; enrolling members; negotiating with providers; paying claims; and providing other insurance functions, such as prior authorization. MA plans also have to qualify as state-licensed insurers, which could entail considerable costs and financial resources.

Our discussions with ACOs suggest their administrative costs, in contrast to those of MA plans, are close to \$200 per beneficiary per year. ACOs do not have the costs of advertising, enrolling, negotiating contracts, and paying claims. Their administrative costs include the expense of setting up and managing the ACO, which should include data analysis and reporting quality measures. However, some companies can provide those services under contract, and some ACOs are using that approach.

Therefore, which model will generate greater savings depends on whether the MA plan's reduction in spending on medical services offsets its higher administrative cost relative to an ACO's spending and costs. There are two basic possibilities:

- If MA health care spending reductions compared with ACO health care spending reductions are greater than \$1,100, then MA plans would be expected to be the lower cost model.
- If MA health care spending reductions compared with ACO health care spending reductions are less than \$1,100, then ACOs would be expected to be a lower cost model than MA.

The amount of service use that MA plans will be able to reduce relative to FFS Medicare and ACO use will depend on several factors. One may be the initial level of service use and fraud in the market. Data suggest MA plans can generate substantial savings in some high-use markets such as Miami. However, if there is less than \$1,300 of unnecessary spending to cut, then FFS Medicare could be a lower cost model. Second, ACO savings could be affected by the ACO's providers' position in the market. One conceptual advantage of MA plans is their ability to lock beneficiaries into a defined provider network. If an ACO's participants constitute the dominant health system in a market, then the ACO model with its lower costs may be more efficient because the ACO should have a similar ability to control utilization.

However, benchmarking could still be an issue even if an ACO is in a dominant market position. Under a historically based benchmark, a regionally based benchmark (based on regional FFS spending), or a blend, an ACO with a dominant market position would have to improve on its own performance over time because its benchmark will reflect its own performance. In contrast, MA benchmarks are based on FFS spending, not MA spending. Thus, MA plans do not face the issue of their own historical performance dictating their benchmark. In addition, MA benchmarks are adjusted so that they are a higher percentage of FFS spending if the county has lower FFS spending relative to the national level. In some counties, MA benchmarks are 115 percent of the FFS average (see the Commission's *MA Payment Basics* document, available at <http://medpac.gov/documents/payment-basics>, for a fuller discussion).

Thus it is not clear a priori whether ACOs are in all circumstances a stepping stone to MA or should remain as ACOs. The challenge going forward is to set MA and ACO benchmarks in such a way that the models can compete and the most efficient model can gain market share in each individual market.

Conclusion

ACOs in Medicare continue to show some success in meeting their goal of high-quality care and lower costs relative to their benchmarks. In addition, some analysts find that their success may be understated by their performance relative to their benchmarks and that they could be saving Medicare more than the benchmarks would indicate. In either case, two-sided-risk ACO models show more savings relative to one-sided models. However, a number of issues confront Medicare two-sided-risk

ACO models if they are to persist in the long term. Some issues, such as the 5 percent incentive in MACRA, could have relatively straightforward solutions, and others, such as the role of hospitals and specialists in ACOs, are more nuanced. Challenges such as asymmetric models and setting benchmarks could require policymakers to decide whether a preference should be given to one model (MA, ACO, FFS) over another and whether that preference should be temporary. ACOs in Medicare have proven to be a popular choice for providers, but whether they remain that way in the long run may depend on the choices policymakers make going forward. ■

Endnotes

- 1 Services that qualify for attribution are defined in regulation. Use of primary care services is required in statute.
- 2 One-sided-risk ACOs can cost money in aggregate for the Medicare program because CMS pays shared savings to successful ACOs but does not collect losses from unsuccessful ACOs (i.e., ACOs that exceed their benchmark).
- 3 These clinician-only ACOs can include hospitals and qualify for the lower loss limit if these hospitals are small, rural hospitals with 100 or fewer beds.
- 4 In 2016, OneCare Vermont was responsible for 43,685 Medicare beneficiaries.
- 5 There are other models that qualify as A-APMs, including the Bundled Payments for Care Improvement Advanced Model, Comprehensive Care for Joint Replacement Model (Track 1: Certified Electronic Health Record Technology), Comprehensive Primary Care Plus Model (CPC+), and the Oncology Care Model (two-sided-risk arrangement). The Commission has questioned the inclusion of the CPC+ model and the Oncology Care Model as A-APMs (Medicare Payment Advisory Commission 2016a).
- 6 We did not adjust for health status because we were using ACO-level, not beneficiary-level, data. Thus, this evaluation is only an approximation of service use.
- 7 Certainty—that is, informing the ACOs of their benchmark at the beginning of the year—may require modifying the definition of two-sided risk if ACOs can withdraw from the program after learning what their benchmarks will be. For example, 3 of the 21 Next Generation ACOs dropped out of the program early on after learning what their benchmarks would be. This practice could affect program savings over time.
- 8 There is no explicit mention whether these savings are net of shared savings payments paid to Pioneer ACO providers.
- 9 The near market includes counties where ACO providers were located in the first performance year, plus all contiguous counties.
- 10 We used American Hospital Association data to identify hospitals that participated in an ACO. MA and ACO penetration data were from CMS.
- 11 Eight percent of revenue for a physician-only ACO is likely to be much less than 10 percent of the benchmark. We calculate that 5 percent of benchmark is the upper bound on risk under the revenue risk model.
- 12 Unlike other CMMI ACO demonstrations in which CMMI has chosen a limited number of ACOs to participate after a competition of sorts, ACOs can join Track 1+ simply by applying; if they meet the requirements, they are in the demonstration. In fact, the application process goes through CMS's MSSP office, not CMMI.
- 13 See pages 43–44 of the memo to Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties about advance notice of methodological changes for calendar year 2019 for Medicare Advantage capitation rates, Part C and Part D payment policies, and the 2019 draft call letter from February 1, 2018 (available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>).
- 14 The president's budget included this idea of a proportional incentive for A-APM participation but did not include an estimate of savings or spending. See page 67 of "Putting America's Health First," available at <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf>.
- 15 ACOs are made up of taxpayer identification numbers (TINs), and any clinician billing through that TIN is automatically on the participant list. Specialists make up about two-thirds of physicians treating Medicare FFS beneficiaries.

References

- Avalere Health. 2018. Medicare financial incentives encourage providers to take on greater financial risk. Press release. January 18. <http://avalere.com/expertise/managed-care/insights/medicare-financial-incentives-encourage-providers-to-take-on-greater-financ>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017a. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2018; Medicare Shared Savings Program requirements; and Medicare Diabetes Prevention Program. Final rule. *Federal Register* 82, no. 219 (November 15): 52976–53371.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017b. *Medicare Shared Savings Program: Shared savings and losses and assignment methodology—Specifications*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017c. New accountable care organization model opportunity: Medicare ACO Track 1+ Model. Fact sheet. July. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/New-Accountable-Care-Organization-Model-Opportunity-Fact-Sheet.pdf>.
- Colla, C. H., V. A. Lewis, L. S. Kao, et al. 2016. Association between Medicare accountable care organization implementation and spending among clinically vulnerable beneficiaries. *JAMA Internal Medicine* 176, no. 8 (August 1): 1167–1175.
- D’Ambrosio, D. 2017. Care Board five-year experiment will focus on keeping patients healthy. *Burlington Free Press*, December 21.
- Dale, S. B., A. Ghosh, D. N. Peikes, et al. 2016. Two-year costs and quality in the Comprehensive Primary Care Initiative. *New England Journal of Medicine* 374, no. 24 (June 16): 2345–2356.
- Duggan, M., J. Gruber, and B. Vabson. 2018. The consequences of health care privatization: Evidence from Medicare Advantage exits. *American Economic Journal: Economic Policy* 10, no. 1: 133–186.
- Fisher, E. S., D. O. Staiger, J. P. Bynum, et al. 2007. Creating accountable care organizations: The extended hospital medical staff. *Health Affairs* 26, no. 1 (January–February): w44–57.
- Government Accountability Office. 2015. *Medicare: Results from the first two years of the Pioneer Accountable Care Organization Model*. Report to the Ranking Member, Committee on Ways and Means, House of Representatives. Washington, DC: GAO.
- Green Mountain Care Board. 2018. *Annual report for 2017*. Montpelier, VT: GMCB.
- Kaiser Family Foundation. 2018. Side-by-side comparison: Medicare accountable care organization (ACO) models. <https://www.kff.org/interactive/side-by-side-comparison-medicare-accountable-care-organization-aco-models/>.
- L & M Policy Research. 2015. *Pioneer ACO evaluation findings from performance years one and two*. Final report prepared for the Centers for Medicare & Medicaid Services by L & M Policy Research. Baltimore, MD: CMS.
- McWilliams, J. M. 2016a. Changes in Medicare Shared Savings Program savings from 2013 to 2014. *Journal of the American Medical Association* 316, no. 16 (October 25): 1711–1713.
- McWilliams, J. M. 2016b. Savings from ACOs—Building on early success. *Annals of Internal Medicine* 165, no. 12 (December 20): 873–875.
- McWilliams, J. M., M. E. Chernew, J. B. Dalton, et al. 2014. Outpatient care patterns and organizational accountability in Medicare. *JAMA Internal Medicine* 174, no. 6 (June): 938–945.
- McWilliams, J. M., M. E. Chernew, and B. E. Landon. 2017a. Medicare ACO program savings not tied to preventable hospitalizations or concentrated among high-risk patients. *Health Affairs* 36, no. 12 (December): 2085–2093.
- McWilliams, J. M., L. G. Gilstrap, D. G. Stevenson, et al. 2017b. Changes in postacute care in the Medicare Shared Savings Program. *JAMA Internal Medicine* 177, no. 4 (April 1): 518–526.
- McWilliams, J. M., L. A. Hatfield, M. E. Chernew, et al. 2016. Supplementary appendix to: McWilliams, J. M., L. A. Hatfield, et al. Early performance of accountable care organizations in Medicare. *New England Journal of Medicine* 374: 2357–66. http://www.nejm.org/doi/suppl/10.1056/NEJMsa1600142/suppl_file/nejmsa1600142_appendix.pdf.
- McWilliams, J. M., M. E. Chernew, B. E. Landon, et al. 2015. Performance differences in year 1 of Pioneer accountable care organizations. *New England Journal of Medicine* 372, no. 20 (May 14): 1927–1936.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2017a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

- Medicare Payment Advisory Commission. 2017b. *Report to the Congress: Regional variation in Medicare Part A, Part B, and Part D spending and service use*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016a. Comment on CMS's proposed rule on the Merit-based Incentive Payment System and alternative payment models, June 15. <http://www.medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-merit-based-incentive-payment-system-and-alternative-pa.pdf?sfvrsn=0>.
- Medicare Payment Advisory Commission. 2016b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016c. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016d. Status report on Medicare accountable care organizations (ACOs). Presentation at the Commission's October public meeting. http://www.medpac.gov/docs/default-source/default-document-library/statusreportonmedicareaccountable_oct16_pres_sec.pdf?sfvrsn=0.
- Medicare Payment Advisory Commission. 2015a. MedPAC comment on CMS's proposed rule on the physician fee schedule and other revisions to Part B, September 8.
- Medicare Payment Advisory Commission. 2015b. MedPAC comment on CMS's Medicare Shared Savings Program: Accountable care organizations proposed rule, February 2.
- Medicare Payment Advisory Commission. 2014a. Comment letter to CMS on accountable care organizations, June 16. <http://www.medpac.gov/docs/default-source/comment-letters/comment-letter-to-cms-on-accountable-care-organizations-june-16-2014-.pdf?sfvrsn=0>.
- Medicare Payment Advisory Commission. 2014b. MedPAC comment letter to CMS on accountable care organizations, June 16.
- Medicare Payment Advisory Commission. 2014c. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2009. *Report to the Congress: Improving incentives in the Medicare program*. Washington, DC: MedPAC.
- Nelson, L. 2012. *Lessons from Medicare's demonstration projects on disease management and care coordination*. Working paper 2012–01. Washington, DC: Congressional Budget Office.
- Newhouse, J. P. 1993. *Free for all? Lessons from the RAND health insurance experiment*. Cambridge, MA: Harvard University Press.
- Nyweide, D. J., W. Lee, T. T. Cuerdon, et al. 2015. Association of Pioneer accountable care organizations vs traditional Medicare fee for service with spending, utilization, and patient experience. *Journal of the American Medical Association* 313, no. 21 (June 2): 2152–2161.
- Office of Inspector General, Department of Health and Human Services. 2017. *Medicare Shared Savings Program accountable care organizations have shown potential for reducing spending and improving quality*. Washington, DC: OIG.
- Office of the Actuary, Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Certification of Pioneer Model savings from Paul Spitalnic, Chief Actuary. April 10.
- Pham, H. H., M. Cohen, and P. H. Conway. 2014. The Pioneer Accountable Care Organization Model: Improving quality and lowering costs. *JAMA* 312, no. 16 (October 22–29): 1635–1636.
- Song, Z., S. Rose, D. G. Safran, et al. 2014. Changes in health care spending and quality 4 years into global payment. *New England Journal of Medicine* 371, no. 18 (October 30): 1704–1714.
- Song, Z., D. G. Safran, B. E. Landon, et al. 2012. The 'Alternative Quality Contract,' based on a global budget, lowered medical spending and improved quality. *Health Affairs* 31, no. 8 (August): 1885–1894.

CHAPTER

9

**Managed care plans for
dual-eligible beneficiaries**

Managed care plans for dual-eligible beneficiaries

Chapter summary

Individuals who receive both Medicare and Medicaid (known as dual-eligible beneficiaries) often have complex health needs but are at risk of receiving fragmented or low-quality care because of the challenges in obtaining care from two distinct programs. Many observers have argued that the two programs could be better integrated by developing managed care plans that provide both Medicare and Medicaid services. Supporters argue that integrated plans would improve quality and reduce federal and state spending because they would have stronger incentives to coordinate care than either program does when acting on its own. However, these plans have been difficult to develop, and only 8 percent of full-benefit dual-eligible beneficiaries are now enrolled in a plan with a high level of Medicare and Medicaid integration.

Since 2013, CMS and 10 states have tested the use of integrated Medicare–Medicaid Plans (MMPs) as part of the financial alignment demonstration. The demonstrations in nine states, with a combined enrollment of about 380,000 dual eligibles, are still under way and will likely continue at least through 2019. (The other demonstration ended as planned in 2017.) There are limited data available on the demonstration’s effects on areas such as quality, service use, and cost because the evaluations of the demonstration are taking longer to complete than expected. However, the information available is generally positive. Although the demonstration has often been difficult to implement, enrollment now appears stable (although participation is lower than many

In this chapter

- Introduction
- Background on dual-eligible beneficiaries
- Update on the financial alignment demonstration
- More states are using Medicaid managed care for dual eligibles
- Medicare plans that serve dual eligibles differ in key respects
- Potential policies to encourage the development of integrated plans
- Conclusion

expected) and quality appears to be improving. During site visits we made to several states, we found that the participating plans have grown more confident about their ability to manage service use as the demonstration has matured, with many plans reporting declines in the use of expensive services such as inpatient care. There also continues to be widespread support for the demonstration among the diverse collection of stakeholders interviewed on our site visits.

The demonstration is part of a broader effort by many states to use Medicaid managed care to provide long-term services and supports (LTSS), such as nursing home care and personal care. Between 2004 and 2018, the number of states that have managed LTSS (MLTSS) programs grew rapidly, from 8 to 24, and more states will likely develop similar programs in the future. The growing use of managed care to provide LTSS—which account for most of Medicaid’s spending on dual eligibles—means that, in many states, the development of health plans that provide both Medicare and Medicaid services is probably the most feasible approach for pursuing closer integration.

Medicare now has four types of integrated plans that serve dual eligibles: the demonstration’s Medicare–Medicaid Plans, Medicare Advantage dual-eligible special needs plans (D–SNPs), fully integrated dual-eligible SNPs (FIDE SNPs), and the Program of All-Inclusive Care for the Elderly. There are significant differences among these plans in several key areas, such as their level of integration with Medicaid, ability to use passive enrollment, and payment methodology. In addition, allowing MMPs and D–SNPs to operate in the same market has been problematic in some states because competition between the plans has reduced enrollment in the more highly integrated MMPs. Policy changes to better define the respective roles of each type of plan or consolidate them in some fashion may be needed.

Three potential policies that would help encourage the development of integrated plans are (1) limiting how often dual eligibles can change their coverage, (2) limiting enrollment in D–SNPs to dual eligibles who receive full Medicaid benefits, and (3) expanding the use of passive enrollment, particularly when beneficiaries first qualify for Medicare. Collectively, these policies would improve care coordination and continuity of care, require D–SNPs to focus on the dual eligibles who stand to benefit the most from integrated care, and encourage more dual eligibles to enroll in plans with higher levels of Medicare–Medicaid integration. ■

Introduction

More than 10 million people qualify for both Medicare and Medicaid and are known as dual-eligible beneficiaries. For these individuals, the federal Medicare program covers medical services such as hospital care, post-acute care, physician services, durable medical equipment, and prescription drugs. The federal–state Medicaid program covers a variety of long-term services and supports (LTSS), such as custodial nursing home care and community-based care, and wraparound services, such as dental benefits and transportation. The program also provides assistance with Medicare premiums and, in some cases, cost sharing.

Dual-eligible beneficiaries are generally in poorer health than other Medicare beneficiaries. For example, as a group, dual eligibles are more likely to have functional impairments, behavioral health conditions, and substance abuse disorders. As a result, dual eligibles account for a disproportionately large share of Medicare spending: In 2013, the most recent year of linked Medicare and Medicaid enrollment and spending data available, they represented about 20 percent of Medicare beneficiaries but accounted for about 34 percent of total Medicare spending. They were also costly for Medicaid, representing about 15 percent of enrollment and about 32 percent of total spending in that program (Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission 2018).

Policymakers have long been concerned that dual eligibles are vulnerable to receiving care that is fragmented or poorly coordinated. Medicare and Medicaid are separate programs—the first purely federal, the second largely operated by states with federal oversight and a mix of federal and state funding. Each program is complex, with its own distinct rules for eligibility, covered services, and administrative processes. Medicare and Medicaid also have relatively little incentive to engage in activities that might benefit the other program. For example, states have relatively little incentive to reduce the use of inpatient care by dual eligibles because Medicare would realize most of the savings. Similarly, Medicare has relatively little incentive to prevent dual eligibles from going into nursing homes, where Medicaid pays for most of their care.

Many observers have argued that the two programs could be better integrated by developing managed care plans that provide both Medicare and Medicaid services. Supporters

argue that integrated plans would improve quality and reduce federal and state spending because they would have stronger incentives to coordinate care than either program does when acting on its own. However, these plans have been difficult to develop, and their enrollment remains low.

Our analysis examines the use of managed care for dual eligibles, focusing on the following topics: an update on CMS’s financial alignment demonstration, which is testing two new models of care for dual eligibles and has focused on managed care plans that provide both Medicare and Medicaid services; the growing use of Medicaid managed care for dual eligibles, which is making managed care the most feasible approach for better Medicare–Medicaid integration in many states; the various types of Medicare health plans that serve dual eligibles; and three potential policies to encourage the development of integrated plans.

Background on dual-eligible beneficiaries

Individuals must separately qualify for both Medicare and Medicaid coverage to become dual-eligible beneficiaries. Roughly half of dual eligibles first qualify for Medicare based on disability (compared with 17 percent of Medicare beneficiaries who are not dual eligibles) and roughly half qualify when they turn 65. Medicaid’s eligibility rules vary somewhat across states, but most dual eligibles qualify because they receive Supplemental Security Income benefits, need nursing home care or have other high medical expenses, or meet the eligibility criteria for the Medicare Savings Programs, which provide assistance with Medicare premiums and cost sharing (Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission 2018). Some individuals who are eligible for Medicaid do not participate in the program, particularly those who qualify for the Medicare Savings Programs (Medicaid and CHIP Payment and Access Commission 2017). In December 2016, about 10.5 million Medicare beneficiaries (18 percent of the total) were dual eligibles.

Dual eligibles divide into two broad groups—“full benefit” and “partial benefit”—based on the Medicaid benefits they receive. Full-benefit dual eligibles qualify for the full range of Medicaid services covered in their state, which generally includes a broad range of primary and acute care services, nursing home care, and other long-term services

**TABLE
9-1**

Dual eligibles had much higher per capita annual spending in 2013 than other Medicare beneficiaries

	Medicare	Medicaid	Total
Dual-eligible beneficiaries			
All	\$18,112	\$11,126	\$29,238
Full benefit	19,256	15,222	34,478
Partial benefit	15,200	695	15,895
All other Medicare beneficiaries	8,593	N/A	8,593

Note: N/A (not applicable). Figures include all Medicare (Part A, Part B, and Part D) and Medicaid spending except Medicare or Medicaid spending on Part A, Part B, or Part D premiums. The Medicaid spending for partial-benefit dual eligibles is for coverage of Medicare cost sharing.

Source: MedPAC analysis of linked Medicare–Medicaid enrollment and spending data.

and supports. In contrast, partial-benefit dual eligibles receive assistance only with Medicare premiums and, in some cases, assistance with cost sharing. In December 2016, there were 7.5 million full-benefit dual eligibles and 3.0 million partial-benefit dual eligibles.

Given the role that factors such as disability and functional impairment play in becoming a dual eligible, it is not surprising that dual eligibles are more likely than other Medicare beneficiaries to report that they are in poor health (18 percent vs. 6 percent) or need help performing three or more activities of daily living (30 percent vs. 9 percent) (Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission 2018).¹ The poorer health of this population leads in turn to higher costs (Table 9-1). Measured on a per capita basis, the average annual Medicare cost for dual eligibles in 2013 was over \$18,000, more than two times higher than for other Medicare beneficiaries. Within the dual-eligible population, those eligible for full Medicaid benefits had higher Medicare costs and much higher Medicaid costs than those eligible for partial Medicaid benefits only. In 2013, Medicare and Medicaid together spent more than \$34,000 per capita, on average, on full-benefit dual eligibles, with Medicare accounting for about 56 percent of the combined spending and Medicaid the other 44 percent.

The high Medicare costs for dual eligibles are driven by a combination of higher utilization of all major types of services and higher per user spending for those who receive care.² For example, in 2013, full-benefit dual eligibles

were more likely than other Medicare beneficiaries to use inpatient care (26 percent vs. 16 percent), and those who were hospitalized had higher inpatient costs (\$19,580 vs. \$16,362, respectively). The Medicaid costs for full-benefit dual eligibles largely comprised spending on LTSS, such as nursing home care and home- and community-based waiver programs. Less than half of full-benefit dual eligibles (42 percent) used LTSS in 2013, but spending on those services accounted for about 80 percent of this population’s total Medicaid costs (Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission 2018).

Update on the financial alignment demonstration

Under the financial alignment demonstration, CMS has been working with 13 states to test 2 new models of care for full-benefit dual eligibles—a *capitated* model and a *managed fee-for-service* (FFS) model. Both models seek to improve the coordination of Medicare and Medicaid for dual eligibles, improve the quality of their care, and lower costs (Centers for Medicare & Medicaid Services 2011):

- Under the capitated model, managed care plans provide the full range of Medicare and Medicaid benefits to dual eligibles. The plans receive a blended Medicare–Medicaid payment rate that is reduced to reflect expected savings from the demonstration.

**TABLE
9-2**

Overview of the financial alignment demonstrations

State	Model type	Eligible population	MOU date	Start/end dates	January 2018 enrollment
California	Capitated	Aged and disabled	March 2013	April 2014 to 2019	116,721
Colorado	Managed FFS	Aged and disabled	February 2014	September 2014 to 2017	—
Illinois	Capitated	Aged and disabled	February 2013	March 2014 to 2019	53,927
Massachusetts	Capitated	Disabled only	August 2012	October 2013 to 2018	19,337
Michigan	Capitated	Aged and disabled	April 2014	March 2015 to 2020	39,638
Minnesota	Alternative	Aged only	September 2013	September 2013 to 2018	38,994
New York (1)	Capitated	Aged and disabled	August 2013	January 2015 to 2019	4,263
New York (2)	Capitated	Aged and disabled	November 2015	April 2016 to 2020	731
Ohio	Capitated	Aged and disabled	December 2012	May 2014 to 2019	75,161
Rhode Island	Capitated	Aged and disabled	July 2015	July 2016 to 2020	14,144
South Carolina	Capitated	Aged only	October 2013	February 2015 to 2018	11,598
Texas	Capitated	Aged and disabled	May 2014	March 2015 to 2020	47,527
Virginia	Capitated	Aged and disabled	May 2013	April 2014 to 2017	—
Washington	Managed FFS	Aged and disabled	October 2012	April 2013 to 2018	19,609

Note: MOU (memorandum of understanding), FFS (fee-for-service). All states use additional eligibility criteria beyond age and disability. New York's first demonstration targets individuals who use certain kinds of long-term services and supports, while the second targets individuals with intellectual and developmental disabilities. All demonstrations will end on December 31 of the indicated calendar year. Massachusetts, Minnesota, and Washington plan to extend their demonstrations for two years, but these extensions have not been finalized and are not reflected in the table. South Carolina can extend its demonstration for two years but has not indicated whether it will do so. The enrollment figure for Washington is for December 2017.

Source: MedPAC analysis of state MOUs, CMS demonstration guidance, and Medicare Advantage enrollment data for January 2018; personal communication with L. Barnette (Centers for Medicare & Medicaid Services 2018c).

- Under the managed FFS model, states provide greater care coordination to dual eligibles who are enrolled in both FFS Medicare and FFS Medicaid. States receive a retrospective performance payment from Medicare if expenditures for demonstration enrollees are below a target amount.

Our update is based on a wide range of CMS guidance related to the demonstration, the evaluations of its effects that have been completed to date, administrative data, and findings from site visits to participating states. Between December 2015 and February 2018, we made eight site visits to six states (California, Illinois, Massachusetts, New York, Ohio, and Texas) and conducted phone interviews with stakeholders in two other demonstration states (Colorado and Washington). In all, we conducted over 80 interviews with a diverse range of stakeholders

that included state Medicaid officials, executives and care coordination staff for health plans participating in the demonstration, several different kinds of providers, and beneficiary advocacy groups. This update focuses primarily on the experience with the capitated model, which most participating states are testing, but also touches on the managed FFS model.

Table 9-2 provides an overview of the programs that are part of the demonstration. There are 14 demonstrations in 13 states (2 of those demonstrations have ended). Most participating states are testing the capitated model; only Colorado and Washington have tested the managed FFS model, while Minnesota is testing an alternative model.³ Most demonstrations are open to both disabled and aged dual eligibles, although one (Massachusetts) is limited to disabled beneficiaries, and two (Minnesota and

Findings from earlier efforts to develop integrated plans

The financial alignment demonstration's capitated model was influenced by an earlier set of demonstrations under which CMS and states developed the first integrated plans for dual eligibles. These efforts started in the 1990s and 2000s, when CMS approved demonstration projects in Wisconsin (1996), Minnesota (1997), and Massachusetts (2004). All three states succeeded in developing integrated plans, and making the plans a permanent part of Medicare was one motivation for the creation of Medicare Advantage dual-eligible special needs plans (D-SNPs) in 2003 (Schmitz et al. 2008). The demonstration plans were converted into D-SNPs in 2006, and many still operate today. CMS is now testing integrated plans on a broader scale with the financial alignment demonstration, but its evaluations are taking longer to complete than initially expected. As a result, much of the research on integrated plans and their effects on spending, service use, and quality of care still draws on the experience of these earlier demonstrations.

The Wisconsin program, known as the Wisconsin Partnership Program (WPP), was designed to serve elderly and disabled dual eligibles who need the level

of care provided in a nursing home but still live in the community, similar to the Program of All-Inclusive Care for the Elderly. In 2004, an evaluation of the program compared WPP enrollees with dual eligibles who had similar characteristics but were not enrolled.⁴ The WPP enrollees had similar or slightly lower rates of hospital use, mortality, and nursing home admission. However, the study found that WPP did not reduce Medicare spending because of the methodology that was used to set the capitation rates for the participating plans (Kane and Homyak 2004).

The Minnesota program, known as Minnesota Senior Health Options (MSHO), was limited to beneficiaries who were 65 or older, and it used a traditional managed care approach. The same 2004 report that evaluated the Wisconsin demonstration also assessed MSHO. The study found that MSHO enrollees in nursing homes had significantly fewer hospital admissions and emergency room visits than comparison groups of dual eligibles. However, MSHO enrollees did not perform significantly better in key areas such as mortality rates and change in functional status over time, and the quality of their nursing home care was similar (Kane and Homyak 2004).

(continued next page)

South Carolina) are limited to aged beneficiaries. CMS approved each demonstration by signing a memorandum of understanding (MOU) with the state that summarizes the key parameters of the demonstration. The first MOU (Massachusetts) was signed in August 2012; the last (for New York's second demonstration) was signed in November 2015. Most of the demonstrations started enrolling beneficiaries about a year after the signing of the MOU.

As of January 2018, about 440,000 dual eligibles were enrolled in the demonstrations, making this one of the largest demonstrations CMS has conducted that is specifically aimed at this population. The four largest demonstrations—California, Ohio, Illinois, and Texas—account for about two-thirds of the national total.

CMS initially planned for the demonstrations to last three years, but it has extended most of them because their evaluations have not been completed. In July 2015, CMS announced that all states could extend their demonstrations for an additional two years; in January 2017, it announced that the first three states to start their demonstrations (Massachusetts, Minnesota, and Washington) could extend them for another two years on top of that and said that other states could receive similar extensions if more time is needed to complete their evaluations (Centers for Medicare & Medicaid Services 2017c, Centers for Medicare & Medicaid Services 2015a). Colorado and Virginia decided against extending their demonstrations and concluded them at the end of 2017.⁵ The other states have finalized their extensions or indicated their intent to do so, except for South Carolina, which has not decided

Findings from earlier efforts to develop integrated plans (cont.)

A 2016 study of MSHO had much more positive findings. This study compared MSHO enrollees with dual eligibles in Minnesota who did not participate and were mostly enrolled in a combination of fee-for-service Medicare and Medicaid managed care. The study found that MSHO enrollees were 48 percent less likely to have an inpatient stay, 6 percent less likely to have an outpatient emergency room visit, 2.7 times more likely to have a visit with a primary care physician, and no more likely to have a visit with a specialist. As for long-term services and supports (LTSS) use, MSHO enrollees were 13 percent more likely to receive home- and community-based services and no more likely to have a nursing home admission. The authors concluded that the integrated MSHO program was associated with desirable patterns of service use and “may have merit for other states” (Anderson et al. 2016).

Like MSHO, the program in Massachusetts—Senior Care Options (SCO)—is also limited to beneficiaries who are 65 and older. One study found that SCO

enrollees, relative to a comparison group of dual eligibles, had lower rates of nursing facility use and lower mortality rates (JEN Associates 2015). However, another study found that SCO enrollment did not have a statistically significant effect on 30-day hospital readmission rates (Jung et al. 2015).

On balance, the findings from the early experiments with integrated plans are moderately positive. Integrated plans have shown some ability to reduce enrollees’ use of hospital services and redirect LTSS use from nursing home care to community-based care. The available research has sometimes found that integrated plans perform no better than other arrangements in some areas (such as readmission rates in the Massachusetts program), but, at the same time, the research has not found that dual eligibles have fared worse in integrated plans. Our understanding of the effectiveness of integrated plans should improve significantly as more evaluations of the financial alignment demonstration become available. ■

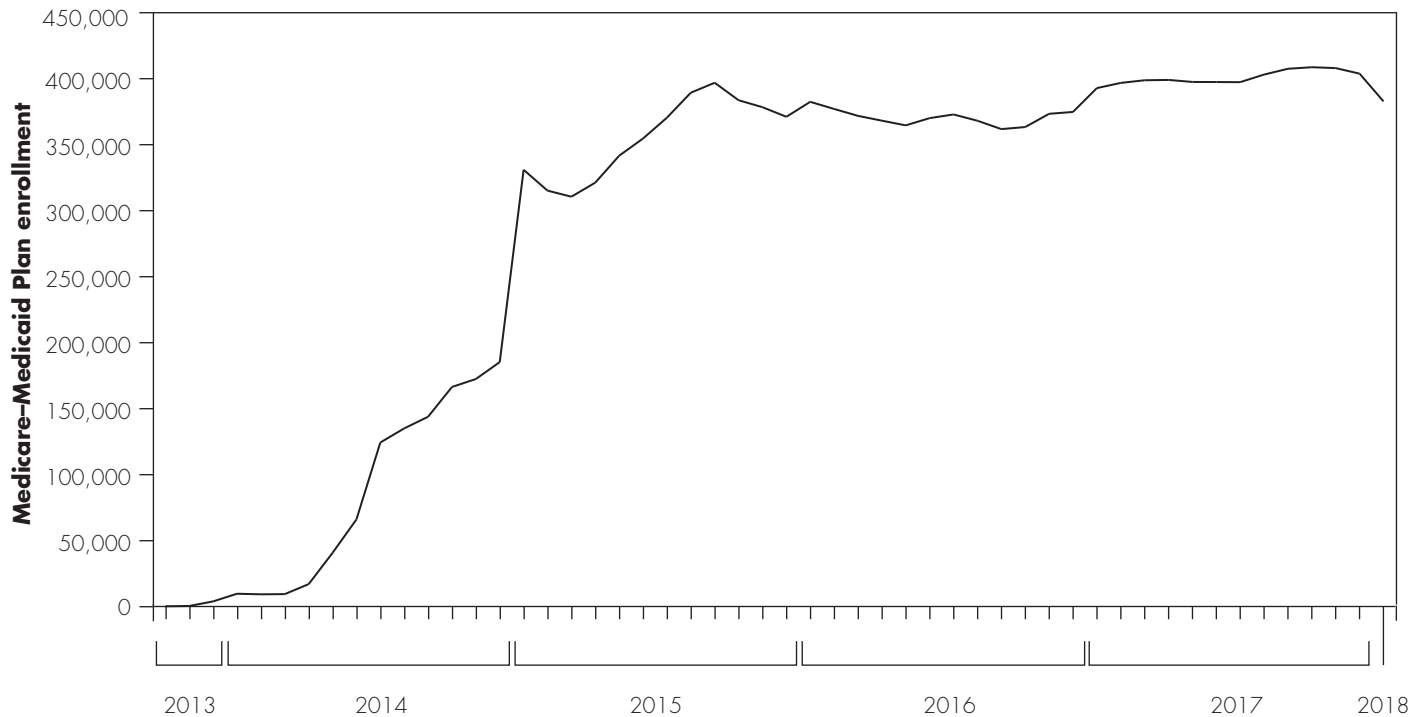
yet (Centers for Medicare & Medicaid Services 2018b). Most of the demonstrations therefore appear likely to last for five to seven years and operate until 2019 or 2020, if not longer.

CMS is conducting the financial alignment demonstration using the authority of its Center for Medicare & Medicaid Innovation (CMMI). Under this authority, the Secretary can test new payment models and subsequently expand the use of a model that he determines will either (1) reduce spending without affecting the quality of care or (2) improve the quality of care without increasing spending. As part of this process, the CMS chief actuary must certify that expanding the model will not increase overall Medicare or Medicaid spending. CMS could thus potentially expand the use of the capitated model and managed FFS model in the future.

Demonstrations using the capitated model

The key feature of the capitated model, which is used by most states, is a managed care plan that provides all

Medicare and Medicaid services. We refer to this type of plan as an *integrated plan*. The use of integrated plans has long been suggested as a way to improve care for dual eligibles, and CMS has tested their use in other demonstrations (see text box on earlier findings). Supporters argue that integrated plans, because of their responsibility for the full range of Medicare and Medicaid benefits, would not have the incentive that each program operating independently has to shift costs to the other program and would have stronger incentives to coordinate care across the programs. Dual eligibles would also find it easier to understand their coverage and obtain care because they would receive integrated materials (such as a single membership card and provider directory instead of separate Medicare and Medicaid versions) and have one point of contact for their care needs. Integrated plans, it has been argued, would thus improve the quality of care for dual eligibles and produce savings by reducing the use of high-cost services such as inpatient hospital care and nursing home care.

**FIGURE
9-1****Total enrollment in Medicare–Medicaid Plans has been relatively stable since mid-2015**

Source: MedPAC analysis of monthly Medicare Advantage enrollment data from CMS.

The integrated plans in the financial alignment demonstration are known as Medicare–Medicaid Plans (MMPs). They provide all Medicare-covered and all or most Medicaid-covered services to their enrollees. The MMPs are required to provide their enrollees with a high level of care coordination and receive a blended capitation rate that combines Medicare Part A, Part B, and Part D and Medicaid payments.

Beneficiary participation

CMS has limited eligibility for the financial alignment demonstration to full-benefit dual eligibles—individuals who are eligible for both Medicare (Part A, Part B, and Part D) and full Medicaid benefits in their state. States can further limit eligibility based on the particular needs of their demonstration, and every state testing the capitated model has done so. For example, 8 of the 10 active demonstrations operate only in certain parts of the state, usually around large metropolitan areas, and 6 exclude beneficiaries enrolled in certain Medicaid home- and community-based waiver programs, particularly those

that serve individuals with intellectual or developmental disabilities. In all, about 1.3 million beneficiaries are eligible for the 10 active demonstrations.

Under the demonstration, states can passively enroll beneficiaries in MMPs. With passive enrollment, beneficiaries are automatically enrolled in MMPs unless they indicate that they do not want to join an MMP, which is known as opting out. (See the Commission’s June 2016 report for a fuller discussion of how passive enrollment has been used in the demonstration and how it is used elsewhere in the Medicare and Medicaid programs.) Every state testing the capitated model has used passive enrollment for at least some beneficiaries, although California, New York, and Rhode Island no longer use it.⁶ In the other states, passive enrollment is now being used largely to enroll beneficiaries who have become dually eligible since the start of the demonstration.

Total enrollment in MMPs grew gradually between 2013 and 2015 because the individual state demonstrations

**TABLE
9-3**

MMP participation rates, by state, as of June 2017

State	MMP enrollment	Eligible beneficiaries	Participation rate
California	118,386	424,000	28%
Illinois	51,063	146,000	35
Massachusetts	16,950	104,000	16
Michigan	39,681	105,000	38
New York (1)	4,708	156,000	3
New York (2)	575	20,000	3
Ohio	75,603	111,000	68
Rhode Island	14,002	30,000	47
South Carolina	8,033	39,000	21
Texas	40,738	165,000	25
Virginia	27,958	67,000	42
Total	397,697	1,367,000	29

Note: MMP (Medicare–Medicaid Plan). Virginia’s demonstration ended in December 2017.

Source: Medicare Advantage enrollment data for June 2017; personal communication with L. Barnette (Centers for Medicare & Medicaid Services 2017).

started at different times, and many were implemented in stages (Figure 9-1). Since mid-2015, overall enrollment has not changed much, usually ranging between 360,000 and 400,000 beneficiaries per month. Enrollment dropped somewhat in January 2018, due largely to the end of Virginia’s demonstration, and stood at about 383,000 beneficiaries.

The participation rates for many demonstrations have been lower than expected and vary widely across states. Table 9-3 shows the MMP enrollment, number of eligible beneficiaries, and participation rate for each demonstration as of June 2017. Across all the demonstrations, only about 29 percent of eligible beneficiaries were enrolled in an MMP. Ohio (68 percent) and Rhode Island (47 percent) had the highest participation rates, while New York had the lowest rates (3 percent in both of its demonstrations). The participation rates for MMPs have been relatively low because many beneficiaries opted out or left the MMP after a short period of time.⁷ In the states we visited, stakeholders said many beneficiaries declined to participate because they were satisfied with their existing care, did not fully understand how the demonstration would affect them, or were encouraged to opt out by providers (Medicare Payment Advisory Commission 2016).

Comparing MMP enrollees and beneficiaries who opted out One question about the demonstration and its use of passive enrollment has been whether the beneficiaries who opted out differed from those who accepted passive enrollment in an MMP. To better examine this issue, we obtained data for the MMPs from the Medicare Advantage Prescription Drug (MARx) system, which CMS uses to process enrollment transactions for all types of Medicare health plans. The MARx data have two advantages over traditional enrollment data: (1) They indicate whether a beneficiary was passively enrolled in an MMP or enrolled voluntarily, and (2) they can be used to identify beneficiaries who were scheduled for passive enrollment but later opted out. The MARx data that we obtained have all transactions involving MMPs from October 2013 (the start of the first capitated demonstration) through April 2016 and thus do not have information for the second New York or Rhode Island demonstrations, which started later in 2016.

During this period, we found that states attempted to passively enroll about 855,000 beneficiaries in MMPs and that 41 percent of them opted out (Table 9-4, p. 252). We also examined whether opt-out rates varied by age, sex, race/ethnicity, and whether the beneficiary was a long-stay nursing home resident at some point during the year.

**TABLE
9-4****Opt-out rates for MMPs varied, October 2013–April 2016**

	Number of beneficiaries (in thousands)	Share of population	Opt-out rate
All passive enrollments	855	100%	41%
Age			
Under 65	307	36	35
65 and older	549	64	45
Sex			
Female	522	61	44
Male	333	39	38
Race/ethnicity			
White	299	35	43
Hispanic	222	26	36
African American	207	24	36
Asian	110	13	56
All other/unknown	17	2	46
Long-term nursing home use			
Zero months	757	89	41
At least 1 month	98	11	42

Note: MMP (Medicare–Medicaid Plan). Components may not sum to totals because of rounding.

Source: MedPAC analysis of MMP enrollment transaction data and Medicare enrollment data. These figures do not include records for beneficiaries who opted out by contacting the state Medicaid agency or beneficiaries with end-stage renal disease.

Beneficiaries ages 65 and older were more likely to opt out than those under age 65 (45 percent vs. 35 percent), and women were more likely to opt out than men (44 percent vs. 38 percent). The similarity between these two metrics is not surprising because dual eligibles over 65 are disproportionately female. As for race/ethnicity, beneficiaries of Asian ancestry were the most likely to opt out (56 percent), while African American and Hispanic beneficiaries were least likely (36 percent). Finally, the opt-out rates for long-stay nursing home residents and other beneficiaries were similar. The figures shown in Table 9-4 are aggregated across all MMP states; the figures for individual states will vary given the differences in their demographic characteristics (such as race/ethnicity) and the eligibility criteria for each demonstration.

These opt-out rates should be viewed as somewhat conservative because the MARx data do not include every beneficiary who opted out. The MARx data can identify beneficiaries who opted out only after CMS has begun the process of passively enrolling them, which starts at least

60 days before the actual enrollment date. (During this 60-day period, states send beneficiaries two notices about their upcoming passive enrollment, and beneficiaries can opt out any time before the scheduled enrollment date.) However, beneficiaries in some states were able to opt out by contacting the state before the start of the passive enrollment process. The beneficiaries who opted out in this manner do not appear in the MARx data because states never began the process of passively enrolling them. CMS does not know how many beneficiaries have used this other method to opt out.

In addition to high opt-out rates, another challenge for MMPs has been high disenrollment rates (enrollees leaving the plan for other coverage). For example, we found that 25 percent of the beneficiaries who were passively enrolled in MMPs disenrolled within the first three months. However, the share of beneficiaries who disenrolled within the first three months varied relatively little across the various categories shown in Table 9-4. For comparison, we also examined beneficiaries who

**TABLE
9-5**

Risk scores for beneficiaries enrolling in Medicare–Medicaid Plans

	2013	2014	2015	2016*
Number of active demonstrations	1	5	9	9
Total enrollment actions				
New MMP enrollees	5,120	241,284	395,334	59,688
Beneficiaries who opted out	N/A	74,448	255,304	24,366
Average risk score				
New MMP enrollees	1.14	1.39	1.59	1.59
Beneficiaries who opted out	N/A	1.48	1.83	1.75
New MMP enrollees, by length of enrollment				
1 to 3 months	905	69,686	102,510	12,276
4 to 6 months	343	25,604	39,277	6,534
7 months or more	<u>3,872</u>	<u>145,994</u>	<u>253,547</u>	<u>40,878</u>
Total	5,120	241,284	395,334	59,688
Average risk scores for new MMP enrollees, by length of enrollment				
1 to 3 months	1.20	1.64	1.86	1.89
4 to 6 months	1.20	1.52	1.72	1.65
7 months or more	1.12	1.24	1.45	1.48

Note: MMP (Medicare–Medicaid Plan), N/A (not applicable). Table does not include records for beneficiaries who opted out by contacting the state Medicaid agency or beneficiaries with end-stage renal disease. There were no opt-outs in 2013 because the only demonstration then under way (Massachusetts) did not begin passive enrollment until 2014. “New MMP enrollees” are those who first joined an MMP in the stated year. “Length of enrollment” is based on the number of months of enrollment through December 2016.
*2016 figures are for enrollment actions with January through April effective dates and do not include the second demonstration in New York or the demonstration in Rhode Island, which both started later in 2016.

Source: MedPAC analysis of MMP enrollment transaction data, Medicare enrollment data, and CMS–hierarchical conditions categories risk score data.

enrolled voluntarily, who represented about 15 percent of all MMP enrollees. The share of voluntary enrollees who disenrolled within the first three months was 17 percent, lower than the figure for passive enrollees but still high for a group that had actively chosen to enroll in an MMP. Like the passive enrollees, the disenrollment rates for voluntary enrollees varied little by age, sex, race/ethnicity, or nursing home use.

Evidence of favorable selection for MMPs We also used the MARx data and MMP enrollment data to examine whether beneficiaries who opted out or disenrolled were healthier or sicker than those who enrolled in MMPs. We compared beneficiaries using their risk scores from the CMS hierarchical condition category (CMS–HCC) risk adjustment model. CMS uses this model to adjust payments to Medicare Advantage (MA) plans and other

plan types, such as MMPs, to account for differences in beneficiaries’ health status. Risk scores are based on a combination of demographic information (such as age, sex, and whether the beneficiary first qualified for Medicare based on a disability) and diagnostic information from claims; scores are scaled to show how a beneficiary’s expected Medicare costs compare with the average expected cost for all FFS beneficiaries. For example, a risk score of 1.0 indicates that the expected costs for a beneficiary equal the overall average, and a risk score of 1.3 indicates that the expected costs for a beneficiary are 30 percent higher than the overall average.

We found that the dual eligibles who have participated in the demonstration appear to be healthier than those who opted out (Table 9-5). For example, in 2014, the beneficiaries who joined an MMP had an average risk

score of 1.39, while the beneficiaries who opted out had an average score of 1.48. The figures for 2015 and 2016 follow the same basic pattern, although the average risk scores for new enrollees and those opting out vary from year to year.

Among beneficiaries who enrolled in MMPs, there were also differences in risk scores when the enrollees were stratified based on the length of time they were enrolled. In 2014, about 241,000 beneficiaries joined MMPs, but almost 70,000 (29 percent) were enrolled for 3 months or less, and about 26,000 (11 percent) were enrolled for between 4 and 6 months.⁸ The beneficiaries who were enrolled for three months or less had a higher average risk score (1.64) than those who were enrolled for four to six months (1.52), who in turn had a higher average risk score than those who were enrolled for seven months or more (1.24). The patterns for 2015 and 2016 were similar. As with Table 9-4 (p. 252), the figures in Table 9-5 (p. 253) are aggregated across all MMP states, and the figures for individual states will vary.

Taken together, these differences in risk scores indicate that favorable selection has occurred in the capitated demonstrations, meaning that the healthier beneficiaries among those eligible have been more likely to participate.⁹ In this respect, the financial alignment demonstration is similar to other managed care programs that feature voluntary enrollment. For example, the Commission has found that Medicare beneficiaries who enroll in MA plans are healthier than FFS enrollees and that beneficiaries who switch from MA plans to FFS coverage have higher risk scores than beneficiaries who remain in MA (Medicare Payment Advisory Commission 2012b). Some older studies also found evidence of favorable selection in voluntary Medicaid managed care programs (American Academy of Actuaries 1996, Scholle et al. 1997).¹⁰ Nevertheless, the presence of favorable selection means that the demonstration is not fully serving relatively sicker dual eligibles, who might benefit the most from better care coordination.

The stakeholders we interviewed on our site visits indicated that many beneficiaries opted out of the demonstration to maintain access to their current providers or because their providers encouraged them to opt out. Beneficiaries with higher risk scores would tend to have higher service use and see a larger number of providers. As a result, they might have been more likely to find that one or more of their providers was not in their MMP's provider

network and more likely to have at least one provider encourage them to opt out. Similarly, beneficiaries with lower risk scores may have had less interaction with the health care system in the past and therefore may be more likely to be satisfied with the plan's provider network.

One concern about favorable selection is that plans may have a financial incentive to avoid serving sicker enrollees. However, many MMPs we interviewed said they would like to have more enrollees, and several expressed support for policies that would make it harder for dual eligibles to disenroll from MMPs. CMS and states also mitigate financial incentives to avoid serving sicker enrollees by risk adjusting the Medicare and Medicaid payments to MMPs, which should reduce this incentive because sicker enrollees also generate more revenues for plans. In addition, CMS increased MMP payment rates for Part A and Part B services after finding that the CMS-HCC model had historically tended to underestimate costs for full-benefit dual eligibles (Centers for Medicare & Medicaid Services 2015b).

Health plan participation

A total of 68 MMPs (counted at the contract level) have participated in the demonstration. Most are sponsored by organizations with prior experience in Medicare Advantage, Medicaid managed care, or both (Weiser and Gold 2015). However, 18 plans have left the demonstration since it started, and only 50 are still participating. CMS has not allowed any new MMPs to join the demonstration so far, although new plans will be able to join in the future when states reprocure their Medicaid managed care plans. Plans have left the demonstration for a variety of reasons:

- Most of the departing plans (11 of 18) were part of New York's first demonstration and left because of low enrollment. The demonstration started with an unusually large number of MMPs (21), but beneficiary participation has been very low (see Table 9-3, p. 251), leaving many plans with very little enrollment. The 11 plans that left the demonstration all had fewer than 300 enrollees.
- Three MMPs left because of Virginia's decision to end its demonstration at the end of 2017.
- Two plans that left in 2015—one in Massachusetts and one in Illinois—cited inadequate payment rates as a primary reason for their decision. However, CMS increased payment rates for MMPs in 2016, and we are not aware of any plan departures since then that have been attributed to inadequate payment rates.

**TABLE
9-6**

Enrollment in individual MMPs varies widely

Enrollment range	MMPs		Enrollees		Average enrollees per MMP
	Number	Share	Number	Share	
Less than 1,000	9	18%	2,432	1%	270
1,001 to 5,000	11	22	34,064	9	3,097
5,001 to 10,000	13	26	89,346	23	6,873
More than 10,000	17	34	257,205	67	15,130
Total	50	100	383,047	100	7,661

Note: MMP (Medicare–Medicaid Plan). MMPs are counted at the contract level.

Source: Medicare Advantage enrollment data for January 2018.

- One plan left the Illinois demonstration at the end of 2017 after the plan’s parent company decided to end all of its Medicaid-related business in the state.

The number of plans in each demonstration varies. California and the first New York demonstration currently have 10 plans each, while the second New York demonstration and Rhode Island have only 1 plan each. The other demonstrations have between two and seven plans. Many MMPs serve only part of the demonstration area. For example, Texas is conducting its demonstration in six counties. The state has five MMPs, but only one to three plans operate in each county.

Each MMP has signed a three-way contract with CMS and the state that specifies its requirements under the demonstration. States initially selected the plans for the demonstration and could limit the number of plans that participate. Plans also had to satisfy CMS requirements and pass a readiness review that examines areas such as network adequacy, financial solvency, care management capabilities, and plan staffing for functions like customer service (Medicaid and CHIP Payment and Access Commission 2015).

The number of dual eligibles enrolled in each MMP varies widely (Table 9-6). Nine MMPs that were operating in January 2018 had fewer than 1,000 enrollees. All of these plans were in New York, and 5 had fewer than 250 enrollees. A total of 30 MMPs had more than 5,000 enrollees, and 17 MMPs had more than 10,000 enrollees.

The largest MMP, sponsored by Inland Empire Health Plan in California, had more than 25,000 enrollees (data not shown).

One question about the demonstration has been whether health plans need a certain level of enrollment to successfully operate an MMP. Before the demonstration, many health plans believed that they would need to make significant upfront investments to provide the level of care coordination required for MMPs. CMS authorized the use of passive enrollment in the demonstration partly to ensure that plans would have enough enrollment to justify those initial investments, and many plans we interviewed indicated that passive enrollment was a key factor in their decision to participate in the demonstration.

During our site visits and in other interviews with MMPs, we asked plan officials whether an MMP needed a minimum level of enrollment to operate effectively. Some plans did not provide a figure, but most of the plans that did indicated that MMPs were easier to operate with at least 5,000 to 7,500 enrollees because they could benefit from economies of scale in providing care coordination, such as hiring staff with clinical expertise in behavioral health, and spreading relatively fixed costs for activities such as the development of member materials. Some plans also said that higher enrollment would make it easier for them to get providers to join their networks. Except for New York, most plans appear to have enough enrollees to adequately test the capitated model.

Evaluations of the demonstration

CMS has contracted with RTI International to evaluate each demonstration's effect on areas such as access to care, service use, quality of care, and cost. These evaluations will include qualitative analyses, such as findings from beneficiary focus groups and interviews with key stakeholders, as well as quantitative analyses using claims, encounter, assessment, and enrollment data. RTI plans to release an annual evaluation report for each demonstration and a final evaluation report that synthesizes findings across all participating states (Walsh et al. 2013).

However, these evaluations are taking much longer to complete than expected. So far, only one annual evaluation for a capitated demonstration has been released, covering the first year of the Massachusetts demonstration (Gattine et al. 2017).¹¹ The delays have been due to difficulties in gathering the data needed to conduct the quantitative analyses. RTI plans to measure the effects of the demonstrations on both Medicare and Medicaid service use by comparing the dual eligibles who are eligible for the demonstrations (whether or not they participate) with similar groups of dual eligibles living in other states. This approach requires a great deal of administrative data, such as Medicaid FFS claims and encounter data from multiple states, MMP encounter data for both Medicare and Medicaid services, Medicare FFS claims, MA encounter data, and Medicare Part D data (Walsh et al. 2013). Some of those data, particularly MMP encounter data and Medicaid data from comparison states, are taking longer to obtain than anticipated.

CMS will release more evaluations as these data issues are resolved, but the annual reports for the first one or two years of each demonstration may not provide much insight into the effects of the capitated model. In the states we visited, there was broad agreement among stakeholders that the demonstrations had been challenging to implement. Many MMPs we interviewed said they had needed roughly 18 to 24 months to fully establish themselves and that their impact on enrollees' service use during that time was limited. The first-year evaluation of the Massachusetts demonstration took a similar view; that report found "limited evidence of the demonstration's effect during the first demonstration year, partly due to initial implementation challenges but also due to the need for allowing adequate time for care interventions at the beneficiary level to affect service utilization" (Gattine et al. 2017).

Many stakeholders we interviewed on our more recent site visits said they were frustrated with the delays in completing the evaluations. At the time of these visits, the demonstrations in California, Massachusetts, New York, Ohio, and Texas had been in operation for about three years. Many stakeholders in those states believed that the demonstrations showed promise and wanted to know what CMS was going to do in the "post-demonstration" era.

Given the delays with the quantitative analyses, RTI has issued several reports with qualitative analyses of the demonstration, such as findings from focus groups of MMP enrollees and a review of how MMPs are providing care coordination (Ptaszek et al. 2017, Weiner et al. 2017). CMS has also issued other data, such as results from surveys of MMP enrollees about their patient experience. The rest of our update on the capitated model incorporates findings from these other data sources and from our site visits.

Care coordination

Under the demonstration, CMS and states hope that greater care coordination for dual eligibles will improve the quality of their care and reduce Medicare and Medicaid spending. MMPs are required to provide care coordination using a model that has three main elements:

- Each enrollee must receive an initial health assessment. Each demonstration has its own deadlines for completing the assessments; most are within 90 days of enrollment. The assessments must be comprehensive, covering physical health, behavioral health, ability to perform activities of daily living, and cognitive status (Medicaid and CHIP Payment and Access Commission 2015). The assessments must also be updated periodically, usually at least once a year.
- Each enrollee must have an individual care plan that is based in part on the results of the assessment. These care plans must be developed by an interdisciplinary team of providers. The membership of the team varies by demonstration but usually includes the enrollee's care coordinator, primary care physician, LTSS providers, and relevant specialists (such as behavioral health providers). Enrollees can also participate if they wish.
- Each enrollee is assigned to a care coordinator who often takes the lead in developing the enrollee's care plan and provides ongoing help in finding and obtaining necessary care.

Learning more about how MMPs provide care coordination was a primary goal of our site visits, and RTI has also issued two reports on the topic as part of its evaluation of the demonstration (Ptaszek et al. 2017, Weiner et al. 2017). The views that we heard during our interviews with stakeholders are consistent with the findings in RTI's reports.

Many MMPs have had trouble completing the initial health assessments on time for two reasons. First, plans have not been able to locate many enrollees because their contact information is out of date. RTI found that most plans had trouble finding between 20 percent and 35 percent of their enrollees, and the plans we interviewed supplied similar figures. Second, some plans we interviewed found it challenging to conduct assessments when large numbers of beneficiaries were passively enrolled at the same time. In 2015, the share of assessments that were completed within 90 days was between 55 percent and 75 percent for most demonstrations (Weiner et al. 2017). Completion rates are higher when beneficiaries who could not be located or did not want to participate in an assessment are excluded, and have been rising over time, from an average of 69 percent in 2014 to 78 percent in 2015 and 89 percent in 2016 (Centers for Medicare & Medicaid Services 2017g).

Our interviews and RTI both found that plans had difficulty with the next stage of the care coordination process—using interdisciplinary teams of providers to formulate care plans. One particular challenge has been low participation by primary care physicians, who are usually not paid for taking part (Weiner et al. 2017).

The MMPs have hired a significant number of care coordinators for the demonstration. In 2015, the plans in the 9 demonstrations then in operation employed almost 4,600 care coordinators. Most coordinators have backgrounds in social work or nursing; those who oversee enrollees with complex needs are more likely to have a clinical background. About 80 percent of coordinators worked on tasks such as providing care management and conducting assessments; the rest worked in other capacities such as supervision (Weiner et al. 2017). On average, the MMPs have 1 care coordinator for roughly every 100 enrollees (if the coordinators working in other capacities are included, the ratio is closer to 1:80).

Care coordinators can work directly for the plan or one of the plan's subcontractors, such as a medical group or social service agency. Most of the plans we interviewed used a mix of these approaches, and many plans had

modified their care coordination arrangements as they gained experience and tested new approaches. Many of the plans we interviewed had increased their use of subcontractors to provide care coordination, particularly as they developed relationships with local social service agencies (such as area agencies on aging or behavioral health providers) and gained a better understanding of the capabilities of those entities. Texas appears to be an exception in this regard; the plans we interviewed there relied entirely on internal employees to provide care coordination.

The MMPs we interviewed said the level of care coordination that enrollees receive depends on their care needs. High-risk enrollees, such as those who use LTSS, receive the most extensive care coordination, such as regular calls from their care coordinators and in-person meetings or assistance in some states. In contrast, lower risk enrollees appear to have much less regular contact with their care coordinators, and their interactions are more likely to be limited to periodic phone calls.

RTI conducted focus groups of MMP enrollees in five states and found that most knew they had a care coordinator or had interacted with that person. Most of the participants who had used care coordination found it helpful, but some beneficiaries had not known they could receive care coordination before they participated in the focus group (Ptaszek et al. 2017). Other reports have found that care coordination has had a significant, positive impact on some enrollees, leading to improvements in their health and functioning (Carver 2016, Gattine et al. 2017, SCAN Foundation 2017).

During our later site visits, some plan representatives we interviewed indicated that the care coordination requirements for the demonstration were too prescriptive. Many of these comments focused on low-risk enrollees, with plans saying that their assessments did not need to be as comprehensive or be completed as quickly as those for higher risk enrollees. Another plan said that interdisciplinary provider meetings were difficult to schedule and were worthwhile only for beneficiaries with very complex needs.

Care coordination requirements have been a major issue in New York in particular, where overly prescriptive requirements appear to be the main reason that its first demonstration has had such low participation. The stakeholders we interviewed said that beneficiary advocacy groups had played a large role in developing the

requirements, which were modeled after those used in the Program of All-Inclusive Care for the Elderly (PACE), and that there had been relatively little input from physicians. Under the requirements, members of the interdisciplinary team of providers (which included the beneficiary's care coordinator and primary care provider) had to meet at the same time, in person, to develop the beneficiary's care plan. Beneficiaries were also expected to participate in the planning meetings, and primary care providers had to complete training on the care planning process.

This approach to care coordination is feasible in PACE because of the central role that adult day-care centers play in that program. The providers on the interdisciplinary team all work at the center (and are employees of the PACE plan) and enrollees typically visit the center several times each week to receive care. In-person meetings of the care planning team, including beneficiaries if they desire, are thus relatively easy to arrange.

This approach did not work well in the demonstration, where enrollees receive care from multiple providers in different locations, and providers were often expected to work with multiple plans. Stakeholders indicated that providers, especially primary care physicians, thought the requirements were overly burdensome and encouraged their patients to opt out. One plan we interviewed said providers also opposed the demonstration because MMPs could authorize only services that were explicitly listed in an enrollee's care plan (the interdisciplinary team had to meet again to approve any additional services, even minor ones), and because providers had to attest that all of their facilities complied with the Americans with Disabilities Act, something they had never been required to do before.

CMS and New York moved relatively quickly to address these concerns, eliminating or scaling back many requirements during the first year of the demonstration. However, many stakeholders indicated that providers still have a negative view of the demonstration, which has made it difficult to increase enrollment.

Service use and access to care

One key question about the capitated model has been whether MMPs can lower costs and improve the quality of care for dual eligibles by reducing their use of expensive services like inpatient care and nursing home care and by promoting greater use of primary care and home- and community-based services (HCBS). When we made our first site visits to California, Illinois, and Massachusetts between December 2015 and February 2016, those

demonstrations had been under way for 18 to 24 months. The plans we interviewed at the time had not yet seen noticeable changes in their enrollees' service use and said it was unrealistic to expect savings that quickly given the initial implementation challenges that plans had faced.

On our later visits—when the demonstrations in California, Massachusetts, New York, Ohio, and Texas had been under way for about three years—plans were much more definitive. Almost every plan we interviewed said the use of inpatient care and emergency room visits by their enrollees had declined. (The MMPs in New York were an exception; they said they had not seen significant changes in service use.) Several plans said that nursing home use was also declining, although those reductions appeared to be smaller. A few plans said they had seen lower service use in other areas, such as post-acute care and certain types of HCBS. However, we did not get a clear sense of whether the use of other services like primary care had changed.

One particularly important area for many dual eligibles is behavioral health. Many stakeholders we interviewed said there was a shortage of behavioral health providers in their area, but they saw this deficiency as a shortcoming of the broader health care system rather than something that was specific to the demonstration. Some stakeholders on our later visits felt the demonstration had expanded access to care for individuals with moderate behavioral health care needs—people who could benefit from treatment but did not have an illness that was severe enough to receive treatment from the traditional behavioral health care system.

The plans we interviewed said consistently that inadequate housing had been a significant challenge in caring for some enrollees. For example, one plan said even a few days in short-term housing could help homeless enrollees who had just been discharged from a hospital by making it easier for them to get appropriate follow-up care. MMPs cannot spend funds on room and board for people who live in the community (a long-standing policy in Medicaid), but some plans we interviewed were trying to develop closer relationships with local housing agencies so they could more easily help their enrollees find housing.

Some states have included additional transportation benefits, such as nonmedical transportation, in their demonstrations to help attract enrollment, but several stakeholders said the service was often unreliable. However, Medicaid programs often have problems

**TABLE
9-7**

MMP performance on the CAHPS® survey has improved, 2015-2017

	2015	2016	2017
Number of MMPs reporting CAHPS data	27	40	45
Share of beneficiaries giving the highest rating for:			
Health plan	51%	59%	63%
Health care quality	55	59	60
Getting needed care	58	58	59
Getting appointments and care quickly	48	50	54
Doctors who communicate well	76	76	77
Customer service	67	71	76
Care coordination	69	69	70
Getting needed prescription drugs	73	77	77

Note: MMP (Medicare–Medicaid Plan), CAHPS® (Consumer Assessment of Healthcare Providers and Systems®). Except for the number of MMPs reporting data, the numbers in this table are the share of beneficiaries giving the highest rating (a 9 or 10 on a 10-point scale or answering “always” when asked about the ability to get appointments when needed). Rates are case-mix adjusted for response bias.

Source: CAHPS survey results for MMPs released by CMS in April 2016, July 2017, and December 2017.

providing transportation benefits, and it was not clear whether the problems that the MMPs had encountered in this area were any worse.

Quality of care

Improving the quality of care for dual eligibles is one of the primary goals of the demonstration. MMPs are required to submit quality data to help CMS and states oversee the demonstration and evaluate its impact. Some requirements are modeled after the MA and Part D programs, while others were developed specifically for MMPs. The MMP-specific measures are a mix of process and structure measures, such as completing health assessments on time and establishing a consumer advisory board, and utilization measures, such as emergency room visits related to behavioral health and diversion of beneficiaries from nursing homes (Centers for Medicare & Medicaid Services 2017e).

Patient experience One source of quality information is the Consumer Assessment of Healthcare Providers and Systems® (CAHPS®), a beneficiary survey that measures patient experience. Like MA plans, MMPs are required to administer the CAHPS survey each year. The survey is usually conducted in the spring and asks enrollees to assess their experience during the previous six months.

For example, CAHPS results for 2017 measure patient experience in late 2016 and early 2017.

CMS has released overall CAHPS results for MMPs for 2015 through 2017 (Table 9-7). The number of plans that reported data grew as the individual state demonstrations were implemented, increasing between 2015 and 2017 from 27 plans to 45 plans.¹² During that period, MMP performance on all measures either improved or remained stable, with the share of enrollees giving their plan the highest possible rating rising from 51 percent to 63 percent. Enrollees also reported improvements in overall health care quality, getting appointments and care quickly, customer service, and getting needed prescription drugs.

These results naturally raise the question of how MMPs perform compared with MA plans and FFS. We do not have the data to make this comparison based on the method used to report CAHPS results in Table 9-7, which shows the share of beneficiaries providing the highest rating for each metric. However, we can compare CAHPS results using another method that calculates the average score on each metric for all survey respondents and rescales that average so it ranges between 0 percent and 100 percent. Using this approach, the results for MMPs, MA plans, and FFS are quite similar, with about

**TABLE
9-8**

Performance of MMPs and MA plans on HEDIS® measures, based on full-benefit dual eligibles only, measurement year 2016

	Enrollees under age 65	Enrollees ages 65 and older
Number of HEDIS measures evaluated	40	43
Number of measures where:		
MMP and MA performance was similar	18	18
MA plans performed better than MMPs	14	15
MMPs performed better than MA plans	8	10

Note: MMP (Medicare–Medicaid Plan), MA (Medicare Advantage), HEDIS® (Healthcare Effectiveness Data and Information Set®). Better performance means that the average measure value for one type of plan was more than 5 percent greater than the average measure value for the other type of plan.

Source: MedPAC analysis of HEDIS data for 2017 (for measurement year 2016) and common Medicare environment and denominator files.

85 percent of enrollees in each sector giving their health plan the highest possible rating.

Clinical quality measures Another source of quality information that MMPs and MA plans both submit is the Healthcare Effectiveness Data and Information Set® (HEDIS®), a set of clinical quality measures. We used HEDIS person-level data to compare MMP enrollees with full-benefit dual eligibles who were enrolled in MA plans.¹³ We looked separately at enrollees who were under 65 and enrollees who were 65 and older because the under-65 population tends to have poorer HEDIS results.

Our evaluation of HEDIS data for 2016 produced mixed results (Table 9-8). We found that MMPs and MA plans had similar results for roughly 40 percent to 45 percent of the measures that both plans collect (18 of 40 measures for enrollees under 65; 18 of 43 measures for enrollees 65 and older). MA plans performed better on a third of the measures, while MMPs performed better on about 20 percent to 25 percent of the measures.

MA plans performed substantially better than MMPs on three measures: control of blood sugar among diabetics, osteoporosis management for women who have experienced a fracture, and medication reconciliation after a hospital discharge. MMPs’ poor performance on the last measure is particularly concerning since they should pay close attention to transitions in care settings as part of their care coordination efforts. MMPs performed better than MA plans (for both age groups) on five measures: control of blood pressure among diabetics, two measures related

to mental health (providing follow-up care within 7 days and 30 days of an inpatient mental health admission), and two measures related to substance abuse (initiation of and engagement in substance abuse treatment).

We also compared HEDIS results for MMPs in 2015 and 2016 and found that MMP performance had improved, on balance. We made this comparison by finding out how many MMPs (measured at the contract level) improved on a given measure during this period. There were 33 measures we could examine on this basis; a plurality of MMPs improved on 12 measures, did worse on 8, and showed no change on the other 13.

There are several caveats to our analysis. First, we used full-benefit dual eligibles in MA plans as a comparison group for MMP enrollees, but there could be systematic differences between the two groups that affect their HEDIS results. For example, MA enrollees actively enrolled in their plans, while most MMP enrollees were passively enrolled and were difficult to contact in some cases. Second, older, more established plans tend to perform better than new plans on quality measures, and MMPs are still relatively new compared with MA plans. Finally, the 2 types of plans have different financial incentives when it comes to quality measures: 11 HEDIS measures are used in the MA star rating system while only 2 HEDIS measures are used in the quality incentive for MMPs, which is known as the “quality withhold.” Many of the measures on which MA plans performed better are used in the star rating system but not the quality withhold,

while the reverse is true for some measures on which MMPs performed better.

Development of a star rating system for MMPs In 2015, CMS began developing a star rating system for MMPs. CMS does not expect to have a fully developed system ready during the demonstration; the agency is working instead to prepare for the possibility that the Secretary would expand the use of the capitated model in the future using CMMI authority. The MMP ratings will differ from the star ratings for MA plans because MMPs will be assessed on their performance in providing both Medicare and Medicaid services. For example, the ratings for MMPs will incorporate measures related to LTSS and Medicaid-covered behavioral health services (Centers for Medicare & Medicaid Services 2015e). The rating system will be tested before being used and will account for differences in beneficiaries' socioeconomic status where appropriate. CMS will decide in the future whether the star ratings will be used to adjust MMP payments, but it has indicated that MMPs would not be subject to payment adjustments under both the quality withhold and the star ratings at the same time (Centers for Medicare & Medicaid Services 2016c).

Lessons from CAHPS and HEDIS results Taken together, the CAHPS and HEDIS results indicate that the quality of care provided by MMPs is improving, but the plans do not perform as well as MA plans in some areas. As CMS develops a star rating system for MMPs, it may want to put particular emphasis on measures where MMPs currently have poor performance. The findings from our examination of HEDIS results—with MA plans tending to perform better than MMPs on measures that are used in the MA star rating system but not the MMP quality withhold, and vice versa—suggest that plans pay closer attention to the measures used to determine their quality rating, particularly if that rating affects their payments.

Payment adequacy

Under the capitated model, MMPs receive three separate capitation payments: one for Part A and Part B services, one for Part D drugs, and one for Medicaid services. The payment methodology for MMPs differs from those used in MA and Part D because MMPs do not submit bids. Instead, for Part A and Part B services, MMPs are paid using county-specific rates that are based on historical FFS and MA spending for beneficiaries who meet the demonstration's eligibility criteria. In most states, the eligible population was largely enrolled in FFS Medicare before the demonstration, so the rates are based primarily

on historical FFS experience. For Part D drugs, MMPs are paid based on the national average bid for all Part D plans. Like Part D plans, MMPs receive a capitated direct subsidy payment as well as prospective payments for estimated reinsurance costs for beneficiaries with high drug costs and for beneficiary cost sharing covered by the Part D low-income subsidy, which all dual eligibles receive. The two Medicare capitation payments are adjusted for differences in beneficiaries' health status using the same risk adjustment models that are used in MA and Part D.

For Medicaid benefits, each state determines its own payment rates, subject to CMS approval. The rates include both federal and state Medicaid spending and typically vary based on beneficiaries' use of LTSS. Medicaid rates are typically highest for beneficiaries in nursing homes and lowest for those not receiving any LTSS, with rates for beneficiaries receiving HCBS somewhere in between. Some states have also "carved out" certain benefits from the demonstration and continue to provide them through FFS arrangements.

CMS and states also reduce the Part A and Part B and Medicaid capitation rates (there is no reduction to the Part D capitation rate) by a certain percentage to reflect savings they assume the MMPs will be able to produce under the demonstration. The savings percentages vary by demonstration but are generally around 1 percent in the first year, 1 percent to 2 percent in the second year, and 2 percent to 5 percent in later years.

In 2016, CMS increased MMP payment rates for Part A and Part B services after finding that the existing MA risk adjustment model underestimated costs for full-benefit dual eligibles (Centers for Medicare & Medicaid Services 2015b, Centers for Medicare & Medicaid Services 2015f).¹⁴ This change raised the payment rates for most MMPs by about 5 percent to 10 percent and was viewed favorably by the plan representatives we interviewed. During our early visits—which took place in late 2015 and early 2016, after the increase in payment rates had been announced but not yet implemented—stakeholder views on the adequacy of the MMP rates varied greatly. Many interviewees in Massachusetts said the existing rates were too low and the initial savings assumptions had proven to be unrealistic. Interviewees in California and Illinois did not express any significant concerns about the rates, although they also thought the initial savings assumptions were not realistic. On our later visits, none

of the stakeholders we interviewed (including those we met with on a follow-up visit to Massachusetts) raised any significant concerns about Medicare's rates, which suggests that the current rates are adequate.

Quality incentives for MMPs MMP payments are also tied to the plans' performance on certain quality measures through a quality withhold. Under the withhold, the Part A and Part B and Medicaid components of the MMP payment rates are reduced by a specified percentage (usually 1 percent in the first year of the demonstration, 2 percent in the second year, and 3 percent in later years) that MMPs can receive later depending on their performance.

MMPs are assessed on their performance on a combination of "core" measures that are used in all capitated demonstrations and state-specific measures. There are five core measures for the first year of the demonstration and seven core measures for later years; the number of state-specific measures varies, with most states having between two and five measures. For the first year, most measures are related to plan administration (such as submitting encounter data and completing assessments) or patient experience (such as customer service) (Centers for Medicare & Medicaid Services 2014). For later years, plans are assessed largely on clinical quality or outcome measures such as readmission rates, medication adherence for diabetes medications, and nursing home use (Centers for Medicare & Medicaid Services 2016b).

CMS and states determine whether plans "pass" each measure by comparing their performance with a benchmark. The benchmarks for the core measures are absolute, meaning they do not change based on how other MMPs perform. In contrast, for the state-specific measures, some benchmarks are absolute while others are relative, meaning the benchmark depends on how other MMPs perform. For example, the benchmark for several state-specific measures is the performance of the state's highest scoring MMP minus 10 percentage points (Centers for Medicare & Medicaid Services 2015c, Centers for Medicare & Medicaid Services 2015d). Starting in the second year of the demonstration, plans can also pass all core measures and some state-specific measures by improving their performance by a sufficient amount (Centers for Medicare & Medicaid Services 2016b).¹⁵ At the end of each year, CMS and states determine what share of the measures each MMP has passed, with each measure weighted equally. Plans that pass fewer than 20 percent of the measures do not receive any of the quality

withhold, while those that pass between 20 percent and 80 percent of the measures receive part of the withhold (either 25 percent, 50 percent, or 75 percent), and plans that pass more than 80 percent receive the entire withhold (Centers for Medicare & Medicaid Services 2014).

The only data on MMP performance for the quality withhold that are currently available are for 2014, when five demonstrations (California, Illinois, Ohio, Massachusetts, and Virginia) were under way. The lack of data is likely due to the same problems with data availability that have hindered work on the demonstration's evaluations. For 2014, MMPs received about 70 percent of the quality withhold, on average. Every MMP received at least some of the withheld funds, and a third of plans received the full amount (Centers for Medicare & Medicaid Services 2017a, Centers for Medicare & Medicaid Services 2017b, Centers for Medicare & Medicaid Services 2017d, Centers for Medicare & Medicaid Services 2017h, Centers for Medicare & Medicaid Services 2017k). Since the quality withhold equaled 1 percent in 2014, that level of performance means the quality withhold reduced the Part A and Part B and Medicaid payments to MMPs by about 0.3 percent, on average. If MMPs perform at a similar level once the quality withhold reaches its ultimate level of 3 percent, the withhold will reduce plan payments by roughly 1 percent, on average.

The quality withhold differs in several respects from the quality bonus program in Medicare Advantage, in which plans that have ratings of 4 stars or better and submit bids that are lower than the MA benchmarks receive additional funding that they use to provide extra benefits to their enrollees:

- The quality incentive for MA plans is structured as a bonus, while the quality incentive for MMPs is structured as a penalty.
- MA plans are assessed on more measures (43) than MMPs (about a dozen measures in most states). However, the smaller number of measures for MMPs is partly due to the lack of good quality measures for LTSS and care coordination, which are still being developed.
- MA plans receive a star rating on each individual measure, and those ratings are combined into an overall star rating. MA plans cannot improve their rating on any individual measure by showing improvement, while MMPs can "pass" most measures

by showing sufficient improvement. However, MA plans can receive a higher overall star rating if they show improvement across multiple measures.

- The MA quality bonus is an all-or-nothing proposition; plans either receive the entire bonus or receive nothing. In contrast, MMPs can receive part of the quality withhold.

Given these differences and the work that CMS has begun to develop a star rating system for MMPs, it is unclear what kind of quality incentive MMPs might face if the Secretary expands the use of the capitated model.

Demonstrations using the managed fee-for-service model

Unlike the capitated model, which relies on managed care plans to improve care and reduce costs, the managed FFS model aims to achieve those goals by providing greater care coordination in an FFS environment. Two states—Colorado and Washington—have been testing the managed FFS model. Colorado ended its demonstration at the end of 2017; Washington’s demonstration is scheduled to end in 2018 but may be extended until 2020.

Under the managed FFS model, the state passively enrolls dual eligibles who have both FFS Medicare and FFS Medicaid in a Medicaid-funded entity that is responsible for providing care coordination. Beneficiaries can receive care coordination services from the entity, but their participation is entirely optional, and they remain enrolled in FFS Medicare and FFS Medicaid regardless. Colorado enrolled all FFS dual eligibles in its demonstration, while Washington has focused on a subset of dual eligibles who are expected to have high costs.

Colorado’s demonstration was part of a broader effort to improve care coordination in FFS Medicaid known as the Accountable Care Collaborative (ACC). The ACC provides care coordination through entities that function somewhat like accountable care organizations. The state had excluded dual eligibles from the ACC when it was first developed and added them through the demonstration. Although the demonstration is now over, the state has decided that dual eligibles will remain in the ACC, and there should be little day-to-day change in their care.

The Washington demonstration relies on entities known as health homes to provide care coordination, with organizations such as area agencies on aging, mental health clinics, and community health centers providing

most of the actual assistance to beneficiaries (Medicare Payment Advisory Commission 2016). RTI has released an evaluation that covers the first 18 months of the demonstration (July 2013 to December 2014). Much like the initial report for the Massachusetts demonstration, the evaluation found “little evidence of the demonstration’s effect” during its initial period of operation. In Washington’s case, the initial impact of the demonstration may have been limited because dual eligibles were enrolled gradually, some health homes found they needed to develop more capacity for providing care coordination, and health homes found it challenging to engage enrollees (Justice et al. 2017).

At the end of each year, states can receive a “performance payment” if the demonstration produces savings for the federal government. CMS calculates the savings by comparing Part A and Part B spending for beneficiaries in the demonstration with an estimate of how much Medicare would have spent without the demonstration. Savings must be at least 2 percent for the state to receive a performance payment (to guard against random variation in program spending), and CMS deducts any additional Medicaid costs when calculating the overall federal savings. The state’s performance payment equals 30 percent to 50 percent of the federal savings, depending on the state’s performance on certain quality measures.

In July 2017, CMS released a report estimating that Washington’s demonstration reduced Medicare spending by \$67 million during its first two and a half years of operation (July 2013 to December 2015), a savings of about 9 percent (Wilkin et al. 2017b). That figure was based on an estimate of what Medicare would have spent on the dual eligibles who were assigned to a health home (about 20,000 beneficiaries) without the demonstration. As noted in our June 2016 report, we are skeptical that the savings from the demonstration could be that large because the number of beneficiaries who actually received care coordination services during this period was relatively low—about 3,000 people, many of whom received care coordination for only part of the time. As for Colorado, an August 2017 report estimated that its demonstration had actually increased Medicare spending by \$10 million in its first 15 months of operation (September 2014 to December 2015), a cost of about 4 percent (Wilkin et al. 2017a). Both reports note that their findings are preliminary and do not account for any changes in Medicaid spending.¹⁶ RTI also plans to estimate the savings from the demonstrations using more rigorous, regression-based methods as part of its evaluations.

Overall assessment of the financial alignment demonstration

Despite the conceptual appeal of integrated plans, their use in Medicare has always been limited. About 30 percent of full-benefit dual eligibles are now enrolled in some type of Medicare managed care plan, but the extent to which those plans integrate with Medicaid varies widely. Even with the demonstration, only 8 percent of full-benefit dual eligibles are enrolled in plans that have a high degree of integration.¹⁷ Before the demonstration, the figure was about 2 percent.

The limited use of integrated plans has traditionally been attributed to several factors. First, states do not benefit financially from any Medicare savings that integrated plans might realize and, thus, have less incentive to develop such plans. Second, integrated plans have found it difficult to generate substantial enrollment because dual eligibles cannot be required to enroll in a plan to receive their Medicare benefits. Third, CMS and states do not have the authority to resolve the many differences between Medicare and Medicaid that make it harder to operate an integrated plan, such as separate grievances and appeals processes and different adequacy requirements for provider networks.¹⁸ Finally, states and health plans have had little experience using managed care to deliver LTSS, which has made it difficult to develop integrated plans.

The experience with the demonstration suggests that policy changes addressing these barriers could lead to greater interest by states and health plans in developing integrated plans:

- The demonstration allows states to benefit financially from the savings that MMPs are expected to achieve in Medicare by applying the same savings assumptions to both the Medicare Part A and Part B and Medicaid components of the MMP payment rates. Even if MMPs ultimately achieve their savings entirely by lowering Medicare costs, states still benefit financially.
- CMS made it easier for MMPs to generate enrollment by allowing states to use passive enrollment. Many MMPs we interviewed said passive enrollment was a key factor in their decision to participate in the demonstration.
- CMS has used demonstration authority to address some of the administrative challenges involved in operating integrated plans. For example, MMPs use a single identification card and a single set of member

materials (such as provider directories) instead of separate Medicare and Medicaid versions, and all MMPs have integrated at least some parts of the grievance and appeals processes.

These features helped generate widespread state interest in the demonstration, with 21 states submitting proposals to test the capitated model (Medicaid and CHIP Payment and Access Commission 2018). And while the demonstrations were often challenging to implement, the experience so far suggests that integrated plans can be developed in many states. With a few exceptions, each state's demonstration has now been under way for at least three years. The continued delays in the evaluations are a significant concern given the widespread interest in understanding the demonstration's impact on access to care, service use, costs, and quality. Nevertheless, much of the information that is currently available, while limited, is relatively positive: Enrollment is stable, quality of care appears to be improving, payment rates appear adequate, plans have grown more confident about their ability to manage service use, and stakeholders remain supportive of the demonstration.

More states are using Medicaid managed care for dual eligibles

States' interest in testing the capitated model in the financial alignment demonstration has been part of a broader shift toward the use of Medicaid managed care for the aged and disabled. Managed care has long been the dominant delivery system in Medicaid for populations such as children, pregnant women, and nondisabled adults. For example, 25 of the 32 states (including the District of Columbia) that expanded Medicaid coverage for low-income adults under the Patient Protection and Affordable Care Act of 2010 enrolled at least 80 percent of those new beneficiaries in managed care (Paradise 2017).¹⁹

However, for many years, states were much less likely to use managed care for their aged and disabled enrollees, many of whom are dual eligibles. LTSS represents a significant share of Medicaid spending on aged and disabled enrollees—about 80 percent for dual eligibles and 35 percent for those who have Medicaid only. LTSS presents distinct challenges to health plans because its services and providers can differ greatly from traditional medical services, and the number of health plans that had “both the experience and the ability to accept risk for

LTSS” was limited (Saucier et al. 2012). As recently as 2004, only eight states had programs that used managed care plans to deliver LTSS to at least some beneficiaries (Saucier et al. 2012).²⁰ In addition, a state cannot require dual eligibles to enroll in Medicaid managed care unless it first obtains a waiver from CMS, a process that can take up to two years.²¹ (States do not need a waiver to require most other beneficiaries to enroll in managed care.) When states require dual eligibles to enroll in Medicaid managed care, the requirement applies only to the delivery of their Medicaid services, not their Medicare services.

Since 2004, the number of states with these programs—often referred to as managed LTSS (MLTSS) programs—has grown rapidly, from 8 states in 2004 to 16 states in 2012 and 24 states today (Lewis et al. 2018, Saucier et al. 2012). Medicaid spending on MLTSS programs has also grown significantly; between 2009 and 2015, spending rose from \$7 billion (5 percent of all Medicaid LTSS spending) to \$29 billion (18 percent of all Medicaid LTSS spending) (Eiken et al. 2017, Eiken et al. 2016). The use of MLTSS will likely grow in the future as additional states develop MLTSS programs and states that already have programs expand them.

We are not aware of a data source that indicates how many dual eligibles are currently enrolled in MLTSS plans. A recent report found that about 1.8 million individuals were enrolled in MLTSS programs (using a combination of 2016 and 2017 data), but that figure includes Medicaid-only beneficiaries, so the number of dual-eligible enrollees would be lower (Lewis et al. 2018). In rough terms, we estimate that perhaps 15 percent of full-benefit dual eligibles were in MLTSS plans in 2017. However, the 24 states that now have MLTSS programs collectively account for about 80 percent of all full-benefit dual eligibles. If these states expand the scope of their MLTSS programs in the future, the share of dual eligibles enrolled in MLTSS plans could rise significantly.

States have been developing MLTSS programs for three main reasons. First, they hope that managed care will lower Medicaid spending and make future spending growth more predictable. Second, they hope that MLTSS plans will improve the quality of care by providing effective care coordination for LTSS users, who often have complex health needs. Finally, states see MLTSS programs as a way to encourage the use of HCBS instead of nursing home care (Libersky et al. 2016). For example, some states have liberalized the eligibility criteria for HCBS as part of their MLTSS programs, and payment rates for MLTSS

plans often include financial incentives to serve enrollees in community settings where possible (Dominiak and Libersky 2016).

Many MLTSS programs have features that are commonplace in Medicaid managed care but can differ substantially from the Medicare Advantage program:

- Most states require at least some beneficiaries to enroll in managed care to receive their Medicaid-covered services, while enrollment in MA plans is voluntary. As a result, dual eligibles in those states may be required to enroll in an MLTSS plan for their Medicaid-covered services, but the same requirement does not apply to Medicare; for example, they can select FFS Medicare coverage or an MA plan, which may or may not be offered by the same parent company that sponsors their Medicaid plan. Some states require the sponsors of their MLTSS plans to offer a companion MA dual-eligible special needs plan so beneficiaries can receive their Medicare and Medicaid benefits from the same parent company if they wish.
- States use competitive procurements to select a limited number of plans to participate in the program. This approach increases the likelihood that all participating plans will have enough enrollment to be financially viable, helps the state obtain lower payment rates, and makes oversight of the plans easier. Medicaid generally requires states to have at least two plans available before they can require beneficiaries to enroll in managed care, and, in practice, states often contract with at least three plans to ensure that mandatory enrollment in managed care can continue even if one plan drops out. In contrast, Medicare does not limit the number of MA plans available in an area, although CMS requires all plans to satisfy a variety of requirements such as provider network adequacy standards.
- States typically have multiyear contracts with their MLTSS plans, which gives the state flexibility in deciding when to conduct its next procurement and gives plans a greater incentive to participate, offer competitive rates, and invest in care coordination. Many contracts have a base period and can be extended for an additional period by the state at its discretion. For example, the latest contract for Arizona’s MLTSS plans has a three-year base period and three optional renewals (a two-year renewal

followed by two one-year renewals) for a potential total length of seven years (Arizona Health Care Cost Containment System 2016). By comparison, the MA program uses annual contracts.

- Many states exclude some groups of enrollees from their MLTSS programs. For example, states have been slower to enroll individuals with developmental disabilities in MLTSS plans. In 2015, MLTSS accounted for 24 percent of LTSS spending for enrollees who were elderly or had physical disabilities, but only 7 percent for enrollees with developmental disabilities (Eiken et al. 2017). Partial-benefit dual eligibles are also routinely excluded from MLTSS programs. States may also initially limit their programs to certain parts of the state and expand them once they have gained experience.
- Some states may exclude or “carve out” certain services from their MLTSS programs and provide them separately. For example, MLTSS plans in a number of states exclude at least some behavioral health services. However, as Medicaid managed care programs mature, states tend to reduce the use of carve-outs and make the coverage provided by plans more comprehensive. In contrast, MA plans are required to provide all Part A and B services, except for hospice, and most plans (including all special needs plans) also provide Part D drug coverage.

Given the growth in MLTSS programs, efforts to better integrate Medicare and Medicaid in many states now take place in an environment where managed care is already being used to provide some services to dual eligibles. As a result, the development of health plans that provide both Medicare and Medicaid services is probably the most feasible approach for pursuing closer integration.

Medicare plans that serve dual eligibles differ in key respects

Although the use of managed care appears to be the most feasible route for better integrating Medicare and Medicaid in many states, this broad concept can be implemented in numerous ways. Medicare has several types of health plans that are aimed at serving dual eligibles but nonetheless differ in key respects. Comparing these plans highlights some of the issues that policymakers may want to consider if they decide to encourage the development

of highly integrated plans. However, the experience with the financial alignment demonstration also suggests that operating multiple types of plans targeted at dual eligibles at the same time can be problematic. Policy changes to better define their respective roles or consolidate them in some fashion may be needed.

In addition to MMPs, Medicare has three other types of health plans that serve dual eligibles and seek to integrate with Medicaid in some way:

- **Dual-eligible special needs plans (D-SNPs)** are MA plans that limit their enrollment to dual eligibles. (In contrast, most MA plans are open to all beneficiaries in the plan’s service area.) These plans were first offered in 2006. The authority to offer D-SNPs was initially set to expire at the end of 2008 but was extended numerous times before the Congress permanently authorized them earlier this year in the Bipartisan Budget Act of 2018. Since 2013, Section 1859(f)(3)(D) of the Medicare statute has required all D-SNPs to have contracts with states that “provide [Medicaid] benefits, or arrange for [such] benefits to be provided.”
- **Fully integrated dual-eligible (FIDE) SNPs** are a subset of D-SNPs that are more highly integrated with Medicaid than regular D-SNPs. These plans must meet a number of additional requirements to obtain the FIDE SNP designation, such as having a Medicaid contract to provide LTSS, and can receive higher payments if their enrollees have sufficiently high frailty levels. The FIDE SNP designation became available in 2012. Like regular D-SNPs, these plans have now been permanently authorized.
- **Program of All-Inclusive Care for the Elderly (PACE)** plans serve beneficiaries who are 55 or older and need the level of care provided in a nursing home. This program is not specifically targeted at dual eligibles like D-SNPs are, but, in practice, virtually all PACE enrollees are full-benefit dual eligibles. The program aims to keep people living in the community instead of nursing homes, and it uses a distinctive model of care based on adult day-care centers that are staffed by an interdisciplinary team that provides therapy and medical services. PACE plans provide all Medicare- and Medicaid-covered services. PACE is the oldest type of integrated plan; it started as a demonstration in the early 1980s and was permanently authorized in 1997.

**TABLE
9-9**
Key differences between Medicare plans that serve dual eligibles

	D-SNP			
	Regular	FIDE SNP	MMP	PACE
Authorization	Permanent	Permanent	Demonstration	Permanent
States where plan is available	41	9	9	31
Number of plans	348	45	50	124
Enrollment	1,695,074	159,158	383,047	41,079
Contracting structure	Separate Medicare and Medicaid contracts	Separate Medicare and Medicaid contracts	Single 3-way contract with CMS & state	Single 3-way contract with CMS & state
Level of integration	Varies widely but generally low	High	High	High
Share of enrollees who are partial-benefit dual eligibles	28%	<1%	<1%	<1%
Passive enrollment	Allowed for default enrollment only	Allowed for default enrollment only	Allowed	Not allowed
Plan can provide noncovered benefits	Yes, using MA rebates	Yes, using MA rebates	Yes, varies by state and plan	Yes
Medicare payment methodology	Plans bid against MA benchmarks	Plans bid against MA benchmarks	Rates are set administratively	Rates are set administratively
Plan eligible for frailty adjustment	No	Yes, if frailty levels are similar to PACE enrollees	No*	Yes
States can share Medicare savings	No	No	Yes	No
Type of quality incentive	MA quality bonus program	MA quality bonus program	Quality withhold	None

Note: D-SNP (dual-eligible special needs plan), FIDE SNP (fully integrated dual-eligible special needs plan), MMP (Medicare–Medicaid Plan), PACE (Program of All-Inclusive Care for the Elderly), MA (Medicare Advantage). Figures do not include Puerto Rico. Many states have more than one type of plan. The number of D-SNPs and FIDE SNPs are based on unique combinations of contract and plan number; the number of MMPs and PACE plans are based on unique contracts. Enrollment figures are for January 2018. The figures for the share of enrollees that are partial-benefit dual eligibles are based on enrollment data for December 2016.

*Starting in 2019, the MMPs in New York's first demonstration will be eligible for a frailty adjustment if the frailty levels of their enrollees are similar to those in PACE.

Dual eligibles can also enroll in other types of plans, such as regular MA plans and special needs plans for individuals who live in long-term care institutions or have certain chronic conditions.

The key features for each type of plan, as well as MMPs, are summarized in Table 9-9. For this comparison, the

term *regular D-SNP* refers to a D-SNP that is not a FIDE SNP. Regular D-SNPs are the most widely used type of plan, with 348 plans in 40 states and the District of Columbia covering almost 1.7 million beneficiaries in January 2018. The use of FIDE SNPs is much more limited; these are available in only 9 states and cover about 159,000 beneficiaries, with 3 states (Massachusetts,

Minnesota, and New Jersey) accounting for about 75 percent of the overall enrollment. Only 11 percent of all D–SNPs (45 of 393 plans) are FIDE SNPs. Finally, PACE plans are available in 31 states, but they are typically small, and overall enrollment has always been fairly low (now about 41,000).

The differences among the plans start with their contracting structure. All D–SNPs have a standard MA contract with CMS to provide Medicare services and a separate contract with the state that details their Medicaid responsibilities. In contrast, MMPs and PACE plans sign three-way contracts with CMS and the state that combine all of their Medicare and Medicaid responsibilities into a single document. For MMPs, each demonstration also has a contract management team (CMT) composed of state Medicaid officials and multiple CMS representatives that oversees the day-to-day management of the three-way contract. RTI found that both sides think the CMT has been “a very successful vehicle for joint oversight of MMP performance” (Chepaitis et al. 2015).

On some site visits, we asked state Medicaid officials and MMP representatives if they preferred the three-way contract over the more traditional approach of separate Medicare and Medicaid contracts. All interviewees that had an opinion preferred the three-way contract. Both states and plans said that the initial development of the three-way contract had been time consuming and challenging but that it had been easier to administer and oversee once in place. However, Medicaid officials in one state said the process for amending the three-way contract could be simplified. One plan we interviewed also said the three-way contract was helpful in getting its parent company’s Medicare and Medicaid divisions to work together more closely.

The level of integration between regular D–SNPs and Medicaid varies widely but is generally low. Since 2013, all D–SNPs have been required to have Medicaid contracts that meet certain minimum requirements. For example, the contract must specify which categories of dual eligibles can enroll, the plan’s service area, the Medicaid benefits the plan will cover, and the plan’s responsibility to provide or arrange for Medicaid benefits. However, states are not required to contract with D–SNPs to provide any Medicaid services, let alone services such as LTSS or behavioral health. Plans that do provide Medicaid services may cover only a limited subset, such as Medicare cost sharing or certain acute care services. At the same time, states that wish to achieve higher levels of integration can do so by

adding additional provisions to their D–SNP contracts (see text box on D–SNPs).²²

CMS found in 2016 that about 75,000 full-benefit dual eligibles in regular D–SNPs received all of their Medicare and Medicaid services from the same parent company and that another 75,000 received all of their Medicare services and a majority of their Medicaid services from the same company (Centers for Medicare & Medicaid Services 2017f, Centers for Medicare & Medicaid Services 2017i). Those figures indicate that only about 15 percent of the full-benefit dual eligibles in regular D–SNPs are in plans that may have a significant level of Medicaid integration.

The other three types of plans have higher levels of integration. FIDE SNPs are required to cover Medicaid LTSS services, although they are not required to cover behavioral health. They must also have a single enrollment process, an integrated model of care that covers both Medicare and Medicaid services, and coordinated Medicare and Medicaid assessment processes (Gibbs and Kruse 2016). These requirements are similar to some of the requirements for MMPs, but the level of integration in MMPs is higher because they provide all or almost all Medicaid-covered services, and more of their administrative processes have been combined. PACE is completely integrated because its plans are required to provide all Medicare and Medicaid services.

Although all four plan types serve dual eligibles, the share of enrollees who are partial-benefit dual eligibles—whose Medicaid coverage is limited to Medicare premiums and, in some cases, cost sharing—is much higher in regular D–SNPs (28 percent) than in the other plan types (less than 1 percent in each). D–SNPs can cover partial-benefit dual eligibles as long as the state agrees to it in its Medicaid contract, while MMPs cannot cover them under the terms of the demonstration.²³ Partial-benefit dual eligibles can join PACE if they meet the program’s eligibility requirements, but, in practice, very few enroll. PACE plans must provide all Medicaid-covered services to their enrollees, regardless of their actual Medicaid eligibility, and any enrollees who are not eligible for full Medicaid benefits have to pay a substantial premium equal to the plan’s monthly Medicaid capitation payment.

The plans also differ in the amount of flexibility they have to spend their Medicare and Medicaid revenues on services that are not covered by either program. Supporters of integrated plans argue that giving plans a significant degree of flexibility would result in better

Using D-SNPs to promote Medicare–Medicaid integration for dual eligibles

A number of states are using Medicare Advantage (MA) dual-eligible special needs plans (D-SNPs) as the vehicle for more closely integrating Medicare and Medicaid for dual-eligible beneficiaries. States have promoted integration by adding extra requirements to their Medicaid managed care contracts and the contracts that D-SNPs are required to sign with state Medicaid agencies. These requirements are designed to increase the number of dual eligibles who are enrolled in a D-SNP and a Medicaid managed care plan offered by the same parent company. The Integrated Care Resource Center, a technical assistance entity sponsored by CMS, reviewed the contracts in many of these states and provided some examples of these extra requirements:

- A growing number of states (at least 10 in 2018) require Medicaid plans that cover aged and disabled beneficiaries (many of whom are dually eligible) and provide long-term services and supports to offer a companion D-SNP. States may also require the D-SNP to serve the same geographic area as the Medicaid plan. These provisions ensure that all dual eligibles enrolled in Medicaid managed care can receive their Medicare benefits from the same parent company if they wish.
- A smaller number of states (at least six in 2018) do not sign D-SNP contracts with companies unless they sponsor Medicaid managed care plans in their state. This requirement eliminates any D-SNPs that do not have a companion Medicaid plan and,

when combined with the first set of requirements discussed above, creates a one-to-one relationship between a state’s Medicaid plans and its D-SNPs.

- A few states have taken additional steps to encourage dual eligibles to enroll in a D-SNP and a Medicaid plan offered by the same parent company. Massachusetts, Minnesota, and New Jersey prohibit their D-SNPs from enrolling beneficiaries who are not also enrolled in the parent company’s companion Medicaid plan, while Arizona periodically reassigns some dual eligibles to a new Medicaid plan that “matches” their D-SNP (i.e., both are offered by the same parent company).
- Some states also require their D-SNPs to provide a variety of additional information about their operations, such as encounter data, bid data, and any MA-related correspondence between CMS and the plan. This added information makes it easier for states to understand the Medicare side of their integration efforts (Verdier et al. 2016).

Although these requirements can improve the integration of Medicare and Medicaid for dual eligibles, their reach is nonetheless limited because Medicare’s freedom-of-choice provision prohibits states from requiring dual eligibles to enroll in Medicaid plans and D-SNPs from the same organization. ■

quality care because noncovered services could reduce overall costs and improve outcomes in some instances. D-SNPs have had the least flexibility and can provide noncovered services only as a supplemental benefit using rebates—the additional funding that MA plans receive if they submit a bid that is lower than the benchmark. CMS has traditionally required these supplemental benefits to be primarily health related, but D-SNPs that meet certain integration requirements can use rebates to cover additional services for individuals who have functional impairments. In addition, the Bipartisan Budget

Act of 2018 gives MA plans greater flexibility to offer supplemental benefits that are not primarily health related starting in 2020. MMPs have more flexibility than D-SNPs to spend their Medicare and Medicaid revenues on noncovered services. A state can require its MMPs to provide certain noncovered services or give each plan discretion to develop its own package of noncovered services. PACE plans have the most flexibility in this area, with broad legislative authority to spend their Medicare and Medicaid revenues on noncovered services.

The ability to passively enroll beneficiaries in each type of plan also varies. D–SNPs can passively enroll some beneficiaries using an MA provision known as “default enrollment” or “seamless conversion” that allows an insurer to automatically enroll individuals who have been in a comprehensive Medicaid managed care plan in a companion D–SNP when those individuals first become eligible for Medicare. States’ use of passive enrollment in MMPs has been a key feature of the financial alignment demonstration. PACE plans cannot use passive enrollment.

The final areas of difference among the plans are related to Medicare payment issues. Rates for D–SNPs are determined using the standard MA payment system, under which plans bid against a predetermined benchmark that CMS calculates using local FFS costs. In contrast, MMPs and PACE plans do not submit bids and are instead paid using rates that are set administratively. (The payment rates for any Medicaid services that each type of plan provides are set separately.) Payment rates for all four plan types are adjusted for differences in beneficiaries’ health status using the MA risk adjustment model. However, PACE plans receive an additional payment, known as a frailty adjustment, because the model underestimates costs for beneficiaries with functional impairments. FIDE SNPs can also receive a frailty adjustment if the frailty level of their enrollees is comparable to PACE enrollees.²⁴ MMPs are the only type of plan where states share some of the savings that the plans are expected to achieve in Medicare. D–SNP and MMP rates both include quality incentives (through the MA quality bonus program and the quality withhold, respectively), while PACE rates do not have a quality incentive.

Allowing D–SNPs and MMPs to operate in the same areas has been problematic in some states

The financial alignment demonstration has effectively given states that are testing the capitated model two ways to use managed care to better integrate Medicare and Medicaid on a large scale: D–SNPs and MMPs. Although PACE is another option, it has never been used on a widespread basis and usually covers no more than 1 percent to 2 percent of a state’s full-benefit dual eligibles.

Each participating state has allowed both plan types to operate in certain markets, but the extent to which a state relies on one type of plan versus the other varies. Some states, like Illinois and Michigan, had relatively low D–SNP enrollment before the demonstration and have

more dual eligibles enrolled in MMPs.²⁵ Other states, like California and Texas, had higher D–SNP enrollment before the demonstration and now have a significant number of dual eligibles enrolled in both types of plans. The low participation in New York’s first demonstration (which is largely due to care coordination requirements that were initially too prescriptive) has meant that D–SNPs remain the state’s predominant plan type. Finally, Massachusetts has both plan types, but they serve different populations and do not overlap (its MMPs serve dual eligibles under age 65, while its D–SNPs serve those ages 65 and older).

The availability of both plan types and differences between the MMP and D–SNP models raise the prospect that insurers and other entities such as insurance brokers may have financial incentives to favor the use of D–SNPs in some instances, which could hinder efforts to encourage dual eligibles to enroll in the more highly integrated MMPs. In some instances, allowing MMPs and D–SNPs to operate in the same areas has been problematic. To some extent, the friction between MMPs and D–SNPs was unavoidable for the demonstration since the states that were most likely to be interested in the capitated model were also likely to be states that had already developed D–SNPs. Nevertheless, the interplay between the two plan types is worth exploring since the Secretary could use CMMI’s authority to expand the use of MMPs in the future.

MMP payment rates for Part A and Part B services can be higher or lower than D–SNP rates

Payment rates for D–SNPs are determined using the same methodology that applies to all non-employer MA plans. (The only exception is the frailty adjustment that some FIDE SNPs receive.) Each plan submits a bid that indicates the amount of funding that the plan requires to provide the Part A and Part B benefit package in a given service area. CMS compares the bid with a benchmark amount for the area, which is determined administratively and equals a certain percentage of local FFS costs. Benchmarks for counties in the highest spending quartile equal 95 percent of FFS costs, while benchmarks for counties in the second, third, and fourth quartiles (with the fourth quartile having the lowest spending) equal 100 percent, 107.5 percent, and 115 percent of FFS costs, respectively. In addition, plans that have a rating of 4 stars or higher in the CMS star system for MA plans also have a bonus amount, usually 5 percent of FFS costs, added to their benchmark.

If the plan's bid is lower than the benchmark, the plan receives a payment that equals its bid plus a "rebate" that equals a percentage (between 50 percent and 70 percent, depending on the plan's star rating) of the difference between the benchmark and the bid. Plans that receive rebates must use them to provide additional benefits to their enrollees, such as lower cost sharing for Part A and Part B services or coverage of supplemental benefits. If the plan's bid is higher than the benchmark, the plan receives a payment that equals the benchmark and must charge beneficiaries a supplemental premium that equals the difference between the bid and the benchmark. (Almost all MA plans bid below their benchmarks.) Finally, the payment rates are adjusted for differences in beneficiaries' health status using the CMS-HCC risk adjustment model.

In contrast, MMPs do not submit bids; instead, CMS determines their payment rates using historical FFS and MA spending for beneficiaries who meet the demonstration's eligibility criteria. In most states, these beneficiaries were largely enrolled in FFS Medicare before the demonstration. The rates are then reduced to reflect MMPs' expected savings and to set aside funding for the demonstration's quality withhold.

During the demonstration, MMPs have benefited from a number of adjustments that increased their overall payments compared with what they would have received as D-SNPs. These adjustments have been largely temporary and have affected both the base payment rates for MMPs and how those rates are adjusted for differences in beneficiaries' health status:

- CMS has increased the MMP rates in most demonstrations (9 of 11) to account for the bad debt payments that, without the demonstration, FFS Medicare would make to providers such as hospitals for services provided to dual eligibles. MA benchmarks also include an allowance for bad debt payments, but it is smaller. This adjustment has increased the FFS component of the MMP rates in most states by about 1.75 percent.
- For 2013 and 2014, CMS "repriced" the claims that were used to measure FFS costs to reflect more current wage data for physicians and hospital employees. This adjustment increased the FFS component of MMP rates by about 3.8 percent in 2013 and 1.8 percent in 2014. Starting in 2015, CMS began making this adjustment when calculating MA benchmarks, so it now applies equally to MMPs and D-SNPs.

- CMS risk adjusts payments to MA plans based on enrollees' demographic information and diagnosis codes from their claims. These adjustments are based on experience in the FFS program, but MA plans have an incentive to submit more diagnosis codes than FFS providers because doing so increases their payments. CMS partially accounts for the effect of this additional coding by applying a "coding intensity adjustment" that reduces payments to MA plans. MMPs have the same incentive to submit more diagnosis codes, but CMS has phased in the application of the coding intensity adjustment to their payments, usually over a three-year period. (New MA plans are subject to the full coding intensity adjustment from the outset.) The rationale for the phase-in is that most MMP enrollees were coming from the FFS program and did not have any additional coding. This transition period has meant that MMPs have received higher payments during the first two years of the demonstration than they would have if they had instead entered the market at the same time as D-SNPs. The increase has varied by state but, for most MMPs, has been between 5 percent and 6 percent in the first year of the demonstration and 2 percent to 4 percent in the second year.
- In 2017, CMS began using a new risk adjustment model that raised payments to both MA plans and MMPs for full-benefit dual eligibles. However, CMS also increased MMP rates for 2016 by amounts that approximated the extra payments that the plans would receive under the new model, effectively allowing MMPs to benefit from the new model a year earlier than D-SNPs. The increase for most MMPs in 2016 was between 5 percent and 10 percent.

For this analysis, we compared MMP payment rates for Part A and Part B services with D-SNP benchmarks, which are both determined administratively by CMS. The MMP rates incorporate all of the adjustments described above. We did not account for the effects of each plan's quality incentive (i.e., we did not reduce MMP rates to account for the quality withhold or increase D-SNP benchmarks to account for the MA quality bonus) or the frailty adjustment that FIDE SNPs can receive. Table 9-10 (p. 272) shows how the relationship between MMP rates and MA benchmarks has changed over time. Since the start of the demonstration, MMP rates have declined relative to MA benchmarks as the temporary increases that CMS made to MMP rates have expired and the reductions

**TABLE
9-10****MMP payment rates have declined relative to MA benchmarks**

	2013	2014	2015	2016	2017
Number of demonstrations	1	5	9	11	11
Total enrollment	3,988	180,730	363,491	368,281	396,509
MMP rates as a share of MA benchmarks	103%	104%	103%	106%	97%
Share of MMP enrollment in counties where rates are:					
≤ 90% of MA benchmark	0%	4%	2%	0%	8%
91% to 95% of MA benchmark	1	15	7	6	18
96% to 100% of MA benchmark	21	10	21	16	38
101% to 105% of MA benchmark	52	22	31	16	32
106% to 110% of MA benchmark	26	26	34	26	4
> 110% of MA benchmark	0	25	5	36	0

Note: MMP (Medicare–Medicaid Plan), MA (Medicare Advantage). Figures are based on enrollment in December of the calendar year. Figures do not include effects of the MMP quality withhold, the MA quality bonus program, or the frailty adjustment that fully integrated dual-eligible special needs plans can receive. Components may not sum to totals due to rounding.

Source: MedPAC analysis of MMP payment rate data and MA benchmarks.

for expected savings under the demonstration have grown larger. For 2017, MMP rates were about 97 percent of MA benchmarks.

Although MMP rates are lower than MA benchmarks in the aggregate, the relationship between the two varies from county to county and over time. Since MMP rates in most states are closely tied to FFS costs, MMP rates are typically lower than MA benchmarks in counties with relatively low FFS spending, such as those where benchmarks equal 107.5 percent or 115 percent of FFS costs. For example, MMP rates were substantially lower than MA benchmarks in Virginia, where the average MMP rate in 2017 was about 100 percent of FFS costs, while the average MA benchmark was about 110 percent of FFS costs. In contrast, MMP rates can be higher than MA benchmarks in counties with relatively high FFS spending, where benchmarks equal 95 percent of FFS costs. This tendency was especially true in the early years of the demonstration, when MMP rates in these areas often exceeded 100 percent of FFS costs because the phasing in of the coding intensity adjustment and the additional payments for bad debt more than offset the reductions for expected savings. In later years, MMP rates may still

equal 95 percent to 98 percent of FFS costs when the full reduction for expected savings is made. The MMPs in these areas thus might receive lower payments if they operated as D–SNPs.

The relationship between MMP rates and MA benchmarks can also vary within a state. Illinois provides a good example. The state’s demonstration is taking place in two areas: a 6-county region that includes Chicago and a 15-county region in central Illinois. When we visited Illinois in 2016, the second full year of its demonstration, the plan representatives we interviewed said MMPs were paid better than D–SNPs in the Chicago region, where the average MA benchmark is about 95 percent of FFS costs, and worse than D–SNPs in the central Illinois region, where the average benchmark is about 109 percent of FFS costs. The demonstration has had significant problems in the central Illinois region; one of the region’s two MMPs withdrew at the end of 2015, and the remaining plan had to suspend operations in some counties for a few months in 2017 because of problems with its provider network.

Table 9-10 shows the distribution of MMP enrollment based on the relationship between MMP rates and MA benchmarks. There have been some relatively large

changes in the distribution as new demonstrations have started, overall enrollment has grown, and the various adjustments that CMS has made to MMP rates have taken effect or expired. For example, the share of enrollees living in counties where MMP rates are greater than 110 percent of MA benchmarks jumped sharply in 2016 because of the one-time increase in MMP rates to account for the effects of the new risk adjustment model. Despite the year-to-year volatility, the share of enrollment in counties where MMP rates were lower than MA benchmarks grew noticeably between 2014 and 2017, from 29 percent to 64 percent.

A full comparison of how health plans are paid when operating as MMPs or D-SNPs would need to account for several other factors. For MMP rates, we would need to account for plan performance on the quality withhold. The available data on MMP performance for the quality withhold (which is for 2014 only) suggest that, when fully implemented, the withhold will reduce MMP payments by about 1 percent, on average, although the reduction for individual plans will vary between 0 percent and 3 percent. For D-SNP rates, we would need to account for the competing effects of the quality bonus, which increases overall payments, and the bidding process, which decreases overall payments. However, our most recent analysis of the MA program suggests that the two largely offset each other: In 2018, the average benchmark for all D-SNPs without the quality bonus was about 103 percent of FFS costs, while the average payment to D-SNPs, after accounting for quality bonuses and plan bids, was 102 percent of FFS costs. Taken together, these data points suggest that our comparison of MMP rates and D-SNP benchmarks is a reasonable approximation of how overall payments for the two types of plans differ.

This comparison of MMP rates and MA benchmarks does not account for more intensive coding of beneficiary diagnoses. Both plan types have an incentive to submit more diagnoses than many FFS providers because doing so increases the plans' total Medicare payments. In MA, we have estimated that excess coding adds about 2 percent to overall MA spending (Medicare Payment Advisory Commission 2018). We have not examined the extent of excess coding by MMPs.

Competition between MMPs, regular D-SNPs, and “look-alike” plans in California

Our first example of the difficulties in having both MMPs and D-SNPs in the same area comes from California. Before the demonstration, there was a large number of

D-SNPs in the seven participating counties, and the state took several steps to encourage dual eligibles to enroll in MMPs instead:

- Companies that offer both plan types had to transfer any D-SNP enrollees who qualified for the demonstration into their MMP. These companies can continue to offer a D-SNP but can use it only for beneficiaries who do not qualify for the demonstration.²⁶
- Companies that offer a D-SNP but not an MMP can continue offering a D-SNP, and the beneficiaries in the plan were exempt from passive enrollment. However, these D-SNPs have not been allowed to enroll any new beneficiaries who qualify for the demonstration. The only new beneficiaries who can enroll are dual eligibles who do not qualify for the demonstration.
- The state is not allowing any companies to offer new D-SNPs in the counties that are part of the demonstration (California Department of Health Care Services 2014).

During one of our visits to California, several stakeholders said that many plan sponsors and enrollment brokers have opposed these restrictions. (The brokers receive commissions when they help people enroll in MA plans such as D-SNPs, but the demonstration prohibits MMPs from using brokers.) Many sponsors have circumvented the state's restrictions by offering what our interviewees referred to as “mirror” or “look-alike” plans. These plans are designed to serve dual eligibles and look like D-SNPs, but they are marketed as conventional MA plans and thus are not affected by the state's limits on D-SNPs.

The look-alike plans resemble D-SNPs because their benefit structures have many of the same distinctive features, such as a beneficiary premium for Part D coverage, the highest allowable limit on beneficiary out-of-pocket costs for Part A and Part B services, and the highest allowable deductible for Part D coverage. These features are not appealing to the broader Medicare population. The other conventional MA plans in these counties usually have no premium, a lower out-of-pocket limit, and no Part D deductible—but these features matter relatively little for dual eligibles because Part D's low-income subsidy (LIS), which all dual eligibles receive, covers their premium (LIS coverage of premiums is subject to a dollar limit, but the premiums for the look-alike plans are usually very

**TABLE
9-11**

California’s demonstration has led to a proliferation of “look-alike” MA plans that enroll dual-eligible beneficiaries

	2013	2014	2015	2016	2017
MMPs					
Number of plans	0	8	10	10	10
Enrollees	0	59,757	117,413	113,673	116,190
Share that are dual eligibles		99%	99%	98%	N/A
D-SNPs					
Number of plans	32	25	21	20	18
Enrollees	155,725	186,779	104,566	80,724	72,696
Share that are dual eligibles	97%	98%	98%	97%	N/A
“Look-alike” MA plans					
Number of plans	4	7	11	18	19
Enrollees	5,032	11,640	61,752	82,186	95,047
Share that are dual eligibles	91%	96%	97%	95%	N/A
Other MA plans					
Number of plans	119	109	121	123	120
Enrollees	905,196	960,069	1,013,621	1,041,715	1,103,697
Share that are dual eligibles	7%	8%	9%	10%	N/A

Note: MA (Medicare Advantage), MMP (Medicare–Medicaid Plan), N/A (not available), D-SNP (dual-eligible special needs plan). These figures are for the seven counties in the Cal MediConnect financial alignment demonstration (Los Angeles, Orange, Riverside, San Bernardino, San Diego, San Mateo, and Santa Clara) and do not include plans or enrollees in the rest of the state. We counted MMPs using contract numbers and all types of MA plans using the combination of contract number and plan number. Enrollment figures are for December of each year. None of the plans shown in this table serve every demonstration county. The figures for other MA plans do not include employer-sponsored plans or Program of All-Inclusive Care for the Elderly plans.

Source: MedPAC analysis of Medicare enrollment data and MA, SNP, and MMP landscape files.

close to this limit), Medicaid covers their Part A and Part B cost sharing, and the LIS covers the Part D deductible. The look-alike plans instead likely have better coverage of supplemental benefits such as dental, vision, and hearing services that Medicare and Medicaid either do not cover or cover to only a limited degree.

The use of look-alike plans has grown steadily during California’s demonstration (Table 9-11). The state’s MMPs began operation in 2014 and 2015 and covered about 116,000 beneficiaries at the end of 2017. Given the state’s restrictions on D-SNPs, enrollment in those plans has dropped sharply (from about 187,000 in 2014 to about 73,000 in 2017), and several sponsors have stopped offering them. However, the decline in D-SNP enrollment has been largely offset by growing enrollment in look-alike plans. Since 2013, the number of look-alike plans

has risen from 4 to 19, and their enrollment has risen from about 5,000 to about 95,000, which exceeds the number enrolled in D-SNPs.²⁷

The ability of plans and brokers to market look-alike plans to dual eligibles is demonstrated by the fact that almost all of their enrollees—95 percent in 2016—are dual eligibles. That figure differs little from the corresponding shares for MMPs and D-SNPs, which are limited to dual eligibles. By comparison, dual eligibles accounted for 10 percent of enrollment in the other MA plans in the counties that are part of the demonstration, and the highest share in any individual plan was less than 30 percent (data not shown).

Competition between MMPs and FIDE SNPs in New York

Operating both D-SNPs and MMPs in the same area has also been a challenge in New York’s first demonstration.

Before the demonstration, the state had developed a program that uses FIDE SNPs to integrate Medicare and Medicaid for dual eligibles who need more than 120 days of home- and community-based LTSS. The demonstration serves the same population, and many stakeholders we interviewed said this overlap had generated confusion among beneficiaries and providers about each program's respective role. The MMPs we interviewed are sponsored by companies that also offer FIDE SNPs, and the officials we met with thought that beneficiary outcomes were similar in the two products. One plan said the MMP was easier to operate in some respects (such as having an integrated enrollment process and a fully integrated system for grievances and appeals) and harder in others (more extensive reporting requirements and shorter deadlines for responding to requests for formulary exceptions for Part D drugs).

In addition, companies that offer both a FIDE SNP and an MMP have had a financial incentive to favor the FIDE SNP. FIDE SNPs receive a frailty adjustment if the frailty level of their enrollees is comparable with that of PACE enrollees. This adjustment typically increases Medicare payments by roughly 5 percent to 10 percent. There has not been any such adjustment for MMPs, so the companies that qualify for the frailty adjustment have received higher payments for their FIDE SNP than they did for their MMP. At the start of the demonstration, the FIDE SNPs also had higher Medicaid payment rates than the MMPs, but the state has since equalized them. As a result, companies that offer both plan types have had little incentive to market the MMP to eligible beneficiaries enrolled in their other products, such as traditional MA plans, regular D-SNPs, or Medicaid MLTSS plans. CMS and the state have modified the demonstration so that MMPs will be eligible for the same frailty adjustment as FIDE SNPs starting in 2019. However, it is unclear how much of an impact this change will have since that is the last year of the demonstration.

The state is currently considering how it will promote Medicare–Medicaid integration after the demonstration ends and has shown interest in consolidating the two programs in some fashion.

Competition between MMPs and regular D-SNPs in Texas

Texas has used Medicaid managed care for many years and now requires most dual eligibles to enroll in MLTSS plans to receive their benefits. For the demonstration, the

state has used the parent companies of those plans as the sponsors for its MMPs. These companies were already required to offer companion D-SNPs in certain highly populated counties, including the ones that are part of the demonstration. As a result, the parent companies of the MMPs also operate D-SNPs in the same markets.

Some observers have suggested that dual eligibles who are not enrolled in a highly integrated plan like an MMP can nonetheless get some of the benefits of better-integrated care by having separate Medicare and Medicaid plans that are sponsored by the same company. Since insurers in Texas offer both options—enrollment in an MMP alone versus parallel enrollment in a D-SNP and a companion MLTSS plan—we asked them which option was better for beneficiaries. The representatives of each plan we interviewed said the MMP was better because it uses one care coordination system to oversee all Medicare and Medicaid benefits instead of separate systems for Medicare and Medicaid that may not always work together closely. Two plans also said the MMP was a better product because of the demonstration's administrative simplifications, such as a single set of member materials and a partially integrated system for grievances and appeals.

However, the Medicare payment rates for the two products differ. The MMP rates were likely higher than D-SNP rates at the start of the demonstration, but that does not always appear to be true now that the demonstration's savings reductions and quality withhold have been fully phased in. One plan we interviewed appeared to get higher payments for its D-SNP, probably because it qualified for the MA quality bonus, and its representatives said that its D-SNP had more additional benefits than its MMP. Another plan, which did not qualify for the quality bonus, indicated that the extra benefits were slightly better in its MMP.

Texas is now reprocurring its MLTSS plans for new contracts that will start in 2020. The state's initial request for proposals (RFP) stated that, in the six demonstration counties, all MLTSS plan sponsors would be required to offer MMPs but would not be allowed to offer D-SNPs, which would have eliminated the competition and overlap between the two products (Texas Health and Human Services Commission 2017). However, some health plans opposed this requirement, and the state removed it from the RFP (Texas Health and Human Services Commission 2018). The representatives for the plans we interviewed

expressed a similar view, saying that offering both D-SNPs and MMPs would give dual eligibles more choices for their coverage. One plan noted that being able to offer a D-SNP was a particular benefit for partial-benefit dual eligibles, who cannot enroll in an MMP.

Potential policies to encourage the development of integrated plans

The Commission has previously examined managed care plans for dual eligibles in other contexts and has consistently supported the development of more highly integrated plans (see text box on managed care plans for dual eligibles, p. 280). The findings in this analysis suggest the need for a broader reassessment of the Medicare plans that serve dual eligibles. Enrollment in highly integrated plans remains low, and the plans that serve dual eligibles differ in numerous ways and may increasingly compete with each other, especially if CMMI expands the use of MMPs. Federal policymakers may want to develop a common framework for these plans by giving them more clearly defined roles or consolidating them in some fashion.

In this section, we examine three policy changes that would help support the development of integrated plans: (1) limit how often dual eligibles can change plans, (2) limit enrollment in D-SNPs to full-benefit dual eligibles, and (3) expand the use of passive enrollment. Collectively, these policies would improve care coordination and continuity of care, require D-SNPs to focus on the dual eligibles who stand to benefit from integrated care, and encourage more dual eligibles to enroll in plans with higher levels of Medicare–Medicaid integration.

Limit how often dual eligibles can change plans

Before 2006, all Medicare beneficiaries could change their health plan—by moving from FFS to a plan, moving from a plan to FFS, or moving from one plan to another plan—on a monthly basis. Since then, several “lock-in” provisions have limited how often most beneficiaries can change plans. These provisions were added to give plans stronger incentives to coordinate care for higher cost beneficiaries, prevent beneficiaries from changing plans in the middle of the year to receive additional benefits, and stabilize plan enrollment (Laschober 2005). Most beneficiaries can now change their MA or Part D plan only

once a year, during the annual enrollment period, or in certain special circumstances. For example, beneficiaries can change plans outside of the annual enrollment period if they move outside of their plan’s service area, enter a nursing home, or lose employer-sponsored coverage. However, the same lock-in provisions do not apply to dual eligibles, who until recently have been able to change their health plan on a monthly basis.

We used Medicare administrative data to see how often dual eligibles change plans compared with other beneficiaries. For this analysis, we examined beneficiaries who had Part A and Part B coverage for the entire year since beneficiaries must have both to enroll in an MA plan, an MMP, or PACE. We also excluded beneficiaries who were dual eligibles for only part of the year to simplify the comparison of dual eligibles with other beneficiaries, and because gaining and losing Medicaid eligibility are both special circumstances where beneficiaries can change plans outside of the annual enrollment period. We focused on voluntary changes and thus excluded instances where beneficiaries had to change plans because they had been in a plan that was no longer offered in their county or because they moved. We did not include instances where FFS beneficiaries changed their stand-alone Part D plan. Finally, we treated passive enrollments in MMPs as voluntary changes since beneficiaries can opt out.

In 2016, dual eligibles were more likely than other beneficiaries to change plans, but the two groups tended to make their changes at different times (Table 9-12). Dual eligibles were less likely to change plans in January, when changes that beneficiaries make during the annual enrollment period take effect.²⁸ About 3.4 percent of dual eligibles made some type of change—from FFS to a plan, from a plan to FFS, or from one plan to another plan—in that month, compared with 5.0 percent for other beneficiaries.²⁹ However, the share of dual eligibles who changed plans between February and December was much higher (7.0 percent compared with 1.3 percent of all other beneficiaries). Dual eligibles represented about 18 percent of the Medicare beneficiaries who we used in our analysis but accounted for 56 percent of the plan changes that occurred between February and December. The demonstration’s use of passive enrollment has raised the number of plan changes for dual eligibles, but figures for earlier years show the same basic pattern.

The share of dual eligibles who change plans (including opting into or out of FFS) has grown in recent years (Table 9-13, p. 278). The growth is partly due to the demonstration;

**TABLE
9-12**

Voluntary plan changes for dual-eligible and all other beneficiaries, 2016

	Dual-eligible beneficiaries		All other beneficiaries	
	Number	Percent	Number	Percent
Total beneficiaries (in thousands)	8,399	100.0%	37,335	100.0%
Voluntary changes that took effect in January 2016:				
Changed from FFS to a plan	87	1.0	606	1.6
Changed from a plan to FFS	33	0.4	232	0.6
Changed plans	<u>169</u>	<u>2.0</u>	<u>1,017</u>	<u>2.7</u>
Total	289	3.4	1,855	5.0
Voluntary changes that took effect in February to December 2016:				
Changed from FFS to a plan	253	3.0	179	0.5
Changed from a plan to FFS	111	1.3	117	0.3
Changed plans	<u>225</u>	<u>2.7</u>	<u>175</u>	<u>0.5</u>
Total	589	7.0	471	1.3

Note: FFS (fee-for-service). We defined a *plan* as a Medicare Advantage plan, cost plan, the Program of All-Inclusive Care for the Elderly, or Medicare–Medicaid Plan. The figures in this table are based on beneficiaries who had Part A and Part B coverage continuously from December 2015 to December 2016 and do not include beneficiaries who were dually eligible for only part of this 13-month period. We did not count instances where beneficiaries changed plans because their plan was no longer available in their area or they moved outside of their plan’s service area as voluntary changes. We did not include instances where FFS beneficiaries changed their stand-alone Part D plan. Components may not sum to totals because of rounding.

Source: MedPAC analysis of common Medicare environment, denominator, and plan crosswalk files.

in the counties that are part of the demonstration, the share of dual eligibles who changed plans at least once grew from 6.8 percent to 14.7 percent. However, there was also growth in the non-demonstration counties, with the share of dual eligibles who made at least one change increasing from 6.5 percent to 8.9 percent. In contrast, other beneficiaries became less likely to change plans.

Dual eligibles are also more likely than other beneficiaries to change plans multiple times during the year. In 2016, 1.7 percent of dual eligibles made two or more changes, compared with 0.3 percent for other beneficiaries (figures not shown in table). The share of dual eligibles making multiple changes has doubled since 2011. As with the share of dual eligibles who changed plans at least once, growth in the share making multiple changes was larger in demonstration counties, but there was also a noticeable increase in the non-demonstration counties.

Finally, we examined how retention rates for health plans differ by type of beneficiary (Table 9-14, p. 279). We

calculated retention rates as the number of beneficiaries who were continuously enrolled in the same plan for the entire year divided by the number who were enrolled in plans at the start of the year. For this analysis, we split the Medicare population into four groups to provide finer detail: full-benefit dual eligibles, partial-benefit dual eligibles, beneficiaries who do not receive Medicaid but qualify for the Part D LIS (who can also change plans on a monthly basis), and all other beneficiaries.

Of the four groups, the beneficiaries who did not qualify for Medicaid or the LIS (“All other beneficiaries” in Table 9-14) had the highest retention rates—almost 98 percent in both 2011 and 2016—which is not surprising since they cannot change their plan during the year except in special circumstances. The retention rates for LIS recipients were lower, at about 94 percent in 2016, but higher than the rates for dual eligibles, which suggests that this group makes less use of its ability to change plans on a monthly basis. The two types of dual eligibles had the lowest

**TABLE
9-13**

The share of dual eligibles who changed plans grew between 2011 and 2016

	Demonstration counties		Non-demonstration counties	
	2011	2016	2011	2016
Dual-eligible beneficiaries used in analysis (in millions)	1.8	2.4	4.9	6.0
Distribution of beneficiaries, based on number of voluntary plan changes:				
No change	93.2%	85.3%	93.5%	91.1%
At least 1 change	6.8	14.7	6.5	8.9
1 change	5.6	11.4	5.5	7.4
2 changes	1.1	2.8	0.8	1.3
3 or more changes	0.2	0.5	0.1	0.2
All other beneficiaries used in analysis (in millions)	7.6	8.9	24.2	28.4
Distribution of beneficiaries, based on number of voluntary plan changes:				
No change	93.5%	93.7%	93.3%	93.9%
At least 1 change	6.5	6.3	6.7	6.1
1 change	6.2	6.0	6.5	5.8
2 changes	0.3	0.3	0.2	0.3
3 or more changes	*	*	*	*

Note: "Demonstration counties" are counties that have at some point tested the capitated model under the financial alignment demonstration. We defined a *plan* as a Medicare Advantage plan, cost plan, the Program of All-Inclusive Care for the Elderly, or Medicare–Medicaid Plan. The figures in this table are based on beneficiaries who had continuous Part A and Part B coverage from the previous December through the end of the calendar year and do not include beneficiaries who were dually eligible for only part of this 13-month period. "Voluntary plan changes" can refer to switching from fee-for-service to a plan, switching from a plan to fee-for-service, or switching from one plan to another plan. We did not count instances where beneficiaries changed plans because their plan was no longer available in their area or they moved outside of their plan's service area as voluntary changes. We also did not include instances where fee-for-service beneficiaries changed their stand-alone Part D plan. Components may not sum to totals because of rounding.
*Less than 0.05 percent.

Source: MedPAC analysis of common Medicare environment, denominator, and plan crosswalk files.

retention rates in 2016, at about 87 percent for full-benefit dual eligibles and almost 90 percent for partial-benefit dual eligibles. The retention rates for full-benefit dual eligibles also declined between 2011 and 2016, with larger declines in demonstration counties.

When the lock-in provisions were first implemented, the exemption for dual eligibles was viewed as a beneficiary protection, to ensure that a group of beneficiaries who often had complex health needs would be able to change their health plan if they had difficulty seeing certain providers or obtaining services. However, health plans are now much more experienced at serving dual eligibles

than they were over a decade ago, and the implementation of the CMS–HCC risk adjustment system has reduced concerns that MA plans would avoid serving higher risk beneficiaries (McWilliams et al. 2012). On the other hand, research has found that MA enrollees who use high-cost services such as short- or long-term nursing home care are more likely to switch to FFS coverage than other MA enrollees (Rahman et al. 2015). Several MMPs we have interviewed said that allowing dual eligibles to switch plans on a monthly basis makes it harder to provide care coordination, which is most effective when there is an ongoing relationship between the beneficiary and the plan.

**TABLE
9-14**

Dual eligibles are less likely to remain in their plan than other Medicare beneficiaries

	Retention rate					
	Demonstration counties		Non-demonstration counties		All counties	
	2011	2016	2011	2016	2011	2016
Full-benefit dual eligibles	87.4%	84.2%	90.6%	88.8%	89.4%	86.6%
Partial-benefit dual eligibles	91.9	88.5	89.2	89.7	89.6	89.5
Part D low-income subsidy enrollees	94.9	93.7	95.3	94.2	95.2	94.1
All other beneficiaries	98.0	97.6	97.5	97.8	97.6	97.7

Note: "Demonstration counties" are counties that have at some point tested the capitated model under the financial alignment demonstration. We calculated retention rates as the number of people who were continuously enrolled in the same plan for the entire year, divided by the number of people who were enrolled in plans in January. We defined a *plan* as a Medicare Advantage plan, cost plan, the Program of All-Inclusive Care for the Elderly, or Medicare-Medicaid Plan. The figures in this table are based on beneficiaries who had continuous Part A and Part B coverage during the year and do not include beneficiaries who experienced any change in their Medicaid or low-income subsidy eligibility during the year. These figures do not include enrollment in stand-alone Part D plans.

Source: MedPAC analysis of common Medicare environment, denominator, and plan crosswalk files.

As a result, some lock-in provisions for dual eligibles may now be appropriate.

CMS recently issued new regulations limiting the ability of dual eligibles to change their coverage (Centers for Medicare & Medicaid Services 2018a). Under the new rules, dual eligibles can change plans only once each calendar quarter during the first nine months of the year; any requests to change plans in the last three months of the year are handled as part of the annual enrollment period and take effect the following January 1. As before, dual eligibles can also change plans under the standard MA and Part D rules that apply to all Medicare beneficiaries, such as changing plans after moving. In addition, any beneficiaries who have been assigned to a plan by CMS or a state (which most often happens when dual eligibles are automatically assigned to stand-alone Part D plans) have 90 days to switch to another plan. However, these changes will probably have little effect because the number of dual eligibles who make multiple changes to their coverage in a given year is relatively small.³⁰ We plan to monitor the effects of the new rules on the behavior of dual eligibles.

In 2008, the Commission recommended that the Congress eliminate the ability of dual eligibles to enroll in MA plans outside of the annual enrollment period unless those beneficiaries were enrolling in a special needs plan. The Commission also recommended that dual eligibles in MA plans should be allowed to return to FFS coverage at any time (Medicare Payment Advisory Commission 2008).

Limit enrollment in D-SNPs to full-benefit dual eligibles

One notable difference between D-SNPs and MMPs is their treatment of partial-benefit dual eligibles, whose Medicaid coverage is limited to assistance with the Part B premium and, in some cases, Part A and Part B cost sharing.³¹ Partial-benefit dual eligibles can enroll in a D-SNP if the state authorizes it in its Medicaid contract with the plan, and most states that have D-SNPs allow it. In contrast, partial-benefit dual eligibles cannot enroll in an MMP under the terms of the financial alignment demonstration.

Across the entire MA program in 2016, most partial-benefit dual eligibles were enrolled in conventional plans (64 percent) instead of D-SNPs (33 percent). (The reverse was true for MA enrollees who are full-benefit dual eligibles, with 63 percent in D-SNPs and 31 percent in conventional plans.)³² Although only a third of the partial-benefit dual eligibles in MA are enrolled in D-SNPs, they nonetheless account for a significant portion of overall D-SNP enrollment. Between 2012 and 2016, the number of partial-benefit dual eligibles enrolled in D-SNPs rose from 213,000 to 422,000, and, during the same period, they also grew as a share of D-SNP enrollment, rising from 20 percent to 26 percent.

The share of D-SNP enrollees that are partial-benefit dual eligibles varies widely across states. In 2016, there were nine states where partial-benefit dual eligibles represented

The Commission's previous work on managed care plans for dual eligibles

The Commission has previously examined each type of health plan that integrates Medicare and Medicaid in some manner. This earlier work has consistently supported the development of more highly integrated plans.

Dual-eligible special needs plans (D-SNPs)—In 2013, the Commission examined the role of special needs plans (SNPs), which are Medicare Advantage (MA) plans that can limit their enrollment to one of three groups of beneficiaries: dual eligibles, beneficiaries who need the level of care provided in a long-term care institution, or beneficiaries with certain chronic conditions. At the time, SNPs were authorized only through the end of 2014, but they have since been permanently authorized.

The Commission examined how well SNPs performed on quality measures compared with other MA plans and concluded that, in certain cases, SNPs were one way to better integrate care for beneficiaries with special health care needs. The Commission recommended that the Congress permanently reauthorize D-SNPs that are highly integrated with Medicaid and allow the authority for other, less integrated D-SNPs to expire (Medicare Payment Advisory Commission 2013).

Program of All-Inclusive Care for the Elderly (PACE)—In 2012, the Commission examined PACE, which serves individuals who are 55 or older and eligible for nursing home care. The program's goal is to keep people living in the community instead of long-term care facilities, and almost all enrollees are dual eligibles. The program completely integrates the financing and delivery of Medicare and Medicaid benefits and gives PACE providers strong incentives to properly coordinate and manage care.

Although research suggests that PACE improves the quality of care for its enrollees, the program has always been limited in scope and has about 41,000 enrollees. The Commission made a series of recommendations to broaden the use of PACE, including extending eligibility to people younger than 55, developing appropriate quality measures to enable PACE providers to participate in the MA quality bonus program, and establishing an outlier protection policy for new PACE providers that serve beneficiaries with unusually high costs (Medicare Payment Advisory Commission 2012b).³³

The financial alignment demonstration—In 2012, the Commission sent a letter to CMS that discussed the financial alignment demonstration, which was then being developed. In its letter, the Commission expressed support for the goals of the demonstration, including the proposed use of passive enrollment.

However, the Commission also expressed several concerns about the demonstration. One area of concern was its potential size. At the time, CMS had said it was interested in enrolling as many as 1 million to 2 million dual eligibles in the demonstration, which the Commission felt amounted to a program change instead of a demonstration. The Commission believed that the demonstration's two new models of care should be tested on a smaller scale before being used more broadly.

The Commission also suggested that the demonstration first aim to improve quality and care coordination for dual eligibles and only after that aim to reduce Medicare and Medicaid spending, and we expressed concern that states might participate in the demonstration as a way to use Medicare funds to supplement Medicaid funds (Medicare Payment Advisory Commission 2012a). ■

2 percent or less of total D-SNP enrollment. Several of these states (Arizona, Massachusetts, Minnesota, and New Jersey) have been leaders in using D-SNPs to improve Medicare-Medicaid integration and do not allow their D-SNPs to cover partial-benefit dual eligibles (Verdier et al. 2016). At the other end of the distribution were eight states

where partial-benefit dual eligibles represented more than 50 percent of total D-SNP enrollment. The figure for the state with the highest share, Alabama, was 69 percent.

Medicaid spending on partial-benefit dual eligibles is a fraction of its spending on full-benefit dual eligibles. In

2013, the most recent year of data available, Medicaid spent \$117 billion on full-benefit dual eligibles and \$2 billion on partial-benefit dual eligibles, not including spending on Medicare premiums. On a per capita basis, Medicaid spent an average of \$15,222 on full-benefit dual eligibles and \$695 on partial-benefit dual eligibles (see Table 9-1, p. 246). Medicaid coverage for partial-benefit dual eligibles is sufficiently limited that states typically exclude them from Medicaid managed care programs and continue covering them on an FFS basis.

The rationale for D-SNPs is that dual eligibles may have difficulty obtaining high-quality care because of the unique challenges of coordinating Medicare and Medicaid coverage and would thus benefit by enrolling in a specialized MA plan that is tailored to their needs instead of a regular MA plan. However, partial-benefit dual eligibles may not need a specialized MA plan given the limited nature of their Medicaid coverage. About half of partial-benefit dual eligibles receive assistance with the Part B premium only, which does not involve the MA plan at all. The other half receives assistance with both the Part B premium and Part A and Part B cost sharing, so that Medicaid functions somewhat like a medigap plan.³⁴ Some states provide a monthly capitated payment to D-SNPs to cover this cost sharing, but, even in these situations, the role of the plans is still limited, and beneficiaries still receive the same assistance with cost sharing if they are enrolled in regular MA plans. In either case, the need to coordinate Medicare's coverage with Medicaid coverage of important services such as LTSS and behavioral health simply does not exist. Policymakers may thus want to consider limiting enrollment in D-SNPs to full-benefit dual eligibles.

One objection to such a limit on D-SNP enrollment is that some partial-benefit dual eligibles will ultimately become full-benefit dual eligibles and then could benefit from the greater coordination of Medicare and Medicaid that D-SNPs provide compared with regular MA plans. However, the share of partial-benefit dual eligibles who later qualify for full Medicaid benefits is relatively small. As an example, we identified the beneficiaries who were partial-benefit dual eligibles in January 2013 and looked at subsequent changes in their Medicaid eligibility. The share of beneficiaries in this cohort who had become full-benefit dual eligibles was 6 percent in January 2014 (one year later), 9 percent in January 2015 (two years later), and 10 percent in January 2016 (three years later). Other cohorts of partial-benefit dual eligibles followed a similar pattern.

Some beneficiaries may move the other way—from full Medicaid eligibility to either partial Medicaid eligibility or no Medicaid eligibility at all. In these cases, CMS allows beneficiaries to remain in D-SNPs for up to six months if they are expected to regain their eligibility.

Another objection to limiting D-SNP enrollment is the disruption that this change would cause for the partial-benefit dual eligibles now enrolled in D-SNPs. One way to address this concern would be to give these plans' sponsors an opportunity to transfer these beneficiaries to a regular MA plan (i.e., an MA plan that is not a special needs plan).³⁵ In 2016, 93 percent of the partial-benefit dual eligibles in D-SNPs were in plans where the parent company offered a regular MA product in the same county. Plan sponsors could be required to meet certain conditions before they could transfer partial-benefit dual eligibles to a regular MA plan, such as ensuring that the provider networks for the two plans are similar and that the regular MA plan does not charge a Part D premium that exceeds the amount of Part D's low-income subsidy, which all partial-benefit dual eligibles receive.

Expand the use of passive enrollment

One major obstacle to using managed care to better integrate care for dual eligibles is that CMS and states cannot require dual eligibles to receive their Medicare and Medicaid benefits from the same parent company—through a highly integrated plan like an MMP or parallel enrollment in a D-SNP and companion Medicaid plan—because of Medicare's freedom-of-choice provision. Expanding the use of passive enrollment could be one way to encourage more dual eligibles to enroll in plans with higher levels of Medicare-Medicaid integration. Passive enrollment has been a controversial feature of the financial alignment demonstration because of the high opt-out and disenrollment rates. Nevertheless, compared with earlier demonstrations in Minnesota and Wisconsin that developed integrated plans and relied entirely on voluntary enrollment, passive enrollment has resulted in higher enrollment than most states would have been able to achieve with a purely voluntary model.³⁶

The use of passive enrollment could be expanded in ways that would affect different parts of the dual-eligible population. One variant that has received increasing attention is an option for MA plans known as default enrollment or seamless conversion. With default enrollment, a parent company that operates a comprehensive Medicaid managed care plan automatically

enrolls the individuals in that plan in a companion D–SNP when they first become eligible for Medicare. Plan sponsors must obtain both CMS and state approval before using default enrollment. Beneficiaries who do not want to enroll in their assigned D–SNP can select a different MA plan or FFS coverage.

Default enrollment can be used to encourage some dual eligibles to receive their Medicare and Medicaid services from the same parent company. Without default enrollment, individuals who are in comprehensive Medicaid plans and become eligible for Medicare often go from having one source of coverage to three: Medicare FFS coverage, a stand-alone Part D plan, and the Medicaid plan (which would continue to cover non-Medicare services such as LTSS). With default enrollment, the individual would instead be enrolled in the same company’s Medicaid plan and D–SNP. Supporters argue that default enrollment promotes care coordination and is less disruptive for beneficiaries because they are already familiar with the parent company and can largely continue seeing their existing providers since many providers accept patients for all of a given company’s products.

The use of default enrollment for dual eligibles is currently limited to about 30 D–SNPs (Centers for Medicare & Medicaid Services 2016d). Many of those plans are located in Arizona and Tennessee, which require their MLTSS plans to offer companion D–SNPs and obtain CMS approval to use default enrollment. In October 2016, CMS suspended approval of new requests to use default enrollment while it reviewed its policies on the issue (Centers for Medicare & Medicaid Services 2016e). At the time, default enrollment was also being used for individuals who were not dual eligibles, such as individuals who had commercial coverage and were being passively enrolled in regular MA plans when they qualified for Medicare. In April 2018, the agency issued new regulations limiting the use of default enrollment to individuals who are in comprehensive Medicaid managed care plans and D–SNPs (Centers for Medicare & Medicaid Services 2018a). The use of default enrollment will likely grow in the future as more states develop Medicaid MLTSS programs, where plans are often required to offer a companion D–SNP.

States that use default enrollment for dual eligibles report that opt-out and disenrollment rates are low. Both Arizona and Tennessee (which have passively enrolled about 7,000 and 5,300 dual eligibles, respectively) found that about 5 percent of beneficiaries opted out before their

passive enrollment in a D–SNP took effect and another 5 percent disenrolled within the first 3 months (Arizona Health Care Cost Containment System 2018, National Association of Medicaid Directors 2018). There have also been very few beneficiary complaints about the default enrollment process. Texas began using default enrollment in mid-2017 to enroll dual eligibles in the MMPs in its financial alignment demonstration. During our site visit there, the plan representatives we interviewed all indicated that these beneficiaries had noticeably lower opt-out and disenrollment rates than other beneficiaries who had been passively enrolled, although they did not provide any supporting data.

Default enrollment can be used for only some dual eligibles—those who qualify for Medicaid first and then for Medicare—and applies only when they first qualify for Medicare. Nevertheless, about half of all dual eligibles qualify for Medicaid first, so more widespread use of default enrollment could ultimately affect a significant number of dual eligibles.

Passive enrollment could also be used more widely for certain beneficiaries in the other half of the dual-eligible population—those who qualify for Medicare first and then for Medicaid. For example, CMS and states could use a strategy that is analogous to default enrollment for beneficiaries who are enrolled in a regular MA plan and later qualify for Medicaid. These individuals could either be automatically enrolled in the parent company’s Medicaid plan and transferred from their current MA plan to the company’s D–SNP, or they could be enrolled in an integrated plan like an MMP. The rationale for using passive enrollment in these situations would be similar to the rationale for default enrollment: improved care coordination and continuity of care. However, using passive enrollment in this manner would likely affect a much smaller number of dual eligibles than default enrollment because many companies that offer MA plans in a state may not offer a Medicaid managed care plan or a fully integrated plan like an MMP.

Finally, passive enrollment could also be used for other types of dual eligibles such as those with Medicare FFS coverage or those enrolled in MA plans where the parent company does not have any Medicaid-related plans. However, the experience with the financial alignment demonstration suggests that passively enrolling these beneficiaries would be more challenging because they would be more likely to lose access to some of their existing providers. States have tried to mitigate this

difficulty by assigning dual eligibles to MMPs that have all or most of their providers in their networks, but the effectiveness of these “intelligent assignment” efforts is somewhat limited.³⁷ Some states also needed to revise their beneficiary notices to make them easier to understand, and even then, several stakeholders we interviewed said that some dual eligibles did not realize they had been passively enrolled until after their MMP coverage had started.

Conclusion

Managed care plans that provide both Medicare and Medicaid benefits for dual eligibles could serve as a vehicle to better integrate the two programs, improve the quality of care, and reduce both federal and state spending. The development of these integrated plans has

been the primary focus of CMS’s financial alignment demonstration. Delays in completing the demonstration’s evaluations are a significant concern given the widespread interest in understanding its impact on access to care, service use, costs, and quality. Nevertheless, much of the information that is currently available, while limited, is relatively positive.

Despite the demonstration’s progress, only 8 percent of full-benefit dual eligibles are enrolled in highly integrated plans. However, more states are enrolling dual eligibles in Medicaid managed care, and interest in developing integrated plans is likely to grow. Federal policymakers may want to reexamine the array of Medicare plans (D–SNPs, FIDE SNPs, MMPs, and PACE) that serve dual eligibles. These plans differ in important respects, such as the degree to which they integrate Medicare and Medicaid, and can sometimes compete against each other. Policy changes to better define their respective roles or consolidate them in some fashion may be needed. ■

Endnotes

- 1 Activities of daily living (ADLs) include eating, using the toilet, personal hygiene, and transferring (being able to move from one setting to another, such as getting in and out of a chair). Most states require Medicaid beneficiaries to need help with two or three ADLs to qualify for nursing home care or community-based forms of long-term care.
- 2 Medicare is the primary payer for any services that are covered by both programs, such as inpatient care and physician services.
- 3 Minnesota is testing new ways to integrate Medicare and Medicaid administrative functions in its Minnesota Senior Health Options (MSHO) program, which integrates care for dual eligibles using Medicare Advantage dual-eligible special needs plans and companion Medicaid managed care plans. The MSHO program is otherwise unchanged (Centers for Medicare & Medicaid Services 2013).
- 4 None of the demonstrations that have tested integrated plans have used random selection to determine which beneficiaries participate. The available studies on integrated plans therefore compare the beneficiaries with a “control” group of dual eligibles with similar demographics and health status. However, the absence of random selection means that the two groups may differ in other, unobserved ways that affect the study’s results.
- 5 Colorado’s managed FFS demonstration had enrolled dual eligibles in a network of care coordination organizations that the state has developed to serve its Medicaid population. The state has continued to enroll dual eligibles in these organizations after the end of the demonstration, so the impact on their care should be minimal (Colorado Department of Health Care Policy & Financing 2017). Virginia has replaced its capitated demonstration with a program that requires dual eligibles to enroll in managed care for their Medicaid benefits and promotes the integration of Medicare and Medicaid by requiring the sponsors of these Medicaid plans to offer companion Medicare Advantage dual-eligible special needs plans (Virginia Department of Medical Assistance Services 2017).
- 6 CMS typically requires states to have at least two MMPs available to conduct passive enrollment. The second New York demonstration has only one MMP and has never used passive enrollment. Rhode Island also has just one MMP, but dual eligibles who had been enrolled in a Medicaid managed care plan offered by the same parent company were transferred to the MMP, a form of passive enrollment known as crosswalking. Rhode Island has not otherwise used passive enrollment.
- 7 Under the demonstration, dual eligibles can leave an MMP at any time. Beneficiaries who choose to leave remain enrolled in the MMP until the end of the month, and their new coverage starts the following month. When beneficiaries disenroll from an MMP, they can switch to FFS or enroll in an MA plan for their Medicare coverage.
- 8 We stratified beneficiaries based on the total number of months they were enrolled in an MMP, even if that crossed into other years. For example, a beneficiary who was enrolled from November 2014 through June 2015 was counted as someone who had been enrolled for a total of eight months.
- 9 These beneficiaries are “healthier” only when compared with the other dual-eligible beneficiaries who can participate in the demonstration. The risk scores in Table 9-5 (p. 253) are all well above 1.0, indicating that the dual eligibles in the demonstration are expected to be much more costly than the average Medicare beneficiary.
- 10 These studies are much older because states have largely moved in the years since to make enrollment in Medicaid managed care mandatory. Favorable selection is thus less of an issue in Medicaid managed care than it once was.
- 11 RTI has also issued annual evaluations for the first year of the demonstrations in Washington, which is testing the managed FFS model, and Minnesota, which is testing an alternate model.
- 12 The number of MMPs reporting CAHPS data is smaller than the total number of MMPs in the demonstration because plans with fewer than 600 enrollees are not required to conduct the survey.
- 13 We excluded MA enrollees in Kaiser plans from our analysis because those plans are outliers with much better performance than other plans. For example, MMPs perform poorly on potentially preventable hospital admissions when Kaiser enrollees are included in the comparison group of MA enrollees, but perform at about the same level when Kaiser enrollees are excluded. Kaiser plans account for about 6 percent of the full-benefit dual eligibles enrolled in MA plans.
- 14 The 2016 increase applied only to the MMPs. In 2017, CMS raised payment rates for all full-benefit dual eligibles, including those in MA plans, by adopting a new version of the risk adjustment model (Centers for Medicare & Medicaid Services 2016a).

- 15 For example, one core measure in the later years of the demonstration is the flu vaccination rate—the share of beneficiaries who receive a flu shot. An MMP passes the measure if its performance (1) meets or exceeds the benchmark of 69 percent or (2) improves by an amount equal to 10 percent of the difference between the benchmark and the plan’s performance in the previous year. A plan that had a vaccination rate of 50 percent in the first year could thus pass the measure in the second year if its rate were 51.9 percent or better (i.e., the previous performance of 50 percent plus 1.9 percentage points, which is 10 percent of the difference between the benchmark of 69 percent and 50 percent).
- 16 For Washington, the estimated Medicare savings for the July 2013 to December 2014 period (\$35 million) are final, while the estimated savings for 2015 (\$32 million) are preliminary.
- 17 This figure is based on December 2016 enrollment in three types of plans that we consider highly integrated—MMPs, fully integrated dual-eligible special needs plans in MA, and PACE.
- 18 The Bipartisan Budget Act of 2018 requires the Secretary to unify the grievances and appeals processes for beneficiaries in MA dual-eligible special needs plans “to the extent feasible.” It is not yet clear how the Secretary will use this authority.
- 19 These figures are based on the states that had expanded coverage as of April 2017. In November 2017, voters in Maine approved a referendum to expand Medicaid coverage, but it has not yet been implemented.
- 20 The eight states were Arizona, Florida, Massachusetts, Michigan, Minnesota, New York, Texas, and Wisconsin.
- 21 States interested in developing programs that require dual eligibles to enroll in managed care must obtain a waiver under Sections 1115 or 1915(b) of the Social Security Act. CMS can approve these waivers for up to five years. However, these waivers are almost always renewed (although they may be modified over time) and effectively amount to permanent changes in a state’s Medicaid program.
- 22 The Bipartisan Budget Act of 2018 requires D–SNPs to meet new standards for Medicaid integration starting in 2021. However, the legislation leaves it to CMS to specify how some of those standards will be implemented, and at this point it is unclear what effect the legislation will have on the level of integration in D–SNPs. Similarly, the legislation requires the Secretary to unify the separate Medicare and Medicaid grievances and appeals processes for D–SNP enrollees “to the extent feasible,” and it is unclear how this authority will be used.
- 23 MMPs have a small number of beneficiaries (about 1,100 as of December 2016) who are partial-benefit dual eligibles. These beneficiaries lost their eligibility for full Medicaid benefits after joining their plan and remained enrolled during a grace period that plans can provide to beneficiaries who are expected to regain full Medicaid eligibility.
- 24 Roughly half of FIDE SNPs qualify for a frailty adjustment in any given year. The adjustment usually increases a plan’s Medicare payments by between 5 percent and 10 percent.
- 25 Illinois has since closed its D–SNPs by exercising its right to stop signing Medicaid contracts with them. Starting in 2018, the state now relies entirely on MMPs as its platform for greater Medicare–Medicaid integration (Integrated Care Resource Center 2017).
- 26 One consequence of this policy was that the beneficiaries who had been in these D–SNPs and subsequently opted out or disenrolled from MMPs could not return to the D–SNPs. They had to choose another MA plan or FFS coverage.
- 27 Three of the 10 companies that sponsor MMPs also offered a look-alike plan in 2017. The three look-alike plans have a combined enrollment of about 38,000 beneficiaries. During our site visit, an official with one of those companies said the company had decided to offer a look-alike plan so it could retain some of the beneficiaries who were opting out or disenrolling from its MMP.
- 28 The annual enrollment period runs from October 15 to December 7, and any changes take effect on January 1. Under the 21st Century Cures Act, starting in 2019, beneficiaries enrolled in MA plans will also have an “open enrollment period” that will run from January 1 to March 31. During this time, they will be able to make one change to their coverage, such as switching to another MA plan or electing FFS coverage.
- 29 These figures are lower than the switching rates that have been published in some other studies, such as Jacobson and colleagues (2016). Our analysis included FFS beneficiaries who did not change their coverage, while other studies may be limited to beneficiaries who are enrolled in plans. As a result, the denominator for our switching rates is larger, and the switching rates are correspondingly lower.
- 30 CMS does not appear to have the authority to fully apply the MA and Part D lock-in provisions to dual eligibles. The Part D statute requires the Secretary to provide a special enrollment period for dual eligibles, so it appears that CMS can limit the added flexibility that dual eligibles have to join, leave, or switch plans, but cannot eliminate it entirely.

- 31 Some partial-benefit dual eligibles also qualify for coverage of the Part A premium if they do not have enough work history to qualify for premium-free Part A coverage.
- 32 The remaining dual eligibles, both partial benefit and full benefit, were enrolled largely in special needs plans that serve beneficiaries with certain chronic conditions.
- 33 The Commission also found that Medicare payments to PACE plans were 17 percent higher than FFS spending on comparable beneficiaries and recommended that PACE plans be paid using the standard MA payment system.
- 34 Unlike medigap plans, Medicaid allows states to limit their coverage of cost sharing for dual eligibles to the difference (if any) between the state's Medicaid rate and the Medicare payment amount. Almost all states use this approach for at least some services.
- 35 CMS allows MA plan sponsors to transfer beneficiaries to new plans at the start of each year, but this process is subject to certain limits. For example, sponsors cannot transfer beneficiaries to a different type of plan (e.g., from an HMO to a preferred provider organization), and they cannot transfer beneficiaries from a SNP to a regular MA plan. However, an exception could be made because partial-benefit dual eligibles would no longer be eligible to enroll in a D-SNP.
- 36 For example, the Minnesota Senior Health Options program had about 5,600 enrollees in 2004, seven years after it started (Kane and Homyak 2004).
- 37 States in the demonstration have typically relied on FFS Medicare and FFS Medicaid claims data to determine which MMP provider network is the "best fit" for a dual eligible. However, there is an inherent lag before these data become available, and they may not capture more recent changes in a beneficiary's providers. States have also had to decide which providers take precedence in assigning dual eligibles to a particular MMP, with some states prioritizing primary care physicians and others prioritizing LTSS providers such as personal care attendants. We have found from our site visits that any algorithm inevitably has shortcomings because the care needs of the dual-eligible population are so diverse.

References

- American Academy of Actuaries. 1996. *Medicaid managed care: Savings, access, and quality*. Washington, DC: AAA.
- Anderson W., Z. Feng, and S. Long. 2016. *Minnesota managed care longitudinal data analysis*. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.
- Arizona Health Care Cost Containment System. 2018. Comment letter on CMS notice of proposed rulemaking CMS-4182-P (Medicare program; contract year 2019 policy and technical changes to the Medicare Advantage, Medicare cost plan, Medicare fee-for-service, the Medicare prescription drug benefit programs, and the PACE program). January 16. <https://www.regulations.gov/document?D=CMS-2017-0156-1549>.
- Arizona Health Care Cost Containment System. 2016. Notice of request for proposal. Solicitation #YH18-0001. Arizona Long-Term Care System (ALTCs) Elderly & Physical Disability (E/PD) Program contract for contractors. https://www.azahcccs.gov/PlansProviders/Downloads/RFPInfo/YH18/ReqForProp/ReqForProp_Solicitation.pdf.
- California Department of Health Care Services. 2014. All plan letter 14-007. June 26. <http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2014/APL14-007.pdf>.
- Carver, G. 2016. *The beneficiary experience: November 2016*. Richmond, VA: Department of Medical Assistance Services.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018a. Medicare program; contract year 2019 policy and technical changes to the Medicare Advantage, Medicare cost plan, Medicare fee-for-service, the Medicare prescription drug benefit programs, and the PACE program. *Federal Register* 83, no. 73 (April 16): 16440-16757.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018b. Personal communication with Lindsay Barnette, Medicare-Medicaid Coordination Office, January 3.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018c. Personal communication with Lindsay Barnette, Medicare-Medicaid Coordination Office, January 25.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017a. *California Medicare-Medicaid Plan quality withhold analysis results: Calendar year 2014*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017b. *Illinois Medicare-Medicaid Plan quality withhold analysis results: Calendar year 2014*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017c. Letter from Tim Engelhardt, Director, Medicare-Medicaid Coordination Office, to MaryAnne Lindeblad, Daniel Tsai, and Marie Zimmerman. January 19.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017d. *Massachusetts Medicare-Medicaid Plan quality withhold analysis results: Calendar year 2014*. Baltimore: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017e. *Medicare-Medicaid capitated financial alignment model reporting requirements*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017f. *Medicare-Medicaid Coordination Office fiscal year 2016 report to Congress*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017g. Medicare-Medicaid financial alignment initiative. May 2017 update.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017h. *Ohio Medicare-Medicaid Plan quality withhold analysis results: Calendar year 2014*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017i. Personal communication with Jennifer Baron, Medicare-Medicaid Coordination Office, May 24.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017j. Personal communication with Lindsay Barnette, Medicare-Medicaid Coordination Office, August 11.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017k. *Virginia Medicare-Medicaid Plan quality withhold analysis results: Calendar year 2014*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016a. Announcement of calendar year (CY) 2017 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. April 4.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016b. Medicare–Medicaid capitated financial alignment model: Quality withhold technical notes (DY 2 & 3). April 29.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016c. MMP quality rating and performance data strategy update. June 15. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FinalMMPQualityRatingsStrategyUpdate061516.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016d. Seamless conversion enrollment policy and data of approved Medicare Advantage organizations. October 21. https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/Chart_of_Approved_MA_Organizations_for_Seamless_Conversion_10-2016.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016e. Seamless enrollment of individuals upon initial eligibility for Medicare. October 21.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. Letter from Tim Engelhardt, acting director of Medicare–Medicaid Coordination Office, to Kay Ghahremani et al. July 16.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. Medicare A/B payment to Medicare–Medicaid Plans participating in the financial alignment initiative for contract year 2016. November 12.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015c. Medicare–Medicaid capitated financial alignment model quality withhold technical notes (DY 1): California-specific measures. July 8. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/DY1QualityWithholdGuidanceCA.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015d. Medicare–Medicaid capitated financial alignment model quality withhold technical notes (DY 1): Illinois-specific measures. June 9. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/ILQualityWithholdGuidanceDY1.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015e. Medicare–Medicaid Plan quality ratings strategy. November 6. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FinalMMPQualityRatingsStrategy110615.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015f. Proposed changes to the CMS–HCC risk adjustment model for payment year 2017. October 28.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare–Medicaid capitated financial alignment model: Quality withhold technical notes (DY 1). June 6. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/DY1QualityWithholdGuidance060614.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. *Memorandum of understanding between the Centers for Medicare & Medicaid Services (CMS) and the state of Minnesota regarding a federal–state partnership to align administrative functions for improvements in Medicare–Medicaid beneficiary experience*. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011. State Medicaid Director letter 11–008, regarding financial models to support state efforts to integrate care for Medicare–Medicaid enrollees. July 8.

Chepaitis, A., A. Greene, S. Hoover, et al. 2015. *Report on early implementation of the demonstrations under the financial alignment initiative*. Waltham, MA: RTI International.

Colorado Department of Health Care Policy & Financing. 2017. Transition and phase-out plan for the Accountable Care Collaborative Medicare–Medicaid Program. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/COTransitionPhase-OutPlan.pdf>.

Dominiak, M., and J. Libersky. 2016. *Medicaid rate-setting for managed long-term services and supports: Basic practices for integrated Medicare–Medicaid programs*. Princeton, NJ: Mathematica Policy Research.

Eiken, S., K. Sredl, B. Burwell, et al. 2017. Medicaid expenditures for long-term services and supports (LTSS) in FY 2015. <https://www.medicaid.gov/medicaid/lts/downloads/reports-and-evaluations/ltssexpendituresffy2015final.pdf>.

- Eiken, S., K. Sredl, B. Burwell, et al. 2016. Medicaid expenditures for long-term services and supports (LTSS) in FY 2014: Managed LTSS reached 15 percent of LTSS spending. <https://www.medicaid.gov/medicaid/ltss/downloads/ltss-expenditures-2014.pdf>.
- Gattine, E., J. Fralich, M. Booth, et al. 2017. *Financial alignment initiative annual report—One Care: MassHealth plus Medicare*. Waltham, MA: RTI International.
- Gibbs, S., and A. Kruse. 2016. *State Medicaid managed long-term services and support programs: Considerations for contracting with Medicare Advantage dual eligible special needs plans*. Hamilton, NJ: Center for Health Care Strategies.
- Integrated Care Resource Center. 2017. Other state approaches to integrating Medicare and Medicaid for dually eligible beneficiaries: Implications for the New York State FIDA demonstration. https://www.health.ny.gov/health_care/medicaid/redesign/fida/mrt101/docs/2017-07-20_ICRC_FIDA_stakeholders_slides.pdf.
- Jacobson, G., T. Neuman, and A. Damico. 2016. *Medicare Advantage plan switching: Exception or norm?* Washington, DC: Kaiser Family Foundation.
- JEN Associates. 2015. *Massachusetts SCO evaluation: Nursing facility residency and mortality summary report*. Boston, MA: JEN Associates.
- Jung, H., A. Trivedi, D. Grabowski, et al. 2015. Integrated Medicare and Medicaid managed care and rehospitalization of dual eligibles. *American Journal of Managed Care* 21, no. 10 (October): 711–717.
- Justice, D., S. Holladay, T. Waidmann, et al. 2017. *Financial alignment initiative annual report: Washington health homes MFFS demonstration. First annual report*. Waltham, MA: RTI International.
- Kane, R., and P. Homyak. 2004. *Multistate evaluation of dual eligibles demonstration: Final report*. Minneapolis, MN: University of Minnesota School of Public Health.
- Laschober, M. 2005. Estimating Medicare Advantage lock-in provisions impact on vulnerable Medicare beneficiaries. *Health Care Financing Review* 26, no. 3 (Spring): 63–79.
- Lewis, E., S. Eiken, A. Amos, and P. Saucier. 2018. The growth of managed long-term services and support programs: 2017 update. <https://www.medicaid.gov/medicaid/managed-care/downloads/ltss/mltssp-inventory-update-2017.pdf>.
- Libersky, J., C. Stepanczuk, R. Lester, et al. 2016. *Medicaid managed long-term services and supports: Themes from site visits to five states*. Princeton, NJ: Mathematica Policy Research.
- McWilliams, J., J. Hsu, and J. Newhouse. 2012. New risk-adjustment system was associated with reduced favorable selection in Medicare Advantage. *Health Affairs* 31, no. 12 (December): 2630–2640.
- Medicaid and CHIP Payment and Access Commission. 2018. *Financial alignment initiative for beneficiaries dually eligible for Medicaid and Medicare*. Washington, DC: MACPAC.
- Medicaid and CHIP Payment and Access Commission. 2017. *Medicare Savings Programs: New estimates continue show many eligible individuals not enrolled*. Washington, DC: MACPAC.
- Medicaid and CHIP Payment and Access Commission. 2015. *Financial alignment initiative for beneficiaries dually eligible for Medicaid and Medicare*. Washington, DC: MACPAC.
- Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2012a. Comment letter on CMS demonstrations with states on integrated care programs for dual-eligible beneficiaries. July 11.
- Medicare Payment Advisory Commission. 2012b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2008. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission. 2018. *Data Book: Beneficiaries dually eligible for Medicare and Medicaid*. Washington, DC: MedPAC and MACPAC.
- National Association of Medicaid Directors. 2018. Comment letter on CMS notice of proposed rulemaking CMS–4182–P (Medicare program; contract year 2019 policy and technical changes to the Medicare Advantage, Medicare cost plan, Medicare fee-for-service, the Medicare prescription drug benefit programs, and the PACE program). January 16. <https://www.regulations.gov/document?D=CMS-2017-0156-1554>.
- Paradise, J. 2017. *Data note: Medicaid managed care growth and implications of the Medicaid expansion*. Washington, DC: Kaiser Family Foundation.

- Ptaszek, A., A. Chepaitis, A. Greene, et al. 2017. *Beneficiary experience: Early findings from focus groups with enrollees participating in the financial alignment initiative*. Durham, NC: RTI International.
- Rahman, M., L. Keohane, A. Trivedi, and V. Mor. 2015. High-cost patients had substantial rates of leaving Medicare Advantage and joining traditional Medicare. *Health Affairs* 34, no. 10 (October): 1675–1681.
- Saucier, P., J. Kasten, B. Burwell, et al. 2012. The growth of managed long-term services and supports (MLTSS) programs: A 2012 update. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/mltssp_white_paper_combined.pdf.
- SCAN Foundation. 2017. The promise of coordinated care. <http://www.thescanfoundation.org/promise-coordinated-care>.
- Schmitz, R., A. Merrill, J. Schore, et al. 2008. *Evaluation of Medicare Advantage special needs plans*. Report prepared by Mathematica Policy Research for the Centers for Medicare & Medicaid Services. Princeton, NJ: Mathematica Policy Research.
- Scholle, S., K. Kelleher, G. Childs, et al. 1997. Changes in Medicaid managed care enrollment among children. *Health Affairs* 16, no. 2 (March/April): 164–170.
- Texas Health and Human Services Commission. 2018. Solicitation addendum #4 for solicitation #HHS0000428. https://checkout.na1.netsuite.com/core/media/media.nl?id=10773829&c=852252&h=cf0616cd7e441e58edde&_xt=.pdf.
- Texas Health and Human Services Commission. 2017. Request for proposals for STAR+PLUS. RFP #HHS0000428. <http://www.txsmartbuy.com/sp/HHS0000428>.
- Verdier, J., A. Kruse, R. Lester, et al. 2016. *State contracting with Medicare Advantage dual eligible special needs plans: Issues and options*. Washington, DC: Integrated Care Resource Center.
- Virginia Department of Medical Assistance Services. 2017. Commonwealth Coordinated Care (CCC) phase-out plan. http://www.dmas.virginia.gov/Content_atchs/altc/Phase-Out%20Plan2.pdf.
- Walsh, E., W. Anderson, A. Greene, et al. 2013. *Measurement, monitoring, and evaluation of state demonstrations to integrate care for dual eligible individuals. Aggregate evaluation plan: Executive summary*. Waltham, MA: RTI International.
- Weiner, J., G. Khatutsky, N. Thach, et al. 2017. *Early findings on care coordination in capitated Medicare–Medicaid Plans under the financial alignment initiative*. Waltham, MA: RTI International.
- Weiser, R., and M. Gold. 2015. *Demonstrations to improve the coordination of Medicare and Medicaid for dually eligible beneficiaries: What prior experience did health plans and states have with capitated arrangements?* Washington, DC: Kaiser Family Foundation. <http://files.kff.org/attachment/report-demonstrations-to-improve-the-coordination-of-medicare-and-medicaid-for-dually-eligible-beneficiaries>.
- Wilkin, J., L. Zhao, T. Trapnell, et al. 2017a. *Preliminary savings report for Colorado managed fee-for-service (MFFS) demonstration period 1: Medicare–Medicaid financial alignment initiative*. Waltham, MA: RTI International.
- Wilkin, J., L. Zhao, T. Trapnell, et al. 2017b. *Report for Washington managed fee-for-service (MFFS) final demonstration year 1 and preliminary demonstration year 2 Medicare savings estimates: Medicare–Medicaid financial alignment initiative*. Waltham, MA: RTI International.

CHAPTER

10

**Medicare coverage policy
and use of low-value care**

Medicare coverage policy and use of low-value care

Chapter summary

Some researchers contend that a substantial share of Medicare dollars is not spent wisely. Many new services disseminate quickly into routine medical care in fee-for-service (FFS) Medicare with little or no basis for knowing whether or to what extent they outperform existing treatments. In addition, there is substantial use of low-value care—the provision of a service that has little or no clinical benefit or care in which the risk of harm from the service outweighs its potential benefit.

In this chapter, we review the coverage processes used in FFS Medicare and by Medicare Advantage (MA) plans and Part D sponsors. FFS Medicare covers many items and services without the need for an explicit coverage policy. When an explicit coverage policy is required, some services do not show that they are better than existing covered services. Coverage policies are often based on little evidence and usually do not include an explicit consideration of a service's cost-effectiveness or value relative to existing treatment options.

MA plans are generally required to provide the same set of benefits that are available to beneficiaries under FFS Medicare. However, MA plans are permitted to use tools that are not widely used in FFS Medicare, such as requiring providers to obtain prior authorization to have a service covered and controlling utilization through the use of cost sharing. Part D plan sponsors

In this chapter

- Primer on Medicare coverage policy
- Evidence of low-value care
- Tools for addressing low-value care
- Conclusion

are responsible for creating and managing formularies, which are lists of drugs their plans cover. By contrast, Medicare FFS lacks the flexibility to use formularies for drugs that Part B covers.

We also review the literature on low-value care, which reveals that such care is prevalent across FFS Medicare, Medicaid, and commercial insurance plans. Evidence suggests that the amount of low-value care in a geographic area is more a function of local practice patterns than payer type.

We analyzed selected low-value services in FFS Medicare using 31 evidence-based measures. In 2014, there were between 34 and 72 instances of low-value care per 100 beneficiaries, depending on whether we used a narrow or broad version of each measure. Between 23 percent and 37 percent of beneficiaries received at least one low-value service, and annual Medicare spending for these services ranged from \$2.4 billion to \$6.5 billion. The spending estimates are conservative because they do not reflect the downstream cost of low-value services (e.g., follow-up tests and procedures).

We examined three case studies of care of potentially low value in FFS Medicare: the trend in starting dialysis earlier in the course of chronic kidney disease, proton beam therapy, and H.P. Acthar Gel[®] (Acthar, a drug covered under Part D). The timing of starting dialysis for end-stage renal disease is a matter of clinical judgment, guided by values of residual kidney function and symptoms and comorbidities present in affected patients. Between 1996 and 2010, there was a trend toward initiating dialysis earlier in the course of chronic kidney disease. Since 2011, this trend has moderated because of the availability of comparative clinical evidence showing that the early initiation of dialysis is not associated with improved outcomes. We estimate that dialysis spending in 2016 for FFS Medicare patients who initiated treatment with higher levels of kidney function (i.e., earlier in the course of chronic kidney disease) ranged from \$500 million to \$1.4 billion.

Proton beam therapy—a type of external beam radiation therapy used primarily for cancer treatment—was initially used for pediatric cancers and rare adult cancers. However, its use has expanded in recent years to include more common conditions, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Medicare’s payment rates are substantially higher for proton beam therapy than other types of radiation therapy. From 2010 to 2016, spending and volume for proton beam therapy in FFS Medicare grew rapidly, driven by a sharp increase in the number of proton beam centers and Medicare’s relatively broad coverage of this treatment. During that

period, spending rose from \$47 million to \$115 million. Prostate cancer was by far the most common condition treated by proton beam therapy in Medicare.

Acthar is an older, Part D–covered drug that has experienced rapid growth in price and Medicare spending over the last several years, despite weak evidence that it is effective for adult indications. Between 2001 and 2017, the average price per vial increased from \$748 to \$38,000. Between 2011 and 2015, Medicare spending for Acthar increased from \$49 million to \$504 million. Fewer than 2,000 clinicians prescribed Acthar to beneficiaries in 2015, and 71 percent of them received at least one nonresearch payment from the manufacturer of Acthar related to the drug. These financial relationships raise questions about conflicts of interest among prescribers of Acthar.

Finally, we discuss six tools that Medicare could consider using to address the use of low-value care.

- Expanding prior authorization, which requires providers to obtain approval from a plan or payer before delivering a product or service, could help reduce the use of low-value care. Although CMS has tested this approach to reduce unnecessary use of power mobility devices, nonemergent ambulance transports, and hyperbaric oxygen therapy, it has not been widely adopted by Medicare.
- Implementing clinician decision support and provider education could decrease low-value care, and studies show that these tools have reduced inappropriate prescribing of antibiotics.
- Increasing cost sharing for low-value services has the potential to reduce their use. Although Medicare does not currently do so, other health plans and payers have raised cost sharing for targeted low-value services, and an evaluation of one program found that it reduced the use of these services.
- Establishing new payment models that hold providers accountable for the cost and quality of care—such as accountable care organizations (ACOs)—creates incentives for organizations to reduce low-value services. Preliminary evidence indicates that Pioneer ACOs (which shared in both savings and losses) were able to reduce low-value care.
- Revisiting coverage determinations on an ongoing basis has the potential to both decrease use of low-value services and result in the development of more rigorous clinical evidence. However, Medicare infrequently revisits its national coverage determinations. Moreover, nearly all of the reconsiderations that

Medicare opened over the past five years have been at the request of external parties (e.g., manufacturers, physicians, and medical associations) and have resulted in expanding coverage for the service under consideration.

- Linking information about the comparative clinical effectiveness and cost-effectiveness of health care services to FFS coverage and payment policies has the potential to improve the value of Medicare spending. Medicare's coverage process considers, but does not require, comparative clinical effectiveness evidence, and the program's rate-setting processes generally do not consider such evidence. For most items and services, Medicare lacks statutory authority to consider evidence on cost-effectiveness in either the coverage or the payment process. ■

**TABLE
10-1**

Overview of Medicare’s coverage processes for Part A and Part B services

	Type of coverage policy	Who develops policy	Where policy applies
Existing billing code or bundled payment system	Explicit policy may not be necessary if service is in existing code or bundle	CMS	Nationwide (binding on all contractors)
NCD	Explicit policy	CMS	Nationwide (binding on all contractors)
Program manuals and memos	Explicit policy	CMS	Nationwide (binding on all contractors)
LCD	Explicit policy that can apply to a service that existing NCDs do not address or policy that further defines an NCD	Medicare’s contractors (medical directors)	Contractor’s regional jurisdiction; policy for a given service can vary across regions

Note: NCD (national coverage determination), LCD (local coverage determination).

Source: MedPAC analysis of the statute and CMS program manuals and guidance.

Primer on Medicare coverage policy

Medicare provides coverage for a broad range of health care services under its Part A, Part B, Part C, and Part D programs, as enumerated in Title XVIII of the Social Security Act. For Part A and Part B services furnished in fee-for-service (FFS) Medicare, the statute requires that the program cover items and services that are included in a Medicare benefit category, are not statutorily excluded, and are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Although the statute sets forth the broad categories of benefits covered by Medicare, neither the statute nor the regulations provide an all-inclusive list of the specific items and services that are reasonable and necessary.

Medicare coverage decisions for most Part A and Part B services are made at both the national level (by CMS) and local level (by Medicare’s administrative contractors). However, many services do not require an explicit coverage determination, such as services paid through CMS’s prospective payment mechanisms. Medicare is not required to consider comparative clinical effectiveness evidence in the coverage process, and the program lacks

explicit statutory authority to consider a service’s cost-effectiveness or value when making coverage decisions.

Under Part C, Medicare Advantage (MA) plans are required to provide the same set of benefits that are available under FFS Medicare, except that FFS Medicare covers hospice care and covers certain services associated with clinical trials under Medicare’s Clinical Trials Policy for MA enrollees. However, MA plans are permitted to use medical management tools not available in FFS Medicare, such as requiring providers to seek prior authorization to have a service covered. Plans also have leeway in controlling utilization through beneficiary cost sharing.

Part D plan sponsors are responsible for creating and managing formularies, which are lists of drugs their plans cover. Part D law and regulations place some constraints on which drugs plan sponsors may cover and how those sponsors operate their formularies. By contrast, Medicare FFS lacks the flexibility to use formularies for drugs that Part B covers.

Medicare coverage for Part A and Part B items and services

As summarized in Table 10-1, there are several ways for services to be covered under FFS Medicare. Medicare coverage occurs for many Part A and Part B items and

services without the need for an explicit coverage policy. If a service falls under a Medicare benefit category and can be reimbursed on the basis of an existing billing code or a bundled payment system (e.g., inpatient prospective payment system), Medicare may cover it without an explicit coverage policy.

When an explicit coverage determination is required, CMS and Medicare administrative contractors (MACs) develop policies at the national and regional level, respectively, to determine whether a service meets one of the covered benefit categories and is reasonable and necessary, in which case, it is covered. MACs develop the majority of explicit coverage policies. These policies, referred to as local coverage determinations (LCDs), determine coverage of specific medical services that apply only in the contractor's regional jurisdiction. LCDs must be consistent with the statute, regulations, and national policies for coverage, payment, and coding.

In addition to the LCD process, CMS develops coverage determinations for specific medical services that apply nationwide through the national coverage determination (NCD) process. A small subset of NCDs links a service's national coverage to participation in an approved clinical study or to the collection of additional clinical data. This policy is referred to as coverage with evidence development (CED), and its goal is to expedite early beneficiary access to innovative technology while ensuring that patient safeguards are in place. The process of developing both LCDs (that are new or have undergone major revision) and NCDs provides opportunities for public comment, and both types of coverage determinations are available in the Medicare Coverage Database on CMS's website.

LCDs and NCDs have similarities (both specify the clinical conditions for which a service is considered to be reasonable and necessary, and both are developed either in response to requests from external parties or internally) and differences, particularly in their scope and flexibility. LCDs are applicable only to services furnished in the MAC's geographic area, while NCDs are applicable nationwide to all services. LCDs permit regional flexibility, are more responsive (compared with NCDs) to community care standards, and allow initial diffusion of new technologies (Jensen 2014). However, there is concern that LCDs result in inequitable variations in coverage across regions (Government Accountability Office 2003).

The national and local processes are not the only means by which Medicare develops and publishes coverage policies. Policies affecting the coverage of services are also published in Medicare's provider manuals and program memorandums, which are often based on the statute or regulations. CMS develops these policies, which apply nationwide to all contractors. Medicare's coding requirements may also implicitly affect the coverage of services.

Over time, Medicare's benefit categories have been expanded to allow reasonable and necessary determinations. For example:

- Beginning in 1994, the Omnibus Budget Reconciliation Act of 1993 expanded Section 1861 of the Social Security Act by covering Part B cancer drugs for indications not approved by the Food and Drug Administration (FDA) if the drug's off-label use is supported by selected third-party drug compendia.
- Beginning in 2000, an executive memorandum directed Medicare to cover the routine costs of qualifying clinical trials and cover services and items that are reasonable and necessary items to diagnose and treat complications due to participation in clinical trials.
- Beginning in 2005, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed Medicare to cover the routine costs of care furnished to Medicare beneficiaries in certain categories of investigational device exemption (IDE) studies.
- Beginning in 2008, the Medicare Improvements for Patients and Providers Act of 2008 gave Medicare the authority to cover selected new preventive services through the NCD process.

Although Section 1862(a)(1)(A) of the Social Security Act requires that a service covered by Medicare be "reasonable and necessary," the statute does not define this criterion. CMS and its contractors generally interpret this section to include services that are judged to be safe and effective, not experimental, and appropriate for the beneficiary's medical needs. CMS has operationalized the following definition of the reasonable and necessary standard: "Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population" (Jensen 2014).

In 1989 and 2000, CMS sought public comments on revising the coverage process that would have considered

Medicare's proposals to consider cost-effectiveness in the coverage process

On two occasions, Medicare tried to interpret the statute's (Section 1862 of the Social Security Act) requirement that Medicare pay only for services that are reasonable and necessary. In 1989, the agency issued a proposed regulation that explicitly considered the cost-effectiveness of services in the coverage process. The proposed rule was never finalized, with stakeholders arguing that the agency could not use criteria for coverage that extended beyond clinical evidence and that the statute did not permit the agency to deny coverage based on cost-effectiveness. In 2000, CMS released a notice of intent (NOI) on new criteria that would have considered cost in the coverage process only for services that provided equivalent clinical benefits compared with an existing covered service but that were more costly. As with the 1989 proposed rule, the new criteria included in the NOI were not finalized.

The 1989 proposed regulation to consider cost-effectiveness in the coverage process

In January 1989, CMS—then the Health Care Financing Administration—released a proposed rule that would have established in regulation criteria to determine whether a health care service was “reasonable and necessary” and therefore covered. The proposed rule sought to add cost-effectiveness to the criteria used in the coverage process to address the increasing availability of new, costly technology, stating, “We believe considerations of cost are relevant

in deciding whether to expand or continue coverage of technologies, particularly in the context of the current explosion of high cost technologies” (Health Care Financing Administration 1989).

According to the proposed methodology, a service would have been considered cost-effective if:

- it was less costly and at least as effective as an alternative covered technology;
- it was more effective and costlier than a covered alternative, but improved health outcomes to justify additional expenditures; or
- it was less effective and less costly than an existing alternative for some beneficiaries but was a viable alternative for others.

CMS proposed implementing the following methodology to determine whether a service or technology was cost-effective:

- Identify the relevant alternative technologies to which the current intervention is to be compared.
- Identify all relevant outcomes from the alternative technologies and, when possible, quantify them (e.g., clinical outcomes, reduced morbidity and mortality, or qualitative outcomes).
- Identify all relevant costs expected (both Medicare and non-Medicare) from the interventions,

(continued next page)

a service's medical benefit and value. In 1989, Medicare formally proposed the use of cost-effectiveness as one of several criteria in its coverage process. In 2000, CMS issued a notice of intent to publish a proposed rule, which outlined an approach to develop coverage decisions that would have assessed a service's medical benefit (i.e., comparative health benefit) and added value (as assessed by total costs, not cost-effectiveness). Taking note of comments from stakeholders, including medical providers and manufacturers, the agency did not finalize

either approach. Consequently, neither the NCD process nor the LCD process considers a service's cost or cost-effectiveness. The text box provides additional detail about Medicare's proposal to consider cost-effectiveness and value in the coverage process.

National coverage determination process

An NCD is a determination by the Secretary (i.e., CMS's Coverage and Analysis Group) as to whether an item or service is covered nationally by Medicare. Essentially, an

Medicare's proposals to consider cost-effectiveness in the coverage process (cont.)

including direct medical costs or savings and indirect costs.

- Consider unquantifiable factors.

According to the proposed rule, cost-effectiveness would not always be used in the coverage process. For example, if a breakthrough technology had no comparable alternative, there would be no comparative

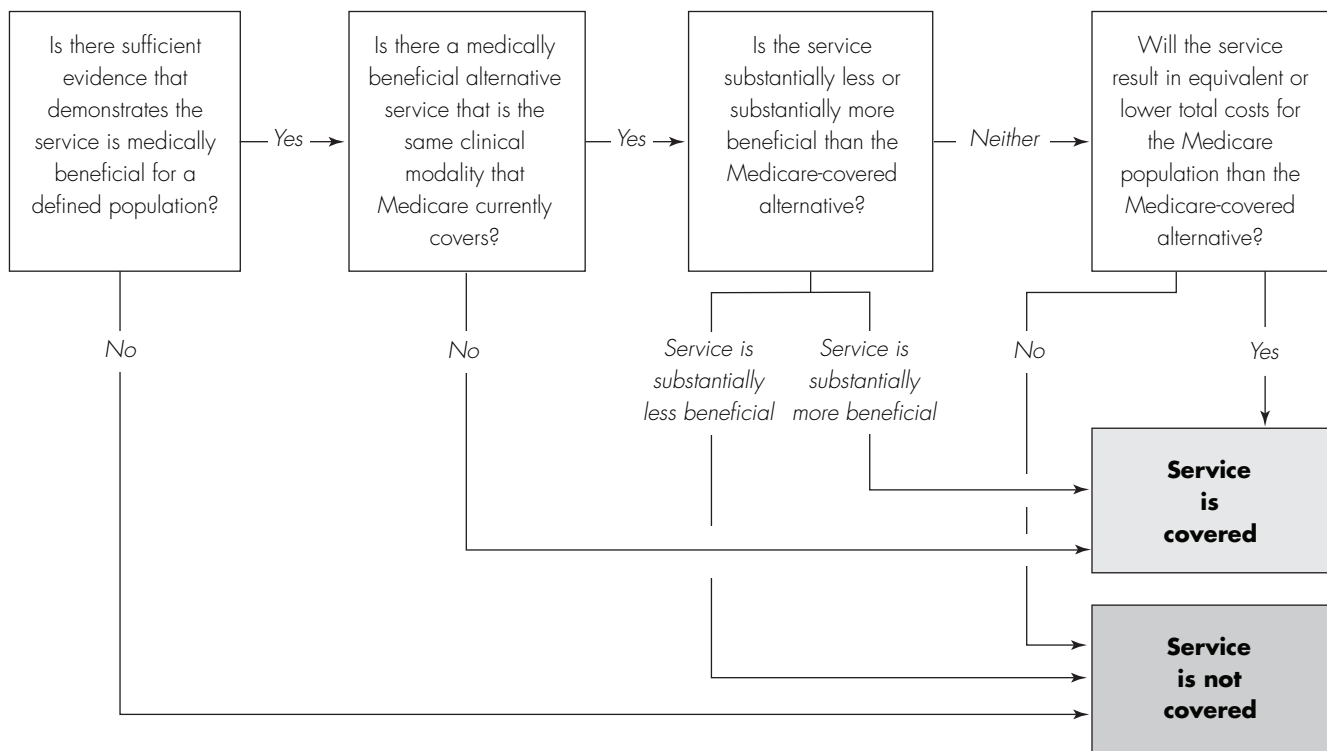
analysis to other available technologies since none existed (Health Care Financing Administration 1989).

Stakeholders, including medical providers and the medical device industry, argued that (1) cost had no role in the coverage process, (2) CMS could not use criteria for coverage that extended beyond what medical experts thought was reasonable and necessary

(continued next page)

FIGURE 10-1

2000 NOI proposed criteria for making coverage decisions



Note: NOI (notice of intent).

Source: MedPAC analysis of notice of intent to publish a proposed rule on criteria for making coverage decisions, Health Care Financing Administration 2000.

NCD is a policy statement that allows Medicare coverage of a particular service with or without clinical conditions (including coverage with evidence development); leaves the determination to the discretion of the MACs; or precludes Medicare coverage.

Because NCDs are developed by CMS, they do not vary from region to region and are thus binding on all of the program's contractors, including MACs, durable medical equipment regional contractors, quality improvement organizations, program safeguard contractors, and

Medicare's proposals to consider cost-effectiveness in the coverage process (cont.)

for an individual's medical need, and (3) the statute did not permit the agency to deny coverage based on whether a service was or was not cost-effective (Pear 1991). Some stakeholders feared the use of cost-effectiveness was a move toward rationing health care (Neumann 2005). CMS did not finalize the proposed rule, which was formally withdrawn in the late 1990s.

The 2000 notice of intent to consider the notion of added value in the coverage process

In May 2000, CMS released an NOI that sought public comments on criteria to determine whether a service was reasonable and necessary under the coverage process if it met the following criteria: The service had to demonstrate medical benefit, and the service had to demonstrate added value to beneficiaries. According to the NOI, cost would be considered in the coverage process in certain circumstances to determine whether a service demonstrated "added value." As shown in Figure 10-1, consideration of cost would have been limited to instances in which two services had equivalent health outcomes and were of the same clinical modality.

CMS provided the following examples of situations in which a service, compared with the current mix of services, would add value and be covered:

- a medically beneficial breakthrough technology;
- a medically beneficial service if no other medical alternative exists;
- a medically beneficial service that is different in clinical modality from the existing item or service;
- a medically beneficial service, even if a less expensive alternative exists but is not included in a Medicare benefit; and

- a medically beneficial item or service that is the same clinical modality as a Medicare-covered alternative and has equal or lower total costs for the Medicare population.

Under the NOI, a service that has equivalent health outcomes and the same clinical modality but is more expensive than a Medicare-covered alternative would not be covered (Figure 10-1).¹ In determining coverage under these criteria, CMS would not compare an item or service that falls within a statutory benefit category with one that is outside the scope of the Medicare program.

The NOI also discussed coverage of a new service that is "substitutable" for a Medicare-covered alternative. The agency sought comments about whether, if the substitutable service has greater total costs to the Medicare program, it should deny coverage but allow the requestor through the reconsideration process to alter the request to seek a positive coverage decision. Another option would be to cover the new service but reduce the payment rate to the same rate as the Medicare-covered alternative (i.e., a least costly alternative policy). Finally, the NOI said that the Medicare program should move toward measuring "quality of life outcomes," and requested public comment on the metric that should be used in the coverage process to quantify this measurement, such as quality-adjusted life years and disability-adjusted life years.

Like the 1989 proposed regulation, stakeholders raised concerns about the NOI, and CMS did not release it as a proposed rule (Foote 2002). While the NOI did not explicitly include cost-effectiveness as a criterion for coverage, some stakeholders perceived that the added-value criterion implied such an analysis (Foote 2002). ■

administrative law judges during the claim appeal process. Since October 2001, NCDs have been binding for MA plans. NCDs take precedence over LCDs that exist on the same clinical topic.

Generally, substantive changes to Medicare policy (e.g., changes in payment policy) are required to go through the notice and comment rule-making procedures. However, NCDs have a separate process to get public

**TABLE
10-2**

Total number of NCDs considered by CMS, by fiscal year, 2006–2016

	Fiscal year										
	2006	2007	2008 ^a	2009	2010	2011	2012	2013	2014	2015	2016
New NCD, covered ^b	1	0	2	3	2	4	5	1	1	3	2
New NCD, noncovered	4	3	3	5	3	0	0	0	0	0	0
New NCD, coverage linked to clinical trial or registry	1	0	0	0	0	1	0	0	1	1	0
New NCD, contractor discretion	0	0	2	0	0	1	0	0	0	0	0
Reconsideration	11	9	6	1	7	5	0	5	3	1	2
Total	17	12	13	9	12	11	5	6	5	5	4
Days elapsed until NCD implementation ^c	81 days	114 days	126 days	127 days	118 days	72 days	81 days	132 days	160 days	245 days	301 days

Note: NCD (national coverage determination). In fiscal year 2007, one NCD did not meet the benefit category definition of durable medical equipment. “Days elapsed until NCD implementation” is an average.

^a In 2008, CMS completed a national coverage analysis for one service, but the agency determined that no NCD was appropriate at the time.

^b Includes NCDs that specified the clinical conditions for which a service is covered, NCDs that are based on existing LCDs, and NCDs that maintained current covered clinical indications.

^c Days elapsed from date of final NCD posted on CMS website (i.e., policy effective date) to date of published implementation instructions.

Source: Commission analysis of information from CMS’s reports to Congress on national coverage determinations between fiscal year 2006 and fiscal year 2016.

comments. The MMA requires that CMS provide a 30-day public comment period after a proposed determination is published. In most instances, CMS also provides opportunities for public input when the NCD process begins.

The NCD process is used less frequently than the local coverage process. As shown in Table 10-2, between fiscal years 2006 and 2016, the number of NCDs that CMS considered ranged from 4 to 17 in a given year. In August 2017, CMS’s website listed roughly 300 active NCDs in its database. By contrast, there were nearly 1,000 final LCDs in Medicare’s online database.² CMS makes fewer NCDs than LCDs because:

- most services do not meet the criteria for CMS to initiate an NCD;

- limited resources can affect CMS’s ability to initiate more NCDs; and
- manufacturers and providers may be apprehensive about requesting an NCD because they perceive that the decision could result in an “all or nothing” scenario in terms of their ability to obtain Medicare payment, and thus they are more likely to pursue LCDs.

A negative NCD can be especially problematic for providers and manufacturers of a service for which Medicare constitutes a large share of the market. However, NCDs are often written for a specific clinical indication of an item or service and can be modified once new clinical information is available.

The NCD process A new NCD is triggered by a request from an external party, including beneficiaries, manufacturers, clinicians, or medical associations; from one of Medicare’s administrative contractors; or by CMS staff. Circumstances that can prompt the agency to initiate an NCD include the following:

- Practitioners, patients, or other members of the public have raised significant questions about the outcomes attributable to the use of items or services for beneficiaries.
- New evidence or reinterpretation of existing evidence indicates that an NCD may be warranted.
- LCDs for a particular item or service vary among the MACs.
- The technology represents a substantial clinical advance and is likely to result in a significant improvement in outcomes or positive impact on the Medicare program.
- Rapid diffusion of an item or service is anticipated, and the evidence does not adequately address questions about the impact on beneficiaries.

NCDs are most commonly requested by manufacturers or individuals who are interested in expanding existing coverage (Tunis et al. 2011). After initiating an NCD, CMS releases a tracking sheet on its website that describes the issue being considered and the actions that have been completed. The agency also opens an initial 30-day public comment period on the topic. After conducting a formal review of the evidence, CMS posts a proposed decision memorandum that provides the agency’s evaluation of the service and opens a second 30-day request for public comments. CMS’s evidence review can be informed by a technology assessment—a systematic analysis of the performance characteristics, safety, effectiveness, outcomes, and appropriateness of a service—from an external entity such as the Agency for Healthcare Research and Quality (AHRQ).³ In addition, CMS can consult with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), an advisory group that was established by the Secretary in 1998 to supplement the agency’s clinical expertise and allow for public input and participation.⁴ MEDCAC consists of experts in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics.

CMS posts final NCDs online in the agency’s NCD manual along with a decision memorandum that summarizes public comments and CMS’s responses to those comments and the scientific basis for the coverage determination (e.g., an analysis and summary of the evidence considered). Under the time frames that the MMA established for developing NCDs, CMS must:

- issue a proposed NCD within 6 months of the request date for an NCD that does not require a technology assessment from an outside entity or deliberation from MEDCAC or within 9 months for a policy that does require an assessment or deliberation from MEDCAC and
- issue a final NCD 60 days after the end of the public comment period.

Researchers have raised concerns about the lack of high-quality evidence that is available when Medicare develops coverage determinations (Chambers et al. 2015b, Foote et al. 2004, Mohr 2012, Neumann et al. 2008, Redberg 2007). For example, between 2009 and 2013, the evidence considered in NCDs was judged by CMS to be “fair” or “poor” for 81 percent of the services evaluated and “good” for only 19 percent of the services evaluated (Chambers et al. 2015b). These researchers did not identify any changes in the quality of evidence that the agency considered in the NCD process during three time periods analyzed (1999 to 2003, 2004 to 2008, and 2009 to 2013). These researchers also found that, between 1999 and 2013, NCDs were more likely to cite the lack of relevant outcomes and the lack of applicability of study results to the Medicare population as limitations of the supporting evidence.

Reconsideration and challenge of an NCD CMS can internally open a reconsideration of an NCD because of new evidence that could support a material change in coverage, for which the agency would seek public comment on relevant questions. In addition, any individual or entity may request that CMS reconsider any provision of an NCD. As shown in Table 10-2, between 2006 and 2016, the number of NCD reconsiderations ranged from 11 in 2006 to 0 in 2012. Of the 11 reconsiderations implemented between 2012 and 2016 (the 5 most recent years available), all but 1 were initiated by an external party requesting a coverage expansion (data not shown). Nine of the 11 reconsiderations expanded national coverage for the service under consideration (e.g., by expanding the covered population or clinical conditions), 1 turned over

coverage to the local coverage process (i.e., MACs' medical directors), and 1 maintained the national coverage policy.

The Benefits Improvement and Protection Act of 2000 (BIPA) created a process to challenge NCDs that is available to certain beneficiaries, referred to as "aggrieved parties," a category that includes an FFS or MA beneficiary or the estate of a Medicare beneficiary. An aggrieved party can file a complaint concerning an NCD, which is reviewed by the Department of Health and Human Services (HHS) Departmental Appeals Board (DAB). Outcomes of an NCD challenge include the agency conducting a reconsideration of the NCD or the DAB issuing a decision (which constitutes final agency action). This challenge is separate from the process of appealing a MAC's decision on individual claims.

Expedited process to remove NCDs Because clinical science and technology evolve, in 2013, CMS adopted (through rulemaking) an expedited process to evaluate the continued need for older NCDs (that have not been reviewed in 10 years) that meet certain criteria, such as NCDs that no longer contain clinically pertinent and current information and that involve services that beneficiaries use infrequently.⁵ CMS expects that removing an NCD will be quicker using the expedited process compared with the reconsideration process. In November 2013, CMS posted 10 NCDs for possible removal and subsequently announced (after a 30-day public comment period) that it would rescind 7 NCDs and retain 3 NCDs (Centers for Medicare & Medicaid Services 2014a). MACs have the discretion to determine coverage for the services specified in a rescinded NCD.

Coverage with evidence development Since 1995, Medicare has linked coverage to the collection of clinical evidence. In making coverage decisions involving CED, CMS (as part of the NCD process) can decide, after a formal review of the medical literature, to cover a service only in the context of an approved prospective clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. CMS adopted CED in 2006.

CED is an approach for Medicare to cover potentially beneficial items and services that lack clear evidence showing their clinical effectiveness in specific patient populations. Under CED, beneficiaries have access

to medical services while clinical evidence is being collected in prospective clinical studies and registries. Because CED provides Medicare the opportunity to generate clinical evidence that otherwise might not have been collected, it enables the program to ultimately develop better, more evidence-based policies.

CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. For example, researchers have reported that older adults are underrepresented in cancer and cardiovascular clinical trials (Dhruva and Redberg 2008, Singh et al. 2017, Talarico et al. 2004). In addition, through CED, Medicare can collect evidence on long-term outcomes and effectiveness in different practice settings that are not always collected in clinical trials (Daniel et al. 2013). However, CED does not duplicate or replace the FDA's authority in assuring the safety and efficacy of drugs, biologics, and devices, and it does not assume the role of the National Institutes of Health in sponsoring clinical trials.

As of April 2018, there were roughly 20 active NCDs that included a CED policy. The design of each CED effort has varied, depending on the service and circumstance leading to the CED policy. A CED cycle is considered "completed" when CMS completes a reconsideration of the coverage determination and removes the CED requirement as a condition of coverage. Since Medicare has linked coverage to the collection of clinical evidence, we are aware of at least three NCDs that have been revised based on the collected evidence:

- In 2003, CMS revised the NCD for lung volume reduction surgery to cover all patients who matched the characteristics of patients in the clinical trial who experienced a survival or quality-of-life benefit.
- In 2013, CMS ended the CED requirement for oncologic uses of fluorodeoxyglucose–positron emission tomography (FDG–PET).
- In 2018, CMS published a coverage decision that ended the CED requirement for the use of MRIs for beneficiaries with implanted pacemakers and other selected implantable devices.

Medicare's statutory justification to apply CED has shifted over time. The agency's earlier CED decisions were made under the Secretary's authority to cover items and services

that are reasonable and necessary (i.e., Section 1862(a)(1)(A) of the statute) (Centers for Medicare & Medicaid Services 2014b). NCDs issued more recently (since 2006) rely on the Secretary’s authority under the statute’s Section 1862(a)(1)(E) that allows Medicare payment for services determined by AHRQ to reflect the research needs and priorities of the Medicare program.⁶ According to CMS, AHRQ reviews and approves the CED questions and general standards for CED studies issued under Section 1862(a)(1)(E). When CED under this section is required, it is because there are outstanding questions about the service’s health benefit in the Medicare population. As such, the service is covered only in the context of a study that requires patient monitoring, data collection, and an open presentation of results. When CED under Section 1862(a)(1)(A) is required, it is because additional clinical information is needed to ensure the appropriate use of the service in the Medicare population to facilitate accurate claims processing and payment (Centers for Medicare & Medicaid Services 2014b).

Because Medicare’s statutory foundation to apply CED is unclear, some researchers argue that Medicare’s use of CED has been hampered and is limited (Daniel et al. 2013, Mohr and Tunis 2010). Mohr and Tunis argued that the agency’s lack of clear statutory authority has affected the research questions and study design of the CED effort and the clinical evidence that was collected as well as Medicare’s ability to develop a proactive mechanism to identify potential CED topics. Daniel and colleagues also noted the challenges in Medicare’s use of CED, citing the lack of well-defined funding sources to conduct such studies, a shared data and research infrastructure, and predictable criteria and methods for conducting studies (Daniel et al. 2013). To improve Medicare’s ability to apply CED, Tunis and colleagues proposed a statutory change that would give CMS explicit authority to apply CED to promising technologies that are particularly important to the Medicare population and require better evidence to answer important questions about their clinical effectiveness (Tunis et al. 2011). Daniel and colleagues called for developing an infrastructure for more routine use of electronic health data (compiled into longitudinal clinical registries) that could support CED and quality measurement and suggested that such an effort be supported by payers, physician groups, and other organizations (Daniel et al. 2013).

Requirement that facilities meet safety requirements

Medicare also issues NCDs that require facilities furnishing certain services and procedures—including

lung cancer screening, ventricular assist devices as destination therapy, and carotid artery stenting—meet certain minimum standards to ensure beneficiary safety. Facilities are sometimes required to participate in a registry that is separate from the CED process. For example, the NCD on lung cancer screening also requires that facilities participate in a registry that collects administrative and clinical information.

Coverage of services furnished in clinical trials

In addition to CED, there are two other coverage policies relating to clinical trials: the Clinical Trial Policy and the Investigational Device Exemption (IDE) Policy. Implemented in 2000, the Clinical Trial Policy was first issued through an executive memorandum. CMS subsequently issued an NCD that explains Medicare’s coverage of the routine costs associated with qualifying clinical trials, as well as services that treat or diagnose complications that may arise from participation in a clinical trial.

Regarding the IDE Policy, under the MMA, Medicare pays for the routine costs of care furnished to beneficiaries in certain categories of IDE studies. For Category A (experimental) devices—those for which “absolute risk” has not been established and the FDA is unsure of the device’s safety and efficacy—Medicare covers the cost of routine care items and services furnished in trials. For Category B devices (nonexperimental/investigational)—where incremental risk is in question or it is known that the device type can be safe and effective—Medicare covers routine care costs as well as the cost of the device.

FDA–CMS Parallel Review Program The FDA–CMS Parallel Review Program, which began as a pilot in 2011, permits a manufacturer to request a concurrent review of clinical evidence for premarket medical devices by the FDA and CMS. The program’s goal is to reduce the time between FDA marketing approval and an NCD (Food and Drug Administration and Centers for Medicare & Medicaid Services 2016). In 2013, both agencies permanently extended the program, which accepts five candidates per year and gives priority to devices that will have the largest impact on Medicare beneficiaries (Food and Drug Administration and Centers for Medicare & Medicaid Services 2016).

Under the program, both agencies provide the manufacturer with feedback about the design and analysis of the device’s pivotal clinical trial and concurrently and independently review the clinical trial evidence and

communicate (as necessary) with the manufacturer during their respective reviews. CMS opens the NCD process on FDA approval. Although an FDA marketing approval does not guarantee a favorable coverage decision by Medicare, the two technologies that have undergone this process have been covered by the program.

Since 2011, CMS has accepted two tests—Cologuard, a colorectal cancer screening test, in 2014, and FoundationOne CDx, a next-generation sequencing test in 2017—into the Parallel Review Program and issued NCDs concerning their coverage.⁷ CMS released the proposed NCD for both tests on the same day that FDA approved the technology, and CMS finalized coverage within four months of the proposed NCD.

The experience to date under the Parallel Review Program shows its potential to expedite the NCD process. Some stakeholders assert that the Parallel Review Program increases collaboration between manufacturers, FDA, and CMS, and it provides beneficiaries with timely and innovative medical devices. However, some stakeholders contend that the program has had a limited impact because it affects few devices and does not address all difficulties that some manufacturers encounter when bringing a device to the U.S. market, such as the timeliness and ease of acquiring a billing code (Podemska-Mikluch 2016). Finally, some stakeholders contend that the program does not address the different evidentiary standards used by FDA and CMS. A device must be “safe and effective” to gain FDA approval, while it must be “reasonable and necessary” to gain CMS approval.

Off-label coverage of anticancer chemotherapy drugs and biologics Effective January 1, 1994, the Omnibus Budget Reconciliation Act of 1993 provided coverage when the indication for an off-label cancer drug is included in third-party drug compendia (privately owned reference guides), which include the American Hospital Formulary Service’s *Drug Information*, National Comprehensive Cancer Network’s *Drugs and Biologics Compendium*, Micromedex’s *DRUGDEX*, *Clinical Pharmacology*, and *Lexi-Drugs*. The MACs have discretion to ensure that such off-label use is reasonable and necessary. In addition, the medical directors may also identify off-label uses that are supported by clinical research published in peer-reviewed literature.

According to some researchers, there is limited transparency about how compendia are assembled and

the conflicts of interest on the part of their contributors, and there are substantial inconsistencies both among and within these resources (Green et al. 2016). In addition, there is also concern that the quality of evidence cited in compendia for off-label cancer drug use is less rigorous than the standards supporting FDA-approved drugs (Abernethy et al. 2009).⁸

Local coverage determination process

MACs review claims for services furnished by providers and pay for only those services that meet Medicare’s coverage requirements.⁹ Consequently, contractors play an important role in protecting the integrity of the Medicare program. The LCD, created by BIPA, is a determination by a MAC’s medical director as to whether an item or service is reasonable and necessary.¹⁰ LCDs (1) specify the circumstances (based on clinical conditions, prerequisite treatments, or other factors) in which a service is considered reasonable and necessary; (2) must be consistent with all statutes, regulations, rulings, and national coverage determinations as well as payment and coding policies; and (3) apply only to services provided in the contractor’s regional (multistate) jurisdiction.

Each medical director develops and manages LCDs according to the requirements set forth in the *Medicare Program Integrity Manual*. Medical directors can develop an LCD based on requests from external parties (e.g., beneficiaries, providers, or manufacturers) in their jurisdiction. According to the manual, MACs must develop LCDs when they have identified a service that is never covered (under certain circumstances) and want to establish automated reviews. Other circumstances for which medical directors have the option to either develop new or revise existing LCDs include:

- a validated, widespread problem demonstrating a significant risk to the Medicare Trust Funds, identified as potentially high-dollar or high-volume services;
- the need to ensure beneficiary access to care;
- frequent denials being issued or anticipated; and
- the contractor’s efforts to create uniform LCDs across multiple jurisdictions.

In addition, LCDs can provide more specific information about an item or service addressed in an NCD. The existence of one or more LCDs does not preclude CMS from making an NCD.

LCDs have a moderate impact on coverage of Part B services. The Office of Inspector General (OIG) estimated that, in 2011, over half (59 percent) of Part B billing codes (for medical procedures, imaging services, evaluation and management visits, drugs, and tests) were subject to an LCD in one or more states, representing about one-quarter of total allowed charges billed for all Part B services (Office of Inspector General 2014).¹¹

The LCD process The process for developing an LCD includes drafting language based on a review of medical literature, the contractor’s understanding of local practices, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. Contractors are required to provide open meetings to discuss draft LCDs, during which interested parties can make presentations of information related to draft policies. In addition, contractors are required to establish carrier advisory committees (CACs) in each state to provide a forum for information exchange between the contractors and medical professionals (physicians and representatives of other medical organizations) and a beneficiary representative. CACs meet at least three times per year and are composed of physicians, a beneficiary representative, and representatives of other medical organizations. Contractors are required to present draft LCD policies to the CAC (after the meeting with the public).

Contractors must provide a comment period of at least 45 calendar days for all new LCDs and revised LCDs that restrict existing LCDs or make a substantive correction. In addition, contractors must provide a 45-day notice period before the final LCD’s effective date. Revised LCDs, for which comment and notice periods are not needed, include policies that liberalize an existing LCD; correct typographical or grammatical errors; add information that clarifies the LCD but does not restrict it; and update a coding issue. All final LCDs are posted on the contractor’s website and on Medicare’s coverage database.

LCD reconsiderations and challenges Similar to the NCD process, there is a reconsideration process for final LCDs that contractors or interested parties can initiate.¹² BIPA also created a process to challenge LCDs, available to an “aggrieved party”—a Medicare FFS or MA beneficiary or the estate of a Medicare beneficiary. Under this process, which is distinct from the existing appeal rights, an aggrieved party can file a challenge either 6 months before receiving the service or 120 days after receiving the

service. The challenge is first reviewed by an administrative law judge, and if complainants are unsatisfied, they can subsequently seek review by the DAB (which would constitute final HHS action). Contractors can initiate a reconsideration process for challenged LCDs.

Variation in LCDs across contractors In contrast to NCDs, LCDs apply only in the contractor’s jurisdiction—with one exception: In 2006, CMS required the four regional contractors for durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (DMEPOS) to jointly develop and use a single set of coverage policies. Consequently, coverage policies for *non-DMEPOS* services can vary across regions because each contractor sets policies within its specified multistate jurisdiction. CMS encourages a contractor operating in two or more states to develop uniform local coverage policies across all jurisdictions to the extent possible and has taken steps to promote consistency among contractors. For example, one MAC develops coverage, coding, and pricing policies for molecular diagnostic tests and other molecular pathology services under the Molecular Diagnostic Program, which are applied in 28 states.

In two recent evaluations of the LCD process, OIG found variations in local coverage policies and recommended that CMS take steps to reduce this variability to ensure beneficiaries’ access to care. Specifically, OIG found:

- In 2011, over half of Part B billing codes were subject to an LCD in one or more states, and LCDs affected coverage for these services differently across states; LCDs defined similar clinical topics inconsistently; and there was no correlation between the number of states with LCDs for services and the unit cost or utilization rate of those services. CMS has taken steps to increase consistency among LCDs but lacks a plan to evaluate LCDs for national coverage, which the MMA required (Office of Inspector General 2014). OIG recommended that CMS continue efforts to increase consistency among existing LCDs and consider requiring MACs to jointly develop a single set of coverage policies. CMS concurred with these recommendations.
- In 2012, MACs varied in the methods and sources used to make coverage determinations for Part B drugs and in the use of payment edits and medical reviews (Office of Inspector General 2016). OIG recommended that CMS assign a single entity to assist

MACs with making coverage determinations and evaluate the cost-effectiveness of edits and medical reviews that are designed to ensure appropriate payments for Part B drug claims. CMS concurred with the second recommendation but not with the first (because a single entity would not capture regional differences, which the agency considers to be a fundamental characteristic of local coverage).

The Government Accountability Office also reported that, due to variations in LCDs, there were coverage inequities for beneficiaries with similar medical conditions and recommended that CMS replace LCDs with NCDs (Government Accountability Office 2003). However, some providers and manufacturers support a regional coverage approach, arguing that it is more responsive to local innovations in medical care than a national approach.

The MMA addressed the variability of LCDs by requiring the Secretary to determine which new LCDs should be adopted nationally and the extent to which greater consistency can be achieved among existing LCDs. To comply with the MMA requirement, CMS convenes workgroups and facilitates communication among the contractor medical directors. For example, CMS convenes face-to-face meetings with the contractors' medical directors multiple times a year to engage in collaborative learning on effective approaches to coverage, address at least one coverage decision topic in a unified manner at each meeting, and develop standardized processes and criteria for coverage decisions when appropriate (Office of Inspector General 2014).

Coverage policies implemented in program manuals

Coverage policies also can be implemented through publication in Medicare's program manuals, memorandums, and rule-making process. Program manuals (including the *Medicare Benefits Policy Manual* and Medicare claims processing manuals) and program memorandums contain operating instructions, policies, and procedures based on statutes, regulations, and directives to further define when and under what circumstances items or services may be covered. For example:

- According to the *Medicare Benefits Policy Manual*, Medicare pays end-stage renal disease (ESRD) facilities furnishing dialysis in a facility or in a patient's home a maximum of 13 treatments during a 30-day month and 14 treatments during a 31-

day month unless there is medical justification for additional treatments. CMS reiterated this policy in the final rule for the 2015 ESRD prospective payment system (Centers for Medicare & Medicaid Services 2014c).

- In April 2016, CMS issued a program memo that provided an overview of Medicare's coverage of inpatient and outpatient services for the treatment of substance abuse, which included a summary of available services.

These policies are developed by CMS staff and are binding on all MACs. The number of coverage policies implemented in this manner is unknown.

Medicare's coding process

CMS's coding requirements may implicitly affect the coverage of new services. Medicare's payment systems are organized around standard sets of codes that describe the services furnished by providers to beneficiaries. All services must be appropriately coded for providers to receive payment from Medicare. Two entities are responsible for assigning new codes. The Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association annually updates codes for procedures and other physician services—CPT codes. The Healthcare Common Procedure Coding System (HCPCS) National Panel, which is composed of CMS and insurer representatives, annually updates codes for medical devices and other products—HCPCS Level II codes. Because the code sets maintained by the American Medical Association CPT Editorial Panel and HCPCS National Panel are designed to serve multiple health insurers, not all of the codes are for services or items covered by Medicare.

Appeals process for Part A and Part B services

Beneficiaries and providers have the opportunity to appeal the denial of an individual claim for coverage for services that contractors believe do not fall within a Medicare benefit category, are not reasonable and necessary, or are otherwise excluded by statute or regulation. Under the current process, if dissatisfied with the outcome, the beneficiary, provider, or representative can appeal the determination. Medicare's five levels in the Part A and Part B appeal process are (1) redetermination by the responsible MAC, (2) reconsideration by a qualified independent contractor, (3) hearing by an administrative law judge, (4) review by the Medicare Appeals Council

within the Departmental Appeals Board, and (5) judicial review in the U.S. District Court. The process for appealing an individual claim is distinct from challenging national and local coverage determinations.

Medicare coverage policy rules as they apply to Medicare Advantage plans

MA plans are required to provide the same set of benefits under Medicare Part A and Part B that are available to Medicare beneficiaries in the Medicare FFS program, except that FFS Medicare covers hospice care and covers certain services associated with clinical trials under Medicare's Clinical Trials Policy for MA enrollees. MA plans must use Medicare-certified providers for the provision of all covered services. An additional service that MA can cover, which is treated as a Medicare-covered service under MA, is skilled nursing facility care without a previous three-day hospital stay (at the option of the MA plan).

MA plans must adhere to NCDs and LCDs applicable in their service areas, with two exceptions. One exception applies to regional preferred provider organization (PPO) plans, which cover wide geographic areas spanning multiple Medicare FFS MAC areas. A regional PPO can choose LCDs of one of those MACs and apply them, exclusively and uniformly, throughout the regional PPO's service area. An additional exception applies to local MA plans that include multiple MAC areas. A local MA plan may choose to apply the LCD that is most generous to the beneficiary (as determined by the Secretary) throughout its entire service area.

The MA plan functions like a MAC in that the plan is responsible for deciding whether coverage of an item or service meets Medicare's reasonable and necessary criterion, using "coverage criteria no more restrictive than original Medicare's national and local coverage policies" (as stated in CMS manual provisions). The plan decision can be appealed, and the plan's reconsidered decision can be appealed to an outside independent review entity. The review entity's decision can be further appealed to an ALJ and subsequent appellate levels if the claim meets the minimum dollar threshold for appeals (currently \$160 for an appeal to an ALJ and \$1,560 for judicial review—the same standard as for appeals in FFS).

Plans are permitted to use tools such as requiring providers to seek prior authorization for certain (typically, expensive) services to have a service covered. Also, plans have leeway in controlling utilization through cost sharing. MA cost sharing can differ from the cost-sharing structure

of FFS Medicare and can be either higher or lower than FFS for particular services (for example, by imposing cost sharing for Medicare-covered home health care). There is an overall limit under which the total expected average actuarial value of cost sharing must be less than or equal to the actuarial value of Medicare FFS cost sharing. By statute, certain specified services may not have cost sharing that exceeds the Medicare FFS level—including, for example, renal dialysis services, chemotherapy administration, and "such other services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries)" (Section 1852(a)(1)(B)(iv)(IV)). Plans cannot impose cost sharing on preventive services that have no cost sharing in FFS.

MA plans can have tiered cost sharing based on the provider an enrollee chooses "as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data," as stated in CMS manual provisions.

Medicare coverage for Part D drugs

Part D is a voluntary prescription drug benefit created by the MMA and implemented on January 1, 2006. Under the Part D program, Medicare contracts with private plans to deliver drug benefits to enrollees. To obtain the drug benefit, Medicare beneficiaries must enroll in a stand-alone prescription drug plan or in a Medicare Advantage–Prescription Drug plan.

Plan sponsors are responsible for creating and managing formularies, which are lists of drugs their plans cover. Part D law and regulations place some constraints on which drugs plan sponsors may cover and how they operate their formularies.

Part D drug definition

To be eligible for coverage under the Part D program, a drug must be approved by the FDA for use and sale in the United States and be prescribed and used for a medically accepted indication. Part D drugs include most outpatient prescription drugs dispensed by retail pharmacies, including self-injectable biological products such as insulin, medical supplies associated with the injection of insulin, and vaccines that are not covered under Part B (42 CFR § 423.100).

There are certain types of drugs that Part D plans are generally not allowed to cover under the basic benefit.

The definition of a Part D drug excludes certain drugs and biological products covered under Medicare Part A or Part B as well as certain drugs or classes of drugs that are not covered under the Medicaid program.¹³ Plan sponsors may, however, cover some of these excluded drugs as part of an enhanced Part D plan's supplemental benefits, but enrollees must pay the full premium cost for those additional benefits.

Formulary requirements

Law and regulations lay out requirements for Part D plan formularies. Plan sponsors must have a pharmacy and therapeutics (P&T) committee composed of members who meet certain requirements regarding background (physicians and pharmacists) and conflicts of interest. P&T committees develop and review their formulary's structure, exceptions policies, and protocols for prior authorization and other forms of utilization management. In making decisions about plan coverage and formulary design, P&T committees must take into consideration the strength of scientific evidence and standards of practice.

CMS reviews and approves each plan's formulary to "ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes" so that it would not substantially discourage enrollment by any group of eligible individuals, such as those with certain conditions (Centers for Medicare & Medicaid Services 2010).

Plan sponsors must include coverage of the types of drugs most commonly needed by Medicare beneficiaries as recognized in national treatment guidelines. For most drug classes, plans must include two distinct drugs that are not therapeutically equivalent or bioequivalent. In addition, CMS requires that "all or substantially all drugs" in six protected classes be included in Part D plan formularies—anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

Coverage determinations and appeals

CMS requires Part D plan sponsors to have an appeal process through which enrollees can challenge a denial of drug coverage (a negative coverage determination) in a timely manner. The goal is to ensure that plan formularies do not impede access to needed medications. However, the burden associated with navigating these processes varies from plan to plan.

A coverage determination is issued by a plan, for example, when an enrollee requests coverage of a drug that is not

on the plan's formulary (formulary exception) or when an enrollee asks that a drug he or she needs that is on a higher cost-sharing tier be assigned to a lower cost-sharing tier because alternative drugs on the plan's lower cost-sharing tier would not be as effective for the individual (tiering exception).

An appeals request begins with a denied request for a formulary exception or lower cost-sharing amount. To initiate an appeals request, an enrollee, the enrollee's prescribing physician, or the enrollee's authorized representative must request a redetermination from the plan. If dissatisfied with the outcome of the redetermination, the enrollee can ask for reconsideration—a review from an independent review entity. If the enrollee remains dissatisfied, he or she may appeal to an ALJ, then to the Medicare Appeals Council, and finally to federal district court.¹⁴

Part D requires quicker adjudication time frames for exceptions than for MA medical benefits because "the majority of Part D coverage requests involve prescription drugs an enrollee has not yet received, which increases the risk of adverse clinical outcomes if access to the drug is delayed" (Centers for Medicare & Medicaid Services 2016a). For example, plan sponsors must make a decision about exceptions and coverage determination within 72 hours of a request or within 24 hours for expedited requests.

Evidence of low-value care

Low-value care is the provision of a service that has little or no clinical benefit or care in which the risk of harm from the service outweighs its potential benefit (Chan et al. 2013, Kale et al. 2013). In addition to increasing health care spending, low-value care has the potential to harm patients by exposing them to the risks of injury from inappropriate tests or procedures and may lead to a cascade of additional services that contain risks but provide little or no benefit (Keyhani et al. 2013, Korenstein et al. 2012). For our analysis of low-value care, we reviewed the literature on the prevalence of low-value care in Medicare, Medicaid, and commercial plans; examined selected low-value services in Medicare using 31 measures; and examined case studies of three services or items paid for by Medicare that are potentially low value because they lack evidence of comparative clinical effectiveness.

Review of the literature on low-value care

Potentially inappropriate use of health care services can take three forms: underuse, misuse, or overuse (Chan et al. 2013). Underuse is the failure to provide a service to a patient when the potential therapeutic benefit of a test or treatment outweighs the risks (e.g., not using aspirin for patients with coronary disease) (Kale et al. 2013). Misuse is the delivery of the wrong care (e.g., prescribing the wrong medication to a patient given her clinically established diagnosis) (Kale et al. 2013, Korenstein et al. 2012). Overuse is providing either a service that has little or no clinical benefit or a service in which the risk of harm outweighs its potential benefit (e.g., using an antibiotic to treat a viral infection or repeating a diagnostic test more frequently than necessary) (Chan et al. 2013, Kale et al. 2013). Another term for overuse is *low-value care* (Schwartz et al. 2014). Some researchers contend that reducing or eliminating low-value services would both improve quality and reduce health care spending, though they acknowledge that it may be difficult to precisely identify such services in clinical practice (Colla et al. 2015).

The medical community's most significant attempt to identify services that represent overuse or low-value care is the "Choosing Wisely" campaign, an initiative of the American Board of Internal Medicine (ABIM) Foundation that is supported by the Robert Wood Johnson Foundation. In the latest iteration of this ongoing effort, over 80 medical specialty societies have identified more than 520 tests and procedures that are often overused (ABIM Foundation 2016). The goal of Choosing Wisely is to promote and inform conversations between clinicians and their patients about appropriate tests and treatments. Evaluations of the effects of Choosing Wisely have shown a small decline in some of the services the initiative targets (Hong et al. 2017, Rosenberg et al. 2015). However, the extent to which these reductions can be directly attributed to the campaign or other interventions that address low-value care is unclear.

There is evidence of substantial use of low-value care in FFS Medicare. A team of researchers developed several measures of low-value care drawn from evidence-based lists (such as Choosing Wisely), recommendations by the United States Preventive Services Task Force (USPSTF), and the medical literature, which they applied to Medicare claims data (Schwartz et al. 2015, Schwartz et al. 2014). It is challenging to reliably identify low-value care with

claims data because they may not have enough clinical detail to distinguish appropriate from inappropriate use. Thus, a key feature of these measures is that they are designed to allow for explicit trade-offs between the sensitivity and specificity of each measure. Increasing the sensitivity of a measure captures more potentially inappropriate use but is also more likely to misclassify some appropriate use as inappropriate. Increasing a measure's specificity leads to less misclassification of appropriate use as inappropriate, at the expense of potentially missing some instances of inappropriate use. The authors developed two versions of each measure: a broader one with higher sensitivity (and lower specificity) and a narrower one with lower sensitivity (and higher specificity).

In their first article, which used 26 measures, Schwartz and colleagues found the following based on 2009 data:

- Based on the broader versions of the measures, there were 80 instances of low-value care per 100 Medicare beneficiaries, and 42 percent of beneficiaries received at least one low-value service. Total Medicare spending for these services was \$8.5 billion.
- Based on the narrower versions of the measures, there were 33 instances of low-value care per 100 beneficiaries, and 25 percent of beneficiaries received at least one low-value service. Total Medicare spending for these services was \$1.9 billion (Schwartz et al. 2014).

The researchers also found that regional spending on low-value care (using the narrower version of each measure) ranged from \$227 per beneficiary in the 5th percentile (in spending) of hospital referral regions (HRRs) to \$416 per beneficiary in the 95th percentile.

The authors grouped the 26 measures into 6 larger clinical categories. Imaging, cancer screening, and diagnostic and preventive testing accounted for most of the volume of low-value care, while imaging and cardiovascular testing and procedures accounted for most of the spending (the sixth category was preoperative testing).

In a second study, Schwartz and colleagues compared the use of low-value services between two groups of beneficiaries: beneficiaries attributed to Medicare Pioneer accountable care organizations (ACOs) and beneficiaries attributed to other health care providers (the control group) (Schwartz et al. 2015). They used the 26 measures of low-

value care from the first study plus 5 new measures. The study compared the change in the use of low-value care between the two beneficiary groups, using the periods before and after the ACO contracts went into effect.¹⁵ The authors found a significant reduction in both volume (–1.9 percent) and spending (–4.5 percent) for low-value services in the ACO group relative to the control group.¹⁶

There is also evidence that delivery of low-value care exists among payers other than Medicare. A study that included patients ages 18 to 64, across all payer types, found that 19 percent of patient encounters with a health care provider included a low-value service (Barnett et al. 2017). This study used nationally representative data from the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS).

Two studies used data from all payers to examine the use of low-value care in Virginia and Minnesota. A study of Virginia claims data for 5.5 million patients in 2014 found that about 1 in 5 patients received at least 1 low-value service and that \$586 million was spent on these low-value services, accounting for 2.1 percent of Virginia’s total health care spending (Mafi et al. 2017). This study examined 44 services determined to be of low value based on Choosing Wisely, the USPSTF, Healthcare Effectiveness Data and Information Set[®] (HEDIS[®]) measures, and clinical guidelines.

A study of Minnesota claims data from all payers examined the prevalence of 18 low-value services in the categories of imaging, disease screening, and preoperative tests in 2014 (Minnesota Department of Health 2017). The rate of low-value imaging ranged from 1.1 percent (thorax computed tomography (CT) scan with and without contrast) to 35.5 percent (CT scan for suspected appendicitis without prior ultrasound). The rate of low-value screening ranged from 0.4 percent (colorectal cancer screening for adults ages 85 and over) to 18.9 percent (prostate-specific antigen (PSA) screening for men age 75 and over). The rate of low-value preoperative tests ranged from 0.5 percent (preoperative pulmonary function test) to 5.5 percent (preoperative chest X-ray).¹⁷ The low-value measures were based on Choosing Wisely, the USPSTF, and the United Kingdom’s National Institute for Health and Care Excellence.

Two studies compared the use of low-value care among commercially insured patients with Medicaid or Medicare patients. Charlesworth and colleagues compared the rate of low-value care in Medicaid patients with commercially

insured individuals in Oregon in 2013 (Charlesworth et al. 2016). This study found that 15 percent of Medicaid patients received a low-value service compared with 11 percent of commercially insured patients. The authors also found that the amount of low-value care appeared to be influenced by local practice patterns. For most measures, Medicaid patients had a higher probability of receiving a low-value service if they lived in a region where commercially insured patients had higher rates of low-value care.

Colla and colleagues used data from 2009 to 2011 to compare the prevalence of seven Choosing Wisely services between commercially insured patients and Medicare FFS beneficiaries (Colla et al. 2017b).¹⁸ The authors found little difference in rates of cardiac screening in low-risk, asymptomatic patients; use of dual-energy X-ray absorptiometry (DXA) scans; opioid use in migraine patients; and cervical cancer screening for women over age 65.¹⁹ Imaging for low back pain was more prevalent among the commercially insured population (29 percent) than Medicare beneficiaries (23 percent), while preoperative cardiac testing was more common among Medicare beneficiaries (46 percent) than commercially insured patients (26 percent). The prevalence of low-value care in HRRs appeared to be largely independent of payer type and instead was likely related to local practice patterns, which is consistent with findings from the study by Charlesworth and colleagues and our analysis of PSA testing among men ages 70 and older in FFS Medicare and MA (see text box on examining a measure of low-value care in MA compared with FFS Medicare, pp. 318–321) (Charlesworth et al. 2016).

Reid and colleagues analyzed low-value care and spending using claims data for patients ages 18 to 64 from a large national commercial plan (UnitedHealthcare) (Reid et al. 2016). They used 28 previously published low-value care measures and found that 7.8 percent of patients received at least one low-value service in 2013, accounting for 0.5 percent of total spending. The most common low-value services were triiodothyronine (T₃) measurement in hypothyroidism, imaging for nonspecific low back pain, and imaging for uncomplicated headache.²⁰

Another type of low-value care is inappropriate drug use, which can harm patients by causing adverse drug events (Landro 2016, Opondo et al. 2012). In addition, the overprescribing of antibiotics can lead to the formation of antibiotic-resistant infections. Adults ages 60 and over are particularly at risk for inappropriate drug use (Morin

et al. 2016). One systematic review of the prevalence of inappropriate prescriptions to adults ages 65 and over found that one in five prescriptions in the primary care setting was inappropriate (Opondo et al. 2012). Another study found that 20 percent of veterans ages 65 and over had been prescribed at least one potentially inappropriate medication, according to a 2006 HEDIS quality measure (Pugh et al. 2006).²¹ A study that used data from the NAMCS and the NHAMCS on patients of all ages found that one in three prescriptions for oral antibiotics in ambulatory settings was inappropriate, and almost 20 percent of antibiotic prescriptions for patients ages 65 and older were inappropriate (Fleming-Dutra et al. 2016).

Although the studies we reviewed differed in their measures of low-value care and the populations they examined, some common themes emerge from the literature. At least some low-value services can be identified with claims data, and low-value care is prevalent across FFS Medicare, Medicaid, and commercial insurance plans. In addition, the amount of low-value care in a geographic area appears to be more a function of local practice patterns than payer type.

Use of selected low-value services in FFS Medicare based on 31 claims-based measures

In a previous analysis examining the use of low-value care in FFS Medicare, the Commission contracted with Schwartz and one of his co-authors (McWilliams) to obtain the algorithms for the 31 measures they developed, which we applied to 100 percent of Medicare claims data from 2012 to 2014 (Schwartz et al. 2015, Schwartz et al. 2014) (see online Appendix 10-A, available at <http://www.medpac.gov>, for a list of the measures and their sources).²² We also performed a separate analysis comparing the prevalence of one low-value service in FFS Medicare and MA—the rate of PSA testing among older men, for whom testing is not recommended (see text box on examining a measure of low-value care in MA compared with FFS Medicare, pp. 318–321). For our analysis of the 31 measures in FFS Medicare, we used 2 versions of each measure based on the original studies: a broader version (more sensitive, less specific) and a narrower version (less sensitive, more specific). For each version, we calculated the number of low-value services per 100 FFS beneficiaries, the share of FFS beneficiaries who received at least one low-value service, and total spending across all FFS beneficiaries for each service.

Even though these measures do not include all low-value services, our results show substantial use of low-value care

in FFS Medicare in 2014. Based on the measures' broader versions, our analysis found about 72 instances of low-value care per 100 beneficiaries, and more than 37 percent of beneficiaries received at least 1 low-value service (Table 10-3, p. 314). Medicare spending for these services was over \$6.5 billion, or 2.0 percent of FFS Medicare spending for the beneficiaries in our sample. Based on the measures' narrower versions, our analysis showed about 34 instances of low-value care per 100 beneficiaries, and almost 23 percent of beneficiaries received at least 1 low-value service. Medicare spending for these services totaled over \$2.4 billion, or 0.7 percent of FFS Medicare spending for the beneficiaries in our sample. Between 2012 and 2014, there was a modest decline in volume and spending on low-value services (data not shown).

The differences between the measures' broader and narrower versions demonstrate that the amount of low-value care detected varies substantially based on the measures' clinical specificity. For example, the broader measure of imaging for low back pain included any back imaging for low back pain and therefore captured more inappropriate use but also probably some appropriate use. The narrower version of this measure excluded certain diagnoses and was limited to imaging provided during the first six weeks of the diagnosis of low back pain; consequently, it counted less than one-third as many cases as inappropriate compared with the broader measure (Table 10-3, p. 314).

The measures we used excluded many low-value services (e.g., imaging for pulmonary embolism without moderate or high pretest probability) because it was difficult to distinguish inappropriate from appropriate use of these services with claims data (Schwartz et al. 2014). Therefore, our analysis likely represents a conservative estimate of the number of low-value services in Medicare. In addition, we did not estimate the downstream cost of low-value services because we could not determine through claims data whether a specific low-value service led directly to a downstream service (e.g., a follow-up test or procedure). Consequently, our spending estimates probably understate spending on low-value care.

Among the measures' broader versions, measures with the highest volume in 2014 were imaging for nonspecific low back pain (12.0 per 100 beneficiaries), PSA screening for men ages 75 and over (9.0), and colon cancer screening for older adults (8.0) (Table 10-3, p. 314).²³ Measures with the highest aggregate Medicare spending were percutaneous coronary intervention with balloon angioplasty or stent placement for stable coronary disease (almost \$1.3

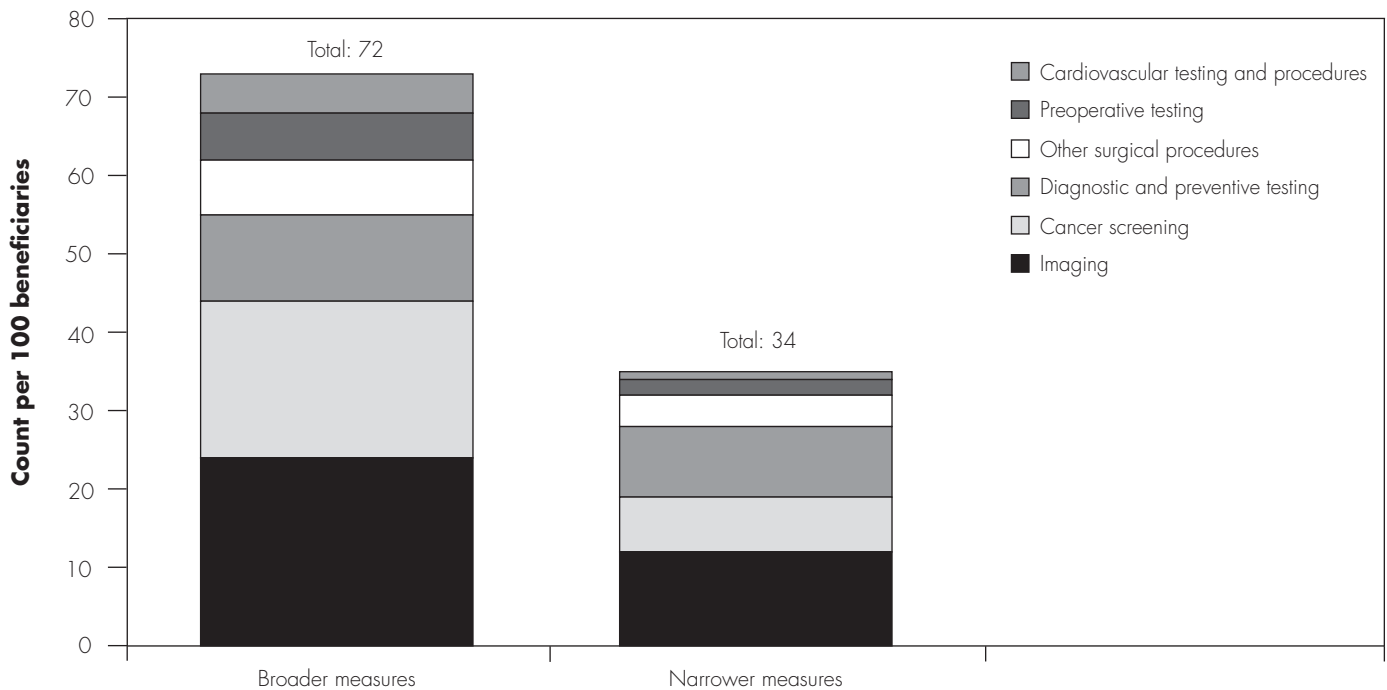
**TABLE
10-3**

Between 34 and 72 low-value services provided per 100 FFS beneficiaries in 2014; Medicare spent between \$2.4 billion and \$6.5 billion on these services

Measure	Broader version of measure			Narrower version of measure		
	Count per 100 beneficiaries	Share of beneficiaries affected	Spending (millions)	Count per 100 beneficiaries	Share of beneficiaries affected	Spending (millions)
Imaging for nonspecific low back pain	12.0	8.9%	\$232	3.4	3.1%	\$66
PSA screening at age ≥ 75 years	9.0	6.2	79	5.1	4.2	44
Colon cancer screening for older adults	8.0	7.5	405	0.3	0.3	3
Spinal injection for low back pain	6.6	3.3	1,261	3.4	2.0	643
Carotid artery disease screening in asymptomatic adults	5.1	4.6	268	4.2	3.8	221
Preoperative chest radiography	4.6	4.1	67	1.1	1.1	17
PTH testing in early CKD	4.5	2.6	83	3.9	2.3	71
Stress testing for stable coronary disease	4.3	4.1	1,198	0.5	0.5	137
T ₃ level testing for patients with hypothyroidism	3.8	2.2	23	3.8	2.2	23
Head imaging for headache	3.6	3.3	242	2.4	2.2	160
Cervical cancer screening at age > 65 years	2.2	2.2	44	1.9	1.9	39
Homocysteine testing in cardiovascular disease	1.5	1.2	12	0.4	0.3	3
Head imaging for syncope	1.2	1.1	78	0.8	0.7	51
Preoperative echocardiography	0.8	0.8	62	0.2	0.2	19
Preoperative stress testing	0.6	0.6	177	0.2	0.2	60
Screening for carotid artery disease for syncope	0.6	0.6	33	0.4	0.4	23
CT for rhinosinusitis	0.6	0.5	39	0.2	0.2	17
Vitamin D testing in absence of hypercalcemia or decreased kidney function	0.5	0.4	8	0.5	0.4	8
Imaging for plantar fasciitis	0.5	0.4	9	0.4	0.3	6
BMD testing at frequent intervals	0.4	0.4	9	0.3	0.3	6
Cancer screening for patients with CKD on dialysis	0.4	0.3	9	0.1	0.1	1
PCI/stenting for stable coronary disease	0.3	0.3	1,284	0.1	0.1	216
Arthroscopic surgery for knee osteoarthritis	0.2	0.2	204	0.1	0.1	108
Vertebroplasty	0.2	0.2	338	0.2	0.2	327
Preoperative PFT	0.2	0.2	2	0.1	0.1	1
Hypercoagulability testing after DVT	0.2	0.1	5	0.1	0.1	2
IVC filter placement	0.1	0.1	33	0.1	0.1	33
Carotid endarterectomy for asymptomatic patients	0.1	0.1	165	0.03	0.03	66
EEG for headache	0.1	0.1	4	0.04	0.04	2
Renal artery stenting	0.1	0.1	152	0.02	0.02	51
Pulmonary artery catheterization in ICU	0.01	0.01	0.2	0.01	0.01	0.2
Total	72.2	37.4	6,526	34.2	22.5	2,425

Note: FFS (fee-for-service) PSA (prostate-specific antigen), PTH (parathyroid hormone), CKD (chronic kidney disease), CT (computed tomography), BMD (bone mineral density), PCI (percutaneous coronary intervention), PFT (pulmonary function test), DVT (deep vein thrombosis), IVC (inferior vena cava), EEG (electroencephalography), ICU (intensive care unit). "Count" refers to the number of unique services. The total for share of beneficiaries affected does not equal the column sum because some beneficiaries received services covered by multiple measures. "Spending" includes Medicare Part A and Part B program spending and beneficiary cost sharing for services detected by measures of low-value care. Spending is based on a standardized price for each service from 2009 that has been updated to 2014. See online Appendix 10-A, available at <http://www.medpac.gov>, for the sources for the measures.

Source: MedPAC analysis of 100 percent of Medicare claims using measures developed by Schwartz and colleagues (Schwartz et al. 2015, Schwartz et al. 2014).

**FIGURE
10-2****Between 34 and 72 low-value services provided per 100 FFS beneficiaries in 2014**

Note: FFS (fee-for-service). "Count" refers to the number of unique services provided to FFS Medicare beneficiaries. See online Appendix 10-A, available at <http://www.medpac.gov>, for a list of the measures and their sources.

Source: MedPAC analysis of 100 percent of Medicare claims using measures developed by Schwartz and colleagues (Schwartz et al. 2015, Schwartz et al. 2014).

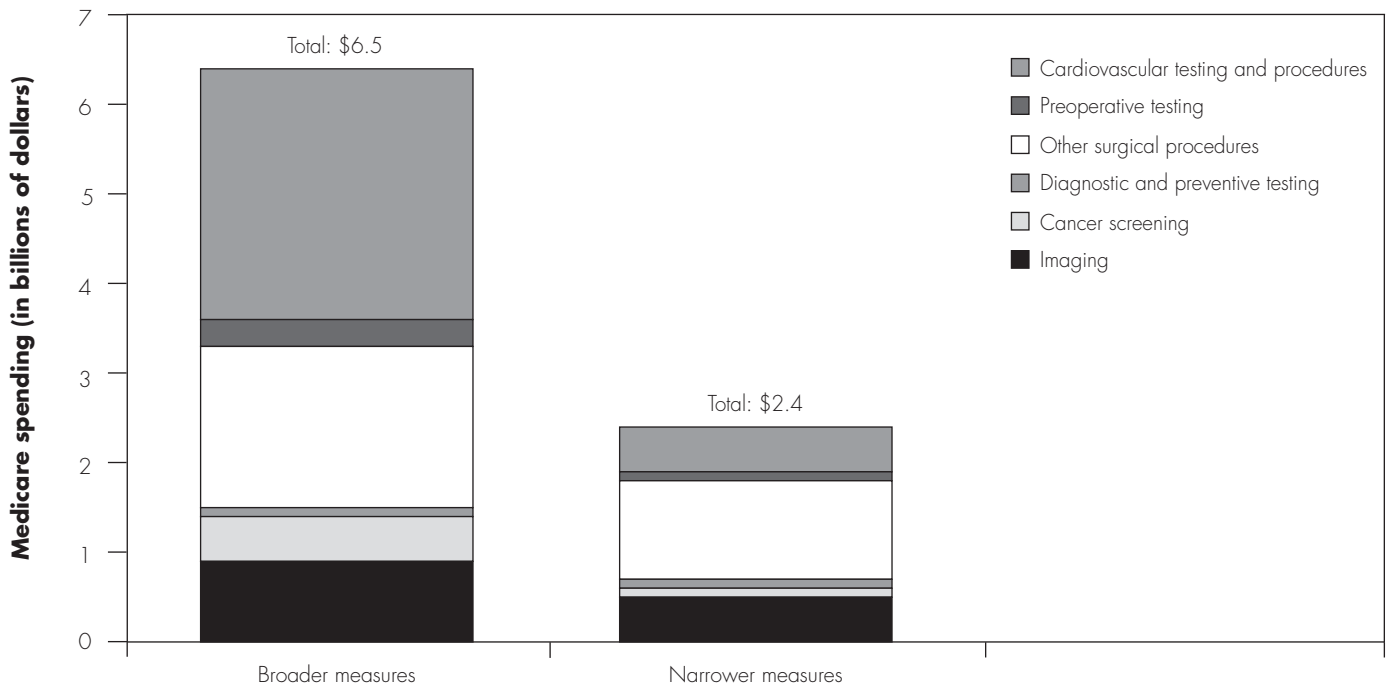
billion), spinal injection for low back pain (almost \$1.3 billion), and stress testing for stable coronary disease (almost \$1.2 billion).

Among the measures' narrower versions, measures with the highest volume in 2014 were PSA screening for men ages 75 and over (5.1 per 100 beneficiaries), screening for carotid artery disease in asymptomatic adults (4.2), and parathyroid hormone measurement for patients with early chronic kidney disease (3.9) (Table 10-3).²⁴ The measures with the highest Medicare spending were spinal injection for low back pain (\$643 million), vertebroplasty or kyphoplasty for osteoporotic vertebral fractures (\$327 million), and screening for carotid artery disease in asymptomatic adults (\$221 million).

After grouping the 31 measures into 6 larger clinical categories, we found that imaging and cancer screening measures in 2014 accounted for 44 low-value services per

100 beneficiaries using the measures' broader versions, or 60 percent of the total number of low-value services (Figure 10-2) (see online Appendix 10-A, available at <http://www.medpac.gov>, for a list of the clinical categories and the measures assigned to each one). In contrast, cardiovascular testing and procedures and other surgical procedures constituted \$4.6 billion in spending, or 71 percent of total spending (Figure 10-3, p. 316). Among the measures' narrower versions, imaging and diagnostic and preventive testing accounted for 21 low-value services per 100 beneficiaries (61 percent of the total number of low-value services), while spending on other surgical procedures and imaging was \$1.6 billion (67 percent of total spending) (Figure 10-2, this page, and Figure 10-3, p. 316).

We also examined geographic variation in the use of low-value services, using a model developed by Schwartz and colleagues that adjusted for geographic differences in demographic characteristics and comorbidities that

**FIGURE
10-3****Medicare spent between \$2.4 billion and \$6.5 billion on low-value care in 2014**

Note: "Spending" includes Medicare Part A and Part B program spending and beneficiary cost sharing for services detected by measures of low-value care. To estimate spending, we used standardized prices to adjust for regional differences in payment rates. The standardized price is the median payment amount per service in 2009, adjusted for the increase in payment rates between 2009 and 2014. This method was developed by Schwartz and colleagues. See online Appendix 10-A, available at <http://www.medpac.gov>, for a list of the measures and their sources.

Source: MedPAC analysis of 100 percent of Medicare claims using measures developed by Schwartz and colleagues (Schwartz et al. 2015, Schwartz et al. 2014).

could affect the use of low-value services.²⁵ Even after adjusting for these factors, we found substantial variation in the use of low-value care. For example, the adjusted number of low-value services per 100 beneficiaries in 2014 was 61 percent higher in the geographic area at the 90th percentile (of use) compared with the area at the 10th percentile (data not shown).²⁶ Of the 10 geographic areas with the highest adjusted number of low-value services, 5 were in Florida (Table 10-4). Because we adjusted for differences in beneficiaries' demographic characteristics and chronic conditions, variation in the use of low-value care could reflect such factors as geographic differences in physician practice patterns, entrepreneurial behavior, and beneficiaries' preferences for care.

We also explored the relationship between use of low-value services and overall Medicare service use (which includes all Part A and Part B services) among geographic

units in 2014. Our measure of overall service use adjusted for regional differences in input prices, special payments to certain providers, and beneficiaries' demographic characteristics and health status. We ran a regression with overall service use per beneficiary as the dependent variable and the adjusted number of low-value services per beneficiary as the explanatory variable. This regression produced a coefficient for the number of low-value services of 0.77 and an R^2 of 0.29. This result indicates a modest positive relationship between low-value care and overall service use, which is not surprising. Beneficiaries who receive more services in general are more likely to receive services classified as low value. In addition, higher use of low-value care and higher overall service use could be driven by similar factors, such as more aggressive practice patterns, patient preferences for more tests and procedures, and a greater supply of providers.

**TABLE
10-4**

Geographic areas with the highest adjusted number of low-value services, 2014

Geographic area	Adjusted number of low-value services per 100 FFS beneficiaries
Yuma, AZ	56
Punta Gorda, FL	53
Miami-Ft. Lauderdale-W. Palm Beach, FL	51
Ocala, FL	51
Sebastian-Vero Beach, FL	51
Naples-Immokalee-Marco Island, FL	49
Beaumont-Port Arthur, TX	48
Hammond, LA	47
New York-Newark-Jersey City, NY/NJ	47
Sumter, SC	46

Note: FFS (fee-for-service). Geographic areas are defined as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, the MSA is divided into multiple areas based on state borders. The number of an area's low-value services is adjusted for the demographic characteristics and comorbidities of the area's beneficiaries. This table is based on the narrower versions of the measures of low-value services (instead of the broader versions) because they represent a more conservative estimate of low-value care. See online Appendix 10-A, available at <http://www.medpac.gov>, for a list of the measures and their sources. The national average number of low-value services per 100 beneficiaries is 32.1.

Source: MedPAC analysis of 100 percent of Medicare claims using measures developed by Schwartz and colleagues (Schwartz et al. 2015, Schwartz et al. 2014).

Case studies of potentially low-value services

We examined three case studies of services that lack evidence of comparative clinical effectiveness and are therefore potentially low value. The services examined in these case studies are early dialysis for end-stage renal disease, proton beam therapy, and H.P. Acthar Gel® (Acthar, a drug covered under Part D).

Case study 1: Trend in starting dialysis earlier in the course of chronic kidney disease

The timing of starting dialysis for end-stage renal disease (ESRD) is a matter of clinical judgment, guided by values of residual kidney function and symptoms and comorbidities present in affected patients. Data from the mid-1990s through 2010 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease (CKD). The proportion of new dialysis patients with higher levels of residual kidney function steadily increased between 1996 and 2010, from 13 percent to 44 percent (Figure 10-4, p. 322). (An estimated glomerular filtration rate (eGFR)—a measure of residual kidney function—above 10 mL/min/1.73 m² is considered a higher level of residual kidney function. Lower values of this measure suggest comparatively less residual kidney function.)

While the share of patients initiating dialysis earlier in the course of CKD decreased modestly between 2011 and 2016 (from 43 percent to 40 percent, respectively), the share remains three times higher than in 1996. The trend of earlier dialysis initiation is seen in other countries, but U.S. dialysis patients are initiated at a higher mean eGFR level than most other countries (Robinson et al. 2014).

Researchers have questioned this early initiation of dialysis in those with late-stage CKD, concluding that it is not associated with improved survival or clinical outcomes (Cooper et al. 2010, Evans et al. 2011, Kazmi et al. 2005, Stel et al. 2009, Traynor et al. 2002). Of the few randomized controlled trials (RCTs) on this topic, the most influential RCT found that survival is similar between patients for whom dialysis is initiated early (with an eGFR equal to 10.0 mL/min/1.73 m² to 14.0 mL/min/1.73 m²) and those for whom dialysis is electively delayed (with an eGFR equal to 5.0 mL/min/1.73 m² to 7.0 mL/min/1.73 m²) and concluded that dialysis can be delayed for some patients until the eGFR drops below 7.0 mL/min/1.73 m² or until more traditional clinical indicators for the initiation of dialysis are present (Cooper et al. 2010). Since publication of this RCT in 2010, the share of early dialysis starts has begun to level off, but it has not yet returned to its earlier levels (Figure 10-4, p. 322). Furthermore, one study

Examining a measure of low-value care in Medicare Advantage compared with fee-for-service Medicare

For the past three years, Medicare Advantage (MA) plans have been reporting the rates of use of a specific low-value service through the Healthcare Effectiveness Data and Information Set® (HEDIS®): the rate of prostate-specific antigen (PSA) testing among men ages 70 and older for whom testing is not recommended (which is different from the age 75 cut-off for other analyses). Unlike measures reported through HEDIS that are based on medical record sampling (411 records per contract), for this measure, plans use administrative or claims and encounter data to report a rate. For this reason, and because the measure applies to a large segment of the population, the measure lends itself to comparison with the Medicare fee-for-service (FFS) population. For the comparison, we computed FFS PSA testing rates using FFS claims data and applying the HEDIS measure specifications.

Because this measure applies to a large number of beneficiaries, we were able to examine MA and FFS

results for this measure by metropolitan areas. That is, we were able to do a market-level analysis using a geographic unit that the Commission has recommended as a possible geographic unit for quality reporting in MA and FFS. The PSA testing measure shows wide variation among MA plans across metropolitan areas—the rate at the 90th percentile is 2.1 times that of the rate at the 10th percentile of metropolitan areas (compared, for example, with the MA breast cancer screening HEDIS measure, which has a 90th-to-10th percentile ratio of 1.2 across metropolitan areas). The data also permit us to analyze variation within markets.

In our analysis, we used data from MA HMO plans on the assumption that HMO plans are more likely to be able to control the use of low-value care and should be expected to perform better than FFS in a given market area. We included only metropolitan statistical areas (MSAs) in which there were at least 1,000 HMO enrollees included in the denominator of the measure (excluding Puerto Rico). Of the 408 metro

(continued next page)

**TABLE
10-5**

Metropolitan areas with the highest rates of nonrecommended PSA testing among Medicare Advantage HMOs

MSA/metro division name	MA			Percentile rank	
	Male enrollees ages 70 and older	Number receiving nonrecommended PSA test	Rate	MA	FFS
Miami–Miami Beach–Kendall, FL	45,052	31,176	69%	100	100
Fort Lauderdale–Pompano Beach–Deerfield Beach, FL	23,540	14,637	62	95	93
McAllen–Edinburg–Mission, TX	4,201	2,462	59	93	43
West Palm Beach–Boca Raton–Delray Beach, FL	13,062	7,438	57	92	99
Beaumont–Port Arthur, TX	2,881	1,516	53	91	95
Knoxville, TN	11,848	6,066	51	90	91
Corpus Christi, TX	5,155	2,635	51	89	88
Jacksonville, FL	5,678	2,899	51	88	52

Note: PSA (prostate-specific antigen), MA (Medicare Advantage), MSA (metropolitan statistical area), FFS (fee-for-service). The denominator used to calculate the rate includes all men ages 70 or over, with certain exclusions (such as prostate cancer diagnosis, dysplasia of the prostate, or prior elevated PSA finding). The exclusions could not be applied to the FFS data, and there may be coding differences between the MA and FFS data, limiting our ability to make a direct comparison of actual MA and FFS rates.

Source: MedPAC analysis of 2017 Healthcare Effectiveness Data and Information Set® data and 2015 FFS claims data.

Examining a measure of low-value care in Medicare Advantage compared with fee-for-service Medicare (cont.)

areas for which we have data reported in the most recent HEDIS reporting period, 113 metro areas (MSAs and metropolitan divisions of large MSAs) met the criterion. The total number of enrollees in the MA denominator for our analysis of the 113 areas was 1.7 million (out of 1.9 million enrollees across all 408 metro areas). The MA results are based on the 2017 HEDIS results for “measurement year” 2016. Our claims-based FFS results are based on claims from 2015.

We found that high rates of nonrecommended PSA testing were common to both MA and FFS in many metropolitan areas. Table 10-5 reports the rates for the metro areas with the highest MA PSA testing rates, along with the percentile ranking across metropolitan areas for MA and for FFS. Table 10-5 shows that

the Miami metropolitan area had the highest relative level of PSA testing among men ages 70 and older for both MA and FFS. (The 100th percentile ranking means that Miami is at the 100th percentile of metro areas.) Among the metropolitan areas shown in Table 10-5, two metropolitan areas show substantially better performance in FFS than in MA: In relation to FFS PSA testing levels across all the 113 metropolitan areas, both the Jacksonville, FL, and McAllen, TX, metro areas have lower FFS rates of PSA testing relative to other areas, while their MA testing rates are very high. (The correlation coefficient of the percentile rankings of the MSAs we examined showed a moderate correlation of 0.60 between an area’s ranking for MA rates and FFS rates.)

(continued next page)

**TABLE
10-6**

Metropolitan areas with the lowest rates of nonrecommended PSA testing among Medicare Advantage HMOs

MSA/metro division name	Male enrollees ages 70 and older	MA		Percentile rank	
		Number receiving nonrecommended PSA test	Rate	MA	FFS
Oakland–Hayward–Berkeley, CA	34,649	5,681	16%	0	46
San Francisco–Redwood City–South San Francisco, CA	15,971	2,660	17	1	11
Sacramento–Roseville–Arden–Arcade, CA	30,600	5,363	18	2	27
Santa Rosa, CA	7,824	1,425	18	3	9
Portland–Vancouver–Hillsboro, OR–WA	29,553	5,804	20	3	19
Denver–Aurora–Lakewood, CO	30,714	6,091	20	4	49
San Jose–Sunnyvale–Santa Clara, CA	20,636	4,100	20	5	54
Salem, OR	5,450	1,084	20	6	16
Seattle–Bellevue–Everett, WA	26,488	5,370	20	7	15
Urban Honolulu, HI	6,600	1,340	20	8	71
Minneapolis–St. Paul–Bloomington, MN–WI	17,851	3,982	22	8	3
Albuquerque, NM	12,388	2,775	22	9	14

Note: PSA (prostate-specific antigen), MA (Medicare Advantage), MSA (metropolitan statistical area), FFS (fee-for-service). The denominator used to calculate the rate includes all men ages 70 and over, with certain exclusions (such as prostate cancer diagnosis, dysplasia of the prostate, or prior elevated PSA finding). The exclusions could not be applied to the FFS data, and there may be coding differences between the MA and FFS data, limiting our ability to make a direct comparison of actual MA and FFS rates.

Source: MedPAC analysis of 2017 Healthcare Effectiveness Data and Information Set® data and 2015 FFS claims data.

Examining a measure of low-value care in Medicare Advantage compared with fee-for-service Medicare (cont.)

Table 10-6 (p. 319) shows the metro areas at the other end of the spectrum—where MA nonrecommended PSA testing rates are low relative to other metro areas (the Oakland, CA, area, at the 0 percentile rank for MA, has the lowest PSA testing rate for MA among the 113 metro areas). Many of the areas (such as the San Francisco area and Minneapolis) have low PSA testing rates in both MA and FFS.

We note that Kaiser Foundation Health Plan (Kaiser) figures prominently in the areas with low use of nonrecommended PSA testing. Except for Albuquerque and Minneapolis, Kaiser has significant MA enrollment in each of the areas listed in Table 10-6 (p. 319). As we noted, the data permit an intramarket analysis, allowing us to look more closely at the different MA plans operating in high-performing markets (Table 10-7). Table 10-7 illustrates what is true for all of the California MSAs shown in Table 10-6 (p. 319), which is that Kaiser is primarily responsible for the area's good performance relative to other market areas (using Sacramento to illustrate the California situation because of the large number of enrollees of other

organizations in that MSA). Other HMOs in the same market do not perform as well as Kaiser. This contrast is not surprising in that Kaiser is a group-model HMO of salaried physicians providing services only to its enrollees, with the health plan (and the Permanente Medical Group) being better able to determine standards of utilization for all their physicians. (The correlation coefficient of the MA and FFS percentile rankings rises to 0.69 if we exclude the MSAs with large Kaiser enrollment.)

Inferences drawn from our analysis of nonrecommended PSA testing in Medicare FFS and MA

Many geographic areas have high levels of PSA testing among MA plans, considering this low-value care measure has been in place for three years. Plans have a financial incentive to control the frequency of this service to reduce costs of the test itself and subsequent tests and services that could be of questionable value. An additional consideration is the incentive of addressing quality of care concerns for a plan and for patients who may be subjected to a battery of tests

**TABLE
10-7**

Within-market nonrecommended PSA testing rates among MA HMOs in the Sacramento–Roseville–Arden–Arcade, CA MSA

Parent organization	MA HMO		
	Male enrollees ages 70 and older	Number receiving nonrecommended PSA test	Rate
Kaiser Foundation Health Plan	21,534	2,627	12%
Centene Corporation	2,176	606	28
UnitedHealth Group	4,419	1,248	28
Anthem	386	130	34
Humana	517	195	38
California Physicians' Service	1,190	477	40

Note: PSA (prostate-specific antigen), MA (Medicare Advantage), MSA (metropolitan statistical area). The denominator used to calculate the rate includes all men ages 70 and over, with certain exclusions (such as prostate cancer diagnosis, dysplasia of the prostate, or prior elevated PSA finding). The overall MA PSA testing rate for the Sacramento MSA for all enrollees in all plans serving the MSA, shown in Table 10-4 (p. 317), is 18 percent.

Source: MedPAC analysis of 2017 Healthcare Effectiveness Data and Information Set® data and 2015 fee-for-service Medicare claims data.

(continued next page)

Examining a measure of low-value care in Medicare Advantage compared with fee-for-service Medicare (cont.)

and procedures that are unwarranted. The incentives for plans to control PSA testing may not translate into an incentive for individual physicians to be judicious in the use of this service, particularly if a plan pays physicians on a fee-for-service basis without any financial risk for physicians tied to their utilization. The high rates among some MA plans suggest that if CMS wishes to see reductions in the use of this low-value service, the PSA testing measure could be included as a star measure in the quality bonus program. For example, the HEDIS MA measure of whether adult body mass index is recorded rose from an average rate of 46 percent in 2012, when first included in the star rating system, to the current average rate of 95 percent across MA plans. Though physicians may be paid on a fee-for-service basis without shared risk, some MA sponsors use star rewards programs to provide annual bonuses that are tied to performance on HEDIS measures that are included as star ratings.

The results also speak to the issue of whether there is “spillover” in care patterns between MA and FFS. A beneficial spillover effect would be that, in areas where MA plans have low rates of PSA testing, the conservative use of the measure would spill over into FFS and reduce overutilization of the service in FFS. The PSA testing data are inconclusive in this respect.

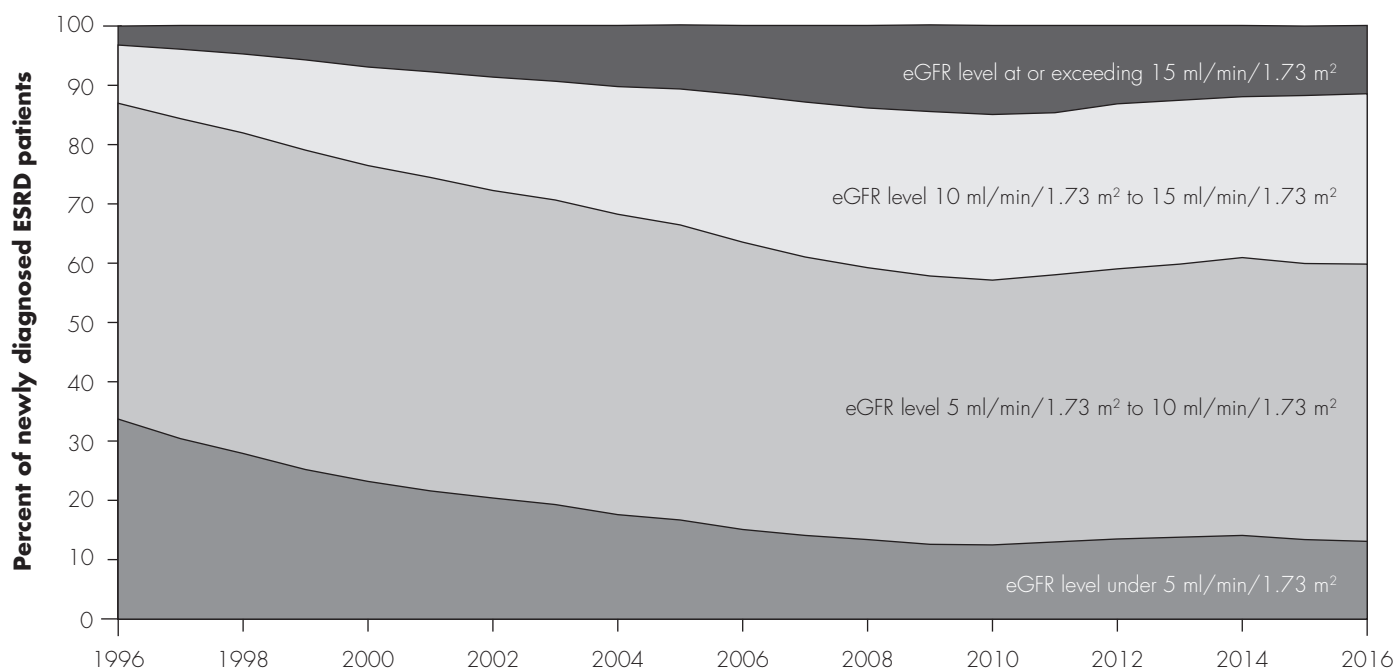
In areas such as Albuquerque and Minneapolis, for example (where Kaiser is not present in the market), is the good performance in both MA and FFS (Table 10-6, p. 319) due to the influence of health plans? Or is it a reflection of the practice patterns of the area’s physician community—in the same way that, in Miami, the high testing rates in both MA and FFS are likely to reflect the community standard of care?

One further observation, given the Commission’s interest in being able to compare quality between MA and FFS, is that the PSA measure is almost exceptional as a measure allowing MA-to-FFS comparisons with the data currently available. The PSA measure has a denominator of 3.3 million across all MA plans, and the measure can be compared with FFS using claims data. For other MA measures, aside from the breast cancer screening measure (a denominator of 3.5 million) and the hospital readmission measure (2.5 million), other HEDIS measures used in the MA star rating system have relatively small denominators (500,000 or fewer—down to 108,000, across MA, for the osteoporosis management measure). For this reason, and because of issues with risk adjustment (for the readmission measure), more work is needed before we are able to do more MA-to-FFS comparisons. ■

reviewing medical records of Department of Veterans Affairs (VA) patients between 2000 and 2009 found that eGFR at dialysis initiation increased, but clinical indicators did not simultaneously increase, indicating that clinical acuity was likely not driving the increase in earlier dialysis initiation (Wong et al. 2016). Moving forward, it will be important to continue monitoring factors that can affect dialysis initiation to ensure that patients receive the most effective and efficient dialysis care.

Our analysis of data on the clinical and demographic characteristics of all patients who started dialysis between 1996 and 2016 found that patients who started dialysis with higher levels of residual function were more likely to be older, male, white, and insured; have certain

comorbidities such as congestive heart failure, diabetes, and cerebrovascular disease; and be unable to ambulate or transfer, be institutionalized, and need assistance with daily activities (Table 10-8, pp. 324–325). Dialysis facility characteristics, including profit status and chain status (data not shown), have a relatively small effect on dialysis timing. Our results are generally consistent with other researchers’, as summarized in the text box on factors influencing the timing of dialysis initiation (pp. 327–329) (Kausz et al. 2000, Li et al. 2017, O’Hare et al. 2011, Slinin et al. 2014). We estimate that Medicare dialysis spending in 2016 for FFS beneficiaries who initiated treatment with higher levels of kidney function ranged from \$500 million to \$1.4 billion.

**FIGURE
10-4****Dialysis has been initiated with higher levels of residual kidney function since 1996**

Note: ESRD (end-stage renal disease), eGFR (estimated glomerular filtration rate). “Higher levels of residual kidney function” refers to patients with an eGFR (a measure of residual kidney function) above 10 milliliters per minute per 1.73 square meters. (Lower values of this measure suggest reduced residual kidney function.) Population includes only patients newly diagnosed with CMS Form 2728.

Source: MedPAC analysis of Medicare’s medical evidence form (Form 2728) submitted by dialysis providers to CMS.

Since 2010, improved comparative clinical effectiveness evidence has moderated the trend of early dialysis The trend of earlier dialysis initiation began in part because older studies—none of which were RCTs—indicated that beginning patients on dialysis at higher levels of renal function would allow them to preserve residual kidney function, prevent or reverse nutritional deterioration, and increase survival rates (CANUSA 1996, Hakim and Lazarus 1995, Lin and Zuo 2015, Owen et al. 1993, Rosansky et al. 2011). Based on this research, multiple national and international nephrology groups began releasing clinical guidelines in the late 1990s that promoted dialysis initiation at progressively higher eGFR values (Lin and Zuo 2015, O’Hare et al. 2011). Although these guidelines were intended to assist providers in making decisions, the circumstances in which patients initiate dialysis are often complicated by additional factors that may not be fully addressed in the guidelines (e.g., eGFR trajectory over time, acute illnesses, and preferences of patients and providers).

The tendency to initiate dialysis early began to shift in the late 2000s as more studies comparing the outcomes

of patients starting dialysis at different times found that beginning dialysis at earlier levels of kidney function provided no advantage over starting dialysis later and, in some cases, led to worse patient outcomes (e.g., mortality) (Beddhu et al. 2003, Rosansky et al. 2009, Wright et al. 2010).

Few RCTs comparing patient outcomes based on dialysis start time have been published (Cooper et al. 2010). The most influential RCT, the Initiating Dialysis Early and Late (IDEAL) RCT, assigned patients to one of two groups: the early-start group (eGFR 10–14 mL/min/1.73 m²) or the late-start group (eGFR 5–7 mL/min/1.73 m²). While patients were supposed to begin dialysis based on the group that they had been assigned to, clinicians were not to delay dialysis if they believed the patient required it. In the end, the late-start group initiated at a higher eGFR than originally anticipated, which provided a smaller between-group difference. Between the two groups, researchers found no significant

differences in survival rates, cardiovascular or infectious events, or quality of life (Table 10-9, p. 326) (Cooper et al. 2010, Harris et al. 2011). IDEAL therefore challenged the previous notion that an earlier start to dialysis led to better patient outcomes.

Some researchers have raised concerns about IDEAL's design and study population. Regarding the timing of patients beginning dialysis, the mean eGFR at dialysis initiation for the late-start group was higher than originally planned, which could minimize potential differences between the two groups (Lin and Zuo 2015). Because the study took place in Australia and New Zealand, some question the generalizability of its results for a U.S. patient population, which is more diverse and has a higher prevalence of comorbidities (Rivara and Mehrotra 2017). Additionally, IDEAL participants had lower use of catheters and in-center hemodialysis than the general U.S. dialysis population.

Recent retrospective studies (that are not RCTs) since 2010 have generally confirmed IDEAL's findings that early initiation of dialysis relative to later initiation does not improve patient outcomes, and for some patients it can lead to worse outcomes (Rivara and Mehrotra 2017, Susantitaphong et al. 2012). Because no clear time frame for dialysis initiation has emerged in the literature, recent studies and the most current clinical guidelines advocate for an individualized approach to initiation based on patient signs and symptoms indicating kidney failure (Lin and Zuo 2015, National Kidney Foundation 2015, Rosansky et al. 2011).

Costs associated with early dialysis initiation We estimate that dialysis spending in 2016 for FFS Medicare beneficiaries who initiated treatment with higher levels of kidney function ranged from \$500 million to \$1.4 billion. The first estimate is based on the additional number of FFS beneficiaries who initiated early treatment (with an eGFR of 10 ml/min/1.73 m² or more) in 2016 relative to 1996. The second estimate is based on the research finding that dialysis began five months earlier in 2007 compared with 1997, which we applied to the number of new FFS Medicare dialysis beneficiaries in 2016.²⁷

Case study 2: Proton beam therapy

Proton beam therapy is a type of external beam radiation therapy used primarily for cancer treatment. Although it was initially a treatment for pediatric cancers and rare adult cancers, its use has expanded in recent years to include more common conditions, such as prostate and

lung cancer. However, there is a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Nevertheless, the number of proton beam centers in the United States has increased rapidly since 2009. Medicare's payment rates are substantially higher for proton beam therapy than other types of radiation therapy, and Medicare has few coverage restrictions on this treatment. Spending and volume for proton beam therapy in FFS Medicare grew rapidly from 2010 to 2016, driven by the sharp increase in the number of centers and Medicare's relatively broad coverage. Prostate cancer was by far the most common condition treated by proton beam therapy in Medicare, accounting for almost half of total spending and volume.

Compared with other types of radiation therapy, proton beam therapy delivers a more focused beam of radiation to the tumor and no "exit" dose that irradiates tissue beyond the tumor (Massachusetts General Hospital Cancer Center 2013). It delivers the majority of radiation to the target site with less scattering of radiation to adjacent normal tissues. Initially, proton beam therapy was used primarily for rare conditions for which it is very important to spare sensitive normal tissues adjacent to the tumor, such as cancers of the brain stem, eye, or spinal cord (Ollendorf et al. 2014). It was also used for many pediatric tumors because low-dose irradiation of normal tissue in pediatric patients can cause acute and long-term toxicity. Recently, however, proton beam therapy has been expanded to treat more common cancers such as prostate, lung, liver, and breast cancer because of its ability to spare adjacent tissues from excess radiation (Ollendorf et al. 2014). Despite growth in the use of proton beam therapy for more common cancers, there are uncertainties about its effects on deep-seated tumors such as prostate tumors; about whether there is more scattering of the beam to adjacent tissues than originally estimated; and about the effects of the neutrons that are produced by proton beams on the radiation dose to the patient (Ollendorf et al. 2014).

The Institute for Clinical and Economic Review (ICER) evaluated the evidence of the overall net health benefit (which takes into account clinical effectiveness and potential harms) of proton beam therapy in comparison with its major treatment alternatives for various types of cancer (Ollendorf et al. 2014).²⁸ ICER concluded that proton beam therapy has superior net health benefit for ocular tumors and incremental net health benefit for adult brain and spinal tumors and pediatric cancers.²⁹ ICER judged that proton beam therapy is comparable with alternative treatments for prostate, lung, and liver

**TABLE
10-8**

Mean levels of residual kidney function by patients' characteristics and site of care, 1996-2016

	Mean eGFR				
	1996	2004	2012	2015	2016
All new dialysis patients	6.9	9.2	10.2	9.9	9.9
Age					
≥18 and ≤45 years	6.3	8.2	9.3	9.1	9.0
>45 and ≤65 years	6.8	9.0	10.1	9.7	9.7
>65 and ≤75 years	7.1	9.5	10.5	10.1	10.1
>75 years	7.1	9.8	10.6	10.3	10.3
Gender					
Male	7.1	9.6	10.5	10.2	10.2
Female	6.6	8.8	9.7	9.5	9.5
Race					
White	7.1	9.5	10.4	10.1	10.1
Nonwhite	6.8	8.8	9.7	9.5	9.5
Beneficiary place of residence					
Rural	6.9	9.2	10.2	9.9	9.8
Urban	7.0	9.5	10.3	10.1	10.0
Nephrologist care before dialysis					
0 to 6 months	N/A	N/A	10.4	10.2	10.1
6 to 12 months	N/A	N/A	10.2	9.9	9.8
12 or more months	N/A	N/A	9.8	9.5	9.5
None	N/A	N/A	10.1	9.9	9.8
Insurance					
MA	N/A	N/A	10.5	10.2	10.2
Dual eligible (Medicare and Medicaid)	7.2	9.8	10.7	10.3	10.3
VA	6.7	9.1	9.6	9.3	9.6
Medicare	7.2	9.7	10.6	10.3	10.3
EGHI or other coverage	6.6	8.6	9.5	9.2	9.2
Medicaid only	6.8	9.1	10.0	9.6	9.6
None	5.9	7.9	8.6	8.3	8.2
Inability to ambulate or transfer					
No	6.8	9.2	10.0	9.7	9.7
Yes	8.2	11.0	12.3	11.9	11.8

Note: eGFR (estimated glomerular filtration), N/A (not available), MA (Medicare Advantage), VA (Department of Veterans Affairs), EGHI (employer group health insurance), CHF (congestive heart failure). Lower values of eGFR suggest less residual kidney function. This analysis includes dialysis patients 18 years of age and older who initiated dialysis in 1996, 2004, 2012, 2015, or 2016. We assigned patients to seven mutually exclusive insurance categories (reported at dialysis initiation) according to the following hierarchy: (1) MA, (2) dually eligible for Medicare and Medicaid, (3) VA, (4) Medicare with or without EGHI, (5) EGHI with or without other coverage; (6) Medicaid only, and (7) none. The presence of comorbid conditions (cerebrovascular disease, CHF, diabetes) includes conditions present at the dialysis initiation or during the 10 years before treatment. "Facility type" refers to the facility at which the patient received dialysis at treatment initiation. "Facility capacity" was measured by assessing the total number of Medicare treatments furnished in the given year; small facilities furnished fewer than 6,500 treatments, while larger facilities furnished 6,500 treatments or more.

Source: MedPAC analysis of Medicare Form 2728 and claims submitted to CMS.

(continued next page)

**TABLE
10-8**

Mean levels of residual kidney function by patients' characteristics and site of care, 1996-2016 (cont.)

	Mean eGFR				
	1996	2004	2012	2015	2016
Institutionalized					
No	N/A	N/A	10.0	9.7	9.7
Yes	N/A	N/A	12.2	11.9	11.8
Needs help with daily activities					
No	N/A	N/A	10.0	9.7	9.7
Yes	N/A	N/A	11.6	11.3	11.2
Cerebrovascular disease					
No	6.8	9.2	10.1	9.8	9.8
Yes	7.5	9.9	10.7	10.4	10.4
CHF					
No	6.4	8.7	9.6	9.3	9.3
Yes	7.8	10.4	11.6	11.3	11.3
Diabetes					
No	6.3	8.6	9.7	9.3	9.3
Yes	7.6	10.0	10.6	10.3	10.3
Facility type					
Freestanding	7.0	9.3	10.2	9.9	9.9
Hospital based	6.7	8.9	10.2	9.9	9.9
Facility capacity					
Small	N/A	9.2	10.0	9.7	9.7
Large	N/A	9.6	10.6	10.2	10.2

Note: eGFR (estimated glomerular filtration), N/A (not available), MA (Medicare Advantage), VA (Department of Veterans Affairs), EGHI (employer group health insurance), CHF (congestive heart failure). Lower values of eGFR suggest less residual kidney function. This analysis includes dialysis patients 18 years of age and older who initiated dialysis in 1996, 2004, 2012, 2015, or 2016. We assigned patients to seven mutually exclusive insurance categories (reported at dialysis initiation) according to the following hierarchy: (1) MA, (2) dually eligible for Medicare and Medicaid, (3) VA, (4) Medicare with or without EGHI, (5) EGHI with or without other coverage; (6) Medicaid only, and (7) none. The presence of comorbid conditions (cerebrovascular disease, CHF, diabetes) includes conditions present at the dialysis initiation or during the 10 years before treatment. "Facility type" refers to the facility at which the patient received dialysis at treatment initiation. "Facility capacity" was measured by assessing the total number of Medicare treatments furnished in the given year; small facilities furnished fewer than 6,500 treatments, while larger facilities furnished 6,500 treatments or more.

Source: MedPAC analysis of Medicare Form 2728 and claims submitted to CMS.

cancer, although the strength of evidence was low for these conditions.³⁰ For example, there was only one RCT comparing proton beam therapy for prostate cancer with an alternative radiation treatment, which found that most patient outcomes for the two treatments were similar. ICER determined that the evidence base for other conditions (including breast and gastrointestinal cancer) was insufficient to determine the net health benefit.

Under a contract with the Agency for Healthcare Research and Quality (AHRQ), the ECRI Institute-Penn Medicine Evidence-based Practice Center reviewed evidence of various treatments for clinically localized prostate cancer, including proton beam therapy (Sun et al. 2014). The report found that the evidence for most treatment comparisons is inadequate to determine the comparative risks and benefits of treatments for prostate cancer.

**TABLE
10-9**

Outcomes of a randomized controlled trial comparing early and late initiation of dialysis

	Late initiation of dialysis	Early initiation of dialysis
Mean eGFR at dialysis initiation (mL/min/1.73 m ²)	9.8	12.0
All-cause mortality (number of events per 100 patient-years)	9.8	10.2
Cardiovascular events (number of events per 100 patient-years)	8.8	10.9
Infectious events (number of events per 100 patient-years)	14.3	12.4
Quality of life (quality-adjusted life-years)	2.1	2.0
Dialysis cost (per patient)	\$96,763	\$117,163

Note: eGFR (estimated glomerular filtration rate). The Initiating Dialysis Early and Late (IDEAL) study randomized patients to one of two groups: planned early dialysis initiation or planned late dialysis initiation. The last two outcomes (quality of life, dialysis cost per patient) came from Harris and colleagues (2011) and used a slightly smaller group of patients from the IDEAL cohort than were used for the analysis in the first four outcomes, which came from Cooper and colleagues (2010). The cost of dialysis per patient is the only category that significantly differed between the two groups.

Sources: Cooper et al. 2010, Harris et al. 2011.

The report called for more RCTs and better designed observational studies to evaluate the alternative therapies.

Although it is expensive to construct a proton beam facility, the expansion of proton beam therapy to more common cancers has spurred substantial growth in the number of these facilities. A large facility with multiple treatment rooms typically costs between \$150 million and \$200 million (Ollendorf et al. 2014). However, a new, compact proton system with one treatment room costs between \$25 million and \$30 million (Beck 2015). As of 2009, there were only six proton beam facilities in the United States. Since then, 21 facilities have opened, 10 facilities are under construction, and 4 facilities are in the planning stage (Particle Therapy Co-Operative Group 2018).³¹

Medicare’s payment rates are higher for proton beam therapy than for other types of radiation therapy

Medicare’s payment rates are substantially higher for proton beam therapy than for other types of external beam radiation therapy, such as intensity-modulated radiation therapy (IMRT). IMRT uses thin beams of radiation that are aimed at the tumor from many angles, which reduces the damage to healthy tissue near the tumor. Both proton beam therapy and IMRT receive a separate payment for each session of treatment, although treatment for most cancers involves many sessions over multiple weeks. For

example, proton beam therapy for prostate cancer involves seven to nine weeks of daily treatment (Yu et al. 2013). When radiation therapy is delivered in a hospital outpatient department, it is paid under the hospital outpatient prospective payment system (OPPS). In 2016, the national OPPS rate for the most common proton beam therapy Healthcare Common Procedure Coding System (HCPCS) codes was \$1,151 per treatment session, compared with \$506 for IMRT.³² When radiation therapy is delivered in a freestanding facility, it is paid under Medicare’s fee schedule for physicians and other health professionals, commonly called the fee schedule. CMS sets national payment rates for most fee schedule services. Services that do not have a national payment rate, such as proton beam therapy, receive payment amounts that are determined separately by each MAC (these are called carrier-priced codes). Because there is no national payment rate for proton beam therapy under the fee schedule, we used claims data to calculate the mean and median payment amount per treatment session for proton beam therapy services in 2016. The mean payment was \$988, and the median payment was \$1,010. By comparison, the national payment rate for IMRT under the fee schedule in 2016 ranged from \$346 to \$348, depending on the code.

According to a study by Yu and colleagues, the median amount paid by Medicare for a course of radiation therapy

Summary of factors influencing the timing of dialysis initiation

While the optimal timing for dialysis initiation is still unknown, we conducted a literature review to better understand the factors that influence the decision to initiate. Most often, the timing is decided by the nephrologist of end-stage renal disease (ESRD) patients and is based on clinical judgment that is guided by values of residual kidney function and the patient's signs and symptoms of kidney failure (e.g., fluid overload, fatigue), including those related to comorbidity (Li et al. 2017, Rosansky et al. 2009).³³ Clinical guidelines also impact dialysis timing, and some practitioners have based dialysis initiation on estimated glomerular filtration rate (eGFR) values specified in earlier clinical guidelines (O'Hare et al. 2011, Robinson et al. 2014). In addition to the level of residual kidney function and clinical guidelines, patient-level and provider-level factors can also impact the decision to begin dialysis, including:

- patients' clinical characteristics,
- patients' demographics,
- nephrologists' training and experience,
- the availability of nephrology care before dialysis initiation, and
- potential financial motivation of dialysis providers and nephrologists.

Clinical guidelines

Clinical guidelines have played an influential role in the timing of dialysis initiation over the past two decades. In 1997, the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) released its first set of guidelines regarding the treatment of chronic kidney disease (CKD), which recommended that dialysis be initiated when

the eGFR fell below 10.5 mL/min/1.73 m² (National Kidney Foundation 1997).³⁴ The 1997 NKF KDOQI guidelines were based on a literature review, which included the Canada–USA Peritoneal Dialysis Study Group (CANUSA) study, an observational study recommending a potential survival benefit for patients who began dialysis between 9 mL/min/1.73 m² and 14 mL/min/1.73 m² (CANUSA 1996, Lin and Zuo 2015). After the release of the NKF guidelines, other nephrology groups followed suit and began specifying levels of kidney function at which time dialysis should begin (or specific levels of function at which time providers should closely monitor patients). In 2006, NKF revised its guidelines and recommended that once patients reached 15 mL/min/1.73 m², “nephrologists should evaluate the benefits, risks, and disadvantages of beginning kidney replacement therapy” (National Kidney Foundation 2006). The revised guidelines were a product of additional studies establishing a link between level of residual kidney function at dialysis initiation and improved nutrition and survival (Rosansky et al. 2011, Shemin et al. 2001, Suda et al. 2000, Termorshuizen et al. 2004). According to researchers, the increased focus that guidelines placed on eGFR values likely contributed to the corresponding rise in eGFR at dialysis initiation (Lin and Zuo 2015, O'Hare et al. 2011).

As more recent literature has indicated that dialysis initiation should not be initiated solely based on calculated kidney function, the content of clinical guidelines has shifted (Rivara and Mehrotra 2017). Multiple national and international nephrology and CKD-focused groups have published updated guidelines regarding initiation of renal replacement therapy, many of which no longer advocate for specific levels of eGFR at which to begin dialysis (e.g., NKF KDOQI 2015 guidelines, the United Kingdom Renal

(continued next page)

for prostate cancer was \$32,428 for proton beam therapy patients and \$18,575 for IMRT patients (Yu et al. 2013). This estimate used claims data from 2008 and 2009 and included all payments for radiation treatment and treatment planning during a three-month period after the start of treatment.³⁵

Rapid growth in spending for and volume of proton beam therapy in Medicare Spending for and volume of proton beam therapy in FFS Medicare grew rapidly from 2010 to 2016 (Figure 10-5, p. 330). Key drivers of this growth include the rapid increase in the number of proton beam centers since 2009 and Medicare's relatively broad

Summary of factors influencing the timing of dialysis initiation (cont.)

Association 2013 guidelines). While the guidelines differ in a few areas, threads of similarity run between the newest versions. Specifically, many include an increased focus on individualized initiation of renal replacement therapy based on patient signs and symptoms of renal failure, while simultaneously moving away from basing initiation solely on calculated levels of kidney function (i.e., eGFR). Shared decision-making between providers and patients has also received increased focus (e.g., the 2010 Renal Physicians Association’s “Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis” guidelines), as has a trend toward safely delaying dialysis when possible.

Patients’ clinical characteristics

As guidelines from nephrology groups have shifted away from focusing predominantly on eGFR levels, the emphasis has been on initiating dialysis based on patient-specific signs and symptoms indicating kidney failure and comorbidities. According to recent guidelines, signs and symptoms that could indicate kidney failure and trigger initiation include volume overload and evidence of uremia (e.g., nausea or vomiting, fatigue). Certain comorbidities (e.g., diabetes) have also been noted in the clinical guidelines as a factor to consider when beginning dialysis. Few studies have systematically evaluated the full breadth of signs and symptoms and comorbidities present at dialysis initiation, but the available literature indicates that individuals with certain comorbidities (e.g., diabetes, congestive heart failure) tend to begin dialysis earlier (Lin and Zuo 2015, O’Hare et al. 2011). Another study indicated wide variation in the signs and symptoms reported at the time of dialysis initiation, with patients beginning dialysis with an average of five different signs and symptoms of kidney failure (Rivara and Mehrotra 2017).³⁶ According to the literature, this wide variation in signs and symptoms present in patients beginning dialysis—in addition to a lack of understanding regarding the optimal timing of dialysis—has contributed to the trend of individualized approaches for dialysis initiation.

Patients’ demographic characteristics

Research indicates that demographic characteristics, including gender and age, may also influence the timing of dialysis initiation (Kausz et al. 2000, Li et al. 2017). Specifically, individuals who are older or male tend to start dialysis earlier than individuals who are younger or female, regardless of clinical severity (Lassalle et al. 2010, Li et al. 2017, O’Hare et al. 2011, Wilson et al. 2007).

Employment and insurance level have also been linked to dialysis start, with individuals who are insured and unemployed starting dialysis at higher levels of kidney function (Kausz et al. 2000, Li et al. 2017). Race can also impact dialysis timing, although these findings are mixed (Li et al. 2017, Streja et al. 2013). Some data also indicate that geography can impact when patients begin dialysis; according to the United States Renal Data System data from 2017, patients living in hospital service areas in the North and Midwest began dialysis at higher eGFRs than individuals living elsewhere (United States Renal Data System 2017). One study reported that decline in eGFR before dialysis initiation occurred more rapidly in younger versus older patients, in African American patients, and in patients with diabetes, but otherwise was similar across patient subgroups (O’Hare et al. 2011).

Nephrologists’ training and experience

Nephrologist characteristics have also been linked to the timing of dialysis initiation. For instance, one study found that nephrologists who were less experienced (defined as zero to eight years of experience) or foreign medical graduates were more likely to begin patients on dialysis earlier (Slinin et al. 2014). According to another study, the number of nephrology providers available in a given state does not impact the timing of dialysis initiation (i.e., a greater number of nephrology providers does not lead to more or earlier dialysis initiations) (Ku et al. 2015). One study found that, while patient-level factors accounted for more of the variation in patients’ eGFR at dialysis initiation, provider-level factors still affected when a patient began dialysis (Li et al. 2017). Understanding provider

(continued next page)

Summary of factors influencing the timing of dialysis initiation (cont.)

characteristics that might impact dialysis initiation is important, especially because providers continue to be predominantly responsible for making the final decision regarding when dialysis will begin (Wong et al. 2016).

The availability of nephrology care before dialysis initiation

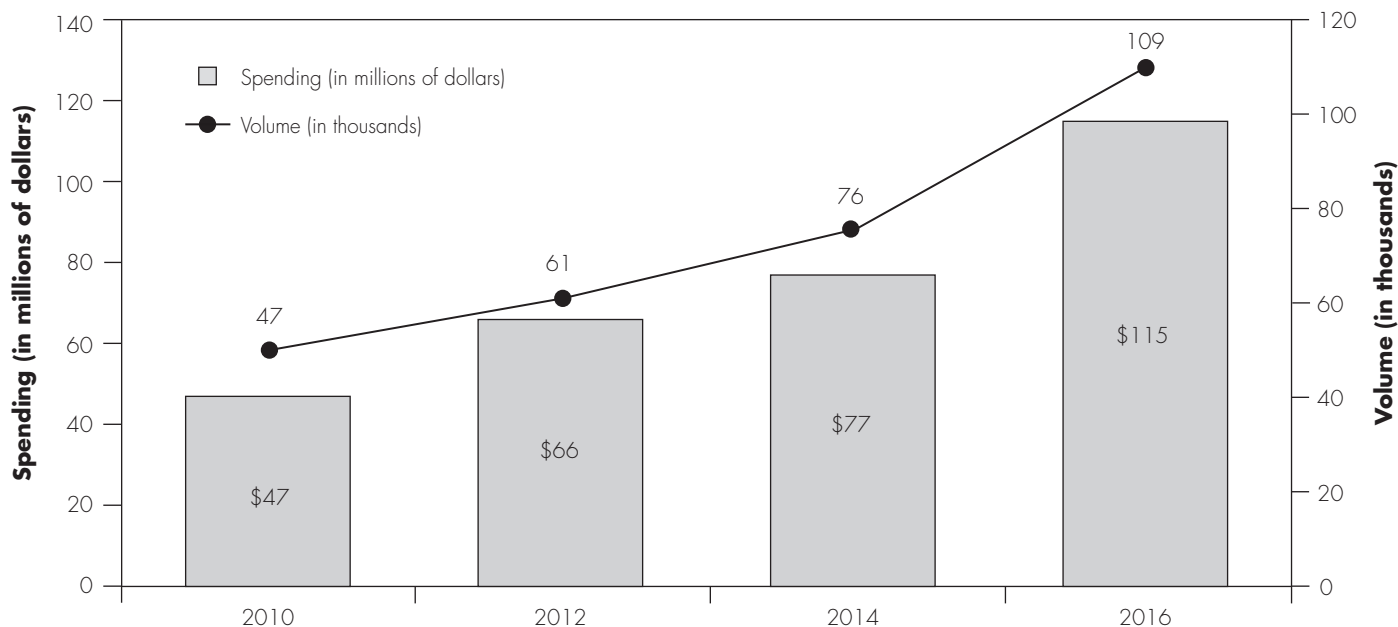
The care a patient receives before renal replacement therapy can impact the timing of dialysis initiation, although the research is mixed as to how timing is affected. While it is believed that patients should be under the care of a nephrologist before beginning dialysis to prevent “crashing” onto dialysis (i.e., an unplanned dialysis start), some research indicates that prior nephrology care can lead to earlier dialysis initiation (Li et al. 2017, Slinin et al. 2014). This literature is mixed, however, with other studies finding that individuals with predialysis nephrology care have lower eGFRs at dialysis initiation than those without predialysis nephrology care (Nee et al. 2017, Slinin et al. 2014). The data also suggest, though, that while predialysis care from a nephrologist might lead to earlier initiation, this relationship decreases the longer a patient receives care from a provider; specifically, individuals who receive care for a year or more before dialysis initiation have lower rates of early initiation (comparable with individuals with no nephrology care) than those who had less than a year of prior care (Slinin et al. 2014).³⁷ Additionally, individuals who have obtained permanent access (i.e., those who have undergone surgery to receive an arteriovenous graft or fistula) have been found to start dialysis earlier than those who have not obtained permanent access (Slinin et al. 2014, Wong et al. 2016).

Potential financial motivation of dialysis providers and nephrologists

Some researchers speculate that dialysis facilities and nephrologists might have a financial incentive to encourage earlier dialysis use (Slinin and Ishani 2014). For example, nephrologists could benefit from initiating dialysis earlier directly through higher physician fees or co-ownership of dialysis facilities or, less directly, through medical directorships of dialysis facilities or greater convenience and efficiency—

that is, by being able to see more patients while rounding in the same dialysis unit (Ramanathan and Winkelmayr 2015). There is a paucity of research in this area, even as some have called attention to how most research on dialysis initiation ignores potential financial motivations (Senekjian 2011). In response, a few recent studies have begun to examine financial motivation with respect to dialysis. One study compared dialysis initiation for veterans who began dialysis in a Department of Veterans Affairs (VA) setting versus a setting outside the VA, and veterans who had their dialysis paid for by the VA versus those who did not (Yu et al. 2015). Differences by setting and payer emerged for the timing of dialysis initiation, with veterans whose dialysis was paid for by the VA—where physicians are salaried and do not handle insurance billing—and administered in VA clinics having the lowest eGFR at dialysis initiation. These findings indicate that the type of health system in which dialysis is begun could impact earlier versus later initiation. This study also found that the differences between groups became more pronounced over the decade-long study period. Additionally, average eGFR at initiation did increase throughout the study period for the entire VA population, indicating that financial incentives may not have been the only factor driving the increase in earlier initiation.

Other studies have argued against financial incentives contributing to differences in eGFR at dialysis initiation. One group examined the difference between for-profit dialysis facilities and nonprofit facilities, expecting that for-profit facilities might have an incentive to start patients early. They found, however, that eGFR at dialysis initiation was fairly similar between the two types of facilities (Rosansky et al. 2009). Additionally, it is unknown whether nephrologist ownership of facilities influences the timing of dialysis initiation, largely because of a lack of available information regarding physician ownership of facilities (Medicare Payment Advisory Commission 2009). In general, research examining financial incentives for beginning dialysis is still in the early phase and has not yet provided conclusive evidence indicating that financial motivation affects the timing of dialysis initiation. ■

**FIGURE
10-5****Spending and volume for proton beam therapy in Medicare grew rapidly, 2010–2016**

Source: MedPAC analysis of claims data for 100 percent of Medicare beneficiaries.

coverage of this treatment. During this period, spending rose from \$47 million to \$115 million (cumulative growth of 144 percent). Spending growth was driven by a 130 percent cumulative increase in volume, as measured by the number of treatment sessions, which increased from 47,420 to 108,960. The number of beneficiaries who received proton beam therapy during this period rose from 1,553 to 3,951 (cumulative growth of 154 percent) (data not shown). The share of volume provided in freestanding centers (vs. hospital outpatient departments) increased from 61 percent to 71 percent (data not shown). Prostate cancer was by far the most common condition treated by proton beam therapy, accounting for 44 percent of total spending in 2016 and 46 percent of total volume. About 1,500 beneficiaries with prostate cancer were treated with proton beam therapy in 2016 (comprising 38 percent of the beneficiaries who received this treatment).

Coverage of proton beam therapy by Medicare and other payers There is no national coverage determination for proton beam therapy in Medicare, but four MACs have LCDs for this treatment. MACs that do not have LCDs

for proton beam therapy cover it as long as it is reasonable and necessary. Three MACs—Cahaba Government Benefit Administrators, CGS Administrators, and First Coast Service Options—have similar LCDs that divide indications for proton beam therapy into two groups and place conditions on coverage for indications in the second group (Centers for Medicare & Medicaid Services 2016b, Centers for Medicare & Medicaid Services 2015a, Centers for Medicare & Medicaid Services 2015c).³⁸ Under Cahaba’s LCD, for example, Group 1 includes conditions for which proton beam therapy is considered medically reasonable and necessary, such as certain tumors of the central nervous system, tumors located at the base of the skull, and intraocular melanomas (Centers for Medicare & Medicaid Services 2015c). Group 2 includes conditions for which proton beam therapy is still under investigation, such as certain lung cancers, breast tumors, liver tumors, and nonmetastatic prostate cancer. Proton beam therapy is covered for these conditions when the intent of treatment is curative (for primary lesions) or life expectancy is greater than two years (for metastatic disease). In addition, the patient must be enrolled in a clinical trial or enrolled

in a national or regional clinical registry.³⁹ Conditions that are not listed for Group 1 or Group 2 are not covered. A fourth MAC—National Government Services—also has an LCD that divides indications for proton beam therapy into two groups but does not require that patients treated for conditions in Group 2 be enrolled in a clinical trial or registry or treated in a protocol designed for evidence development (Centers for Medicare & Medicaid Services 2015b).⁴⁰

In 2006, the Medicare carrier for Virginia (TrailBlazer Health Enterprises) proposed an LCD that contained a least costly alternative (LCA) policy for proton beam therapy that would have paid for this treatment at the same payment rate as IMRT for some conditions (including prostate cancer) and the same rate as conventional radiation for other conditions (TrailBlazer Health Enterprises 2006).⁴¹ Under an LCA policy, comparative clinical effectiveness evidence is used to determine the payment of alternative treatment options (assigned to separate billing codes) based on the rate of the lowest cost service. TrailBlazer did not implement the LCA.

Unlike Medicare's relatively broad coverage of proton beam therapy, Washington State has more limited coverage of this treatment for state government health insurance programs. The state covers proton beam therapy for ocular cancers, pediatric cancers, and central nervous system tumors, but covers it for other nonmetastatic cancers only at the state agency's discretion and only if the patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy (Washington State Health Care Authority 2014). Washington State has a unique health technology assessment program to determine which services will be covered for state employees, FFS Medicaid beneficiaries, and workers-compensation claimants. An independent clinical committee of health care practitioners—the Health Technology Clinical Committee (HTCC)—reviews evidence-based reports about whether certain medical devices, procedures, and tests are safe and effective to determine whether the state should pay for the technology. The HTCC bases its decisions on the safety, effectiveness, and cost-effectiveness of the technology. The state used this process to determine coverage for proton beam therapy.

Two national commercial insurers (Aetna and Anthem) cover proton beam therapy for certain conditions but not prostate cancer. Aetna considers it medically necessary for chordomas or chondrosarcomas at the base of the skull or

cervical spine, cancer in children, and uveal melanomas (cancers of the eye) (Aetna 2014). The insurer considers it not medically necessary for localized prostate cancer because it has not been proven to be more effective than other types of radiation. Aetna considers it experimental and investigational for all other indications. Anthem covers proton beam therapy for the same conditions as Aetna, plus a few others (e.g., central nervous system lesions) (Anthem 2018). Anthem considers it investigational and not medically necessary for all other indications, including localized prostate cancer.

Case study 3: H.P. Acthar Gel®

H.P. Acthar Gel (Acthar) is an older, Part D-covered drug that has experienced rapid growth in prices and Medicare spending over the last several years, despite weak evidence that it is effective for adult indications. Between 2001 and 2017, the average price per vial increased from \$748 to \$38,000. Between 2011 and 2015, Medicare spending for Acthar increased from \$49 million to \$504 million. Fewer than 2,000 clinicians prescribed Acthar to beneficiaries in 2015, and 71 percent of them received at least one nonresearch payment from the manufacturer of Acthar related to the drug. Two-thirds of the total payments were compensation for services other than consulting, such as promotional speaking fees. These financial relationships raise questions about conflicts of interest among prescribers of Acthar.

Acthar is an injectable biologic that was approved by the FDA in 1952 and is indicated for the treatment of infantile spasms in children and eight other immunologic diseases or conditions, such as exacerbations of multiple sclerosis (MS) in adults (Food and Drug Administration 2015, Shakil and Redberg 2017).⁴² When the drug was approved, the FDA did not require clinical trials to demonstrate its effectiveness (Morgenson 2014).

The evidence that Acthar is effective for adult conditions is weak (Shakil and Redberg 2017). Most of the studies of Acthar for adult conditions are small, retrospective or prospective observational studies that do not compare Acthar with other drugs or placebo. Two small, prospective randomized trials from the 1980s compared Acthar with intravenous methylprednisolone (a cheaper drug) for patients with acute relapse of MS (Barnes et al. 1985, Thompson et al. 1989). Both studies found that, three months after treatment started, both drugs produced comparable clinical benefits. A randomized trial conducted in the 1960s used several clinical measures

**TABLE
10-10****Medicare Part D spending and volume for H.P. Acthar Gel[®] grew rapidly, 2011-2015**

	2011	2012	2013	2014	2015	Percent change, 2011-2015
Gross spending (millions)	\$49	\$141	\$263	\$391	\$504	919%
Number of prescriptions	1,471	3,387	6,752	9,611	11,209	662
Spending per prescription	\$33,621	\$41,763	\$38,889	\$40,702	\$44,964	34
Number of beneficiaries who filled a prescription	853	1,583	2,431	2,932	3,104	264
Spending per beneficiary	\$57,980	\$89,357	\$108,014	\$133,421	\$162,371	180
Number of prescriptions per beneficiary	1.7	2.1	2.8	3.3	3.6	109

Note: Gross spending does not reflect manufacturers' rebates.

Source: MedPAC analysis of Medicare drug spending data from CMS.

to compare Acthar with a placebo for patients with an acute exacerbation of MS (Rose et al. 1970). Four weeks after treatment began, patients who received Acthar were statistically more likely to improve than patients who received placebo according to some measures but not others.⁴³ However, the differences between Acthar and placebo were generally modest, and the study had a relatively short observation period.

Even though Acthar has been on the market since 1952, its price has increased rapidly since 2001, when the drug was acquired by Questcor (Shakil and Redberg 2017). Between 2001 and 2014, the average price per vial increased from \$748 to \$34,034 (Robinson 2017). In 2014, Acthar was acquired by Mallinckrodt, which raised the price per vial in 2017 to \$38,000 (Lopez 2017).

The manufacturers of Acthar have been able to sustain a high price for the drug in part because there is no generic version. Although Acthar's patent has expired, it received orphan drug status from the FDA in 2010 for treatment of infantile spasms. Orphan drug status conveyed market exclusivity (sole marketing rights) to the manufacturer for seven years, which ended in October 2017. In 2013, Questcor acquired the U.S. rights to a synthetic version of Acthar called Synacthen Depot. The Federal Trade Commission filed a complaint alleging that Questcor

acquired the competing drug to prevent another company from purchasing it and selling it in the United States, which enabled Questcor to preserve its monopoly over Acthar and maintain very high prices (Federal Trade Commission 2017b). Mallinckrodt, which had purchased the rights to Acthar, settled the charges in 2017 and agreed to license the rights to develop and market Synacthen Depot in the United States to another company (Federal Trade Commission 2017a). However, Synacthen Depot is not yet on the market. A separate manufacturer (ANI Pharmaceuticals) is also developing a generic competitor to Acthar that is not yet on the market (PRNewswire 2018).

Between 2011 and 2015, Medicare spending for Acthar under Part D increased from \$49 million to \$504 million (cumulative growth of 919 percent), driven by 264 percent growth in the number of beneficiaries who received the drug and 180 percent growth in spending per beneficiary (Table 10-10).⁴⁴ Although a very small number of beneficiaries receive Acthar, spending per beneficiary is remarkably high. From 2011 to 2015, the number of beneficiaries prescribed the drug rose from 853 to 3,104, while spending per beneficiary increased from almost \$58,000 to over \$162,000. At the same time, the average number of prescriptions per beneficiary grew from 1.7 to 3.6, and spending per prescription rose from almost

**TABLE
10-11**

Payments by manufacturer of H.P. Acthar Gel® to physicians who prescribed it to Medicare beneficiaries, by payment category, 2015

	Payments		Physicians		Payments per physician	
	Amount (in thousands)	Share of total	Number*	Share of all physicians who received a payment**	Mean	Median
Compensation for services other than consulting	\$3,295	67%	211	17%	\$15,617	\$9,950
Travel and lodging	869	18	207	17	4,198	1,846
Consulting fee	470	10	162	13	2,901	2,700
Food and beverage	267	5	1,233	100	217	120
Education	7	<1	220	18	31	6
Total	4,908	100	1,235		3,974	127

Note: Table excludes research payments and ownership interests. "Compensation for services other than consulting" includes payments for speaking, training, and educational engagements that are not related to continuing education.
 *There were 1,235 unique physicians who received at least one payment from the manufacturer. This column does not sum to 1,235 because a physician could have received payments in multiple categories.
 **This column indicates the share of physicians who received a payment in each category from the manufacturer. Because a single physician could have received payments in multiple categories, this column does not sum to 100 percent.

Source: MedPAC analysis of Medicare Part D prescription drug event data from CMS and Open Payments data (general payments file) from CMS.

\$34,000 to almost \$45,000.⁴⁵ Based on our analysis of Medicare Part D prescription drug event data, 1,743 clinicians prescribed Acthar in 2015 (data not shown). The top decile of Acthar prescribers accounted for 41 percent of total Acthar prescriptions and 40 percent of total spending. In Medicare Part D, the most frequent prescribers of Acthar are rheumatologists, neurologists, and nephrologists (Hartung et al. 2017).

In 2017, most Part D plans did not cover Acthar, and those that covered it used utilization management tools to control its use. Less than 6 percent of stand-alone prescription drug plans and about one-quarter of Medicare Advantage–Prescription Drug plans included Acthar on their formularies (these figures are not weighted by the number of enrollees in each plan). All of the plans that listed Acthar on their formularies required prior authorization for it, and a small number of these plans also had quantity limits. We do not have information on whether Acthar was included in formularies or subject to prior authorization in previous years.

We linked Medicare data from 2015 on Acthar prescribers to data from 2015 on payments to physicians from drug

and device manufacturers, which we obtained from CMS’s Open Payments system. Under Open Payments, manufacturers report to CMS information about certain payments and other transfers of value to physicians and teaching hospitals (Centers for Medicare & Medicaid Services 2017a, Medicare Payment Advisory Commission 2017). We found that 71 percent of clinicians (1,235) who prescribed Acthar to Medicare beneficiaries in 2015 received at least one nonresearch payment from the manufacturer related to the drug. The collective value of these payments was \$4.9 million. On average, each physician received \$3,974 in payments (median of \$127). Of the total payments for Acthar, 44 percent were received by neurosurgeons, 25 percent by rheumatologists, 14 percent by nephrologists, and 11 percent by neurologists (data not shown).

Two-thirds of the total payment amount was compensation for services other than consulting, 18 percent was for travel and lodging, 10 percent was for consulting fees, and 5 percent was for food and beverage (Table 10-11). Compensation for services other than consulting includes payments for speaking, training, and educational engagements that are not related to continuing education

(e.g., a manufacturer pays a physician to talk about a drug to other physicians at a restaurant) (Centers for Medicare & Medicaid Services 2017c). About 200 physicians (17 percent of Acthar prescribers who received payments from the manufacturer) received compensation for services other than consulting, with each physician receiving \$15,617, on average (median of \$9,950). Almost all Acthar prescribers who received payments from the manufacturer received food and beverage; the average value per physician was \$217 (median of \$120).

We also examined manufacturer payments received by the top 10 percent and the bottom 10 percent of Acthar prescribers in 2015.⁴⁶ Eighty-six percent (149) of the highest prescribing physicians received at least one nonresearch payment related to Acthar, compared with 62 percent (108) of the lowest prescribing physicians. The top 10 percent of prescribers received a total of \$1.8 million in payments with a per physician average of \$11,759 (median of \$286). By contrast, the bottom 10 percent of prescribers received a total of \$270,000 in payments with a per physician average of \$2,498 (median of \$107).

The financial relationships between Acthar's manufacturer and physicians who prescribe it raise questions about potential conflicts between physicians' obligations to act in the best interest of their patients and the commercial interests of the manufacturer. Studies have shown that physicians' financial interactions with drug manufacturers are associated with greater willingness to prescribe more expensive drugs (Watkins et al. 2003, Wazana 2000). A recent study found that physicians who received meals related to the promotion of specific brand-name medications had a higher rate of prescribing those medications to Medicare beneficiaries (DeJong et al. 2016).

Tools for addressing low-value care

There are various tools available to payers to reduce the use of low-value services. The tools that are appropriate for a given service depend on the strength of the evidence for the service's value (including its comparative clinical effectiveness), the availability of clinical information to determine the service's value, and the service's cost. Administrative tools such as coverage determinations, prior authorization, and changes to beneficiary cost sharing may be appropriate when there is strong evidence that a service is low value for certain patients or settings,

payers have access to clinical information to determine when the service is provided in a low-value circumstance, and the service is costly. For example, there is robust evidence that imaging for nonspecific low back pain does not improve patient outcomes, and MRI scans of the lower back region receive high Medicare payment rates (Chou et al. 2011). In addition, a payer could obtain information about a patient's diagnoses and symptoms to determine whether an imaging study for back pain is low value from claims or by requiring the provider to submit additional information (e.g., through an online system). For example, a diagnosis of cancer, trauma, or neurological impairment could indicate that the imaging study is not low value.

Another tool is an LCA policy, in which payers set a single payment rate for a group of clinically similar services based on the lowest cost item. This policy may be suitable for a service that is much more expensive than a comparable service but there is no evidence that the costlier service is clinically superior to the cheaper one. For example, Medicare pays higher rates for proton beam therapy than IMRT, but there is a lack of evidence that proton beam therapy offers a clinical advantage over IMRT for prostate cancer.

New payment models, such as models that hold providers accountable for the cost and quality of care, may be appropriate for services for which it is more difficult to distinguish low value from high value. For example, the timing of initiation of dialysis depends on a host of factors, such as the values of residual kidney function and the patient's clinical characteristics. One approach is to give providers clinical discretion on when to initiate dialysis if they participate in a model that holds them accountable for total spending and outcomes. Compared with administrative tools such as coverage policies that determine when dialysis may be initiated, this approach would give providers more discretion and may be easier to implement. In addition, payment systems in which providers take responsibility for spending and outcomes could be effective at reducing the use of multiple low-value services. In these models, providers have an incentive to reduce the use of services that do not improve quality or outcomes; have more access to clinical information for determining value than payers; and can decide which low-value services to target based on their prevalence, potential savings, and the cost of interventions to reduce the use of low-value care.

We describe six tools Medicare could consider employing to address the use of low-value care:

- requiring prior authorization for certain types of services
- implementing clinician decision support and provider education
- altering beneficiary cost sharing
- establishing new payment models that foster delivery system reform
- revisiting coverage determinations on an ongoing basis
- linking FFS coverage and payment to clinical comparative effectiveness and cost-effectiveness information

Prior authorization

CMS has adopted prior authorization to reduce the unnecessary use of certain types of durable medical equipment (DME) and other services. Under prior authorization, a provider must obtain approval from a plan or payer for a product or service before delivering it. CMS has tested prior authorization in a variety of demonstrations since 2012, one of which led to the establishment of a national prior authorization process for some types of DME. The Secretary's authority to conduct these demonstrations and implement a national process comes from a variety of sources, including amendments to the Social Security Act and the statutory authority of CMS's Center for Medicare & Medicaid Innovation (CMMI) to test innovative payment and delivery reform models.

In 2011, the Commission recommended that the Congress direct the Secretary to establish a prior authorization program for clinicians who order substantially more advanced diagnostic imaging services (MRI, CT, and nuclear medicine) than their peers (Medicare Payment Advisory Commission 2011). The goal of this approach was to ensure that clinicians who order more of these services than other clinicians use them appropriately. This recommendation has not been adopted.

Prior Authorization of Power Mobility Device Demonstration

On September 1, 2012, CMS launched the first of its prior authorization demonstrations, the Medicare Prior Authorization of Power Mobility Device Demonstration. The demonstration relies on the Secretary's authority to conduct demonstrations to investigate and prosecute fraud in the Medicare program, as laid out in Section 402(a)(1)

(J) of the Social Security Amendments of 1967 (Centers for Medicare & Medicaid Services 2012). Originally applied to FFS beneficiaries in seven states, the demonstration established a prior authorization process for certain power mobility devices (PMDs) (i.e., power wheelchairs) for parts of the country especially prone to fraud and errors. In its first year (September 2012 to September 2013), the demonstration decreased monthly expenditures from \$12 million to \$3 million without impacting beneficiary access to medically necessary items (Centers for Medicare & Medicaid Services 2014e). The demonstration was later extended until August 31, 2018, and expanded to include a total of 19 states.⁴⁷ The PMD Demonstration also led to the development of two new prior authorization demonstrations: the Prior Authorization of Repetitive, Scheduled Non-emergent Ambulance Transport Model and the Prior Authorization Model for Non-Emergent Hyperbaric Oxygen (HBO) Therapy.

Since the PMD Demonstration, CMS has also established a national prior authorization process for certain DMEPOS products (Centers for Medicare & Medicaid Services 2014e). Under Section 1834 of the Social Security Act, CMS is authorized to develop and maintain a master list of DMEPOS products that are frequently used unnecessarily and to establish a prior authorization process for items on the list. As of July 2017, two power wheelchair products were subject to the national prior authorization process (Centers for Medicare & Medicaid Services 2015e).

Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport Model

The Medicare Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Model began on December 1, 2014. The model is a joint effort between CMMI and the Center for Program Integrity. It originally applied to transports occurring within three states, which were chosen because they had high incidences of improper payment for these services (Centers for Medicare & Medicaid Services 2014d, Medicare Payment Advisory Commission 2013). Under this model, a repetitive ambulance service is defined as "a medically necessary ambulance transportation that is furnished in 3 or more round trips during a 10-day period, or at least 1 round trip per week for at least 3 weeks" (Centers for Medicare & Medicaid Services 2015d). For the trip to be medically necessary, the beneficiary must be bed confined or medically required to be transported by ambulance; for example, a trip would not be covered if the beneficiary could be transported by another

method but another method is unavailable. A common example of a covered RSNAT would be a bed-confined beneficiary needing transport to a dialysis appointment. Because of promising early results, the demonstration was expanded through the Medicare Authorization and CHIP Reauthorization Act of 2015 to five additional states and the District of Columbia (DC), beginning in 2016 (Centers for Medicare & Medicaid Services 2015d).⁴⁸

According to its first interim evaluation, the model reduced RSNAT service use and expenditures for ESRD beneficiaries across the 8 model states and DC in 2015 and 2016, with an estimated average reduction of 2.5 RSNAT trips and \$432 in RSNAT expenditures per ESRD beneficiary per quarter (Asher et al. 2017).⁴⁹ In addition, our analysis shows a national decline from 2013 to 2016 in nonemergent ambulance trips to dialysis facilities for ESRD beneficiaries. Although prior authorization likely contributed to the decrease in payments and use of RSNAT services, in October 2013, CMS reduced payment rates by 10 percent for nonemergency basic life support trips to dialysis facilities for ESRD beneficiaries. This payment decrease, which was based, in part, on a previous Commission recommendation, may have contributed to the reported savings (Medicare Payment Advisory Commission 2013).⁵⁰

Quality of care according to the evaluation was mixed, with quantitative analyses evaluating outcomes and access (e.g., mortality, dialysis services) showing little to no change because of the model. The evaluation found an increase in the number of emergency dialysis treatments, but there was not an increase in hospitalizations or emergency department utilization (Asher et al. 2017). Qualitative analysis (e.g., discussions with dialysis facilities, providers, and beneficiaries) suggests that the model may have resulted in some beneficiaries delaying or missing treatment. In the Commission's 2013 mandated report on ambulance services, we suggested that dialysis facilities should be allowed to provide transportation services to their patients by creating exceptions to the anti-kickback statute and the civil monetary penalty law prohibiting inducements to Medicare and Medicaid beneficiaries (Medicare Payment Advisory Commission 2013). Allowing facilities to transport patients to dialysis sessions would ensure that patients do not miss dialysis treatments because of a lack of transportation. Facilities would not be required to offer this service to their patients, and the cost of operating it would not be factored into the bundled payment for dialysis facilities. Later evaluations

from CMS will continue to monitor the success of the demonstration. These evaluations should consider the impact of the 23 percent payment reduction beginning on October 1, 2018, for nonemergency ESRD ambulance transports mandated by the Bipartisan Budget Act of 2018.

Prior Authorization Model for Non-Emergent Hyperbaric Oxygen Therapy

The Prior Authorization Model for Non-Emergent Hyperbaric Oxygen Therapy began on March 1, 2015, and ended on March 1, 2018. Hyperbaric oxygen (HBO) therapy is a treatment that exposes the entire body to oxygen under increased atmospheric pressure and can be provided in an outpatient facility or hospital (Centers for Medicare & Medicaid Services 2016d). The model is a joint effort between CMMI and the Center for Program Integrity and applies to FFS beneficiaries who receive HBO therapy in a hospital outpatient facility, have one of five conditions (e.g., osteoradionecrosis), and reside in one of three model states.⁵¹ According to preliminary data released by CMS, the model slightly decreased expenditures for nonemergent HBO therapy in model states by approximately \$5.33 million over the first 13 months of the model (Centers for Medicare & Medicaid Services 2016c). A formal evaluation of the model is currently under way.

Clinician decision support and provider education

Another set of tools that Medicare could use to reduce the use of low-value care is clinician decision support (CDS) and provider education. According to the literature, interventions that include CDS and performance feedback have the potential to address low-value services, and provider education paired with other strategies also shows promise (Colla et al. 2017a). A related tool is shared decision-making, in which providers communicate information to patients about the outcomes, probabilities, and uncertainties of treatment options, and patients communicate their values and the relative importance they place on benefits and harms (Medicare Payment Advisory Commission 2010).

A 2009 study aimed at reducing inappropriate prescribing of fluoroquinolones, a commonly prescribed antibiotic in ambulatory care and emergency department visits, found that combining provider education with CDS could decrease prescribing of these antibiotics by 30 percent (Wong-Beringer et al. 2009). Additionally, the study showed improved patient outcomes. Another study

examined the impact of combining computerized reviews with clinician education on antibiotic use in a VA hospital (Feucht and Rice 2003). This effort reduced unnecessary intravenous antibiotic use by 26 percent and inappropriate prescriptions of more than five days by 16 percent.

A study by Meeker and colleagues analyzed the effects of behavioral interventions on inappropriate antibiotic prescriptions by primary care clinicians in Boston and Los Angeles (Meeker et al. 2016). Providers were randomly assigned to one of three interventions: suggested alternatives, accountable justification, and peer comparison. This study found that accountable justification (the clinician was prompted to enter free-text justifications for prescribing an antibiotic in the patient's electronic health record) and peer comparison (clinicians were sent emails that compared their antibiotic prescribing rate with those of other providers) were the most effective at lowering inappropriate antibiotic prescribing. Accountable justification decreased prescribing by 18.1 percent, while peer comparison decreased prescribing by 16.3 percent (Meeker et al. 2016).

CMS is developing the Appropriate Use Criteria (AUC) Program that will require clinicians to use CDS when ordering advanced diagnostic imaging services for Medicare beneficiaries (Centers for Medicare & Medicaid Services 2017b).⁵² Under this program, clinicians who order these services will need to consult with CDS software and obtain feedback on whether the services adhere to AUC developed by medical societies or other provider-led entities. Clinicians will be required to use CDS software that is certified by CMS based on certain requirements. CMS is in the process of developing this program, which is scheduled to begin on January 1, 2020. However, a prior demonstration of this approach raises questions about its effectiveness. Under the Medicare Imaging Demonstration (2011 to 2013), physicians who ordered certain advanced imaging studies received feedback about the appropriateness of their orders through CDS software (Timbie et al. 2014).⁵³ An evaluation of this demonstration found that 65 percent of the orders could not be rated for appropriateness because they could not be linked to a clinical guideline used by the CDS systems. This result occurred because the information entered by physicians was not sufficiently precise to match a guideline or a guideline did not exist for the specific clinical scenario. CMS is using the experiences from this demonstration to develop the AUC Program (Centers for Medicare & Medicaid Services 2015f).

The goal of shared decision-making is to improve patients' knowledge of their condition and alternative treatments so they can arrive at treatment decisions with their clinicians that reflect their values and preferences (Medicare Payment Advisory Commission 2010). Information is often conveyed through patient decision aids that give patients evidence-based, objective information on treatment options for a given condition. Shared decision-making programs often focus on preference-sensitive care (i.e., care that depends on patient preferences when two or more options exist). Several low-value services are preference sensitive, such as cancer screening for older adults, imaging for nonspecific low back pain, spinal injection for low back pain, and arthroscopic surgery for knee osteoarthritis (Schwartz et al. 2015). By conveying evidence-based information to patients about the benefits and risks of treatment options, these programs could help reduce the use of low-value care. The American Cancer Society's recommendation for prostate cancer screening states that men should make an informed decision with their provider about whether to be screened after receiving information about the uncertainties, risks, and potential benefits of screening (American Cancer Society 2016). Studies of shared decision-making programs have found that they reduced invasive treatments without adverse effects on health outcomes (O'Connor et al. 2009, O'Connor et al. 2004).

Altering beneficiary cost sharing

Altering beneficiary cost sharing for certain services is another potential tool to address low-value care. Reducing cost sharing for high-value services should encourage consumers to seek these services. Conversely, increasing cost sharing for services that are deemed low value should discourage patients from obtaining these services. Among the Commission's recommended changes to the benefit design of FFS Medicare is that the Congress should give the Secretary authority to alter or eliminate cost sharing based on evidence of the value of services (Medicare Payment Advisory Commission 2012). Although CMS does not adjust cost sharing in FFS Medicare based on the clinical value of services, CMMI is testing a model that allows MA plans in several states to offer reduced cost sharing or additional benefits to enrollees with certain chronic conditions (Centers for Medicare & Medicaid Services 2018). However, this model does not allow plans to increase cost sharing for low-value services.

Outside of Medicare, some plans and payers adjust cost sharing for different services based on evidence

of their clinical benefits (Chernew et al. 2007). A 2016 study evaluated the impact of such an approach—called value-based insurance design (VBID)—by a large public employer in Oregon (Gruber et al. 2016). The program increased cost sharing for services that were deemed low value: sleep studies, endoscopies, advanced imaging, and surgery for low back pain. The analysis found that the VBID program significantly reduced utilization of the targeted services. However, further evaluations of these types of interventions are needed (Colla et al. 2017a).

New payment models that foster delivery system reform

Medicare could also use new payment models that encourage delivery system reform to reduce low-value care. Payment models that hold providers accountable for the cost and quality of care may create incentives for the efficient delivery of care, including decreased use of low-value services (Colla et al. 2017a).

One such model is the accountable care organization (ACO), in which a group of providers takes responsibility for the cost and quality of care for a group of patients. If an ACO is successful in controlling (or decreasing) costs while maintaining or increasing quality, it may be eligible to share savings with the plan or payer. ACOs that are at one-sided risk are eligible to share savings but are not at risk for losses, while ACOs at two-sided risk share in both savings and losses. One way for ACOs to constrain costs without reducing quality is to reduce the use of low-value services. Preliminary evidence indicates that ACOs at two-sided risk were able to significantly reduce low-value services during their first performance year, which suggests that strong financial incentives can motivate ACOs to target low-value care.

A study by Schwartz and colleagues analyzed the use of 31 low-value services during the first year of Medicare's Pioneer ACO demonstration, a two-sided-risk model (Schwartz et al. 2015). The researchers compared the change in the use of low-value care in the ACO model with the change in a control group, using the periods before and after the ACO contracts went into effect. The authors found a significant reduction in both volume and spending for low-value services in the ACO group relative to the control group. Another study examined the performance of ACOs in the Medicare Shared Savings Program (MSSP) in their first year of operation and found that these ACOs did not achieve significant reductions in the use of low-value services relative to the control group (McWilliams et al. 2016). At the time of the evaluation, all MSSP ACOs were

at one-sided risk. Because these two studies examined only the first year of each ACO model and the models were different in ways other than their type of risk, the evidence is too limited to conclude that one-sided-risk ACOs are unable to reduce the use of low-value care.⁵⁴

Under a payment model similar to ACOs, ESRD Seamless Care Organizations (ESCOs) take responsibility for cost and quality for a group of beneficiaries on dialysis. Large ESCOs are required to accept two-sided risk, but smaller ESCOs may choose either two-sided or one-sided risk.⁵⁵ The ESCO model decreased costs in the first year of operation: Most of the savings resulted from lower inpatient and post-acute care spending rather than significant reductions in unnecessary readmissions or emergency department use (Marrufo et al. 2017). Researchers have not evaluated the impact of the ESCO model on specific low-value services.

Revisiting coverage determinations on an ongoing basis

Revisiting NCDs on an ongoing basis has the potential to reduce low-value care. Even though the majority of determinations are established with “fair” or “poor” evidence, Medicare infrequently revisits its national coverage decisions (see Table 10-2, p. 302). Moreover, nearly all of the reconsiderations that Medicare opened over the past five years have been at the request of external parties (e.g., manufacturers, physicians, medical associations) and have resulted in expanding coverage for the service under consideration. Researchers have raised concerns about the lack of high-quality evidence needed when Medicare develops coverage determinations (Chambers et al. 2015b, Foote et al. 2004, Neumann et al. 2008, Redberg 2007).

In addition, there is concern that services shown to be of high value for the clinical conditions covered in an NCD might be furnished to beneficiaries who do not meet the NCD's clinical criteria (and thus result in low-value care). Huo and colleagues used the National Health Interview Survey to examine the age and smoking history of a sample of individuals who said they had undergone lung cancer screening with low-dose CT. These researchers found that individuals undergoing this screening may not meet the criterion for smoking history specified in Medicare's NCD for this service (Huo et al. 2017).⁵⁶

Some policymakers contend that the Secretary could be more preemptive and establish criteria that would identify NCDs for reconsideration on an ongoing basis. The

criteria could consider the rigor of the clinical evidence that Medicare considered when establishing the NCD. For example, NCDs that were implemented with “fair” or “poor” clinical evidence or without comparative clinical effectiveness evidence could be revisited on an ongoing basis. Criteria could also consider the service’s impact on the Medicare Trust Funds and the rate at which the service diffuses among the Medicare population. On an ongoing basis, the Secretary could assess whether the beneficiary population receiving a service covered under an NCD meets the clinical criteria specified in the NCD. Such an ongoing, preemptive process could ultimately lead to the development of more rigorous clinical evidence and decrease the use of low-value services.

Linking FFS coverage and payment to clinical comparative effectiveness and cost-effectiveness information

Comparative clinical effectiveness—which compares the clinical effectiveness of two or more treatment options for the same condition—serves as the foundation for cost-effectiveness analysis, which compares costs and clinical outcomes of two or more treatment alternatives. Linking information about the comparative clinical effectiveness and cost-effectiveness of health care services to FFS policies has the potential to improve value in Medicare spending.

Over the past decade, policymakers have recognized the importance of comparative clinical effectiveness evidence. In June 2007, we recommended that the Congress establish an independent entity to sponsor credible research on comparative effectiveness and disseminate this information to patients, providers, and payers (Medicare Payment Advisory Commission 2007). The Patient Protection and Affordable Care Act of 2010 (PPACA) established an independent nonprofit entity, the Patient-Centered Outcomes Research Institute (PCORI), to fund and disseminate comparative clinical effectiveness research.

Medicare considers comparative clinical effectiveness evidence in the coverage process when it is available, but such evidence is not required. The program generally does not consider comparative clinical effectiveness evidence in its rate-setting processes and lacks explicit statutory authority to consider a service’s cost-effectiveness when making coverage decisions or setting payment rates. In addition, the use of cost-effectiveness analysis is constrained because PPACA prohibits the Secretary from using certain outcome measures that cost-effectiveness

studies use—quality-adjusted life years or similar measures—to determine coverage or payment. Federal agencies and researchers have supported the use of comparative clinical effectiveness and cost-effectiveness information by Medicare. Some payers, including risk-bearing Medicare providers and purchasers, have the flexibility to use cost-effectiveness evidence for medical and pharmacy management. We examined case studies describing two organizations—PCORI and ICER—that generate information on the value of medical services that has the potential to improve value in Medicare spending.

FFS Medicare generally does not use comparative clinical effectiveness information in coverage and payment policies

Under the local and national coverage processes, a formal review of the medical, technical, and scientific evidence is conducted to evaluate the relevance, usefulness, and medical benefits of an item or service to Medicare beneficiaries. Medicare’s coverage process has the flexibility to consider comparative clinical effectiveness evidence when such evidence is available. However, coverage is generally determined without any requirement for evidence demonstrating that the service in question is equally or more effective than other available, covered treatment options (Pearson and Bach 2010).

The statute includes several constraints in Medicare’s use of comparative clinical effectiveness evidence. For example, Medicare cannot use comparative clinical effectiveness evidence that AHRQ produces under MMA’s Section 1013 to withhold coverage of prescription drugs. Since 2010, PPACA imposes constraints on Medicare’s use of comparative clinical effectiveness research conducted by PCORI when making coverage decisions and setting payment rates. When such evidence is available, the program:

- must use an iterative and transparent process (which includes public comment and consideration of the effect on subpopulations) in formulating coverage decisions;
- cannot use the evidence as the sole source of information to deny coverage;
- cannot use evidence in determining coverage, payment, or incentive programs that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill; and

- cannot use evidence in determining coverage, payment, or incentive programs in a manner that precludes or discourages an individual from choosing a treatment based on how the individual values the trade-off between extending the length of her life and the risk of disability.

Medicare’s payment systems are determined by statutory provisions that generally do not consider a service’s comparative clinical effectiveness. For example, the Part B fee schedule does not consider comparative clinical effectiveness evidence. Payment rates for new services are based on the relative costliness of the inputs used to provide the service: work, practice expenses, and professional liability insurance expenses. Consequently, a new service might be paid at a higher rate than clinically similar treatment options.

The payment rates under the outpatient and inpatient hospital prospective payment systems (PPSs) are generally based on the hospitals’ reported charges converted to costs. However, under Medicare law, CMS considers clinical evidence to encourage the early adoption of cost-increasing, quality-improving technologies. For certain new technologies, the agency considers whether they provide a “substantial clinical improvement” compared with existing technologies to determine whether they qualify for temporary (two to three years) pass-through payments under the outpatient hospital PPS and add-on payments under the inpatient hospital PPS. To qualify for the additional payment, new devices in the outpatient setting and new services and technologies in the inpatient setting must meet a cost threshold and must demonstrate that they provide a substantial clinical improvement compared with treatment alternatives.

Before 2010, CMS linked available comparative clinical effectiveness information in the rate-setting process for certain items and services not covered under a PPS. Referred to as the LCA and functional equivalence policies, Medicare set a single payment rate for a group of clinically similar Part B drugs assigned to separate payment codes based on the lowest cost item. For example:

- Under the LCA policy, Medicare used the prevailing payment policy (which, in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), has been the average sales price plus 6 percent since 2005) to

determine the payment rate for luteinizing hormone-releasing hormone (LHRH) agonists for prostate cancer (assigned to separate billing codes) in a drug class and then set the payment rate for all the clinically comparable drugs (in that class) based on the least costly one. LCA policies were implemented in LCDs in which the MACs decided to cover a particular product in its geographic jurisdiction. As a result of two federal court rulings, Medicare has not used LCA policies since 2010.⁵⁷

- Medicare applied an LCA-type policy—referred to as the functional equivalence policy—on the national level to set the payment rate for anti-anemia drugs paid for under the outpatient hospital PPS. Medicare used the functional equivalence standard in 2004 and 2005. After the enactment of the MMA, the payment rate for each biologic was set based on 106 percent of its average sales price beginning in 2006. In addition, the MMA prohibited the use of the functional equivalence standard for drugs and biologics in the hospital outpatient setting.

The policies’ rationale is that beneficiaries, Medicare, and taxpayers should not pay more for a service when a similar service can be used to treat the same condition and produce the same outcome but at a lower cost.

Other federal agencies have estimated that expanded use of LCA policies would result in savings for beneficiaries and taxpayers. The Congressional Budget Office (CBO) included the use of LCA for Part B drugs in its 2008 budget options related to health care (Congressional Budget Office 2008). The Office of Inspector General (OIG) has twice recommended that the Secretary apply LCA policies to LHRH agonists (Office of Inspector General 2004). Most recently, OIG, in a 2012 report, recommended that CMS seek legislative authority to implement LCA policies for “certain clinically comparable products under circumstances it deems appropriate” (Office of Inspector General 2012). In this report, OIG determined that if LCA policies for the LHRH agonists had not been rescinded, Medicare spending would have been reduced by \$33 million, from \$264 million to \$231 million, over one year (between June 2010 and June 2011).

Some researchers have proposed linking information about the comparative clinical effectiveness of health care services to FFS payment policies to improve value in Medicare spending. For example, Pearson and Bach

proposed that Medicare adopt a “dynamic pricing policy” that would base payment for a new service on the usual statutory formulas, but, after three years, the service’s payment rate would be reduced if comparative clinical effectiveness information did not show that it offered clinical advantages compared with its alternatives (Pearson and Bach 2010).

Some commercial payers link evidence of comparative clinical effectiveness to coverage and payment. For example, one commercial payer concluded that, among drugs in a particular therapeutic class (targeted immune modulators), there is a lack of reliable evidence that any one agent is superior to other agents. Consequently, the payer considers the more costly drugs medically necessary only if the patient has a contraindication, intolerance, or incomplete response to the less costly agents (Aetna 2018).

FFS Medicare generally does not consider cost-effectiveness information in coverage and payment policies

Although the Medicare coverage process for Part A and Part B services considers clinical effectiveness evidence, it generally does not explicitly consider evidence on either cost-effectiveness or cost. Only for preventive services (including vaccinations and colorectal cancer screen tests), and based on legislative requests and statutory directives, has Medicare explicitly considered the cost-effectiveness of a service when making a national coverage decision.

Pneumococcal vaccine, the first preventive service added to the Medicare benefits package, in 1981, was based on a congressionally requested cost-effectiveness analysis, which showed it to be cost saving (Chambers et al. 2015a). Since then, the program has considered the cost-effectiveness of other preventive services, including colorectal cancer screening, breast and cervical cancer screening, and other preventive services. For example, the Omnibus Budget Reconciliation Act of 1987 included a provision requiring the Secretary to conduct a demonstration project to determine the influenza vaccine’s cost-effectiveness. More recently, Medicare considered cost-effectiveness evidence in the NCDs for preventive services, including screening for HIV infection in 2009 and counseling to prevent tobacco use in 2010. Both NCDs cited the provision in the Medicare Improvements for Patients and Providers Act of 2008 that the Secretary, in making determinations for preventive services, “may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may

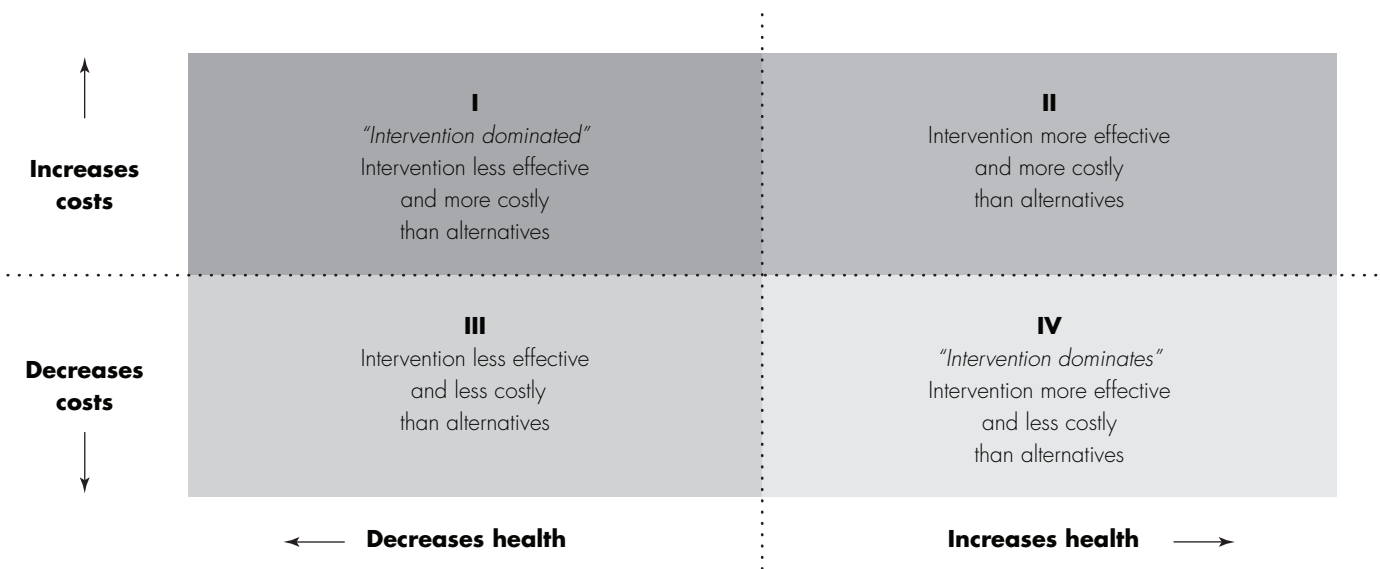
take into account the results of such assessment in making such determination.”

What is cost-effectiveness analysis?

Cost-effectiveness analysis compares the incremental cost in dollars of one intervention with another in creating one unit of health outcome. It has been used to assess a wide range of interventions, including vaccination against pneumococcal pneumonia, bypass surgery for coronary artery disease, and diabetes prevention programs. The results of cost-effectiveness analyses are typically summarized in a series of incremental cost-effectiveness ratios that show, for one intervention compared with another, the cost of achieving an additional unit of health (outcome). To estimate expected health effects and costs, cost-effectiveness analyses require data on each treatment’s clinical effectiveness (including comparative clinical effectiveness evidence, if available), health outcomes, and health care resource use and costs.

All cost-effectiveness analyses require that researchers measure the effect (outcome) of a medical intervention on the quantity of health gained. Some cost-effectiveness analyses express health benefits in terms of outcomes specific to the treatment and disease under investigation, such as the number of cancer cases prevented or the number of cancer-related hospital admissions prevented. While this approach is advantageous in that it focuses narrowly on the disease under consideration, the results of such cost-effectiveness studies cannot be compared with the cost-effectiveness of treatments for other conditions. Alternatively, some cost-effectiveness analyses express health benefits in terms of the number of years of life gained. Although the results of such studies can be compared across different treatments and conditions, the outcome measure—increased survival—does not account for the quality of the additional time that is gained due to a medical intervention. Thus, an added month of life with disability or pain is valued the same as an added month without disability or pain.

Expert panels have recommended that cost-effectiveness analyses use outcome measures that integrate both quantity-of-life and quality-of-life effects (Drummond et al. 2015, Gold et al. 1996, Neumann et al. 2017). For example, the quality-adjusted life year (QALY) estimates the gains from improved morbidity (quality gains) and improved survival (quantity gains) into a single metric. QALYs provide a common currency to assess the extent of the benefits that patients gain from a variety

**FIGURE
10-6****The impact of medical interventions on outcomes and costs**

Note: The figure (often referred to as “the cost-effectiveness plane”) evaluates the impact of medical interventions in terms of their net outcomes and net costs as a grid, with four quadrants showing the impact of interventions as either increasing or decreasing health and costs.

Source: Drummond et al. 2015.

of services in terms of health-related quality of life and survival. To calculate QALYs, weights (ranging from 0 to 1) are assigned to each time period that corresponds to the quality of life during that period. The measure is the arithmetic product of life expectancy and a measure of the quality of the remaining life years. Alternatives to QALYs include healthy-years equivalents, saved young life equivalents, and disability-adjusted life years. Each measure has its own limitations and is subject to debate. Economic evaluations that value increases in survival time and changes in quality of life into one measure are sometimes referred to as *cost-utility analyses*.

By providing estimates of costs (in the numerator) and outcomes (in the denominator), cost-effectiveness analysis shows the tradeoffs involved in choosing among alternative interventions. Researchers commonly think of the value of alternative medical interventions—in terms of their net outcomes and net costs—as a grid, with four quadrants showing the impact of services as either increasing or decreasing health and either increasing or decreasing costs (Figure 10-6) (Drummond et al. 2015).

Researchers refer to this grid as the “cost-effectiveness plane.”

In Figure 10-6, an intervention that falls into Quadrant IV “dominates” because it is more effective and less costly than its alternative. In contrast, an intervention that falls into Quadrant I is “dominated” because it is less effective and more costly than its alternative. An intervention that is more costly and more effective than its alternative falls into Quadrant II, while an intervention that is less costly and less effective than its alternative falls into Quadrant III. Although a new, high-priced innovation may be cost-effective (i.e., have a lower incremental cost-effectiveness ratio) compared with an existing high-priced treatment option, there can be significant financial implications for beneficiaries and taxpayers (Bach 2015).

The number of cost-effectiveness analyses has grown steadily over time. Between 1990 to 1999, the number of published cost-effectiveness analyses averaged 34 per year; by contrast, between 2010 to 2014, the number of published studies averaged more than 500 per year (Baumgardner and Neumann 2017). However, the

application of cost-effectiveness analysis is not equivalent across medical interventions. Between 2010 and 2012, researchers found that nearly half (46 percent) of studies evaluated pharmaceuticals (Neumann and Cohen 2015). Between 1990 and 2012, pharmaceutical manufacturers sponsored an increasing proportion of cost-utility analyses (Neumann and Cohen 2015). During this period, an increasing share of cost-utility studies evaluated oncology interventions while a decreasing share evaluated cardiovascular studies.⁵⁸

The availability of efficacy data on drugs from FDA clinical trials partly accounts for the higher proportion of published studies assessing drugs. In addition, as one component of their pricing strategy, manufacturers may need to show the value of a new drug to formulary committees and other purchasers. Manufacturers also use cost-effectiveness analysis to predict the price that purchasers will be willing to pay for a new drug (Neumann 2005).

Designing a cost-effectiveness analysis When measuring the outcomes and costs of alternative medical interventions, researchers must construct a conceptual model. Such models range from the simple (such as decision trees) to the complex (such as Markov models).

Recognizing the complexity of cost-effectiveness analysis, several panels have endorsed guidelines designed to ensure and improve the quality of such analyses (Gold et al. 1996, Neumann et al. 2017). Recommendations for conducting cost-effectiveness analyses have also been issued by health care organizations, including the World Health Organization and the International Society for Pharmacoeconomics and Health Outcomes, and physician groups, including the American College of Cardiology and the American Heart Association.

A cost-effectiveness analysis typically addresses the following methodological issues:

- **The method of defining costs.** Costs include direct medical (e.g., cost of medical services to payers and patients), direct nonmedical (e.g., transportation costs), and non-health care costs (also referred to as indirect costs) (e.g., value of lost productivity due to illness or death). For example, lost productivity is a measure of the costs associated with impaired ability to work or engage in leisure activities and lost economic productivity due to death.

- **The perspective of the analysis.** The findings of a cost-effectiveness analysis vary depending on the researcher's point of view. A cost-effectiveness analysis from a societal perspective includes everyone who is affected by the service; all health outcomes; and costs borne by insurers and patients, other medical costs, and nonmedical costs. By contrast, a cost-effectiveness analysis from a health care purchaser's viewpoint would include only those outcomes and costs that affect the purchaser. Some researchers recommend that cost-effectiveness analyses report a reference case based on both the health care perspective and the societal perspective (Neumann et al. 2017).
- **The sources of clinical effectiveness data.** Researchers use data from numerous sources, including FDA clinical trials and practical clinical trials, patients' medical records, health care claims submitted to insurers, and health surveys.
- **The selection of alternative interventions.** Some researchers recommend that the complete range of available interventions that are likely to be considered by providers and other decision makers should be included, such as existing practice and no treatment (as appropriate) (Drummond et al. 2015, Neumann et al. 2017). Omission of relevant comparators can produce misleading results. For example, researchers may overestimate the cost-effectiveness of an intervention (and underestimate its incremental cost-effectiveness ratio) because an intervention has not been compared with more cost-effective alternatives that are available (Drummond et al. 2015).
- **The time horizon.** Researchers must choose the period of time to measure a service's costs and outcomes. The time horizon of the analysis should extend far enough into the future to capture important health effects, and the choice of a time horizon should not bias the analysis in favor of one intervention over another (Drummond et al. 2015). Analyses with a societal perspective often follow patients over their lifetime, while analyses with a health care purchaser's perspective often use a shorter time period (e.g., five years).
- **The discounting of costs and outcomes.** When the time horizon of the analysis extends into the future, researchers often convert future costs and future health outcomes to present value. In doing so, researchers

adjust the cost-effectiveness ratios for the different timing of costs and outcomes.

- ***The uncertainty of the clinical events, costs, and outcomes.*** Sensitivity analyses vary the assumptions of the clinical, cost, and outcome data to test for the robustness of the results, to identify the data elements to which the results are particularly sensitive, and to test the point at which one intervention becomes more costly or more effective than another.
- ***The measurement of outcomes.*** Outcomes can be measured in terms of the quantity of health gained, such as number of life-years gained, number of hospital admissions avoided, and number of cases of a particular illness prevented. Alternatively, researchers use measures that combine both the quantity and quality of health gained, such as QALYs, which are widely used in economic evaluations (Drummond et al. 2015). Consensus panels, researchers, and organizations have endorsed using QALYs because the metric reflects effects on both morbidity and mortality and provides a basis for broad comparisons of the health effects of various interventions and policies (Drummond et al. 2015, Gold et al. 1996, Neumann et al. 2017). Even though QALYs are widely used in economic evaluations, the measure has attracted several criticisms, as described in the text box on concerns about QALYs. PPACA prohibits the Secretary from using QALYs (or similar measures) as a threshold to determine Medicare coverage or reimbursement.

Issues and concerns surrounding the use of cost-effectiveness analysis by payers and purchasers

Over the years, numerous stakeholders—drug and device manufacturers, providers, patients, and health economists—have raised issues and concerns about the use of cost-effectiveness information by Medicare and other public and private payers and purchasers.

- ***Some stakeholders mistrust the methods used to conduct cost-effectiveness studies.*** Researchers have noted that methodological approaches vary from study to study. Evaluations of the same services and diseases can sometimes have different results (Eddy 2005, Neumann 2005). The lack of clear reporting on methods has led to concerns from some stakeholders that cost-effectiveness analysis is not transparent. The desire for comparability led the original U.S. Panel on Cost-effectiveness in Health and Medicine

to seek standardization in the conduct and reporting of cost-effectiveness analyses through the creation of a reference case. Since the publication of the original panel's recommendations in 1996, more studies are adhering to the guidelines of the panel (Neumann 2009, Neumann et al. 2005).

Some stakeholders are also concerned that analyses contain the biases of the sponsors who fund the studies and the researchers who conduct them. For example, studies funded by the pharmaceutical industry tend to report more favorable results (Bell et al. 2006, John-Baptiste and Bell 2010, Lane et al. 2016).

- ***Cost-effectiveness analysis might slow innovation.*** Some stakeholders are concerned that payers' use of cost-effectiveness in the coverage process might reduce manufacturers' incentives for innovation by creating a hurdle to launch medical services (Neumann 2005). For example, manufacturers have noted that a negative NCD by Medicare has an enormous (negative) effect on manufacturers' revenues. In contrast, some observers argue that there is an inherent need to strike a balance between incentives for innovation and access to high-value services and that the use of cost-effectiveness analysis might stimulate manufacturers to bring more cost-effective products to market. Others argue that payers do not have to use information on cost-effectiveness analysis rigidly. For example, payers could use information from cost-effectiveness analyses to prioritize quality initiatives.
- ***Affinity for new technology could bias the public against use of cost-effectiveness in coverage decisions.*** Some researchers contend that stakeholders' resistance to the use of cost-effectiveness analysis might stem from the affinity for new medical technology in the United States. Research using survey data found that 9 of 10 adults agree that there is a strong link between being able to get the most advanced technology and receiving high-quality health care and that Americans expressed more interest in new medical discoveries than survey participants from European countries (Schur and Berk 2008).
- ***Cost-effectiveness analysis might interfere with the clinician–patient relationship.*** Some clinicians contend that using cost-effectiveness analysis could affect their advocacy duties and the trust necessary for

Concerns about using QALYs in economic evaluations

Quality-adjusted life years (QALYs) are widely used in economic evaluations and have been endorsed by several research panels (Gold et al. 1996, Neumann et al. 2017). Among the measure's strengths:

- QALYs can account for gains in both the quantity and quality of health gained. By contrast, assessing only the quantity of health gained, such as life-years gained or number of strokes avoided, does not consider changes in an individual's disease symptoms, functional capacity, and well-being (i.e., quality of life).
- QALYs can be used across a wide variety of diseases and treatments, enabling the comparison of interventions both within and across disease and treatment categories. For example, health losses associated with treatments for myocardial infarctions can be expressed commensurately with health losses associated with pneumonia.

Nonetheless, there is debate among researchers and others about their use (Drummond et al. 2015, Gold et al. 1996). The debate about QALYs centers on the techniques and methods used to develop QALYs and concerns that QALYs may not reflect societal

values and may be biased against certain populations, including the elderly and the disabled. In addition, some stakeholders contend that the measure is in contrast to the movement toward personalized medicine and patient-centered care (Partnership to Improve Patient Care 2018).

The Patient Protection and Affordable Care Act of 2010 prohibits the Secretary from using QALYs (or similar measures) as a threshold to determine coverage, reimbursement, or incentive programs under Title XVIII of the Social Security Act (Medicare and Medicaid). According to the statute:

- “The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”
- “The Secretary shall not use evidence or findings from clinical comparative effectiveness research . . . in determining coverage, reimbursement, or incentive programs . . . in a manner that treats extending the life of an elderly, disabled, or terminally ill person as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.” ■

good relationships with their patients by interfering with their ability to prescribe clinically necessary care (Neumann 2004).

- ***Cost-effectiveness analysis might impair beneficiaries' access to certain services and might lead to rationing.*** Some stakeholders are concerned that payers' use of cost-effectiveness analyses, particularly in the coverage process, might affect access to care. For example, a policy that covers only those services that have cost-effectiveness ratios below a specific threshold would result in patients not having access to all services. Some stakeholders are concerned that payers and purchasers will use

cost-effectiveness information for cost-containment purposes only, not for promoting appropriate care. Researchers who conducted focus groups have countered that, when members of the lay public are presented with cost-effectiveness information in a systematic way, they may be willing to use such information to inform priorities for coverage (Gold and Taylor 2007, Gold et al. 2007).⁵⁹ Researchers found that 75 percent of focus group participants felt “somewhat” or “very” comfortable with the use of cost-effectiveness analysis to inform Medicare coverage of new treatments, while 10 percent said that it should “never” be used.

Use of cost-effectiveness by other public and private entities

There is no exhaustive research on the use of cost-effectiveness analysis by commercial payers, pharmacy benefit managers (PBMs), or other purchasers. Nonetheless, reports in the lay press suggest an increasing interest in determining the value of medical interventions, including examining information on comparative clinical effectiveness and cost-effectiveness. In particular, there appears to be increased interest in determining the clinical effectiveness and value of pharmaceuticals to inform formulary decisions. Medicare organizations that take on financial risk, including MA plans and ACOs, have flexibility in using cost-effectiveness in the design of their medical and pharmacy management programs.

A recent analysis found that 14 of 17 commercial payers considered cost-effectiveness analyses in an average of 14 percent of their coverage policies; 3 payers did not report reviewing information on cost-effectiveness (Chambers et al. 2016).⁶⁰ In workshops on cost-effectiveness analysis, about 75 percent of California health care leaders (of public and private health care organizations) who participated said that such analysis should be a factor in decisions by commercial payers (Bryan et al. 2009).⁶¹ The three most frequently cited barriers in using such cost-effectiveness information were:

- the risk of litigation if the organization denies access to treatments that are known to be medically effective but do not demonstrate long-term cost-effectiveness,
- the disconnect between the long-term perspective of cost-effectiveness analysis and the short-term horizons of the payers' decisions, and
- concern about result bias in cost-effectiveness studies with commercial sponsorship (Bryan et al. 2009).

Methodological concerns were not a major theme of the potential barriers to using information on cost-effectiveness.

Over the past few years, there has been increasing interest by commercial payers, purchasers, and PBMs in value-based arrangements. The extent to which these arrangements assess cost-effectiveness is unknown. In addition, the fact that ICER and other organizations have launched value frameworks over the past decade suggests the growing acceptance of value and cost-effectiveness assessments. Value frameworks have also been introduced by medical professional groups and provider organizations, including Memorial Sloan Kettering Cancer

Center, the American Society of Clinical Oncology, the American College of Cardiology, and the American Heart Association.

Data are limited on the extent to which commercial entities use results generated from ICER's and other organizations' frameworks. However, the sponsorship of ICER by commercial payers, purchasers, and PBMs suggests that these organizations are seeking information on the cost-effectiveness of health care services. For example, in 2016, Prime Therapeutics, a PBM, joined ICER as a flagship member (Prime Therapeutics 2016). According to ICER, pharmacy benefit managers, insurers, and government agencies have used ICER reports in negotiating pricing and preferred formulary placements with manufacturers. Nearly half of all published cost-effectiveness studies evaluated pharmaceuticals, and, between 1990 and 2012, pharmaceutical manufacturers sponsored an increasing proportion of such studies. The move toward value-based payment and outcomes-based payment among private entities that include payers and pharmaceutical manufacturers is ostensibly oriented toward assessing the cost-effectiveness of medical interventions.

The VA uses cost-effectiveness analysis to inform drug formulary decisions (Al et al. 2004). In 2017, ICER announced a collaboration with the VA's Pharmacy Benefits Management Services Office to incorporate the use of ICER drug assessment reports in drug coverage and price negotiations with the pharmaceutical industry (Institute for Clinical and Economic Review 2017).

Other countries use cost-effectiveness analysis in their decisions to cover drugs and in their negotiations with drug companies. For example, the United Kingdom's National Institute for Health and Care Excellence (NICE), founded in 1989, includes cost-effectiveness analyses in its guidance on pharmaceuticals, medical devices, and other medical services.⁶² However, the use of cost-effectiveness evidence has not proceeded without some debate. For example, in 2009, to address growing concern about access to new cancer drugs, NICE introduced additional flexibility when appraising treatments that extend survival in patients with short life expectancy (Dillon and Landells 2018).

Overview of the Patient-Centered Outcomes Research Institute

PCORI is a public-private entity established by PPACA and tasked with identifying comparative effectiveness

research (CER) priorities, funding CER efforts, and disseminating CER findings. The statute authorizing the agency prohibits the use of QALYs, specifically stating:

The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended.

Because of this stipulation, the organization states it does not consider cost or cost-effectiveness to be an outcome of direct importance to patients (Patient-Centered Outcomes Research Institute 2017).

PCORI is governed by a 21-member board of governors who are appointed by the Comptroller General of the United States. The board must include the directors of the National Institutes of Health and AHRQ (or their designees) and 19 other members (including 7 clinicians, 3 patient representatives, 3 drug and device industry representatives, 3 private-payer representatives, 1 quality improvement or health services researcher, and 2 representatives from the federal and state governments) with expertise in clinical health sciences research. There is also a 17-member methodology committee whose members are also appointed by the comptroller general of the United States, which sets methodology standards for the organization's research.

The Patient-Centered Outcomes Research Trust Fund

PPACA created the Patient-Centered Outcomes Research Trust Fund (PCORTF) to fund CER efforts between fiscal year 2010 and fiscal year 2019 from three funding streams: appropriations from the general Treasury, transfers from the Medicare Trust Funds, and a fee assessed on private insurance and self-insured health plans.⁶³ On an annual basis, PCORI receives 80 percent of PCORTF's funds, and HHS receives the remainder. The majority of HHS's funding goes to AHRQ and supports CER dissemination and research capacity-building efforts. Unless reauthorized by the Congress, PCORTF's funding will expire on September 30, 2019. Between fiscal years 2010 and 2017 (the most recent year available), PCORTF funding has totaled \$2.4 billion from all revenue streams (the general Treasury, Medicare Trust Funds, private insurance and self-insured health plans, and earned interest).

PCORI's research process Per PPACA, PCORI established, with public comment, five broad national research priorities (and funding allocations) in 2012 to guide the organization's funding of CER efforts:

- assessment of prevention, diagnosis, and treatment options (40 percent of funding)
- improving health care systems (20 percent of funding)
- communication and dissemination of research (10 percent of funding)
- addressing disparities (10 percent of funding)
- accelerating patient-centered outcomes research and methodological research (20 percent of funding)

In addition to these five broad national priorities, PCORI established nine research criteria to identify how each priority would be addressed.⁶⁴

PCORI's most studied conditions include mental/behavioral health disorders, cancer, cardiovascular diseases, neurological disorders, nutritional and metabolic disorders, and trauma/injury. PCORI's top three populations of interest are racial/ethnic minorities, individuals of low socioeconomic status, and older adults.⁶⁵ In 2015, PCORI began funding pragmatic clinical trials—observational studies that compare two or more alternatives for preventing, diagnosing, treating, or managing a particular clinical condition. PCORI has stated that \$5 million to \$15 million in funding will be available for these trials (Patient-Centered Outcomes Research Institute 2013).

In 2014, PCORI created the National Patient-Centered Clinical Research Network (PCORnet), whose goal is to improve the national infrastructure for comparative effectiveness research by using large amounts of health data to address patients' and clinicians' health-related questions. Researchers can access large sets of health and health care data through electronic medical records and claims data gathered in real-world settings (e.g., clinics and hospitals) (National Patient-Centered Research Clinical Network 2018). This network currently includes 128 million individuals' data that can be used for randomized clinical trials, large observational studies, and other research (Government Accountability Office 2018).

PPACA mandated that the Government Accountability Office (GAO) release two reports evaluating activities funded by PCORI. In its first report, GAO assessed the organization's financial statements and concluded that PCORI was operating in line with the expectations that PPACA laid out (Government Accountability Office 2015). In its second report, GAO found that PCORI funded some 600 research-related infrastructure and methods projects for roughly \$2 billion. Of the total funding, PCORI awarded 79 percent to fund comparative-effectiveness research projects, 16 percent to create PCORnet, and the remaining 5 percent to fund projects related to methods development and dissemination (Government Accountability Office 2018).

PCORI's dissemination process presents research findings on its website—one for consumers and patient audiences and a more technical version for medical professionals—within 90 days after the results are finalized. In fiscal year 2016, 190 articles associated with PCORI-funded projects were published, an increase from 56 articles in fiscal year 2014. With respect to its use in clinical care, PCORI reports that two of its studies on prostate cancer were included in medical resource software used by academic medical centers (Government Accountability Office 2018).

Concerns about PCORI Patient advocacy groups like the Partnership to Improve Patient Care have commented on PCORI's commitment to supporting patient-centered research that engages patients and aids in their health care decisions (Schulte 2015). Additionally, some researchers have perceived the positive effects of its mission. For example, the PCORI board has worked to ensure transparency, credibility, and access, holding open board meetings every other month in various cities across the United States (Washington and Lipstein 2011).

However, some organizations and researchers from different political perspectives have raised concerns about PCORI. Mazur and colleagues noted that less than one-third of PCORI studies involve or are relevant to primary care—the largest patient care platform in the United States (Mazur et al. 2016). Researchers from the Center for American Progress raised concerns that PCORI was not adequately funding comparative clinical effectiveness research (Emanuel et al. 2016).

In interviews that GAO conducted with stakeholders (including health policy experts and PCORI contractors), some interviewees expressed concern that PCORI's research priorities are broad and lack specificity (Government Accountability Office 2015). According

to GAO, payer representatives noted limitations to the usefulness of PCORI's research findings because they do not take treatment costs into account (Government Accountability Office 2018). Some have recommended that the organization strategically plan its agenda to address research questions that comparative-effectiveness research can answer quickly and decisively (Sox 2012). The findings of such studies would ideally make their way into everyday medical practice and demonstrate PCORI's ability to fund important transformative comparative-effectiveness research.

Overview of the Institute for Clinical and Economic Review

ICER is an independent nonprofit organization founded in 2005 with the goal of providing independent analysis of evidence on the value and effectiveness of medical interventions, including drugs, medical devices, tests, and delivery system innovations. Nonprofit foundations provide 78 percent of the organization's funding. Their largest individual source of funding comes from the Laura and John Arnold Foundation. The remaining 22 percent of their support comes from other nonprofit organizations, pharmaceutical manufacturers, health plans, and pharmacy benefit management companies.⁶⁶ ICER does not accept funding from manufacturers or private insurers to perform reviews of specific technologies (Institute for Clinical and Economic Review 2018b).

ICER's evaluations include a systematic review of the clinical and economic literature on a given intervention and an analysis of the cost-effectiveness and potential budget impact associated with the intervention. As part of its comparative clinical effectiveness assessment, the analyses provide sources of evidence, the strengths and limitations of individual studies, and an evaluation of the net health benefit of the treatment options being considered. ICER's analyses apply evidence of a treatment's comparative clinical effectiveness to determine its cost-effectiveness, usually over the lifetime of patients (when feasible). ICER also assesses the potential budget impact of a new drug over a five-year period, taking into account assumptions about the treatment's projected uptake. ICER calculates cost-effectiveness from the health system perspective as its base case but performs a scenario analysis to include work productivity when feasible. The primary measure of ICER's cost-effectiveness analysis is the QALY; other measures, such as the cost per life-year gained and cost per avoided event (e.g., stroke), are also reported.

According to ICER, the organization aims to make its research and methodology process as transparent and public as possible. According to ICER’s patient and manufacturer engagement guide, there are both formal and informal opportunities for patients, manufacturers, and other stakeholders to provide input and comment during the report development process. ICER recently announced that its executable versions of draft cost-effectiveness models will be shared with relevant manufacturers during the evidence review process. In addition, the organization recently updated its value assessment framework and provided opportunities for public comment from stakeholders. ICER’s new value framework seeks to inform decisions that are aimed at achieving sustainable access to high-value care for all patients. Long-term value is the primary anchor for ICER’s framework, but the organization also considers short-term affordability in its assessments.

For example, a recent ICER report on the comparative clinical effectiveness and value of chimeric antigen receptor T-cell therapies (tisagenlecleucel and axicabtagene ciloleucel) for treatment of two types of B-cell cancers concluded that each product was cost-effective (with incremental long-term cost-effectiveness ratios below or within \$50,000 per QALY and \$150,000 per QALY gained) (Institute for Clinical and Economic Review 2018a). However, ICER also concluded that the potential short-term budget impact for one of the products, axicabtagene ciloleucel, would exceed ICER’s annual \$915 million annual budget impact threshold at the product’s current price.⁶⁷ According to ICER, the added cost of a new service that exceeds its annual budget impact threshold may be difficult for a payer to absorb over the short term without displacing other needed services or contributing to a rapid growth in insurance costs, which might affect patients’ access to high-value care. Other examples of its completed and current analyses include reports evaluating the CER and value of drug treatments for hepatitis C, prostate cancer, hemophilia type A, migraines, osteoporosis, and cystic fibrosis and of nondrug treatments of low back pain.

Concerns about ICER Some stakeholders have argued that ICER fills a necessary void in the U.S. health care system. Many see the impact that ICER could have on shaping health care and assessing the value of treatments. With the rise of prescription drug prices in the United States, some researchers have called for the need to assess the benefits and value of drugs and other interventions (Neumann

and Cohen 2015). Since there is no federal government organization that performs research similar to ICER, some stakeholders have said that the organization will have a valuable and growing influence on the health care system (Silverman 2016).

Other stakeholders assert that ICER’s evaluations of the affordability of drugs favor insurance companies. In addition, representatives of pharmaceutical and medical device manufacturers and other health care organizations have raised many concerns about ICER. For example, these stakeholders have (1) asserted that ICER’s models used to assess a therapy’s value are not sufficiently transparent to the public; (2) taken issue with the methods used to assess value (e.g., the overreliance on data from randomized clinical trials and the use of QALYs to assess cost-effectiveness); (3) asserted that patients, patient groups, family caregivers, and others have not been sufficiently engaged in the analytical process.

Two evaluations criticized the five-year time horizon ICER uses in its budgetary evaluations: “ICER’s approach is problematic because it penalizes high-value new technologies, treats all drugs the same regardless of the severity of the underlying condition, encourages a myopic view (overweighting upfront costs and ignoring savings and health benefits that occur after 5 years), downplays existing waste and inefficiency in the system, and provides disincentives to companies developing a drug with broad public health impacts” (Lakdawalla and Neumann 2016, Neumann and Cohen 2017). Neumann and Cohen further criticized ICER’s use of cost-effectiveness thresholds (\$50,000 per QALY to \$175,000 per QALY gained), arguing that these judgments should be made by payers and their enrollees, and argued that ICER should assess a treatment’s cost-effectiveness from the societal perspective, not solely from the health system perspective.⁶⁸

Conclusion

FFS Medicare’s coverage process allows many new services to disseminate quickly into routine medical care without evidence that they are superior to existing treatments. In addition, there is substantial use of low-value care. A very conservative estimate of Medicare spending on low-value services ranges from \$2.4 billion to \$6.5 billion per year. There is additional spending on

potentially low-value services such as early initiation of dialysis, proton beam therapy, and H.P. Acthar Gel. The spending estimates do not reflect the downstream cost of low-value services (e.g., follow-up tests and procedures). Because other payers also cover low-value services, payers may want to coordinate their efforts to identify and reduce low-value care. There are many policy tools that Medicare could consider adopting to reduce the use of low-value services, such as prior authorization, clinician decision

support and provider education, altering beneficiary cost sharing based on the clinical value of a service, new payment models, revisiting coverage determinations on an ongoing basis, and linking FFS coverage and payment to clinical comparative effectiveness and cost-effectiveness information. CMS has developed early experience with some of these tools, such as prior authorization and new payment models. ■

Endnotes

- 1 CMS explained that, since it anticipated limiting the application of cost considerations to a “narrow situation when two services have equivalent health outcomes and are of the same clinical modality,” it would have needed to conduct a simple cost analysis in such cases.
- 2 The Commission’s estimate of the number of LCDs does not take into account the duplication of LCDs within a given region.
- 3 Instances in which CMS may request an external technology assessment include the following: (1) the evidence to review is extensive, making it difficult to complete an internal technology assessment within the statutory time frame; (2) there are significant differences in opinion among experts concerning the relevant evidence; and (3) the review requires clinical or methodological expertise not available among CMS staff at the time of the review.
- 4 The MMA requires that CMS consult with outside clinical experts if the MEDCAC is not convened.
- 5 Other factors that CMS considers for removing NCDs under the expedited process include the following: local contractor discretion would better serve the needs of the program, the technology is obsolete and no longer marketed, and the NCD has been superseded by subsequent Medicare policy.
- 6 Under Section 1862(a)(1)(E) of the statute, the Secretary has the authority to “conduct and support research through the AHRQ administrator with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.”
- 7 The Symplicity renal denervation system for treatment-resistant hypertension is the only other device known to be accepted into the Parallel Review Program, according to its manufacturer (Medtronic 2013). The device’s parallel review process, which began in 2013, was discontinued in 2014 after the manufacturer announced that the device did not achieve its primary efficacy endpoint in a clinical trial (Gafney 2014).
- 8 For example, Medicare covers off-label use of bevacizumab for metastatic breast cancer despite the FDA’s removal of this clinical indication from the biologic’s label in 2011. In 2016, Medicare’s Part B spending for bevacizumab for breast cancer totaled \$17 million, which represents 2 percent of the biologic’s FFS Medicare spending.
- 9 Currently, there are 4 MACs that process durable medical equipment claims and 12 MACs that process all other Part A and Part B claims.
- 10 Before BIPA, Medicare’s contractors developed local medical review policies (LMRPs). The difference between an LMRP and LCD is that an LCD is a determination as to whether an item or service is reasonable and necessary, while LMRPs may also contain benefit category and statutory exclusion provisions.
- 11 OIG’s estimates are based on a review of LCDs for Part B services (excluding durable medical equipment items) in effect during a one-week period in 2011.
- 12 Interested parties include beneficiaries residing or receiving care in a contractor’s jurisdiction, providers doing business in a contractor’s jurisdiction, and any interested party doing business in a contractor’s jurisdiction.
- 13 Under law, drugs or classes of drugs or their medical uses that may be excluded from coverage or otherwise restricted under Medicaid under Sections 1927(d)(2) or (d)(3) of the Social Security Act (except for smoking cessation agents) are excluded from the definition of a Part D drug (42 CFR § 423.100). Examples of excluded drugs include drugs for weight loss or gain, drugs for erectile dysfunction, drugs for relief of cough and colds, nonprescription drugs, drugs used for cosmetic purposes or hair growth, drugs used to promote fertility, and prescription vitamins and minerals, except prenatal vitamins and fluoride preparation products.
- 14 The amount in controversy must be greater than the specified dollar thresholds.
- 15 The authors adjusted for differences in beneficiaries’ sociodemographic and clinical characteristics and geographic location.
- 16 The study adjusted for changes in each group’s sociodemographic and clinical characteristics (e.g., the presence of specific chronic conditions and the total number of conditions) between the precontract period and postcontract period.
- 17 Both of these measures were limited to low-risk, noncardiac surgery.
- 18 The study used data on patients with commercial insurance from the Health Care Cost Institute, which maintains a database of claims on individuals who are under age 65 with employer-sponsored insurance from Aetna, Humana, Kaiser Permanente, and UnitedHealthcare.

- 19 The DXA scan measures bone mineral density.
- 20 The T₃ service is a lab test that measures the level of T₃ in the blood. The test is used to evaluate and manage thyroid dysfunction.
- 21 The HEDIS measure for high-risk medication is described as the share of Medicare members ages 66 and older who had at least one dispensing event for a high-risk medication, or the share of Medicare members ages 66 and older who had at least two dispensing events for the same high-risk medication.
- 22 Schwartz and colleagues published a study that used 26 of their measures to calculate the amount of low-value care in FFS Medicare in 2009 (Schwartz et al. 2014).
- 23 The broad version of the PSA screening measure includes all PSA tests for men ages 75 and over. It includes both screening and diagnostic billing codes.
- 24 The narrow version of the PSA screening measure includes PSA tests for men ages 75 and over who do not have a history of prostate cancer. It includes screening (but not diagnostic) billing codes.
- 25 For each geographic area, the model included demographic variables (e.g., age, race, sex, and Medicaid enrollment), clinical variables (e.g., the presence of specific chronic conditions and the total number of conditions), and a dummy variable.
- 26 We used the narrow versions of the measures for this analysis because they represent a more conservative estimate of low-value care.
- 27 Researchers estimated that, among patients of all insurance types, dialysis was initiated at a mean of 147 days earlier in 2007 compared with 1997 (O'Hare et al. 2011).
- 28 The study was produced for the Washington State Health Technology Assessment Program.
- 29 *Superior net health benefit* means that the evidence suggests a moderate-to-large net health benefit versus comparators. *Incremental net health benefit* means that the evidence suggests a small net health benefit versus comparators.
- 30 *Comparable net health benefit* means the evidence suggests that, while there may be trade-offs in effectiveness or harms, overall net health benefit is comparable with comparators.
- 31 One facility (Indiana University Health Particle Therapy Center) closed in 2014 and is not included in these numbers.
- 32 There are four HCPCS codes for proton beam therapy. Code 77520 is in ambulatory payment classification (APC) group 5623, which had a payment rate of \$506 in 2016. This code accounted for only 1 percent of the volume of proton beam therapy codes paid under the OPSS in 2016. HCPCS codes 77522, 77523, and 77525 are in APC group 5625, which had a rate of \$1,151 in 2016. These codes accounted for the remaining 99 percent of volume.
- 33 Providers may also consider a patient's trajectory of kidney failure (i.e., the rate of decline in eGFR levels) when considering when to begin dialysis.
- 34 The NKF KDOQI guidelines are the most commonly used clinical guidelines in the United States. The NKF does accept financial support from the industry.
- 35 The authors adjusted for selection bias by matching proton beam therapy patients with IMRT patients with similar clinical and demographic characteristics.
- 36 As described earlier, these signs and symptoms of kidney failure could fall under the larger symptom categories of fluid overload or evidence of uremia. The specific signs and symptoms examined in this study included lower extremity edema, pulmonary edema, pericarditis, shortness of breath, cognitive dysfunction, pruritus, nausea or vomiting, anorexia, diarrhea, constipation, fatigue, muscle cramps, pain, sleep disturbance, sexual dysfunction, depressive symptoms or anxiety, altered taste, muscle weakness, hiccups, or dizziness.
- 37 The relationship between predialysis nephrology care and earlier initiation could also partially be explained by individuals who "crash" onto dialysis having much lower eGFRs, and thus bring down the average for those receiving no nephrology care (Slinin et al. 2014).
- 38 Cahaba Government Benefit Administrators covers providers in Alabama, Georgia, and Tennessee. CGS Administrators covers Kentucky and Ohio. First Coast Service Options covers Florida, Puerto Rico, and the Virgin Islands. Of the 27 proton beam facilities in the United States as of April 2018, 8 are located in states covered by these 3 MACs.
- 39 The clinical trial must be approved by an institutional review board and meet the standards of scientific integrity and relevance to the Medicare population as described in the *Medicare National Coverage Determinations Manual*. The clinical registry must be compliant with the principles established in AHRQ's *Registries for Evaluating Patient Outcomes: A User's Guide*.
- 40 National Government Services covers providers in Connecticut, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, New York, Rhode Island, Vermont, and Wisconsin. Its LCD limits coverage of proton beam therapy

- for conditions in Group 2 to providers who have demonstrated experience in data collection and analysis with a history of publication in the medical literature.
- 41 Carriers were the Medicare contractors who processed and paid claims for Part B services before Medicare established the MACs.
 - 42 The other indications are rheumatic, collagen, dermatologic, allergic, ophthalmic, respiratory, and edematous states.
 - 43 For example, 65 percent of patients who received Acthar improved on the Disability Status Scale after four weeks, compared with 48 percent of patients who received placebo (the difference was significant at $p < 0.05$). According to a measure of each patient's overall condition, 82 percent of patients who received Acthar improved, compared with 69 percent of patients who received placebo, but the difference was not statistically significant ($p < 0.05$).
 - 44 At the time this report was prepared, CMS had not yet released Part D data from 2016.
 - 45 Spending per prescription is higher than the average price per vial because spending per prescription does not reflect manufacturers' rebates, and some prescriptions are for more than one vial.
 - 46 There were 174 prescribers in each decile.
 - 47 The model originally applied to California, Florida, Illinois, Michigan, New York, North Carolina, and Texas. The 12 additional states added in the extension included Arizona, Georgia, Indiana, Kentucky, Louisiana, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, Tennessee, and Washington.
 - 48 The three original states included in the demonstration were South Carolina, New Jersey, and Pennsylvania. Through the expansion, Delaware, the District of Columbia, Maryland, North Carolina, Virginia, and West Virginia were added.
 - 49 The evaluation included only ESRD beneficiaries because they constitute about 75 percent of Medicare RSNAT claims.
 - 50 The payment reduction was mandated by statute. It began before the demonstration started and may have influenced ambulance provider behavior during the demonstration evaluation period. However, the evaluation used a differences-in-differences study design to control for external changes that occurred during the demonstration.
 - 51 The three states included in the model were Illinois, Michigan, and New Jersey.
 - 52 This program was mandated by the Protecting Access to Medicare Act of 2014.
 - 53 The demonstration was mandated by the Medicare Improvements for Patients and Providers Act of 2008 and applied to 12 common imaging services. Participation by physicians was voluntary.
 - 54 One of the other ways in which the models were different was their beneficiary attribution method. ACOs in the Pioneer ACO Model had beneficiaries attributed to them prospectively (at the beginning of the year), while MSSP ACOs had beneficiaries attributed to them retrospectively (at the end of the year).
 - 55 Large dialysis organizations (those with 200 or more dialysis facilities) that participate in the ESCO model are required to be at two-sided risk, while small dialysis organizations (those with fewer than 200 dialysis facilities) have the option to choose between one-sided and two-sided risk.
 - 56 Medicare's NCD for lung cancer screening covers low-dose CT once per year for beneficiaries between the ages of 55 and 77, who do not have symptoms of lung cancer, who have a history of smoking at least one pack per day for 30 years, and who either are current smokers or have quit smoking within the last 15 years. The NCD also requires that beneficiaries have an office visit (before the screening visit) that is devoted to counseling and shared decision-making on tobacco-related issues and the relative harms and benefits of lung cancer screening.
 - 57 The courts asserted that the statute's provision for Part B drugs based on its average sales price precludes Medicare from applying LCA policies. More information about this topic can be found in the Commission's June 2010 report to the Congress (Medicare Payment Advisory Commission 2010).
 - 58 In terms of diseases studied, cost-utility studies evaluated cardiovascular diseases (18 percent of the studies overall), oncology (15 percent), and infectious diseases (15 percent).
 - 59 The focus group participants received information about methods used to conduct cost-effectiveness analyses and information about the effectiveness of treatments for 14 conditions. They were asked to prioritize the coverage of these 14 treatments under assumptions of a constrained Medicare budget. They were then given cost-effectiveness information to revisit and discuss their rankings. Provision of cost-effectiveness information influenced their priorities.
 - 60 Across the 14 payers, cost-effectiveness was factored into between 8 percent to 43 percent of policies.
 - 61 A total of 58 people participated in the workshops on cost-effectiveness analysis sponsored by the California Health Care Foundation.

- 62 NICE uses QALYs in its cost-effectiveness analyses.
- 63 The fee equaled \$1 per insured person in fiscal year 2013 and \$2 per insured person in fiscal year 2014; thereafter, the fee is increased by the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.
- 64 These research criteria are (1) impact on health of individuals and populations, (2) probability of improvability through research, (3) inclusiveness of different populations, (4) the ability to address current gaps in knowledge/variations in care, (5) impact on health care system performance, (6) potential to influence decision-making, (7) patient centeredness, (8) rigorous research methods, and (9) efficient use of research resources.
- 65 This finding is based on the number of projects (out of a total of 365). A project may study more than one condition or population of interest.
- 66 Other nonprofit and for-profit entities that fund ICER include Blue Cross Blue Shield of Massachusetts, Blue Shield of California Foundation, the California Health Care Foundation, Express Scripts, Genentech, Johnson & Johnson, and Kaiser Permanente.
- 67 ICER's short-term budgetary impact analysis includes an estimate of the share of patients who could be treated at selected prices without crossing a budget impact threshold that is aligned with overall growth in the U.S. economy. Factors included in the calculation of ICER's budget threshold include growth in U.S. gross domestic product, total personal medical health care spending, contribution of drug spending to total health care spending, and average annual number of new molecular entity approvals.
- 68 A cost-effectiveness analysis with a societal perspective incorporates direct medical, direct nonmedical (e.g., transportation), and indirect costs (e.g., lost productivity), regardless of who incurs the costs (Gold et al. 1996). By contrast, an analysis with a payer perspective may incorporate only direct medical costs incurred by the payer.

References

- Abernethy, A. P., G. Raman, E. M. Balk, et al. 2009. Systematic review: Reliability of compendia methods for off-label oncology indications. *Annals of Internal Medicine* 150, no. 5 (March 3): 336–343.
- ABIM Foundation. 2016. Choosing Wisely: Facts and figures. <http://www.choosingwisely.org/about-us/facts-and-figures/>.
- Aetna. 2018. Psoriasis and psoriatic arthritis: Targeted immune modulators. http://www.aetna.com/cpb/medical/data/600_699/0658.html.
- Aetna. 2014. Clinical policy bulletin: Proton beam and neutron beam radiotherapy. http://www.aetna.com/cpb/medical/data/200_299/0270.html.
- Al, M. J., T. Feenstra, and W. B. Brouwer. 2004. Decision makers' views on health care objectives and budget constraints: Results from a pilot study. *Health Policy* 70, no. 1 (October): 33–48.
- American Cancer Society. 2016. American Cancer Society recommendations for prostate cancer early detection. <https://www.cancer.org/cancer/prostate-cancer/early-detection/acs-recommendations.html>.
- Anthem. 2018. Proton beam radiation therapy medical policy. https://www.anthem.com/medicalpolicies/policies/mp_pw_a053258.htm.
- Asher, A., G. Haile, A. Goldstein, et al. 2017. *First interim evaluation report of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT)*. Report prepared by Mathematica Policy Research for the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS.
- Bach, P. B. 2015. New math on drug cost-effectiveness. *New England Journal of Medicine* 373, no. 19 (November 05): 1797–1799.
- Barnes, M. P., D. E. Bateman, P. G. Cleland, et al. 1985. Intravenous methylprednisolone for multiple sclerosis in relapse. *Journal of Neurology, Neurosurgery, and Psychiatry* 48, no. 2 (February): 157–159.
- Barnett, M. L., J. A. Linder, C. R. Clark, et al. 2017. Low-value medical services in the safety-net population. *JAMA Internal Medicine* 177, no. 6 (June 1): 829–837.
- Baumgardner, J. R., and P. J. Neumann. 2017. Balancing the use of cost effectiveness analysis across all types of health care innovations. *Health Affairs* blog, April 14.
- Beck, M. 2015. Big bets on proton therapy face uncertain future. *Wall Street Journal*, May 26.
- Beddhu, S., M. H. Samore, M. S. Roberts, et al. 2003. Impact of timing of initiation of dialysis on mortality. *Journal of the American Society of Nephrology* 14, no. 9 (September): 2305–2312.
- Bell, C. M., D. R. Urbach, J. G. Ray, et al. 2006. Bias in published cost effectiveness studies: Systematic review. *British Medical Journal* 332, no. 7543 (March 25): 699–703.
- Bryan, S., S. Sofaer, T. Siegelberg, et al. 2009. Has the time come for cost-effectiveness analysis in US health care? *Health Economics Policy Law* 4, no. Pt 4 (October): 425–443.
- CANUSA. 1996. Adequacy of dialysis and nutrition in continuous peritoneal dialysis: Association with clinical outcomes. Canada-USA (CANUSA) Peritoneal Dialysis Study Group. *Journal of the American Society of Nephrology* 7, no. 2 (February): 198–207.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare Advantage Value-Based Insurance Design Model. <https://innovation.cms.gov/initiatives/vbid/>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017a. The facts about Open Payments data. <https://openpaymentsdata.cms.gov/summary>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017b. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2018; Medicare shared savings program requirements; and Medicare diabetes prevention program. Final rule. *Federal Register* 82, no. 219 (November 15): 52976–53371.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017c. Natures of payment. <https://www.cms.gov/OpenPayments/About/Natures-of-Payment.html>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016a. Advance notice of methodological changes for calendar year (CY) 2017 for Medicare Advantage capitation rates, Part C and Part D payment policies and 2017 call letter. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtSpecRateStats/Downloads/Advance2017.pdf>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016b. Local coverage determination (LCD): Proton beam therapy (L36658) for CGS Administrators, LLC. <https://www.cms.gov/medicare-coverage-database/>.

Centers for Medicare & Medicaid Services. 2016c. Medicare prior authorization of non-emergent hyperbaric oxygen (HBO) therapy model status update. https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Downloads/HBOPriorAuth_StatusUpdate_111616.pdf.

Centers for Medicare & Medicaid Services. 2016d. Non-emergent hyperbaric oxygen therapy model operational guide. https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Downloads/HBOPriorAuth_OperationalGuide_111816.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. Local coverage determination (LCD): Proton beam radiotherapy (L33937) for First Coast Service Options Inc. <https://www.cms.gov/medicare-coverage-database/>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. Local coverage determination (LCD): Proton beam therapy (L35075) for National Government Services Inc. <https://www.cms.gov/medicare-coverage-database/>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015c. Local coverage determination (LCD): Radiology: Proton beam therapy (L34282) for Cahaba Government Benefit Administrators. <https://www.cms.gov/medicare-coverage-database/>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015d. Medicare program; expansion of prior authorization for repetitive scheduled non-emergent ambulance transports Notice. *Federal Register* 80, no. 205 (October 23): 64418–64421.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015e. Medicare program; prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies. Final rule. *Federal Register* 80, no. 250 (December 30): 81674–81707.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015f. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to Part B for CY 2016. Final rule with comment period. *Federal Register* 80, no. 220 (November 16): 70886–71386.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014a. Final decision for national coverage determinations proposed for removal on November 27, 2013. <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=29&mcctype=Expedited+Process+to+Remove+National+Coverage+Determinations&MCDIndexType=7&bc=AgAEAAAAAAAAAAAA%3D%3D&>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014b. Guidance for the public, industry, and CMS staff: Coverage with evidence development. <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014c. Medicare program; end-stage renal disease prospective payment system, quality incentive program, and durable medical equipment, prosthetics, orthotics, and supplies. Final rule. *Federal Register* 79, no. 215 (November 6): 66120–66265.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014d. Medicare program: prior authorization of repetitive scheduled nonemergent ambulance transports Final rule. *Federal Register* 79, no. 220 (November 14): 68271–68273.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014e. Prior authorization to ensure beneficiary access and help reduce improper payments. Press release. May 22. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-05-22.html>.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare program; Prior Authorization for Power Mobility Device (PMD) Demonstration. Notice. *Federal Register* 77, no. 150 (August 3): 46439–46441.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. *Prescription Drug Benefit Manual. Chapter 6: Part D drugs and formulary requirements*. Baltimore, MD: CMS. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

Chambers, J. D., M. D. Chenoweth, and P. J. Neumann. 2016. Mapping US commercial payers' coverage policies for medical interventions. *American Journal of Managed Care* 22, no. 9: e323–e328.

Chambers, J. D., M. J. Cangelosi, and P. J. Neumann. 2015a. Medicare's use of cost-effectiveness analysis for prevention (but not for treatment). *Health Policy* 119, no. 2 (February): 156–163.

- Chambers, J. D., M. D. Chenoweth, J. Pyo, et al. 2015b. Changing face of Medicare's national coverage determinations for technology. *International Journal of Technology Assessment in Health Care* 31, no. 5: 1–8.
- Chan, K. S., E. Chang, N. Nassery, et al. 2013. The state of overuse measurement: A critical review. *Medical Care Research and Review* 70, no. 5 (October): 473–496.
- Charlesworth, C. J., T. H. Meath, A. L. Schwartz, et al. 2016. Comparison of low-value care in Medicaid vs commercially insured populations. *JAMA Internal Medicine* 176, no. 7 (July 1): 998–1004.
- Chernew, M. E., A. B. Rosen, and A. M. Fendrick. 2007. Value-based insurance design. *Health Affairs* 26, no. 2 (March–April): w195–w203.
- Chou, R., A. Qaseem, D. K. Owens, et al. 2011. Diagnostic imaging for low back pain: Advice for high-value health care from the American College of Physicians. *Annals of Internal Medicine* 154, no. 3 (February 1): 181–189.
- Colla, C. H., A. J. Mainor, C. Hargreaves, et al. 2017a. Interventions aimed at reducing use of low-value health services: A systematic review. *Medical Care Research and Review* 74, no. 5 (October): 507–550.
- Colla, C. H., N. E. Morden, T. D. Sequist, et al. 2017b. Payer type and low-value care: Comparing Choosing Wisely services across commercial and Medicare populations. *Health Services Research* (February 19).
- Colla, C. H., N. E. Morden, T. D. Sequist, et al. 2015. Choosing wisely: Prevalence and correlates of low-value health care services in the United States. *Journal of General Internal Medicine* 30, no. 2 (February): 221–228.
- Congressional Budget Office. 2008. *Budget options, volume 1: Health care*. Washington, DC: CBO. December.
- Cooper, B. A., P. Branley, L. Bulfone, et al. 2010. A randomized, controlled trial of early versus late initiation of dialysis. *New England Journal of Medicine* 363, no. 7 (August 12): 609–619.
- Daniel, G. W., E. K. Rubens, and M. McClellan. 2013. Coverage with evidence development for Medicare beneficiaries: Challenges and next steps. *JAMA Internal Medicine* 173, no. 14 (July 22): 1281–1282.
- DeJong, C., T. Aguilar, C. W. Tseng, et al. 2016. Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Internal Medicine* 176, no. 8 (August 1): 1114–1122.
- Dhruva, S. S., and R. F. Redberg. 2008. Variations between clinical trial participants and Medicare beneficiaries in evidence used for Medicare national coverage decisions. *Archives of Internal Medicine* 168, no. 2 (January 28): 136–140.
- Dillon, A., and L. J. Landells. 2018. NICE, the NHS, and cancer drugs. *Journal of the American Medical Association* 319, no. 8 (February 27): 767–768.
- Drummond, M. F., M. J. Sculpher, K. Claxton, et al. 2015. *Methods for the economic evaluation of health care programmes*. United Kingdom: Oxford University Press.
- Eddy, D. 2005. The role of cost-effectiveness analysis in decision-making for CMS. Presentation at MedPAC public meeting, March 11, Washington, DC.
- Emanuel, Z., T. Spiro, and T. Huelskoetter. 2016. *Re-evaluating the Patient-Centered Outcomes Research Institute*. Washington, DC: Center for American Progress.
- Evans, M., G. Tettamanti, O. Nyren, et al. 2011. No survival benefit from early-start dialysis in a population-based, inception cohort study of Swedish patients with chronic kidney disease. *Journal of Internal Medicine* 269, no. 3 (March): 289–298.
- Federal Trade Commission. 2017a. FTC approves sublicense for synacthen depot submitted by Mallinckrodt ARD Inc. Press release. July 14. <https://www.ftc.gov/news-events/press-releases/2017/07/ftc-approves-sublicense-synacthen-depot-submitted-mallinckrodt>.
- Federal Trade Commission. 2017b. Mallinckrodt will pay \$100 million to settle FTC, state charges it illegally maintained its monopoly of specialty drug used to treat infants. Press release. January 18. <https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it>.
- Feucht, C. L., and L. B. Rice. 2003. An interventional program to improve antibiotic use. *Annals of Pharmacotherapy* 37, no. 5 (May): 646–651.
- Fleming-Dutra, K. E., A. L. Hersh, D. J. Shapiro, et al. 2016. Prevalence of inappropriate antibiotic prescriptions among U.S. ambulatory care visits, 2010–2011. *Journal of the American Medical Association* 315, no. 17 (May 3): 1864–1873.
- Food and Drug Administration. 2015. Highlights of prescribing information for H.P. Acthar Gel. https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022432s000lbl.pdf.
- Food and Drug Administration and Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. Program for parallel review of medical devices. Notice. *Federal Register* 81, no. 205: 73113–73115.

- Foote, S. B. 2002. Why Medicare cannot promulgate a national coverage rule: A case of *regula mortis*. *Journal of Health Politics, Policy & Law* 27, no. 5 (October): 707–730.
- Foote, S. B., D. Wholey, T. Rockwood, et al. 2004. Resolving the tug-of-war between Medicare’s national and local coverage. *Health Affairs* 23, no. 4 (July–August): 108–123.
- Gafney, A. 2014. How the failure of Medtronic’s Symplicity device spells trouble for FDA. <https://www.raps.org/regulatory-focus/E2%84%A2/news-articles/2014/1/how-the-failure-of-medtronic-s-symplicity-device-spells-trouble-for-fda>.
- Gold, M., and E. F. Taylor. 2007. Moving research into practice: Lessons from the US Agency for Healthcare Research and Quality’s IDSRN program. *Implementation Science* 2 (March 29): 9.
- Gold, M. R., J. E. Siegel, L. B. Russell, et al. 1996. *Cost-effectiveness in health and medicine*. New York, NY: Oxford University Press.
- Gold, M. R., S. Sofaer, and T. Siegelberg. 2007. Medicare and cost-effectiveness analysis: Time to ask the taxpayers. *Health Affairs* 26, no. 5 (September–October): 1399–1406.
- Government Accountability Office. 2018. *Comparative effectiveness research: Activities funded by the Patient-Centered Outcomes Research Trust Fund*. GAO–18–311. Washington, DC: GAO.
- Government Accountability Office. 2015. *Comparative effectiveness: Initial assessment of the Patient-Centered Outcomes Research Institute*. GAO–15–301. Washington, DC: GAO.
- Government Accountability Office. 2003. *Divided authority for policies on coverage of procedures and devices results in inequities*. Washington, DC: GAO.
- Green, A. K., W. A. Wood, and E. M. Basch. 2016. Time to reassess the cancer compendia for off-label drug coverage in oncology. *Journal of the American Medical Association* 316, no. 15 (October 18): 1541–1542.
- Gruber, J., J. Maclean, B. Wright, et al. 2016. *The impact of increased cost-sharing on utilization of low value services: Evidence from the State of Oregon*. NBER working paper no. 22875. Cambridge, MA: National Bureau of Economic Research.
- Hakim, R. M., and J. M. Lazarus. 1995. Initiation of dialysis. *Journal of the American Society of Nephrology* 6, no. 5 (November): 1319–1328.
- Harris, A., B. A. Cooper, J. J. Li, et al. 2011. Cost-effectiveness of initiating dialysis early: A randomized controlled trial. *American Journal of Kidney Diseases* 57, no. 5 (May): 707–715.
- Hartung, D. M., K. Johnston, S. Van Leuven, et al. 2017. Trends and characteristics of U.S. Medicare spending on repository corticotropin. *JAMA Internal Medicine* 177, no. 11 (November 1): 1680–1682.
- Health Care Financing Administration, Department of Health and Human Services. 1989. Medicare program; criteria for making medical services coverage decisions that relate to health care technology. Final Rule. *Federal Register* 54, no. 18 (January 30).
- Hong, A. S., D. Ross-Degnan, F. Zhang, et al. 2017. Small decline in low-value back imaging associated with the ‘Choosing Wisely’ campaign, 2012–14. *Health Affairs* 36, no. 4 (April 1): 671–679.
- Huo, J., C. Shen, R. J. Volk, et al. 2017. Use of CT and chest radiography for lung cancer screening before and after publication of screening guidelines: Intended and unintended uptake. *JAMA Internal Medicine* 177, no. 3 (March 1): 439–441.
- Institute for Clinical and Economic Review. 2018a. *Chimeric antigen receptor T-cell therapy for B-cell cancers: Effectiveness and value*. Boston, MA: ICER.
- Institute for Clinical and Economic Review. 2018b. Sources of funding, updated January 2018. <https://icer-review.org/about/support/>.
- Institute for Clinical and Economic Review. 2017. The Institute for Clinical and Economic Review to collaborate with the Department of Veterans Affairs’ Pharmacy Benefits Management Services Office. Press release. <https://icer-review.org/announcements/va-release/>.
- Jensen, T., Centers for Medicare & Medicaid Services. 2014. CMS coverage perspective diagnostic tests. http://mdic.org/wp-content/uploads/2014/06/Role-of-Regulatory-Science-MDIC-in-Molecular-Diagnostics_A-CMS-Perspective.pdf.
- John-Baptiste, A., and C. Bell. 2010. Industry sponsored bias in cost effectiveness analyses. *British Medical Journal* 341 (October 13): c5350.
- Kale, M. S., T. F. Bishop, A. D. Federman, et al. 2013. Trends in the overuse of ambulatory health care services in the United States. *JAMA Internal Medicine* 173, no. 2 (Jan 28): 142–148.
- Kausz, A. T., G. T. Obrador, P. Arora, et al. 2000. Late initiation of dialysis among women and ethnic minorities in the United States. *Journal of the American Society of Nephrology* 11, no. 12 (December): 2351–2357.
- Kazmi, W. H., D. T. Gilbertson, G. T. Obrador, et al. 2005. Effect of comorbidity on the increased mortality associated with early initiation of dialysis. *American Journal of Kidney Diseases* 46, no. 5 (November): 887–896.

- Keyhani, S., R. Falk, E. A. Howell, et al. 2013. Overuse and systems of care: A systematic review. *Medical Care* 51, no. 6 (June): 503–508.
- Korenstein, D., R. Falk, E. A. Howell, et al. 2012. Overuse of health care services in the United States: An understudied problem. *Archives of Internal Medicine* 172, no. 2 (January 23): 171–178.
- Ku, E., K. L. Johansen, A. A. Portale, et al. 2015. State level variations in nephrology workforce and timing and incidence of dialysis in the United States among children and adults: A retrospective cohort study. *BMC Nephrology* 16 (January 15): 2.
- Lakdawalla, D., and P. Neumann. 2016. Budget criteria and drug value assessments: A case of apples and oranges? *Health Affairs* blog. September 22. <http://healthaffairs.org/blog/2016/09/22/budget-criteria-and-drug-value-assessments-a-case-of-apples-and-oranges/>.
- Landro, L. 2016. To get doctors to do the right things, try comparing them to their peers. *Wall Street Journal*, June 26.
- Lane, J. D., M. W. Friedberg, and C. L. Bennett. 2016. Associations between industry sponsorship and results of cost-effectiveness analyses of drugs used in breast cancer treatment. *JAMA Oncology* 2, no. 2 (February): 274–276.
- Lassalle, M., M. Labeeuw, L. Frimat, et al. 2010. Age and comorbidity may explain the paradoxical association of an early dialysis start with poor survival. *Kidney International* 77, no. 8 (April): 700–707.
- Li, Y., Y. Jin, A. Kapke, et al. 2017. Explaining trends and variation in timing of dialysis initiation in the United States. *Medicine* 96, no. 20 (May): e6911.
- Lin, Z. H., and L. Zuo. 2015. When to initiate renal replacement therapy: The trend of dialysis initiation. *World Journal of Nephrology* 4, no. 5 (November 6): 521–527.
- Lopez, L. 2017. Something weird’s going on with the doctors prescribing one of pharma’s most controversial blockbuster drugs. *Business Insider*, March 21.
- Mafi, J. N., K. Russell, B. A. Bortz, et al. 2017. Low-cost, high-volume health services contribute the most to unnecessary health spending. *Health Affairs* 36, no. 10 (October 1): 1701–1704.
- Marrufo, G., B. Negrusa, D. Ullman, et al. 2017. *Comprehensive EndStage Renal Disease Care (CEC) Model: Performance Year 1 annual evaluation report*. Report prepared by the Lewin Group for the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS.
- Massachusetts General Hospital Cancer Center. 2013. A landmark study compares proton beam therapy with standard radiation therapy. *Advances at Mass General Cancer Center*, Fall.
- Mazur, S., A. Bazemore, and D. Merenstein. 2016. Characteristics of early recipients of Patient-Centered Outcomes Research Institute funding. *Academic Medicine* 91, no. 4 (April): 491–496.
- McWilliams, J. M., L. A. Hatfield, M. E. Chernew, et al. 2016. Early performance of accountable care organizations in Medicare. *New England Journal of Medicine* 374, no. 24 (June 16): 2357–2366.
- Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2011. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2010. *Report to the Congress: Aligning incentives in Medicare*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.
- Medtronic. 2013. Symplicity™ Renal Denervation System one of first devices accepted to participate in concurrent review for joint FDA premarket approval and Medicare national coverage determination. Press release. <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1802710>.
- Meeker, D., J. A. Linder, C. R. Fox, et al. 2016. Effect of behavioral interventions on inappropriate antibiotic prescribing among primary care practices: A randomized clinical trial. *Journal of the American Medical Association* 315, no. 6 (February 9): 562–570.

- Minnesota Department of Health. 2017. *Analysis of low-value health services in the Minnesota all payer claims database*. Issue brief. St. Paul, MN: Minnesota Department of Health. <http://kff.org/medicare/issue-brief/medicares-income-related-premiums-a-data-note/>.
- Mohr, P. 2012. Looking at CER from Medicare's perspective. *Journal of Managed Care Pharmacy* 18, no. 4 Suppl A (May): S5–8.
- Mohr, P. E., and S. R. Tunis. 2010. Access with evidence development: The US experience. *Pharmacoeconomics* 28, no. 2: 153–162.
- Morgenson, G. 2014. Questcor reveals adverse events data for acthar for first time. *New York Times*, July 10.
- Morin, L., M. L. Laroche, G. Texier, et al. 2016. Prevalence of potentially inappropriate medication use in older adults living in nursing homes: A systematic review. *Journal of the American Medical Directors Association* 17, no. 9 (September 1): 862e1–862e9.
- National Kidney Foundation. 2015. KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 update. *American Journal of Kidney Diseases* 66, no. 5 (November): 884–930.
- National Kidney Foundation. 2006. *2006 updates: Clinical practice guidelines and recommendations*. New York, NY: NKF.
- National Kidney Foundation. 1997. NKF-DOQI clinical practice guidelines for peritoneal dialysis adequacy. *American Journal of Kidney Diseases* 30, no. 3 supplement 2 (September): S67–136.
- National Patient-Centered Clinical Research Network. 2018. Research. <http://www.pcornet.org/research/>.
- Nee, R., E. Fisher, C. M. Yuan, et al. 2017. Pre-end-stage renal disease care and early survival among incident dialysis patients in the US military health system. *American Journal of Nephrology* 45, no. 6: 464–472.
- Neumann, P. J. 2009. Costing and perspective in published cost-effectiveness analysis. *Medical Care* 47, no. 7 supplement 1 (July): S28–32.
- Neumann, P. J. 2005. *Using cost-effectiveness analysis to improve health care*. New York, NY: Oxford University Press.
- Neumann, P. J. 2004. Why don't Americans use cost-effectiveness analysis? *American Journal of Managed Care* 10, no. 5 (May): 308–312.
- Neumann, P. J., and J. T. Cohen. 2017. ICER's revised value assessment framework for 2017–2019: A critique. *Pharmacoeconomics* 35, no. 10 (October): 977–980.
- Neumann, P. J., and J. T. Cohen. 2015. Measuring the value of prescription drugs. *New England Journal of Medicine* 373, no. 27 (December 31): 2595–2597.
- Neumann, P. J., D. Greenberg, N. V. Olchanski, et al. 2005. Growth and quality of the cost-utility literature, 1976–2001. *Value in Health* 8, no. 1 (January–February): 3–9.
- Neumann, P. J., M. S. Kamae, and J. A. Palmer. 2008. Medicare's national coverage decisions for technologies, 1999–2007. *Health Affairs* 27, no. 6 (November–December): 1620–1631.
- Neumann, P. J., G. D. Sanders, L. B. Russell, et al. 2017. *Cost-effectiveness in health and medicine*. New York, NY: Oxford University Press.
- O'Connor, A. M., C. L. Bennett, D. Stacey, et al. 2009. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*, no. 3. <http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD001431.pub5/full>.
- O'Connor, A. M., H. A. Llewellyn-Thomas, and A. B. Flood. 2004. Modifying unwarranted variations in health care: Shared decision making using patient decision aids. *Health Affairs Web Exclusives*: VAR63–72.
- O'Hare, A. M., A. I. Choi, W. J. Boscardin, et al. 2011. Trends in timing of initiation of chronic dialysis in the United States. *Archives of Internal Medicine* 171, no. 18 (October 10): 1663–1669.
- Office of Inspector General, Department of Health and Human Services. 2016. *MACs continue to use different methods to determine drug coverage*. OEI-03-13-00450. Washington, DC: OIG.
- Office of Inspector General, Department of Health and Human Services. 2014. *Local coverage determinations create inconsistency in Medicare coverage*. OEI-01-11-00500. Washington, DC: OIG.
- Office of Inspector General, Department of Health and Human Services. 2012. *Least costly alternative policies: Impact on prostate cancer drugs covered under Medicare Part B*. OEI-12-12-00210. Washington, DC: OIG.
- Office of Inspector General, Department of Health and Human Services. 2004. *Medicare reimbursement for Lupron*. OEI-03-03-00250. Washington, DC: OIG.
- Ollendorf, D. A., J. A. Colby, and S. D. Pearson. 2014. *Proton beam therapy*. Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. https://icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf.

- Opondo, D., S. Eslami, S. Visscher, et al. 2012. Inappropriateness of medication prescriptions to elderly patients in the primary care setting: A systematic review. *PLoS One* 7, no. 8: e43617.
- Owen, W. F., Jr., N. L. Lew, Y. Liu, et al. 1993. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. *New England Journal of Medicine* 329, no. 14 (September 30): 1001–1006.
- Particle Therapy Co-Operative Group. 2018. Particle therapy facilities in operation. <https://www.ptcog.ch/index.php/facilities-in-operation>.
- Partnership to Improve Patient Care. 2018. *Uses and misuses of the QALY: Ethical issues with QALYs and alternative measures of value*. Washington, DC: PIPC.
- Patient-Centered Outcomes Research Institute. 2017. What is PCORI's official policy on cost and cost-effectiveness analysis? <https://help.pcori.org/hc/en-us/articles/213716587-What-is-PCORI-s-official-policy-on-cost-effectiveness-analysis->
- Patient-Centered Outcomes Research Institute. 2013. Introducing a new PCORI research funding initiative—Large pragmatic clinical trials. <https://www.pcori.org/blog/introducing-new-pcori-research-funding-initiative-large-pragmatic-clinical-trials>.
- Pear, R. 1991. Medicare to weigh cost as a factor in reimbursement. *New York Times*, April 21.
- Pearson, S. D., and P. B. Bach. 2010. How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement. *Health Affairs* 29, no. 10 (October): 1796–1804.
- Pizzi, L. T. 2016. The Institute for Clinical and Economic Review and its growing influence on US healthcare. *American Health and Drug Benefits* 9, no. 1 (February): 9–10.
- Podemska-Mikluch, M. 2016. *FDA-CMS Parallel review: A failed attempt at spurring innovation*. Arlington, VA: Mercatus Center George Mason University.
- Prime Therapeutics. 2016. Prime Therapeutics joins ICER as flagship member. Press release. <https://www.primetherapeutics.com/en/news/pressreleases/2016/prime-joins-icer-release.html>.
- PRNewswire. 2018. ANI Pharmaceuticals reports record full year results, reports fourth quarter 2017 results, and provides 2018 guidance. <https://www.prnewswire.com/news-releases/ani-pharmaceuticals-reports-record-full-year-results-reports-fourth-quarter-2017-results-and-provides-2018-guidance-300604056.html>.
- Pugh, M. J., J. T. Hanlon, J. E. Zeber, et al. 2006. Assessing potentially inappropriate prescribing in the elderly Veterans Affairs population using the HEDIS 2006 quality measure. *Journal of Managed Care Pharmacy* 12, no. 7 (September): 537–545.
- Ramanathan, V., and W. C. Winkelmayr. 2015. Timing of dialysis initiation: Do health care setting or provider incentives matter? *Clinical Journal of the American Society of Nephrology* 10, no. 8 (August 7): 1321–1323.
- Redberg, R. F. 2007. Evidence, appropriateness, and technology assessment in cardiology: A case study of computed tomography. *Health Affairs* 26, no. 1 (January–February): 86–95.
- Reid, R. O., B. Rabideau, and N. Sood. 2016. Low-value health care services in a commercially insured population. *JAMA Internal Medicine* 176, no. 10 (October 1): 1567–1571.
- Rivara, M. B., and R. Mehrotra. 2017. Timing of dialysis initiation: What has changed since IDEAL? *Seminars in Dialysis* 37, no. 2 (March): 181–193.
- Robinson, B. M., J. Zhang, H. Morgenstern, et al. 2014. Worldwide, mortality risk is high soon after initiation of hemodialysis. *Kidney International* 85, no. 1 (January): 158–165.
- Robinson, E. 2017. Medicare spent more than \$650 million in two years on a drug prescribed by less than 1 percent of physicians: Study. <https://news.ohsu.edu/2017/02/13/medicare-spent-more-than-650-million-in-two-years-on-a-drug-prescribed-by-less-than-1-percent-of-physicians-study>.
- Rosansky, S., R. J. Glasscock, and W. F. Clark. 2011. Early start of dialysis: A critical review. *Clinical Journal of the American Society of Nephrology* 6, no. 5 (May): 1222–1228.
- Rosansky, S. J., W. F. Clark, P. Eggers, et al. 2009. Initiation of dialysis at higher GFRs: Is the apparent rising tide of early dialysis harmful or helpful? *Kidney International* 76, no. 3 (August): 257–261.
- Rose, A. S., J. W. Kuzma, J. F. Kurtzke, et al. 1970. Cooperative study in the evaluation of therapy in multiple sclerosis. *Neurology* 20, no. 5 (May): 1–59.
- Rosenberg, A., A. Agiro, M. Gottlieb, et al. 2015. Early trends among seven recommendations from the Choosing Wisely campaign. *JAMA Internal Medicine* 175, no. 12 (December): 1913–1920.
- Schulte, F. 2015. Is Obamacare's Research Institute worth the billions? National Public Radio. <http://www.npr.org/sections/health-shots/2015/08/04/428164731/is-obamacares-research-institute-worth-the-billions>.

- Schur, C. L., and M. L. Berk. 2008. Views on health care technology: Americans consider the risks and sources of information. *Health Affairs* 27, no. 6 (November–December): 1654–1664.
- Schwartz, A., B. Landon, A. Elshaug, et al. 2014. Measuring low-value care in Medicare. *JAMA Internal Medicine* 174, no. 7 (July): 1067–1076.
- Schwartz, A. L., M. E. Chernew, B. E. Landon, et al. 2015. Changes in low-value services in year 1 of the Medicare Pioneer Accountable Care Organization Program. *JAMA Internal Medicine* 175, no. 11 (November): 1815–1825.
- Senekjian, H. O. 2011. Regarding early initiation of dialysis. *American Journal of Kidney Diseases* 58, no. 3 (September): 492; author reply 492.
- Shakil, S., and R. F. Redberg. 2017. New (very high) prices on old drugs. *JAMA Internal Medicine* 177, no. 11 (November 1): 1568.
- Shemin, D., A. G. Bostom, P. Laliberty, et al. 2001. Residual renal function and mortality risk in hemodialysis patients. *American Journal of Kidney Diseases* 38, no. 1 (July): 85–90.
- Silverman, E. 2016. This nonprofit is playing a valuable role in framing the drug price discussion. *STAT*, April 12.
- Singh, H., B. Kanapuru, C. Smith, et al. 2017. FDA analysis of enrollment of older adults in clinical trials for cancer drug registration: A 10-year experience by the U.S. Food and Drug Administration. *Journal of Clinical Oncology* 35, no. 15: 10009.
- Slinin, Y., H. Guo, S. Li, et al. 2014. Provider and care characteristics associated with timing of dialysis initiation. *Clinical Journal of the American Society of Nephrology* 9, no. 2 (February): 310–317.
- Slinin, Y., and A. Ishani. 2014. What drives early dialysis initiation and how do we optimize timing of RRT? *Clinical Journal of the American Society of Nephrology* 9, no. 10 (October 7): 1671–1673.
- Sox, H. 2012. The Patient-Centered Outcomes Research Institute should focus on high-impact problems that can be solved quickly. *Health Affairs* 31, no. 10 (October): 2176–2182.
- Stel, V. S., F. W. Dekker, D. Ansell, et al. 2009. Residual renal function at the start of dialysis and clinical outcomes. *Nephrology Dialysis Transplantation* 24, no. 10 (October): 3175–3182.
- Streja, E., S. B. Nicholas, and K. C. Norris. 2013. Controversies in timing of dialysis initiation and the role of race and demographics. *Seminars in Dialysis* 26, no. 6 (November–December): 658–666.
- Suda, T., K. Hiroshige, T. Ohta, et al. 2000. The contribution of residual renal function to overall nutritional status in chronic haemodialysis patients. *Nephrology Dialysis Transplant* 15, no. 3 (March): 396–401.
- Sun, F., O. Oyesanmi, J. Fontanarosa, et al. 2014. *Therapies for clinically localized prostate cancer: Update of a 2008 systematic review*. Prepared by staff from the ECRI Institute for the Agency for Healthcare Research and Quality. AHRQ publication no. 15-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality.
- Susantitaphong, P., S. Altamimi, M. Ashkar, et al. 2012. GFR at initiation of dialysis and mortality in CKD: A meta-analysis. *American Journal of Kidney Diseases* 59, no. 6 (June): 829–840.
- Talarico, L., G. Chen, and R. Pazdur. 2004. Enrollment of elderly patients in clinical trials for cancer drug registration: A 7-year experience by the US Food and Drug Administration. *Journal of Clinical Oncology* 22, no. 22 (November 15): 4626–4631.
- Termorshuizen, F., F. W. Dekker, J. G. van Manen, et al. 2004. Relative contribution of residual renal function and different measures of adequacy to survival in hemodialysis patients: An analysis of the Netherlands Cooperative Study on the Adequacy of Dialysis (NECOSAD)-2. *Journal of the American Society of Nephrology* 15, no. 4 (April): 1061–1070.
- Thompson, A. J., C. Kennard, M. Swash, et al. 1989. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. *Neurology* 39, no. 7 (July): 969–971.
- Timbie, J., P. Hussey, L. Burgette, et al. 2014. *Medicare Imaging Demonstration evaluation report for the report to Congress*. Report prepared for the Centers for Medicare & Medicaid Services. Santa Monica, CA: RAND Corporation.
- TrailBlazer Health Enterprises. 2006. *Draft LCS for proton beam radiotherapy-R18B (DL22108)*. Baltimore, MD: CMS. https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=22107%3a10.
- Traynor, J. P., K. Simpson, C. C. Geddes, et al. 2002. Early initiation of dialysis fails to prolong survival in patients with end-stage renal failure. *Journal of the American Society of Nephrology* 13, no. 8 (August): 2125–2132.
- Tunis, S., R. A. Berenson, S. Phurrough, et al. 2011. *Improving the quality and efficiency of the Medicare program through coverage policy*. Washington, DC: Urban Institute.
- United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2017. *USRDS 2017 annual data report*. Bethesda, MD: NIDDK.

- Washington, A. E., and S. H. Lipstein. 2011. The Patient-Centered Outcomes Research Institute—Promoting better information, decisions, and health. *New England Journal of Medicine* 365, no. 15 (October 13): e31.
- Washington State Health Care Authority. 2014. Health Technology Clinical Committee findings and decision on proton beam therapy. [https://www.hca.wa.gov/assets/program/pbt_final_findings_decision_071114\[1\].pdf](https://www.hca.wa.gov/assets/program/pbt_final_findings_decision_071114[1].pdf).
- Watkins, C., L. Moore, I. Harvey, et al. 2003. Characteristics of general practitioners who frequently see drug industry representatives: National cross sectional study. *British Medical Journal* 326, no. 7400 (May 31): 1178–1179.
- Wazana, A. 2000. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *Journal of the American Medical Association* 283, no. 3 (January 19): 373–380.
- Wilson, B., L. Harwood, H. Locking-Cusolito, et al. 2007. Optimal timing of initiation of chronic hemodialysis? *Hemodialysis International* 11, no. 2 (April): 263–269.
- Wong-Beringer, A., L. H. Nguyen, M. Lee, et al. 2009. An antimicrobial stewardship program with a focus on reducing fluoroquinolone overuse. *Pharmacotherapy* 29, no. 6 (June): 736–743.
- Wong, S. P., E. K. Vig, J. S. Taylor, et al. 2016. Timing of initiation of maintenance dialysis: A qualitative analysis of the electronic medical records of a national cohort of patients from the Department of Veterans Affairs. *JAMA Internal Medicine* 176, no. 2 (February): 228–235.
- Wright, S., D. Klausner, B. Baird, et al. 2010. Timing of dialysis initiation and survival in ESRD. *Clinical Journal of the American Society of Nephrology* 5, no. 10 (October): 1828–1835.
- Yu, J. B., P. R. Soulos, J. Herrin, et al. 2013. Proton versus intensity-modulated radiotherapy for prostate cancer: Patterns of care and early toxicity. *Journal of the National Cancer Institute* 105, no. 1 (January 2): 25–32.
- Yu, M. K., A. M. O’Hare, A. Batten, et al. 2015. Trends in timing of dialysis initiation within versus outside the Department of Veterans Affairs. *Clinical Journal of the American Society of Nephrology* 10, no. 8 (August 7): 1418–1427.

A P P E N D I X

A

**Commissioners' voting
on recommendations**



Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation and to document the voting record in its report. The information below satisfies that mandate.

Chapter 1: Mandated report: The effects of the Hospital Readmissions Reduction Program

No recommendations

Chapter 2: Using payment to ensure appropriate access to and use of hospital emergency department services

2-1 The Congress should:

- allow isolated rural stand-alone emergency departments (more than 35 miles from another emergency department) to bill standard outpatient prospective payment system facility fees and
- provide such emergency departments with annual payments to assist with fixed costs.

Yes: Bricker, Buto, Christianson, Coombs, Crosson, DeBusk, Ginsburg, Grabowski, Hoadley, Nerenz, Pyenson, Redberg, Safran, Samitt, Thomas, Thompson, Wang

2-2 The Congress should reduce Type A emergency department payment rates by 30 percent for off-campus stand-alone emergency departments that are within six miles of an on-campus hospital emergency department.

Yes: Bricker, Buto, Christianson, Coombs, Crosson, DeBusk, Ginsburg, Grabowski, Hoadley, Nerenz, Pyenson, Redberg, Safran, Samitt, Thomas, Thompson, Wang

Chapter 3: Rebalancing Medicare's physician fee schedule toward ambulatory evaluation and management services

No recommendations

Chapter 4: Paying for sequential stays in a unified prospective payment system for post-acute care

No recommendations

Chapter 5: Encouraging Medicare beneficiaries to use higher quality post-acute care providers

No recommendations

Chapter 6: Issues in Medicare's medical device payment policies

No recommendations

Chapter 7: Applying the Commission's principles for measuring quality: Population-based measures and hospital quality incentives

No recommendations

Chapter 8: Medicare accountable care organization models: Recent performance and long-term issues

No recommendations

Chapter 9: Managed care plans for dual-eligible beneficiaries

No recommendations

Chapter 10: Medicare coverage policy and use of low-value care

No recommendations

Acronyms

Acronyms

24/7	24 hours per day, 7 days per week	CIVHC	Center for Improving Value in Health Care
A-APM	advanced alternative payment model	CKD	chronic kidney disease
ABIM	American Board of Internal Medicine	CMMI	Center for Medicare & Medicaid Innovation
ACC	Accountable Care Collaborative	CMS	Centers for Medicare & Medicaid Services
ACO	accountable care organization	CMS-HCC	CMS hierarchical condition category
Acthar	H.P. Acthar Gel [®]	CMT	contract management team
ADL	activity of daily living	COP	condition of participation
AED	automatic external defibrillator	COPD	chronic obstructive pulmonary disease
AHRQ	Agency for Healthcare Research and Quality	CPAP	continuous positive airway pressure
AKS	anti-kickback statute	CPC+	Comprehensive Primary Care Plus Model
ALJ	administrative law judge	CPI-U	consumer price index for all urban consumers
AMI	acute myocardial infarction	CPT	Current Procedural Terminology
APC	ambulatory payment classification	CT	computed tomography
APR-DRG	all-patient refined–diagnosis related group	DAB	Departmental Appeals Board
AQC	Alternative Quality Contract	DHS	designated health services
ASC	ambulatory surgical center	DME	durable medical equipment
ASPE	Assistant Secretary for Planning and Evaluation	DMEPOS	durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies
AUC	Appropriate Use Criteria [Program]	DRG	diagnosis related group
BBA	Balanced Budget Act of 1997	DSH	disproportionate share
BBA	Bipartisan Budget Act of 2015	D-SNP	dual-eligible special needs plan
BBA	Bipartisan Budget Act of 2018	DVT	deep vein thrombosis
BIPA	Benefits Improvement and Protection Act of 2000	DXA	dual-energy X-ray absorptiometry
BMD	bone mineral density	E&M	evaluation and management
BPCI	Bundled Payments for Care Improvement	ED	emergency department
CABG	coronary artery bypass graft	EEG	electroencephalography
CAC	carrier advisory committee	eGFR	estimated glomerular filtration rate
CAH	critical access hospital	EGHI	employer group health insurance
CAHPS[®]	Consumer Assessment of Healthcare Providers and Systems [®]	EHR	electronic health record
CBA	competitive bidding area	EMS	emergency medical services
CBO	Congressional Budget Office	ESCAPE	Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times
CBP	Competitive Bidding Program	ESCO	ESRD Seamless Care Organization
CBSA	core-based statistical area	ESRD	end-stage renal disease
CCJR	Comprehensive Care for Joint Replacement	FDA	Food and Drug Administration
CDC	Centers for Disease Control and Prevention	FDG-PET	fluorodeoxyglucose–positron emission tomography
CDS	clinician decision support	FFS	fee-for-service
CEC	Comprehensive ESRD Care [Model]	FIDE SNP	fully integrated dual-eligible special needs plan
CED	coverage with evidence development	FQHC	federally qualified health center
CER	comparative effectiveness research	GAO	Government Accountability Office
CERT	Comprehensive Error Rate Testing		
CFR	Code of Federal Regulations		
CHF	congestive heart failure		

GPO	group purchasing organization	LMRP	local medical review policy
HAC	hospital-acquired condition	LTCH	long-term care hospital
HACRP	Hospital-Acquired Condition Reduction Program	LTSS	long-term services and supports
HBO	hyperbaric oxygen	MA	Medicare Advantage
H-CAHPS®	Hospital Consumer Assessment of Healthcare Providers and Systems®	MAC	Medicare Appeals Council
HCBS	home- and community-based services	MAC	Medicare administrative contractor
HCC	hierarchical condition category	MACRA	Medicare Access and CHIP Reauthorization Act of 2015
HCD	home and community day	MARx	Medicare Advantage Prescription Drug [system]
HCFA	Health Care Financing Administration	MDH	Medicare-dependent hospital
HCPCS	Healthcare Common Procedure Coding System	MEDCAC	Medicare Evidence Development & Coverage Advisory Committee
HEDIS®	Healthcare Effectiveness Data and Information Set®	MedPAC	Medicare Payment Advisory Commission
HF	heart failure	MHCC	Maryland Health Care Commission
HHA	home health agency	MIPPA	Medicare Improvements for Patients and Providers Act of 2008
HHS	Department of Health and Human Services	MIPS	Merit-based Incentive Payment System
HIV	human immunodeficiency virus	MLTSS	managed long-term services and supports
HMO	health maintenance organization	MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
HRR	hospital referral region	MMP	Medicare–Medicaid Plan
HRRP	Hospital Readmissions Reduction Program	MOU	memorandum of understanding
HSA	health service area	MRI	magnetic resonance imaging
HSA	hospital service area	MS	multiple sclerosis
HTCC	Health Technology Clinical Committee	MSA	metropolitan statistical area
HVIP	hospital value incentive program	MS-DRG	Medicare severity–diagnosis related group
ICD	implantable cardioverter-defibrillator	MSHO	Minnesota Senior Health Options
ICER	Institute for Clinical and Economic Review	MSPB	Medicare spending per beneficiary
ICU	intensive care unit	MSSP	Medicare Shared Savings Program
IDE	investigational device exemption	N/A	not applicable
IDEAL	Initiating Dialysis Early and Late [study]	N/A	not available
IDS	integrated delivery system	NAMCS	National Ambulatory Medical Care Survey
IFEC	independent freestanding emergency center	NCD	national coverage determination
IMD	implantable medical device	NCQA	National Committee for Quality Assurance
IMPACT	Improving Medicare Post-Acute Care Transformation Act of 2014	NextGen	Next Generation
IMRT	intensity-modulated radiation therapy	NHAMCS	National Hospital Ambulatory Medical Care Survey
IPPS	inpatient prospective payment system	NHSN	National Healthcare Safety Network
IQRP	Inpatient Quality Reporting Program	NICE	National Institute for Health and Care Excellence
IRF	inpatient rehabilitation facility	NKF	National Kidney Foundation
IVC	inferior vena cava	NOI	notice of intent
KDOQI	Kidney Disease Outcomes Quality Initiative	NTA	nontherapy ancillary
LCA	least costly alternative	OACT	Office of the Actuary
LCD	local coverage determination	OCED	off-campus emergency department
LDO	large dialysis organization	OIG	Office of Inspector General
LHRH	luteinizing hormone-releasing hormone		
LIS	low-income [drug] subsidy		

OPPS	outpatient prospective payment system	PTH	parathyroid hormone
P&T	pharmacy and therapeutics	PY	performance year
PAC	post-acute care	QALY	quality-adjusted life year
PACE	Program of All-Inclusive Care for the Elderly	QIO	Quality Improvement Organization [Program]
PAC-PRD	Post-Acute Care Payment Reform Demonstration	RAC	recovery audit contractor
PBM	pharmacy benefit manager	RAD	respiratory assist device
PBP	population-based payment	RBRVS	Resource-based Relative Value Scale
PBPM	per beneficiary per month	RCT	randomized controlled trial
PCI	percutaneous coronary intervention	RFP	request for proposal
PCIP	Primary Care Incentive Payment [program]	RKF	residual kidney function
PCORI	Patient-Centered Outcomes Research Institute	RSNAT	Repetitive Scheduled Non-Emergent Ambulance Transport
PCORnet	National Patient-Centered Clinical Research Network	RUC	Relative Value Scale Update Committee
PCORTF	Patient-Centered Outcomes Research Trust Fund	RVU	relative value unit
PCR	payment-to-cost ratio	SACH	solid ankle cushion heel
PDAC	pricing, data analysis, and coding	SCH	sole community hospital
PDP	prescription drug plan	SCO	Senior Care Options
PFS	physician fee schedule	SES	socioeconomic status
PFT	pulmonary function test	SGR	sustainable growth rate
PMD	power mobility device	SNF	skilled nursing facility
POD	physician-owned distributor	SNFRM	Skilled Nursing Facility 30-Day All-Cause Readmission Measure
PPA	potentially preventable admission	SNP	special needs plan
PPACA	Patient Protection and Affordable Care Act of 2010	SPA	single payment amount
PPO	preferred provider organization	SSI	Supplemental Security Income
PPR	potentially preventable readmission	TIN	taxpayer identification number
PPS	prospective payment system	USPSTF	United States Preventive Services Task Force
PQI	Prevention Quality Indicator	VA	Department of Veterans Affairs
PSA	prostate-specific antigen	VBID	value-based insurance design
PSI	patient safety indicator	VBP	value-based purchasing
PTAC	Physician-Focused Payment Model Technical Advisory Committee	WPP	Wisconsin Partnership Program

More about MedPAC

Commission members

Francis J. Crosson, M.D., chairman

Los Altos, CA

Jon B. Christianson, Ph.D., vice chairman

School of Public Health at the University of Minnesota

Minneapolis, MN

Term expires April 2018

Alice Coombs, M.D.

Milton Hospital and South Shore Hospital

Weymouth, MA

Jack Hoadley, Ph.D.

Health Policy Institute, Georgetown

University

Washington, DC

David Nerenz, Ph.D.

Henry Ford Health System

Detroit, MI

Rita Redberg, M.D., M.Sc.

University of California at San Francisco

Medical Center

San Francisco, CA

Craig Samitt, M.D., M.B.A.

Anthem Inc.

Indianapolis, IN

Susan Thompson, M.S., R.N.

UnityPoint Health

West Des Moines, IA

Term expires April 2019

Amy Bricker, R.Ph.

Express Scripts

St. Louis, MO

Jon B. Christianson, Ph.D.

Brian DeBusk, Ph.D.

DeRoyal Industries

Powell, TN

Paul Ginsburg, Ph.D.

Brookings Institution

Washington, DC

Bruce Pyenson, F.S.A., M.A.A.A.

Milliman Inc.

New York, NY

Pat Wang, J.D.

Healthfirst

New York, NY

Term expires April 2020

Kathy Buto, M.P.A.

Arlington, VA

Francis J. Crosson, M.D.

David Grabowski, Ph.D.

Harvard Medical School

Boston, MA

Dana Gelb Safran, Sc.D.

Blue Cross Blue Shield of Massachusetts

Boston, MA

Warner Thomas, M.B.A.

Ochsner Health System

New Orleans, LA

Commissioners' biographies

Amy Bricker, R.Ph., is president of the Supply Chain Division of Express Scripts Inc. in St. Louis, MO. She also has responsibility for Inside Rx, an Express Scripts subsidiary. She has held leadership roles at Express Scripts in pharmacy network management, supply chain economics, and retail contracting and strategy. Prior positions include regional vice president of account management and director of clinical sales with Walgreens Health Services and director of community retail pharmacy for BJC HealthCare. She currently serves on the boards of two nonprofit organizations: Memory Care Home Solutions and Youth in Need. Ms. Bricker received a bachelor of science in pharmacy at St. Louis College of Pharmacy.

Kathy Buto, M.P.A., is an independent consultant and an expert in U.S. and international health policy. She serves on the Healthcare Leadership Council of the Healthcare Financial Management Association and as a venture adviser to Incube Labs LLC. She also serves on the board of the Arlington Free Clinic and as a member of Women of Impact, a women's health care leadership group. Her previous positions include vice president of global health policy at Johnson & Johnson, senior health adviser at the Congressional Budget Office, deputy director of the Center for Health Plans and Providers at the Health Care Financing Administration (now Centers for Medicare & Medicaid Services), and deputy executive secretary for health at the Department of Health and Human Services. Ms. Buto received her master's in public administration from Harvard University.

Jon B. Christianson, Ph.D., is the James A. Hamilton Chair in Health Policy and Management in the Division of Health Policy and Management at the School of Public Health at the University of Minnesota. His research has addressed the areas of health finance, payment structures, rural health care, managed care payment, and the quality and design of care systems. Dr. Christianson received his Ph.D. in economics from the University of Wisconsin.

Alice Coombs, M.D., is a critical care specialist and an anesthesiologist at Milton Hospital and South Shore Hospital in Weymouth, MA. She is also an associate professor in anesthesiology and critical care medicine at the Medical College of Virginia/Virginia Commonwealth

University Health System. She is board certified in internal medicine, anesthesiology, and critical care medicine. Dr. Coombs is past president of the Massachusetts Medical Society (MMS) and a member of MMS's Committee on Ethnic Diversity. She chaired the Committee on Workforce Diversity that is part of the American Medical Association's (AMA's) Commission to Eliminate Health Care Disparities and has served on the Governing Council for the AMA Minority Affairs Consortium and the AMA Initiative to Transform Medical Education. She currently serves on the AMA Women Physicians Section Executive Committee. She helped to establish the New England Medical Association, a state society of the National Medical Association that represents minority physicians and health professionals. Dr. Coombs has served as a member and vice chair of the Massachusetts Board of Registration in Medicine Patient Care Assessment Committee. In addition, she was a member of the Massachusetts Special Commission on the Health Care Payment System, the Massachusetts Health Policy Advisory Committee, and the Massachusetts Health Disparities Council.

Francis J. Crosson, M.D., spent 35 years as a physician and physician executive at Kaiser Permanente. In 1997, he founded and for 10 years led the Permanente Federation LLC, the national umbrella organization for the physician half of Kaiser Permanente. Later he served as senior fellow at the Kaiser Permanente Institute for Health Policy and director of public policy for The Permanente Medical Group. From July 2012 through October 2014, he was group vice president of the American Medical Association in Chicago, IL, where he oversaw work related to physician practice satisfaction, efficiency, and sustainability. He previously served on MedPAC from 2004 to 2010, including as vice chair from 2009 to 2010. Dr. Crosson received his medical degree from the Georgetown University School of Medicine.

Brian DeBusk, Ph.D., is chief executive officer of DeRoyal Industries in Powell, TN, which operates in the surgical, orthopedic, wound care, and health care information technology markets. He also serves as vice chairman of Lincoln Memorial University in rural Tennessee, which includes graduate medical education programs for physicians, physician assistants,

nurse practitioners, and nurses. Dr. DeBusk's prior employment includes General Electric, Inobis, and Pace Energy Systems. He has served on the faculty of both the University of Tennessee and Lincoln Memorial University, teaching classes in information technology and business strategy. Dr. DeBusk holds a Ph.D. in electrical engineering from Vanderbilt University and a master of business administration from Emory University.

Paul Ginsburg, Ph.D., is the Leonard Schaeffer Chair in Health Policy Studies at the Brookings Institution in Washington, DC, and professor of health policy at the University of Southern California, where he is affiliated with the USC Schaeffer Center for Health Policy and Economics. Prior positions include founder and president of the Center for Studying Health System Change, founding executive director of the Physician Payment Review Commission, senior economist at RAND, and deputy assistant director at the Congressional Budget Office. Dr. Ginsburg earned his doctorate in economics from Harvard University.

David Grabowski, Ph.D., is a professor in the Department of Health Care Policy at Harvard Medical School in Boston, MA. His research primarily focuses on the economics of aging, with an emphasis on post-acute and long-term care financing, organization, and delivery of services. Dr. Grabowski served as a member of two CMS technical expert panels that focused on the home health prospective payment system and the quality measures used in the home health value-based purchasing model. He serves on the editorial board of several journals, including the *American Journal of Health Economics* and *Medical Care Research & Review*. Dr. Grabowski received his Ph.D. in public policy from the Irving B. Harris School of Public Policy at the University of Chicago.

Jack Hoadley, Ph.D., is research professor emeritus at the Health Policy Institute in the McCourt School of Public Policy at Georgetown University in Washington, DC. Dr. Hoadley previously served as director of the Division of Health Financing Policy for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation; as principal policy analyst at MedPAC and its predecessor organization, the Physician Payment Review Commission; and as senior research associate with the National Health Policy Forum. His research expertise includes health financing for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP); pharmaco-economics and prescription drug

benefit programs; and private sector insurance coverage. Dr. Hoadley has published widely on health care financing and pharmaco-economics and has provided testimony to government panels.

David Nerenz, Ph.D., is director of the Center for Health Policy and Health Services Research at the Henry Ford Health System in Detroit, MI, as well as director of outcomes research at the Henry Ford Neuroscience Institute and vice chair for research in the Department of Neurosurgery at Henry Ford Hospital. He has served on the National Committee for Quality Assurance's Culturally and Linguistically Appropriate Services Workgroup, the Accountable Care Organization Technical Advisory Committee of the American Medical Group Association, and most recently as co-chair of the National Quality Forum's Expert Panel on Risk Adjustment for Sociodemographic Factors. Dr. Nerenz has served in various roles with the Institute of Medicine, including as chair of the Committee on Leading Health Indicators for Healthy People 2020. He serves on the editorial boards of *Population Health Management and Medical Care Research and Review*.

Bruce Pyenson, F.S.A., M.A.A.A., is principal and consulting actuary at Milliman Inc. in New York, NY. His work has focused on diverse aspects of health care and insurance, including recent work related to alternative payment models for accountable care organizations, such as shared savings, as well as financial modeling of therapeutic interventions. He has co-authored publications on such topics as the cost-effectiveness of lung cancer screening, pandemic influenza, and site-of-service cost differences for chemotherapy. Mr. Pyenson is a fellow of the Society of Actuaries and a member of the American Academy of Actuaries.

Rita Redberg, M.D., M.Sc., is professor of clinical medicine at the University of California at San Francisco (UCSF) Medical Center. A cardiologist, Dr. Redberg is also core faculty at the UCSF Philip R. Lee Institute of Health Policy Studies and adjunct associate at Stanford University's Center for Health Policy/Center for Primary Care and Outcomes Research. She is editor of *JAMA Internal Medicine* and chairperson of CMS's Medicare Evidence Development and Coverage Advisory Committee. Dr. Redberg serves in numerous positions on committees of the American Heart Association and the American College of Cardiology and was a Robert Wood Johnson Health Policy Fellow. She did her undergraduate work at Cornell University and has graduate degrees from

the University of Pennsylvania Medical School and the London School of Economics.

Dana Gelb Safran, Sc.D., is the Chief Performance Measurement and Improvement Officer and Senior Vice President, Enterprise Analytics, at Blue Cross Blue Shield of Massachusetts. In that role, she is responsible for leading efforts to use data, measurement, incentives, and reporting to improve the quality, outcomes, and affordability of care. Dr. Safran is also an associate professor at Tufts University School of Medicine. She currently serves on a number of state and national advisory bodies related to health care quality and affordability, including the National Quality Forum Consensus Standards Approval Committee and the CMS Technical Expert Panel on the Quality Rating System. Dr. Safran received her Sc.D. in health policy and management from the Harvard School of Public Health.

Craig Samitt, M.D., M.B.A., is executive vice president and chief clinical officer at Anthem Inc. He has led major health systems for 20 years, most recently serving as president and CEO of HealthCare Partners, a division of DaVita HealthCare Partners, and, from 2006 through 2013, as president and CEO of Dean Health System in Madison, WI. Before joining Anthem, Dr. Samitt served as partner and global provider practice leader in Oliver Wyman's Health & Life Sciences Practice and previously held senior executive roles at Fallon Clinic, Harvard Pilgrim Health Care, and Harvard Vanguard Medical Associates. He is chair emeritus of the Group Practice Improvement Network and previously served as an advisory and faculty member of CMS's Accountable Care Organization Accelerated Development Learning Sessions. Dr. Samitt received his B.S. in biology from Tufts University, his M.D. from Columbia University College of Physicians and Surgeons, and his M.B.A. from the Wharton School.

Warner Thomas, M.B.A., is president and CEO of the Ochsner Health System in New Orleans, LA. He oversees a network of 10 hospitals, 45 health centers and clinics, and 2,200 affiliated physicians. The Ochsner system includes the Ochsner Medical Center in New Orleans, the Ochsner Clinic group practice, rurally based and subacute care hospitals, skilled nursing and rehabilitation facilities, and hospice. The Ochsner Medical Center operates one of largest accredited non-university-based graduate medical education programs in the United States. It is also one of the largest Medicare risk contractors in the region and offers an accountable care organization for Medicare. Mr.

Thomas's prior positions include chief operating officer of the Ochsner Clinic, vice president of managed care and network development at the Southern New Hampshire Medical Center, and senior auditor and consultant at Ernst & Young. He received his master of business administration from Boston University Graduate School of Management.

Susan Thompson, M.S., R.N., is senior vice president of integration and optimization with UnityPoint Health, an integrated delivery system serving Iowa, central and western Illinois, and central Wisconsin. Ms. Thompson is also the chief executive officer of UnityPoint Health Accountable Care, L.C., an Iowa limited liability company that brings together a diverse group of health care providers including hospitals, employed and independent physicians, and other providers, as well as other health initiatives. Previously, she was president and chief executive officer of UnityPoint Health—Fort Dodge, which serves a predominantly rural and aging population and included a sole community hospital, a primary care and multispecialty physician group, management contracts with five critical access hospitals throughout the region, and a Pioneer Accountable Care Organization. She also served in successive clinical and management positions at Trinity Regional Medical Center, as intensive care staff nurse, director of quality systems, assistant director of patient-focused care, chief information officer, chief operating officer, and chief executive officer. Ms. Thompson obtained her B.S. in nursing and her M.S. in health services management from Clarkson College in Omaha, NE.

Pat Wang, J.D., is chief executive officer of Healthfirst in New York, NY. Healthfirst is a not-for-profit provider-sponsored health plan that serves Medicare enrollees, including those who are eligible for low-income subsidies and those who are dually eligible for Medicare and Medicaid. Healthfirst incorporates a payment model that transfers risk to hospital and physician partners. Ms. Wang previously served as senior vice president of finance and managed care for the Greater New York Hospital Association. She received her law degree from the New York University School of Law.

Commission staff

James E. Mathews, Ph.D.
Executive director

Dana K. Kelley, M.P.A.
Deputy director

Analytic staff

.....
Catherine Bloniarz, M.S.
Stephanie Cameron, Sc.M.
Carol Carter, Ph.D.
Evan Christman, M.P.Aff.
Zachary Gaumer, M.P.S.
David V. Glass, M.S.
Scott Harrison, Ph.D.
Andy Johnson, Ph.D.
Kim Neuman, M.A.
Brian O'Donnell, M.P.P.
Jennifer Podulka, M.P.Aff.
Nancy Ray, M.S.
Eric Rollins, M.P.P.
Rachel Schmidt, Ph.D.
Jeffrey Stensland, Ph.D.
Shinobu Suzuki, M.A.
Ledia Tabor, M.P.H.
Ariel Winter, M.P.P.
Daniel Zabinski, Ph.D.

Research assistants

.....
Emma Achola
Sydney McClendon

Assistant director

.....
Paul Masi, M.P.P.

Special assistant and scheduler

.....
Olivia Berci

Administrative staff

.....
Allan Holland
Wylene Carlyle
Timothy Gulley
Tina Jennings, MTESL
Howard Patterson
Cynthia Wilson

