JUNE 2016

REPORT TO THE CONGRESS

Medicare and the Health Care Delivery System

MEDPAC Medicare Payment Advisory Commission

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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.

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Francis J. Crosson, M.D., Chairman
Jon Christianson, Ph.D., Vice Chairman
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June 15, 2016

The Honorable Joseph R. Biden
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 2016 *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 nine chapters of this report, we consider:

- using competitive pricing to set beneficiary premiums in Medicare.
- Medicare's new framework for paying clinicians.
- developing a unified payment system for post-acute care.
- the broader context for Medicare drug spending.
- Medicare Part B drug and oncology payment issues.
- improving the Medicare Part D prescription drug program.
- improving efficiency and preserving access to emergency care in rural areas.
- telehealth services and the Medicare program.
- issues affecting dual-eligible beneficiaries—CMS's financial alignment demonstration and the Medicare Savings Programs.

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,

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.

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Executive summary

Executive summary

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

- ***Using competitive pricing to set beneficiary premiums in Medicare***—Medicare could seek to encourage beneficiaries to choose the more efficient option (traditional fee-for-service (FFS) or Medicare Advantage (MA)) for receiving Medicare benefits in different geographic areas. The incentives for beneficiaries to choose more efficient (high quality, low cost) models would be designed to reinforce the incentives that encourage providers and plans to provide care in a more efficient manner. We examine three illustrative designs that could be considered for achieving these goals.

- ***Medicare's new framework for paying clinicians***—The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the sustainable growth rate (SGR) system and established a new approach to updating payments to clinicians. This approach creates incentives for clinicians to participate in alternative payment models (APMs). We present basic principles to guide the implementation of the APM provisions and discuss some key considerations for the Merit-based Incentive Payment System also created by MACRA.

- ***Developing a unified payment system for post-acute care***—The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) requires the Commission to develop a prototype prospective payment system (PPS) spanning the post-acute care (PAC) settings. Our work confirms that a PAC PPS is feasible and within reach. Given the long-standing problems with Medicare's payment for PAC, moving to a unified PAC PPS is desirable, and the chapter outlines a series of design considerations. A truly reformed PAC payment system will ultimately need to embrace episode-based payments.

- ***Medicare drug spending in its broader context***—The Commission remains concerned about the rapid growth in drug prices because that growth can affect beneficiary access to needed medications as well as the financial sustainability of the Medicare program. But Medicare is part of a larger drug marketplace, and the program's drug payment policies can only affect drug pricing indirectly. Here, we consider external factors that influence the prices Medicare pays for prescription drugs.

- ***Medicare Part B drug and oncology payment policy issues***—Medicare Part B covers drugs that are administered by infusion or injection in clinicians' offices and hospital outpatient departments. It also covers certain drugs furnished by suppliers. We discuss several broad issues: potential modifications to the way Medicare Part B pays for drugs in general (e.g., reducing dispensing and supplying fees) and approaches to improve the quality and efficiency of oncology care in particular (e.g., clinical pathways and bundling) since more than half of Medicare Part B drug spending is associated with anticancer drugs.

- ***Improving the Medicare Part D prescription drug program***—The Commission has documented several years of rapid growth in the reinsurance portion of Part D. Here, we recommend improvements intended to put Part D on a more stable financial path. One set of changes would give plan sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees. Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true out-of-pocket (OOP) spending, while providing greater insurance protection through a real cap on OOP spending. The recommended improvements would also moderately increase financial incentives for enrollees who receive the low-income subsidy (LIS) to use lower cost drugs and biologics.

- ***Improving efficiency and preserving access to emergency care in rural areas***—Efficiently providing access to inpatient and emergency services is a growing challenge in sparsely populated rural areas. We discuss giving isolated rural hospitals the option of converting to an outpatient-only model that may be more sustainable in communities with declining inpatient volumes. The objectives of a new outpatient-only option would be to ensure access to essential services. We outline two potential options for communities that lack the population to

support efficient high-quality inpatient services: a 24/7 emergency department model and a clinic with ambulance services model.

- ***Telehealth services and the Medicare program***—We present our analysis of telehealth services—a multidimensional set of health care services delivered through a range of online, video, and telephone communication. This chapter is intended to inform policymakers as they consider how telehealth services will fit into the Medicare program in the future. The Commission raises issues for policymakers to consider in addressing the question of expanding telehealth services in Medicare under the MA program, under bundled and accountable care payment models, and under the traditional FFS model.
- ***Issues affecting dual-eligible beneficiaries: CMS's financial alignment demonstration and the Medicare Savings Programs***—We provide a status report on the financial alignment demonstration project—an initiative by CMS and states to test new models of care for dual eligibles—and examine the potential cost of three illustrative scenarios for expanding the Medicare Savings Programs (MSPs), which are Medicaid programs that provide assistance with Medicare premiums and cost sharing to certain low-income Medicare beneficiaries.

Using competitive pricing to set beneficiary premiums in Medicare

Medicare has different payment rules for its FFS and MA programs that can create inequities and inefficiencies for beneficiaries and taxpayers. The Commission has been studying how Medicare could structure its premium designs to encourage beneficiaries to choose the most efficient (high quality, low cost) option for receiving Medicare benefits across different geographic market areas. It will be important to understand the options available for the determination of beneficiary premiums if the Congress considers a premium support model in Part A and Part B of Medicare. (Medicare already uses a premium support model for its Part D drug benefit.)

In Chapter 1, we examine the potential of three illustrative premium designs to encourage beneficiaries to use the more efficient delivery system (FFS Medicare—which includes accountable care organizations (ACOs)—or MA) in their area. These designs are:

- a nationally set base premium that buys FFS Medicare in every market;
- a nationally set base premium that buys either FFS Medicare or a reference MA plan—whichever costs less—in each market; and
- locally set base premiums that buy either FFS Medicare or a reference MA plan—whichever costs less—in each market.

Under each design, beneficiaries can enroll in either FFS or MA, but the premium they pay will differ depending on the underlying per capita spending for FFS and MA. The federal contribution will be financially neutral across payment systems—that is, equal for FFS and MA in each market.

Under the second and third designs, beneficiaries who choose the more costly payment system will pay a higher premium. How much higher that premium would be depends on the difference between average FFS costs and the cost of the reference MA plan in the geographic market area. Under either design, policymakers could choose to mitigate the increase in beneficiary premiums in a number of ways, such as by limiting how much premiums can vary across delivery systems or by phasing in any increase over time.

The statutory and structural differences between MA and FFS (and ACOs, although they are considered part of FFS), including elements beyond premium design, raise important issues of equity and implementation that will need to be resolved to maximize the value of the Medicare program to beneficiaries and taxpayers. Medicare needs to determine whether and how to establish payment and quality rules that reward the more efficient system of care in a market, how to encourage beneficiaries to receive care through that system, and how to provide the information beneficiaries need to make informed decisions.

Medicare's new framework for paying clinicians

MACRA repealed the SGR system and established a new approach to updating payments to clinicians. This new approach creates incentives for clinicians to participate in APMs such as ACOs, bundled payment models, and medical homes. Essentially, MACRA establishes two paths for payment updates—a path for clinicians who participate in eligible alternative payment entities and a path for all other clinicians.

Beginning in 2019 and continuing through 2024, payment updates are set to zero, but clinicians will receive a 5

percent add-on payment if the level of revenue they receive through eligible alternative payment entities meets a certain threshold. From 2026 on, clinicians meeting the revenue threshold will receive a higher update than other clinicians. A separate program for assessing the performance of clinicians who do not qualify for the APM incentive payment—the Merit-based Incentive Payment System (MIPS)—will determine whether those clinicians receive a bonus or a penalty on their FFS payments. Thus, how CMS defines eligible alternative payment entities and how clinicians qualify for the incentive payment are of great interest to clinicians. At the same time, MIPS bonuses and penalties—although budget neutral in aggregate—could have a large effect on payments for individual clinicians and hence on the relative attractiveness of the APM and MIPS paths.

Chapter 2 presents the Commission's principles that should guide the development of APMs and discusses some key considerations for the design of MIPS. The Commission intends its discussion to be a road map to thinking through the issues raised in MACRA and helping move the Medicare program from one oriented toward FFS payment to one that encourages delivery system reform oriented toward payment for value. The Commission's basic principles for APMs are the following:

- Clinicians should receive an incentive payment only if the eligible alternative payment entity in which they participate is successful in controlling cost, improving quality, or both.
- The eligible alternative payment entity should be at financial risk for total Part A and Part B spending.
- The eligible alternative payment entity should be responsible for a beneficiary population sufficiently large to detect changes in spending and quality.
- The eligible alternative payment entity should have the ability to share savings with beneficiaries.
- CMS should give eligible alternative payment entities certain regulatory relief.
- Each eligible alternative payment entity should assume financial risk and enroll clinicians.

With regard to MIPS, we outline some lessons that can be learned from CMS's experience with the existing performance incentive programs that may be incorporated into the eventual MIPS program, and we discuss how to consider factors such as quality and resource use at the individual clinician level. We also reinforce the Commission's position that quality measures should emphasize population-based outcomes.

We conclude with observations on the importance of coordinating MIPS and APM implementation to reduce the chance of unintended consequences. In developing and implementing these programs, the broader challenge will be to further the sustainability of the Medicare program and ensure access to services for Medicare beneficiaries.

Mandated report: Developing a unified payment system for post-acute care

IMPACT requires the Commission to develop a PPS that spans the four PAC settings—skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities, and long-term care hospitals. The Act requires the Commission to recommend features of a unified PAC PPS and, to the extent feasible, consider the impact of moving to such a payment system. Chapter 3 meets this requirement.

In Chapter 3, we report that a PAC PPS is within reach. The Commission's research found that it is feasible to develop a common unit of payment for PAC services, with patient and stay characteristics forming the basis of risk adjustment. Available administrative data can accurately predict the costs (and establish payments) for most of the patient groups we examined, but patient assessment data collected using a common assessment tool would increase the accuracy for certain types of stays. We conclude the following:

- Because of differences in Medicare's coverage policies across the PAC settings, separate models will be needed to establish payments for nontherapy ancillary services and for the combination of routine and therapy services.
- Because costs are so much lower in HHAs compared with institutional PAC settings, payments for stays in HHAs will need to be adjusted to avoid large overpayments.
- A short-stay outlier policy (to prevent large overpayments) and a high-cost outlier policy (to prevent large losses by providers and protect beneficiary access to care) will be necessary components of a PAC PPS.
- Payment adjustments to capture differences in costs beyond providers' control (such as the cost of labor)

should be made on an empirical basis only and should apply to all stays, regardless of setting.

- Initial payments can be based on current practices and costs, but over time, payments should be revised to reflect appropriate, high-quality care provided as efficiently as possible.

We estimate that a PAC PPS would redistribute payments among types of stays (e.g., from physical rehabilitation to medically complex care). Under a PAC PPS, profitability would be more uniform across different types of stays or patients; therefore, providers would have less financial incentive to admit certain types of patients over others. At the same time, payment would no longer be based in part on the number of services furnished, so providers would have less financial incentive to provide unnecessary services. A PAC PPS would also redistribute payments from higher cost settings and providers to lower cost settings and providers. We would expect PAC providers to be responsive to the policy changes that would accompany a PAC PPS. Specifically, we would expect that high-cost providers would lower their costs to match the PAC PPS payments and that all providers would change their coding practices to record patient diagnoses more completely.

To temper the initial impact of the PAC PPS, policymakers may wish to consider a transition period for implementation of a new payment system for PAC to give providers time to adjust their costs to PAC PPS payments. Conversely, given our encouraging results using currently available data, the Secretary could consider implementing a unified PAC PPS sooner than is currently legislated, with refinements made over time to incorporate patient assessment data.

Policymakers will also need to consider the level of payments. The Commission estimates that, in 2013, payments for PAC were 19 percent higher than the cost of stays, suggesting the continued need for rebasing. A transition policy should consider when and how large the rebasing should be. The Secretary should also have the authority to periodically rebase payments so they remain aligned with costs. As in any payment system, the relative weights that adjust the base payments would need to be recalibrated regularly to reflect changes in practice patterns. The Secretary would need to monitor the impacts of the new PAC PPS carefully to detect inappropriate provider responses and other adverse effects and to make refinements as warranted.

Next, we discuss setting-specific regulations that might be waived at the same time the PAC PPS is implemented to "level the playing field" among providers in different settings. Over the longer term, the Secretary should consider developing a "core" set of conditions of participation for all PAC providers and a limited set of additional requirements for providers that opt to treat patients who require specialized care. Regulations should focus on what is required to treat specific types of patients rather than on requirements geared to specific institutional settings. In addition, as Medicare moves to a unified PAC PPS, the program should consider standard cost sharing when beneficiaries use any PAC service.

Although a common PPS for PAC stays would begin to rationalize Medicare's payments, it would not correct the underlying incentives in FFS payment to increase volume or provide low-quality care if it is less costly to do so. Therefore, along with a PAC PPS, the Secretary should implement a readmission policy to prevent unnecessary hospital readmissions and a value-based purchasing policy to tie payments to outcomes (to protect beneficiaries against stinting) and resource use (to prevent unnecessary service use, including serial PAC stays).

In the longer term, however, Medicare needs to move providers toward greater accountability for spending and quality over an episode of care. Providers would be at financial risk for the entire episode of care, thereby dampening the incentive to provide unnecessary care and encouraging care coordination. A unified PAC PPS should be considered a good transition to broader episode-based payment reforms that encourage care organized around the episodes. Finally, the Commission emphasizes that until a PAC PPS is implemented, CMS and the Congress need to move forward with standing recommendations that would improve the accuracy and equity of payments within each setting.

Medicare drug spending in its broader context

It is becoming increasingly difficult for Medicare to ensure that access to medications remains affordable for beneficiaries while keeping Medicare financially sustainable for taxpayers. Medicare's influence on drug pricing is indirect: Providers, private health plans, and pharmacy benefit managers negotiate drug prices, and these market-based dynamics largely determine Medicare drug costs. At the same time, factors external to Medicare significantly influence the prices the program pays for prescription drugs.

Chapter 4 provides this context for better understanding the Commission's analyses of Medicare's payments for drugs covered by Part B and Part D (which are presented in subsequent chapters). The chapter describes the roles of other government agencies involved in funding basic pharmaceutical research and in the process of regulating the market for drugs in the United States.

Medicare Part B drug and oncology payment policy issues

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments. It also covers certain drugs furnished by suppliers. Medicare pays for most Part B–covered drugs based on the average sales price (ASP) plus a 6 percent add-on. In 2014, Medicare and its beneficiaries paid nearly $21 billion dollars for Part B–covered drugs paid under this method. Chapter 5 explores potential modifications to the way Medicare pays for Part B drugs, including the following:

- ***Restructuring the ASP add-on payment***—There are concerns that the 6 percent add-on to ASP may create incentives for use of higher priced drugs when lower priced alternatives exist, although few studies have looked at this issue. We modeled a policy option that changes part of the 6 percent add-on to a flat fee.
- ***Promoting price competition***—By definition, the largest component of Medicare's payments for Part B drugs is the ASP, not the 6 percent add-on. If policymakers wish to influence Part B drug payments to a larger degree than possible through add-on payments, they could consider Medicare payment policies that create more incentives for price competition among drugs or that put downward pressure on the ASP. We examine three such policy options. The first would limit the amount that Medicare's ASP-based payment for a drug could grow during a specified period of time, which could help insulate the program from substantial price increases. The second would combine billing codes for Part B drugs with similar health effects into consolidated codes, to spur price competition among those drugs. The third policy would restructure Medicare's prior competitive acquisition program (through which physicians could obtain Part B drugs from a Medicare-selected vendor) as a way to create more robust incentives for efficient, high-quality care than currently exist under the ASP payment system.
- ***Reducing dispensing and supplying fees***—Medicare Part B pays substantially higher dispensing fees for inhalation drugs and supplying fees for oral anticancer, oral antiemetic, and immunosuppressive drugs than the rates paid by Medicare Part D plans and Medicaid. The Commission recommends reducing the Part B dispensing and supplying fees to rates similar to those paid by other payers.

Chapter 5 also considers approaches to improve the quality and efficiency of oncology care since more than half of Medicare Part B drug spending is associated with anticancer drugs. In the Commission's June 2015 report to the Congress, we began to examine bundled approaches as a mechanism to make providers sensitive to the cost of the entire episode of care for the oncology patient (e.g., the hospitalization as well as the Part B drugs associated with a cancer care treatment regimen). For this report, we examined four approaches designed to improve the efficiency of oncology care. Two of these approaches are oncology clinical pathways and risk-sharing agreements made between product manufacturers and payers. Two broader approaches take a more holistic view of cancer care by improving care management and coordination. These approaches include oncology medical homes and bundling Part B oncology drugs with non-oncology services, which would hold providers accountable for the total cost of services across an episode of care.

Improving Medicare Part D

In 2015, more than 39 million Medicare beneficiaries received outpatient prescription drug coverage through Part D. A key goal for the Part D program is to ensure that beneficiaries have access to appropriate medications while keeping the program financially sustainable for beneficiaries and taxpayers. The current structure of Part D (which started in 2006) reflects a system of federal protections designed to encourage broad participation of private plan sponsors in a (then) new program. The markets for both Medicare Advantage prescription drug plans and stand-alone prescription drug plans are now firmly established, and it is time to consider whether the program's incentives need to be restructured to better ensure financial sustainability.

The Commission has documented many years of spending increases in Medicare's open-ended reinsurance subsidy paid to plans for their enrollees' catastrophic drug spending. Much of those spending increases have been driven by the growing number of enrollees without the LIS who reach the OOP threshold and by increases in

the average price of drugs (which reflects both growth in drug prices and changes in the mix of drugs used). Going forward, many new biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, even if the drugs have therapeutic competitors. These new, more expensive products will exert strong upward pressure on beneficiary premiums and program costs borne by the taxpayer.

In keeping with the Part D program's market-based approach, in Chapter 6 the Commission recommends improvements intended to prepare Part D for the future. Together, the recommendations make up a package of interrelated steps. One set of changes would give plan sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees. Medicare's overall subsidy of basic Part D benefits would remain unchanged at 74.5 percent, but plan sponsors would receive more of that subsidy through capitated payments rather than open-ended reinsurance payments. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above Part D's OOP threshold to 20 percent. When combined with the Commission's recommendation to provide greater OOP protection for beneficiaries, the insurance risk that plan sponsors bear for catastrophic spending would rise from 15 percent to 80 percent. At the same time, we recommend that plan sponsors be given greater flexibility to use formulary tools to manage benefits. Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, while providing greater insurance protection to all non-LIS enrollees through a real OOP cap. Although some enrollees would incur higher OOP costs than they do today, beneficiaries with the highest levels of drug spending would see reductions in OOP costs. The recommended improvements would also moderately increase financial incentives for enrollees who receive the LIS to use lower cost drugs and biologics.

Under the combined recommendations, Part D's set of risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk adjustment system. Similarly, because plans would have greater flexibility to use management tools, CMS would need to continue monitoring plan operations to ensure appropriate beneficiary access, such as reviewing formularies and pharmacy networks. The agency would also need to ensure that the appeals and grievance procedures under Part D function effectively.

Improving efficiency and preserving access to emergency care in rural areas

Efficiently providing access to inpatient and emergency services is a growing challenge in sparsely populated rural areas. Declining populations can lead to fewer hospital admissions and reductions in efficiency, which can cause financial and staffing difficulties for hospitals. Low volumes may also make it difficult for clinicians at rural hospitals to have enough experience with different types of patients and clinical situations to provide outcomes equal to neighboring facilities with higher volume.

Most rural hospitals are critical access hospitals (CAHs), which receive cost-based payment for Medicare inpatient and outpatient services. The CAH model requires a hospital to maintain acute inpatient services, which is not the best solution for all rural communities. Many small towns do not have a population size sufficient to support efficient, high-quality inpatient services. However, such communities may be reluctant to discontinue providing inpatient services because doing so would mean giving up the supplemental payments that their hospitals receive through the CAH cost-based payment model. Other hospitals are paid under the PPS, and their supplemental payments for being small rural providers are also tied to maintaining inpatient services. Chapter 7 discusses two models that would allow communities in which CAHs and PPS hospitals lack the patient volume needed to support efficient, high-quality inpatient services to voluntarily shift to an outpatient-only model while maintaining some supplemental Medicare funding that would keep these entities financially viable:

- ***24/7 emergency department model***—Under this model, the supplemental payments hospitals currently get for maintaining CAH inpatient services are redirected to support stable access to emergency care. A rural hospital that gives up acute inpatient services and cost-based payment would receive an annual grant or fixed payment from Medicare to help cover the standby costs of 24/7 emergency services. The facility would also be paid Medicare outpatient hospital PPS rates for outpatient services (including emergency care, radiology services, lab services, and telehealth services). The facility would be paid Medicare SNF PPS rates if it chose to use inpatient beds as SNF beds.

- ***Clinic and ambulance model***—Under this model, communities that cannot support a 24/7 emergency department could opt to convert their existing inpatient facilities into a primary care clinic with an affiliated ambulance service. Similar to the federally qualified health center model, Medicare would pay prospective rates for primary care visits and ambulance transports. It would also provide an annual grant or fixed payment to support the capital costs of having a primary care practice, the standby costs of the ambulance service, and uncompensated care costs.

As the Commission has maintained in previous reports, supplemental payments beyond the standard PPS rates should be targeted to isolated rural providers that are essential for access to care. Keeping an emergency department open that is a short distance (e.g., 2 or 10 miles) away from a competitor is not the same public policy priority as keeping an emergency department open that is a larger distance (e.g., 30 or 60 miles) away from all other providers. Therefore, a new program to support stand-alone emergency departments in rural areas should be limited to facilities that are located at some minimum distance in road miles from the nearest hospital (or comparable level of care).

Telehealth services and the Medicare program

Chapter 8 provides the Commission's analysis of telehealth services—a multidimensional set of health care services delivered through a range of online, video, and telephone communication. The chapter is intended to inform policymakers as they consider how telehealth services will fit into the Medicare program in the future. Certain forms of telehealth may have the ability to improve access to and quality of care while reducing costs. Two key issues affecting costs are whether telehealth services are a supplement to or a substitute for existing services and whether the potential for more convenient services would generate new utilization.

Medicare's coverage of telehealth under FFS is limited to certain services and providers and to care provided in rural locations. MA plans must cover telehealth services that are covered under FFS Medicare and can provide telehealth services that are adjunct to delivering services covered under FFS Medicare. In addition, MA plans can cover telehealth services as extra benefits beyond what FFS Medicare covers, if approved by CMS. Medicare also permits providers participating in certain special programs run by the Center for Medicare & Medicaid Innovation to provide telehealth benefits beyond those covered under FFS Medicare.

Medicare telehealth use is low but has grown rapidly in recent years. Medicare beneficiaries using telehealth services tend to be under 65, disabled, and dually eligible for Medicare and Medicaid, and they tend to reside in rural areas. Beneficiaries use telehealth services for psychiatric care and basic medical consultations. Outside of the Medicare program, interest in telehealth services has grown also, but the use of these services is not widespread. Commercial insurers and most state Medicaid programs cover some telehealth services to expand convenience and access to primary care. A growing share of large-scale employers provide telehealth services to create convenience for their employees and reduce their health care spending. The Department of Veterans Affairs has also implemented telehealth programs for its patients.

Evidence is mixed regarding the efficacy of telehealth services to expand access and create convenience, improve quality and outcomes, and reduce costs. Evidence that certain telehealth services improve access and create convenience is much stronger compared with that regarding quality improvement or cost reduction. Telehealth for patients with chronic conditions has shown some positive quality and cost results. More targeted research isolating specific telehealth interventions for specific patient populations is needed.

If policymakers consider expanding telehealth services in the Medicare program, they should differentiate among the financial incentives that exist under Medicare's payment models. In MA, many bundled payment models, and ACOs, the financial risk of providing such services falls to the insurers or providers. By contrast, under traditional FFS Medicare, the additional cost for telehealth services would be borne by the Medicare program, unless such services were substitutes for traditional face-to-face clinical services.

Issues affecting dual-eligible beneficiaries: CMS's financial alignment demonstration and the Medicare Savings Programs

Policymakers have long been concerned that dual-eligible beneficiaries—those who qualify for both Medicare and Medicaid—may receive fragmented or ineffective care because they are generally in poorer health than other Medicare beneficiaries and must obtain care through two distinct programs. These concerns also reflect the high costs of caring for dual-eligible beneficiaries. In

2011, dual eligibles represented about 20 percent of Medicare beneficiaries but accounted for about 35 percent of Medicare spending. For Medicaid, dual eligibles represented about 14 percent of enrollment and about 33 percent of total spending.

Chapter 9 provides a status report on the "financial alignment" demonstration project, an initiative by CMS and states to test new models of care for dual eligibles in 13 states. About 450,000 dual eligibles are currently enrolled in the demonstrations. Most demonstrations are testing a "capitated" model, which uses health plans known as Medicare–Medicaid Plans, or MMPs, to provide all Medicare and Medicaid benefits to dual eligibles. MMPs are required to provide extensive care coordination for their enrollees. MMPs vary in how they provide this care coordination and are still trying to refine and improve their approaches. Six MMPs have left the demonstration since it began, with some citing inadequate payment rates as one factor. CMS recently increased the payment rate for Part A and Part B services, based on research that the existing risk adjustment model tends to underestimate costs for full-benefit dual eligibles.

Enrollment in the MMPs has been lower than some expected. Under the demonstration, states can "passively" (that is, automatically) enroll dual eligibles in MMPs to help ensure that the plans have enough enrollment to justify up-front investments in care coordination activities. However, many beneficiaries have opted out because they are satisfied with their existing care or are uncertain about how the demonstration will affect them. Passive enrollment has helped generate sufficient participation for most MMPs, but its use could be improved in the future.

Chapter 9 also examines the potential cost of three illustrative scenarios for expanding the Medicare Savings Programs (MSPs), which are Medicaid programs that provide assistance with Medicare premiums and cost sharing to certain low-income Medicare beneficiaries. We summarize MSP eligibility rules and assistance and examine the potential effects of expanding MSP eligibility under three illustrative scenarios. The scenarios highlight some of the key issues that policymakers would need to consider as part of an MSP expansion, such as the relationship between the eligibility rules for MSPs and those for the Part D low-income subsidy, how much Medicare cost-sharing assistance MSPs should provide (in particular, whether states can continue to limit their payments for cost sharing), and whether MSPs should be federalized in some fashion. ■

CHAPTER 1

Using competitive pricing to set beneficiary premiums in Medicare

CHAPTER 1

Using competitive pricing to set beneficiary premiums in Medicare

Chapter summary

Last year, the Commission began exploring the statutory and structural differences between the traditional fee-for-service (FFS) Medicare program, Medicare Advantage (MA), and accountable care organizations (ACOs). Medicare has different payment rules for the three payment systems that can create payment inequities and inefficiencies for beneficiaries and taxpayers. One issue that the Commission studied was how beneficiary premiums and the federal contribution for FFS and MA coverage would vary in different parts of the country under different premium designs. Because beneficiaries in ACOs are part of FFS Medicare, only two of Medicare's payment systems—FFS and MA—are relevant to the study of premiums.

With respect to premium design, Medicare could seek to encourage beneficiaries to choose the most efficient option for receiving Medicare benefits while maintaining equity for beneficiaries across markets. The incentives that encourage beneficiaries to choose more efficient models would be aligned with the incentives that encourage providers and MA plans to provide care in a more efficient manner.

This chapter provides additional information on the three illustrative designs that the Commission constructed last year to examine their potential to encourage beneficiaries to use the more efficient system (FFS or MA) in their area. These designs are:

In this chapter

- a nationally set base premium that buys FFS Medicare in every market;
- a nationally set base premium that buys either FFS Medicare or a reference MA plan—whichever costs less—in each market; and
- locally set base premiums that buy either FFS Medicare or a reference MA plan—whichever costs less—in each market.

Under each design, beneficiaries can enroll in either FFS or MA, but what premium they pay to do so differs. In addition, the federal contribution is financially neutral across payment systems—that is, equal for FFS and MA in each market. We used the MA plan with the median bid as the reference plan, but that is a design choice. The determination of beneficiary premiums is important because it is a key element of proposals to adopt a premium support model in Part A and Part B of Medicare. (Medicare already uses a premium support model for its Part D drug benefit.)

Under the second and third designs, beneficiaries who want to use the more costly payment system would pay a higher premium. How much higher that premium would be depends on the difference between average FFS costs and the cost of the reference MA plan in the geographic market area. About 45 percent of beneficiaries live in areas where the difference in costs between FFS and the median MA plan is less than $50 per month, but 34 percent live in areas where the difference is more than $100 per month. Under these designs, most beneficiaries who would see premiums increase by $100 or more are FFS enrollees who live in large metropolitan areas with relatively high FFS spending and elect to remain in FFS. Also, MA enrollees in a number of smaller markets with relatively high MA benchmarks and spending would also see similar increases if they elect to remain in MA. Under the illustrative designs, policymakers could choose to mitigate the increase in beneficiary premiums in a number of ways, such as limiting how much premiums could vary across delivery systems or phasing in any increase over time.

The statutory and structural differences between MA and FFS (and ACOs, although they are not discussed separately from FFS in this chapter), including elements beyond premium design, raise important issues of equity and implementation that will need to be resolved to maximize the value of the Medicare program to its beneficiaries and taxpayers. Medicare needs to determine whether and how to set payment rules that reward the more efficient system of care in a market, how to encourage beneficiaries to receive care through that system, and how to provide the information they need to make informed decisions. ■

Introduction

Under the current Medicare program, there are three payment systems: traditional fee-for-service (FFS), Medicare Advantage (MA), and accountable care organizations (ACOs). Traditional FFS pays providers for individual services (or in some cases for a set of services, such as an inpatient hospital stay), according to the payment rates established by the program. By contrast, under MA, Medicare pays private plans a risk-adjusted per person (or capitated) payment rate to provide the Part A and Part B benefit package to plan enrollees. Medicare introduced ACOs in 2012. Under the ACO system, a group of providers is accountable for the spending and quality of care for a group of beneficiaries attributed to them. The goal of the ACO program is to give groups of FFS providers incentives to reduce Medicare spending and improve quality, similar to the incentives for MA plans. However, only some ACOs currently bear two-sided risk; most share only savings, not losses.

In the traditional FFS Medicare and ACO systems, beneficiaries essentially have no restrictions on choice of provider. In the MA system, the MA plan can restrict provider choice to a specified network of providers; beneficiaries receiving care from providers outside the network pay more. In this respect, MA plans are more like commercial plans commonly available to the population not eligible for Medicare.

Under current law, Medicare's payment rules, quality improvement measures, and incentives are different and inconsistent across the three payment systems. Various approaches to making those rules more consistent have been considered. In its June 2014 report, the Commission focused on setting a common spending benchmark for MA plans and ACOs based on local FFS spending. That report's focus on equal benchmarks as a key element of synchronizing Medicare policy across payment systems represented a refinement of the principle of financial neutrality between FFS and MA.

In its June 2015 report, the Commission found that which payment system had the lowest program spending varied from market to market. The report also explored changing the method for calculating beneficiary premiums, including examples in which the lower of local FFS spending or MA plan bids would determine the reference point for the federal contribution and beneficiary premium. In these examples, individuals who want to receive Medicare benefits through the more expensive system would pay a higher premium, which is a key element of proposals to use a premium support model in Part A and Part B of Medicare. (Medicare already uses a premium support model for its Part D drug benefit.) Finally, we examined the need to make sure that the reporting of patient diagnoses is more consistent across the three systems (Medicare Payment Advisory Commission 2015a).

If the payment rules and incentives for the FFS, MA, and ACO systems were synchronized and geared toward making each more competitive, beneficiaries and the Medicare program would both benefit. First, beneficiaries could choose a system and providers that match their preferences. Second, competition among the systems could expose inefficiencies and drive market share away from the less efficient systems. For example, in markets where per capita FFS spending is high, MA plans could best FFS by offering additional benefits at a lower cost. Similarly, if FFS had lower costs than MA plans in some markets, FFS could take market share from higher cost MA plans (or the plans could exit the market). By having all systems compete, beneficiaries in each market can choose which system provides them the best value. However, some beneficiaries would likely have to pay more than they do now for their existing coverage.

The Commission has for many years supported giving Medicare beneficiaries a choice between traditional FFS and private plans under MA. The original goal for private plans in Medicare was to provide a mechanism for introducing innovation into the program while constraining Medicare spending. Private plans have greater flexibility to develop innovative approaches to care and can more readily use care management tools and techniques than traditional FFS. This flexibility enables private plans to reduce spending and improve the quality of health care services. In turn, Medicare beneficiaries' ability to choose between traditional FFS and MA plans could lower program spending if Medicare payments to plans were reduced to capture some of those gains. However, as the Medicare program adopted the goal of making MA plans available to all beneficiaries—even in markets where plans are not able to effectively compete with FFS based on cost—plan payments were increased above FFS levels, not reduced. Higher payments resulted in higher MA enrollment and higher costs to the program.

MA benchmarks are now transitioning to levels that are closer to FFS, as required by the Patient Protection and Affordable Care Act of 2010, and plans have reduced

Other factors besides premiums that affect beneficiary choice

The illustrative examples in this chapter show how beneficiary premiums will vary depending on the choice that a beneficiary makes between fee-for-service (FFS) Medicare and among Medicare Advantage (MA) plans. However, the premium amount is not the sole factor that a beneficiary would consider in making a choice. Additional financial considerations include the expected level of cost sharing for services, the presence of a cap on out-of-pocket spending, and the value a beneficiary expects to derive from any additional benefits a plan might offer. Other considerations include factors such as the extensiveness of the network of providers available through a plan, whether one's current providers are in a plan's network, and ease of access to a plan's providers. Sometimes such factors affect the cost of a plan; for example, a preferred provider organization is likely to be more expensive in a given market than an HMO with a narrow network.

The factors to consider can also vary among categories of Medicare beneficiaries. For example, a person with disabilities who has fashioned his or her own "network" of providers in FFS may be reluctant to enroll in a plan that does not have contracts with all of the person's providers. The decision-making process can also be especially challenging for beneficiaries with mental or cognitive impairments.

Plan quality is also an important factor, and in the current MA system, differences in quality are reflected in higher payments to plans through the quality bonus program, which can translate into more generous benefits for enrollees. The extra benefits become a financial incentive to enroll in higher quality plans. Thus, from the point of view of a beneficiary choosing among plans, there are both financial and nonfinancial aspects to differences in quality among plans. In addition, all plans are expected to meet a minimum level of quality performance based on their star ratings; plans that do not can be terminated from the program. Having appropriate quality standards is especially important to ensure that the lowest bidding plans that are most attractive to low-income beneficiaries do not have lower bids because of lower quality.

Beneficiaries need certain tools or resources to be able to make informed decisions about their health care choices, but the tools that are now available are lacking

(continued next page)

their bids relative to FFS. But on average, taxpayers and beneficiaries continue to subsidize the MA program through higher taxes and higher Part B premiums. In its March 2016 report to the Congress, the Commission estimated that MA plans currently cost the Medicare program, on average, about 102 percent of FFS program costs. (Substantial variation exists in the relative costliness of MA and FFS across local markets. Payments to MA plans are also higher than that figure suggests because plans report more diagnoses for their enrollees, on average, compared with FFS enrollees.)

In this chapter, we continue to examine the challenges of using various premium designs to give beneficiaries an incentive to use the more efficient delivery system. We see this approach as one step toward synchronizing Medicare's payment rules across the three different systems. On the issue of beneficiary premiums, we have updated figures on the three examples that we outlined in our June 2015 report and provide additional information about markets where FFS or MA enrollees would face large premium increases. Given the potential magnitude of the increases in many areas, we also discuss ways that policymakers could mitigate their impact on beneficiaries.

Alternative methods of determining beneficiary premiums

Under the current system, beneficiaries choose between FFS and MA plans to receive Medicare benefits. The two systems can look very different in terms of premiums, benefit design, and choice of providers. The Commission maintains that the Medicare program should pay the same on behalf of beneficiaries, on average, regardless of which choice the beneficiaries make, to encourage beneficiaries to choose the system that they perceive as affording them

Other factors besides premiums that affect beneficiary choice (cont.)

in some respects. Currently, beneficiaries are able to compare MA plans using the Plan Finder tools at www.medicare.gov and can consult with State Health Insurance Assistance Programs (SHIPs). In an earlier report, the Commission examined ways in which the Plan Finder could be improved (Medicare Payment Advisory Commission 2015b), and, in connection with informing beneficiaries about low-income assistance programs, the Commission recommended that the Secretary increase SHIP funding for outreach to low-income Medicare beneficiaries (Medicare Payment Advisory Commission 2008).

In the illustrative examples discussed in this chapter, plan differences are expressed as premium differences that can be clearly communicated to beneficiaries. In the current MA environment, plans offer extra benefits when they have low bids in relation to current benchmarks. A premium support model could accommodate the offering of additional benefits in the interest of promoting innovation and offering greater choice to beneficiaries. Using the funds that, in our examples, are used to provide cash rebates to beneficiaries, plans could instead finance extra benefits. Plans could also offer extra benefits as riders that beneficiaries would purchase. If plans were allowed to offer extra benefits, then, to facilitate comparisons among plans, there could be standardized sets of benefit packages or there could be an actuarial standard whereby beneficiaries can more readily compare the value of the extra benefits in one plan versus another.

A difficult issue is how to compare quality between the FFS sector in an area and MA plans—a topic the Commission addressed in its March 2010 report to the Congress (Medicare Payment Advisory Commission 2010) and again in the June 2014 report to the Congress (Medicare Payment Advisory Commission 2014). Beneficiaries would have to be able to compare the quality of FFS with the quality of MA plans, but we are not yet at the point where such comparisons can be made. Once such comparisons can be made, a quality bonus program could be incorporated in a premium support model by giving beneficiaries a financial incentive to choose a higher quality plan in the form of reduced premiums for the higher quality plans. Such an approach allows the incentive to apply to either MA plans or FFS, depending on which option has higher quality. ■

the highest value in terms of cost and quality. The program should not subsidize one choice more than another.

To examine how different approaches to calculating beneficiary premiums could influence a beneficiary's choice between FFS and MA, we considered different ways to determine beneficiary premiums using FFS spending and MA plan bids for 2016.[1] In our analysis, we defined a market area, calculated each market's FFS spending, and recalculated each market's MA plan bids from service-area bids. For simplicity, all FFS spending and MA plan bids in our analysis were expressed as per beneficiary per month amounts and standardized for a beneficiary of average health status. Moreover, we excluded the quality bonus payments that MA plans can now receive. Quality is a complex issue and is only one of the factors that beneficiaries weigh when comparing FFS and MA (see text box on factors that affect beneficiary choice).

Definition of market areas

For our analysis, we wanted to define market areas that best matched insurance markets served by private plans. Using market areas that are too small can result in many areas with a small number of FFS beneficiaries, and there can be instances of adjacent areas with very different levels of FFS spending. However, if a market area is too large, the cost of serving beneficiaries can vary widely within the area. Accordingly, we adopted a definition of market areas that is larger than the county definition currently used in the MA program.[2]

- In urban areas, we use collections of counties located in the same state and the same core-based statistical area (CBSA), which is a collective term for both metropolitan areas (50,000 or more in population) and micropolitan areas (10,000 to 49,999 in population). Each area consists of one or more counties and includes the counties containing the core urban areas

TABLE 1–1 **Distribution of market areas by average monthly FFS spending per beneficiary, 2016**

Average monthly FFS spending per beneficiary	Number of market areas	Share of beneficiaries
$563–$600	6	0.5%
$600–$700	242	13.3
$700–$800	639	44.8
$800–$900	276	32.9
$900–$1,234	68	8.5
Overall average ($784)	1,231	100

Note: FFS (fee-for-service). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending is per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia.

Source: MedPAC analysis of Medicare Advantage (MA) plan bids for 2016 and MA enrollment data for January 2016.

and any adjacent counties that have a high degree of social and economic integration with the urban core.

- Among counties outside CBSAs, we use health service areas (HSAs) as defined by the National Center for Health Statistics. HSAs consist of collections of counties where most of the short-term hospital care received by beneficiaries living in those counties occurs in hospitals in the same collection of counties.

The data used in our analysis included 1,231 market areas in the 50 states and the District of Columbia.

Average FFS spending per beneficiary in market areas

To calculate a beneficiary premium for FFS Medicare in a given market area, we determined the equivalent of an FFS "bid" based on the area's FFS spending. To calculate FFS spending that is comparable with MA plan bids for 2016, we used the projected average monthly FFS spending per beneficiary for 2016 and excluded hospice, direct graduate medical education, and indirect medical education payments.[3] We standardized the calculation for a beneficiary of average health status. We calculated market-area average spending by using county-level FFS spending and weighting those figures by the area's number of FFS beneficiaries as of January 2016.

Table 1-1 shows the distribution of market areas by average monthly FFS spending per beneficiary for 2016, ranging from $563 to $1,234. About 15 percent of beneficiaries lived in areas with FFS spending below $700 a month; about 45 percent in areas with spending between $700 and $800 a month; and about 40 percent of beneficiaries in areas with FFS spending above $800. Across the market areas in our analysis, the average monthly FFS spending was $784.

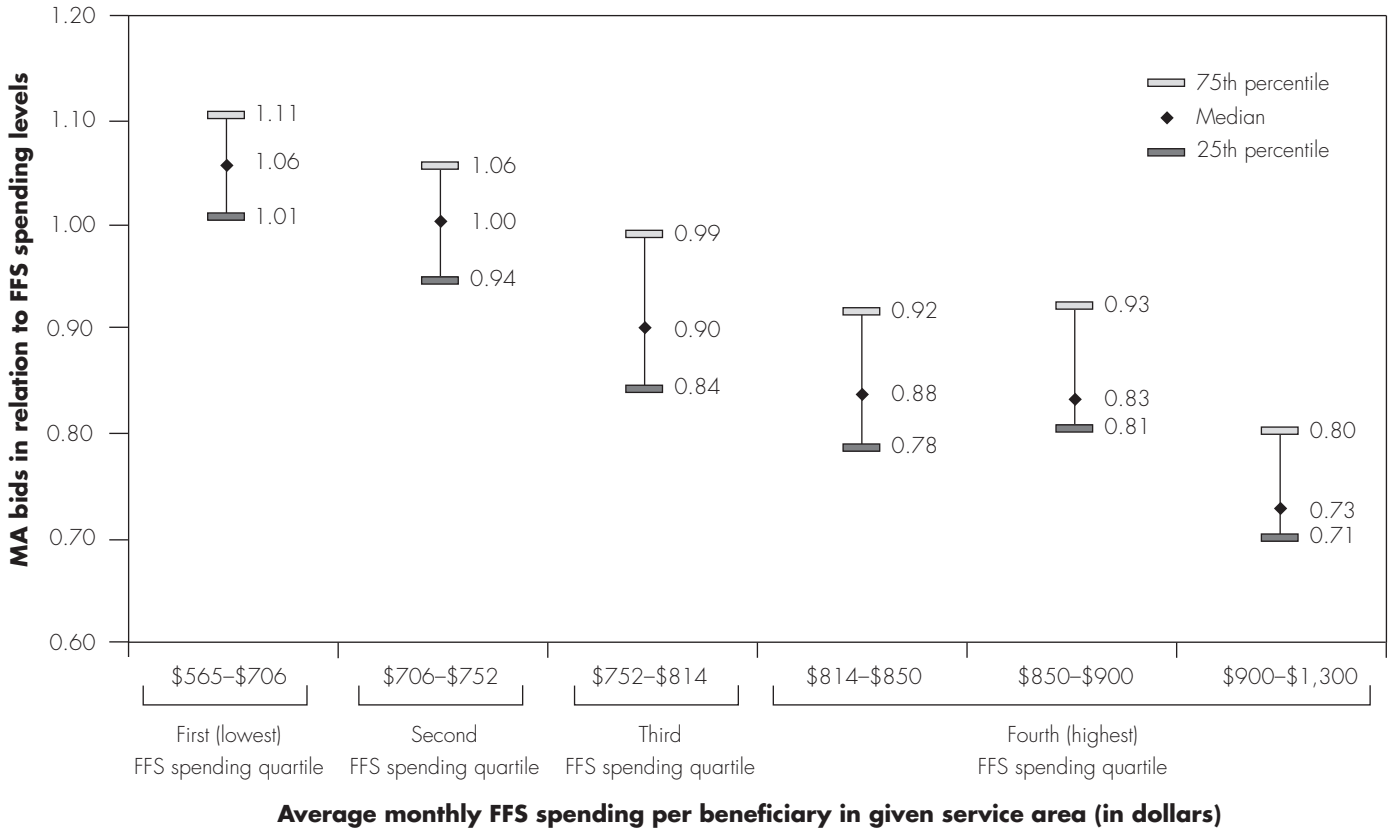
These spending figures are based on the cost-sharing structure of the current FFS benefit, which differs from MA in certain respects. For example, MA plans have an annual cap on beneficiary out-of-pocket spending while the FFS benefit does not. We used the existing FFS benefit design for this analysis, but the Commission has previously recommended making several changes to it, such as adding an annual cap on beneficiary out-of-pocket spending (Medicare Payment Advisory Commission 2012).

Adjustments to MA plan bids for market areas

Under current law, MA plans are required to cover all Medicare Part A and Part B benefits except hospice.[4] For each county, CMS sets the MA benchmark. This local MA benchmark represents a bidding target and is set using statutory formulas and adjusted for the plan's quality ranking. Under current law, MA benchmarks are increased relative to local FFS spending in low-spending areas and decreased in high-spending areas, so there is less variation in MA benchmarks than in FFS spending across areas. Furthermore, current MA plan

FIGURE 1–1

Medicare Advantage bids in relation to FFS spending levels, 2016



Note: FFS (fee-for-service), MA (Medicare Advantage). The figure excludes employer group plans, special needs plans, and plans in the territories.

Source: MedPAC analysis of MA bid and FFS expenditure data from CMS.

bids are highly correlated with MA benchmarks, and as a result, there is less variation in MA plan bids than in FFS spending across areas (see Figure 1-1, which shows how plan bids and FFS spending compare across the four spending quartiles that are currently used to calculate MA benchmarks).

Given the local MA benchmark, each MA plan selects counties that make up its service area and submits a bid for the service area.[5] The plan's bid reflects its costs to provide the Part A and Part B benefit package for a beneficiary of average health status and includes plan administrative cost and profit.[6] In our analysis, MA plan bids are monthly amounts for the Part A and Part B benefit portion only and are standardized for a beneficiary of average health status. Because the current MA plan bids are for plan-defined service areas, we made the following assumptions in our analysis to convert plan bids at the service-area level to plan bids at the market-area level:

- We assumed that plan bids were constant over the entire plan-defined service areas, where service areas can be larger or smaller than market areas.
- We assumed that if a plan was offered to at least half of the market area's Medicare beneficiaries, the plan would serve the entire market area with its current bid. If the plan was not offered to at least half of the area's beneficiaries, we assumed that the plan would not bid to serve that market area.
- We excluded bids for plans with little or no projected enrollment in the market area—which we defined as fewer than 100 projected enrollees—because those bids would not necessarily reflect costs for those areas.

TABLE 1–2 **Distribution of market areas by number of eligible MA plan bids in market area, 2016**

Number of eligible plan bids in market area	Number of market areas	Share of beneficiaries	Average FFS spending per beneficiary	Average MA penetration rate (in percent)
Zero*	208	2.4%	$799	8.2%
1 to 2	278	6.2	759	17.3
3 to 5	372	14.8	753	21.0
6 to 10	211	20.0	760	30.1
11 to 20	126	30.7	774	34.4
More than 20	36	26.0	834	42.0

Note: MA (Medicare Advantage), FFS (fee-for-service). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016.

*Market areas have no eligible plan bids if either (1) no MA plans are available in those areas or (2) we excluded all of the available MA plans based on the criteria we used for our analysis. The average penetration rate of 8.2 percent in these areas reflects enrollment in MA plans that we excluded from our analysis, such as employer group plans and special needs plans.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

- We excluded plans that were not open to all of a service area's beneficiaries, such as employer group plans and special needs plans.

The number of MA plan bids that met those criteria varied across market areas in our analysis (Table 1-2). About 2 percent of beneficiaries lived in a market area without an eligible MA plan, and another 6 percent had only one or two MA plans available to them. However, more than 90 percent of beneficiaries had at least 3 MA plans available in their market areas, and more than 25 percent had more than 20 MA plans available.

Illustrative examples for calculating beneficiary premiums

Under current law, there is no premium for Part A for beneficiaries entitled to Medicare who receive Social Security or Railroad Retirement Board benefits or are entitled to Medicare because they have end-stage renal disease.[7] All beneficiaries who elect Part B pay a monthly base premium for that coverage, set at about 25 percent of Part B national average benefit costs per beneficiary; conversely, the government's subsidy equals 75 percent of the Part B costs. The base Part B premium is set nationally and does not vary across areas.[8]

Beneficiaries in the traditional FFS program pay the same Part B premium in any area of the country. In contrast, MA enrollees' premiums (Part B and MA plan premiums) vary, depending on how plan bids compare with the local MA benchmark. If plan bids are higher than the benchmark, then MA enrollees pay the Part B premium and the difference between the bid and the benchmark as an additional premium. If plan bids are lower than the benchmark, then beneficiaries pay the Part B premium and receive the difference between the bid and the benchmark in extra benefits and reduced premiums, including in a few cases a reduced Part B premium. (Most MA plans tend to offer extra benefits rather than premium reductions.)

Applying the current-law method for calculating the base Part B premium to our data—25 percent of Part B spending per beneficiary—results in a base premium of $106 per month. (That figure equals 0.25 × $424, where $424 equals the Part B share of average FFS spending of $784.) This amount represents about 13.5 percent of average combined Part A and Part B FFS spending per beneficiary—and an implied government subsidy rate of 86.5 percent of combined Part A and Part B spending.[9] Our calculated base premium of $106 per month is lower than the actual Part B premium for 2016 of $121.80 per month, but this difference is to be expected given the adjustments we made in calculating FFS spending in our data.[10]

We examined other ways to calculate beneficiary premiums. For illustrative purposes, we considered three

TABLE 1–3 **Three illustrative examples for calculating beneficiary premiums**

Illustrative example	Base premium	What base premium pays for
Example 1 Beneficiary pays *national* base premium for FFS in every market	13.5% of national FFS	FFS Medicare in every market
Example 2 Beneficiary pays *national* base premium for lower of local FFS or reference MA bid in each market	13.5% of national FFS	FFS Medicare or reference MA plan, whichever costs less
Example 3 Beneficiary pays *local* base premium for lower of local FFS or reference MA bid in each market	13.5% of either local FFS or reference MA bid, whichever costs less	FFS Medicare or reference MA plan, whichever costs less

Note: FFS (fee-for-service), MA (Medicare Advantage). In our three examples, we assume that the base premium is set to 13.5 percent of the Medicare Part A and Part B benefit cost, which represents 25 percent of the overall Part B share of the benefit cost. The government subsidy is then 86.5 percent of the benefit cost.

approaches that differed in the base premium charged and in the Medicare option that the beneficiary can buy for the base premium (Table 1-3). Under all three examples, beneficiaries may choose an option other than the one the base premium pays for. In that case, individual beneficiaries' total premium equals the base premium plus the difference between the option they choose and the option the base premium pays for. Two of the following designs have a base premium set as a share of national average FFS spending and one has a base premium set as a share of either local average FFS spending or the bid for the reference MA plan, whichever is lower:

- ***Example 1—***The base premium is set at 13.5 percent of the *national* average FFS spending. Beneficiaries would pay this amount for FFS Medicare in every market. Under this approach, the premium for beneficiaries choosing an MA plan in their market area equals the base premium plus the difference between the plan bid and their market area's average FFS spending.
- ***Example 2—***The base premium is set at 13.5 percent of the *national* average FFS spending. Beneficiaries would pay this amount for either FFS Medicare or the reference MA plan—whichever costs less—in each market. (We used the MA plan with the median bid as the reference plan, but that is a design choice.) Under this approach, if FFS spending is lower than the MA bid, the base premium pays for FFS Medicare. But if FFS is higher than MA, the base premium pays for MA, meaning that the Medicare option the base premium pays for would vary across market areas, depending on how FFS spending compares with MA.
- ***Example 3—***The base premium is set at 13.5 percent of either the *local* average FFS spending or the bid for the reference MA plan—whichever costs less. Beneficiaries would pay this amount for the less expensive option in each market.[11] (As above, we used the MA plan with the median bid as the reference plan.) Under this approach, in markets where either the local FFS spending or the bid for the reference MA plan is lower than the national average FFS spending, the base premium would be lower than the nationally set base premium. In markets where both local FFS spending and the bid for the reference MA plan are higher than the national average FFS spending, the opposite would be true, and the base premium would be higher than the nationally set base premium.

These examples differ from current law in several respects. MA plans now bid against benchmarks that are not set competitively but instead are set administratively through statutory provisions specifying benchmark levels. Plans that bid below the benchmark receive a portion of the difference as a rebate that they can use to provide extra benefits. Under these examples, the administratively set benchmarks would be eliminated, and the competition between FFS spending and MA plan bids would determine the reference point for the federal contribution and beneficiary premium. The current system of rebates and

An alternative approach: Greater use of competitive pricing within the MA program

One of the objectives of a premium support model is to achieve savings for the Medicare program. Premium support achieves savings by promoting competition—between the fee-for-service (FFS) sector and Medicare Advantage (MA) plans, and among MA plans—and by using incentives that are aligned across beneficiaries, providers, and plans to promote efficiency. Under our three illustrative examples, beneficiary incentives are clearly expressed as differential premiums that beneficiaries face based on the choices they make. The differential premiums reflect the differences in program costs among the available choices. As one of the choices under this approach, FFS is essentially a bidding plan that competes with MA plans.

Some proposals that seek to achieve savings for the Medicare program aim to do so through greater competition that is limited to the MA sector. The proposals rely on the concept that a system in which benchmarks are determined through plan competition, rather than set administratively, achieves more appropriate prices in MA and can better generate program savings. Such a proposal was put forth by the Bipartisan Policy Center (BPC) in 2013 (Bipartisan Policy Center 2013), and a similar approach appeared in President Obama's 2017 budget proposal. Both proposals would use competition among MA plans to determine an area benchmark for MA plans (set at the average bid or at a specific percentile level) and would use that benchmark as the basis for MA payment in areas where program savings are achieved relative to current law. Each proposal (initially, in the case of the BPC) calls for plans to bid on a package that is an enhancement of the Medicare basic Part A and Part B package, in recognition of the current level of extra benefits available through MA plans. In the BPC proposal, the additional benefits are a standardized set of benefits; in the President's budget proposal, the actuarial value of the additional benefits would be 5 percent of the area benchmark—which is standardized in the sense that it facilitates plan comparisons when beneficiaries are evaluating the value of one plan compared with another.

In both proposals, the government contribution toward the plan costs would be at the competitively set benchmark level. Plans that bid below the benchmark would provide, as they currently do, extra benefits to beneficiaries (in the President's proposal, equal to the full difference between the bid and benchmark), or (in the BPC proposal) plans would return the full difference to beneficiaries in the form of a cash rebate. In both proposals, if savings are not expected in a given area under the new benchmark approach, the area benchmark would continue to be the administratively set benchmark as determined under current law—which is one aspect of the proposals that is intended to ensure savings if the alternative benchmark is used. In either proposal, the alternative, competitively set benchmark would be lower than current benchmarks.

Currently, 96 percent of nonemployer, non–special needs plans are bidding at a level below the statutory benchmark. As illustrated in Table 1-4, p. 14, there can be a wide range of bids in a market. With a benchmark set at the weighted average of MA bids, or at a set

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extra benefits would also be eliminated, and plans (or FFS, in the second and third examples) that cost less than the benchmark would instead use any savings to reduce beneficiaries' premiums.[12] These examples would thus move Medicare from a model in which MA plans compete (with FFS and with each other) largely by offering extra benefits to a model in which MA plans and FFS compete more on price, as reflected in the beneficiary premium.

In addition, these examples all include FFS costs as one of the options that determine beneficiary premiums. In that sense, expected FFS costs serve as a "bid" analogous to those submitted by MA plans. We include both FFS and MA plans in the calculation of premiums to promote equity so that the relative costs of all forms of Medicare coverage are taken into account. Furthermore, the presence of the FFS program in these examples, particularly the second and third examples, could serve as a reference

An alternative approach: Greater use of competitive pricing within the MA program (cont.)

percentile of bids, some MA bids would be below the newly determined benchmark and others would be above it. Thus, by design, in any market in which the alternative benchmark is used, we would expect to see program savings under static assumptions of current bid and MA enrollment levels. However, the large majority of current MA enrollees are in plans that do not charge an additional premium beyond the Part B premium, and many enrollees are in plans with generous extra benefits. Thus, in an environment where some plans will be charging a plan premium, we would expect movement of beneficiaries among MA plans and shifts between MA and FFS.

These proposals would not affect FFS costs or premiums, unlike the illustrative examples presented in this chapter, and they also depart from the principle of financial neutrality between FFS and MA that the Commission has supported. However, this system would reduce payments to plans in areas where the benchmarking option based on MA bids applied (because it would be expected to create savings compared with the current benchmarking approach) and could result in lower supplemental benefits for MA enrollees—for example, in areas such as Miami where current extra benefits have a much higher value than the level of extra benefits contemplated in either proposal. In some markets, the value of the extra benefits in the benchmarking option based on MA bids could be close to, or even be greater than, the current level of extra benefits offered in MA. Because the benchmarking option based on MA bids is most likely to take effect in areas that are already paying plans less than FFS Medicare, it could lead to some loss of MA enrollment in the very places where the MA program is producing savings for Medicare. In the Miami market, for example, average per capita spending is $1,102 in 2016, while the median MA bid is $744. Under the existing MA payment system, a plan that submits a bid of $800 would receive a rebate that it could use to offer extra benefits; under an alternate payment system where the MA benchmark is based on the median bid, that plan would now have to charge an additional premium. As a result, some plans could be less desirable for beneficiaries than FFS Medicare since there would be no extra cost associated with choosing the FFS option.

In short, the benchmarking system based on MA bids would save program spending in some markets, given that we assume no changes in bidding and enrollment patterns. It would reduce spending by reducing payments to plans and reducing payments to fund supplemental benefits for MA enrollees. In Miami, for example, plans would look less attractive than they do now, and some plan members might disenroll to enter FFS Medicare, which is far more costly in terms of program expenditures. Therefore, in the long run, savings from benchmarking based on MA bids are not assured. Given this possibility, one strategy to prevent migration from MA to FFS would be to impose an additional premium in FFS in the markets where MA is less costly and the benchmarking system based on MA bids takes effect. Even though FFS would not be treated as a bidding plan in these markets, as in the illustrative examples discussed in this chapter, a policy decision is whether there should be an additional charge for beneficiaries choosing FFS in these markets to make FFS a relatively less attractive option. ■

point in negotiations between plans and providers and help to keep payment rates close to FFS levels. However, the inclusion of FFS is a design choice. Some proposals would expand the use of competitive pricing, but only within the MA program (see text box on an alternative approach).

To illustrate what premiums would look like in dollar terms under these examples, we applied them to three market areas—Portland, OR; Columbus, OH; and Miami, FL. As shown in Table 1-4 (p. 14), the three areas have different levels of per beneficiary FFS spending, ranging from Portland's $652 to Miami's $1,102; Columbus's $744 is about 5 percent below the national average of $784. Each area has many MA plans and high MA penetration (i.e., at least 42 percent of Medicare beneficiaries in each area are in MA plans). In all three examples, we used the median MA plan bid as the reference MA plan bid, which is also a design choice. (For example, the reference

TABLE 1–4 **Per beneficiary FFS spending and plan bids in selected market areas, 2016**

	Market area		
	Portland, OR	**Columbus, OH**	**Miami, FL**
Number of Medicare beneficiaries (in thousands)	292	294	429
Average monthly FFS spending	**$652**	**$744**	**$1,102**
Number of MA plan bids	23	26	25
MA penetration rate	58%	42%	64%
Range of MA plan bids			
Lowest bid	$571	$605	$630
25th percentile bid	701	699	671
Median bid	**712**	**704**	**744**
75th percentile bid	744	786	780
Highest bid	819	926	922
Number of counties in area	5	10	1

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

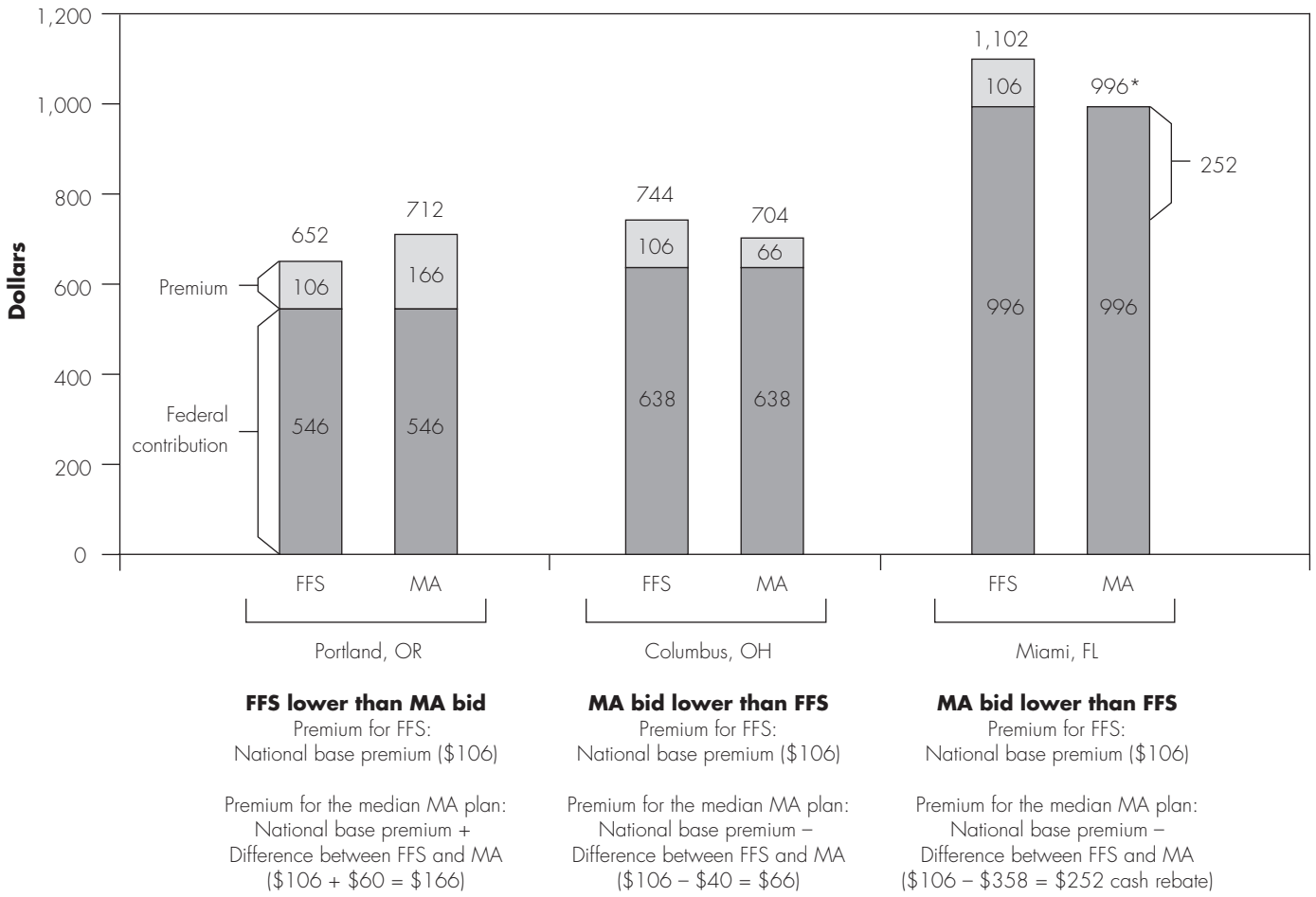
bid could be the lowest bid, the second lowest bid, a weighted average bid, etc.) The median plan bid in these three markets varies less than the FFS spending in those markets, in part because the current-law MA benchmarks in 2016 for those markets also vary less than the average FFS spending.

Using the data from these three markets, Figure 1-2 illustrates the first example for calculating beneficiary premiums. The base premium in all three market areas is $106, or 13.5 percent of the national average FFS spending ($784). In Portland, the reference MA bid is higher than local average FFS spending, and the difference between MA and FFS spending equals $60 ($712 minus $652). Therefore, if the beneficiary chooses MA, the premium for the median plan equals the base premium ($106) plus the difference ($60), or $166. (Premiums for MA plans whose bids are lower than $712 would be less than $166; premiums for MA plans whose bids are higher than $712 would be more than $166.) In contrast, in Columbus and Miami, the median MA plan bid is lower than local average FFS spending by $40 and $358, respectively. Therefore, the premium in Columbus for the median MA plan, which equals the base premium plus the difference, is $66 ($106 minus $40) and in Miami is –$252 ($106 minus $358). For simplicity, a negative premium can be thought of as a reduction of the entire premium plus a cash payment. In this example, we assumed that the beneficiary receives the entire difference between FFS and MA. However, how to share this difference between the beneficiary and the program is a policy decision. For example, under current rules, if MA plans bid below the benchmark, the program retains a share of the difference and the balance is commonly returned to the beneficiary in the form of extra benefits.

In the second example, the base premium of $106 no longer pays for FFS Medicare in every market (Figure 1-3, p. 16). Instead, it pays for either FFS or MA—whichever costs less—in each market. Therefore, in Portland, where FFS is lower than MA, the base premium pays for FFS, whereas in Columbus and Miami, where MA is lower than FFS, the base premium pays for MA. The difference between FFS and MA is added to the beneficiary premium of the higher cost option in each market. In other words, while the beneficiary pays the base premium of $106 for FFS in Portland and for MA in Columbus and Miami,

FIGURE 1–2

Example 1: Illustration of beneficiary paying nationally set base premium for FFS in every market



Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016. MA figures are for the plan with the median bid.
*In Miami, the MA plan would receive $744 and the beneficiary would receive a cash rebate of $252.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

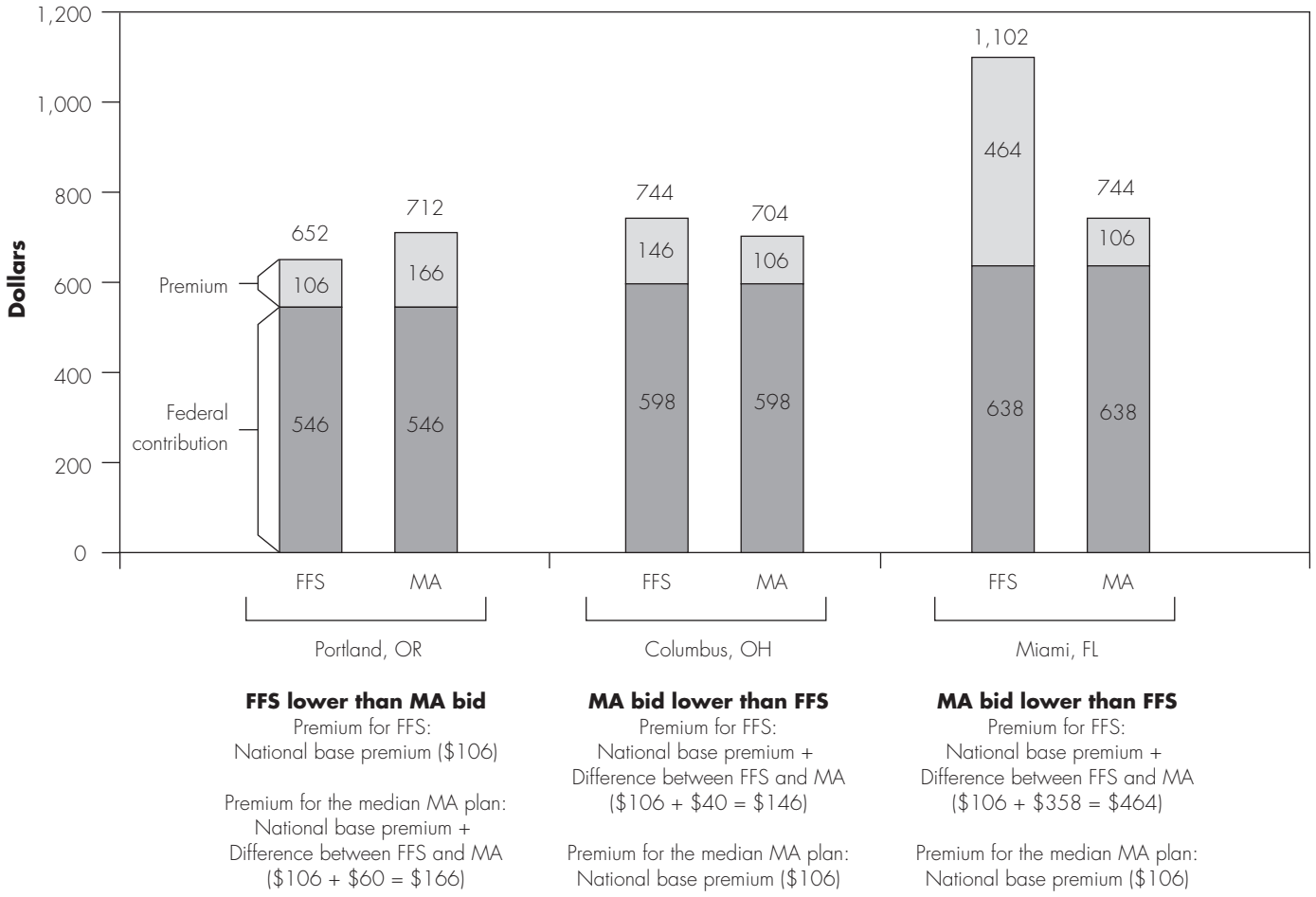
beneficiaries pay a higher premium if they choose MA in Portland and FFS in Columbus and Miami.

Finally, under the third example, the base premium is set to 13.5 percent of either local FFS spending or the bid for the reference MA plan, whichever is lower: $88 in Portland, $95 in Columbus, and $100 in Miami (Figure 1-4, p. 17). These changes in the base premium, compared with those under the second example, reflect the beneficiary sharing in the geographic variation in the cost of the less expensive option across market areas. As in the second example, the base premium pays for either FFS or MA—whichever costs less—in each area. In other words, beneficiaries pay the base premium for FFS in Portland and for MA in Columbus and Miami, but they pay a higher premium if they choose MA in Portland or FFS in Columbus and Miami.

The first and second examples for calculating beneficiary premiums highlight how the difference in the average monthly cost of the Medicare benefit under FFS and MA within each market area can be shared between the program and the beneficiary. Differences in the median MA bid relative to FFS in each market are summarized in

FIGURE 1–3

Example 2: Illustration of beneficiary paying nationally set base premium for either FFS or MA, whichever costs less, in each market



Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016. MA figures are for the plan with the median bid.

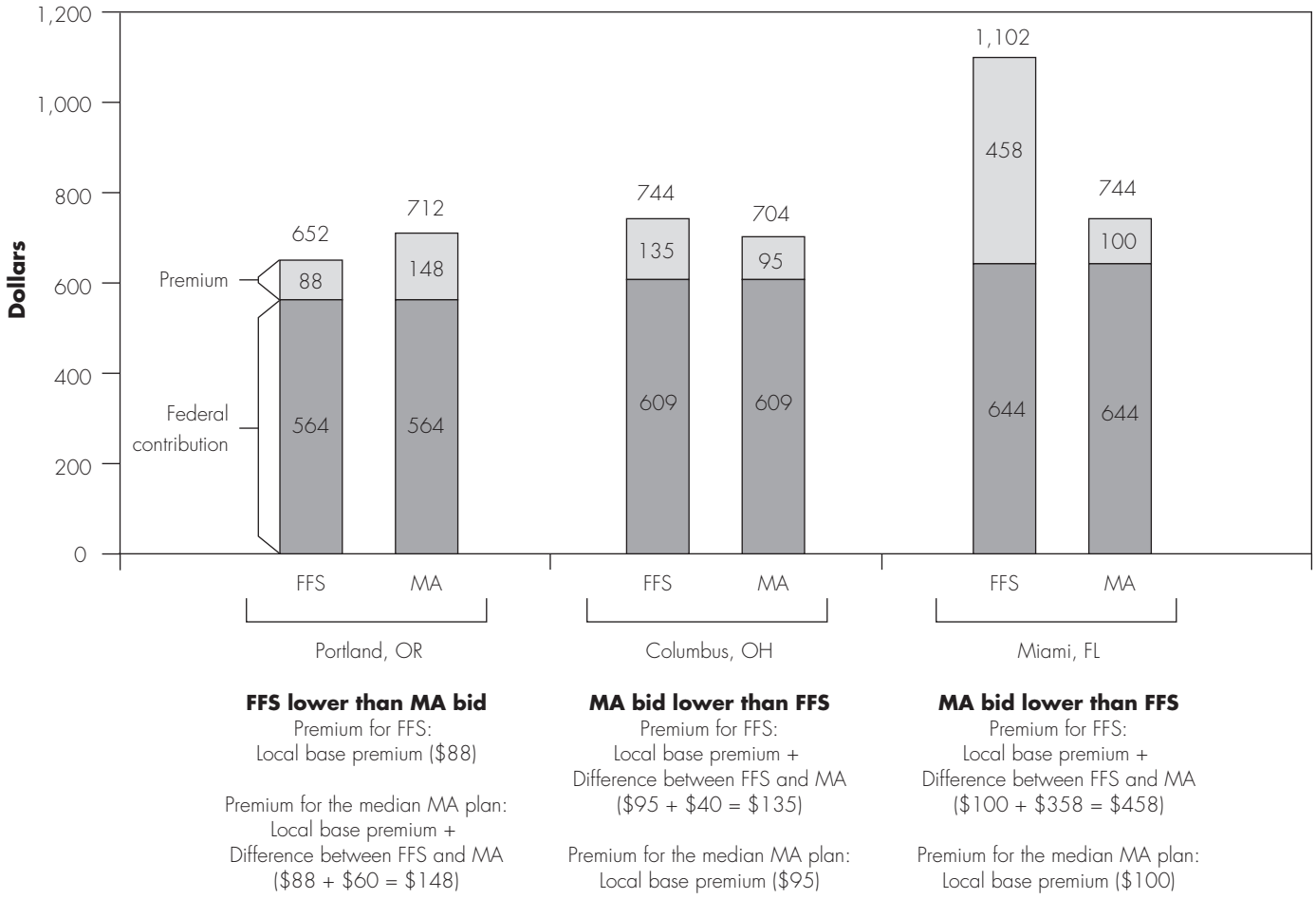
Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

Table 1-5 (p. 18): $60 in Portland; –$40 in Columbus; and –$358 in Miami. Under the first example, the beneficiary who chooses MA pays the entire difference if MA costs more than FFS, and gets the entire difference if MA costs less than FFS. In contrast, in the second and third examples, the beneficiary who chooses the higher cost option pays the entire difference regardless of which option—either FFS or MA—is higher cost.

In all three illustrative examples, the difference between the average FFS spending and the median MA bid is a key variable in calculating beneficiary premiums. Especially in the second and third examples, this difference is the additional premium that beneficiaries would pay if they were to choose the higher cost option between FFS and the reference MA plan. Figure 1-5 (p. 19) summarizes the distribution of the differences between FFS and MA for all market areas. About 45 percent of beneficiaries are in market areas where the difference is less than $50. About 3 percent of beneficiaries are in market areas where the median MA bid is higher than FFS spending by $100 or more. In contrast, about 31 percent of beneficiaries are in market areas where FFS spending is higher than the median MA bid by $100 or more. Figure 1-5 also shows

FIGURE 1–4

Example 3: Illustration of beneficiary paying locally set base premium for either FFS or MA, whichever costs less, in each market



Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016. MA figures are for the plan with the median bid.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

that, even among market areas where FFS is higher by a large amount, Miami remains an outlier, with a difference of $358. In all other markets, the difference between FFS and MA is less than $300.

Markets that would see large changes in premiums

In addition to the overall distribution shown above, we highlight some of the market areas where the difference between FFS spending and the median MA bid is $100 or more in either direction, under our static assumptions about plan bidding and beneficiary behavior. These areas are ones where enrollees in the MA plan with the median bid would have to pay a significantly higher premium to remain in their plan, or FFS enrollees would have to pay a significantly higher premium to remain in FFS.

There are 51 market areas where the median MA bid is higher than FFS spending by $100 or more. About 1.3 million beneficiaries (3 percent of all Medicare beneficiaries) live in these areas, and about 450,000 of them are in MA plans. These areas generally have relatively few beneficiaries, low FFS spending, and MA benchmarks that typically equal 115 percent of FFS

TABLE 1–5 **Summary of illustrative examples for calculating beneficiary premiums**

	Market area		
	Portland, OR	**Columbus, OH**	**Miami, FL**
Median MA plan bid	$712	$704	$744
Average monthly FFS spending	652	744	1,102
Difference between MA and FFS	60	–40	–358
Example 1: Beneficiary pays nationally set base premium for FFS Medicare in every market			
FFS premium	106	106	106
MA premium for median plan	166	66	–252
Federal contribution	546	638	996
Example 2: Beneficiary pays nationally set base premium for either FFS Medicare or reference MA plan, whichever costs less, in each market			
FFS premium	106	146	464
MA premium for median plan	166	106	106
Federal contribution	546	598	638
Example 3: Beneficiary pays locally set base premium for either FFS Medicare or reference MA plan, whichever costs less, in each market			
FFS premium	88	135	458
MA premium for median plan	148	95	100
Federal contribution	564	609	644

Note: MA (Medicare Advantage), FFS (fee-for-service). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries and MA enrollees are as of January 2016. In our examples, we use the median MA plan bid as the reference MA plan bid. "Difference" is between the median MA plan bid and average FFS spending. For simplicity, a negative premium can be thought of as a reduction of the entire premium plus a cash payment. These figures are based on current MA bids; with different bidding and enrollment patterns, the differences between the examples may be greater than portrayed here.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

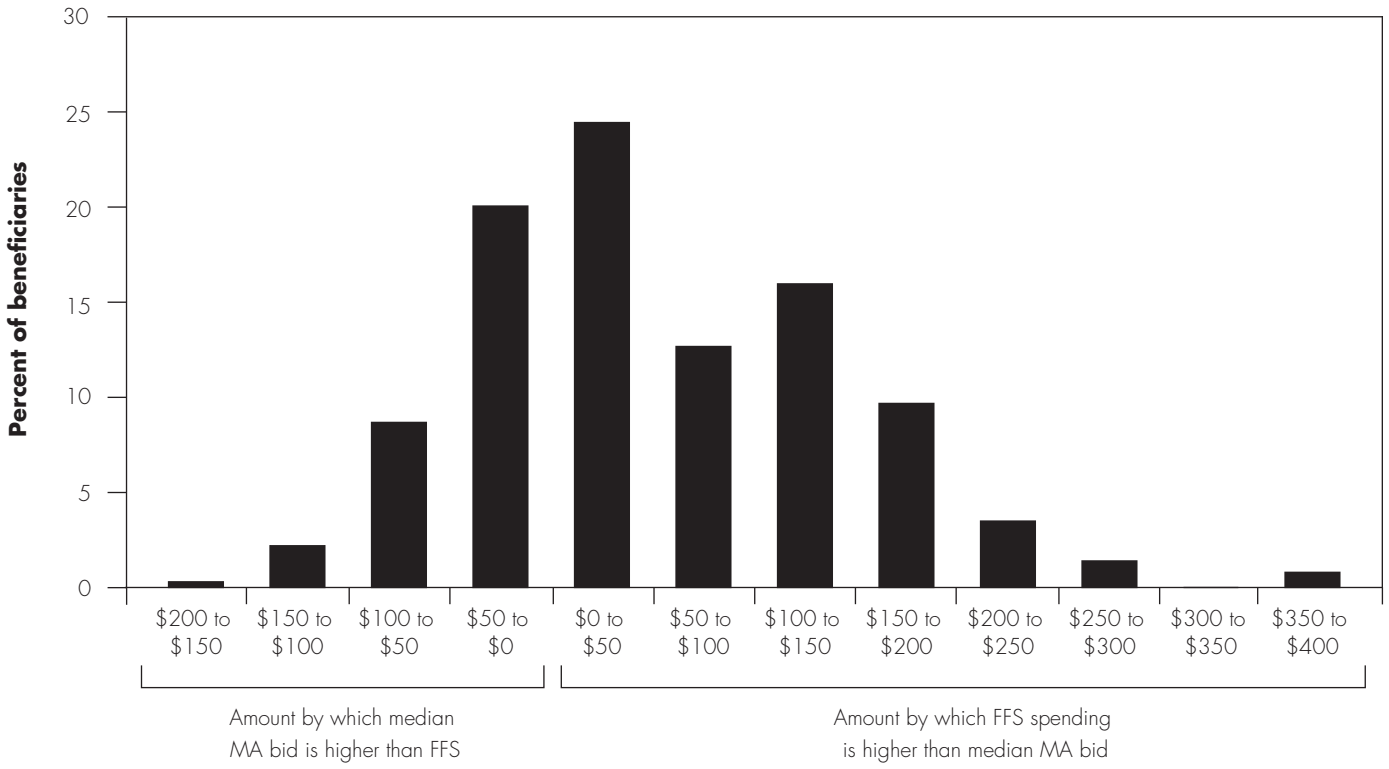
spending under the current MA payment system. Table 1-6 (p. 20) shows the 10 largest areas in this group, based on MA enrollment, which together account for about 75 percent of the group's MA enrollees. The group's largest single market area is Rochester, NY, which has about 130,000 MA enrollees and accounts for almost 30 percent of the total for the group. Only Rochester and Honolulu have more than 50,000 MA enrollees.

Table 1-6 (p. 20) also shows the estimated monthly premium that FFS enrollees and enrollees in the MA plan with the median bid would pay in 2016 under the third example. Since local FFS spending in these market areas is lower than the national average, basing premiums on local FFS costs instead of national FFS costs would reduce premiums for all beneficiaries living in these areas. For 2016, we estimate that basing premiums on local FFS costs would reduce monthly premiums in these market areas by $6 to $30, and would thus partly offset the higher premiums that MA enrollees in those market areas would face.

At the other end of the distribution, there are 123 market areas where FFS spending is higher than the median MA bid by $100 or more. About 16.7 million beneficiaries (31 percent of all Medicare beneficiaries) live in these market areas, and about 10.8 million are in FFS. These markets are generally larger, with relatively high FFS spending, numerous MA plans available, and MA benchmarks that typically equal 95 or 100 percent of FFS spending under the current MA payment system. Table 1-7 (p. 21) shows the 10 largest market areas in this group, based on FFS

FIGURE 1–5

Distribution of beneficiaries based on the difference between average FFS spending and the median MA plan bid, 2016



Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The number of Medicare beneficiaries is as of January 2016. Out of 1,231 market areas in our dataset, 208 market areas have no eligible plan bids, either because no MA plans are available in those areas or because we excluded all of the available MA plans for our analysis. The market areas with no eligible plan bids have about 1.3 million beneficiaries, or 2 percent of the overall total.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

enrollment, which together account for about 50 percent of the group's FFS enrollees and include many of the nation's largest metropolitan areas. The 10 largest market areas each have at least 300,000 FFS enrollees.

Table 1-7 (p. 21) also shows the estimated monthly premium that FFS enrollees and enrollees in the MA plan with the median bid would pay in 2016 under the third example. Since the bid for the median MA plan in these market areas is usually lower than national average FFS spending, basing premiums on the lower of local FFS costs or the bid for the median MA plan would typically lower premiums for the MA enrollees in these areas by roughly $5 to $20. This reduction would also partly offset the higher premiums that FFS enrollees in those market areas would face relative to current law.

Options for mitigating or delaying the impact on beneficiaries

Given the size of the increase in premiums that many beneficiaries would face under the examples presented earlier, policymakers may also want to consider measures that would mitigate the impact on beneficiaries. Broadly speaking, policymakers would need to decide how much of the increase in premiums beneficiaries should ultimately face, and how quickly premiums should reach that ultimate level. Policymakers would also need to consider how changes in the calculation of beneficiary premiums would affect low-income Medicare beneficiaries and state Medicaid programs.

As a first question, policymakers would need to decide whether beneficiaries should ultimately face the full

TABLE 1–6

Ten largest market areas (based on MA enrollment) where the median MA plan bid exceeds average FFS spending by $100 or more, 2016

	Medicare beneficiaries (in thousands)			Monthly premium under Example 3		Change from current premium under Example 3	
Market area	**Total**	**FFS**	**MA**	**FFS**	**MA**	**FFS**	**MA**
Rochester, NY	214	82	132	$79	$214	–$27	$61
Honolulu, HI	168	87	81	81	185	–25	65
Lancaster, PA	101	63	37	90	210	–16	84
Erie, PA	55	30	25	90	191	–16	84
Hawaii-Kauai, HI	52	33	19	84	266	–22	72
Lebanon, PA	29	18	11	90	210	–16	84
Braxton-Doddridge-Gilmer-Harrison-Lewis-Upshur, WV	32	22	9	85	224	–21	73
Gratiot-Ionia-Mecosta, MI	27	19	9	100	205	–6	41
Schuyler-Steuben, NY	26	17	8	82	195	–24	68
La Crosse, WI	21	13	8	76	252	–30	55

Note: MA (Medicare Advantage), FFS (fee-for-service). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries, FFS enrollees, and MA enrollees are as of January 2016. MA premium figures are for beneficiaries enrolled in the plan with the median bid in each market area; beneficiaries enrolled in other MA plans in those market areas would pay different amounts. The figures for the change from the current premium under Example 3 account for supplemental MA premiums that beneficiaries now pay under current law.

Source: MedPAC analysis of MA plan bids for 2016 and MA enrollment data for January 2016.

increase in premiums that would result from the three illustrative examples discussed earlier in this chapter or only part of the increase. All three examples are designed to encourage beneficiaries to choose the most efficient option in their area for receiving Medicare benefits. Policymakers could decide that a smaller differential in premiums would still be sufficient to encourage beneficiaries to use the most efficient option and could therefore limit the allowable difference between the FFS premium and the premium for the reference MA plan to a specific dollar or percentage amount. Another option would be to grandfather existing Medicare beneficiaries and use the new method of calculating premiums only for future Medicare beneficiaries, although this option could be challenging for CMS to administer.

The new method of calculating premiums could also be implemented over several years to minimize disruptions for beneficiaries and give them time to adjust to the new system. During the transition period, premiums could be a weighted average of the amount calculated under the current method and the amount calculated under the new method, with the weight for the new method rising over time. In addition, policymakers could limit the annual increase in premiums that beneficiaries would face during the transition period to a specific dollar or percentage amount. Under this approach, the transition period would be longer for beneficiaries who live in market areas where premiums would change significantly under the new method.

Policymakers would also need to decide how a new method for calculating premiums would treat low-income Medicare beneficiaries and the states. The distribution for dual-eligible beneficiaries based on the difference between average FFS spending and the median MA bid is similar to the overall distribution shown in Figure 1-5 (p. 19), although our analysis suggests that dual eligibles are somewhat more likely to live in market areas where FFS spending exceeds the median MA bid by $50 to $200. Medicaid currently pays the Part B premium for about 15 percent of Medicare beneficiaries through the Medicare Savings Programs (MSPs), which provide assistance to beneficiaries with income below 135 percent of the federal poverty level. The second and third examples outlined above would require

TABLE 1–7

Ten largest market areas (based on FFS enrollment) where average FFS spending exceeds the median MA plan bid by $100 or more, 2016

	Medicare beneficiaries (in thousands)			Monthly premium under Example 3		Change from current premium under Example 3	
Market area	**Total**	**FFS**	**MA**	**FFS**	**MA**	**FFS**	**MA**
Chicago, IL	1,177	934	243	$244	$97	$138	–$9
New York, NY	1,493	923	570	243	95	137	–11
Los Angeles, CA	1,372	720	652	294	99	188	–7
Northeastern New Jersey	700	581	119	239	98	133	–8
Houston, TX	743	453	289	377	89	271	–17
Nassau-Suffolk, NY	518	424	94	253	98	147	–8
Baltimore, MD	454	410	43	249	112	143	6
Phoenix, AZ	672	392	280	248	89	142	–17
Dallas, TX	535	369	166	282	98	176	–8
Tampa-St. Petersburg, FL	602	307	295	301	85	195	–21

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending and MA plan bids are per beneficiary per month and standardized for a beneficiary of average health status. Market areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. The numbers of Medicare beneficiaries, FFS enrollees, and MA enrollees are as of January 2016. MA premium figures are for beneficiaries enrolled in the plan with the median bid in each market area; beneficiaries enrolled in other MA plans would pay different amounts.

Source: MedPAC analysis of Medicare Advantage plan bids for 2016 and MA enrollment data for January 2016.

beneficiaries to pay higher premiums for the more expensive system for receiving Medicare benefits, which would increase MSP spending and effectively shift responsibility for some Medicare spending to the Medicaid program, or require beneficiaries to pay the difference to enroll in FFS or higher cost MA plans, depending on the area.

Policymakers could limit the impact on states by exempting MSP enrollees from the higher premiums or by placing a limit on the amount that MSPs are required to cover. For example, the Part D low-income subsidy provides assistance with Part D premiums, but covers the full amount for only a subset of lower premium plans. Policymakers could use a similar approach for the MSPs. Alternatively, policymakers could also expand eligibility for the MSPs if they decided that the higher premiums would pose a hardship for beneficiaries who currently do not have incomes low enough to qualify for the MSPs. Policymakers could also limit the impact on states by federalizing some or all of the MSPs (a topic discussed in Chapter 9 of this report).

In addition, certain other categories of beneficiaries may warrant special treatment. Within the FFS population, beneficiaries who have supplemental coverage (medigap or employer-sponsored supplemental coverage) use more services than beneficiaries who do not, which increases average FFS expenditures. This higher utilization is not due to greater health needs. In its June 2012 report to the Congress, the Commission recommended that an additional charge be imposed on supplemental insurance in recognition of the "additional costs to the program that are not fully reflected in their supplemental premiums" (Medicare Payment Advisory Commission 2012). If beneficiaries would be expected to pay a higher premium for FFS in a market area, a distinction could be made between those beneficiaries with supplemental coverage and those without it. The former would face a higher cost in choosing FFS (that is, the amount added to their FFS premiums would be higher than for people with no supplemental coverage).

In the same way that providers can get payment bonuses by participating in alternative payment models (APMs) in FFS such as ACOs, beneficiaries could also be allowed to benefit from involvement in APMs in a premium support model. In this case, the amount added to the FFS premium would be lower for such beneficiaries, although the reduction could be small in some market areas. (In

administering such a policy, there would be issues of how to identify such individuals, what the minimum level of APM involvement would be, etc.)

As part of the transition, policymakers would also need to ensure that beneficiaries understand the tradeoffs of enrolling in FFS or a particular MA plan under the new system. Premiums are an important factor in making that decision, but there are also several other important elements to consider (see the earlier text box (pp. 6–7) on factors that affect beneficiary choice and the limitations discussed below). Policymakers could help inform beneficiaries by providing additional funding to State Health Insurance Assistance Programs and improving the decision-making tools available to beneficiaries.

Finally, the options outlined above are not mutually exclusive. Many of them could be combined.[13]

Limitations of our analysis

Our analysis has important limitations. First, in illustrating only three premium designs, our analysis does not represent a definitive or comprehensive set of design choices. Differences in design choices can have a major impact on beneficiaries and on an area's health care marketplace. Our June 2013 chapter on competitively determined plan contributions provides a broader discussion of key design elements (Medicare Payment Advisory Commission 2013). Furthermore, the examples used to illustrate the relative effects of a particular design may not be realistic as actual policy choices.

Second, our analysis uses plan bids under the current MA program as a proxy for the total cost of providing the Medicare benefits through private plans because they are the best measure we have. However, these bids are the plans' responses to current rules, which are different from all three illustrative examples. Under different rules, MA plans are likely to bid differently. For example, current MA bids are highly correlated with current MA benchmarks, which range from 95 percent to over 125 percent of FFS spending in 2016. Without those administratively set benchmarks, as in our analysis where federal contributions were based on the lower of either FFS spending or the MA bid, plans would likely change their bids. Additionally, plan bids would be different if MA plans defined their own service area, as under current law, compared with the program defining a market area, as under our illustrative examples. Moreover, under different rules for calculating beneficiary premiums and the federal contribution, MA plans would likely make different decisions regarding whether to enter or exit a particular market area and how much to bid.

Third, as we noted earlier, we assumed in our analysis that the current system of rebates and extra benefits for MA plans would be eliminated and that differences in the relative cost of FFS and MA would be reflected in the beneficiary's premium. Extra benefits could be included as part of a new method for calculating beneficiary premiums, but such a change would raise policy issues that are beyond the scope of this chapter.

Finally, our analysis does not discuss how beneficiaries would respond to changes in their premiums. Our examples show that methods for calculating beneficiary premiums could have a major effect on beneficiaries' finances. But a premium is only one of many factors beneficiaries might care about. In making a choice with the highest value to them, some beneficiaries would need to trade off premiums and other aspects of the benefit package as well as their perception of quality and other factors affecting their choices. This process can be difficult and complex. For example, under current law, choosing traditional Medicare offers no restrictions on providers but may require additional choices among Medicare supplemental plans and among Part D plans; choosing an MA plan may simplify the process by offering all Medicare benefits—Part A, Part B, Part D, and supplemental coverage—in a single plan but would necessitate receiving care from a limited network of providers. When choices require considering multiple dimensions simultaneously, beneficiaries' ability to compare and make tradeoffs among a large set of options would likely be limited. Moreover, if the difference in premiums among choices is too great, the choice that the beneficiary would otherwise consider most attractive might be prohibitively expensive and therefore not a realistically viable choice. These issues are additional policy considerations that must be factored into designing beneficiaries' financial incentives.

Conclusion

For many years, the Commission has supported the concept of financial neutrality between FFS Medicare and Medicare Advantage. That concept was first applied at an aggregate level, with the Commission recommending that total payments to MA plans should not exceed what it would cost the government, on average, to serve the

same beneficiaries in the FFS program. Starting with its June 2015 report and continuing with this chapter, the Commission has extended this concept to individual beneficiaries and, in this chapter, has illustrated the effects of having the government's contribution be the same in both FFS and MA.

Since the cost of FFS and MA coverage varies both within and across markets, equalizing the government contribution would require beneficiary premiums to vary, with beneficiaries paying higher premiums for the more costly delivery system. Policymakers could equalize the government contribution in many different ways, and this chapter has used three illustrative examples to explore some of the possible effects.

Average spending for FFS and MA differs significantly in many areas of the country, so equalizing the government contribution would, if implemented fully, result in much higher premiums for some beneficiaries. In one of our illustrative examples, about a third of Medicare beneficiaries live in areas where monthly premiums for some beneficiaries would increase by $100 or more. Most of the beneficiaries facing higher premiums would be FFS enrollees, but MA enrollees in some areas would also be affected. Our illustrative examples also differ in their effect on current beneficiaries; under our first example, most beneficiaries would not face higher premiums for their existing coverage (since the FFS premium would stay the same and most MA enrollees are in plans that are less expensive than FFS), while under our second and third examples, a majority of beneficiaries would face higher premiums for their existing coverage (since the base premium would be tied to the less costly form of coverage, which would lead to higher FFS premiums in many areas).

Given the potential magnitude of the premium increases if any of these illustrative examples were adopted, there would likely need to be some sort of transition period to mitigate the initial impact on beneficiaries. As part of the glide path to the new system, policymakers could place an overall limit on how much premiums for FFS enrollees could increase, phase in the higher premiums over time, or both. The potential impacts on low-income beneficiaries and state Medicaid programs would also be important considerations. ■

Endnotes

1 Under current law, beneficiary premiums for Medicare Part A and Part B are separate. Most beneficiaries pay no premium for Part A based on their employment history, whereas all beneficiaries who elect Part B pay a monthly premium set at about 25 percent of Part B benefit costs per beneficiary. In this chapter, we define beneficiary premiums as a set share of combined Part A and Part B benefit costs, but we do not specify the mechanism through which it would be collected.

2 To mitigate these problems, in 2005 the Commission recommended combining counties into larger payment areas for MA, consisting of metropolitan statistical areas (MSAs) and health service areas outside MSAs (Medicare Payment Advisory Commission 2005).

3 FFS spending data are from CMS's 2016 MA rate calculation data. We only excluded hospice, direct graduate medical education, and indirect medical education to make FFS spending comparable with what MA plans now include in their bids. How these payments would be handled under a new method for calculating beneficiary premiums is a policy choice.

4 With some exceptions, all MA plans must also offer an option that includes the Part D drug benefit, although payments for the Part D benefit are handled separately. For the purposes of this analysis, we used only the Part A and Part B component of the bid.

5 The local MA benchmark for a plan serving only one county is the county benchmark rate. Plans serving multiple counties have a weighted benchmark based on the expected enrollment coming from each county. Regional preferred provider organization plans, another option within MA, bid in relation to regional benchmarks, which are set under a different methodology.

6 We use current MA plan bids for 2016 because they represent the latest data available. As discussed, county benchmarks under the current MA program can differ significantly from county FFS spending, and plan bids tend to be correlated with benchmarks, not FFS spending. Therefore, MA plan bids would likely change if benchmarks and rules changed.

7 For individuals who are not eligible for premium-free Part A and have 30–39 quarters of Medicare-covered employment, the premium is $226 per month in 2016. For individuals who are not eligible for premium-free Part A and have fewer than 30 quarters of Medicare-covered employment, the premium is $411 per month. There are very few individuals in these two categories.

8 Higher income beneficiaries pay higher monthly premiums (as high as $390 a month in 2016) based on their modified adjusted gross income.

9 Part A is primarily financed through dedicated payroll taxes paid by current employers and employees. If we took these payments into account, the ultimate government subsidy would be lower.

10 The difference between the estimated and actual Part B premium amounts is also partly due to the fact that the actual Part B premium includes an additional amount that is meant to bolster the reserves of the Part B trust fund.

11 This example differs slightly from the version that we used in our June 2015 report. In the previous version, the base premium simply equaled 13.4 percent of local average FFS spending. (That figure differs slightly from the 13.5 percent used in this report because it was based on older data.) We modified this example because the previous version would have increased premiums for all beneficiaries living in areas with high FFS spending, even those enrolled in less costly MA plans.

12 There are alternative policy designs that could contemplate offering enhanced benefits in addition to premium reductions, but they are beyond the scope of this current chapter.

13 For example, the Medicare Modernization Act of 2003 required the Secretary to conduct a demonstration project in up to six metropolitan areas that would have adjusted Part B premiums for FFS enrollees based on how average FFS costs in those areas compared with the average MA bid. FFS premiums would have been increased if FFS were more expensive than MA, and reduced if FFS were less expensive than MA. However, any increase in premiums for FFS enrollees would have been phased in over four years and would not have applied to anyone receiving the Part D low-income subsidy, which has broader eligibility rules than the MSPs. The increased premium could also never be more than 5 percent higher than the original Part B premium. The demonstration, originally scheduled to begin in 2010, was never implemented and Congress repealed it in 2010.

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CHAPTER 2

Medicare's new framework for paying clinicians

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Chapter summary

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the sustainable growth rate (SGR) system and established a new approach to updating payments to clinicians. This approach incentivizes clinicians to participate in alternative payment models (APMs). Examples of APMs could be accountable care organizations, bundled payment models, and medical homes. MACRA establishes specific criteria for "eligible alternative payment entities," which operate under one of these APMs. Essentially, MACRA establishes two paths for payment updates—a path for clinicians who participate in eligible alternative payment entities and a path for all other clinicians.

Beginning in 2019 and continuing through 2024, clinicians will receive a 5 percent incentive payment if the level of revenue they receive through eligible alternative payment entities meets a certain threshold. In 2025, there will be no update and no incentive payments, and from 2026 on, clinicians meeting the revenue threshold will receive a higher update than clinicians who do not meet that threshold. Thus, how CMS defines eligible alternative payment entities and how clinicians qualify for the incentive payment are of great interest to clinicians.

For clinicians who do not qualify for the APM incentive payment, a separate program exists for assessing clinicians on their performance—the Merit-based Incentive Payment System (MIPS). Performance on MIPS will determine

In this chapter

whether clinicians receive a bonus or a penalty on their fee-for-service (FFS) payments. Although budget neutral in aggregate, these bonuses and penalties could have a large effect on payments for individual clinicians and hence on the attractiveness of the APM and MIPS paths.

In this chapter, we present the Commission's principles concerning the APM provisions and discuss some key considerations for the design of MIPS. The principles for the APM provisions are meant to inform the debate on how APMs should be defined in regulation and, more broadly, how APMs should function in the quest both to improve quality and to contain costs for beneficiaries and the taxpayers who support Medicare. These principles help further shape a program aimed at controlling costs and improving quality in Medicare. For MIPS, we outline some lessons that can be learned from CMS's experience with the existing performance incentive programs that may be incorporated into the eventual MIPS program, and we seek to reinforce the Commission's position that quality measures should emphasize population-based outcomes. Finally, we conclude with observations on the importance of coordinating MIPS and APM implementation to reduce the chance of unintended consequences for the Medicare program, its beneficiaries, and taxpayers.

The following are the Commission's basic principles for APMs:

- Clinicians should receive an incentive payment only if the eligible alternative payment entity in which they participate is successful in controlling cost, improving quality, or both.
- The eligible alternative payment entity should be at financial risk for total Part A and Part B spending.
- The eligible alternative payment entity should be responsible for a beneficiary population sufficiently large to detect changes in spending and quality.
- The eligible alternative payment entity should have the ability to share savings with beneficiaries.
- CMS should give eligible alternative payment entities certain regulatory relief.
- Each eligible alternative payment entity should assume financial risk and enroll clinicians.

Given the principles above, certain implementation issues are expected to arise because APMs will continue to function for the foreseeable future in a largely FFS environment with beneficiaries free to move among providers. These implementation issues include the definition of the statutory term *risk beyond a nominal amount* and attribution of beneficiaries to eligible alternative payment entities. This discussion of MIPS addresses how to consider factors such as quality

and resource use at the individual clinician level. Finally, there will be an issue of how to balance MIPS and APM incentives. In developing and implementing these programs, the broader challenge will be to further the sustainability of the Medicare program and ensure access to services for Medicare beneficiaries. The Commission intends its discussion of the principles and issues in this chapter to help provide a road map for thinking through the complex issues raised by MACRA and to help move the Medicare program from one oriented toward FFS payment to one that encourages delivery system reform oriented toward payment for value. ■

Introduction

Medicare pays physicians and other health professionals providing care to Medicare beneficiaries using a fee schedule under Part B of the program. In 2013, Medicare paid over $68.6 billion to 876,000 professionals, including 573,000 physicians and 303,000 nurse practitioners, physician assistants, therapists, chiropractors, and other practitioners.

On the one hand, Medicare's fee schedule is incredibly complex, comprising over 7,000 services and their respective payment rates that can further vary based on where the service is provided and the circumstances under which it is provided. On the other hand, the fee schedule is simple in that each of the 7,000 payment codes corresponds to a set fee, and the clinician is paid for each code. Increasing the volume of services, therefore, increases payment. Under this structure, payments increased, with growth in real (that is, adjusted for inflation) spending per beneficiary for physician services averaging 2.4 percent from 1991 to 1998 (Medicare Payment Advisory Commission 2001).

To control the increase in spending for services covered under Medicare's fee schedule for clinicians, the Congress created the sustainable growth rate (SGR) system in 1997. The SGR was meant to control the growth of fee schedule spending by making the conversion factor update (that is, the percentage amount by which the rates in the fee schedule are increased or decreased each year) subject to a limit determined by a formula tied to the gross domestic product and other factors. After positive updates in its first two years, the SGR system resulted in a negative update in 2002 and continued to do so for the rest of its existence. The Congress overrode the negative update in 2003 and every year thereafter, but this created ever-larger negative updates because of the way the SGR system operated and the mechanism of the overrides, thus making the system difficult and costly to repeal.

From a Medicare spending control aspect, the SGR had two major limitations. First, it addressed only clinician spending, not Medicare spending in total. Second, it acted as a blunt instrument, reducing fee updates across the board, regardless of which clinicians were responsible for high spending levels. Thus, there was no connection between an individual clinician's behavior and the resulting reward or penalty. In fact, some service categories grew far more rapidly than others over the SGR's 15-year existence, yet the annual updates were uniform across all specialties (Medicare Payment Advisory Commission 2016).

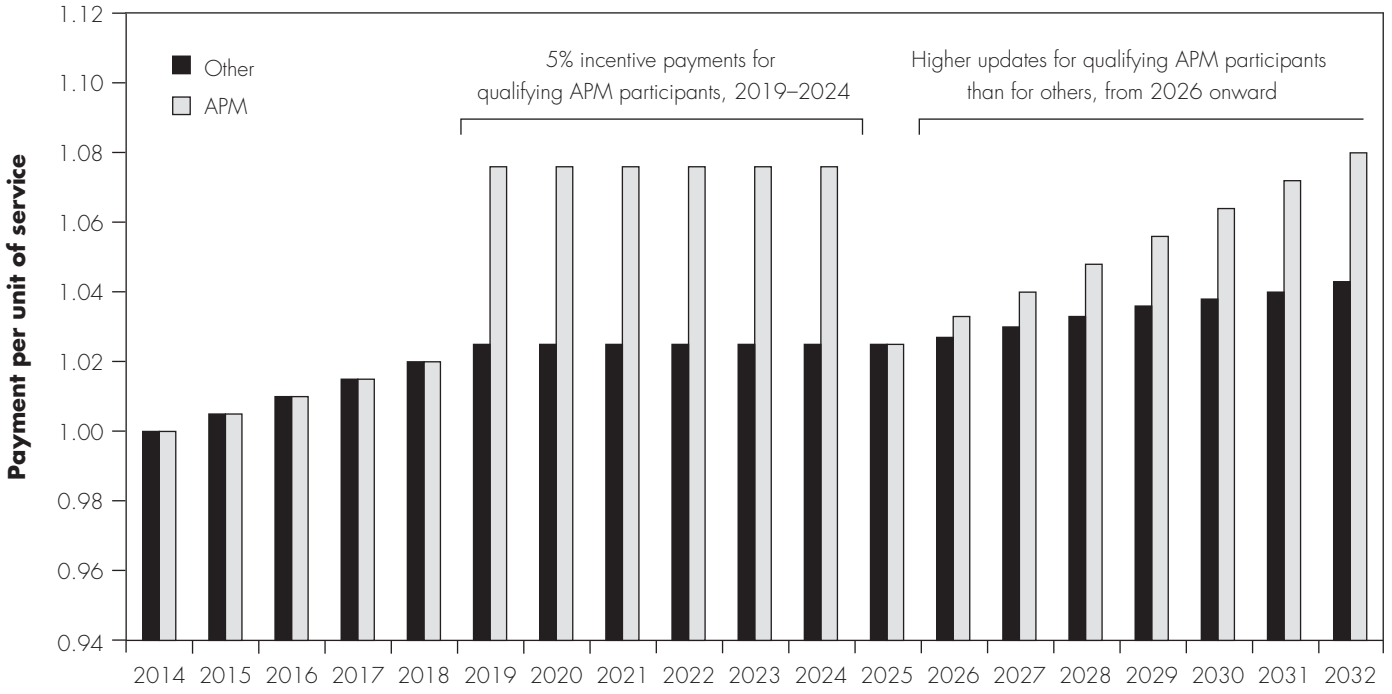
The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the SGR system and established a new approach to updating payments to clinicians. Rather than use a formula, MACRA specified the clinician fee schedule update each year. Specifically, the updates are 0.5 percent each year for 2016, 2017, and 2018; zero for 2019 through 2025; and either 0.75 percent or 0.25 percent from 2026 on. However, Medicare's payments to clinicians will follow two separate paths—a path for clinicians who participate in eligible alternative payment entities (EAPEs) (the alternative payment model (APM) path) and a path for all other clinicians.

In 2019 through 2024, clinicians participating in an APM will receive a 5 percent incentive payment if they have a sufficient share of revenue coming through one or more EAPEs. From 2026 on, clinicians meeting the threshold criterion for participation in EAPEs will receive a higher update than clinicians who do not meet that criterion. (There is no update and no incentive payment in 2025 for anyone.) Thus, how eligible alternative payment entities are defined and how clinicians qualify for the incentive payment are very important policy decisions.

For clinicians who do not qualify for the APM incentive payment, a separate program—the Merit-based Incentive Payment System (MIPS)—exists for assessing clinicians on their performance in four areas: quality, resource use, meaningful use of certified electronic health records, and clinical practice improvement activities. Clinician performance relative to others in MIPS will determine whether clinicians receive a bonus or a penalty on their fee-for-service (FFS) payments. Although budget neutral in aggregate, these bonuses and penalties could have a large effect on payments for individual clinicians and hence on the relative attractiveness of the APM versus MIPS paths.[1]

The SGR was designed to control Medicare spending under the fee schedule by adjusting conversion factor updates. MACRA has some elements that could potentially serve to control spending. Specifically, the updates in MACRA are slightly lower than recent updates, and MACRA includes elements in APMs and MIPS designed to help address two of the SGR's limitations. First, eligible alternative payment entities must bear some financial risk for spending, which might help limit spending growth. Second, MIPS has a resource use component, and individual clinicians get bonuses and

FIGURE 2–1 **Illustrative update path for qualifying APM participants and all other clinicians**



Note: APM (alternative payment model). The figure shows a stylized example in which the provider received 1.0 payment per unit of service in 2014.

penalties in direct relation to their performance. The principles we propose for APMs and MIPS are designed to make these indirect spending controls as effective as possible.

Statutory provisions for clinician payment in MACRA

MACRA repealed the SGR and in its place set statutory updates for the fee schedule, set broad parameters for how participation in APMs affects a clinician's payment, and established MIPS for clinicians not eligible for the APM incentive payment.

Updates set in law

The statutory update in MACRA for all clinicians billing Medicare through the fee schedule was 0.5 percent in July 2015 and January 2016.[2] The update in January 2017, 2018, and 2019 will also be 0.5 percent. Beginning in 2019, clinicians who meet the criteria set out in the law as qualifying APM participants will receive an incentive payment of 5 percent of their fee schedule payments for each year that they qualify through 2024. The incentive payment will be distributed as a lump sum each year. Qualifying APM participants will also receive a higher yearly update (0.75 percent) than others (0.25 percent) in 2026 and later years. Figure 2-1 illustrates that Medicare payments to qualifying APM participants per unit of service will decline between 2024 and 2025.

Provisions for alternative payment models and eligible alternative payment entities

MACRA establishes criteria for how eligible alternative payment entities are defined and how a clinician becomes a qualifying participant (see text box for a definition of terms). For each year that an incentive payment or higher update is possible, clinicians must qualify anew as participating in an eligible alternative payment entity. For example, a physician could qualify in 2019 and receive a 5

Definitions of key terms

Alternative payment model (APM): APMs are defined by statute as all models in the Center for Medicare & Medicaid Innovation (CMMI) (except Innovation Awards), Medicare demonstration authority through Section 1866C of the Social Security Act, the Medicare Shared Savings Program, or a demonstration required by law.

Eligible alternative payment entity (EAPE): An entity that operates under an APM that meets three criteria: (1) the model requires use of certified electronic health record technology; (2) the model makes payment based on a set of quality measures comparable with the Merit-based Incentive Payment System; and (3) the model requires the entity to bear financial risk for monetary losses under such alternative payment model in excess of a nominal amount or be a medical home expanded under Section 1115A(c).

Qualifying APM participant: A clinician who has a minimum share of his or her professional services revenue (or patients) coming through an EAPE.[3] The numerical share is set in statute and rises each year. Qualifying APM participants receive the APM incentive payment.

APM incentive payment: A 5 percent incentive payment (applied to the clinician's Medicare fee-for-service professional payments from the previous year) from 2019 to 2024 paid directly from the Medicare program to clinicians who are qualifying APM participants. ■

percent incentive payment but not qualify in the next four years and receive no incentive payment and a zero update.

From 2026 onward, the incentive for clinicians to participate in an APM is a higher update, not the 5 percent incentive payment. A clinician must meet the qualifying APM participant criteria yearly to receive the higher update. The differential payment updates from 2026 into the future also compound, so CMS will have to develop an individual-level update based on whether the clinician received the higher update in prior years. In other words, if a clinician qualifies for the higher update in 2026 but not thereafter, he or she would have a different payment rate than the clinician who qualifies in multiple years. Each clinician's update history from 2026 onward has to be known to determine his or her payment rate in the succeeding years. This process could be difficult for CMS to implement and for clinicians to understand.

Eligible alternative payment entities will be a subset of all entities participating in APMs

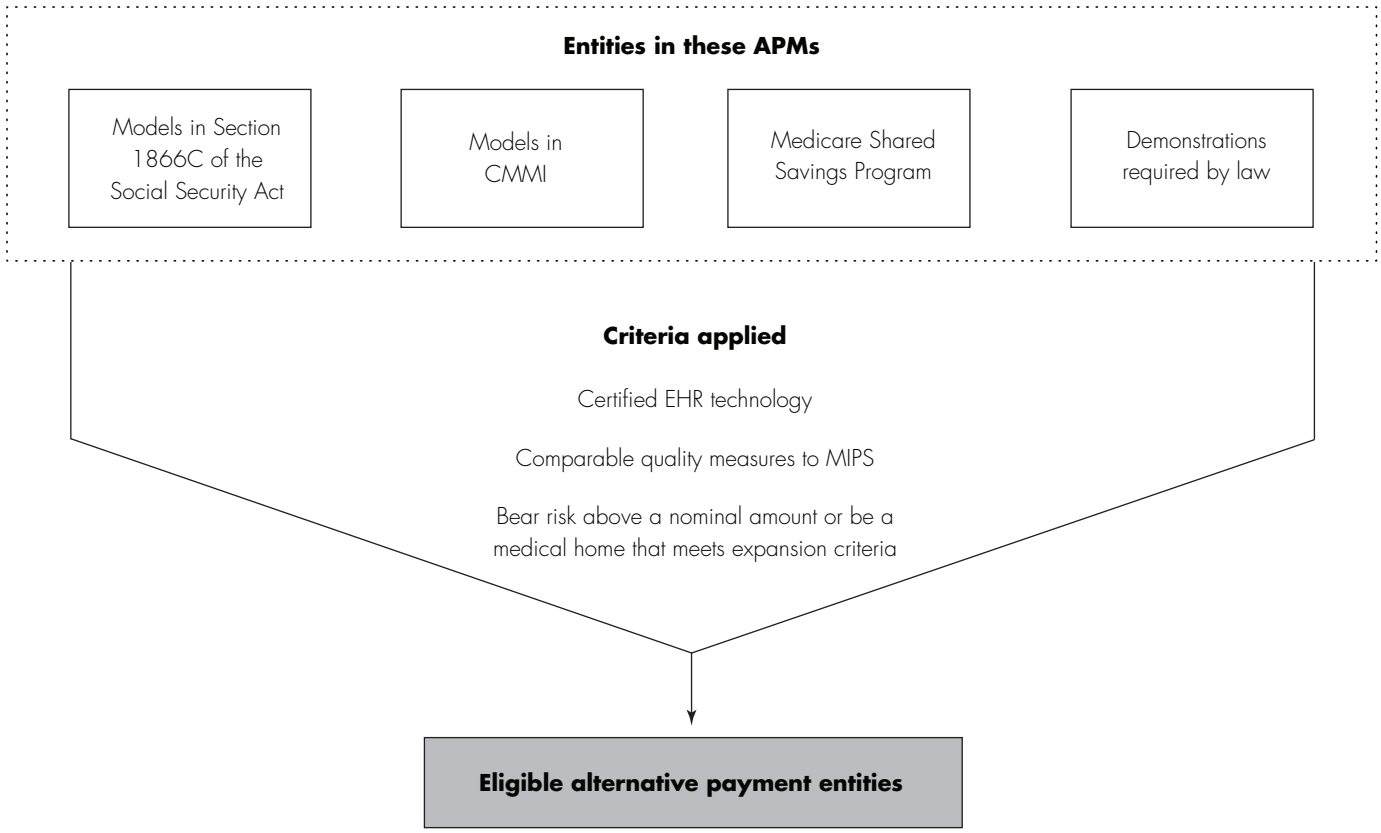
The pool of APMs under MACRA includes all models in the Center for Medicare & Medicaid Innovation (CMMI) (except for Innovation Awards), models in Section 1866C of the Social Security Act (the Health Care Quality Demonstration), the Medicare Shared Savings Program (MSSP), and demonstrations required by law.

Currently, CMMI runs approximately 60 separate models in 7 categories: accountable care, episode-based payment initiatives, primary care transformation, initiatives focused on Medicaid and the Children's Health Insurance Program, initiatives focused on dual-eligible beneficiaries, initiatives focused on accelerating new payment and delivery models, and initiatives to speed the adoption of best practices. In addition, the Medicare Shared Savings Program, which is part of permanent Medicare law, is also considered an APM.

MACRA sets certain criteria for this group of *all* APMs and then defines a subgroup of them as *eligible*. The law makes a further distinction to define the *entities* that operate under these eligible alternative payment models—referred to as EAPEs. EAPEs must participate in an APM that:

- requires use of certified electronic health record (EHR) technology,
- provides for payment based on quality measures comparable to MIPS, and
- requires the entity to bear financial risk above a nominal amount or be a medical home meeting the expansion criteria (see text box, pp. 38–39).

FIGURE 2–2 **Eligible alternative payment entities will be a subset of entities participating in APMs**



Note: APM (alternative payment model), CMMI (Center for Medicare & Medicaid Innovation), EHR (electronic health record), MIPS (Merit-based Incentive Payment System). Models in Section 1866C of the Social Security Act refer to the Health Care Quality Demonstration Program. All CMMI models are APMs except for models under the Innovation Awards. The Medicare Shared Savings Program is a part of permanent Medicare law.

An illustrative example may be useful. Consider an APM that is a risk-bearing accountable care organization (ACO) model. Posit that this particular model requires ACOs under the model to do the three things that correspond to MACRA's statutory language: have certified EHR technology, make payment based on quality measures comparable to MIPS, and bear financial risk above a nominal amount. Then, any ACO in this specific model would be an EAPE, and the clinicians who participate in the ACOs in this model could, if their revenue met the criteria (discussed next), qualify for the APM incentive payment.[4] The clinicians in the EAPE would receive the APM incentive payment as a lump sum, sent directly to them from the Medicare program.

A key point is that the statute strictly limits EAPEs to only those that meet the three criteria (Figure 2-2). Although many entities operate under APMs, very few will be EAPEs under the statutory definition because the models under which they operate often do not meet the three criteria set out in law (see online Appendix 2-A, available at http://www.medpac.gov, for a discussion of the number of beneficiaries currently in APMs).

Another mechanism for the development of APMs is through the Physician-Focused Payment Model Technical Advisory Committee (PTAC) established by MACRA. This panel could develop or approve models and submit them to the Secretary of Health and Human Services for consideration. The PTAC was chartered in January 2016, and the Secretary has a statutory deadline of November 1, 2016, to establish criteria for physician-focused payment models that could be used by the PTAC in their review of

models. Any models reviewed by PTAC would be tested by CMMI to be considered an APM.

Clinicians become qualifying APM participants based on meeting a specified threshold

MACRA specifies how a clinician becomes a qualifying APM participant. Qualification can be based on the clinician's Medicare FFS payment or the share of Medicare patients in a Medicare EAPE, and in later years, the share of payment or patients in EAPEs from all payers combined (Medicare and other payers). To start with, a qualifying APM participant must have at least a minimum share of his or her Medicare FFS professional services payments coming through an EAPE. This criterion allows the clinician to receive the 5 percent APM incentive payment. CMS may also make this determination based on the share of beneficiaries coming through the EAPE instead of the share of payments. This criterion could allow more (or different) clinicians to qualify.

The minimum share is set in statute and increases over time. In 2019 and 2020, clinicians must have at least 25 percent of their FFS payment coming through an EAPE, 50 percent in 2021 and 2022, and 75 percent in 2023 and later. If a clinician meets the threshold, he or she receives a 5 percent incentive payment for that year, regardless of whether the EAPE is successful at lowering spending or improving quality. In addition, the incentive payment is applied to all the clinician's professional services paid by FFS Medicare, irrespective of the amount of Medicare payment associated with the EAPE.

Clinicians with revenue from Medicare Advantage (MA) cannot count their MA revenue in the Medicare FFS EAPE determination. CMS is required by the statute to submit a study to the Congress that "examines the feasibility of integrating alternative payment models in the Medicare Advantage payment system…[and] shall include the feasibility of including a value-based modifier and whether such modifier should be budget neutral." This study is due June 2016.

MACRA establishes an alternative calculation for clinicians who do not meet the criteria for qualifying participants in EAPEs based solely on their Medicare FFS payment. This all-payer calculation starts in 2021. Consider the following example: A clinician participates in an EAPE, does not meet the Medicare revenue threshold for being a qualifying participant based on his or her Medicare FFS revenue alone, but has a significant share of revenue from a private insurer. CMS could certify that the relationship between the private insurer and the clinician meets the requirements for an EAPE under the statutory definition. With this certification, the clinician could add the revenue from the private insurer to his or her Medicare revenue to see whether the individual meets the threshold when all revenues from EAPEs are taken into account. Under this all-payer variant, the clinician would need to provide CMS with information on the nature of his or her contract with the payer so that CMS could determine whether it met the EAPE criteria.[5] There are also rules for partial-year qualifying APM participants.[6]

The APM incentive payment applies to all of a clinician's FFS revenue

The 5 percent incentive payment is applied to all of the clinician's prior-year professional services billed under the Medicare fee schedule (not just the share of revenue coming through any EAPE). The APM incentive payment is paid separately from regular fee schedule services as a lump sum directly from the Medicare program to the clinician. The APM incentive payment is not counted as spending for the purposes of computing savings (or losses) for ACOs or other shared savings models. It also is not counted as spending for the next year's incentive payment calculation. If clinicians are in an EAPE that does not use FFS payment (e.g., if an ACO receives a partially capitated payment from Medicare and the clinician is not paid FFS), CMS is directed to establish processes for making APM incentive payments to those clinicians.[7]

The Merit-based Incentive Payment System

Under MACRA, clinicians who are not qualifying APM participants are subject to payment adjustments under the Merit-based Incentive Payment System (MIPS). MIPS consolidates three existing payment adjustment programs for clinicians: the Physician Quality Reporting System (PQRS), the value-based payment modifier (also called the value modifier (VM)), and the payment adjustment for the meaningful use of EHRs (see text box, pp. 42–43). MACRA continues these separate payment adjustments through 2018 and then repeals the individual payment adjustments and establishes the MIPS to take effect in 2019.

The medical home provision

Under the statutory definition of eligible alternative payment entities, medical homes do not need to meet the financial risk criterion if the model is certified for national expansion by CMS's Office of the Actuary. Whether this policy is executed will depend on the performance of the medical home models currently under way.

The expansion criterion referenced in the Medicare Access and CHIP Reauthorization Act of 2015 is the statutory authority given to CMS in the Center for Medicare & Medicaid Innovation (CMMI) authorizing statute. Under this authority, the Secretary of Health and Human Services may, based on the results from the independent evaluations mandated for each CMMI project, expand the "duration or scope" of a model (including nationally) if it would reduce spending without harming the quality of care or would improve quality (without increasing spending). CMS's Office of the Actuary must certify that the expansion of the model would not increase spending. The set of CMMI models that could be considered medical homes falls in the category description of "primary care transformation," under which nine models are currently listed. Three models are no longer active (the Federally Qualified Health Center Advanced Primary Care Practice Demonstration, the Frontier Extended Stay Clinic Demonstration, and the Medicare Coordinated Care Demonstration); one model is in development (Advanced Primary Care Initiatives); and the Transforming Clinical Practices Initiative is a quality improvement initiative, not a payment model. Another model listed (the Graduate Nurse Education Demonstration) entails providing resources for hospitals to train clinical nursing staff and is not therefore a medical home model. The four remaining models are as follows:

- ***Comprehensive Primary Care Initiative (CPCI)***—CPCI operates in seven regions and consists of financial support to eligible primary care practices to help them advance in five areas: risk stratification, access and continuity, care planning, patient engagement, and coordination. The payment model includes a monthly care management fee plus shared savings and includes participation by other payers. In evaluations of the first two years, spending for attributed beneficiaries was lower than expected in the first year, and no significant difference in the second. In neither year were reductions sufficient to recoup the cost of the care management fees, so in total the program increased Medicare spending. There were few changes in quality (Taylor et al. 2015). CPCI is scheduled to end in December 2016.

(continued next page)

MIPS will assign a composite score to each clinician that will determine how much the clinician's payment rate is increased or decreased from the base amount. The basic MIPS adjustments are budget neutral. The maximum *negative* MIPS adjustment factors are set in statute: 4 percent in 2019; 5 percent in 2020; 7 percent in 2021; and 9 percent in 2022 and subsequent years. The maximum *positive* adjustment may be larger than these figures for two reasons. First, the adjustment factors can be scaled up or down to achieve budget neutrality for the basic MIPS adjustment. Second, MACRA appropriated an additional $500 million a year for exceptional performance, defined as the quartile of performance above the performance threshold.

MIPS, effective 2019, applies to clinicians who do not qualify as APM participants. Under MIPS, upward and downward payment adjustments would apply based on the clinician's performance in four areas: quality, resource use, clinical practice improvement activities, and meaningful use of EHR. The legislation allows CMS to retain the measurement process for PQRS, EHR, and VM for use in MIPS, but merges the individual adjustments into the one MIPS adjustment. The clinician's composite score will reflect the weighted performance in the four areas; once phased in, quality and resource use will make up 30 percent each, clinical practice improvement activities will account for 15 percent, and EHR meaningful use will be 25 percent.[8]

The medical home provision (cont.)

- ***Comprehensive Primary Care Plus (CPC+)***—This newly announced model will replace the existing CPCI model and is scheduled to run from January 2017 through 2021. It uses largely the same framework as CPCI for primary care practices to achieve milestones in five areas. The payment model will continue to include a monthly care management fee for attributed beneficiaries and will include an at-risk performance fee and an option for practices to receive partial capitation.
- ***Independence at Home (IAH)***—Under the IAH Demonstration (mandated by law in the Patient Protection and Affordable Care Act of 2010 and subsequently extended by the Congress), participating practices that focus on home-based primary care can receive shared savings for their attributed beneficiaries. Under current law, Medicare covers home visits by Medicare clinicians. The IAH Demonstration extends a shared savings opportunity to practices. Under the statute, the number of IAH participants is capped. CMS has not released an evaluation of IAH to date, although it did issue a press release citing first-year shared savings results: 9 of 17 practices received shared savings payments, and all 17 practices improved quality for at least 3 of 6 quality measures (Centers for Medicare & Medicaid Services 2015c).
- ***Multi-payer advanced primary care practice (MAPCP)***—Under the MAPCP, CMS joined seven states in making enhanced primary care payments to practices that have characteristics of the patient-centered medical home. States established requirements for participation and add-on payment amounts. After the first year, there was no significant difference from expected program spending for beneficiaries treated in MAPCP practices, although one part of Vermont's initiative did have statistically significant savings. Performance across states varied, with the evaluators concluding that two states (of eight) reduced the rate of spending growth below trend. Evidence regarding quality improvements or utilization reduction was also mixed or not evident (McCall et al. 2015).

The Department of Health and Human Services has not promulgated rules to date to expand any of the medical home models under the CMMI authority. Two of the models (CPCI and MAPCP) would not meet the criteria for expansion in current law based on their results to date, and CMS has not released an independent evaluation of the third (the IAH Demonstration). Therefore, in developing our thinking regarding alternative payment model policy, we have focused on an accountable care–type model instead of a medical home model. ■

The category of clinical practice improvement activities must include the following: expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, and participation in an APM. It can also include other activities to be defined in regulation. The Secretary may vary the weights based on relevance to the clinician's specialty.

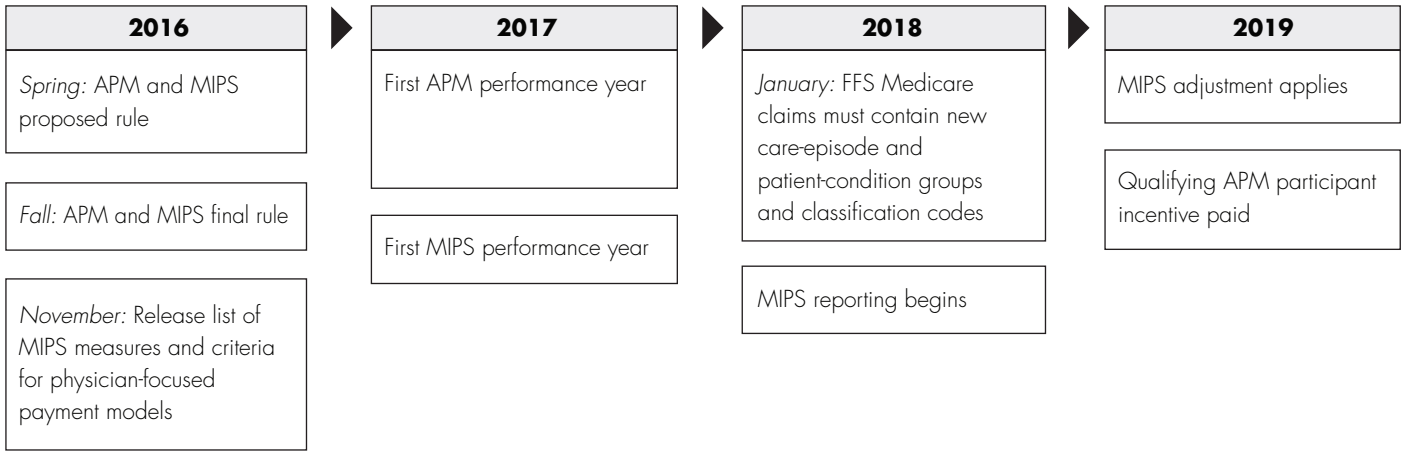
The performance standards in each area will be established by the Secretary and will be based on historical performance, improvement, and opportunity for continued improvement. Each clinician receives a MIPS adjustment factor based on his or her composite performance in all four areas.

The Secretary retains discretion to modify some of the policies regarding the MIPS program—developing options for virtual group assessment, using EHR or clinical registries to collect performance measures, and developing a feedback program to assist clinicians. The Secretary can establish a process for informal review of clinicians' MIPS scores, but the scores are not subject to appeal.

Time frame and linkage between APM and MIPS

CMS faces an expedited time frame for issuing guidance and setting rules for MACRA implementation (Figure 2-3, p. 40). To date, the agency has discussed MACRA in a Request for Information in October 2015, the physician

FIGURE 2–3 **Projected APM and MIPS development time frame for 2019 payment year**



Note: APM (alternative payment model), MIPS (Merit-based Incentive Payment System), FFS (fee-for-service). Dates are illustrative, based on current CMS process and statutory deadlines. The new codes required on claims are to identify the particular relationship that the clinician has to the patient.

fee schedule rule for 2016 (issued in November 2015), and a proposed rule published May 9 (Centers for Medicare & Medicaid Services 2016, Centers for Medicare & Medicaid Services 2015d).

The time line also highlights the choice that clinicians face. Importantly, MIPS is the default option not only at the beginning of the process but also throughout the years leading up to the payment year.

As shown in Figure 2-4, clinicians could participate in an APM, such as an ACO or a medical home. The entity in which the clinician participates could be an EAPE. However, even if the clinician is in an EAPE, he or she may not have sufficient revenue or beneficiaries coming through the entity to be a qualifying APM participant. The determination of whether a clinician is a "qualifying participant" is made anew each year as the clinician's circumstances and the thresholds change. If the clinician is in an APM that is not determined to be an EAPE or the clinician does not have a sufficient share of services coming through the EAPE, then he or she becomes subject to MIPS as the default.

The existence of multiple points on the APM path for a given payment year at which clinicians could qualify or not qualify for the APM incentive payment underscores the importance of MIPS as the default. Clinicians will be on either the APM or the MIPS payment path, but they may not know at a given point in time which path will ultimately prevail.

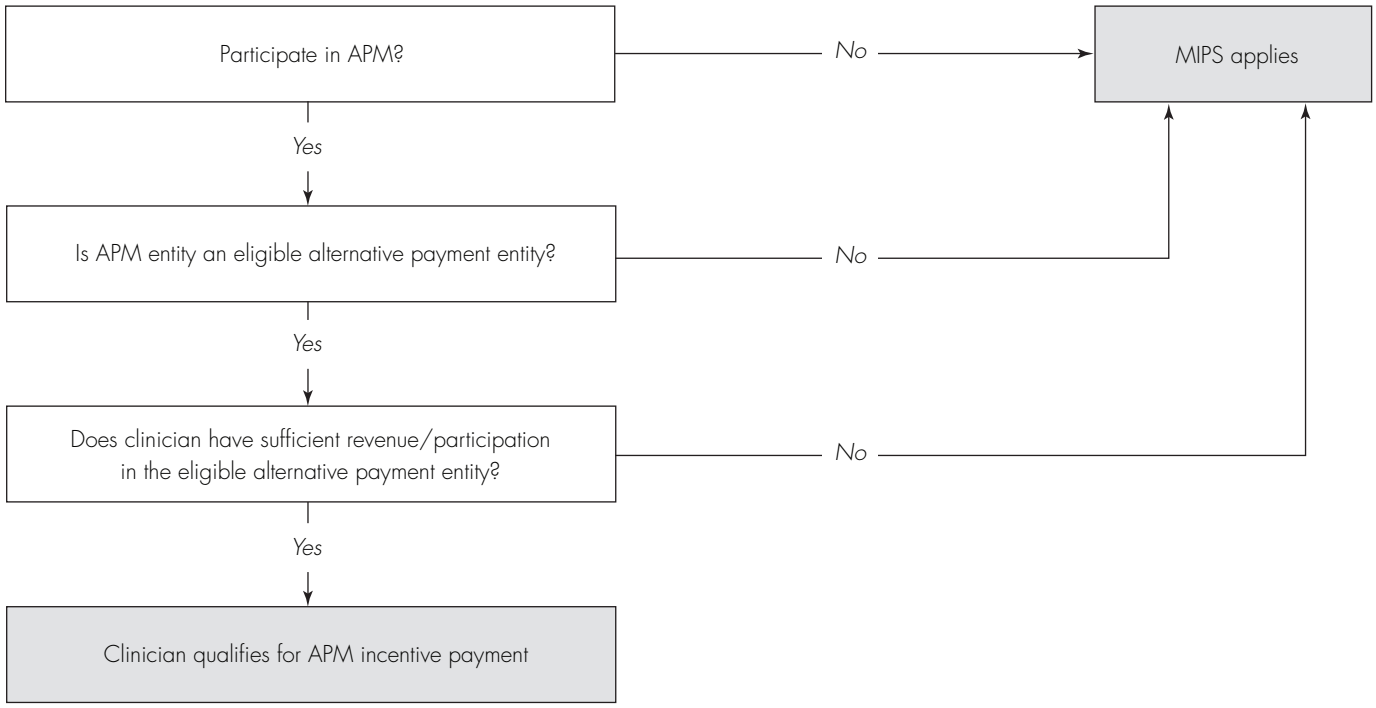
For example, clinicians can elect to be in an APM in 2017, but CMS may not make the determination of whether they are qualifying APM participants until 2019. If CMS determines that they are not qualifying APM participants, then the MIPS applies, so clinicians may need to report on measures required by MIPS in the years before 2019. (Currently, some payment models allow entities to report quality as a substitute for PQRS. CMS could choose to take a similar approach with respect to MIPS.)

Principles for eligible alternative payment entities

MACRA lays out the basic requirements for EAPEs and the thresholds clinicians must reach to be qualifying APM participants. CMS will write the regulations for the implementation of MACRA with more detail on how EAPEs will qualify. The Commission recommends certain principles to inform the development and implementation of EAPEs. These principles represent a

FIGURE 2–4

MIPS is the default option for clinicians at multiple points



Note: MIPS (Merit-based Incentive Payment System), APM (alternative payment model).

departure from MACRA in some cases to help further shape a program oriented toward controlling costs and improving quality in Medicare.

The basic principles are as follows:

- Clinicians should receive an incentive payment only if the eligible alternative payment entity in which they participate is successful in controlling cost, improving quality, or both.
- The eligible alternative payment entity should be at financial risk for total Part A and Part B spending.
- The eligible alternative payment entity should be responsible for a beneficiary population sufficiently large to detect changes in spending and quality.
- The eligible alternative payment entity should have an ability to share savings with beneficiaries.
- CMS should give the eligible alternative payment entity regulatory relief.
- Each eligible alternative payment entity should assume financial risk and enroll clinicians.

The subsequent principles build from the first principle that incentive payments should be made only if the EAPE is successful in controlling cost, improving quality, or both. In other words, incentive payments would be available only for clinicians in entities that improved value for their beneficiaries. Notably, this principle departs from the MACRA legislation; incentive payments under MACRA are made to qualifying APM participants irrespective of the entity's performance. This first principle derives from the Commission's long-held view that Medicare payments should not be dictated by the status of the provider but rather by the value of the service provided to the beneficiary. For example, our work on paying the same amount for the same service across settings has resulted in recommendations for equalizing payments for certain services whether provided in hospital outpatient or clinician office settings (Medicare Payment Advisory Commission 2014b, Medicare Payment Advisory Commission 2012). This principle, as it applies to APMs, is discussed in the following sections.

The Physician Quality Reporting System, value-based payment modifier, and meaningful use of electronic health records

Under current law, CMS oversees three key programs that adjust payments for physicians and other health professionals based on performance: the Physician Quality Reporting System (PQRS), the value-based payment modifier (also called the value modifier (VM)), and payment adjustments for the meaningful use of electronic health records (EHRs).

Physician Quality Reporting System

Under current law (from 2015 through 2018), eligible professionals who do not satisfactorily report under the PQRS receive a payment adjustment of –2 percent. To avoid a downward adjustment in 2018, eligible professionals must submit data on nine PQRS measures in 2016, covering at least three of the National Quality Strategy domains. Eligible professionals for whom fewer than nine measures apply must report on the measures that apply to them for more than 50 percent of all of their patients.

Currently there are at least 10 ways that clinicians can report PQRS measures or report through an alternative mechanism, depending on whether they report as a group or as an individual and whether they participate in the Comprehensive Primary Care Initiative or an accountable care organization model (Centers for Medicare & Medicaid Services 2015a).

Value-based payment modifier

Current law requires that CMS develop and apply a VM to individuals billing under the fee schedule. This VM must adjust fee schedule payments for each clinician based on the quality of care provided to Medicare beneficiaries as compared with the cost of that care. By law, the VM first applied to payments in 2015, and using a phased approach starting with the largest clinician practices, will apply to all individual clinicians and clinician groups by 2017.

TABLE 2–1

Measures included in the value-based payment modifier

Type of measure	Measure
Quality measures	The PQRS measures reported by the clinician
	Patient experience (CAHPS® measures)
	Claims-calculated measure: All-cause readmissions
	Claims-calculated measure: Potentially preventable admissions (acute conditions)
	Claims-calculated measure: Potentially preventable admissions (chronic conditions)
Cost measures	Claims-calculated per capita costs: All beneficiaries
	Claims-calculated per capita costs: Beneficiaries with diabetes
	Claims-calculated per capita costs: Beneficiaries with coronary artery disease
	Claims-calculated per capita costs: Beneficiaries with chronic obstructive pulmonary disease
	Claims-calculated per capita costs: Beneficiaries with heart failure
	Claims-calculated Medicare spending per beneficiary

Note: PQRS (Physician Quality Reporting System), CAHPS® (Consumer Assessment of Healthcare Providers and Systems®). CMS may elect to not use some measures for certain clinicians if there are insufficient numbers. Only large groups must report the CAHPS measures.

Source: CMS. Revisions to payment policies under the physician fee schedule and other revisions to Part B for calendar year 2016. CMS–1631–P.

(continued next page)

The Physician Quality Reporting System, value-based payment modifier, and meaningful use of electronic health records (cont.)

TABLE 2–2 **Maximum value-based payment modifier payment adjustments in 2018**

		Low quality	Average quality	High quality
Physicians, NPs, PAs, CNSs, and CRNAs in groups with 10 or more eligible professionals	Low cost	0.0%	+2.0x	+4.0x
	Average cost	–2.0%	0.0%	+2.0x
	High cost	–4.0%	–2.0%	0.0%
	Did not report PQRS	–4.0%	–4.0%	–4.0%
Physicians, NPs, PAs, CNSs, and CRNAs in groups with 1 to 9 eligible professionals	Low cost	0.0%	+1.0x	+2.0x
	Average cost	–1.0%	0.0%	+1.0x
	High cost	–2.0%	–1.0%	0.0%
	Did not report PQRS	–2.0%	–2.0%	–2.0%

Note: NP (nurse practitioner), PA (physician assistant), CNS (clinical nurse specialist), CRNA (certified registered nurse anesthetist), PQRS (Physician Quality Reporting System). The amount of the total value-based payment modifier increase (x) will be calculated after the end of the performance period based on the penalties and downward adjustments. There will be an increase in the positive payment adjustment for clinicians or groups with average or high quality who have a relatively high average beneficiary risk score. The maximum adjustments are bigger for large groups because CMS applies smaller adjustments to groups/individuals who are newly measured.

Source: CMS. Revisions to payment policies under the physician fee schedule and other revisions to Part B for calendar year 2016. CMS–1631–P.

The VM is calculated in two steps for each clinician or group at the level of the tax identification number. First, an eligible professional must successfully report on a minimum number of quality measures through PQRS. Those who do not successfully report through PQRS are subject to an automatic negative payment adjustment under the VM (in addition to the PQRS penalty).

Clinicians who successfully report PQRS measures then move on to the cost and quality tiering process (based on the measures in Table 2-1). The quality and cost measures are risk adjusted, and an attribution process exists for the claims-based measures. The cost measures are adjusted by specialty. CMS is phasing in the VM by clinician group size. In 2015, groups of 100 clinicians or more were subject to the VM.

In the first year, each clinician or group is measured, and they have the option of electing a zero adjustment. (For example, in 2017, all individuals and groups are subject to the VM, but solo practitioners, who will be in their first year, could elect no adjustment.) By 2018, all groups and individual clinicians will be subject to the VM under the terms shown in Table 2-2. In 2019, the VM will be repealed and replaced with MIPS.

Meaningful use of electronic health records

Under the American Recovery and Reinvestment Act of 2009, eligible professionals and hospitals were able to receive incentive payments for the meaningful use of certified electronic health record technology from 2011 through 2014 through either Medicare or Medicaid. Under the Medicare EHR incentive payment program, up to $44,000 was available to clinicians who demonstrated meaningful use.

Beginning in 2015, eligible professionals who do not successfully demonstrate EHR meaningful use are subject to a payment penalty, starting at 1 percent and increasing each year that an eligible professional does not demonstrate meaningful use, to a maximum of 5 percent. To avoid a payment penalty in 2015, clinicians had to attest that they met the 10 measures and objectives outlined in regulation as "Modified Stage Two" of EHR meaningful use. ■

In addition, the principles work together. For example, EAPEs could receive regulatory relief from statutory requirements designed to protect against overuse only if they are at risk for total Part A and Part B spending for their attributed beneficiaries. Similarly, having a beneficiary population of sufficient size to detect changes in spending or quality is of particular importance when measuring total spending and the kinds of population-based outcome measures (such as avoidable hospitalizations) of greatest importance to beneficiaries and the program.

Clinicians should receive incentive payments only if the eligible alternative payment entity in which they participate is successful at controlling cost, improving quality, or both

In the Commission's view, incentive payments should not be awarded for simply participating in an EAPE but should also be contingent on quality and spending performance. Performance already has some importance, in that the EAPE must—with an exception for certain medical homes—bear financial risk for monetary losses in excess of a nominal amount. However, if that risk for the entity were very low, it might be outweighed by the guaranteed 5 percent incentive payment for the clinicians, and so they might not have sufficiently strong incentive to control their spending.

An argument for awarding incentive payments simply for participating in an EAPE could be that investment is needed in new models and that they cannot be expected to work right away. Change is difficult in itself, and moving to something different requires an impetus. By this logic, it might be reasonable to have Medicare provide the initial investment to get models started and allow providers to invest in the tools needed to change how they provide care.[9]

However, a concern about rewarding providers for simply being in an EAPE as a transitional policy rather than rewarding the entity's performance is that, once a program is in place, historically Medicare has found it difficult to reduce rewards for being in a particular program or achieving a certain designation. Thus, one could argue that EAPEs should be required to meet a performance goal from the start. If the defining criteria for EAPEs are broad and do not require improved performance, it might be very difficult to roll them back if they are unsuccessful—with consequences for the sustainability of the Medicare trust funds.

The eligible alternative payment entity should be at financial risk for total Part A and Part B spending

MACRA requires that EAPEs be at financial risk (except for certain medical homes), have the capability to measure quality, and use EHRs. But entities do not have to improve value for the clinicians in them to receive the incentive payment. Making EAPEs responsible for total spending and patient outcomes might help move the FFS payment system from volume to value, encourage care coordination, and more broadly reform the delivery system. EAPEs could be at risk for total spending for a year or for an episode of care, depending on how the EAPE is defined. Risk in this context means that an entity would get a reward if performance exceeded expected performance and a penalty if actual performance were less than expected performance.

EAPEs should be at risk for total Part A and Part B spending, initially.[10] Under an ACO-like design, if spending is lower than a target, the APM would share in the savings, and if spending is higher than the target, the APM would share in the loss (the design could include limits on the loss or gain, such as risk corridors). The sharing percentage could be adjusted by performance on quality measures. Other designs, such as a per beneficiary payment that is contingent on performance calibrated to total Part A and Part B spending, could also be contemplated. Such approaches would limit risk yet still hold with the principle of performance being assessed on total Part A and Part B spending.

The basic argument for making the EAPE accountable for all Medicare spending per year for an attributed or enrolled patient is twofold: Such accountability is necessary (1) to achieve the clinical and financial integration promised by a reformed payment system and (2) to reduce the risk of excess spending without value.

We illustrate the importance of this principle by looking at the extreme alternative—holding the EAPE responsible only for the direct spending delivered by clinicians in the entity (that is, only fee schedule services).[11] This alternative would be unlikely to lead to improved value. First, there would be no incentive to coordinate care or reduce unnecessary services provided outside the entity. For example, there would be no reward for reducing readmissions because that would be a service delivered by a hospital, not by the EAPE's clinicians. A model in which the entity was at risk for only its direct revenue

would thus produce a disincentive for true savings or care coordination. In addition, such a design would encourage the entity's primary care clinicians to reduce their direct services and refer to specialists outside the entity—conceivably the direct opposite of what would be desirable to improve quality and control total spending.

Second, the structure of the APM incentive payment could reinforce FFS incentives to increase volume, particularly if the entity is responsible only for the spending of its own clinicians. The level of the APM incentive payment is based on the clinician's FFS revenue. A clinician who bills more services to Medicare receives a higher APM incentive payment than a clinician who bills fewer services to Medicare. Indeed, if the amount of revenue "at risk" is capped at 2 percent of the entity's own billing and the incentive payment is 5 percent, providing additional services would net 100 percent of billing plus at least 3 percent. The incentive to provide more (or more intensive) services would be even greater than it is now. This scenario also underscores the importance of defining what spending the EAPE is responsible for and the meaning of "risk above a nominal amount."

The eligible alternative payment entity should be responsible for a beneficiary population sufficiently large for CMS to detect changes in spending or quality

The third principle is to require EAPEs to be responsible for a sufficient number of beneficiaries for CMS to reliably detect changes in spending or quality.

Detecting changes in spending

The statute requires that an EAPE bear financial risk for monetary losses in excess of a nominal amount. To determine whether a loss occurred, CMS has to determine what spending the entity is responsible for, what that spending would have been for these beneficiaries in the absence of the entity (a spending benchmark), and what spending actually occurred.

To measure spending reliably, a sufficient number of cases are needed so that the signal is not overcome by the noise of random variation. This requirement is of particular importance when the EAPE is responsible for all Part A and Part B spending for an attributed patient. As an example, the MSSP requires that a minimum of 5,000 beneficiaries be attributed to an ACO. Even with 5,000 beneficiaries, there is sufficient random variation that the difference between actual and benchmark spending must exceed 3.9 percent to be counted as meaningful (in the case of one-sided-risk MSSP ACOs). Requiring EAPEs to be responsible for a minimum number of beneficiaries or cases could further restrict the number of entities that qualify, but otherwise it would be difficult to determine whether a meaningful change in spending occurred. One way to reach a minimum number would be to allow EAPEs to aggregate geographically dispersed clinicians to increase the number of attributed beneficiaries. This strategy is currently being used by certain rural MSSP ACOs.

Detecting changes in quality

The Commission supports assessing quality performance for ACOs and MA plans in comparison with local FFS performance on the basis of a small number of measures primarily focused on outcomes, such as potentially avoidable hospital admissions and emergency department visits, readmissions, mortality, and patient experience (Medicare Payment Advisory Commission 2014a). To do so, a minimum number of attributable beneficiaries for EAPEs is necessary for CMS to detect changes in performance on these key outcome measures.

MACRA requires that EAPEs have quality measures "comparable" to MIPS. This requirement links the two paths explicitly. However, MIPS, in contrast to EAPEs, is designed by law to assess performance at the individual clinician level, which poses a number of technical challenges. In any case, the methodologies used for quality measures in MIPS should not constrain EAPEs from innovating with respect to quality measurement. One way to ensure that constraint does not occur is to break the statutory link between EAPE quality and MIPS quality, or to interpret "comparable" quality measures in the broadest way possible. Another way is to ensure that the MIPS quality measurement process is less burdensome to clinicians and focuses on the most effective measures.

Eligible alternative payment entities should have the ability to share savings with their beneficiaries

One of the challenges for EAPEs will be to encourage involvement of the beneficiaries in their care decisions and incentivize use of providers that increase value. Beneficiary involvement would help entities' efforts to control spending and improve quality. Strategies to affect beneficiary behavior could include lower cost sharing for using providers in the entity or a reward after the fact if most visits were with entity providers (this is the route

proposed in the Next Generation ACO program). The Commission has noted that the lack of any mechanism for beneficiaries to share in savings accruing to ACOs was a shortcoming of that program and suggested that reduced cost sharing for primary care services in the ACO be allowed. If CMS could incorporate opportunities for beneficiaries to share in potential savings of EAPEs, the entities might be able strengthen beneficiary engagement.

CMS should give eligible alternative payment entities certain regulatory relief

Certain existing Medicare regulations were designed to prevent excessive service use. To the extent that an EAPE is at two-sided risk for total Part A and Part B spending, the entity could be given relief from some of those regulations. For example, Medicare statute requires a three-day inpatient hospital stay before use of a skilled nursing facility (SNF). In the case of an entity with two-sided risk, this regulation could be waived because the entity has a strong incentive not to overuse SNF stays that are not clinically appropriate (particularly if the SNF is not in the ACO). The Commission's work on ACOs has established the principle that ACOs bearing two-sided risk should be given regulatory relief. Similarly, EAPEs, to the extent that they are at risk, could be given relief from certain regulations. However, the extent to which the entity is at risk would dictate the regulatory relief provided.

Each eligible alternative payment entity should assume financial risk and enroll clinicians

Each EAPE should have a single body (such as a governing board) responsible for assuming risk, enrolling or certifying clinicians, and allocating bonuses or losses. From the entity's perspective, the power of the incentive is increased by allowing the EAPE to make its own rules for sharing savings and losses among its clinicians in a way that would reinforce incentives for care coordination and higher quality. Otherwise, it would need to be subject to CMS's administration of risk, enrollment, and rewards, which would not likely be optimal for payment entities in different geographic areas.

From CMS's perspective, the EAPE is at risk for financial loss. If that entity is not defined clearly, CMS would have to allocate losses and rewards to clinicians individually. That approach may be feasible, but difficult to carry out.

Delegating the responsibility of allocating rewards and penalties from the Medicare program to a single responsible entity would give maximum flexibility for delivery system reform. Each EAPE will differ in terms of the patients it serves, the delivery system in which it operates, and the resources available to improve patient care. Thus, a single body could allocate bonuses and penalties in ways that maximize value.

Implementation issues

Certain implementation issues will arise regarding EAPEs. They include defining what is "risk in excess of a nominal amount," specifying how beneficiaries and providers are attached to entities, and limiting beneficiaries and providers to a certain number of entities. Some of these issues could be addressed in regulations while others may require legislation.

Defining risk in excess of a nominal amount

MACRA requires that EAPEs be at "risk in excess of a nominal amount." This requirement could be construed as a very small amount of risk—for example, the "risk" of the entity's investment in setting up the entity. We have defined *risk* in this report to mean that an entity would get a reward if performance exceeded expected performance and a penalty if performance were less than expected.[12]

It follows from our principles that the EAPE should be at sufficient financial risk to motivate clinician improvement and counter FFS volume incentives. First, there must be sufficient incentive to motivate clinicians to improve the quality of the care they deliver. Forming entities, figuring out what processes to improve, changing processes, and making improvement continual all require effort and investment. The possible reward would need to be perceived as being sufficient to make that investment pay off. Part of the reward for clinicians would be the 5 percent incentive payment on clinician revenue and part would be the prospect of a reward if actual spending were below expected spending. Second, without sufficient risk, the FFS incentive to increase the volume of services that clinicians can bill for is undiminished and in fact reinforced because the 5 percent bonus is computed on the clinician's total FFS revenue (not just the revenue coming through the EAPE). Thus, the incentive to reduce spending must be sufficient to counter this increased volume incentive as well.[13]

Although being at financial risk in excess of a nominal amount does not seem to be a significant threshold,

currently only a small number of models could truly qualify if "risk in excess of a nominal amount" is defined as the difference between actual and expected benefit spending. A few existing models presently have shared risk for total population costs (Pioneer ACOs, Track 2 and Track 3 MSSP ACOs, Next Generation ACOs, and some End-Stage Renal Disease Seamless Care Organizations). Another select few have shared risk for a certain episode or time frame (Bundled Payments for Care Improvement).

Attributing or enrolling beneficiaries

The Medicare program currently uses several methods to attribute beneficiaries to entities (see online Appendix 2-B, available at http://www.medpac.gov). In addition to attribution methods (which are passive), there are also enrollment methods (which are active). Attribution is used in the MSSP ACO program, and enrollment is used for Medicare Advantage. The Pioneer ACO model uses attribution as the principal method, but there was a limited test of enrollment in addition to attribution. That model of attribution plus limited enrollment is being extended to the Next Generation ACOs also. Under MACRA, a key implementation decision will be to decide whether alternative payment models should be required to use passive attribution of beneficiaries, active enrollment of beneficiaries, or a combination of both.

Under passive attribution, beneficiaries are associated with an entity without the beneficiary making any active choice. For example, beneficiaries are attributed to MSSP ACOs based on their Medicare claims history. Passive attribution has three advantages relative to enrollment for an EAPE: (1) the entity does not have the expense of marketing itself to beneficiaries; (2) it gives the entity a better chance to have a sufficient number of beneficiaries to reliably measure performance; (3) it helps ameliorate concerns about selection—that is, the possibility for the providers to steer patients with certain characteristics into or out of the entity. Beneficiaries could be attributed to the entity and subsequently given a chance to opt out, but they would not be required to opt in (enroll). Behavioral economics has shown that an opt-out scenario such as passive attribution is much more likely to engender participation than an opt-in scenario (Choi et al. 2002). However, beneficiary engagement—involving beneficiaries in helping make their health care decisions—can be much lower in an opt-out scenario because beneficiaries do not take an active role in signing up or enrolling. For example, in the Medicare ACO models (in which beneficiaries are free to go to any provider participating in Medicare), some ACOs have had trouble motivating beneficiaries to use providers in the ACO instead of outside the ACO. This situation can make it more difficult to coordinate care and control spending.

The basic argument for enrollment is that beneficiaries should have the choice to join or not join an entity that could have an effect on their health care. If a beneficiary had to enroll to be in an EAPE, the beneficiary would be more engaged and be more aware of the entity's goals. However, for this to happen, there would need to be a marketing and education effort before the beneficiary made that choice. Either CMS or the EAPE would have to develop and fund that effort. In addition, enrollment could theoretically lead to selection problems, which could argue for limiting it. For example, enrollment in Pioneer ACOs was limited to beneficiaries who had been attributed in previous years to forestall selection issues.

One form of enrollment is attestation. Attestation is a declaration by a beneficiary that a certain clinician is the beneficiary's chosen primary care provider. The advantage of attestation in an APM context is that beneficiaries do not have to be aware of the existence of an EAPE, but just need to know who they commonly go to for care.[14] There are some precedents that suggest beneficiaries are willing to designate which clinician is their primary care provider. For example, in the Chronic Care Management (CCM) payment code, beneficiaries consent to receive CCM services from a provider and even pay for that privilege; there is cost sharing for the CCM payment (although thus far there has been relatively low use of the CCM code). More beneficiaries might be willing to select a primary care provider if that choice were associated with additional benefits or lower cost sharing (for the use of providers in the EAPE vs. providers outside, for example). A beneficiary's selection of a primary care provider could be considered selecting the EAPE that the primary care provider participates in. Such a design could be combined with passive attribution to increase the number of beneficiaries in an EAPE and yet preserve beneficiary choice and increase beneficiary engagement.

Restricting the number of EAPEs a beneficiary or a provider can be in per year

MACRA appears to permit clinicians to participate in, and beneficiaries to be attributed to, multiple EAPEs in a year. There are pros and cons to restricting the number

of entities in which either a clinician or a beneficiary can participate in during the year. Limiting the number of entities per beneficiary (e.g., by specifying that the EAPE must be at risk for all spending for the beneficiary for the full year, or stating that beneficiaries cannot be in more than one EAPE at a time) would simplify assessing performance and calculating incentive payments. This method could also improve coordination if beneficiaries know that one provider or entity is responsible for the full continuum of their care.

On the other hand, limiting the number of entities per beneficiary or provider would decrease the number of such entities and could restrict options for certain specialties. For example, if the number of EAPEs were limited to only one per patient per year, entities in bundled payment models could be less likely to have many patients attributed to them because some patients may already have been attributed to a different EAPE.

Also, if beneficiaries are attributed to EAPEs based on their relationship with a clinician, that clinician would need to be unequivocally associated with one entity so that the beneficiary could be attributed unequivocally to that same entity. Clinicians who are not used for attribution could still participate in multiple entities.

Considerations for MIPS

MIPS sets out the framework for Medicare to measure and report clinicians' performance and to adjust their payments. To start with, MIPS consolidates the three existing performance programs: the PQRS, meaningful use of certified EHR technology, and the VM. MIPS will assess clinician performance in four areas—quality, resource use, meaningful use of certified EHR technology, and clinical practice improvement activities. MIPS is the default option for clinicians who make no affirmative choice to join an EAPE and will apply to clinicians who do participate in an EAPE but do not have sufficient revenue coming through the EAPE to meet the statutory minimum participation level.

Policy making with respect to MIPS will build on Medicare program experience with the performance systems currently in use—PQRS, VM, and meaningful use of certified EHR technology. Medicare's experiences with these programs give some insight into the challenges facing individual clinician performance measurement.

Attempts to measure clinician performance have limitations

Since 2007, CMS has had a clinician-level quality reporting system (i.e., PQRS), to which additional requirements and capacities have been added to build to a value-based purchasing program for clinicians. The VM began applying to clinicians and clinician groups in 2015.

Along the way, policymakers have learned several lessons. The first is the questionable utility of the PQRS measures. PQRS consists largely of clinician-reported process measures such as whether the clinician ordered the appropriate tests or conducted appropriate follow-up. The benefit of such measures is that they are completely within the clinician's control. The drawback is that the measures are often poor signals of ultimate outcomes of importance to the patient (such as improvement in functioning or avoiding unnecessary hospital stays). For example, the most commonly reported measure in PQRS (with 110,000 clinicians reporting in 2014) is measure 130: *Documentation of Current Medications in the Medical Record* (Centers for Medicare & Medicaid Services 2015a). While documentation of medications is important, reporting that this happened (often requiring chart review or EHR extraction) to Medicare adds a burden that may not be commensurate with the value of the measure. Reporting and analyzing such ineffective measures absorbs resources for clinicians and CMS that could be used in a more productive way.

In addition, performance on these clinician-reported process measures is often tightly clustered, limiting the ability to differentiate clinicians based on their performance. Some measures are "topped out," which means that virtually all providers report doing them. One example of a measure that is topped out is measure 242: *Coronary Artery Disease (CAD) Symptom Management*, which had a mean performance rate of 99.9 percent in 2014 (Centers for Medicare & Medicaid Services 2015a). In general, if one goal of quality measurement is to spur improvement, it is unlikely to do so if all clinicians can perform well on the measures without actually improving.

A different approach to quality measurement, which the Commission finds of greater value for assessing the performance of groups such as ACOs and Medicare Advantage plans, is to focus on outcome measures (such as readmissions, mortality and patient experience) (Medicare Payment Advisory Commission 2014a). However, these measures are not as statistically reliable as

process measures at the individual clinician level and must be risk adjusted. In addition, claims-based and patient-experience measures require attribution to clinicians, who may not feel that they should accept full responsibility for (or could influence) the outcome at hand.[15]

CMS has attempted to straddle these two approaches in the current VM. The VM uses nine clinician-reported PQRS measures, three claims-based avoidable-hospitalization measures, and six claims-based resource use measures. The use of both clinician-reported quality measures (clinicians choose their 9 from nearly 300 PQRS measures) and claims-derived measures (requiring minimum thresholds, risk adjustment, and attribution rules) has contributed significantly to both the program's complexity and its indeterminate findings. In the VM's first year, CMS applied it to groups with 100 clinicians or more. Of this group of large practices (for whom quality and resource use measures should be more reliable than average, given their large panel sizes), CMS determined that 80 percent of those measured could not be differentiated from average (i.e., were within one standard deviation of the mean) (Centers for Medicare & Medicaid Services 2015b).[16]

Possible paths forward

MIPS will shine a bright light on these performance measurement limitations as clinicians face increasing penalties for nonreporting and low performance and possibly large rewards for high scores. It is therefore important to improve and possibly simplify the current set of measures rather than just incorporate all the current programs into MIPS. Improving the value of the quality measure set and using claims-based quality and resource measures are two ways to move toward strengthening performance measurement. Additional issues will be risk adjustment, attribution or other methods of attaching beneficiaries to clinicians, definition of episodes, and comparison groups.

Improve the value of the quality measure set

Some of the quality measures in PQRS are inefficient, meaning that their benefit is outweighed by the burden imposed by reporting, collecting, and analyzing them. CMS should move expeditiously to eliminate such measures from the measure set, particularly those that impose a reporting burden, are poorly linked to outcomes of importance for beneficiaries and the program, and reinforce FFS incentives to overprovide clinically marginal care.

One reason for the multiplicity of measures and reporting methods in PQRS is CMS's attempt to ensure that all clinicians have multiple measures on which they can report.[17] Another way to ensure this coverage is to add clinician-level measures that can be calculated solely from claims. Of particular importance are measures of overuse or inappropriate care, especially in the FFS environment, where clinicians have a financial incentive to overprovide low-value care. CMS could consider adding more measures of low-value care to the MIPS measure set, such as claims-calculated measures of low-value care (Medicare Payment Advisory Commission 2016). CMS has retired some measures and added overuse measures in the past few years. MACRA also appropriated additional funding for CMS to develop quality measures, which represents an opportunity to improve the quality measure set.

Consider approaches using claims-based quality and resource use measures

The Commission has supported claims-based outcome measures for use in assessing ACO and MA performance (relative to FFS performance in a local area) and making payment adjustments based on quality for ACOs and MA plans that perform better than FFS in their local area (Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014a). We outline three possible considerations for using a similar approach for clinician-level performance.

Exploit and improve the measures currently in use For use in the VM, Medicare is currently calculating six resource use measures and three quality measures using claims (Centers for Medicare & Medicaid Services 2015b).[18] Some of these measures could be used more directly in the Medicare program. They could be used in MIPS, for example, or to identify persistent outliers. More claims-based measures could also be developed. In addition, some of the claims-derived measures may be more reliable than widely believed. For example, the Commission has done work showing that, for half of physicians, a relative resource use measure could be calculated with moderate reliability (Miller et al. 2010). It might be possible to improve the reliability of these individual- and group-level measures using multiple years of data, or potentially data from other payers. In addition, there may be opportunities to augment claims-based measures with information from electronic medical records that could be reported on claims.

Assess performance at an aggregate level One way to handle the problem of reliability at the individual

clinician level is instead to aggregate across providers. This aggregation is part of what makes it possible to assess ACO and MA performance using broader outcome measures. The Medicare program could assess performance across all FFS clinicians in a local area and consider whether modest payment adjustments would be appropriate at the extreme ends of performance for those clinicians considered as a group. (Although this approach would seem to create an issue similar to the SGR problem of being a collective assessment, the assessment would be at a local level, not nationwide. It might be possible to define *local* in a way that would make this assessment more acceptable to clinicians.) Such an approach could also motivate discussions of quality improvement and redirecting resources to localities needing improvement (Medicare Payment Advisory Commission 2011).

Focus on outliers The Medicare program could also use outcomes and resource use measures to focus on persistent clinician outliers—that is, clinicians whose performance diverges radically from their peers year after year. The benefit of such an approach is that it could focus Medicare's attention on clinicians with the most divergent patterns. It also could help identify clinicians with aberrant billing patterns that indicate fraud or inappropriate use. Measures of low-value care and relative resource use may be particularly relevant.

In setting MIPS policy, CMS should focus on improving the value of its quality programs

Minimizing the burden of quality reporting and maximizing the use of claims data, which the Medicare program already collects, as a source for quality measurement can improve the program in two ways. First, it will simplify the administration of MIPS. Second, it could provide a more seamless transition between the two programs (MIPS and APMs) as clinicians move from one to the other. In addition, ensuring that MIPS is consistent in principle with the kind of measurement that is most desirable for assessing ACO and MA plan performance (as well as APMs, potentially) would provide consistency across the Medicare program.

Considering MIPS and APM incentives

If one goal of MACRA is to "push" clinicians from FFS and "pull" them into EAPEs, then the incentives for clinicians must be sufficiently strong to achieve that goal. However, constructing such incentives will be a challenge (in part because clinicians in EAPEs will often continue to be paid under FFS). Giving clinicians a 5 percent incentive payment if they participate in EAPEs and meet the threshold is a strong draw. However, some clinicians may be convinced they could get rewards under MIPS that would be greater than the incentive payments for being in an EAPE—possibly with less disruption to their practice.[19]

The maximum penalties under MIPS rise from 4 percent to 9 percent over time; however, bonuses for good performance could be much higher because of the way the budget-neutrality calculation is made. For example, if there is a large share of clinicians losing 9 percent for poor performance and relatively few clinicians being rewarded for good performance, the rewards for those few could greatly exceed 9 percent.[20] Clinicians' confidence in making an a priori judgment about their relative performance under MIPS will depend on what measures are included in MIPS and how predictable performance under MIPS will be. Of particular importance will be CMS's ability to reliably differentiate among individual clinicians' performance using the MIPS framework, which in our view will be limited at best.

However, clinicians do not face a clear choice between the APM and the MIPS paths. A clinician's choice is to participate in one (or more) models and hope that the entities in which he or she participates are deemed EAPEs by CMS and that enough of his or her personal billings go through the EAPEs each year to meet the threshold for qualifying participation. Further, this calculation has to be made every year, and the threshold gets higher each year. Because a participating clinician's ability to meet the APM threshold is not a foregone conclusion, clinicians in EAPEs may also report under MIPS in the event that the APM threshold is not met. For this reason, MIPS and APMs should be aligned.

Taking similar approaches to similar issues

There are several considerations that argue for resolving issues that will arise in both MIPS and APMs in similar ways to avoid unintended consequences and to reduce the burden on clinicians when they inevitably move across programs—either by design or by circumstance. MACRA requires the quality measures for EAPEs to be comparable to those in MIPS. But MIPS could resemble the current VM and could use some inefficient quality measures because of the particular challenge of assessing quality at the individual clinician level. Clinicians will face the uncertainty of whether they will qualify to meet

the threshold for the APM incentive payment and the exemption from MIPS even if they participate in an EAPE.

The issue of how beneficiaries are attributed to an EAPE will be of consequence to determine how much of a clinician's billings go "through" the entity. At the same time, certain measures under MIPS (for example, those concerned with resource use) will also depend on how beneficiaries are attributed to clinicians. In addition, resource use will need to be defined in each program. Will it mean total Part A and Part B spending for attributed beneficiaries, as we suggest in the APM context, or something else such as episode spending? These and other issues will need to be addressed consistently across both programs to avoid opportunities for arbitrage that might otherwise arise. Such opportunities could be disadvantageous for the program and create confusion and burden for clinicians. Measurement in MIPS also should be designed to increase the value of the quality and resource use measures that clinicians report and that CMS uses for adjusting payments.

At the same time, limitations that may be present in the FFS environment (particularly those arising from the need to measure an individual clinician's performance) should not limit efforts to better measure EAPEs' performance. Certain entities may closely resemble ACOs, and the Commission has suggested that ACOs and MA plans, which have taken responsibility for Medicare spending and quality for a population of Medicare beneficiaries, could best be measured using population-based outcome measures.

Conclusion

We conclude that clinician quality reporting under MIPS should be designed to minimize the collection of inefficient quality measures and improve the overall value of the quality programs, as discussed earlier. Such a design will make it easier for all clinicians to report under MIPS if they unexpectedly do not meet the requirements to be qualifying participants in EAPEs. Resource use and other measures should track across the MIPS and APM paths to the extent possible to avoid unintended consequences. However, the end goal of using a small set of population-based outcome measures for APM entities, ACOs, and MA plans should not be compromised. In short, as regulations are written for both APMs and MIPS, these issues and definitions will have to be carefully coordinated to create the right incentives for clinicians. The right incentives will result in delivery system reforms that further the goal of controlling Medicare spending and improving quality while preserving or improving access for Medicare beneficiaries. ■

Endnotes

1 The basic MIPS adjustments are budget neutral, but there is an additional amount appropriated for high performers for a limited period.

2 The actual update in any year will be the result of all provisions in law; for example, in 2015, a misvalued code target reduced the update.

3 CMS can use either a revenue calculation or a patient calculation to determine whether a clinician meets the threshold to be a qualifying participant. Exactly what "revenue coming through" an EAPE means will be defined in regulation. It could depend on what spending the EAPE is responsible for. For example, if the EAPE a clinician is participating in is responsible for all of its attributed beneficiaries' Part A and Part B spending, then all of the clinician's billing for any of those beneficiaries could be defined as coming through the EAPE. If the EAPE's responsibility is limited to spending during an episode, then the revenue coming through the EAPE could be limited to spending billed during the episode.

4 The following is a more concrete example. The Pioneer ACO model is an alternative payment model (run through CMMI authority). The Montefiore ACO is an entity operating a Pioneer ACO. For the Montefiore ACO to be an eligible alternative payment entity, the Pioneer ACO model would have to require risk above a nominal amount, use of certified EHR technology, and payment based on quality measures comparable to MIPS.

5 The criteria for these all-payer EAPEs are largely the same as for Medicare EAPEs: The payment arrangement requires use of certified EHR technology, makes payment based on a set of quality measures comparable to MIPS, and requires them to assume risk for losses above a nominal amount, or the entity is a medical home. The financial losses language in the statute for the all-payer calculation is slightly different from the Medicare APM calculation. Specifically, the all-payer language refers to "nominal financial risk if actual aggregate expenditures exceed expected aggregate expenditures."

6 In general, partial-qualifying APM participants can elect to be excluded from MIPS payment adjustments.

7 For example, the Next Generation ACO demonstration has an option for ACOs to receive partial capitation payments.

8 Each of these terms will need to be defined in regulation. For example, *resource use* could mean the measures in use in the value-based payment modifier, which are five per capita spending measures and the Medicare spending per beneficiary measure. The category weights reflect the fully phased-in weights. In the first two years, resource use weights will be lower and quality weights will be higher.

9 Models to improve care coordination in FFS Medicare have had only modest success to date. See the Commission's June 2012 report to the Congress.

10 It is not clear how APMs could be responsible for Part D spending at this time. We are continuing to assess approaches to incorporating Part D spending into shared savings models.

11 This alternative is extreme in the sense that it is at the opposite end of the spectrum from total Part A and Part B spending. Some have proposed that the EAPE be responsible only for spending by its clinicians or the spending they directly control.

12 There could be limits on the risk involved, particularly if the APM covers small entities. These limits could involve risk corridors, caps on individual spending, or other features of the model.

13 Another option would be to limit the billing on which the 5 percent incentive payment is computed to the revenue coming "through" eligible entities. This option would eliminate the threshold requirement (e.g., 25 percent of billings in 2019) and the uncertainty of clinicians as to whether they would be eligible for the incentive payment. This approach would require a legislative change.

14 In the APM context, when beneficiaries are still free to go to any provider, attestation has very little downside for the beneficiary because the beneficiary does not give anything up in attesting.

15 Current claims-based attribution rules (like those used in the VM) can be more useful for assessing the performance of primary care clinicians than some specialty clinicians because those attributions are often based on a plurality of evaluation and management visits.

16 The Medicare program may be unable to differentiate clinicians because of both the measures in use and the small number of cases applicable for each measure.

17 Even with multiple options, in 2016, 40 percent of clinicians did not successfully report PQRS measures—and as a result accepted penalties totaling 4 percentage points.

18 The six resource use measures (called "cost measures" in the VM) are per capita spending measures for four chronic conditions, total per capita spending, and the Medicare spending per beneficiary measure.

19 These considerations might also change clinicians' judgments about the desirability of being in MA networks. Although there are many other considerations, such as being in an insurer's network for other products and the insurer's market share in the community, how a clinician thinks he or she will fare in MIPS may change the desire to accept MA plan payment rates and agree to MA plan contracting terms.

20 In the 2016 VM calculation, the upward adjustment for good performance was nearly 16 percent (or 32 percent for the highest performance) because about 40 percent of clinicians and groups subject to PQRS did not successfully report PQRS quality measures. The maximum upward adjustment by 2022 under MIPs will be 37 percent.

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CHAPTER 3

Mandated report: Developing a unified payment system for post-acute care

RECOMMENDATION

The Commission has voted to forward to the Congress the report on the unified post-acute care payment system required by the Improving Medicare Post-Acute Care Transformation Act of 2014.

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

CHAPTER 3

Mandated report: Developing a unified payment system for post-acute care

Chapter summary

Post-acute care (PAC) providers—skilled nursing facilities, home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals—offer important recuperation and rehabilitation services to Medicare beneficiaries. Though the similarity of patients treated by different PAC providers is well documented, Medicare continues to pay different prices for similar patients depending on the setting. Currently, Medicare pays for PAC services using separate prospective payment systems (PPSs) for each setting, with two of those settings encouraging the provision of therapy services over medically complex care. Furthermore, there is considerable variation in the supply and use of PAC providers across the country. There is also an absence of evidence-based criteria guiding decisions about where beneficiaries should be treated and how much care they should receive. While a common payment system does not address all of these shortcomings, it would begin to base payments for PAC on patient characteristics, not on the site of service, and begin to eliminate the distinctions between settings.

Section 2(b)(1) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) requires the Commission to develop a PPS spanning the four PAC settings, using the uniform assessment data gathered during CMS's Post-Acute Care Payment Reform Demonstration (PAC–PRD). The Act requires the Commission to submit a report by June 30, 2016, that recommends features of a unified, cross-setting PAC payment system and,

In this chapter

to the extent feasible, considers the effects of moving to such a system. IMPACT also requires the Secretary of Health and Human Services to collect and analyze common patient assessment information and submit a report to the Congress recommending a PAC PPS. The Secretary's report is expected sometime in 2022. After the Secretary's report, the Commission is required to submit a second report outlining the details of a prototype design for a PAC PPS, which, according to the statute, will be due in 2023.

This chapter meets IMPACT's requirement for the Commission's first report. The Commission voted to forward to the Congress this report on the design of a unified post-acute care payment system.

We used a two-part strategy, each with its own data set, to consider the design of a unified PAC PPS and estimate the effect of a PAC PPS. First, we used data from the PAC–PRD to develop models that predicted the cost of PAC stays using patient and stay characteristics. Costs predicted this way could form the basis of payments under a PAC PPS. The PAC–PRD gathered uniform information about patients that is currently unavailable for other stays (such as their functional status and the costs of the routine care they received), but its sample is limited. So while the sample could illustrate what a "best possible" design might include, its lack of representativeness undercuts its utility in modeling a new payment system's effects. Therefore, after confirming that administratively available data could accurately predict the costs of most stays, we used a second large data set (all PAC stays in 2013) to further explore the design and impact of a PAC PPS.

Our work confirms that a PAC PPS is feasible and within reach. Given the long-standing problems with Medicare's payment for PAC, moving to a unified PAC PPS is highly desirable. However, a truly reformed PAC payment system will ultimately need to embrace episode-based payments to focus providers on the care needs and outcomes of a patient throughout the episode of care and to dampen the incentives to furnish unnecessary services. In the interim, a uniform PPS that bases payments on patient characteristics will focus providers on each beneficiary's care needs while reducing program spending on unnecessary services.

Design of a PAC PPS

Models that use patient characteristics were able to accurately predict the average costs of most stays. We "stress tested" the models by examining how accurate the predictions were for 40 patient groups, including 4 definitions of medically complex stays, and found the models were accurate for almost all of the groups. Regarding patient groups with predicted costs that differed substantially from the stays' actual costs, current practices (such as the provision of therapy unrelated to patient

characteristics) or the cost structures of high-cost settings explained the results. We conclude the following:

- It is feasible to develop a common unit of service (a stay) and a uniform adjustment method.
- Patient and stay characteristics can form the basis of risk adjustment.
- Given differences in coverage across PAC settings, separate models should be used to establish payments for ancillary services other than therapy, called nontherapy ancillary services, and for the combination of routine and therapy services.
- Because the costs of HHAs are so much lower compared with institutional PAC care, payments for stays in HHAs will need to be adjusted to avoid large overpayments to these agencies.
- Available administrative data can accurately predict the costs for most PAC stays, but patient assessment data collected using a common assessment tool can increase the accuracy for certain types of stays.
- A short-stay outlier policy (to prevent large overpayments) and a high-cost outlier policy (to prevent large losses by providers and protect beneficiary access to care) will be necessary components.
- There is not strong support for the current adjusters for rural providers or IRFs that participate in teaching programs.
- Payment adjustments to capture differences in costs beyond providers' control (such as the cost of labor) should be made on an empirical basis only and should apply to all stays, regardless of setting.
- Initial payments can be based on current practices and costs, but over time, payments should be revised to reflect appropriate, high-quality care provided as efficiently as possible.

Impact of a PAC PPS

We estimate that a PAC PPS would redistribute payments among types of stays (e.g., from physical rehabilitation to medically complex care) and from higher cost settings and providers to lower cost settings and providers. Under a PAC PPS, the profitability would be more uniform across different types of stays or patients; therefore, providers would have less financial incentive to admit certain types of patients over others. At the same time, payment would no longer be based in part on the number of services furnished, so providers would have less financial incentive to provide unnecessary services. Our estimates should be thought of as indicating the direction that the redistribution of payments would take and the relative cost values, but should not be thought of as point estimates. Given the objective of a PAC PPS

to base payment on patient characteristics rather than setting, policymakers should expect these directional impacts.

Based on Medicare's experience with the implementation of setting-specific payment policies, we would expect PAC providers to be responsive to the policy changes that would accompany a PAC PPS. Specifically, we would expect high-cost providers to lower their costs to match the PAC PPS payments and all providers to change their coding practices to record patient diagnoses more completely. In addition, we would expect providers to be less likely to engage in financially motivated selection of certain types of patients over others. In the interim, a transition period, during which providers are paid a blend of "old" and "new" rates, would give providers time to adjust their costs. A high-cost outlier policy that begins with a relatively large outlier pool (but made smaller over time) would help providers adapt and protect patient access to needed care.

Conforming regulatory requirements

As Medicare begins to pay PAC providers under a single payment system, it needs to give providers more flexibility to offer services that span the PAC continuum of care. The Commission considered setting-specific regulations that might be waived when the PAC PPS is implemented. Two time lines should be considered for waiving regulatory requirements:

- ***Near term***—Concurrent with the PAC PPS implementation, consider waiving select setting-specific requirements.
- ***Longer term***—Develop a "core" set of conditions of participation for all PAC providers and a limited set of additional requirements for providers that opt to treat patients who require specialized care. Regulations should focus on requirements needed to be able to treat specific types of patients rather than on requirements geared to specific settings.

In addition, as Medicare moves to a unified PAC PPS, the program should consider a standard cost-sharing requirement when beneficiaries use any PAC service. Under this policy, beneficiaries could select a provider and setting based on the care they would expect to receive rather than on the financial implications of selecting one setting over another.

Implementation issues

While a PAC PPS and the accompanying companion policies would require large changes for many providers, the PAC industry has consistently shown that it is highly responsive to policy changes. Further, recent acquisition and merger activity indicates a high level of interest among at least some PAC providers in offering

a continuum of PAC. That said, to temper the initial impact of the PAC PPS, the Secretary will need to consider:

- ***The transition period***—This period refers to the number of years over which the transition from "old" to "new" payments, and the blend of the two, takes place. Given how well administrative data could accurately predict the cost of most clinical groups of stays and the extended time table outlined in IMPACT, the Secretary could consider moving ahead of schedule to implement a PAC PPS. As functional status data become available, the PPS could be revised to incorporate these patient characteristics.
- ***The level of payments***—We estimate that payments in 2013 were 19 percent higher than the cost of stays. Consistent with the Commission's recommendations over multiple years, payment rates for PAC need to come down. A transition policy should consider when and how large the rebasing should be.

Over time, the risk adjustment factors could be refined if systematic overpayments or underpayments for certain types of cases occurred. As in any payment system, the relative weights should be recalibrated regularly to reflect changes in practice patterns. The Secretary should also have the authority to periodically rebase payments so they remain aligned with costs.

Companion policies to adopt when implementing a PAC PPS

Although a common PPS for PAC stays would begin to rationalize Medicare's payments, it would not correct the underlying incentives in fee-for-service payment to increase volume or provide low-quality care if it is less costly to do so. Therefore, the Secretary should implement the following companion policies to dampen these incentives:

- a readmission policy to prevent unnecessary hospital readmissions and
- a value-based purchasing policy to tie payments to outcomes (to protect beneficiaries against stinting) and resource use (to prevent unnecessary service use, including serial PAC stays).

In the longer term, Medicare needs to move providers toward greater accountability for spending and quality over an episode of care. Providers would be at financial risk for the entire episode of care, thereby (1) dampening the incentive to generate unnecessary PAC stays or to stint on needed services and (2) encouraging care coordination. By aligning payments with the cost of stays across PAC settings, a unified PPS represents a good transition to broader episode-based payment reforms that encourage care organized around the episodes rather than settings.

The Commission underscores that until a PAC PPS is implemented, CMS and the Congress need to move forward with standing recommendations that would improve the accuracy and equity of payments within each setting. Because the current time line for implementing a PAC PPS is years away, these refinements to the individual payment systems would better align program payments to providers' costs, eliminate known biases in the payment systems, and help ensure access for beneficiaries with varying care needs.

Monitoring provider responses to the PAC PPS

When a unified PAC PPS is implemented, the Secretary will need to establish a monitoring program to detect inappropriate provider responses, including:

- choosing to treat some patients and not others;
- stinting on care that may lower quality and outcomes;
- providing unnecessary PAC stays; and
- delaying care that shifts, but does not lower, program spending.

As indicators of the adequacy of Medicare's payments, the Secretary should also track Medicare margins and cost growth. As any unintended consequences of the PPS are documented, the Secretary would need to make refinements. ■

Introduction

Post-acute care (PAC) providers—skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs)—offer Medicare beneficiaries a wide array of services, ranging from recuperation and rehabilitation services to hospital-level services. Among beneficiaries enrolled in fee-for-service (FFS) Medicare and discharged from an acute care hospital in 2013, 42 percent went on to use PAC. In 2014, Medicare spent almost $60 billion on PAC services—$29 billion in SNFs, $18 billion in HHAs, $7 billion in IRFs, and $5 billion in LTCHs.

There is considerable overlap in types of patients treated across the four settings.[1] Several factors account for this overlap: variation in the supply and use of PAC providers across the country, lack of clear criteria identifying which patients need PAC (and how much), and a dearth of evidence-based guidelines to direct beneficiaries to the setting with the best outcomes (Medicare Payment Advisory Commission 2014). Despite the overlap in patients, Medicare continues to pay considerably different rates for similar patients depending on the setting (Gage et al. 2012). Reflecting this ambiguity, Medicare per capita spending for PAC varies more than for any other type of service (Medicare Payment Advisory Commission 2011b). Because the settings overlap in the mix of patients PAC providers treat, Medicare ideally should move away from separate PAC payment systems and toward a common payment system that spans the four settings, with payments based on patient characteristics, not on the site of service.

The Congress has asked for guidance on how to establish a unified payment system by requesting two reports from the Commission. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) requires the Commission to first evaluate and recommend features of a prospective payment system (PPS) that spans the PAC settings, using the uniform assessment data gathered previously during CMS's Post-Acute Care Payment Reform Demonstration (PAC–PRD) (completed in 2011) (see text box, p. 102). In this first report, the Commission presents an approach for a unified, cross-setting PAC payment system and, to the extent feasible, considers the impact of moving to such a system. IMPACT also requires the Secretary of Health and Human Services to collect and analyze common patient assessment information and submit a report to the Congress recommending a PAC PPS. The Secretary's report is expected sometime in 2022. After the Secretary's report, the Commission is required to submit a second report outlining the details of a prototype design for a PAC PPS that, according to the statute, will be due in 2023. On this timetable, a PAC PPS would be implemented after 2023, perhaps as early as 2025.

This chapter meets IMPACT's requirement for the Commission's first report, due June 30, 2016. We found that a unified PAC PPS is feasible with the currently available administrative data, though we acknowledge that patient assessment data would improve the accuracy of payments for some types of patients. Our findings are summarized in Table 3-1, pp. 64–65. Given the well-established problems with the current PAC payment landscape, it is imperative that policymakers advance a unified PPS as soon as practicable.

Features of a PAC PPS

The primary objective of PAC payment reform is to establish a common payment system that spans the four PAC settings, with payments based on patient characteristics, not on the site of service. Under a unified PAC PPS, a common unit of service and a common base price would be established. Setting the stay as the unit of service would eliminate the incentive under per diem payments, such as in the current SNF payment system, to keep patients longer than necessary to generate additional revenues. The per stay payment would be adjusted up or down, depending on the patient's condition, comorbidities, functional status, cognitive status, and impairments. Payments would be higher for beneficiaries who were sicker or more functionally impaired when those conditions raised the cost of care. Ideally, across various conditions treated, payments would be equally proportional to the costs of the stay, so there would be no advantage to treating some conditions over others. The amount of therapy provided within a stay would no longer drive payment, thus correcting this shortcoming of the current SNF and HHA payment systems.

As in any PPS, a unified design would include the following elements:

- a uniform unit of service defining the encounter for which payment will be made (such as a stay);
- a base rate reflecting the cost to provide services included in the unit of service;

TABLE 3–1 **Summary of findings for a PAC PPS (cont. next page)**

Design features	Discussion
Common unit of service (the stay)	A common unit avoids the incentive to furnish unnecessary days or visits, but the incentive to discharge patients prematurely needs to be monitored.
Common risk adjustment using administrative data on patient characteristics	Administrative data can establish accurate payments for most types of stays. Payments are tied to patient characteristics and avoid the incentive to furnish unnecessary rehabilitation care as a way to generate payments. In the future, functional assessment data could be added to the risk adjustment.
Two payment models to reflect differences in benefits across settings	One model establishes payments for routine and therapy care; a separate model establishes payments for nontherapy ancillary care (such as drugs).
Alignment of payments for home health stays	Without aligning payments to costs of home health stays, care in this setting would be considerably overpaid.
Empirically based payment adjusters applied to all settings	Setting-specific adjusters would reinforce adverse incentives under existing separate payment systems.
High-cost outlier policy	A high-cost outlier policy helps ensure access to care for high-cost patients while protecting providers that treat them from large losses.
Short-stay outlier policy	A short-stay outlier policy protects the program from large overpayments and discourages premature discharges.
No broad rural adjusters	Results do not support a broad rural or frontier adjustment. However, the Secretary should evaluate the need for an adjustment for low-volume, isolated providers.
No IRF teaching adjustment	Results do not support an IRF teaching adjustment. Combined with an outlier policy, risk adjustment could establish accurate payments.
More data regarding an adjustment for providers treating high shares of low-income patients	Our examination found a possible need for an adjustment for IRFs with the highest shares of low-income patients; we lacked the data to examine providers in settings other than IRFs. The Secretary should evaluate the need for such an adjustment across all PAC settings.
Impact of changes	
Payment shifts among types of stays	Changes increase payments for medical and most medically complex stays and reduce payments for stays with high rehabilitation services unrelated to patient care needs.
Payment shifts among providers and settings	Changes in payments reflect a provider's mix of the types of stays it treats, its therapy practices, and its existing cost structures.
More uniform profitability across types of stays	Changes dampen incentive to selectively admit certain types of patients.
Conforming regulatory requirements	
Near term: Waiving of select regulatory requirements	The Secretary should evaluate which setting-specific regulatory requirements should be waived when the PPS is implemented. Waiving regulatory requirements would give providers flexibility to offer a broad mix of PAC services and would allow providers to begin to change their cost structures to adapt to a new payment system.
Longer term: "Core" set of requirements for all PAC providers and specific requirements to treat patients with specialized care needs	Core and specific requirements move toward uniform requirements across settings and provide flexibility to treat specialized patient care needs.
Standardized beneficiary cost sharing for PAC	Standardized cost sharing reduces the influence of financial considerations for patients choosing where to receive PAC.

Note: PAC (post-acute care), PPS (prospective payment system), IRF (inpatient rehabilitation facility).

TABLE 3–1 **Summary of findings for a PAC PPS (cont.)**

Design features	Discussion
Implementation issues	
Level of payments	Some amount of rebasing is necessary to align payments and costs.
Transition period	Transition period gives providers time to adjust their cost structures. Providers could be allowed to skip the transition and elect to be paid under the new PAC PPS. An initial PAC PPS could be implemented sooner using administrative data for risk adjustment, with future refinements to the risk adjustment implemented once uniform patient assessment data are available.
Authority for Secretary to periodically revise and rebase payments	Refinements will maintain alignment of payments to costs.
Companion policies	
Readmission policy	Readmissions policy counters the incentive to furnish poor-quality care that might result in hospital readmissions.
Value-based purchasing that includes a resource use measure	Value-based purchasing ties payments to outcomes and helps prevent unnecessary service provision, including serial PAC stays.
Monitoring	
Monitoring of quality, volume of PAC stays, and selective admissions	Measures would detect inappropriate provider responses, including stinting on care, generating unnecessary PAC stays, delaying care, and patient selection (which could indicate a misalignment of payments to costs).
Evaluation of the adequacy of Medicare payments	Evaluation signals whether payments are adequate to cover the costs of efficient providers in treating beneficiaries, thereby helping to ensure appropriate access to care.

Note: PAC (post-acute care), PPS (prospective payment system), IRF (inpatient rehabilitation facility).

- a case-mix adjustment reflecting differences in patient severity that affect costs, which would raise or lower the base rate;
- other adjusters to capture differences in costs beyond the provider's control, such as the cost of labor, and unmeasured differences in the cost of care. Under current law, some PPSs adjust payments for rural location, the unmeasured costs of training residents, and the unmeasured costs of treating low-income patients. In a unified PPS, any adjuster would apply to all settings;
- short-stay policies to adjust payments for unusually short (and low-cost) stays; and
- outlier payments to adjust payments for unusually high-cost stays.

A PAC PPS would continue to pay on an FFS basis, so incentives would remain for providers to admit patients with marginal care needs, provide the minimum number of services to obtain a full payment, and discharge patients quickly to another provider or setting. A PAC PPS, therefore, should not be considered the end point for payment reform; rather, the unified payments it would establish would represent a necessary first step in a longer term restructuring of how Medicare should pay providers.

Ultimately, the Commission believes Medicare needs to move away from FFS payment and toward integrated payment and delivery systems, such as episode-based payments. Episode-based payments would put providers at risk for all health care spending (including an average number of physician visits) and outcomes (such as readmissions) during a sustained period of time, such as 90 days. Episode-based payments would dampen the incentives to shift care beyond the initial PAC stay because providers would be responsible for care throughout the episode (though the incentive to generate PAC episodes would remain). Toward this end, in 2016, CMS will begin

Better estimates of stay-level routine costs are needed

Current Medicare claims do not include information about the relative routine resource use across stays, most notably differences in nursing care required by patients. Facilities charge a uniform room rate for all patients, but nursing costs—which on average account for about half of a post-acute care stay's costs—vary considerably across patients' nursing care needs.[2] To estimate the costs of stays accurately, CMS needs stay-level information about the variation in these routine costs. Without such information, CMS must either assign every stay or day the same routine costs (resulting in routine payments that are too high for some stays and too low for others) or rely on data collected from the Post-Acute Care Payment Reform Demonstration (PAC–PRD) that is not representative and over time will grow increasingly out of date.

For this study, we relied on the resource use information gathered by the PAC–PRD to estimate routine costs, but a long-term solution is needed so that payments can vary by differences in patients' needs for nursing care. CMS could require providers to establish differential daily rates to match the nursing requirements for the patient day. Charges would be higher for more intensive days and lower for days with lower nursing resource use. Alternatively, CMS could issue guidance on the use of existing revenue centers to bill for days with higher nursing intensity. Basing routine charges on resource needs and converting these charges to costs would make costs proportionately higher for patients with higher care needs. Another option would be to periodically field a study of resource use from a representative sample of providers. Because fielding such a study would be costly, it would be unlikely to be conducted on a regular basis, so its findings would become outdated over time. In addition, a sample would be limited in how accurate the costs could be for subgroups of stays. For these reasons, it is not a preferred solution. ■

a 5-year test in 67 markets of a 90-day bundled payment for joint replacement cases. By requiring hospitals located in these markets to participate, CMS will help ensure that participating providers are representative and that the findings will be generalizable.[3] By establishing a uniform payment based on patient characteristics, a PAC PPS would create a preferred framework on which to build episode-based payments.

Broad approach to designing a PAC PPS

This chapter meets IMPACT's requirements for the Commission's first report, due June 30, 2016. The mandate requires the Commission to use data from the PAC–PRD to evaluate and recommend features of a unified PPS. The law also requires the Commission to consider, to the extent feasible, the impact of moving from setting-specific PPSs to a unified payment system. Given time and data constraints, the Commission developed an approach to establish a common base rate and relative weights to raise or lower payments for a stay. Using this approach, we tested the feasibility of using administrative data to predict the costs of PAC stays (defined as a discharge in IRFs and LTCHs, an episode in HHAs, and the Medicare-covered days in a SNF), determined how to account for differences in costs and covered services across the PAC settings, and evaluated the accuracy with which our PAC PPS payment models predicted the costs of caring for PAC patients. We also conducted analyses to indicate the need for other payment adjustments under a PAC PPS.

Test feasibility of using administrative data to predict the cost of stays and estimate effect of a unified PAC PPS

IMPACT required the Commission to use the uniform assessment data gathered during CMS's post-acute care payment demonstration, known as PAC–PRD (completed in 2011), to evaluate and recommend features of a PAC PPS. CMS's PAC–PRD developed and tested an instrument to gather commonly defined patient assessment information across patients treated in participating SNFs, HHAs, IRFs, and LTCHs.[4] The demonstration also measured patient resource use, compared patient outcomes across settings, and developed models to explain differences in routine and therapy

TABLE 3–2 **Overview of Commission's mandate and approach to the analyses**

Mandate	Methodology	Purpose
Evaluate and recommend features of a PAC PPS using data from the PAC–PRD	• "Full" model uses data from PAC–PRD sample to predict relative costs of stays	• Use unique data in the PAC–PRD to test feasibility of a PAC PPS
Consider the impact of implementing a PAC PPS	• "Administrative" model uses only existing data to predict relative costs of stays (in PAC–PRD sample) • Full and administrative models using the same PAC–PRD stays are compared	• Assess the accuracy of administrative model (without the unique data), which could be used on a large number of stays
	• If equally accurate, use administrative model on 2013 PAC stays to estimate effects	• Estimate impact using a large number of stays

Note: PAC (post-acute care), PPS (prospective payment system), PRD (Payment Reform Demonstration).

resource use across stays. The data collected during the demonstration have unique strengths because they include information we do not have from other sources: uniform patient assessment information across the settings and stay-level routine resource use (most notably nursing costs; see text box on needing better estimates of stay-level routine costs). But participation in the PAC–PRD was voluntary, and the sample of stays and providers was small. As a result, data from participating providers was intended to be illustrative but not representative of the PAC industry nationally (Gage et al. 2012). Therefore, we needed an approach that would take advantage of the unique PAC–PRD data while compensating for the limited generalizability of the sample.

Working with researchers from the Urban Institute, we devised the following strategy to fulfill the statutory requirements to use the PAC–PRD data and model the impact of doing so (Table 3-2):

- First, to evaluate and recommend features of a PAC PPS, we developed a "full" model to predict the costs of stays using the unique data in the PAC–PRD and existing administrative data, including claims, beneficiary risk scores, and demographic information from enrollment files. The ratios of the average predicted costs to the average actual costs of stays were used to establish a relative weight for each stay, measuring how the predicted cost of any given stay compares with the average cost. When used to establish payments, these relative weights would raise or lower payment for the stay relative to the average "base" payment. The purpose of this step was to establish the relative costs of stays and test the feasibility of a PAC PPS.
- Second, because common assessment data are not available for the vast majority of PAC encounters, we built another model using only existing administrative data (the "administrative model") and analyzed the same PAC–PRD stays used in the full model.
- Third, we compared the accuracy of predicted costs using the full model with the accuracy of predicted costs using the administrative model for the same stays. The purpose of this step was to determine whether the administrative model could explain an equal share of the variation in costs across stays and if it could be used to establish payments that on average equaled the costs of stays for the broad patient groups we examined. We found that the administrative model was almost as accurate as the full model and therefore could be used to estimate the impact of a PAC PPS using the universe of PAC stays from 2013.
- Finally, to analyze the impact of a PAC PPS on patients and providers, we compared actual 2013 payments to PAC providers with simulated PAC PPS payments based on the predicted costs using the administrative model. We also compared our PAC PPS payments with the actual cost of stays to assess whether PAC PPS payments would cover the actual

costs of stays. In our impact analyses, we assumed that implementation of the PAC PPS would be budget neutral (i.e., total payments under the unified PPS would equal total actual spending in 2013); we also assumed no changes in provider behavior (Wissoker and Garrett 2016).

Account for differences in coverage and lower costs of home health care

The mandate requires the Commission to develop a PPS that spans the four PAC settings. For this work, the Commission did not consider changes to current coverage policies, which vary by setting on a number of dimensions. First, eligibility for services differs by PAC setting. Medicare covers inpatient hospital services, including those provided in IRFs and LTCHs, if it is reasonable and necessary to furnish the services on a hospital inpatient basis. In addition, for IRF services to be covered, the beneficiary must: (1) require active and ongoing therapy in at least two modalities (one of which must be physical or occupational therapy); (2) require supervision by a rehabilitation physician; and (3) be able to actively participate in and benefit from intensive therapy that typically consists of three hours of therapy a day at least five days a week. Care in a SNF is covered if the beneficiary requires skilled nursing or skilled rehabilitation services on a daily basis. Home health care is covered if the beneficiary is confined to the home and needs skilled nursing or rehabilitation services on an intermittent basis.

Notably, Medicare coverage of SNF services requires a 3-day inpatient hospital stay within the immediately preceding 30 days. No such requirement exists for coverage of IRF, LTCH, and HHA services. Because current Medicare rules do not require a prior short-term acute care hospital stay for services to be covered in these three settings, we included community admissions to these settings in our analyses.

In addition, the allowable number of days of care differs. Medicare places no limit on the number of days that home health care can be provided, as long as services meet medical necessity requirements. By contrast, Medicare limits SNF coverage to 100 days per spell of illness and covers inpatient hospital stays, including those in IRFs and LTCHs, for up to 90 days per spell of illness.[5]

Further, the services and supplies covered in the PAC settings differ. For beneficiaries in IRFs and LTCHs, Medicare covers bed and board; nursing services; diagnostic and therapy services; medical social services; and drugs, biologicals, supplies, appliances, and equipment ordinarily furnished for the care and treatment of hospital inpatients. Medicare covers the same services in SNFs (albeit often at a lower level of care). The mix of individual, group, and concurrent therapies is limited in SNFs, but not in the other settings. For beneficiaries receiving home health care, Medicare specifically excludes from coverage some services and supplies that are routinely provided in the other PAC settings, including meals or other food service arrangements, housekeeping services, drugs and biologicals, and respiratory care furnished by a respiratory therapist.

Because the costs and payments for HHA stays do not include nontherapy ancillary services (such as drugs), we 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) services costs of stays in SNFs, IRFs, and LTCHs.[6] We combined the results of the two models and evaluated the feasibility of a PAC PPS by comparing total actual costs (including zero NTA costs for HHA stays) with total predicted costs (including zero predicted NTA costs for HHA stays).

Another consideration in developing our model was the large difference in costs between home health care and facility-based PAC care. Because routine and therapy costs are so much lower for stays treated in HHAs compared with stays treated in the institutional settings (SNFs, IRFs, and LTCHs), we included a home-health indicator in the model predicting routine and therapy costs. Without this adjustment, the model would predict costs that are too high for HHA stays and too low for stays in institutional PAC settings; if used to establish payments, the model would substantially overpay HHAs and underpay the other PAC providers. The adjustment needs to be accurate so that it neither encourages nor discourages the use of HHA. The decision to use any provider should be based on the appropriateness of the care provided, not the payment incentives.

Estimate the cost of care

Ideally, a PAC PPS would base payments on the cost of furnishing appropriate care by efficient providers. In the near term, however, payments would reflect current practice that may be neither efficient nor appropriate care. The current designs of the PPSs shape the amount and mix of therapies patients receive. The SNF PPS encourages providers to furnish rehabilitation therapy because, as the

amount of therapy they provide increases, payments rise even more, making these services profitable (Medicare Payment Advisory Commission 2016, Office of Inspector General 2015). HHAs have been highly responsive to therapy thresholds included in the HHA PPS (Medicare Payment Advisory Commission 2011a, U.S. Senate Committee on Finance 2011). The PPS designs also influence the mix of therapy modalities: IRFs are required to furnish at least two therapy modalities while the SNF case-mix groups are based on the number of modalities and minutes of therapy. These payment policies encourage providers to furnish services that are not tied to patients' care needs.

In addition to payment policies, a variety of factors shape where and how much PAC beneficiaries receive. Some factors can be measured, such as differences in patients' conditions and functional abilities. However, even the best data cannot fully capture patients' clinical conditions, so unexplained differences between patients will remain. At the same time, other factors can influence where a patient is treated and the care furnished, including patient and family preferences, practicality of the beneficiary's home environment for home care, the proximity and configuration of PAC resources in the market, the acute care hospital's financial interest in one or more PAC settings, and the available PAC options at time of discharge.

Further complicating the landscape of PAC use is the lack of evidence-based guidelines to help discern which beneficiaries need PAC, how much care they need, and where those services are best provided. Few studies have compared outcomes across settings and conditions, with the PAC–PRD being the exception (see online Appendix 3-A, available at http://www.medpac.gov). In addition, coverage rules (e.g., whether there was a prior hospital stay), payment rules (e.g., an IRF must furnish intensive therapy or LTCH stays need to average 25 days), and incentives inherent in the various PPS designs also influence where and how much PAC beneficiaries receive, which in turn is captured in the cost of a stay. In summary, we know that current practice patterns do not necessarily reflect the cost of efficient and appropriate PAC use, but we do not know what the patterns of care *should* be.

PAC PPS payments could be based on the costs of the lowest cost setting that treats a certain type of patient, but this basis is not a likely starting point for designing a PPS. For example, even though most beneficiaries prefer to be discharged home, many are too frail or sick to be managed at home. Other beneficiaries who otherwise could go home do not have the necessary support to do so. Still other beneficiaries require specialized services, such as ventilator care, that in some markets are provided only in certain settings. As in any PPS design, policymakers would need to decide whether nonclinical factors should be considered in establishing payments.

Given the lack of clarity about the appropriate mix of PAC services, we based PAC payments on the current mix of settings and the costs of stays (in 2013, the year of the data used). By including all costs during the stay, the approach implicitly accepts differences in length of stay across settings that are likely influenced by payment rules and incentives. Under a PAC PPS, we expect differences in cost and length of stay across settings to narrow over time. Further, where patients are treated may shift to reflect the design and incentives of the new PPS.

Using an average of current practice patterns to establish payments is a conservative approach that would give high-cost settings and providers time to adjust their costs to lower payments inherent in the averaging. To further minimize disruptions to beneficiaries, providers, and health care markets, a transition period to the new payment system should be considered. Over time, as with Medicare's other PPSs, payments under the PAC PPS would be recalibrated to reflect changes in costs as practice patterns change. Likewise, the case-mix adjusters would be revised periodically to reflect changes in the relative costs of treating different conditions. Such revisions to base rates and case-mix adjusters are customarily required to maintain accurate payments.

Evaluate the accuracy of the relative predicted costs of stays

To evaluate the robustness of our models' estimates of PAC stay costs, we looked at two metrics. First, we assessed the accuracy of the average predicted per stay costs compared with the average actual costs across all stays and for many types of stays based on clinical condition and beneficiary characteristics (see text box on methodology, pp. 70–74). This comparison indicates whether a PAC PPS would establish accurate relative costs across all stays and the various types of stays we examined. If the models accurately predicted the average cost of stays, we could conclude that they captured the cost variation across stays. Because current HHA and SNF PPSs encourage the provision of therapy services unrelated to a patient's condition, we expected that, for some types of stays (for example, orthopedic conditions),

Methodology to estimate actual costs per post-acute care stay and predict stay costs using patient characteristics

The Improving Medicare Post-Acute Care Transformation Act of 2014 required the Commission to use the uniform assessment data gathered during CMS's Post-Acute Care Payment Reform Demonstration (PAC–PRD) (completed in 2011) to evaluate and recommend features of a single prospective payment system (PPS) to pay for post-acute care (PAC) services. The data collected during the demonstration have unique strengths because they include information we do not have from other sources: uniform patient assessment information across the settings and stay-level routine resource use (most notably, nursing costs). Because participation in the PAC–PRD was voluntary, participating providers were not representative of the PAC industry nationally. Furthermore, the PAC–PRD sample of stays and providers was small.[7] Therefore, our methodology was designed to take advantage of the unique PAC–PRD data while compensating for the sample's limited generalizability. This approach required us to estimate the costs of the stays included in the PAC–PRD sample and PAC stays in 2013.

Estimating the costs of PAC–PRD stays

The sample used to analyze the PAC–PRD stays included 107 providers and 6,409 stays across the 4 PAC settings—home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). The PAC–PRD sample is not nationally representative: Stays in IRFs and LTCHs are overrepresented, while SNF stays are underrepresented compared with their share of all PAC stays nationally. We weighted the PAC–PRD stays so that the weighted distribution across settings matched that of the national distribution of PAC stays in 2013.

To estimate therapy and nontherapy ancillary (NTA) costs, we converted charges from the PAC claims to costs using facility-specific and department-specific cost-to-charge ratios from each provider's Medicare cost report. Routine costs were estimated differently because SNF, IRF, and LTCH claims do not include patient-level measures of routine services (the claims include a flat daily room and board charge). We calculated an average routine cost per day from each provider's Medicare cost report and multiplied it by the average length of stay for stays in the PAC–PRD for that provider. Then, using the routine cost and resource-use data from the PAC–PRD, we developed a relative weight for each stay and adjusted the stay's routine cost up or down relative to the facility average.[8] All costs were standardized for differences in wages and adjusted for the growth in costs across the three years of data collection. The costs per stay included overhead costs and the costs associated with teaching programs and treating low-income patients.

Estimating the cost of 2013 PAC stays

The analysis of the 2013 PAC stays included 8.9 million stays across the 4 settings (about 10 percent of stays had missing data and were dropped). The stays included all conditions, reflecting the assumption that the PAC PPS would be used to pay for all stays regardless of principal reason to treat or the patient's comorbidities. The variables included in predicting costs per stay in the PAC–PRD data were included in the model predicting the costs of 2013 PAC stays, but the relative importance of each variable (the coefficient) was re-estimated based on the 2013 data.

The costs per stay included overhead costs and the costs associated with teaching programs and treating low-income patients (in IRFs).[9] We estimated therapy and NTA costs by converting charges on the PAC claims to costs using facility-specific and department-specific cost-to-charge ratios. All costs were standardized using the provider's wage index.

For 2013 stays, we did not have measures of routine relative resource use (see text box on needing better measures of routine costs, p. 66). Therefore, we imputed "actual" stay costs by developing a model to predict the routine resource use for the stays in the PAC–PRD—using patient characteristics and length of stay (or, in the case of HHA episodes, the number of visits)—and applying this model to the 2013 PAC stays. We calculated an average routine cost per stay from each provider's Medicare cost report and used the model prediction to adjust a stay's routine cost up or

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Methodology to estimate actual costs per post-acute care stay and predict stay costs using patient characteristics (cont.)

TABLE 3–3

Comparison of data used to predict costs per stay in the "full" and "administrative" models

Model feature	PAC–PRD stays using: Full model	PAC–PRD stays using: Administrative model	2013 PAC stays using administrative model
Predictors of costs			
Age	X	X	X
Diagnoses and comorbidities	X	X	X
Patient severity and treatments	X	X	X
Impairments	X	Some proxies	Some proxies
Functional status	X	No	No
Cognitive status	X	Proxies	Proxies
Routine (nursing) resource use	X	X	Estimated
Number of PAC stays	6,409	6,409	8.9 million
Number of providers	107	107	24,953

Note: PAC–PRD (Post-Acute Care Payment Reform Demonstration), PAC (post-acute care). The full model was based on unique patient assessment information and routine resource-use data collected during CMS's PAC–PRD, as well as readily available administrative data such as claims information from PAC stays and the preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores from the Medicare Advantage risk score files, and cost report information for PAC providers. The administrative model was based only on administrative data. Both models combine the results of a model that predicts the costs of routine and therapy care combined and one that predicts nontherapy ancillary costs.

Source: Urban Institute analysis of PAC–PRD stays and 2013 PAC stays for MedPAC.

down relative to the facility average.[10] The same patient and stay characteristics used to predict the total costs of stays were used to predict the routine costs.

Modeling the predicted cost of stays

We first developed a "full" model to predict the costs of each stay using the unique data in CMS's PAC–PRD. These data provided information on patients' motor and cognitive function and routine resource use (predominantly nursing care). In addition, we used claims information from PAC stays and the preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers (Table 3-3). Information on diagnoses and the primary reason to treat was collected from prior hospital stay claims and from PAC stay claims for patients admitted from the community. Comorbidities data were likewise collected from hospital stay claims and claims from PAC stays for patients admitted from the community. Indicators of ventilator care and severe wound care needs were obtained from the PAC stay claims. The clinical, demographic, and stay information was used to predict the cost of each stay. Although we used one model to predict the costs for all stays, we assessed the model's accuracy by examining our results for numerous clinical categories (see discussion of evaluating the design, pp. 76 and 78).

We developed two models to predict each stay's actual costs (one model for routine and therapy costs and another for NTA costs) using patient and stay characteristics. We combined the cost estimates generated by the two models and evaluated the results by comparing total actual costs (including zero NTA costs for HHA stays) with the total predicted costs (including zero predicted NTA costs for HHA stays). Similarly, under a PAC PPS, relative weights for each

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Methodology to estimate actual costs per post-acute care stay and predict stay costs using patient characteristics (cont.)

stay would be based on the total of the predicted costs generated by the two models.

We used the following information to predict the cost of stays:

- patient age and disability status;
- primary reason to treat (defined using Medicare severity–diagnosis related groups (MS–DRGs) taken from the hospital claim when there was a preceding hospital stay and simulated from PAC claims for stays without a preceding hospitalization) aggregated into broad "reason to treat" groups included in the PAC–PRD;
- patient comorbidities (taken from the hospital claim when there was a preceding hospital stay, simulated from PAC claims for stays without a preceding hospitalization);
- days spent in the intensive and coronary care units during the prior hospital stay;
- the patient's severity of illness using the all-patient refined–diagnosis related groups (APR–DRGs) based on the diagnostic information from the immediately preceding hospital stay (or simulated for patients admitted directly from the community);
- the number of body systems involved with the patient's comorbidities (taken from the hospital claim when there was a preceding hospital stay, simulated from PAC claims for stays without a preceding hospitalization);
- patient's risk score;
- patient's cognitive status;
- patient's functional status; and
- impairments and treatments (bowel incontinence, severe wounds or pressure ulcers, use of certain high-cost service items, and difficulty swallowing).[11]

The full and administrative models include the same factors except where data are not available in administrative data—functional assessment information and indicators of certain high-cost care items (complex wound care management, specialty surface or bed, and cardiac monitoring). To compensate for the lack of functional status information in the administrative models, we included information about a patient's frailty in these models.[12] The definitions of some factors differ between the full and administrative models because we substituted claims-based proxies for PAC–PRD data where approximations could be made. Specifically, the PAC–PRD data include a variable indicating the patient was on a ventilator, had bowel incontinence, or received complex care management. For the administrative models, we relied on International Classification of Diseases, Ninth Revision (ICD–9) codes in the PAC claims to indicate bowel incontinence and the presence of ventilator care. Because there was no readily available data on complex care management, we excluded this indicator from the administrative model. The PAC–PRD data include measures of cognitive function; for the administrative models, we used ICD–9 codes for coma, dementia, Alzheimer's disease, schizophrenia, and depressive disorders as proxies for this dimension. The PAC–PRD data include information on a patient's difficulty swallowing; in the administrative models, we used ICD–9 codes for dysphagia as a proxy for swallowing difficulties.

We avoided including in the model indicators of service use that might be manipulated by providers (such as the amount of rehabilitation therapy, the number of therapy disciplines, or the use of oxygen without a link to a respiratory diagnosis). However, we did include indicators for ventilator care, tracheostomy care, and continuous positive airflow pressure because the cost of these services is significant, and use is much less likely to be influenced by payment policy. We also excluded measures of socioeconomic status because they would effectively mask differences in the cost of stays depending on the share of low-income patients treated by a provider.

Costs were predicted using Poisson regression models.[13] These models were developed to evaluate whether a PAC PPS is feasible; further refinements to

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Methodology to estimate actual costs per post-acute care stay and predict stay costs using patient characteristics (cont.)

the predictors may improve their ability to explain cost differences across stays. The Secretary of Health and Human Services could decide to use a regression-based approach (similar to the PPS for psychiatric hospitals), in which the payment for each stay is based on the stay's characteristics (there are no case-mix groups but, rather, a set of adjusters that establish the payment). Alternately, the Secretary could use the results of regression models as the basis of case-mix groups.

Comparing payments and costs

To compare the estimated payments generated by our PAC PPS models with the actual costs of and actual payments for stays, actual payments were adjusted by each provider's area wage index. Thus, payments and costs exclude differences in input costs across geographic areas. Payments include any relevant adjustments for rural location, teaching, low-income share, outliers, and the amounts paid by the beneficiary (any coinsurance and deductibles).

Evaluating the design of the PAC PPS

To evaluate the potential accuracy of a PAC PPS and estimate its impact on payments, we examined the accuracy of the models in aggregate (across all stays) and their effects on many patient groups. Stays from the four settings were assigned to one or more groups based on the stays' characteristics. (We created these groups to report the results of the PPS design, but the underlying prediction models remain the same across all groups.) These groups "stress test" the models by looking at how well they perform for different clinical conditions and various definitions of medically complex patients. The groups we examined include:

Clinical condition—Twenty of the 22 clinical conditions we examined were based on information (diagnosis and procedure codes) from claims for the preceding hospital stay and, where there was no prior acute hospital stay within 30 days, from claims for the PAC stay. Two clinical conditions, ventilator care and severe wound care, were based on information from the PAC claim. For stays without a prior hospital stay, the MS–DRG assignment was simulated using information from the PAC claim. Except for stays for patients with serious mental illness, the clinical condition groups were mutually exclusive, with stays first assigned to ventilator care, then severe wound care; all other stays were assigned to a major diagnosis category (MDC) based on the MS–DRG. We report on the following 13 clinical conditions because they accounted for at least 2 percent of stays, were clearly defined, or were of particular interest:

- ventilator care;
- severe wound care;
- stroke;
- other neurology medical—medical stays assigned to MDC 1, excluding stroke;
- orthopedic medical—medical stays assigned to MDC 8;
- orthopedic surgical—surgical stays assigned to MDC 8;
- respiratory medical—medical stays assigned to MDC 4;
- cardiovascular medical—medical stays assigned to MDC 5;
- cardiovascular surgical—surgical stays assigned to MDC 5;
- infection medical—medical stays assigned to MDC 18;
- hematology medical—medical stays assigned to MDC 16 or MDC 17;
- skin medical—medical stays assigned to MDC 9; and
- serious mental illness—stays for beneficiaries with schizophrenia, bipolar disorder, or severe depression, identified using the hierarchical condition code indicators 57 or 58. This group and the other clinical groups are not mutually exclusive; a stay can be assigned to another clinical group and to the serious mental illness group.

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Methodology to estimate actual costs per post-acute care stay and predict stay costs using patient characteristics (cont.)

Medically complex—We examined four definitions of *medically complex*. The definitions (and the stays included in each) overlap to some degree.[14]

- *Multiple body systems*—stays in institutional PAC settings for patients with diagnoses involving five or more body systems. About 5 percent of stays are included in this group.
- *Chronically critically ill*—stays for patients who spent eight or more days in the intensive care or coronary care unit during the preceding hospital stay or were on a ventilator in the PAC setting. About 5 percent of stays are included in this group.
- *Severity of illness (SOI) Level 4 (the highest level)*—stays for patients assigned to the highest severity group (Group 4, indicating extreme severity) using the APR–DRG based on the diagnostic information from the immediately preceding hospital stay (or simulated for patients admitted directly from the community). About 4 percent of stays are included in this group.
- *Highest acuity patients*—stays for patients categorized as SOI Level 4 during the prior hospital stay who were not treated in HHAs (they were too sick to be discharged home) and were also on dialysis and had severe wounds. This group represents a subset of outlier stays and makes up about 0.003 percent of all stays.

Patient impairment and functional status—We looked at two aspects of patient frailty and functional status.

- *Impaired cognition*—For the PAC–PRD stays, we defined these as patients assessed as moderately or severely impaired; for the 2013 stays, we defined these as patients who were in a coma or had dementia or Alzheimer's disease.
- *High and low function*—For the PAC–PRD stays, we assigned stays to high and low function groups using Rasch motor scores, a combination of mobility and self-care at admission to the PAC setting. High and low function was defined as the top (highest functioning) and bottom (lowest functioning) quartiles of the distribution of Rasch scores. This information was not available for 2013 PAC stays; therefore, results for these groups were not reported.
- *Patient frailty*—We used the JEN Frailty Index to assign stays to the top (most frail) and bottom (least frail) of the distribution of the frailty scores.

Other stay and patient characteristics—We also examined the following patient groups:

- Low and high therapy—For institutional PAC stays, the groups include stays with the lowest (bottom quartile) and highest (top quartile) therapy costs as a share of total stay costs. For home health stays, the low group includes the 40 percent of HHA stays with no therapy costs.
- Community admissions—Patients admitted from the community, including patients with no hospital stay within the 30 days preceding the PAC stay, identified by the lack of a matching hospital claim.
- Patients with a prior hospitalization—Identified by matching hospital claims to PAC PPS claims.
- Patients with disabilities.
- Patients dually eligible for Medicare and Medicaid.
- Patients with end-stage renal disease.
- Patients age 85 and older. ■

actual costs would be higher than costs predicted on the basis of patient characteristics alone. We also expected that the predicted costs of stays treated in high-cost settings would be lower than their actual costs because many types of stays are also treated in lower cost settings. For all stays, the predicted costs of stays would reflect the current mix of settings where similar patients are treated.

Because the objective of a PAC PPS is to pay the same rates for the same patient type and care needs regardless of setting, a design that perfectly matches the new payments to current stay costs by setting would simply replicate the large differences in current payments based on setting and undermine the purpose of a PAC PPS. Therefore, we focused our evaluation on our ability to predict costs by *patient categories* rather than our ability to explain the variation in the costs by *setting*.

The second metric used to determine the robustness of our models is how well they explained the variation in costs across all stays (using a statistical measure known as *R*-squared). We did not develop or test condition-specific models (i.e., one model for stroke patients, another for orthopedic stays).

Findings from our full and administrative models

Our analysis of 2013 PAC stays found that a stay-based PAC PPS using patient characteristics could establish accurate relative costs of stays in aggregate and across most of the patient groups we examined. Because payments would be based on patient characteristics and not the amount of therapy care, the PAC PPS would raise payments for medically complex stays and lower payments for rehabilitation stays compared with current (2013) payments. Compared with current policy, payments would be more uniformly related to the costs of stays across the patient groups, so PAC providers would have less incentive to selectively admit certain types of patients over others. For patient groups with predicted costs that were substantially different from actual costs, current practices (such as the provision of therapy unrelated to patient characteristics) or cost structures of high-cost settings explained these results.

Providers and settings with high costs that are unrelated to patient characteristics would experience reductions in payments, but since the objective of the unified PPS is to establish payments based on a patient's characteristics, this result should not be "corrected" with payment adjusters. Over time, we would expect providers to lower their costs to match the PAC PPS payments. In the interim, a transition with blended rates could dampen the incentive to selectively admit certain types of patients over others. The patient characteristics included in the risk adjustment could be refined over time if systematic overpayments or underpayments occurred. Similarly, the relative weights should be recalibrated regularly to reflect changes in practice patterns.

Our work examined the need for stay-level and provider-level adjustments. The results indicate the need for two stay-level adjusters: (1) an adjustment for stays that are unusually short to prevent substantial overpayment for these stays and (2) a high-cost outlier policy for exceptionally high-cost stays. We modeled illustrative short-stay and high-cost outlier policies. A short-stay policy would more closely align payments with the considerably lower costs of short stays. We found that a high-cost outlier policy would increase payments for stays with ventilator care and severe wound care and for the four medically complex groups. Because payments would increase for these types of stays, providers could have less financial incentive to avoid these patients.

Under a unified PPS, provider-level adjusters should be considered only when they could be applied to all settings. We did not find clear evidence for the need for broad rural adjusters, a more targeted rural policy for isolated providers, or a teaching adjustment for IRFs; a robust risk adjustment method combined with an outlier policy would most likely be able to accommodate the cost of these stays. We did not have adequate information to assess the need for an adjustment for providers that treat unusually high shares of low-income patients.

Our analysis assumed PAC spending would remain the same under a unified PPS. However, the level of PAC payments is high (across all stays, payments in 2013 exceeded the actual costs of stays by 19 percent), so policymakers should consider rebasing payments. Rebasing would be consistent with the Commission's recommendations to rebase HHA and SNF payments, which constitute over 90 percent of PAC payments.

Models using only administrative data can accurately predict the per stay costs for most patient groups

To estimate the impact of a PAC PPS, we needed to use PAC stays over an entire year rather than the small, unrepresentative sample of PAC–PRD stays. Thus, we could use only administrative data (including information on diagnoses, comorbidities, demographics, risk scores, select high-cost service use indicators, and a limited set of proxies for patient impairments and cognitive status) since patient assessment and resource-use data collected specially for the PAC–PRD would not be available.

Therefore, we used PAC–PRD data to develop "full" predictive models (that include the patient assessment and routine resource use information) and re-estimated the models with the same PAC–PRD stays using information only available in administrative data (the "administrative" models).

Compared with the full models, the administrative models were almost as accurate in predicting the average actual cost of the PAC–PRD stays across most of the clinical condition, medically complex, and other patient groups we examined (Table 3-4). The average predicted costs were very similar to the average actual cost of stays (ratios are close to 1.0) for most of the 22 clinical groups (10 are shown in the table). Also, the models were accurate for three of the four definitions of medically complex stays (the fourth, an outlier group that includes less than 1 percent of stays, is discussed below). The administrative models were also accurate for the demographic groups.

The ratios are close to 1.0 for most groups because the models predicting the cost of stays include many of the same patient characteristics (or proxies for them) that are used to define the reporting groups. Thus, any reporting group with the same definition will have a ratio close to 1.0. The models include over 60 indicators of clinical characteristics to adjust the predicted costs of stays and, since we wanted to assess how the PAC PPS would affect different groups of beneficiaries, many of the same indicators were also used to define our reporting groups. For example, we included an indicator for stroke to predict the cost of stays, and we also reported the models' results for this group of patients. Of note, the prediction models did not include indicators of community admission, dual eligibility, or disability status, yet the model performed well for these groups. Finally, for groups for which the full model's predicted costs differed substantially from the stays' actual costs (where the ratios deviate from 1.0, such as the functional status groups), the administrative models produced similar results (discussed below).

Across all PAC–PRD stays, the administrative and full models explained a high and similar percent of the variation in stay costs (60 percent and 57 percent, respectively).[15] From these results, we concluded that the administrative models could be used to establish accurate relative costs for stays and to estimate the impact of a PAC PPS using PAC stays in 2013.

The administrative models were not as accurate as the full models for some patient groups. Compared with the full models, the administrative models' predictions were slightly less accurate for patients on ventilators, likely because the ventilator indicator used in the administrative model (ICD–9 codes) is not a completely reliable indication of ventilator use in PAC settings. The administrative models performed poorly for the highest acuity group, an outlier group comprising less than 1 percent of stays (though the administrative models performed better than the full models for this group). Compared with other patient groups, a larger share of these stays were treated in LTCHs. However, because the models predict the average cost for the group based on the mix of settings for all PAC–PRD stays, including lower cost SNFs and IRFs, the averaging of costs lowered LTCHs' predicted costs.

The administrative models also performed relatively poorly for PAC–PRD patients with high and low functional status. Clearly, functional assessment data, such as that collected in the PAC–PRD, are important to predict these stays' costs accurately. Without such data, the models predict costs that are too high for patients with high levels of function and too low for patients with low levels of function, even though the results by clinical group suggest that these differences average out across the stays within each clinical group. The results suggest that functional assessment data would improve the accuracy of predicting costs and counter the incentive for providers to avoid low-functioning patients. Although an extensive array of patient assessment information may not be needed to improve risk adjustment, assessment information is also used to plan the care for each patient, develop outcome measures (such as changes in function during the PAC stay), and track processes of care. A broader set of assessment data may be needed for these other purposes.

Some patient categories indicate where administrative data are adequate and where they are lacking to establish accurate relative costs of stays. The ratios for the cognitively impaired group are only slightly less accurate than the full model, indicating that a diagnosis-based measure could be a reasonable substitute until patient assessment information becomes available. However, to the extent that diagnosis coding for these conditions is missing or does not adequately capture the degree of impairment, better information about cognition (either from more complete diagnosis coding or, in the longer term, from patient assessment information) would improve the predicted costs of these stays and assign proper payment to them. More complete and accurate diagnostic coding would also improve the accuracy of the administrative models' predictions for patients on ventilators.

TABLE 3–4

Models with and without PAC–PRD information are equally accurate in predicting the costs of PAC–PRD stays for most patient groups and could be used to set relative weights

Characteristic	Share of stays	Ratio of average predicted to average actual cost of stays: Full models (Include unique PAC–PRD data)	Ratio of average predicted to average actual cost of stays: Administrative models (Exclude unique PAC–PRD data)
All stays		1.00	1.00
Clinical group			
Orthopedic surgical	17%	1.00	1.00
Cardiovascular medical	9	0.99	1.00
Other neurology medical	8	1.00	1.00
Respiratory medical	8	1.02	1.03
Orthopedic medical	7	1.02	1.03
Cardiovascular surgical	5	0.99	0.98
Severe wound care	5	0.99	0.99
Stroke	4	1.00	1.00
Serious mental illness	3	0.99	0.99
Ventilator care	3	1.00	0.93
Functional status and frailty			
High functional status	22	1.04	1.22
Low functional status	32	0.97	0.90
Least frail	6	1.19	1.09
Most frail	10	0.95	0.99
Cognitively impaired	40	0.99	0.96
Medically complex			
Multiple body-system diagnoses	2	0.97	0.96
CCI	12	1.01	0.99
Severely ill (SOI = 4)	7	0.98	0.97
Highest acuity	0.2	0.66	0.74
Other patient characteristics			
Community admitted	28	0.96	0.91
Stays with prior hospital stay	72	1.01	1.02
Disabled	20	1.00	1.00
Dual eligible	20	0.98	0.97
ESRD	3	1.00	0.99
Percent of variation in costs explained (R^2)		60%	57%

Note: PAC–PRD (Post-Acute Care Payment Reform Demonstration), CCI (chronically critically ill), SOI (severity of illness), ESRD (end-stage renal disease). The table shows the ratios of average predicted costs compared with the average actual costs for the sample PAC–PRD stays included in each group. A predicted-to-actual ratio of 1.0 indicates that the average predicted costs are equal to the average actual costs and that the model would establish accurate relative weights for a payment system. The sample is based on stays included in CMS's PAC–PRD between 2008 and 2010 (n = 6,409 stays). The full models are based on unique patient assessment information and routine resource-use data collected during CMS's PAC–PRD, as well as readily available administrative data such as claims information from post-acute care (PAC) stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models are based only on administrative data. The administrative and full models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. Patients' level of function was determined using Rasch motor scores at PAC admission. Patients' level of frailty was determined using a frailty index. CCI stays include patients who spent eight or more days in an intensive care unit during the preceding hospital stay or were on a ventilator in the PAC setting. Severely ill stays include patients who were categorized as SOI Level 4 during the immediately preceding hospital stay. "Multiple body-system diagnoses" includes patients with diagnoses involving five or more body systems who were treated in institutional PAC settings. "Highest acuity" refers to patients who were categorized as SOI Level 4 and received PAC in institutional settings only, were on dialysis, and had severe wounds or pressure ulcers.

Source: Analysis of PAC–PRD stays for MedPAC by the Urban Institute.

The average predicted cost for community-admitted patients was more accurate with the patient assessment data (the ratio of the average predicted to average actual stay cost was 0.96 for the full model but decreased to 0.91 for the administrative model). It is possible that patient assessment data provide additional information about community-admitted stays that lack the clinical information obtained from prior hospital stay claims. Without the patient assessment data, it is more difficult to predict these stays' costs. Under a PAC PPS that used diagnoses to determine payments more directly, all providers, including HHAs, would code diagnostic information more completely, and the accuracy of the predicted costs for these stays would likely improve.

In summary, administrative models accurately predicted the relative cost of stays for most patient groups, performing almost as well as models that included more extensive (but currently not readily available) information about patients. Groups with less accurate cost predictions (stays for patients with high and low functional status and the highest acuity patients) illustrate the importance of functional assessment information and a robust risk adjustment method to predict the costs for certain stays accurately.

Models using only administrative data accurately predicted the per stay costs for PAC stays in 2013

Having confirmed the performance of the administrative models to predict costs accurately for the PAC–PRD sample of stays, we applied our methods for evaluating the models' accuracy to the broader universe of 2013 PAC stays. We found that the administrative models accurately predicted the average actual costs for most of the 30 patient groups we examined. For patient groups with predicted costs that were substantially different from actual costs, providers' therapy practices, current PPS designs, and the cost structures of high-cost settings explained the results. The overall results confirm that administrative models could be used to estimate the impact of a unified PAC PPS.

Results by clinical group

The administrative models accurately predicted the average cost of PAC stays in 2013 for the 13 clinical groups reported in Table 3-5.[16] The ratios of the average predicted costs to the average actual costs were at or near 1.0, indicating that the model would establish accurate relative cost weights.

Results for the cognitively impaired, frailty, and medically complex groups

The models also predicted average costs that were close to average actual costs for all but one of the functional status, frailty, and medically complex groups. Relative weights based on the predicted costs would be accurate for the least and most frail patients, patients who are cognitively impaired, patients who have diagnoses involving five or more body systems, patients who are chronically critically ill, and patients assigned to the highest severity level (severity of illness (SOI) Level 4).

One exception is the group of highest acuity stays, an outlier group with an average predicted–to–average actual cost ratio of 0.80. Compared with other patient groups, a larger share of these stays was treated in LTCHs (54 percent). Nevertheless, almost half of these stays were treated in SNFs and IRFs, which have much lower costs than LTCHs. Like all groups, the average predicted cost reflects the mix of settings where the stays were treated, resulting in an average predicted cost that was much lower than the average actual cost. We note this exception because it may signal that the models do not adequately predict costs for exceptionally high-cost stays, though they appear to work well for the other definitions of *medically complex*. In designing a PAC PPS, the risk adjustment method should result in accurate payments for patients with predictably high costs. Otherwise, providers would likely avoid admitting these patients. For exceptionally costly stays, an outlier policy would make additional payments to help defray providers' losses and help protect beneficiary access to needed care.

Results by other stay and patient characteristics

We expected that the average predicted costs for stays with low and high shares of therapy costs would be considerably different from these stays' average actual costs. For patients who receive high amounts of therapy services unrelated to their care needs, we expected our model would predict costs that, on average, are lower than actual costs (since the amount of therapy received may have little relationship to the patients' diagnoses and comorbidities). Conversely, for patients who receive low amounts of therapy (such as medical patients with multiple comorbidities), we expected our model to predict costs that are higher than actual costs.

The results were exactly as expected. For stays with a high share of therapy costs, the average predicted costs were lower than the average actual costs of the stays, with a predicted-to-actual cost ratio of 0.66 for HHA stays and

TABLE 3–5

Administrative models predicting the cost of stays based on patient characteristics accurately predict costs of 2013 PAC stays for almost all patient groups

Reporting group	Actual cost	Predicted cost	Ratio of predicted to actual cost	Percent of stays
All stays	$5,653	$5,653	1.00	100%
Clinical group				
Cardiovascular medical	3,781	3,786	1.00	14
Orthopedic medical	4,190	4,187	1.00	10
Orthopedic surgical	7,711	7,727	1.00	10
Respiratory medical	5,868	5,945	1.01	9
Other neurology medical	4,401	4,394	1.00	8
Serious mental illness	7,323	7,298	1.00	5
Severe wound	8,082	7,868	0.97	5
Skin medical	3,683	3,602	0.98	4
Cardiovascular surgical	6,952	7,030	1.01	3
Infection medical	8,736	8,822	1.01	3
Stroke	12,181	12,164	1.00	2
Hematology medical	3,521	3,536	1.00	2
Ventilator	51,219	51,219	1.00	<1
Frailty and cognitive impairment				
Least frail	2,668	2,681	1.00	7
Most frail	9,645	9,567	0.99	11
Cognitively impaired	6,967	6,962	1.00	20
Medically complex				
Multiple body-system diagnoses	16,033	16,035	1.00	5
CCI	14,375	14,445	1.00	5
Severely ill (SOI = 4)	17,740	17,739	1.00	4
Highest acuity	29,593	23,750	0.80	<0.1
Other stay and patient characteristics				
Low/no therapy share of costs: HHA stays	1,207	2,198	1.82	29
Low/no therapy share of costs: Institutional PAC	14,408	15,222	1.06	8
High therapy share of costs: HHA stays	3,488	2,318	0.66	30
High therapy share of costs: Institutional PAC	13,144	12,117	0.92	8
Community admitted	2,850	2,854	1.00	50
Stays with prior hospital stay	8,461	8,457	1.00	50
Disabled	5,517	5,517	1.00	26
Dual eligible	5,572	5,543	0.99	32
ESRD	6,856	6,872	1.00	4
Very old (85+ years old)	5,687	5,678	1.00	30

Note: PAC (post-acute care), CCI (chronically critically ill), SOI (severity of illness), HHA (home health agency), end-stage renal disease (ESRD). The table shows the ratios of average predicted costs compared with the average actual costs in 2013 for all PAC stays included in the group. A predicted-to-actual ratio of 1.0 indicates that the average predicted cost is equal to the average actual cost and that the model would establish accurate relative weights for a payment system. Predicted payments are based on a payment model that uses readily available administrative data such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. Patients' level of frailty was determined using a frailty index. "Multiple body-system diagnoses" includes patients with diagnoses involving five or more body systems who were treated in institutional PAC settings. CCI stays include patients who spent eight or more days in an intensive care or coronary care unit during the preceding hospital stay or were on a ventilator in the PAC setting. Severely ill stays include patients who were categorized as SOI Level 4 during the immediately preceding hospital stay. "Highest acuity" refers to patients who were categorized as SOI Level 4 and received PAC in institutional settings only, were on dialysis, and had severe wounds or pressure ulcers.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

0.92 for institutional PAC stays. For stays with a low share of therapy costs, the average predicted costs were higher than the average actual costs, with ratios of 1.82 for HHA stays and 1.06 for institutional PAC stays. Over time, under a PAC PPS, we would expect these ratios to move toward 1.0 as providers changed their therapy practices (and costs) to match patients' care needs.

We also examined model performance for stays for beneficiaries who were dually eligible for Medicare and Medicaid, disabled, over 85 years old, or on dialysis. The ratio of the average predicted costs to the average actual costs was at or near 1.0 for these groups, underscoring the finding that relative cost weights based on the administrative models would be accurate for these patients' stays. The model also accurately predicted the average costs for community admissions and stays with a prior hospitalization.[17]

Finally, we examined the need for a short-stay outlier policy. Such a policy reduces payments for stays that are unusually short to avoid large overpayments that would otherwise occur if payments for these stays were based on the cost of stays of average duration. The current IRF, LTCH, and HHA PPSs include short-stay outlier policies. (Because the SNF PPS is based on days, the PPS adjusts payments by length of stay.) A short-stay outlier policy could pay on a per day or per visit amount up to the per stay amount for the case. We found the average predicted costs for short stays were substantially higher than the stays' average actual costs because the estimates assumed average lengths of stay. The average predicted costs were 50 percent higher than the average actual cost for short IRF stays, more than double the average actual cost of short LTCH stays, more than three times the average actual cost for short HHA stays, and more than four times the average actual cost for short SNF stays (see Table 3-10, p. 90). Therefore, we modeled an illustrative short-stay policy and include those results in the impact section (p. 87).

Comparisons by setting and provider group

The goal of a PAC PPS is to establish uniform prices across settings, basing payments on a patient's characteristics and not on where the patient is treated or the amount of therapy service furnished. Given that many types of patients treated in the higher cost settings (IRFs and LTCHs) are also treated in lower cost settings, we would expect the predicted costs (and, thus, the payments) for stays to be considerably lower than the actual costs of the higher cost settings. This result would be a desirable outcome of moving from setting-specific PPSs to a consolidated payment system in which providers are paid the same amount for treating the same patient, regardless of setting. (The home health setting would be an exception because its cost structure is fundamentally different from that of institutional settings). Likewise, within a setting, we would expect providers with high costs relative to those of other providers treating similar mixes of patients to have predicted costs (and, thus, payments) that are lower than their actual costs. Such results do not warrant correction: A PPS should not compensate providers for having high costs that are unrelated to their mix of patients or local wage rates. A transition to the PAC PPS would give providers time to adjust their cost structures and provision of care to match the needs of their patients.

Our results confirmed these expectations (Table 3-6). The high-cost settings (IRFs and LTCHs) had average predicted costs below their average actual costs, with ratios of 0.88 and 0.68, respectively. We separately examined LTCH stays that met the recently enacted patient-specific LTCH criteria and found that the average predicted costs were closer to the average actual costs (0.76).[18] The average predicted costs for SNF stays were higher than the average actual costs (the ratio was 1.09), most likely because the model predicted the cost of a stay using a broader array of a patient's conditions and comorbidities than the current SNF payment system. A smaller contributing factor may be that higher cost settings treat some of the same types of patients, thereby raising the predicted costs for all PAC stays. The ratio for HHAs was 1.0 because we set predicted costs equal to actual costs as one way to account for the very different costs of this setting.

Regardless of PAC setting, providers that typically had high costs relative to other providers in the same setting also had ratios below 1.0. In all PAC settings, hospital-based providers and nonprofit providers often have relatively high costs and, as expected, their average predicted costs were lower than their average actual costs. Hospital-based providers had a ratio of 0.83, while nonprofit providers had a ratio of 0.96. Providers located in geographic areas with high utilization (such as the region that includes Arkansas, Louisiana, Oklahoma, and Texas) had average predicted costs that were lower than their average actual costs (the ratio for this region was 0.93, not shown).

We explored the need for provider-level adjustments. Under current policy, PAC providers receive higher payments

TABLE 3–6 **As expected, predicted stay costs based on patient characteristics differ from certain providers' actual costs, using administrative models to analyze 2013 PAC stays**

Reporting group	Actual cost	Predicted cost	Ratio of predicted to actual cost	Percent of stays
All stays	$5,653	$5,653	1.00	100%
Setting				
HHA	2,269	2,269	1.00	69
SNF	11,281	12,289	1.09	26
IRF	15,446	13,569	0.88	4
LTCH				
All stays	36,521	25,006	0.68	2
Qualifying stays	41,467	31,318	0.76	1
Provider characteristics				
Hospital based	7,463	6,160	0.83	11
Freestanding	5,433	5,592	1.03	89
Nonprofit	6,259	6,028	0.96	22
For profit	5,385	5,496	1.02	75
Government	7,773	6,769	0.87	3

Note: PAC (post-acute care), HHA (home health agency), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The table shows the ratios of average predicted costs compared with the average actual costs in 2013 for all PAC stays included in the group. A predicted-to-actual ratio of 1.0 indicates that the average predicted costs are equal to the average actual costs and that the model would establish accurate relative weights for a payment system. Predicted payments are based on a payment model that used readily available administrative data such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. All LTCHs are included in the freestanding group. LTCH-qualifying stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

when they serve beneficiaries in rural areas. While these policies vary in the size and nature of the additional payment, they all are premised on the principle of preserving access to care for beneficiaries living in rural areas. However, the Commission has determined that these rural "add-ons" are distributed too broadly, providing additional payments to providers in rural areas even if those areas have adequate or high utilization and provider supply (Medicare Payment Advisory Commission 2012). Instead, the Commission has posited that rural adjustments should be tied to low volume and isolation. Medicare should not subsidize two low-volume providers in close proximity to each other, even in a remote area, because doing so may discourage providers from achieving economies of scale by consolidating. Rather, any rural policy should target *isolated* low-volume providers.

We found that providers in most rural areas would receive adequate payments under a reformed system, with the ratios ranging from 0.97 for providers in frontier areas (that account for 0.3 percent of stays) to 1.03 for providers in rural-adjacent and rural-nonadjacent areas. Less than 10 percent of rural stays had ratios of predicted-to-actual costs less than 1.0, and most of those had ratios of 0.99, indicating little need for even a targeted rural policy.

If a targeted rural policy is considered, it should subsidize remote, low-volume providers to ensure access—for example, providers located more than 20 miles from another provider.

Further, a targeted policy could help ensure access to only the most commonly provided PAC services—such as those provided by HHAs and SNFs. Ensuring both a home-based and institutional PAC option would cover a broad range of posthospital needs, permitting those who can be discharged home to do so and those needing a higher level of care access to it. Other more specialized services, such as those provided in IRFs and LTCHs, are used less frequently and could be considered referral services. As PAC providers are given more regulatory flexibility,

institution-based providers might offer a wider range of PAC services than they do currently (see section on waiving regulatory requirements, p. 92). As payments for medically complex patients increase, SNFs could invest in the resources to treat these patients (Table 3-6, p. 81).

Under the current IRF PPS, IRFs receive additional payments for treating high shares of low-income patients. Yet setting-specific adjustments (except in the case of an adjustment for the lower costs of HHAs) undermine the broad purpose of a unified PPS. Under a PAC PPS, any adjustment should be considered for all PAC providers. We did not have the data to explore low-income shares in PAC settings other than IRFs. We examined the ratio of the average predicted to the average actual costs by quintile of low-income share (i.e., the bottom 20th percentile, the 20th to 40th percentile, etc.). We found that only IRFs with the highest shares of low-income patients had an average predicted cost that was lower than the ratio for all IRFs. The Secretary should evaluate whether a low-income share adjustment is needed for all PAC settings and whether the adjuster should be graduated or only for providers with the highest shares.

As with the additional payments for high shares of low-income patients, IRFs alone receive an adjustment for teaching programs, yet such an adjuster would make sense only if it is applicable to all PAC settings. The predicted-to-actual cost ratio for IRF teaching facilities was not that different from the ratio for all IRFs, particularly when combined with an outlier policy, and did not provide a clear indication that a separate adjuster should be considered. It is possible that a robust risk adjustment method could adequately address any cost differences in teaching facilities.

Estimated impact of a PAC PPS on payments

The results of our administrative models indicate that a PAC PPS base payment could be set at the average predicted costs of all PAC stays and adjusted up or down using relative weights based on each stay's predicted costs. To analyze the impact of moving to such a PAC PPS, we made three comparisons. First, as a reference, we compared current (2013) payments with the actual costs of stays to evaluate relative profitability by type of stay. Next, we compared current (2013) payments with estimated PAC PPS payments (calculated using our administrative models) to assess how payments would be redistributed across types of stays, settings, and providers. Last, we compared estimated PAC PPS payments with the actual costs of stays to evaluate the relative profitability of stays under the unified payment system.

In our analysis, we assumed the PAC PPS would be implemented initially on a budget-neutral basis, with total estimated payments set equal to actual payments made for all PAC services in 2013. Our estimates do not reflect policy changes since 2013, such as the enactment of LTCH policies for qualified stays. Our estimates also do not assume any changes in provider behavior. For example, over the coming years, LTCHs are likely to change their patient mix and costs of stays; we have not factored such potential changes into our estimates.[19]

Under current policy, the profitability of different types of stays varies considerably. A PAC PPS would redistribute payments and narrow those differences. Providers would therefore not have strong financial incentives to admit some patients over others or favor rehabilitation care over treating medically complex cases. Payments would increase for medically complex stays (except those that are essentially outlier cases) and would decrease for stays that are predominantly for physical rehabilitation because current (2013) payments for therapy services are less related to patient characteristics. A PAC PPS would also shift payments from high-cost settings to lower cost settings. The estimated aggregate spending under a PAC PPS was set to be budget neutral relative to spending in 2013, so the level of payments would remain high relative to the costs of stays. The level of payments and the time frame for making reductions are two issues policymakers should consider when implementing a PAC PPS.

Payments under current policy result in widely varying profitability and high levels of payments

Under current (2013) policy, profitability varied considerably across types of stays (Table 3-7). Payment-to-cost ratios ranged from 0.97 for institutional PAC stays with no or low therapy costs to 1.60 for HHA stays with low shares of therapy services. The variation in profitability reflects many factors, including the mix of where PAC stays are treated; the overall high level of payments compared with costs (particularly in HHAs and SNFs); and the biases of the HHA and SNF PPSs that favor physical rehabilitation care over treating medically complex patients. Clinical groups with the highest relative profitability included other neurology medical and orthopedic (surgical and medical). The therapy biases in the current HHA and SNF PPSs are seen in the very high ratio of current (2013) payments to actual costs for stays with the highest therapy share of costs (1.12 and 1.37 for

TABLE 3–7

The ratios of payments to the actual cost of stays would be more uniform under a PAC PPS for most groups, using administrative models to analyze 2013 PAC stays

Reporting group	Percent of stays	Ratio of current (2013) payments to actual stay costs	Percent change in payments between PAC PPS and current (2013) payments	Ratio of PAC PPS payments to actual stay costs
All stays	100%	1.19	0%	1.19
Clinical group				
Cardiovascular medical	14	1.19	0	1.19
Orthopedic medical	10	1.26	–6	1.18
Orthopedic surgical	10	1.22	–2	1.19
Respiratory medical	9	1.14	6	1.20
Other neurology medical	8	1.26	–6	1.18
Serious mental illness	5	1.19	0	1.18
Severe wound	5	1.09	6	1.15
Skin medical	4	1.15	0	1.16
Cardiovascular surgical	3	1.10	9	1.20
Infection medical	3	1.18	2	1.20
Stroke	2	1.18	0	1.18
Hematology medical	2	1.11	7	1.19
Ventilator	<1	1.11	7	1.19
Frailty and cognitive impairment				
Least frail	7	1.24	–4	1.19
Most frail	11	1.16	1	1.18
Cognitively impaired	20	1.24	–4	1.18
Medically complex				
Multiple body-system diagnoses	5	1.14	4	1.19
CCI	5	1.10	9	1.19
Severely ill (SOI = 4)	4	1.11	7	1.19
Highest acuity	<0.1	1.07	–11	0.95
Other stay and patient characteristics				
Low/no therapy share of costs: HHA stays	29	1.60	35	2.16
Low/no therapy share of costs: Institutional PAC	8	0.97	29	1.25
High therapy share of costs: HHA stays	30	1.12	–30	0.79
High therapy share of costs: Institutional PAC	8	1.37	–20	1.09
Community admitted	50	1.25	–5	1.19
Stays with prior hospital stay	50	1.16	2	1.19
Disabled	26	1.17	1	1.19
Dual eligible	32	1.22	–3	1.18
ESRD	4	1.16	3	1.19
Very old (85+ years old)	30	1.21	–2	1.18

Note: PAC (post-acute care), PPS (prospective payment system), CCI (chronically critically ill), SOI (severity of illness), HHA (home health agency), end-stage renal disease (ESRD). The table shows the ratios of average payments in 2013 to average costs in 2013 for all the PAC stays included in the group, as well as the ratios of estimated payments under a PAC PPS to average costs in 2013 for all the PAC stays in each group. A payment-to-cost ratio of 1.0 indicates that payments equal the actual costs. Estimated payments under a PAC PPS are based on a payment model that uses readily available administrative data, such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. Patients' level of frailty was determined using a frailty index. "Multiple body-system diagnoses" includes patients with diagnoses involving five or more body systems who were treated in institutional PAC settings. CCI stays include patients who spent eight or more days in an intensive care or coronary care unit during the preceding hospital stay or were on a ventilator in the PAC setting. Severely ill stays include patients who were categorized as SOI Level 4 during the immediately preceding hospital stay. "Highest acuity" refers to patients who were categorized as SOI Level 4 and received PAC in institutional settings only, were on dialysis, and had severe wounds or pressure ulcers.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

HHA and institutional PAC stays, respectively). Clinical groups with the lowest relative profitability included ventilator, severe wound, cardiovascular surgical, and hematology medical groups and the medically complex groups. The wide range in the relative profitability can encourage providers to prefer treating beneficiaries with primarily physical rehabilitation care needs to medically complex patient groups.

Across all stays, payments in 2013 were 19 percent higher than the actual costs of stays. Given the high level of payments to providers in these settings, the Commission has repeatedly recommended reductions of or freezes on payment rates under their current payment systems.

A PAC PPS would shift payments away from physical rehabilitation care that is unrelated to patient characteristics

A comparison of payments made under our proposed PAC PPS with those made under current (2013) payment policy indicates that a PAC PPS would increase payments for many of the medical and patient impairment and severity groups, while lowering payments for stays in the patient groups where physical rehabilitation care is a large component of care (Table 3-7, p. 83). The difference, in broad terms, results from basing payments on patient characteristics rather than on the amount of therapy, which may be unrelated to care needs. Across the clinical groups, estimated changes in payments ranged from increases of 9 percent for cardiovascular surgical groups to decreases of 6 percent for the orthopedic and the other neurology medical groups. However, the model would not lower payments indiscriminately for rehabilitation care. If a patient had clinical characteristics and impairments indicating higher than average care needs, payments for the stay would be above average.

As for the medically complex groups, we estimated that payments under a PAC PPS would increase for three groups from between 4 percent (for stays with multiple body-system diagnoses) to 9 percent (for stays in the chronically critically ill (CCI) group). The large decrease (–11 percent) observed in payments for the "highest acuity" group (essentially an outlier group) reflects the mix of settings where these stays are treated. Because almost half of the stays in this group are treated in SNFs and IRFs, the average payment under a PAC PPS would fall for cases treated in LTCHs. In contrast, payments for ventilator stays (a group dominated by stays treated in LTCHs) would increase 7 percent, reflecting the relative costliness of this care that is not reduced by stays treated in lower cost settings. These two examples illustrate that the changes in payments are a function of many factors, including whether the stays are predominantly medical or rehabilitative *and* the mix of settings where the stays are treated.

Across the other stay and patient characteristics, payments would increase substantially for stays with low therapy costs, which are likely to be medical in nature, and decrease substantially for stays with high therapy costs. Payments on average would decrease for stays with high therapy costs because a portion of the therapy provided is unrelated to a patient's care needs. Payments would decrease for stays in the least frail patient group (92 percent of these stays were treated in HHAs), again, most likely because a portion of this care was unrelated to the patient's care needs.

A PAC PPS would result in more uniform ratios of payments to costs

Compared with payment-to-cost ratios under current policy, these ratios under a PAC PPS would become more uniform for the clinically defined groups (Table 3-7, p. 83). With a few exceptions, the PAC PPS payment-to-cost ratios vary little across patient groups and cluster around the overall average (1.19). One exception is the highest acuity group (a small outlier group), whose ratio is considerably lower (0.95). Although PAC PPS payments would almost cover these stays' costs, the ratio is much lower than for the other groups. Any PAC PPS design needs to account for stays that are predictably costly relative to others (and not rely on outlier payments), so that the relative profitability of these cases is similar to other cases. Otherwise, providers would have an incentive to avoid such costly patients.

As expected, the high-therapy groups had estimated payment-to-cost ratios that deviated from the average. The ratio of PAC PPS payments to actual costs was 0.79 for high-therapy HHA stays and 1.09 for high-therapy institutional PAC stays. Providers with high shares of therapy costs would need to adjust their therapy practices to bring their costs in line with the PAC PPS payments that reflect patients' estimated care needs.

As providers adjust their practices and costs to the PAC PPS payments, differences between a provider's payments and costs would narrow, and taking one type of stay over another would be of limited financial advantage. To allow time for such adjustments and protect beneficiary access to care, the PAC PPS should be phased in over time, with a transition that blends current and PAC PPS payments.

A transition would help mitigate the patient selection that could otherwise occur by providers in high-cost settings until they aligned their costs with the lower payment rates. Over time, payments should be recalibrated to reflect the relative changes in providers' costs, consistent with the maintenance of all PPSs.

Because the law asked us to examine the feasibility of designing a PAC PPS, we modeled estimated payments under a PAC PPS at the same level of payments as current law. With the aggregate payment-to-cost ratio at 1.19, policymakers may consider whether this overall high level of payment relative to costs is warranted. Rebasing to bring payments more in line with providers' costs could be initiated at the same time a PAC PPS is implemented or phased in over time.

A PAC PPS would redistribute payments across settings and providers

The goal of a PAC PPS is to establish uniform payments for patient groups, regardless of setting (with lower payments to HHAs because their costs are so much lower than institutional PAC providers). Under a unified PPS, we expect payments would be redistributed across individual providers and PAC settings based on the mix of patients treated, the provider's therapy practice, and existing cost structures. Payments would be based on patient characteristics rather than setting. The estimates in our analysis suggest the direction and relative values of changes produced by a PAC PPS and should not be considered point estimates.

Under a PAC PPS, estimated payments to IRFs and LTCHs would decrease by 12 percent and 25 percent, respectively, because the stay costs of lower cost settings treating many of the same types of patients would be included in setting the payment (Table 3-8). Compared with all LTCH stays, the reductions for LTCH-qualifying stays would be considerably smaller (–17 percent compared with –25 percent) because this subcategory overlaps less with similar stays treated in other settings. Payments to SNFs would increase for two reasons. First, the PAC PPS design would base payments on patients' diagnoses and comorbidities, which could raise payments for patients with comorbidities (only some of which are recognized in the SNF PPS). Second, the higher costs of IRFs and LTCHs would raise the average cost of stays also treated in SNFs (though this effect would be small since the high-cost settings account for only 6 percent of stays).

We estimated that payments to hospital-based providers would increase 13 percent, while payments to freestanding providers would decline by 2 percent. Payments to nonprofit providers were estimated to increase 10 percent, while payments to for-profit providers would decrease 3 percent. We estimated that payments to providers located in high-use areas of the country (such as Arkansas, Louisiana, Oklahoma, and Texas) would decrease by 8 percent (results not shown).

A PAC PPS would create incentives for many providers to change their practices and cost structures. High-cost providers and PAC settings would need to lower their costs in line with those of other providers and settings

TABLE 3–8 **Estimated changes in payments under a PAC PPS compared with 2013 payments, by provider category**

Reporting group	Percent change
All stays	0%
HHA	–1
SNF	8
IRF	–12
LTCH	
All stays	–25
Qualifying stays	–17
Hospital based	13
Freestanding	–2
Nonprofit	10
For profit	–3
Government	4
Urban	0
Rural	3
Frontier	7

Note: PAC (post-acute care), PPS (prospective payment system), HHA (home health agency), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The table shows the percent change in estimated average payments under a uniform PAC PPS, relative to average payments in 2013 for all the PAC stays included in the group. Estimated payments under a PAC PPS were based on a payment model that uses readily available administrative data such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. All LTCHs are included in the freestanding group. LTCH-qualifying stays are those that meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

treating similar mixes of patients. Over time, there would be no financial advantage of one PAC setting over another; indeed, distinctions between settings could disappear. In the near term, the impact of a PAC PPS on any individual provider could differ from the general trends we report. Factors that could affect providers individually include the mix of patients treated, the PPS design and incentives under which the provider is currently paid, the provider's current therapy practices, and the provider's ability to reduce its costs. For example, because PAC PPS payments would not be tied to the amount of rehabilitation therapy furnished, providers that systematically furnish therapy unrelated to their patients' care needs would experience larger declines in payments compared with providers treating similar mixes of patients but with different therapy practices. Under a new PAC PPS, some providers might opt to change the way they organize care (for example, some could decide to offer a continuum of PAC) and the types of cases they treat (for example, a provider could opt to treat beneficiaries with specialized care needs).

Outlier policies would more closely align payments to the cost of stays

Under a PAC PPS (based on patient characteristics and average costs across all PAC providers) payments would, on average, be accurate. However, because some patients' needs are much greater or much less than expected, the new payment system would require outlier policies to help compensate providers for extraordinarily high-cost cases and help the program prevent large overpayments for extraordinarily low-cost cases.

High-cost outlier policy

A high-cost outlier policy protects providers from incurring exceptionally large losses from treating unusually high-cost stays and helps ensure beneficiary access to care. High-cost outlier policies establish payments that cover a portion of the losses incurred so that a provider retains an incentive to be efficient. For treating an exceptionally high-cost stay, a provider receives the PPS payment and must cover the difference between the PPS payment and a fixed-loss amount. Then, the provider is paid a portion of the costs above the fixed-loss amount.

An outlier policy design needs to specify the share of payments to redistribute to high-cost cases (the size of the outlier "pool"), the amount of loss that triggers an outlier payment (the "fixed-loss amount"), and the share of costs covered beyond the fixed loss. The size of the pool and the fixed-loss amount are interrelated: a larger pool would include more stays, so outlier payments would begin after a smaller fixed-loss amount, while a smaller pool would be established with a higher fixed-loss amount. Outlier policies are generally financed by lowering the base payments for all cases by a small amount so that total spending remains the same.

Three of the four PPSs for PAC services (HHA, IRF, and LTCH) currently include an outlier policy; the SNF PPS does not. (The SNF per day payments offer some protection against large losses because payments increase with length of stay). In designing an outlier policy, the Secretary would need to determine the size of the outlier pool, the fixed-loss amount, and the share of the cost covered by the outlier payment. Setting a large outlier pool with the initial implementation of a PAC PPS is an attractive option because it would offer more protection for providers and help ensure access to care for beneficiaries while providers transition to full PAC PPS rates. Separate pools for HHA and institutional PAC stays would allow HHAs with unusually high costs to qualify for outlier payments. Otherwise, because HHAs' costs are so much lower than those of institutional PAC providers, HHAs would be unlikely to incur high enough costs to receive an outlier payment. Over time, as differences in costs and practices narrowed across providers and settings, the size of the pool would need to be reduced. In the future, the Secretary could also consider a uniform outlier policy for all PAC providers, rather than separate pools.

We modeled an illustrative high-cost outlier policy to gauge the general impact of such a policy. In this example, we established two pools—one for home health stays and one for institutional PAC stays. Each pool was set at 5 percent of spending and paid for 80 percent of the difference between the estimated cost of the stay and the outlier threshold.

Across most of the clinical, impairment, and medically complex groups, the illustrative high-cost outlier policy made little or no difference in payments (Table 3-9, pp. 88–89). Payments for most of the groups changed by 2 percent or less, indicating that although base rates would be lower, outlier payments were spread across clinical groups such that there was little reduction or gain in the aggregate. Clinical groups with changes in revenues of 3 percent or more included ventilator, severe wound care, and two of the medically complex groups (severely ill and highest acuity groups). For these groups, payments increased under a PAC PPS with the illustrative outlier policy and resulted in payments that were higher than the

stays' actual costs, with payments ranging from 7 percent higher than stay costs (highest acuity group) to 26 percent higher (ventilator group).

Short-stay outlier policy A short-stay outlier policy attempts to counter the incentives under a stay-based or episode-based payment system for providers to treat and promptly discharge patients to another setting or home. A short-stay outlier policy protects the program and taxpayers from excessive payments that would otherwise result for these short stays and protects beneficiaries from transfers that could be motivated by financial rather than clinical considerations. By establishing payments based on the average cost of short stays, the policy should neither encourage nor discourage short stays.

To illustrate the directional impact of a short-stay outlier policy, we modeled a day-based payment (or visit based, in the case of HHAs). We calculated the average per day cost for short stays across all institutional PAC stays and paid short stays this average daily rate for the number of days in the stay. Similarly, for home health episodes, we calculated the average per visit cost for the short episodes and paid short stays this average per visit rate for the number of visits in the stay. We added 20 percent to the payment for the first day of the stay (or visit) to acknowledge the higher costs typically incurred the first day of a stay (or episode).

The illustrative short-stay outlier policy more closely aligned payments to the costs of the short stays (Table 3-10, p. 90). Under substantially lower payments for short stays, all the payment-to-cost ratios were closer to the overall average (1.19) compared with payments without a policy. The ratios for payments for IRFs and LTCHs (0.80 and 0.72) were below 1.0 because the average cost of all stays includes stays treated in SNFs, which typically have lower costs. Though clearly needing refinement, the example illustrates the intent and impact of such a policy.

If past behavior is any indication, a short-stay outlier policy could encourage providers to extend stays so they qualified for full payments. This financial incentive would be reduced if short-stay outlier payments were calculated so that providers were not penalized for discharging patients before the short-stay threshold and a steep "cliff" did not exist between the payment for a full stay and that for a short stay. For example, CMS could consider paying more for the first day (or visit) of care, which typically has higher costs than later days in the stay. Although our illustration includes setting-specific length of stay thresholds, over time, as practice patterns converged, we would expect that a single threshold could define short stays.

The Secretary could consider extending recovery audit contractor (RAC) reviews to identify aberrant patterns of short stays. As an initial effort, RACs could develop audits to flag providers with unusually high shares of stays that are just long enough to qualify for the full-stay payments (but still well below the average duration). Although providers are unlikely to welcome RAC reviews, their focus to date on HHAs and SNFs has been small relative to program spending in these two settings. HHAs and SNFs make up about 13 percent of Medicare Part A and Part B spending but only about 5 percent of the payment corrections made by RACs (Centers for Medicare & Medicaid Services 2015b).

Policy considerations in implementing and maintaining the PAC PPS

In designing a PAC PPS, the Secretary will need to define when a stay begins and ends for beneficiaries with serial PAC stays. The Secretary will also need to define a policy that eases providers through the transition from setting-specific PPSs to a unified PAC PPS. In addition, the Secretary should consider an aggregate level of payments, given the high level of current PAC spending relative to providers' costs. Finally, the Secretary should have the authority to make ongoing refinements to the PAC PPS—including regular recalibration of the relative weights and periodic rebasing of payments—to reflect changes in costs and practice patterns over time. These ongoing refinements would be designed to maintain payment accuracy to help ensure that providers have no financial incentive to admit certain types of patients over others and that beneficiaries are protected from impaired access to needed care.

Defining the stay

The task of defining a stay is straightforward for the patient who returns home after one PAC stay (with or without home health care). The stay would begin at admission to the PAC provider and end at discharge (or at the end of the 60-day episode for home health care). Likewise, when a beneficiary is discharged from one PAC setting and admitted to a second setting, the stay would begin at admission to the first PAC provider and end when discharged to the second setting. However, identifying the beginning and end of a PAC stay is more complicated for the patient requiring multiple levels of institutional PAC

TABLE 3–9

Comparison of estimated payments under a PAC PPS with and without an illustrative high-cost outlier policy (cont. next page)

Reporting group	Ratio of payments to actual costs *without* an outlier policy	Percent change in payments *with* an outlier policy	Ratio of payments to actual costs *with* an outlier policy
All stays	1.19	0%	1.19
Clinical group			
Cardiovascular medical	1.19	0	1.19
Orthopedic medical	1.18	–1	1.17
Orthopedic surgical	1.19	–2	1.17
Respiratory medical	1.20	0	1.20
Other neurology medical	1.18	0	1.19
Serious mental illness	1.18	1	1.19
Severe wound	1.15	3	1.19
Skin medical	1.16	1	1.17
Cardiovascular surgical	1.20	–1	1.19
Infection medical	1.20	0	1.20
Stroke	1.18	–1	1.18
Hematology medical	1.19	0	1.20
Ventilator	1.19	6	1.26
Frailty and cognitive impairment			
Least frail	1.19	–1	1.18
Most frail	1.18	0	1.18
Cognitively impaired	1.18	0	1.18
Medically complex			
Multiple body-system diagnoses	1.19	2	1.21
CCI	1.19	2	1.22
Severely ill (SOI = 4)	1.19	3	1.22
Highest acuity	0.95	12	1.07
Other stay and patient characteristics			
Low/no therapy share of costs: HHA stays	2.16	–4	2.07
Low/no therapy share of costs: Institutional PAC stays	1.25	2	1.28
High therapy share of costs: HHA stays	0.79	4	0.82
High therapy share of costs: Institutional PAC stays	1.09	0	1.09
Community admitted	1.19	0	1.19
Stays with prior hospital stay	1.19	0	1.18
Disabled	1.19	1	1.20
Dual eligible	1.18	1	1.19
ESRD	1.19	2	1.21
Very old (85+ years old)	1.18	–1	1.18

Note: PAC (post-acute care), PPS (prospective payment system), CCI (chronically critically ill), SOI (severity of illness), HHA (home health agency), ESRD (end-stage renal disease), SNF (skilled nursing facility) IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The illustrative outlier policy set the threshold so that outlier payments would equal 5 percent of total estimated payments for home health providers and 5 percent of total estimated payments for institutional providers. Outlier payments would cover 80 percent of the costs above the fixed-loss threshold. Patients' level of frailty was determined using a frailty index. The table shows the ratios of average payments in 2013 to average costs in 2013 for all the PAC stays included in the group, as well as the ratios of estimated payments under a PAC PPS to average actual costs in 2013 for all the PAC stays in each group. A payment-to-cost ratio of 1.0 indicates that payments equal the actual costs. Estimated payments under a PAC PPS are based on a payment model that uses readily available administrative data such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. "Multiple body-system diagnoses" includes patients with diagnoses involving five or more body systems who were treated in institutional PAC settings. CCI stays include patients who spent eight or more days in an intensive care or coronary care unit during the preceding hospital stay or were on a ventilator in the PAC setting. Severely ill stays include patients who were categorized as SOI Level 4 during the immediately preceding hospital stay. "Highest acuity" refers to patients who were categorized as SOI Level 4 and received PAC in institutional settings only, were on dialysis, and had severe wounds or pressure ulcers. All LTCHs are included in the freestanding group. LTCH-qualifying stays are those that meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

TABLE 3–9 **Comparison of estimated payments under a PAC PPS with and without an illustrative high-cost outlier policy (cont.)**

Reporting group	Ratio of payments to actual costs *without* an outlier policy	Percent change in payments *with* an outlier policy	Ratio of payments to actual costs *with* an outlier policy
Setting and provider characteristics			
HHA	1.19	0	1.19
SNF	1.29	–1	1.27
IRF	1.04	–2	1.03
LTCH			
All stays	0.81	14	0.93
Qualifying stays	0.90	12	1.00
Hospital based	0.98	0	0.98
Freestanding	1.22	0	1.22
Nonprofit	1.14	0	1.14
For profit	1.21	0	1.21
Government	1.03	2	1.05
Urban	1.19	0	1.19
Rural	1.19	0	1.19
Frontier	1.15	1	1.16

Note: PAC (post-acute care), PPS (prospective payment system), CCI (chronically critically ill), SOI (severity of illness), HHA (home health agency), ESRD (end-stage renal disease), SNF (skilled nursing facility) IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The illustrative outlier policy set the threshold so that outlier payments would equal 5 percent of total estimated payments for home health providers and 5 percent of total estimated payments for institutional providers. Outlier payments would cover 80 percent of the costs above the fixed-loss threshold. Patients' level of frailty was determined using a frailty index. The table shows the ratios of average payments in 2013 to average costs in 2013 for all the PAC stays included in the group, as well as the ratios of estimated payments under a PAC PPS to average actual costs in 2013 for all the PAC stays in each group. A payment-to-cost ratio of 1.0 indicates that payments equal the actual costs. Estimated payments under a PAC PPS are based on a payment model that uses readily available administrative data such as claims information from PAC stays and preceding hospital stays, demographic information from the Medicare enrollment files, beneficiary risk scores, and cost report information for PAC providers. The administrative models combine the results of a model that predicts the costs of routine and therapy care and one that predicts nontherapy ancillary costs. "Multiple body-system diagnoses" includes patients with diagnoses involving five or more body systems who were treated in institutional PAC settings. CCI stays include patients who spent eight or more days in an intensive care or coronary care unit during the preceding hospital stay or were on a ventilator in the PAC setting. Severely ill stays include patients who were categorized as SOI Level 4 during the immediately preceding hospital stay. "Highest acuity" refers to patients who were categorized as SOI Level 4 and received PAC in institutional settings only, were on dialysis, and had severe wounds or pressure ulcers. All LTCHs are included in the freestanding group. LTCH-qualifying stays are those that meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

care that is provided by a single PAC provider. Under a PAC PPS, some institutional providers may opt to offer a continuum of PAC services, yet, for these stays, the beginning and end of a PAC stay is less clear, especially for patients who are unlikely to recover to a prior level of functioning and whose PAC stay will at best stabilize or delay deterioration.

For example, a patient admitted to an institutional PAC provider for high-acuity care, such as prolonged mechanical ventilation, may need additional rehabilitative care after weaning and recovery from the ventilator. In the past, such a patient might have received PAC care in an LTCH and been discharged to a SNF or IRF for intensive rehabilitation. Medicare would have made one payment (under the LTCH PPS) for the first PAC stay and another (under the SNF or IRF PPS) for the subsequent PAC stay. Under a unified PAC PPS, however, PAC providers might diversify by providing multiple levels of care, making it more difficult to determine when one PAC stay ends and another begins and therefore when a second payment should be triggered. The ventilator patient who receives care from a PAC provider with the capacity to provide both ventilator care and intensive physical therapy might not be discharged after weaning and recovery but instead remain in the facility for additional therapy. Medicare would need to determine when, and whether, to make a second (or subsequent) payment for additional care.

TABLE 3–10

Comparison of estimated payments under a PAC PPS with and without an illustrative short-stay policy

Reporting group	Ratio of payments to actual costs *without* a short-stay policy	Percent change in payments *with* a short-stay policy	Ratio of payments to actual costs *with* short-stay policy
All	1.19	0%	1.19
HHA episodes with 4 or fewer visits	3.36	–60	1.36
Shortest stay, 10th percentile			
SNF (6 or fewer days)	4.81	–63	1.77
IRF (7 or fewer days)	1.80	–56	0.80
LTCH (11 or fewer days)	2.23	–67	0.72

Note: PAC (post-acute care), PPS (prospective payment system), HHA (home health agency), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). Payments under a PAC PPS reflect a stay-based payment. Payments with a short-stay policy reflect the illustrative short-stay policy that paid a per day (or per visit, in the case of HHA episodes) amount based on the average cost per day (or per visit).

Source: The Urban Institute analysis of 8.9 million PAC stays in 2013.

Under the current SNF PPS, a significant change in a beneficiary's clinical status triggers a new assessment and a change in the daily payment rate. If this approach were used in a stay-based PAC PPS, volume growth would need to be carefully monitored to ensure that providers were not reassessing patients solely to generate additional stays and payments. A measure of resource use, such as Medicare spending per beneficiary–PAC, could help discourage this behavior. Ultimately, Medicare should move away from FFS payment and toward integrated payment and delivery systems, such as episode-based payments, that make providers responsible for the quality of care and spending throughout the episode of care (though the incentive to generate new PAC episodes would remain).

Alternatively, CMS could require physicians and other health professionals to attest that continued PAC is needed, require prior authorization for subsequent PAC use, or rely on a third-party benefit manager to control the provision of unnecessary PAC.

The complexity of defining a stay in a PAC PPS underscores the need to move as quickly as practicable to episode-based payments. Under episode-based payment, providers would be paid for services furnished during the entire episode of care, making it easier to determine the beginning and the end of the PAC encounter. That said, the definition of the episode will be arbitrary and providers will still have an incentive to generate new episodes.

A transition policy

A transition period will give providers time to adjust their costs and mix of patients, thereby protecting providers from large financial loss and beneficiaries from impeded access to care. A typical transition policy blends over multiple years the mix of payments under current policy with payments under a new policy, with current policy weighted more in early years and new payments weighted more in later years, until rates are fully established by the new system. The implementation of HHA, SNF, IRF, and LTCH PPSs included multiyear transitions with blended rates but allowed providers to bypass the transition and be paid the national PPS rates immediately, which many providers opted for. This bypass option could be contemplated with the implementation of the PAC PPS. If such a provision were included in the PAC PPS, low-cost providers and settings would likely choose this option. The recent merger and acquisition activity in the PAC industry indicates that many providers and health systems anticipate and welcome the integration of PAC (Medicare Payment Advisory Commission 2016). By eliminating the different rules and regulations for separate payment systems, a PAC PPS will allow providers to offer a broad array of PAC services to beneficiaries.

A transition policy might consider introducing a PAC PPS using administrative models sooner than the timetable laid out in IMPACT and transitioning to models that

include patient assessment data as they become available. This approach would allow the Secretary to implement a unified PPS sooner than under the current schedule. The Secretary is required to use two years of uniform patient assessment data in the design of a PAC PPS, and these data will not begin to be collected until October 2018. On this timetable, it is unlikely that a unified system could be proposed before 2024. Our results indicate that, at least in aggregate and for most of the patient groups we examined, the predicted costs of stays were generally accurate without the patient assessment information. However, these data were important for accuracy in predicting the costs for certain patient groups (such as patients with high and low function). The Secretary might consider introducing a PAC PPS without the functional assessment data earlier than the current time line and refine the PPS over time as these data become available. To help compensate for inaccurate payments for high-cost stays, a larger outlier pool could be established initially, with the pool size declining as assessment data and PPS refinements were incorporated into the PAC PPS.

The implementation of a PAC PPS should not detract from the need to revise the payment systems for HHAs and SNFs and to rebase the level of payments in these two settings. Even under a transition policy and increased payments from Medicare Advantage (MA) plans, payments generated by the existing PPSs are likely to constitute a portion of the payment for several years. In addition, under Medicare's broader structural reforms—such as accountable care organizations (ACOs), the bundled payment initiatives, CMMI's Comprehensive Care for Joint Replacement (CJR) Payment Model, and MA plans—payments or payment benchmarks are based on FFS payments. Therefore, accurate setting-specific FFS payments will remain highly relevant for years.

Level of payments

As a general principle, Medicare payments should be based on the resources needed to provide high-quality care efficiently in the most appropriate setting. However, the lack of evidence-based guidelines and studies comparing outcomes across settings limits the program's ability to do so. In the absence of such information, a conservative strategy in designing a PAC PPS would be to set payments initially based on the current mix of settings and costs.

As part of a transition, the Secretary will need to evaluate the level of aggregate payments. Our analysis of 2013 PAC stays found that aggregate payments for PAC exceeded the costs of care by 19 percent. The Commission has repeatedly recommended reductions of or freezes on payments to providers in these four settings to bring Medicare's payments more closely in alignment with providers' costs (Medicare Payment Advisory Commission 2016). The Secretary could lower payments throughout the transition period or begin the reductions after the unified PPS is in place and providers have adjusted their practices and costs to the level of payments.

Policymakers could consider several ways to set an aggregate PAC spending level that is different from the current level. One alternative would be for the aggregate level to incorporate the Commission's standing recommendations regarding updates to PPS rates. For example, the aggregate pool of dollars could incorporate freezing the SNF, IRF, and LTCH rates, and reducing HHA rates.

Another alternative would be to apply our findings about efficient providers in HHAs and SNFs in establishing the aggregate pool of PAC spending. Our analysis of efficient HHAs found that their costs were 11 percent lower than other HHAs' costs, while efficient SNFs had costs that were 8 percent lower than those of other SNFs (Medicare Payment Advisory Commission 2016). Policymakers could establish an aggregate spending pool that reflects some or all of these differences in costs between efficient and other providers for at least these two settings. (Policymakers could also make assumptions about the cost differences between efficient and other providers in other sectors, but the Commission has not analyzed those.)

Alternatively, the Secretary could consider the geographic variation in PAC costs in setting the level of payments. Stay costs in 2013 varied 30 percent across CMS regions (from $5,154 in New England to $6,783 in Region 7, which includes Iowa, Kansas Missouri, and Nebraska). These differences capture variation in the mix of PAC and, for HHAs and SNFs, the amount of care furnished to beneficiaries with similar characteristics. In earlier work, the Commission found that, across markets, Medicare spending on PAC varied more than any other service, reflecting variation in the mix of PAC providers and the frequency of PAC use (Medicare Payment Advisory Commission 2011b). Considering this variation, the Secretary could set payments based not on the average cost but at some level below the average, say at the 40th percentile of costs. Low-cost settings and providers located in markets without high-cost providers (such as New York state, where there are no LTCHs) could be at an advantage since nationally set rates would include some

use of high-cost settings. Conversely, high-cost settings and providers in markets with multiple high-cost providers would be under pressure to lower their costs more in line with the benchmark.

Periodic refinements to maintain the accuracy of the PAC PPS

Under a new PAC PPS, practice patterns would change as high-cost providers lower their costs and shift their mix of patients and services furnished. Also, costs for medically complex care could increase if providers make investments in staffing and equipment to treat a more complex mix of patients. In addition, coding practices are likely to improve, which could increase payments even though the stays and their associated costs did not change. Therefore, the Secretary should have the authority to periodically recalibrate and rebase the payments made for stays.

In its ongoing maintenance of the PAC PPS, the Secretary should update the relative weights that adjust payments up or down for each type of case. These revisions would help ensure that Medicare's payments capture changes in the relative costs of stays. In addition, if ongoing monitoring of the PAC PPS uncovered systematic problems with the design, the Secretary would need to make revisions to correct them. For example, in existing PPSs, the patient classification systems and the risk adjustment methods are often revised over time to better differentiate stays and ensure that stays with similar resource requirements are paid similar amounts.

The Secretary should also have the authority to rebase payments if changes in practices and costs outpace changes in payments. Experience with PAC providers indicates they are highly nimble at adjusting to policy changes, and margins under new PPSs have generally increased substantially. To protect the program and taxpayers from excessively high payments relative to the cost of stays, the Secretary would need the authority to rebase payments, if necessary, to maintain the alignment of payments with the cost of stays.

Under a more aggressive implementation timetable than outlined in IMPACT, a PAC PPS could be implemented without functional data (with perhaps a larger outlier pool to compensate unusually high-cost stays) earlier than mandated. At a later date, newly available functional assessment data could refine the risk adjustment. Given the importance of functional data for gauging patient outcomes and improving the accuracy of payments for some patient groups, CMS should move as expeditiously as possible in collecting uniform patient assessment information (even ahead of the time line laid out in IMPACT if possible).[20] Likewise, the PPS could evolve to use information gathered from PAC claims and the unified patient assessments. Doing so would facilitate the processing of claims and allow providers to estimate their payments for a stay more easily.

Changing regulatory requirements under a PAC PPS

Despite overlap in types of cases treated in the four PAC settings, Medicare has different regulatory requirements (in terms of payment policies and conditions of participation) for each setting (see online Appendix 3-B, available at http://www.medpac.gov). These requirements distinguish PAC settings from each other and from acute care hospitals. The regulatory requirements for LTCHs and IRFs are more stringent and costly to meet than those for SNFs and HHAs. For example, LTCHs and IRFs must meet all Medicare conditions of participation for acute care hospitals. The LTCH and IRF regulations influence the intensity of care provided, which can increase these providers' costs of care, even though the types of patients treated in these two settings are also treated in SNFs.

Because PAC payment reform would narrow differences in payments across settings, setting-specific regulations should also be reduced to the extent possible. Otherwise, providers in different settings would be paid the same for treating the same patient but would incur very different costs associated with their particular regulatory requirements. While overhauling Medicare's conditions of participation would be a complex undertaking, under a PAC PPS, CMS would need to consider leveling the regulatory playing field by waiving certain requirements specific to a particular setting. Over time, CMS should consider specifying regulatory requirements by patient type rather than by PAC setting. The Congress would need to make conforming changes to Medicare coverage for home-based and institutional PAC.

Near term: Waive certain regulatory requirements

Under a PAC PPS, because all conditions in PAC settings would be paid under a single payment system, policymakers would need to consider waiving regulatory requirements that raise the costs of IRFs and LTCHs. Many of these waivers would need to be implemented

concurrently with the start of the PAC PPS and, in some cases, the Secretary would need the authority to implement them.[21] Otherwise, a provider could be paid PAC PPS rates but still be held to meeting setting-specific requirements, some of which raise the cost of care. Waiving certain requirements would allow providers to bring their costs more in line with the payments they would receive under a PAC PPS and give providers the flexibility to offer a range of PAC services to different patients. Having a provider meet different regulatory requirements based on the patient treated would be similar to current SNF policy for swing beds that permit small rural hospitals to use their beds for acute or SNF care, as needed.

In considering which policies to waive and what, if anything to replace them with, the Secretary would need to consider any unintended consequences of such actions and the feasibility of enforcement and monitoring compliance without medical record review. Policies that CMS could consider waiving include:

- the intensive rehabilitation therapy requirement for IRFs;
- the 60 percent rule for IRFs;
- the frequency of physician visits and on-duty presence of physicians in IRFs; and
- the 25-day length-of-stay requirement for LTCHs.

The Secretary could also consider standardizing the rules for therapy coverage across the four settings, including the number of therapy disciplines required, the allowed mix of therapy modalities (individual, group, and concurrent), and coverage for restorative/rehabilitation services and maintenance services.

Some regulations serve to limit inappropriate admissions. For example, the three-day hospital stay requirement for SNFs is an important barrier to prevent nursing homes from recertifying long-stay residents as Part A–covered SNF stays to receive higher Medicare SNF payments. The Commission previously recommended the Secretary allow up to two observation days to count toward the three-day requirement (Medicare Payment Advisory Commission 2015). If the hospital stay requirement is waived entirely, Medicare's liability for PAC could increase substantially. Alternatively, for certain types of patients, Medicare might need to establish a uniform policy regarding preceding hospital stays that applies to all PAC providers. The three-day SNF requirement is waived for entities participating in the Center for Medicare & Medicaid Innovation's Bundled Payment for Care Improvement Initiative and some ACOs, and for hospitals participating in the CJR Model.[22]

Shorter stays for patients treated in LTCHs could prompt some clinicians working in this setting to have more timely conversations with patients and their families about a patient's prognosis, which might lead some beneficiaries to elect to use hospice care.

The effect of waiving requirements could be limited by state licensure or other regulations that providers in those states must meet. For example, state-mandated minimum staffing ratios for nursing homes could be more stringent than Medicare's requirements, so waiving federal requirements would have little effect on providers that are certified for both Medicaid and Medicare. Providers required to meet such state regulations could have less flexibility than providers in other states.

Longer term: Develop a common set of PAC requirements

In the longer term, the Secretary could establish a single set of conditions of participation for institutional PAC providers. A common set of regulatory requirements for all institutional PAC providers would ensure a baseline level of competency while allowing providers the flexibility to adjust their mix of services and staffing to meet patients' needs. Because of the large differences between home health care and facility-based PAC care, home health care could require its own set of regulations.

The domains of these requirements could include staffing levels and patient mix, physician availability, frequency and content of patient assessments and care plans, staff training and competency requirements, infection control, patient rights, compliance and ethics, use of multidisciplinary teams, and discharge planning.

Standardizing regulatory requirements across PAC providers should not necessarily result in the application of current SNF regulations to all institutional providers. A common set of requirements could raise the staffing and physician oversight requirements for SNFs and result in facilities having to meet separate requirements for PAC patients and long-term care patients, who typically require a lower level of care.[23]

In addition to developing a common set of regulations across PAC settings, CMS could develop specific requirements for providers (in any setting) that opt to serve patients with particular care needs. For example,

TABLE 3–11 **Cost sharing required of beneficiaries using post-acute care in 2016**

HHA	SNF	IRF and LTCH
None	• A daily copayment ($161 in 2016) begins on day 21 of the SNF stay. • No coverage after day 100 per spell of illness (a spell begins when a beneficiary has not had inpatient hospital care or skilled care in a SNF for 60 consecutive days).	• Hospital deductible ($1,288 in 2016) generally met with a preceding acute hospital stay. • For stays that exceed 60 days (the hospital stay plus the IRF or LTCH stay), the beneficiary is responsible for a $322 daily copayment (in 2016) for days 61 through 90 of hospital care. • For stays that exceed 90 days, in 2016 the daily copayment is $644 and Medicare coverage is limited to a lifetime reserve of 60 days. • For beneficiaries admitted from the community, there is a $1,288 deductible (in 2016).

Note: HHA (home health agency), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital).

Source: Centers for Medicare & Medicaid Services. Medicare program; CY 2016 inpatient hospital deductible and hospital and extended care services coinsurance amounts. CMS–8059–N.

providers that admit patients who need prolonged ventilator care could be required to have sufficiently trained staff and equipment to provide appropriate nursing care and respiratory therapy and to demonstrate use of evidence-based ventilator weaning practices. Providers opting to treat patients with extensive wounds might need to demonstrate competence in wound care management. Those treating medically complex patients could be required to have adequate nursing and physician staff to manage these patients' care. Those treating patients with intensive rehabilitation care needs (such as patients with burns or those with brain or spinal cord injuries) could be required to have the therapy staff and equipment to furnish this care. Concentrating on requirements for treating types of patients rather than for settings could improve patient outcomes. For example, studies have found that severely ill patients benefit from LTCH care (Gage et al. 2012, Kennell and Associates Inc. 2010, Medicare Payment Advisory Commission 2004). Any PAC provider treating conditions with special care requirements would have to meet the relevant requirements for each condition, thus shifting the requirements from setting specific to condition specific.

Condition-based requirements may encourage some providers to specialize in certain types of conditions, such as ventilator care. By concentrating specialized services in providers that meet minimum standards for these services, the quality of care beneficiaries receive is likely to increase. However, the concentration could result in beneficiaries having to travel farther to receive these specialized services, similar to referral centers treating beneficiaries from a larger geographic market than other hospitals.

Standardizing beneficiary cost sharing

Under Medicare's current rules, coverage for PAC and cost-sharing requirements differ, depending on where beneficiaries are treated, and can influence beneficiary choices about where to receive their care (Table 3-11). For example, under current policy, there is no cost sharing for HHA use, and there are no limits on coverage. In contrast, beneficiaries using SNF services face daily copayments beginning on day 21 of their SNF stay, and program coverage ends entirely on day 101 of a stay. In our analytic sample of 2.3 million SNF stays in 2013, one quarter of stays were 12 days or shorter, the median was 22 days, and one-quarter of stays were 39 days or longer. Although most Medicare supplemental policies cover the SNF cost sharing, two plans (enrolling about 6 percent of beneficiaries opting to purchase medigap policies) do not. A prior three-day hospital stay is also required for Medicare coverage, so beneficiaries who do not have a preceding inpatient stay or who have a hospital stay

shorter than three days are not covered by the program. Beneficiaries not meeting the SNF coverage rules, who have purchased supplemental policies that do not cover SNF cost sharing or who have not purchased supplemental coverage, can opt to be treated by HHAs or IRFs.

Beneficiaries using IRFs and LTCHs (settings that do not require a prior inpatient hospital stay for Medicare coverage) incur Part A deductibles if they are admitted directly from the community (about 15 percent of LTCH and IRF users). Although many IRF and LTCH users are unlikely to be candidates for home health care (which has no such deductible), some orthopedic procedures (such as knee replacements) are increasingly performed in ambulatory surgical centers. Some beneficiaries use IRFs because they do not meet SNF coverage rules but do meet the IRF coverage rules (because they can tolerate intensive rehabilitation therapy). Almost all medigap plans cover the Part A deductible, but one plan does not. Its enrollees (about 2 percent of medigap enrollees) and beneficiaries without supplemental coverage might avoid the institutional PAC settings because of financial considerations. In addition, beneficiaries without supplemental policies might avoid LTCHs or transfer out of that setting if their stays exceed 60 days since additional cost sharing begins on day 61 of the LTCH stay (the same is true for IRF users, but almost no IRF users stay that long).

As Medicare moves toward uniform payments for PAC care, the Secretary should consider standardizing its cost-sharing requirements across PAC settings. Consistent with the Commission's previous work on benefit redesign, a uniform cost-sharing arrangement across PAC settings could result in more rational PAC use for those beneficiaries who currently choose a PAC setting based at least in part on the cost-sharing requirements (Medicare Payment Advisory Commission 2012). For example, there could be a uniform copayment for the use of any PAC services. Beneficiaries would not have a financial incentive to select one PAC setting over another, thus making their choice of PAC independent of any financial consideration. A copayment would also encourage beneficiaries to consider the need to initiate or continue to use PAC. Uniform cost sharing would impose cost sharing for beneficiaries who use home health care, consistent with a Commission recommendation to impose cost sharing for community-admitted beneficiaries (Medicare Payment Advisory Commission 2011a). Because many beneficiaries have supplemental insurance, medigap policies would need to conform so that the cost-sharing policies are effective. The Secretary could consider waiving the copayment requirement for low-income beneficiaries.

Companion policies to dampen FFS incentives

Under a PAC PPS, providers would still be paid on an FFS basis with all the financial incentives such a system entails. Providers would have an incentive to reduce the costs of care during the PAC stay by stinting on care or discharging patients prematurely. At the same time, they would have a financial incentive to increase the number of PAC stays, for example, by admitting patients with marginal care needs or by referring beneficiaries to subsequent PAC use.

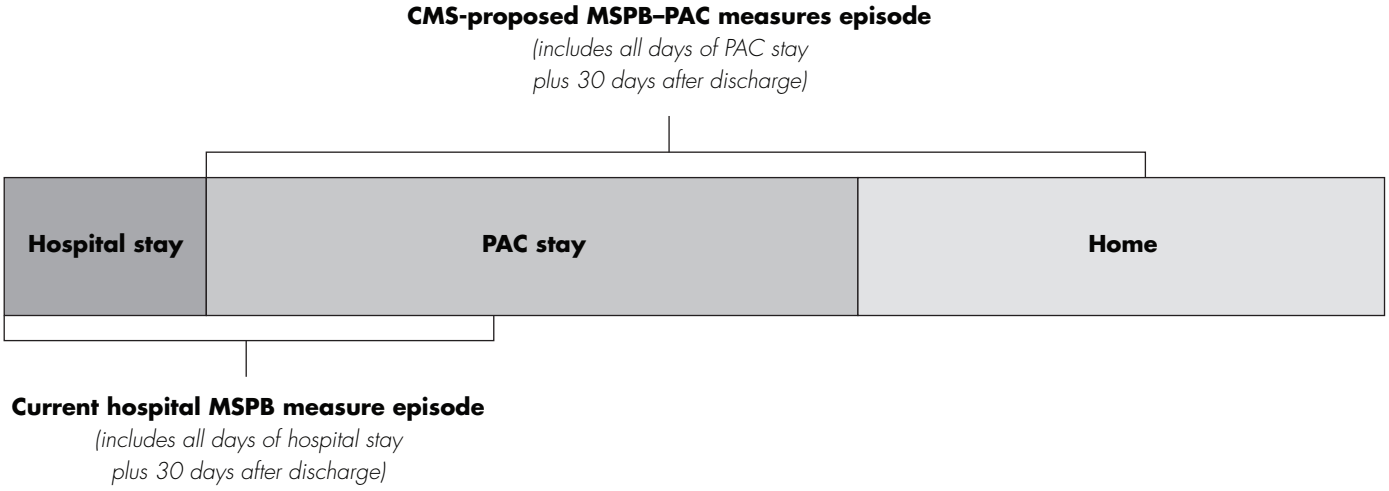
Episode-based payments dampen these incentives by paying a provider for all services furnished during a defined period of time. Providers would be discouraged from increasing the number of back-to-back PAC stays or shifting care to after the PAC stay because they remain financially responsible for all care within the episode time frame. Episode-based payments encourage providers to furnish high-quality care because poor quality can result in costly readmissions. In short, bundled payments have the potential to meet several objectives simultaneously: improve care coordination and the quality of services, rationalize service use and lower program spending, and lower potentially avoidable readmissions.

However, until these broad structural reforms are in place, CMS must implement companion policies to dampen the FFS incentives to generate serial PAC stays and to stint on care. The companion policies include value-based purchasing (VBP) (including a measure of Medicare spending per beneficiary) and a readmissions policy. CMS could also consider outsourcing the management of PAC services to a third party. In addition to implementing companion policies with the new PAC PPS, CMS must closely monitor provider response to the new payment system to guard against unintended consequences that adversely affect quality of care for Medicare spending.

Value-based purchasing

To counter the FFS incentives to generate unnecessary volume, delay care until after the PAC stay, and stint on services, CMS would need to implement VBP concurrently with the implementation of a PAC PPS. By tying a portion of payments to measures of quality and resource use, providers would have an incentive to provide adequate care

FIGURE 3–1 **Comparison of the current hospital MSPB measure and proposed MSPB–PAC measures**



Note: MSPB (Medicare spending per beneficiary), PAC (post-acute care).

to achieve good outcomes while using resources efficiently within an episode's fixed payment. Without such a policy, providers could lower their costs by stinting on services and could generate subsequent PAC stays as a way to increase revenue. In addition to encouraging efficient care, Medicare spending per beneficiary–post-acute care (MSPB–PAC) measures could detect stinting by identifying providers with unusually low spending.

A VBP program must include quality measures and resource use measures both. Otherwise, providers could sacrifice quality to keep spending low. Resource use measures could include the MSPB–PAC measures, which the Secretary is required by IMPACT to develop.[24] In January 2016, CMS proposed measures to gauge spending during a PAC stay and the 30 days after discharge from the PAC setting. Similar to the hospital MSPB measure, the MSPB–PAC measures would include spending for the admission to a PAC setting and spending on services furnished within 30 days of discharge (Figure 3-1). For post-acute care use following a hospital stay, the MSPB–PAC measures would align the incentives of hospitals (and the related physician services) and PAC providers.

Quality measures could include risk-adjusted rates of potentially avoidable readmissions (to hospitals and PAC settings) and community discharge and changes in function (once these data are routinely collected by PAC providers). Measures of care coordination could include the number of days between discharge from the hospital and follow-up care with a primary care practitioner and potentially avoidable emergency department visits.

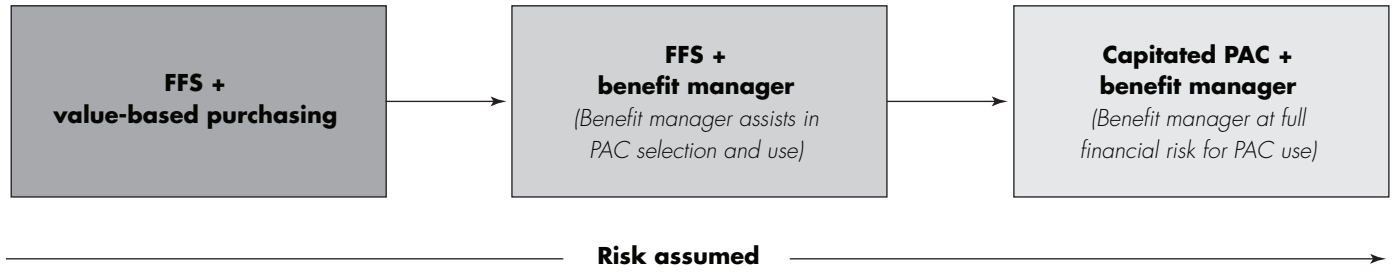
The current status of VBP varies by PAC setting. In January 2016, CMS implemented a VBP program for HHAs in 9 states, which began with monitoring performance on 24 measures. In the Protecting Access to Medicare Act of 2014, the Congress required CMS to design a VBP program for SNFs that will affect payments beginning October 2018. The SNF VBP program begins with an all-cause all-condition readmission measure, but the law requires the Secretary to replace it with a measure of potentially avoidable readmissions as soon as practicable. Although a provision in the Patient Protection and Affordable Care Act of 2010 requires VBP pilot programs in LTCHs and IRFs by 2016, competing priorities and a lack of funding have prevented CMS from initiating work on these pilots.

A readmission policy

The other companion policy that needs to accompany a PAC PPS is a readmission policy for all PAC providers. By holding providers accountable for readmissions to hospitals that occur during PAC stays, a readmission

FIGURE 3–2

Options for a third-party benefit manager shifts the risk from Medicare onto third-party benefit managers



Note: FFS (fee-for-service), PAC (post-acute care).

policy creates incentives for providers to furnish adequate quality of care to keep patients out of the hospital. A readmission policy thus counters the incentive under any PPS to stint on care. Ideally, readmission rates would be one of the measures in a VBP program so that a single program's incentives shape provider behavior.

The status of readmission policies varies by PAC setting. In 2012, the Commission recommended that CMS implement a readmission policy for SNFs, and in 2014 it recommended that CMS implement a home health readmission policy for post-acute home health episodes. CMS is moving forward with readmission policies for SNFs and HHAs as part of VBP programs. Although LTCHs and IRFs do not have readmission or VBP policies in development, providers in both settings are subject to pay-for-reporting on this measure.[25] The 30-day readmission rates for certain types of LTCH patients are currently lower than other settings, likely due to the hospital-level capabilities of the setting (Gage et al. 2012). (See online Appendix 3-A, available at http://www.medpac.gov, on comparing outcomes across PAC settings.) Given the potential regulatory changes made concurrent with a PAC PPS, LTCHs may have more incentive to discharge patients earlier, which could potentially increase readmissions. A readmission policy would counter the financial incentive that all providers, including LTCHs, would have to underprovide care.

Pay a third party to manage PAC

Medicare could also consider contracting with a third-party benefit manager to manage PAC services. The benefit manager could receive a separate payment to manage PAC services or, accepting more risk, could be financially responsible for the costs of PAC services in a given market. Because the third-party manager would be at risk for all care within the market for a defined period, it would have a financial incentive to steer beneficiaries toward the lowest cost appropriate setting for PAC. Beneficiaries would retain their freedom of choice, but the third-party manager could encourage beneficiaries to select certain providers or settings over others.

A third-party benefit manager typically compares data on an individual patient's characteristics (comorbidities, functional and activity status, and cognition) with data on other patients. Using these matched patients' experience, the benefit manager estimates the time (the number of days) likely needed to achieve a functional outcome (such as a certain gain in function), length of stay in different PAC settings, and risk of hospital readmission. These predictions inform the selection of the setting and specific provider. The third-party manager achieves savings by avoiding PAC use altogether, shifting use from high-cost to low-cost PAC settings, and by lowering the amount of PAC used.

There are conflicting views about the need for and desirability of a third-party benefit manager. The need for a PAC benefit manager and the form such management would take would depend in part on how effective outcome measures were at changing provider behavior and where the financial risk lies for appropriate, low-cost PAC (Figure 3-2). At one end of the risk continuum, FFS would remain in place, and value-based purchasing would offer risk and rewards for good outcomes and low resource use

over an episode of care (current policy). If the incentives are sufficiently large, providers would deliver low-cost, high-quality care and benefit managers would not be needed. Those with reservations about benefit managers believe that the clinical team should drive placement decisions and that tracking meaningful outcomes and making providers responsible for them is the best way to ensure good care for beneficiaries. For them, benefit managers are overly focused on lowering costs without a focus on the care needs of the beneficiary.

At the other end of the risk spectrum, a benefit manager would accept full risk for all PAC. A benefit manager would pay PAC providers and Medicare would no longer make FFS payments for these services. Medicare would thus shift the risk for PAC to the benefit manager, who would have financial incentives to ensure that beneficiaries received high-quality, well-coordinated care. In a middle strategy, a benefit manager could assist beneficiary decision making and help manage PAC use over an episode of care. Benefit managers would be paid a nominal amount and would likely share in any savings achieved by avoided readmissions or lower PAC spending.

A benefit manager would insert a third party into the decision making and management of care provided to beneficiaries, which could enhance beneficiary decision making but add administrative burden to an already complex discharge process. From the beneficiary perspective, a benefit manager could facilitate the decision about where to get PAC and guide beneficiaries to high-quality providers. The manager could also determine whether the beneficiary required institutional PAC or could be safely treated at home. The providers included in the manager's network would determine whether the choices were convenient for the family and included high-quality providers. However, a thin network or one composed of marginal-quality providers could raise concerns that care is more difficult to access and is inadequate. In addition, some clinicians could oppose needing to get approval from a third party that may be unfamiliar with the patient's circumstances, especially if it increases their administrative burden. The process the benefit manager used to make referral decisions would influence how well the managers were received. Referral decisions based on direct interaction with the patient and caregivers would be more likely to gain acceptance than referrals based on information indirectly conveyed by a benefit manager.

Currently, some MA plans, ACOs, and participants in CMS's bundling initiative contract with a benefit manager to manage PAC use. Kindred, a diversified provider of PAC services, recently launched a national referral service staffed by nurses to provide consumers with PAC resources, including PAC referrals and insurance coverage information. Kindred plans to develop a PAC benefit management model to manage specific patient populations on behalf of payers and health system entities like ACOs (Kindred 2016).

Monitoring provider responses to a PAC PPS

Under payment reforms such as episode-based payment, providers will be at risk for the quality and cost of services over a sustained period. Providers will have a financial interest to furnish efficient, high-quality care to keep their episode costs low, thereby reducing the need for the Secretary to monitor undesirable provider responses. However, until such payment reforms are implemented, the Secretary must carefully monitor provider behavior, including providing poor-quality care, selectively admitting certain types of stays over others, and generating unnecessary PAC stays to generate revenue. Similarly, monitoring the early results of a PAC PPS and making modifications as needed will be essential.

To monitor quality, the Secretary should track potentially avoidable readmission rates, potentially avoidable complication rates, changes in patient function during the PAC stay, and beneficiary experience. Measures that are tracked over longer periods of time, such as rates for 60 or 90 days, would hold providers accountable for a longer recovery period that may make more sense for PAC but could begin to include events unrelated to the initial reason for PAC. For stays admitted directly from the community, the Secretary should also track admission rates. To assess care coordination, the Secretary could monitor rates of potentially avoidable emergency department visits and rates of observation stays, as well as the number of days between discharge from the hospital and follow-up care with a physician or other clinician. Patient-reported satisfaction with care would add a valuable perspective on the success of care coordination among providers and settings.

To evaluate whether providers were engaged in patient selection, the Secretary should monitor changes in the

rates of PAC use and the mix of patients across settings. If PAC providers considered the payment rates for certain types of cases to be too low, these patients might be difficult to place and could remain in hospitals. Therefore, hospital lengths of stay by condition would also need to be monitored. Because we expect large changes in the mix of patients across the different settings, the Secretary will need to identify providers' aberrant practice patterns and conduct focused reviews of their claims. If the Secretary decides to move forward with implementing a PAC PPS sooner than is legislated, using administrative data, particular attention should be paid to access to PAC for patient groups for which payments relative to costs may be lower than for other patient groups. Some patient selection may be unavoidable under any PPS, but the Secretary should identify a handful of patient types of most concern (for example, the sickest or frailest) and monitor PAC use rates across providers. Systematic patterns could indicate a problem with the PPS that refinements (such as changes to the risk adjustment) could address. Provider responses could also prompt changes in policy, such as larger penalties under a readmission policy or larger financial risks under a VBP program.

To gauge whether providers were generating unnecessary PAC stays, the Secretary should monitor PAC use rates, including initial PAC use after discharge from the hospital and from any subsequent PAC provider. The use rates of subsequent PAC would also suggest whether providers were shifting care to another PAC provider rather than managing the care themselves. The Secretary should also monitor changes in PAC lengths of stay. Three of the four settings already have incentives to keep stays (or episodes) short, but we expect SNF stays to shorten under a stay-based payment system. Under a unified PAC PPS, we also expect lengths of stay to equilibrate across settings. However, without simultaneously monitoring quality metrics, we would not be able to determine whether any changes in lengths of stay represented better or worse care.

Similar to the efficient provider work the Commission has conducted, the Secretary could evaluate the share of providers that are low cost *and* high quality. Over time, the Secretary could assess the PAC PPS's impact on providers' ability to be both. This analysis could also provide benchmarks for PAC providers and for the VBP program.

Finally, the Secretary would need to monitor indicators of the adequacy of Medicare's payments (such as cost growth and Medicare margins) to ensure beneficiary access to care. This monitoring would include examining not only indicators in the aggregate but also distributions and the types of providers whose experience differed from the average. Such deviations could detect problems in the payment system warranting correction.

In 2014, the Congress moved to correct the lack of comparable outcome measures and standardized patient assessment information for PAC providers. IMPACT requires the Secretary to develop standardized quality measures across the four PAC settings, including measures of functional and cognitive status, changes in function and cognition, medication reconciliation, incidence of major falls, hospital readmissions, discharge to community, resource use, and accurate communication and transferring of health information and patient preferences. The Act also requires PAC providers to gather standardized patient assessment information at admission and discharge, including measures of function, cognition, specialized services (such as ventilator care, dialysis, and central line placement), medical conditions and comorbidities, and impairments (such as incontinence and difficulty swallowing). This information can be used to risk adjust costs and outcomes so that fair comparisons can be made across and within settings.

Implications for the design of a PAC PPS

A PAC PPS is feasible and would break down the silos between settings. Payments would be based on patient characteristics, not the setting, and would correct some of the shortcomings of current PPSs. Our work informs the design of a PAC PPS along with the adjusters that should be considered and those that do not appear to be warranted. Concurrent with the implementation of a PAC PPS, the Secretary should consider waiving select setting-specific regulatory requirements to give providers more flexibility in furnishing PAC care. In the future, the Secretary should also consider conditions of participation that focus on requirements to treat certain types of patients. Because a PPS will retain the FFS incentives to furnish unnecessary PAC stays, the Secretary needs to implement companion policies to dampen these incentives. Finally, the Secretary needs to develop a monitoring program to detect any unintended or inappropriate provider responses. Over the longer term, the Secretary needs to move forward with broader payment reforms that put providers at risk for furnishing high-quality, efficient care over an episode. The Commission underscores that until a PAC PPS is implemented, CMS and the Congress

need to move forward with our standing recommendations that would improve the accuracy and equity of payments within each setting. Because the current time line for implementing a PAC PPS is years away, these refinements to the individual payment systems would better align program payments to providers' costs, eliminate known biases in the payment systems, and help ensure access for beneficiaries with varying care needs.

Overall design of the PAC PPS

With respect to the design of the PAC PPS, our work confirms the following:

- A common unit of payment (a stay) and a common risk adjustment method are possible.
- Patient and stay characteristics (without indicators of therapy use) can form the basis of risk adjustment.
- Given differences in coverage across the PAC settings, separate models should be used to establish payments for NTA services and for the combination of routine and therapy services.
- Because the costs are so much lower in HHAs compared with institutional PAC care, payments for home health stays will need to be adjusted to avoid large overpayments to this setting.
- Administratively available data can accurately predict the costs for most stays, but patient data are needed to accurately predict the costs of certain types of stays.
- Initial payments can be based on current practices and costs, but, over time, payments should be revised to reflect efficient, appropriate care.

Payment adjusters

The goal of a PAC PPS is to establish common payments for similar patients (aside from the needed adjustment for HHA stays). Therefore, any adjustment made to a payment for a stay should apply to stays treated in any setting. Further, under a PAC PPS, we expect providers to change their providers' costs and practices; adjusters that undercut these intended impacts (e.g., adjusters for high-cost settings) should be avoided.

Our work indicates the need for the following adjusters:

- a short stay policy and
- an outlier policy.

There was less clear evidence of a need for:

- a broad rural or frontier adjustment and
- a teaching adjustment for IRFs.

More work needs to be done:

- to examine the need for an adjustment for low-volume, isolated providers;
- to confirm the need for an adjustment for providers treating high shares of low-income patients; and
- to define and adjust for medically complex patients.

Policy considerations in implementing and maintaining a PAC PPS

The Secretary will need to consider:

- the definition of a *stay*;
- the transition period—the number of years of the transition and how to blend "old" and "new" payments during this period;
- the level of payments; and
- periodic refinements to maintain the accuracy of payments.

Changing regulatory requirements under a PAC PPS

As Medicare begins to pay PAC providers under a single payment system, it needs to give providers more flexibility to offer services that span the PAC continuum of care. In addition, the program could consider standardizing cost sharing when beneficiaries use PAC services. Two time lines should be considered for waiving regulatory requirements:

- ***Near term***—At the same time the PPS is implemented, waive select setting-specific requirements; and
- ***Longer term***—Develop a common "core" set of conditions of participation for all PAC providers and specific requirements for providers that opt to treat patients who require specialized resources.

Companion policies to adopt with the implementation of a PAC PPS

Although a common PPS for PAC stays would begin to rationalize Medicare's payments, it would not correct the underlying incentives in FFS payment to generate

unnecessary PAC stays or to provide low-quality care if it is less costly. Therefore, the Secretary will need to implement the following companion policies to dampen these incentives:

- establish a readmission policy to prevent unnecessary hospital readmissions and
- tie payments to outcomes to protect beneficiaries against stinting.

The Secretary could consider using benefit managers to improve care coordination and efficiency of PAC.

In the longer term, Medicare needs to move toward putting providers at risk for spending over an episode of care. Because providers would be at risk for readmissions and downstream spending, there would be less need for these companion policies.

Monitor provider responses to the PAC PPS

The Secretary must establish a monitoring program to detect inappropriate provider responses, including:

- stinting on care, which may lower quality and outcomes;
- patient selection, which may impair some beneficiaries' access to care;
- unnecessary PAC stays; and
- delays in care that shift, but do not lower, program spending.

As indicators of the adequacy of Medicare's payments, the Secretary should also track:

- Medicare margins;
- cost growth; and
- a count of "efficient" providers—that is, providers that are relatively low cost and high quality.

As any unintended consequences of the PAC PPS are documented, the Secretary will need to make revisions. ■

Section 2(b)(1) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT)

(b) STUDIES OF ALTERNATIVE PAC PAYMENT MODELS.—

(1) MedPAC.—Using data from the Post-Acute Payment Reform Demonstration authorized under section 5008 of the Deficit Reduction Act of 2005 (Public Law 109–171) or other data, as available, not later than June 30, 2016, the Medicare Payment Advisory Commission shall submit to Congress a report that evaluates and recommends features of PAC payment systems (as defined in section 1899B(a)(2)(D) of the Social Security Act, as added by subsection (a)) that establish, or a unified post-acute care payment system under title XVIII of the Social Security Act that establishes, payment rates according to characteristics of individuals (such as cognitive ability, functional status, and impairments) instead of according to the post-acute care setting where the Medicare beneficiary involved is treated. To the extent feasible, such report shall consider the impacts of moving from PAC payment systems (as defined in subsection (a)(2)(D) of such section 1899B) in existence as of the date of the enactment of this Act to new post-acute care payment systems under title XVIII of the Social Security Act. ■

Endnotes

1 In an analysis of 22 conditions frequently treated in IRFs and SNFs, beneficiaries had similar risk profiles (or the lower cost SNF patients had higher risk profiles) (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015). Many areas of the country have no LTCHs, and patients who might otherwise go to LTCHs are discharged from acute care hospitals to SNFs and IRFs (Medicare Payment Advisory Commission 2014). The Post-Acute Care–Payment Reform Demonstration conducted by CMS found considerable overlap in the patients treated across the four settings (Gage et al. 2012).

2 In the PAC–PRD sample, routine costs made up 38 percent of LTCH stay costs, 47 percent of IRF stay costs, 49 percent of HHA stay costs, and 60 percent of SNF stay costs.

3 In contrast, voluntary demonstrations can draw participation from providers most able to innovate but unlikely to be representative of the industry, making it difficult to draw conclusions about how a demonstration will scale up to the entire industry.

4 The assessment gathered baseline information about a patient's status before the current spell of illness, as well as current medical information, functional and cognitive status, impairments, and discharge information.

5 A spell of illness begins when a beneficiary has not had inpatient hospital care or skilled care in a SNF for 60 consecutive days. Each beneficiary has a lifetime reserve of 60 additional inpatient hospital days that can be used after the 90 days of inpatient hospital coverage have been exhausted.

6 Nontherapy ancillary services include drugs, respiratory care, ventilator services, and other miscellaneous ancillary services such as laboratory tests and radiological exams. They account for 13 percent of SNF and IRF stay costs and 35 percent of LTCH stay costs.

7 Our analysis of PAC–PRD stays had the following composition: 60 percent were treated in HHAs, 12 percent in SNFs, 17 percent in IRFs, and 11 percent in LTCHs. This composition differs considerably from the nationwide distribution of 2013 PAC stays: 70 percent in HHAs, 25 percent in SNFs, 4 percent in IRFs, and 2 percent in LTCHs. Our analysis of the 107 PAC–PRD providers had the following composition: 38 percent were HHAs, 26 percent were SNFs, 22 percent were IRFs, and 13 percent were LTCHs. This provider mix also differs considerably from the nationwide distribution in 2013: 52 percent were SNFs, 43 percent were HHAs, 4 percent were IRFs, and 1 percent were LTCHs.

8 The relative weight measured each stay's relative routine resource use compared with all stays for that provider.

9 Because the overhead share of the total cost of a stay was similar across settings (though the levels differed), we did not model fixed and variable costs separately.

10 An alternative approach could have estimated the average routine cost per day (readily available from the cost report) and then multiplied that figure by each stay's length. However, we know that patient care costs vary by more than length of stay, which our chosen approach attempts to capture.

11 Severe wound care includes patients with a nonhealing surgical wound; an infected wound; a wound for a patient who is morbidly obese; a fistula; osteomyelitis; or a Stage III, Stage IV, or unstageable pressure wound.

12 The measure of frailty we used was the JEN Frailty Index, an algorithm developed by JEN Associates Inc. to identify frail older adults who may be at risk of institutionalization. The index is based on 13 grouped categories of diseases or signs found to be significantly related to concurrent or future need for long-term care services. The algorithm uses diagnosis codes from claims. We included the 13 components to the index in the administrative models because functional status information was not available.

13 Compared with ordinary least squares regression, the Poisson regression gives less emphasis to infrequent but exceptionally high-cost stays. In addition, Poisson models can more easily handle dependent variables with zero values (such as stays with no NTA or therapy costs).

14 Across institutional PAC stays, three-quarters of stays did not qualify for any definition of *medically complex*. Of those that did, about 40 percent qualified for more than one definition. Across HHA stays, most stays (96 percent) did not qualify for the definitions of medically complex that included HHA stays (severity of illness Level 4 and chronically critically ill). Of the small share of HHA stays that did, most qualified for only one of the definitions, while 21 percent qualified for both definitions.

15 The share of the variation explained by the full and administrative models is high because the indicator for the use of home health care (compared with institutional care) gives the models a strong boost in predicting the cost of the stay. Further, both models include over 60 clinical characteristics to predict the cost of stays. The results of the full and administrative models (using the PAC–PRD stays) are similar because both include the same key patient characteristics—the home health indicator, the primary reason to treat, and

secondary diagnoses—and both models have sufficient cases (6,400) to handle the number of variables (about 100) included in them.

16 This list is expanded from the previous tables because the stay counts were high enough to report their results. The 13 clinical groups account for 75 percent of stays. We examined several other clinical groups, and the results were similar to those reported here. We did not report them separately because each group either accounted for less than 1 percent of stays or were a mix of clinical conditions (such as "other surgical") for stays that did not fall into one of the clinically meaningful groups listed.

17 About two-thirds of HHA users, 12 percent of IRF users, 9 percent of LTCH users, and 10 percent of SNF users did not have a hospital stay within the preceding 30 days and were considered community admissions for this study.

18 Beginning October 1, 2015, the LTCH PPS applies only to LTCH discharges that had an immediately preceding acute care hospital stay if the acute care stay included at least three days in an intensive care unit or the patient received prolonged ventilator services in the LTCH. All other LTCH discharges are paid an amount based on Medicare acute care hospital PPS.

19 Since 2013, LTCH payment policies have changed, with large reductions in payments for stays that do not meet LTCH criteria. In response to these policies, we expect LTCHs to change the mix of patients they treat and their cost structures. Although we did not attempt to model any changes in LTCH behavior, by using data collected after the implementation of the new policy, the Secretary would be able to take these changes into account in the PAC PPS design.

20 IMPACT requires PAC providers to submit standardized patient assessment information beginning October 1, 2018, for IRFs, SNFs, and LTCHs, and January 1, 2019, for HHAs.

21 The Secretary has the authority to define inpatient rehabilitation facilities, including a compliance rate (although by law the compliance rate cannot be higher than 60 percent). The definition of a long-term care hospital is in statute.

22 The three-day hospital stay is waived for entities participating in Bundled Payments for Care Improvement (BPCI) Initiative Model 2 (including the initial hospital stay and all Part A and Part B services during the episode), but a hospital admission is still required (Lewin Group 2015). ACOs waive the inpatient stay requirement entirely, allowing admissions to SNFs directly from a beneficiary's home, physician's office, observation status, the emergency room, or a hospital stay shorter than three days. The requirement is not waived for beneficiaries who reside in a nursing home (Centers for Medicare & Medicaid Services 2015a). Both alternative payment models waive certain requirements to allow limited home health care visits. BPCI waives the direct supervision requirement for 1 home visit every 30 days (and pays for the visits under the physician fee schedule), while ACOs allow limited home visits for beneficiaries who do not meet the homebound requirement (Centers for Medicare & Medicaid Services 2015b, Lewin Group 2015). The three-day hospital stay requirement is also waived for hospitals participating in the hip and knee replacement demonstration if the nursing home has at least a 3-star rating.

23 In 2015, CMS proposed long-term care regulations that overhaul the requirements for long-term care facilities (Centers for Medicare & Medicaid Services 2015c). Among its revisions, the proposal would require nursing facilities to have sufficient staff to provide nursing care to each resident in accordance with his or her care plan and individual needs and ensure that their staff has appropriate competencies and skill sets to assure resident safety. CMS did not rule out more stringent minimum nursing-hour requirements, such as a requirement that a registered nurse be present at all times.

24 IMPACT requires the Secretary to implement a resource use measure in the quality public reporting programs for PAC providers beginning October 1, 2016, for SNFs, LTCHs, and IRFs and on January 1, 2017, for HHAs.

25 Both settings have interrupted-stay policies in place. A provider does not receive a second stay payment if a beneficiary's stay is interrupted for a predetermined amount of time with an admission to an acute care hospital.

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CHAPTER 4

Medicare drug spending in its broader context

CHAPTER 4

Medicare drug spending in its broader context

Prescription drugs are a critical component of health care. Because of the role of drugs in treating conditions, it is important that Medicare ensures that its beneficiaries have access to appropriate medication therapies. By providing benefits that include prescription drug coverage, Medicare has expanded patient access to needed medications. However, it is becoming increasingly difficult to make sure that access to medications remains affordable for beneficiaries and to keep Medicare financially sustainable for taxpayers.

In recent years, manufacturers have introduced products at launch prices of tens of thousands of dollars per treatment regimen, and sometimes higher (Howard et al. 2015, LaMattina 2016). Prices for some medications that have already been on the market—including certain generics—have also grown faster than other components of health care spending (Martin et al. 2015, Nisen 2015). However, payers, including Medicare, have found it difficult to assess the relative value of these drugs and, thus, whether they are worth the high prices. In some cases, clinical evidence and real-world experience have indeed demonstrated calculable value for Medicare beneficiaries. In other cases, however, evidence of effectiveness that head-to-head clinical trials would provide is lacking. In addition, available clinical trial evidence often does not include patients with demographic and clinical characteristics similar to those of Medicare beneficiaries.

As the primary source of health care benefits for 57 million individuals, Medicare is the largest source of financing for small-molecule drugs and biologics.[1] The Commission estimates that, in 2013, Medicare paid for about $112 billion in prescription drugs across all settings of care, or 19 percent of total program spending (Medicare Payment Advisory Commission 2015a). This spending was about one-third of U.S. pharmaceutical sales for that year (Long 2015). Because the Medicare program accounts for such a large share of overall drug spending, program payment policies can have a significant financial effect on health care providers and other parts of the industry, including pharmaceutical manufacturers, drug supply chains, pharmacies, pharmacy benefit managers, and insurers.

However, Medicare's influence on drug pricing is indirect, and the program pays for drugs differently depending on the care setting. Medicare pays for most drugs used during the course of a hospital stay, outpatient department visit, or skilled nursing facility stay as part of prospective payment bundles. However, physicians and hospital outpatient departments also bill Medicare separately for certain expensive infusible or injectable drugs covered under Medicare Part B. In that case, the program pays providers on the basis of the drug's average sales price (ASP) plus a 6 percent add-on. For Medicare Advantage plans, the program pays capitated amounts based in part on average drug costs in traditional Medicare. Under Part D, which

covers prescription drugs, Medicare pays private plans a combination of capitated amounts and reinsurance subsidies to provide outpatient prescription drug benefits to enrollees. Thus, hospitals, skilled nursing facilities, physicians, and private health plans and their pharmacy benefit managers negotiate drug prices, and this "market" mechanism determines Medicare drug costs.

In addition, it is important to recognize that Medicare exists within an American health care environment that involves a broad mix of not only public and private payers and local provider markets but also federal and state laws, agencies, and policies. These external environmental factors also have a significant influence on the prices Medicare pays for prescription drugs. Major influences include:

- ***Biomedical research and development***—Funding for medical research through the National Institutes of Health and other organizations creates and influences basic knowledge about the mechanisms of disease and can provide the foundation on which new drugs are developed and manufactured. Similarly, tax credits for research and experimentation affect the extent to which developers and manufacturers invest resources in new compounds to treat disease and decisions about which diseases will be targeted. Such financial resources can lead to more investment, which can lead to the creation of larger numbers of new drugs and biologics.

- ***Patents and exclusivity***—The federal government, through the Patent and Trademark Office and the Food and Drug Administration (FDA), grants temporary monopolies to pharmaceutical companies in the form of patents as well as data and marketing "exclusivity" for a period of time. Laws such as the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act of 2009 (enacted as part of the Patient Protection and Affordable Care Act of 2010) laid out processes by which manufacturers may market approved drugs and biologics without entry of competitors. Patents and periods of exclusivity provide a financial incentive for innovation by permitting the innovator to price products higher than if there were free entry of competitors. Patents are awarded for 20 years, and FDA approval to market a therapy triggers a period of 5 years of exclusivity for new small-molecule drugs and a 12-year period for new biologics. The length of a drug's effective market protection depends on when the developer received a patent, how long the developer takes to assemble evidence on safety and effectiveness, and how long the FDA takes to evaluate that evidence. In addition, there are legal processes that affect how and when competitors may challenge manufacturers' market protection and processes manufacturers use to extend patents.

- ***Drug approval and oversight***—Laws and regulations of the FDA describe the process for approving drugs and biologics, evidentiary standards for approval, and rules about the indications for and processes by which the drug can be marketed (e.g., through direct-to-consumer advertising). The FDA's processes for reviewing applications and the speed at which it does so directly affects the number of medicines available on the market, as well as how many therapeutic substitutes and generics are available within a drug class.

- ***Importation and resale of drugs***—The Federal Food, Drug, and Cosmetic Act prohibited interstate shipment and importation of unapproved drugs. A subsequent provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 allowed the FDA to permit some importation of drugs from Canada, but only if the Secretary of Health and Human Services certifies that such an action would pose no additional risk to the public's health and safety and would reduce costs for consumers. The FDA enforces these rules to promote the safety of drugs sold in this country and, to date, pharmacists and wholesalers have not been permitted to import drugs. At the same time, drug prices in the United States are significantly higher than they are in other developed countries (Congressional Budget Office 2004, Engelberg et al. 2016).

- ***Policies of other government programs***—Policies established for certain government programs affect drug prices for other payers, including Medicare. For example, the Department of Veterans Affairs receives statutory discounts on drug prices, and Medicaid's "best price" provision requires makers of innovator drugs to provide either a rebate of about 23 percent of the average manufacturer price or the lowest price that a manufacturer has negotiated with other payers, whichever results in lower prices net of rebates. Those discounts, in turn, may increase Medicare drug costs and those of other payers and lead to higher launch prices for new drugs (Congressional Budget Office 1996).

- ***State laws and regulations***—States have varying types of laws under which pharmacists may substitute generic drugs for their brand-name counterpart, often without involving the prescriber. This practice has helped promote expansion of generic market shares, which puts downward pressure on prices for competing brand-name drugs (Shrank et al. 2010). Many states are enacting laws that set standards for substitution of a highly similar biologic product in place of an original biologic product (National Council of State Legislatures 2015).

Medicare's drug payment policies can affect drug pricing, prescribing, and spending patterns indirectly. For example, the Commission has examined the ASP system that reimburses physicians for Part B drugs and will continue to examine the effects of the 6 percent add-on and whether that policy should be revised (Medicare Payment Advisory Commission 2015b). The Commission is continuing to examine other potential policy changes that could provide greater "value-based" incentives for managing Part B drug use, such as consolidated billing codes, bundled payments, reference pricing, risk-sharing arrangements, and coverage with evidence development (Medicare Payment Advisory Commission 2015b, Medicare Payment Advisory Commission 2010). In addition, the structure of Medicare Part D reinsurance for plan beneficiaries with high drug spending may serve to weaken plan incentives to manage the drug spending of high-cost enrollees (Medicare Payment Advisory Commission 2015b). Part D beneficiary incentives and the ability of plans to manage drug costs also affect Medicare drug costs. Finally, while Part D has broadened access to drugs, that access, in turn, raises concerns about risks of polypharmacy and opioid misuse, which have their own costs for beneficiaries and program spending (Medicare Payment Advisory Commission 2015b).

The Commission remains concerned about the rapid growth in drug prices because that growth can affect beneficiary access to needed medications, as well as the financial sustainability of the Medicare program. Within the context in which Medicare operates, the Commission will continue to recommend changes to Medicare policies intended to promote drug price competition and improve incentives for providers and beneficiaries to seek better value when they purchase drugs. Accordingly, in the chapters that follow, the Commission has advanced its thinking in two areas: (1) Part B drug payment approaches (e.g., the ASP add-on payment, reactivation of the competitive acquisition program, and bundling of oncology drugs) and (2) the Part D outpatient prescription drug benefit (reduction of reinsurance payments, changes to beneficiary incentives, and greater flexibility for plans to manage drug costs). ■

Endnotes

1 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. (See Chapter 5 of the Commission's June 2009 report to the Congress for more detail.)

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CHAPTER 5

Medicare Part B drug and oncology payment policy issues

RECOMMENDATION

5 The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

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

CHAPTER 5

Medicare Part B drug and oncology payment policy issues

Chapter summary

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs). It also covers certain drugs furnished by suppliers. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). In 2014, Medicare and its beneficiaries paid nearly $21 billion dollars for Part B–covered drugs paid under this method.

This chapter focuses on two broad issues: potential modifications of the way Medicare Part B pays for drugs, in general, and approaches to improve the quality and efficiency of oncology care, in particular, because more than half of Medicare Part B drug spending is associated with anticancer drugs.

Medicare's payment methodology for Part B drugs

Our work focuses on three aspects of Medicare's payment methodology for Part B drugs. First, we explore whether there is a better way to structure the add-on payment to ASP. Second, we examine whether there are payment policies that could be considered to promote more price competition among Part B drugs and put downward pressure on ASP. Third, the Commission recommends reducing the dispensing and supplying fees for certain Part B drugs furnished by inhalation drug suppliers and pharmacies to levels similar to those paid by other payers.

In this chapter

The 6 percent add-on to ASP has garnered attention because of concern that it may create incentives for use of higher priced drugs when lower priced alternatives exist. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. It is difficult to know whether the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

We model a policy option that converts part of the 6 percent add-on to a flat fee: 103.5 percent of ASP + $5 per drug administered per day. Compared with current policy, this option would increase add-on payments for drugs with an ASP per administration of less than $200 and reduce add-on payments for higher priced drugs. This policy option is estimated to save about 1.3 percent of the $21 billion in Part B drug spending (assuming no utilization changes). It might also increase the likelihood that a provider would choose a lower cost drug in situations where differently priced therapeutic alternatives exist, potentially generating additional savings for Medicare and its beneficiaries.

In considering a change to the ASP add-on, it is important to consider the effect of the policy on providers' ability to purchase drugs within the Medicare payment amount. Analysis of proprietary data on invoice prices for 34 high-expenditure Part B drugs suggests that for two-thirds of the drugs in our analysis, at least 75 percent of the volume was sold to clinics (e.g., physicians and outpatient hospitals) at an invoice price below 102 percent of ASP. This finding suggests that, in general, there likely is room for a reduction to the add-on portion of the payment rates for Part B drugs. However, small providers might have difficulty purchasing drugs at the Medicare payment rate, although the likelihood of this occurrence would depend on how drug manufacturers respond to the payment changes. If some oncology practices had difficulty purchasing drugs at the Medicare payment rate, this circumstance might contribute to the ongoing trend toward more hospital-based oncology care.

In addition to concerns over financial incentives associated with the 6 percent add-on, there are also concerns about the overall level of prices Medicare Part B pays for drugs. The largest component of Medicare's payments for Part B drugs is the ASP; the 6 percent add-on is a relatively small share of total payments. If policymakers wish to influence Part B drug payments to a larger degree than possible through add-on payments, they could consider Medicare payment policies that create more incentives for price competition among drugs or that put downward pressure on ASP. We examine three such policies:

- ***ASP inflation limit***—Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for a drug can increase over time. We examine the idea of placing a limit on how much Medicare's ASP-based payment for a drug can grow as a way to protect against the potential for a dramatic price increase and to generate savings for drugs undergoing rapid ASP growth.
- ***Consolidated billing codes***—The structure of the ASP payment system—with single-source drugs and biologics each being paid their own ASP rate under separate billing codes—does not promote price competition among drugs with similar health effects. We explore the idea of using consolidated billing codes for Part B drugs with similar health effects, including biosimilars, to spur price competition among these Part B drugs.
- ***Restructuring the Part B–drug competitive acquisition program***—From mid-2006 through 2008, Medicare operated a competitive acquisition program (CAP) in which physicians who enrolled in the CAP obtained Part B drugs from a Medicare-selected vendor instead of buying the drug directly and billing Medicare for the product. Medicare's CAP faced challenges due to low physician enrollment in the program and the vendor's limited leverage to negotiate discounts. We explore ways to restructure a CAP to encourage physician enrollment by offering shared savings to physicians, reducing or eliminating the ASP add-on payment in the traditional buy-and-bill system, and giving physicians more options for how they obtain drugs under the program. To enhance the vendor's negotiating leverage, we consider the possibility of permitting the vendor to have a formulary.

Medicare Part B pays substantially higher dispensing fees for inhalation drugs and supplying fees for oral anticancer, oral antiemetic, and immunosuppressive drugs than the rates paid by Medicare Part D plans and Medicaid. The Medicare Part B rates have been in effect since 2006 and were set by CMS based on limited data. Under these circumstances, the Commission recommends reducing the Part B dispensing and supplying fees to rates similar to other payers.

Improving the efficiency of oncology care in fee-for-service Medicare

In 2014, Medicare spending for anticancer drugs accounted for about 55 percent of the nearly $21 billion spent on Part B drugs paid under the ASP methodology to providers in physician office and HOPD settings and to suppliers. In the Commission's June 2015 report to the Congress, we began to examine bundled approaches as a mechanism to make providers more sensitive than under current Medicare payment to the cost of Part B drugs associated with a cancer care

treatment regimen. With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area amenable to bundling.

We continue to examine approaches that seek to improve the efficiency of oncology services while improving care quality. With Medicare's coverage and payment policies for Part B anticancer drugs and their administration in mind, we examined factors that can influence clinicians' prescribing of anticancer drugs. In addition, we examined four examples of narrower versus broader approaches designed to improve the efficiency of oncology care in Medicare and non-Medicare populations. The two narrower approaches—risk sharing and clinical pathways—attempt to improve the value of drug spending:

- Risk-sharing agreements made between product manufacturers and payers link payment for a drug to patient outcomes, such as a clinical measure (e.g., laboratory value) or an event (e.g., inpatient hospital admission). Product manufacturers and commercial payers have implemented these agreements in the United States and internationally.
- Oncology clinical pathways consist of treatment protocols adopted by commercial payers and providers (hospitals and clinicians) to standardize drug treatment, reduce unnecessary variation, improve quality of care, and reduce costs. Some payers and providers have implemented various approaches that link compliance with clinical pathways to financial incentives.

By contrast, the two broader approaches—medical homes and bundled payments—take a more holistic view of cancer care, seeking to improve care management and coordination:

- The oncology medical home is built on the concept of patient-centered care; the expectation is that enhanced services, such as team-based care, will expand patient access and education and that clinical practices will improve health outcomes and reduce cost. The Center for Medicare & Medicaid Innovation funded an oncology medical home under a three-year grant, which ended in 2015. Commercial payers have also implemented oncology medical homes.
- Bundling Part B oncology drugs with non-oncology services holds providers accountable for the total cost of services across an episode of care. UnitedHealthcare implemented such an approach under which practices were paid ASP for chemotherapy drugs (instead of ASP plus a negotiated add-on amount), an episode fee (based on the contracted drug add-on amount to ASP), and fee-for-service for most other services. Practices were eligible for shared savings if quality improved or total costs decreased. ■

Background on Part B drug payment

Medicare Part B covers infusible and injectable drugs administered in physician offices and hospital outpatient departments (HOPDs). Specifically, Medicare Part B covers these drugs that are administered by infusion or injection in clinicians' offices and HOPDs if they (1) meet the statutory definition of a drug or a biological,[1] (2) are usually not self-administered, (3) are incident to a clinician's service, (4) are reasonable and necessary for the diagnosis or treatment of an illness or injury, and (5) have not been determined by the Food and Drug Administration (FDA) to be less than effective. Medicare Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs and certain oral anticancer, oral antiemetics, and immunosuppressive drugs).

In accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays physicians and suppliers for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).[2, 3] Medicare payment for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS) is generally under the discretion of CMS, which established a rate of ASP + 6 percent. Low-cost drugs and certain other drugs are packaged into payment for other services under the OPPS instead of being paid separately.[4] Like other Medicare services, Part B–covered drugs are subject to the budget sequester effective April, 1, 2013, through 2024.[5] In this chapter, we use the term *drug* to refer to drugs and biologics (unless otherwise noted).[6]

In addition to a payment of ASP + 6 percent for a Part B–covered drug, Medicare makes a separate payment for administration of the drug under the fee schedule for physicians and other health professionals (also referred to as the physician fee schedule, or PFS) or OPPS.[7] Medicare also pays a dispensing or supplying fee to pharmacies that dispense (to beneficiaries) inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs and pays a furnishing fee to providers of clotting factor. The data presented in this section reflect only the ASP + 6 percent payments and do not include the drug administration payments or the supplying, dispensing, or furnishing fees (unless specifically noted).

In 2014, Medicare spending (program payments and beneficiary cost sharing) for Part B–covered drugs paid ASP + 6 percent amounted to nearly $21 billion dollars (nearly $17 billion in program payments and more than $4 billion in beneficiary cost sharing). Of that spending, physician offices accounted for over $12 billion; HOPDs, over $7 billion; and suppliers, over $1 billion.

To get a sense of the drivers of Medicare Part B spending growth in recent years, we analyzed the change in spending between 2009 and 2013 and examined how changes in utilization and drug prices contributed to this change. This analysis is complicated by two types of policy changes that took place between 2009 and 2013. First, some drugs that were separately payable in 2009 became bundled or packaged by 2013. To remove the effect of these changes from our trend analysis, we excluded these drugs (i.e., drugs furnished by dialysis facilities and drugs that became packaged under the OPPS). Second, Medicare payment rates for Part B drugs changed over this period (some HOPD drugs were paid ASP + 4 percent in 2009, and all drugs were subject to the sequester beginning April 2013). To get the clearest picture of how growth in utilization and drug prices affects spending growth, we standardized the 2009 and 2013 payment rates to equal ASP + 6 percent. Under these assumptions, we estimate that Medicare payments for Part B drugs would have grown at an average annual rate of 10.1 percent between 2009 and 2013 (Table 5-1, p. 122).[8] About one-third of this spending growth was due to an increase in the number of beneficiaries using Part B drugs (which increased at an average annual rate of 3.6 percent). Roughly two-thirds of the spending growth was due to an increase in the average payment per Part B drug user (which increased at an average annual rate of 6.3 percent). Growth in the average payment per Part B drug user was partly due to an increase in the number of drugs per user, a number that grew at an average rate of 1.5 percent per year. Most of the growth in the average payment per Part B drug user reflects growth in the average payment per drug, which increased 4.8 percent per year on average during this period. This growth in the average payment per drug likely reflects a combination of price increases among existing products and shifts toward a more expensive mix of drugs, including adoption of new drugs.

In recent years, total Medicare Part B drug spending has grown more rapidly for HOPDs than for physician offices and suppliers (average annual growth of about 18 percent and 6 percent, respectively, for the period between 2009 and 2013, data not shown). Of Medicare Part B drug spending in outpatient hospitals in 2014, over half was attributable to hospitals that participate in the 340B Drug Pricing Program. Nonprofit hospitals that qualify for the

TABLE 5–1

Change in Medicare spending and utilization for separately payable Part B drugs, 2009–2013

	2009	2013	Average annual growth 2009–2013
Total payments (in billions)	$13.1	$19.3	10.1%
Number of beneficiaries using a Part B drug (in millions)	15.1	17.4	3.6
Average total payments per beneficiary who used Part B drugs	$869	$1,111	6.3
Average number of drugs per beneficiary	1.26	1.33	1.5
Average payment per drug	$691	$834	4.8

Note: This analysis includes all Part B drugs paid average sales price plus 6 percent (ASP + 6 percent) as well as the small group of Part B drugs that are paid based on the average wholesale price or that are contractor priced. Excluded from the analysis were any Part B drugs that became bundled or packaged between 2009 and 2013 (e.g., drugs that became packaged under the outpatient prospective payment system, regardless of the setting where they were furnished, and drugs furnished by dialysis facilities) and data for critical access hospitals (which are paid 101 percent of cost). We eliminated the effect of payment formula changes between 2009 and 2013 by standardizing the payment rates in the two years to be ASP + 6 percent (i.e., adjusting the payment rate for certain hospital outpatient department drugs in 2009 from ASP + 4 percent to ASP + 6 percent and by removing the effect of the sequester on Part B drug spending in 2013). The average annual growth rates displayed in the table may differ slightly from the average annual growth rates calculated using the 2009 and 2013 values displayed in the table due to rounding.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

340B Drug Pricing Program receive substantial discounts on Part B drugs.[9] In March 2016, the Commission recommended that Medicare payments for Part B drugs to 340B hospitals be reduced by 10 percent of ASP and the resulting program savings be directed to fund the Medicare uncompensated care pool for hospitals (Medicare Payment Advisory Commission 2016).

Medicare Part B covers drugs for a wide range of indications, although a small number of products and conditions account for a large share of spending. The top 10 drugs that account for the most Part B spending fall into three general areas: cancer, rheumatoid arthritis, and macular degeneration (Table 5-2). Nine of the 10 highest expenditure products are biologics. The 10 highest expenditure products accounted for 47 percent of Medicare spending on Part B drugs paid under the ASP + 6 percent methodology in 2014. Payments for these 10 products on a per administration and annual per beneficiary basis are substantial, ranging from $1,100 to $5,400 per administration and $2,500 to $30,000 per beneficiary per year in 2014 (Table 5-2). Beyond these high-expenditure drugs are additional Part B drugs used by small numbers of beneficiaries with higher per administration and per beneficiary payment amounts.

Part B also pays for many inexpensive drugs under the ASP payment system. For about 45 percent of Part B–covered drug administrations, Medicare's ASP + 6 percent payment per drug administered was less than $10 (Table 5-3). For an additional 15 percent of drug administrations, the ASP + 6 percent payment per drug administered ranged from $10 to $49. Examples of very commonly used, inexpensive Part B–covered drugs include corticosteroids, drugs used during imaging, vitamin B12, and saline. The average ASP + 6 percent payment per administration for these products was generally less than $15, and for some products, less than $5.

Medicare's Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set the ASP + 6 percent payment rate. That means, for example, the ASP + 6 percent payment rate for the third quarter of a year is based on ASP data from the first quarter of the year.[10]

In theory, the two-quarter lag in the ASP + 6 percent payment rates may provide a disincentive for manufacturers to institute large, rapid price increases because they may cause providers' acquisition costs to exceed the Medicare payment rate and potentially affect providers' willingness to purchase the product.

Payment rates for single-source drugs and biologics, multiple-source drugs, and biosimilars are set differently.

TABLE 5–2

Top 10 Part B–covered drugs by total expenditures, 2014

HCPCS code	Short description	Common indication or type of drug	Total Medicare payments (in billions)	Number of beneficiaries who used drug (in thousands)	Average ASP + 6 percent payment	
					Per administration	Per beneficiary
J9310	Rituximab	Cancer, RA	$1.5	68	$5,400	$21,900
J2778	Ranibizumab	Macular degeneration	1.3	142	2,000	9,300
J0178	Aflibercept	Macular degeneration	1.3	132	2,100	9,700
J2505	Pegfilgrastim	Cancer supportive	1.2	98	3,300	11,700
J1745	Infliximab	RA	1.2	59	3,400	19,600
J9035	Bevacizumab	Cancer, macular degeneration	1.1	215	1,100	3,800
J0897	Denosumab	Osteoporosis, cancer supportive	0.8	293	1,200	2,500
J9305	Trastuzumab	Cancer	0.6	18	2,900	30,000
J9355	Pemetrexed	Cancer	0.6	23	5,400	24,200
J9041	Bortezomib	Cancer	0.5	20	1,500	23,200

Note: HCPCS (Healthcare Common Procedure Coding System), ASP (average sales price), RA (rheumatoid arthritis). Nine of these top 10 high-expenditure products are biologics; pemetrexed is the only nonbiologic drug in the top 10. Total Medicare payments include the effect of the sequester. Average ASP + 6 percent payment amount per administration and per beneficiary are calculated at the drug billing code level and do not include the effect of the sequester. These averages are calculated after removing extreme values from the data (i.e., values that are less than the 1st percentile and greater than the 99th percentile for the HCPCS code). Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data.

Each single-source drug and biologic (except biosimilars) is paid based on 106 percent of its own ASP. For multiple-source drugs, both the brand-name and generic versions of the drug are paid under the same billing code and receive the same ASP + 6 percent payment rate based on the weighted average of ASPs for all brand-name and generic products. Biosimilars are paid 100 percent of their ASP, plus 6 percent of the ASP for the reference biologic. In the 2016 PFS final rule, CMS finalized a policy that all biosimilar products associated with the same reference product will be grouped together in one billing code and paid the same rate. The reference biologic, however, will retain its own billing code and be paid 106 percent of its own ASP.

Is the 6 percent add-on the provider's margin?

The margin an individual provider realizes on a specific Part B drug could be more or less than 6 percent (with negative margins also possible) because, for several reasons, the price an individual provider pays for a drug may differ from the ASP used to establish the Medicare payment rate.[11]

Since ASP is an average across all purchasers, net of rebates, discounts, and price concessions, some purchasers

TABLE 5–3

Low-priced drugs accounted for most Part B drug administrations, while high-priced drugs accounted for most Part B drug expenditures, 2014

Medicare ASP + 6 percent payment per drug administered per day	Percent of:	
	Drug administrations	Medicare Part B drug payments
Less than $10	45%	0.3%
$10–49	15	0.6
$50–199	12	3
$200–399	9	6
$400–999	6	9
$1,000–1,999	7	26
$2,000–4,999	5	34
$5,000 or more	1	21

Note: ASP (average sales price). Analysis includes Part B–covered drugs that are paid ASP + 6 percent and furnished by physicians, hospital outpatient departments, and suppliers. Drugs billed under not-otherwise-classified billing codes are excluded from the analysis. For drugs furnished by suppliers, the data reflect each prescription rather than each day the drug was administered. Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Medicare claims data.

will pay more and some will pay less than the average (unless the manufacturer has uniform pricing). For example, if manufacturers offer discounts or rebates based on volume, small purchasers may pay higher prices than large purchasers. To the extent that prices vary by type of purchasers, ASP may not reflect the average price paid by each purchaser type. For example, the average price paid by physicians and outpatient hospitals for a product could be less than ASP if other types of purchasers (e.g., pharmacies) pay higher prices.

Price changes can also affect the margin a provider realizes on a Part B drug. With the two-quarter lag in the ASP + 6 percent payment rate, a price increase lowers a provider's margin and a price reduction increases that margin temporarily until ASP catches up.[12] For example, when a generic version of a drug first enters the market, the lag in ASP results in a large profit margin for providers because their payment for the generic drug is based on the brand-name price for at least two quarters (Office of Inspector General 2012, Office of Inspector General 2011a). For single-source drugs and biologics, the pricing dynamics may be different, depending on whether the drug or biologic faces competition from therapeutic alternatives. That is, the manufacturer of a single-source drug may increase prices with less concern about the effect it will have on providers' margins (and potentially the manufacturer's sales volume) if therapeutic alternatives do not exist for its drug. In contrast, if a single-source drug faces competition from other, therapeutically similar drugs, a manufacturer may take into account how a price increase would affect providers' margins on its drug compared with competitor products.

Certain additional factors, such as prompt-pay discounts and wholesaler markups, can create a gap between manufacturers' reported ASP and the average purchase price across providers. For example, manufacturers may offer prompt-pay discounts to drug wholesalers who pay manufacturers quickly. Prompt-pay discounts, which are reported by industry stakeholders to be in the range of 1 percent to 2 percent, lower ASP. These discounts are reported to be an important source of revenue for wholesalers that are largely not passed on to final purchasers (e.g., physicians and hospitals). When these discounts are not passed on from wholesalers to providers, the average price paid by providers for a drug could end up higher than the manufacturer's reported ASP. Another factor that can affect a provider's margin on a drug is wholesaler markup. That markup is not included in ASP (since it does not affect the revenue earned by manufacturers), but it can increase the price paid by physicians and hospitals. For some drugs, the average price paid by providers for a drug could be higher than ASP due to wholesaler markup. To the extent that wholesaler markup reflects fixed fees like shipping and handling, its effect may be most significant on provider margins for very inexpensive drugs (Medicare Payment Advisory Commission 2007).

To get a sense of how providers' acquisition costs compare with Medicare's payment amount, we obtained proprietary data from IMS Health Incorporated (IMS) on invoice prices for Part B drugs.[13] These data provide information on the distribution of invoice prices by drug and by channel (i.e., type of purchaser). We examined data for the clinic channel, which includes physician offices, HOPDs, dialysis clinics, nonhospital surgical centers, and public health service clinics. The data are available for the clinic channel as a whole; they are not reported for finer categories of purchasers. The IMS data for the clinic channel include discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we did not use data on the average invoice price. Instead, we focus on invoice prices for the top half of the price distribution (i.e., the 50th, 75th, and 90th percentiles). The prices in the IMS data reflect all on-invoice discounts and rebates but not off-invoice rebates. As a result, in some cases the IMS data overstate the actual end-price paid by the purchaser. We do not report any prices for specific drugs due to the terms of our contract with IMS.

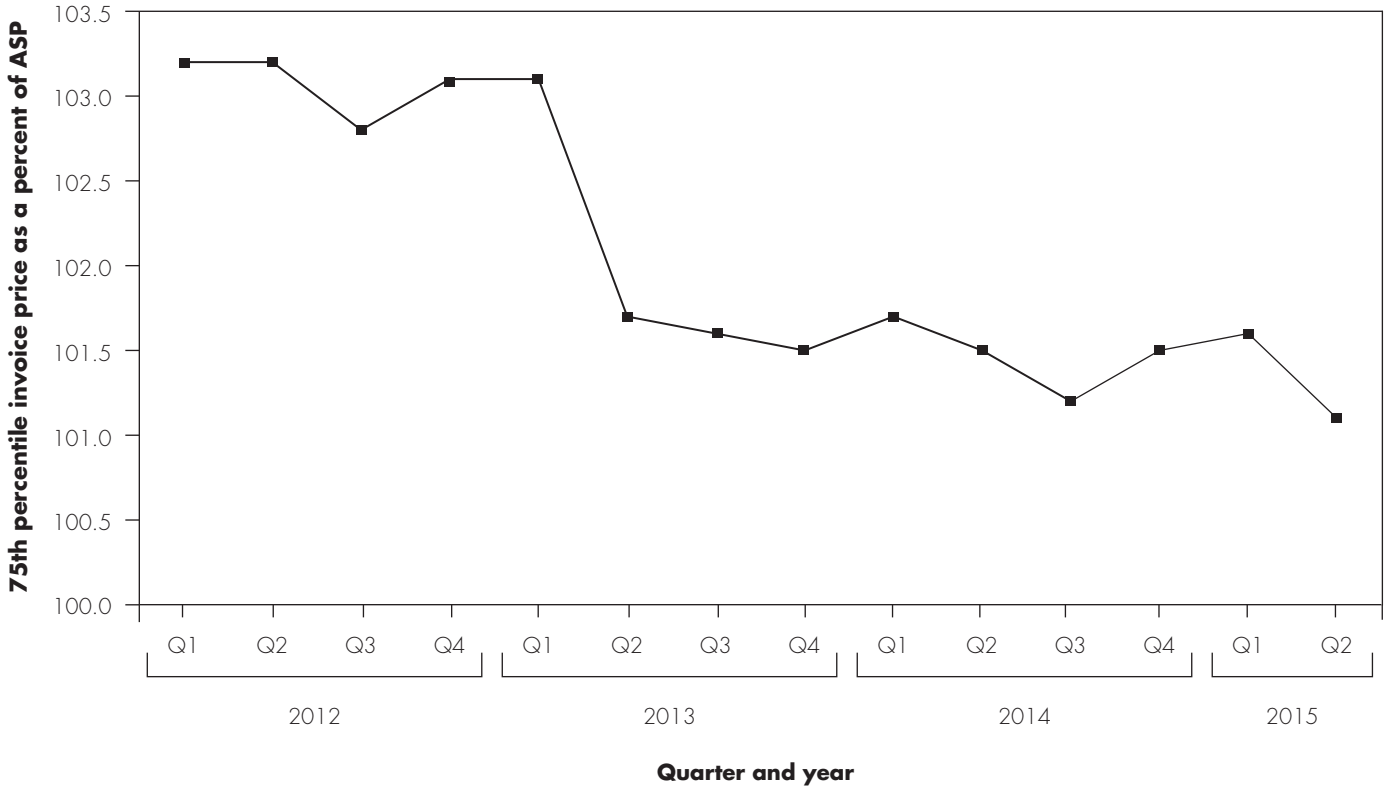
Our analysis of invoice prices focuses on 34 high-expenditure Part B drugs for which we have quarterly invoice price data for the entire period from the first quarter of 2012 to the second quarter of 2015. Overall, these 34 drugs accounted for about two-thirds of Medicare spending on Part B drugs in 2014. Because we do not report invoice prices per our contract with IMS, we divide the invoice price of each drug by 100 percent of the ASP that was in effect for payment purposes in that quarter to create a ratio of the invoice price to ASP.[14] We summarize the results across the group of 34 drugs in our analysis.

We conducted two analyses using these data. First, we examined the trend in the ratio of the 75th percentile invoice price to ASP over time. Then, we observed the distribution of the invoice-price-to-ASP ratios across the 34 drugs in the first quarter of 2015.

Figure 5-1 shows the trend in invoice prices in the clinic channel as a percentage of ASP between the first quarter

FIGURE 5–1

Trend in the median of 75th percentile invoice price as a percent of ASP for clinics across 34 Part B drugs



Note: ASP (average sales price). The data are for the clinic channel of sales, which includes physician offices, hospital outpatient departments, dialysis centers, nonhospital surgical centers, and public health service clinics. Figures reflect invoice prices as a percentage of the ASP that was in effect for Medicare payment purposes that quarter. Figures reflect invoice price data for 34 drugs that have high total expenditures and for which invoice price data were available for every quarter during the period from the first quarter of 2012 to the second quarter of 2015. For drugs with multiple national drug codes (NDCs), the data for the highest volume NDC was used. Data come from a sample of wholesalers and do not include direct sales by manufacturers. The percentile distribution of the ratio of invoice prices to ASP is at the drug unit level. Invoice prices reflect on-invoice discounts and rebate, but do not reflect off-invoice rebates.

Source: This information is a MedPAC estimate derived from the use of information under license from the following IMS Health Incorporated information service: Pricetrak for the period of the first quarter of 2012 through the second quarter of 2015.

of 2012 and the second quarter of 2015. Specifically, the chart shows the median 75th percentile invoice price as a percentage of ASP across the 34 drugs over this time period.[15] For example, if the median 75th percentile invoice price was 103 percent of ASP, that would mean that for half of the drugs (17 of 34), at least 75 percent of the volume was sold to clinics at an invoice price of 103 percent of ASP or less.

We used information on the trend in invoice prices as a percentage of ASP over time to examine how providers' margin on Part B drugs was affected by the sequester. Beginning in the second quarter of 2013, the sequester reduced the total Medicare payment providers received for Part B drugs from 106 percent of ASP to 104.3 percent of ASP. As shown in Figure 5-1, across the 34 drugs, the median 75th percentile invoice price as a percentage of ASP declined markedly in the quarter that the sequester went into effect. Between the first quarter of 2012 and the first quarter of 2013, the median 75th percentile invoice price oscillated around 103 percent of ASP. Beginning in the second quarter of 2013 and continuing through the second quarter of 2015, the median 75th percentile invoice price oscillated around 101.5 percent of ASP. These data suggest that some manufacturers may have responded to the sequester by changing their pricing patterns in a way that mitigated the effect of the sequester on some providers. There are several ways the ratio of the 75th

TABLE 5–4 **Distribution of invoice prices for 34 Part B drugs, 1st quarter 2015**

	Invoice price as a percent of ASP		
	50th percentile	**75th percentile**	**90th percentile**
Percent of 34 drugs with invoice price as percent of ASP:			
Less than 100%	59%	35%	18%
100% to 101.9%	21	29	6
102% to 103.9%	6	12	26
104% to 105.9%	6	12	21
106% or greater	9	12	29
Median 75th percentile invoice price as percent of ASP across the 34 drugs	99.7% ASP	101.6 % ASP	104.0% ASP

Note: ASP (average sales price). The data are for the clinic channel of sales, which includes physician offices, hospital outpatient departments, dialysis centers, nonhospital surgical centers, and public health services clinics. Figures reflect invoice price data for 34 drugs that have high total expenditures. For drugs with multiple national drug codes (NDCs), the data for the highest volume NDC was used. Data come from a sample of wholesalers and do not include direct sales by manufacturers. The percentile distribution of invoice prices is at the drug unit level. Prices reflect on-invoice discounts and rebates but not off-invoice rebates. Invoice prices are for the first quarter of 2015 and are displayed as a percentage of the ASP that was in effect for payment purposes in the first quarter of 2015. Numbers may not sum to 100 percent due to rounding.

Source: This information is a MedPAC estimate derived from the use of information under license from the following IMS Health Incorporated information service: Pricetrak for the first quarter of 2015.

percentile invoice price to ASP for the clinic channel could decline. For example, the ratio could decline if invoice prices in the clinic channel grew more slowly than ASP (which could occur if prices in the clinic channel declined or grew more slowly than other channels). A decline in this ratio could also occur if price variation across purchasers narrowed. These types of pricing dynamics likely vary across drugs.

Table 5-4 provides a more detailed look at the distribution of invoice prices as a percentage of ASP across the 34 drugs in the first quarter of 2015.[16] (These 34 drugs accounted for about two-thirds of Medicare Part B spending in 2014.) Thirty-five percent of the drugs had a 75th percentile invoice price that was less than 100 percent of ASP, and another 29 percent of the drugs had a 75th percentile invoice price that was between 100 percent of ASP and 101.9 percent of ASP. In other words, for about two-thirds of the drugs (22 out of 34 drugs) at least 75 percent of the volume was sold at an invoice price that was less than 102 percent of ASP. The remainder of the drugs had a 75th percentile invoice price that for 12 percent of drugs ranged from 102 percent to 103.9 percent of ASP; for another 12 percent of drugs, from 104 percent to 105.9 percent of ASP; and for another 12 percent of drugs, 106 percent or more of ASP.

For a few drugs, the invoice price in the clinic channel was lower than 100 percent of ASP for the vast majority of units sold. Because ASP is an average across all types of purchasers (with some exceptions), if a manufacturer charged lower prices to clinics than to other purchasers, the clinics could have acquired the drug for less than ASP.

For a few drugs, invoice prices were greater than 106 percent of ASP, which may be the result of a combination of factors. The data do not include off-invoice rebates. Actual prices would be lower than the invoice price in situations where off-invoice rebates were available (which might occur for products with therapeutic alternatives if, for example, the manufacturer offered off-invoice rebates based on the volume of product purchased over a specified time period). It might also reflect small purchasers not getting the same discount as other purchasers in some cases.

Another source of information on acquisition costs is a report from the Office of Inspector General (OIG) examining acquisition costs for two drugs for wet age-related macular degeneration (AMD) and certain other eye conditions (Office of Inspector General 2011b). OIG surveyed ophthalmologists to obtain data on

their acquisition costs in the first quarter of 2010 for ranibizumab (Lucentis) and bevacizumab (Avastin). Ranibizumab is a biologic with a label indication for wet AMD for which Medicare paid just over $2,000 per dose in 2010. Bevacizumab is a biologic that is used off label for wet AMD at a significantly lower cost; Medicare paid roughly $50 per dose on average in 2010.[17] OIG found that, on average, ophthalmologists reported acquiring ranibizumab for 5 percent below the Medicare ASP + 6 percent payment amount in the first quarter of 2010. Since that time, another biologic called aflibercept (Eylea) with the same label indications as ranibizumab has come on the market with a Medicare payment rate per administration similar to ranibizumab. In 2014, ranibizumab and aflibercept together accounted for about $2.7 billion in Medicare program and beneficiary spending.

What was the purpose of the 6 percent?

When a provider administers a Part B–covered drug, Medicare pays 106 percent of ASP for the drug and makes a separate payment to the provider under the PFS or OPPS for administering the drug. There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent was intended to cover drug storage and handling costs.[18] Others contend that the 6 percent was intended to maintain access to drugs for smaller practices and other purchasers who may pay above-average prices for the drugs. Others suggest that the 6 percent was intended to compensate for the financing costs associated with maintaining an inventory of drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (e.g., prompt-pay discounts). Another rationale is that the percentage add-on was intended to provide protection for providers when price increases occur and the payment rate has not yet caught up.

Does the percentage add-on to ASP influence use of high-cost drugs?

Providers' prescribing decisions may depend on a variety of factors. A number of clinical considerations may influence a provider's choice among therapeutic alternatives. For example, drugs may vary in terms of their effectiveness in treating patients with certain conditions or comorbidities, and they may differ in terms of side effects. In addition, providers may take into account whether a drug is on label or off label for a patient's condition or whether a drug is compounded.

Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP creates an incentive to use higher priced drugs when cheaper therapeutic alternatives are available (Hutton et al. 2014, Sanghavi et al. 2014). Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs. At the same time, other financial considerations might create an incentive to use lower priced drugs in some situations. For example, some have argued that when selecting a drug, a provider may take into account the cost sharing associated with each drug and the patient's ability to pay, which might lead to choosing a lower priced drug for some patients. Also, the capital cost associated with acquiring and keeping an inventory of a high-priced drug may be a disincentive for some providers to furnish expensive drugs. With respect to oncology specifically (which accounts for roughly 55 percent of Part B drug spending), clinical pathways are used by some payers and providers to guide clinicians' choice of a patient's most appropriate drug regimen. Publicly available information is lacking on how much of the time the clinician has the opportunity within oncology pathways to choose among differently priced drugs that are equally appropriate for a given patient.

Few studies exist examining whether Medicare's 6 percent add-on influences providers' choice of drugs. One study by Jacobson and colleagues of oncologists' prescribing patterns for lung cancer suggests that drug choice may to some degree be influenced by the higher add-on (Jacobson et al. 2010). Looking at five chemotherapy drugs for lung cancer, Jacobson and colleagues found a modest increase in use of the most expensive cancer drug after Medicare began paying for Part B drugs based on ASP + 6 percent in January 2005 (9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, whereas 11.0 percent of beneficiaries used that drug in the 10 months after). A study by OIG reported some movement toward higher priced drugs among a group of therapeutically similar prostate cancer drugs. When the least costly alternative policy for certain prostate cancer drugs was removed in 2010 and the products began to be paid based on 106 percent of their own ASPs, OIG found that utilization shifted away from the lowest priced

prostate cancer drug toward higher priced competitor products (Office of Inspector General 2012).

Option for restructuring the ASP add-on

Building on our work in the June 2015 report that explored budget-neutral options to restructure the ASP add-on, we explored an option to restructure the ASP add-on percentage that would generate savings.[19] The policy option we modeled is 103.5 percent of ASP + $5 per drug per administration day.[20] In developing this option, we sought to balance the desire to reduce the percentage add-on by a substantial amount with the desire to retain some percentage add-on to accommodate price variation or other factors that might lead to some purchasers acquiring drugs at a price greater than ASP. In developing this option, we also sought to keep the flat fee at a modest level, to lessen any incentives a flat fee might create for overuse of inexpensive drugs. This option is illustrative; other percentage add-ons and flat fees could be explored. Also, other approaches could be explored, such as reducing the percentage add-on without establishing a flat fee (e.g., to 105 percent of ASP) or paying the lesser of two payment formulas (e.g., the lesser of 103.5 percent of ASP + $5 per drug per day or 106 percent of ASP).

In modeling the policy option, we assume that it applies to all Part B drugs currently paid ASP + 6 percent, including those furnished by physicians, HOPDs, and suppliers.[21] Our analysis is focused on the pre-sequester payment rates. The sequester would reduce the payment amount under this option to 101.8 percent of ASP + $4.92 per drug per day.

This policy option would have the effect of increasing payments for low-priced drugs and decreasing payments for higher priced drugs. Add-on payments would increase for drugs with an ASP per administration of less than $200 and decrease for drugs with an ASP per administration higher than $200.[22] Overall, we estimate that this policy option would save about 1.3 percent over current policy (based on 2014 claims data and assuming no changes in utilization). If these rates had been paid in 2014, the Medicare program would have saved about $215 million and Medicare beneficiaries about $55 million.

The revenue effects of the policy option by provider type are shown in Table 5-5. The option would reduce Part B drug revenues overall for physicians and HOPDs. HOPDs and physicians that use expensive Part B drugs—such as oncologists, rheumatologists, and ophthalmologists—would see the largest reduction in Part B drug revenues (by between 1.5 percent and 2.1 percent).[23, 24] As a share of these providers' total Medicare revenues, the effect would be smaller—a 0.1 percent reduction for hospitals and a reduction of 0.9 percent to 1.3 percent for the three physician specialties. The option would result in a small increase in payments to primary care physicians and certain specialists (e.g., orthopedic surgeons, cardiologists, and infectious disease specialists) who tend to use lower cost drugs and who would benefit from the flat-fee add-on. The policy option would also lead to a very slight decrease in payments for supplier-furnished drugs.

This policy option—designed to mitigate the current payment system's potential to incentivize use of higher priced drugs—would reduce the difference in the add-on payment between a higher priced and lower priced drug by roughly 40 percent. Table 5-6 (p. 130) provides an illustration of how this policy might play out for differently priced drugs that are therapeutic alternatives. Research by Schrag and colleagues identified two products that can be added to two regimens (FOLFOX and FOLFIRI) for treatment of metastatic colon cancer with similar survival and quality of life, but with different prices (Schrag et al. 2015). Table 5-6 (p. 130) models Medicare payments for these two products for an eight-week treatment cycle under current policy and the policy option. Under current policy of ASP + 6 percent, the add-on payment for cetuximab is about $540 more per treatment cycle than bevacizumab. With the policy option of 103.5 percent of ASP plus $5 per drug per day, the difference in add-on payments between the two products is reduced by about 40 percent to $315.[25]

The changes in payment rates under this policy option could have a number of effects. As discussed previously, the policy option would reduce, but not eliminate, the difference in the add-on payments among differently priced drugs. In situations where different Part B drugs exist to treat a patient's condition effectively, this policy option might increase the likelihood that a provider would choose the least expensive drug. To the extent that this type of substitution occurred and changed utilization patterns, the policy option might generate additional savings (beyond those described above) for both the Medicare program and beneficiaries.

It is also possible that the flat-fee portion of the add-on could lead to increased spending for some products,

TABLE 5–5

Impact of the policy option on Part B drug revenues by type of provider

	Medicare payments in 2014 (in billions)		Option: 103.5% ASP + $5 per drug per day	
	Part B drugs	All types of services	Percent change in Part B drug revenues	Percent change in Medicare payments for all services
Physicians	**$12.0**	**$55.0**	**–1.0%**	**–0.2%**
Oncology	5.5	7.9	–1.5	–1.1
Ophthalmology	2.6	5.5	–2.0	–0.9
Rheumatology	1.2	1.7	–1.8	–1.3
Primary care	0.7	11.0	1.5	0.1
Urology	0.3	2.0	–1.2	–0.2
Neurology	0.2	1.0	–1.7	–0.4
Orthopedic surgery	0.2	3.3	4.5	0.3
Cardiology	0.1	4.2	1.6	0.0
Infectious disease	0.1	0.3	1.1	0.2
Other specialties	1.0	18.0	2.4	0.1
Outpatient hospitals	**7.2**	**164.2**	**–2.1**	**–0.1**
Urban	6.4	147.3	–2.1	–0.1
Rural	0.8	15.7	–2.0	–0.1
Nonprofit	5.5	116.7	–2.1	–0.1
For profit	0.4	23.7	–2.0	0.0
Government	1.3	22.6	–2.1	–0.1
Major teaching	2.4	40.2	–2.1	–0.1
Minor teaching	2.4	57.3	–2.0	–0.1
Nonteaching	2.4	65.3	–2.0	–0.1
≤100 beds	0.9	15.7	–2.0	–0.1
101–250 beds	1.8	46.5	–2.0	–0.1
251–500 beds	2.3	56.6	–2.0	–0.1
501+ beds	2.3	44.2	–2.1	–0.1
Suppliers	**1.6**	**3.0**	**–0.4**	**–0.2**

Note: ASP (average sales price). The policy option is modeled to apply to all Part B–covered drugs that are currently paid ASP + 6 percent, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. Estimates of Medicare payments for all types of services by type of provider exclude providers who did not bill for at least one Part B–covered drug. Medicare payments include Medicare program payments and beneficiary cost sharing and include the effect of the sequester. Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Spending figures by category may not sum to total due to missing data on provider characteristics for a small number of providers.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

although we have sought to reduce the likelihood of that outcome through the use of a modest flat-fee add-on ($5 per drug per day). As noted in our June 2015 report, a flat add-on might create incentives for use of some drugs in smaller, more frequent doses, which could lead to increased add-on payments (Medicare Payment Advisory Commission 2015). It is also possible that a flat add-on might create incentives for overuse of inexpensive drugs because the add-on would represent a substantial increase in these drugs' payment rate. Manufacturers of very inexpensive drugs might also respond to the flat fee by increasing their prices. The flat fee we model in this policy option is modest, so the risk of the flat fee leading to these effects is likely to be low.

TABLE 5–6 **Illustration of the effect of the policy option on Medicare payments for two therapeutic alternatives used in chemotherapy regimens for metastatic colon cancer**

			Total payment for an 8-week regimen		Add-on portion of the payment for an 8-week regimen	
	106% ASP per 10 mg	Number of 10-mg units per 8-week cycle	Current: 106% ASP	Option: 103.5% ASP + $5 per drug per day	Current: 6% ASP	Option: 3.5% ASP + $5 per drug per day
Bevacizumab	$70.842	160	$11,335	$11,087	$642	$394
Cetuximab	$53.809	388	$20,878	$20,405	$1,182	$709
Difference					$540	$315

Note: ASP (average sales price). The example of two therapeutic alternatives is identified in research by Schrag and colleagues (2015). Both bevacizumab and cetuximab are products that can be added to the FOLFOX and FOLFIRI regimens with similar survival rates and quality of life, according to their research. Calculations of payments are the Commission's estimates based on ASP + 6 percent and assumptions about dosing. Bevacizumab estimates assume a dose of 5 mg/kg every 2 weeks, and cetuximab estimates assume a dose of 500 mg/m^2 every 2 weeks. Estimates assume a patient with a weight of 80 kg and a body surface area of 1.94 m^2. Estimates are for an eight-week treatment cycle.

Source: MedPAC estimates based on ASP + 6 percent payment rates for the first quarter of 2016 from CMS.

In considering a change to the ASP add-on, it would be important to consider the effect on providers' ability to purchase drugs within the Medicare payment amount. Our analysis of proprietary data on the ratio of invoice prices to ASP for 34 Part B drugs suggests that, in general, there likely is room for a reduction to the ASP add-on. Nonetheless, small providers might have difficulty purchasing expensive drugs at the Medicare payment rate, but this would depend on how drug manufacturers respond to the payment changes. When Medicare began paying 106 percent of ASP in 2005, manufacturers responded by reducing price variation across purchasers (Medicare Payment Advisory Commission 2006). Our analysis of proprietary data on the ratio of invoice prices to ASP for 34 Part B drugs also suggests that some manufacturers responded to the sequester in ways that mitigated the effect of that payment change on some providers. If the ASP add-on were restructured, it is possible that manufacturers would respond in a way that maintained small purchasers' ability to obtain expensive drugs at the Medicare payment rate. Alternatively, it is possible that price variation across purchasers would persist and that smaller oncology practices, for example, might decide to send patients to the larger oncology practices or HOPDs for certain expensive drugs.

Some stakeholders raise concerns that changing the ASP add-on could accelerate a trend toward hospitals buying community oncology practices. Several reasons have been cited for hospitals' acquisition of these practices (e.g., availability of 340B discounts at some hospitals, general reimbursement pressures, a movement toward integrated care models, and interest among some physicians in employment rather than running a practice). If a change to the ASP add-on resulted in some practices having difficulty purchasing drugs at the Medicare payment rate, this circumstance might contribute to the trend toward more hospital-based oncology care. However, it is in drug manufacturers' interest to support community oncology practices since acquisition of practices by hospitals, some of which participate in the 340B program, would potentially subject more manufacturer sales to 340B discounts.

Other payment policy approaches

In addition to concerns about financial incentives under Medicare's 6 percent add-on payment, there are also concerns about the prices overall that Medicare Part B pays for drugs. The largest component of Medicare's payment is the ASP; the 6 percent add-on is a relatively small share of total payments. If policymakers wish to influence Part B drug payments to a larger degree than possible through add-on payments, they could consider Medicare payment policies that create more incentives for price competition among drugs or that put downward

TABLE 5–7 **Growth in ASP for the top 20 highest expenditure drugs, January 2005–2016**

HCPCS code	Short description	Total Medicare payments in 2014 (in billions)	Average annual ASP growth, from January to January of each year				Earliest year of ASP data if not 2005
			2005–2016	2005–2010	2010–2015	2015–2016	
J9310	Rituximab	$1.5	5.2%	5.0%	5.2%	6.0%	
J2778	Ranibizumab	1.3	–0.6*	–0.2*	–0.4	–2.1	2008
J0178	Aflibercept	1.3	0.0*	N/A	0.0*	0.0	2013
J2505	Pegfilgrastim	1.2	4.8	0.8	8.1	9.5	
J1745	Infliximab	1.2	3.8	2.0	4.8	7.8	
J9035	Bevacizumab	1.1	2.0	0.1	3.4	4.3	
J0897	Denosumab	0.8	1.8*	N/A	0.6*	5.5	2012
J9355	Trastuzumab	0.6	4.9	4.1	5.4	6.0	
J9305	Pemetrexed	0.6	3.9	4.5	3.7	1.8	
J9041	Bortezomib	0.5	4.6	6.1	4.0	0.4	
J0129	Abatacept	0.3	8.6*	1.4*	11.2	19.0	2007
J2353	Octreotide depot	0.3	5.8	4.9	5.8	10.7	
J9033	Bendamustine	0.3	4.1*	–0.6*	4.2	8.2	2009
J0885	Epoetin alfa	0.3	1.4	–2.1	4.5	3.7	
J0881	Darbepoetin alfa	0.3	1.4	–4.4	6.6	6.4	
J9264	Paclitaxel protein bound	0.3	1.9*	3.0*	0.7	3.6	2006
J8521	Capecitabine	0.3	4.0	13.7	5.2	–36.8	
J9228	Ipilimumab	0.3	2.7*	N/A	2.2*	4.2	2012
J9055	Cetuximab	0.3	0.7	0.0	1.6	0.1	
J2323	Natalizumab	0.3	10.8*	4.7*	13.5	9.9	2008
Median average annual ASP growth across top 20 drugs			3.8	2.0	4.4	4.9	
Consumer price index for urban consumers			2.0	2.6	1.5	1.4	

Note: ASP (average sales price), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). Medicare payments include Medicare program payments and beneficiary cost sharing and include the effect of the sequester.
*Indicates that ASP payment rates were not available for the full time period listed, and the average annual growth rate was calculated based on the earliest year for which data were available.

Source: MedPAC analysis of ASP + 6 percent payment rates and Medicare claims data from CMS.

pressure on ASP. We explore three potential policies: (1) a limit on ASP growth over time, (2) consolidated billing codes for Part B drugs, and (3) restructuring the competitive acquisition program for Part B drugs.

Limit on ASP growth

Under Medicare's ASP payment system, growth in Medicare's ASP + 6 percent payment rates for individual drugs is driven by manufacturer pricing policies. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for an individual drug can increase over time. Table 5-7 shows how ASP has grown over time for the 20 highest expenditure Part B drugs (as of 2014). Between January 2005 and January 2016, the median average annual growth rate of ASP across these drugs was 3.8 percent. Underneath this aggregate figure there are trends that vary by time period. For these drugs, the median average annual growth rates of ASP from 2005 to 2010, 2010 to 2015, and 2015 to 2016 were 2.0 percent, 4.4 percent, and 4.9 percent, respectively. Across these drugs, ASP growth at the median was slower than inflation (as measured by the consumer price index for all

urban consumers (CPI–U)) in the early years of the ASP payment system, but has exceeded inflation since 2010.

Some drugs experienced higher ASP growth than others. For example, over the course of the ASP payment system (from 2005 to 2016), several drugs had average annual ASP growth of roughly 5 percent or more (i.e., natalizumab, abatacept, octreotide depot, rituximab, trastuzumab, and pegfilgrastim). In the last year, more of these drugs have experienced ASP growth of at least 5 percent. Between January 2015 and January 2016, 10 of the top 20 high-expenditure drugs had ASP growth of 5 percent or more, with 4 of these drugs having ASP growth of roughly 10 percent or more. Capecitabine, a drug that first experienced generic entry in September 2013, provides an example of how a drug's ASP can grow rapidly over a number of years before generic entry and then drop substantially after generics become available. From January 2005 to January 2014, capecitabine's ASP grew at an average rate of 13 percent per year; after generic entry between January 2014 and January 2016, the ASP decreased at an average rate of roughly 30 percent per year (data for these time periods not shown in chart).

One policy option that could be considered is limiting the amount that Medicare's ASP + 6 percent payment for a product can grow over time. Such a limit could provide the Medicare program and beneficiaries with protection from the possibility that a manufacturer could institute a dramatic price increase. It could also potentially generate savings for existing drugs that have experienced ASP growth higher than inflation. It would not, however, address the issue of high launch prices for new products, and it might spur some manufacturers to set a higher launch price. Some may argue that such an administrative constraint on price growth is contrary to having market conditions and competitive forces drive payments for Part B drugs; however, in some instances, a competitive market might not exist (e.g., if there are no competitors for a given drug or if payment systems are not structured to facilitate competition among products with similar health effects).[26]

A limit on ASP growth could be implemented in different ways. One way could be through a rebate mechanism. Another approach would be to limit growth in Medicare's payments to physicians and hospitals made at the ASP + 6 percent rate.

Manufacturers could be required to pay Medicare a rebate if ASP grows faster than a specified threshold, similar to the inflation portion of the Medicaid rebate. The Medicaid rebate has two components: (1) a specified rebate amount based on a percentage of the average manufacturer price (AMP) or the difference between AMP and best price and (2) an additional rebate if a drug's AMP has grown faster than the rate of inflation (as measured by CPI–U since a base year).[27] The inflation portion of the rebate is equal to the difference between the actual AMP and what AMP would have been if it had grown at the rate of inflation. This inflation rebate ensures that the inflation-adjusted prices paid by the Medicaid program for drugs do not increase over time. Under a Medicare inflation rebate modeled after the Medicaid inflation rebate, manufacturers would be required to pay Medicare a rebate when ASP grew faster than inflation.[28]

Alternatively, a limit could be placed on the amount that the ASP + 6 percent payment rates to physicians and HOPDs can increase over time. Each quarter when CMS establishes the ASP + 6 percent payment amounts, CMS could pay the lesser of (1) the actual ASP + 6 percent for the quarter or (2) an inflation-adjusted ASP + 6 percent. The inflation-adjusted ASP + 6 percent would be calculated by taking the ASP + 6 percent from a base year and increasing it by a measure of inflation that occurred between the base year and the quarter for which payment is being established.

These two approaches to an ASP inflation limit—a Medicare rebate or a limit on Medicare's payments to physicians and hospitals—have different implications for various stakeholders. The options differ in terms of which entity bears the financial risk. Drug manufacturers bear the financial risk under a rebate approach. If the ASP grows faster than the inflation benchmark, manufacturers would pay Medicare the difference through a rebate. Under a limit on the ASP + 6 percent payment rates, physicians and hospitals would bear the financial risk. These providers could lose money if a limit on Medicare's ASP + 6 percent payment rates over time meant that the payment rates for some drugs did not keep up with providers' acquisition costs.

The approaches also could have different implications for beneficiaries in terms of who saves and how much. An inflation limit on the ASP + 6 percent payment rates to providers would lead to savings for beneficiaries in two ways: (1) Medicare program savings would translate into a lower Part B premium for all beneficiaries, and (2) beneficiaries who use Part B drugs would save by paying 20 percent of a lower price. An ASP inflation rebate would lead to the first type of savings for beneficiaries (lower Part B premiums) and could lead to the second type of savings (lower beneficiary cost sharing), depending on

how it was structured. Under the simplest approach, the rebate would not affect the Medicare ASP + 6 percent payment rates to providers and thus not affect beneficiary cost sharing. But other ways of implementing the rebate would allow the beneficiary to realize lower cost sharing. For example, CMS could reduce the cost-sharing amount for those drugs subject to a rebate (to the level it would have been if an ASP inflation cap had been imposed on the provider payment rate), and the Medicare program could increase its payment to the provider to make up the difference. The program would then receive rebates from the manufacturer afterwards, keeping the full amount of the rebates. The net result would be that the beneficiary realizes 20 percent of the rebate through lower cost sharing and the program realizes 80 percent of the rebate (i.e., total rebates minus the additional amount the program paid the provider to make up for the reduced beneficiary cost sharing).

Regardless of which rebate structure was chosen, certain key decisions would have to be made. An inflation benchmark would need to be selected. The Medicaid rebate uses CPI–U, but other inflation benchmarks could be considered. Policymakers would need to define the base year from which growth in ASP and inflation was measured. Options for a base year include the quarter of first marketing (which would be likely to produce the most savings but may be viewed as a retroactive penalty if applied to existing products) or some period shortly before consideration of the policy (e.g., 2015), which would give manufacturers notice of the policy while limiting their ability to respond by increasing prices before the policy went into effect.

Policymakers would also need to decide whether there would be any exceptions to this policy. One concern is that an ASP inflation limit might adversely affect a manufacturer of a low-cost drug that is in shortage—for example, if it increased the drug's price in conjunction with efforts to bring more product to market. The FDA maintains a list of drugs in shortage, so policies could be developed to exempt products in shortage from the ASP inflation cap.

Consolidated billing codes

Under the ASP payment system, most drug products have their own billing code and receive a payment rate equal to 106 percent of their individual ASP. This method is used for the vast majority of single-source drugs and biologics. In contrast, generic drugs, along with their associated brand-name drug, are paid under one billing code based on the volume-weighted average ASP for the products in the code. Because of the single billing code and the low research and development costs for generic drugs, Medicare payment rates for drugs that become generic generally decline substantially over time (Medicare Payment Advisory Commission 2010).

The structure of the ASP payment system does not promote strong price competition among single-source drugs and biologics where there are therapeutic alternatives. In some therapeutic classes, there are several single-source products with similar health effects. Because the Medicare program pays for each of these products in its own billing code based on its own ASP, there is less pressure for price competition among these products. For example, among the list of the top 20 highest expenditure drugs, some drugs that are competitors are each paid under separate billing codes based on their separate ASPs (for example, epoetin alfa (Procrit/Epo) and darbepoetin alfa (Aranesp), which are used to stimulate production of red blood cells, and ranibizumab and aflibercept, which treat wet AMD and certain other eye conditions). The upward trend in ASP payment rates for these drugs demonstrates that price competition has been limited among single-source competitor products under the ASP payment system. Despite moderate declines in ASPs for epoetin alfa and darbepoetin alfa during the first five years of the ASP payment system (at an average annual rate of roughly –2 percent and –4 percent per year, respectively), these products' ASPs have grown significantly since that time (Table 5-7, p. 131). Between 2010 and 2016, the ASPs for epoetin alfa and darbepoetin alfa have increased at an average rate of roughly 4.0 percent and 6.5 percent per year, respectively. With ranibizumab and aflibercept, price competition has been very limited. Aflibercept's ASP has not changed and ranibizumab's ASP has declined modestly (0.6 percent per year on average).

The Commission has held that Medicare should pay similar rates for similar care. With respect to drugs, that principle may suggest paying single-source drugs and biologics with similar health effects under the same billing code at the same payment rate. Doing so would be expected to generate more price competition among products than separate billing codes. With two or more similar products paid under the same billing code and paid at a rate that is based on the volume-weighted ASP for the products, drug manufacturers would have an incentive to lower their price relative to their competitors to make their product more attractive to providers and garner market share. Because research and development costs

for single-source drugs and biologics are higher than for generic drugs, we would not expect the prices of these products under a combined billing code policy to decline to the level observed with generic drugs. Nonetheless, we would expect prices to be lower than they are currently, which would translate into savings for beneficiaries and taxpayers.

The issue of consolidated billing codes is also relevant to biosimilar and reference biologics. CMS proposed and finalized a policy that all biosimilar products associated with a particular reference product will be paid under a single billing code and receive a payment equal to 100 percent of the weighted average ASPs for the biosimilar products plus a constant dollar add-on equal to 6 percent of the reference product's ASP. The reference biologic remains in its own separate billing code and continues to be paid 106 percent of its own ASP.

Grouping biosimilar and reference products together under one billing code and paying them the same rate would be expected to generate greater price competition relative to two separate codes for these products. Reference biologics receive patent protection and 12 years of exclusivity before a biosimilar can enter the market, during which time the reference biologic faces little price competition. Once the patent and exclusivity periods elapse, competitive biosimilar manufacturers are able to enter the market facing less risk than the reference biologic manufacturer and are able to produce a similar product at lower cost. Under a single payment rate, the biosimilar and reference products would all face the same incentive to compete based on price and quality and generate the best price for beneficiaries (who are liable for 20 percent cost sharing for Part B drugs) and taxpayers. The effect of including the reference product and biosimilars under a single billing code was considered by the Congressional Budget Office in 2008 when it estimated that an abbreviated approval process for biosimilars would generate more savings if the reference product and biosimilars were assigned to the same Medicare Part B billing code rather than each product assigned separate billing codes (Congressional Budget Office 2008).

Some stakeholders have criticized a policy of consolidated billing codes for single-source drugs and biologics with similar health effects or for biosimilars and reference products as reducing incentives for research and development for these products. Others argue that given the large market for Part B drugs, there is likely to continue to be interest in the development of drugs even in the presence of a consolidated billing code policy. If CMS were to develop a process for establishing consolidated billing codes for therapeutically similar drugs, it could include consideration of a variety of issues—for example, the potential effect on access to care, program spending, and future research on drugs in the category. Additionally, some industry stakeholders contend that high prices are needed in general to fund research and development. Currently, there is insufficient objective, transparent data available on the research and development costs of new drugs, biologics, and biosimilars.

Some stakeholders also contend that combined billing codes could have an adverse impact on beneficiary access. Some assert that if a beneficiary needs a particular product paid under a combined billing code and that product is more expensive than the code's other products, the clinician would be unwilling to supply the drug to the beneficiary. While a combined billing code would create incentives for use of the lowest priced product, the clinician would continue to have the choice to select the product most appropriate for the patient. The payment rate for a combined billing code is based on the volume-weighted average ASP for all the products, not the ASP of the lowest cost product. Under this methodology, the rate paid for a combined code's lowest priced product would be higher than if it were paid under a separate code. Thus, clinicians earn more net revenue than they otherwise would on the least costly drug, and that additional revenue could help offset the cost of a higher priced drug if needed by a particular patient.

A key issue to be considered with consolidated billing codes is how CMS would determine when products should be grouped together and when they should retain their separate billing codes. A choice is available about what types of products this policy could apply to. If the policy were applied to biosimilars and reference products, the FDA's determination that the products are biosimilar would serve as a basis for CMS putting the biosimilar and reference products under the same billing code. If the policy were applied to groups of single-source drugs and biologics with similar health effects, a process would be needed to identify groups of products that achieve comparable clinical outcomes. It would also be important that CMS solicit input from clinical experts (including practicing physicians in the relevant specialties) and a wide range of stakeholders, including beneficiaries and the public. As part of this process, CMS could seek a technology assessment from groups with clinical expertise. Examples of some existing bodies that could play a role in

this process include the Medicare Evidence Development & Coverage Advisory Committee and the Agency for Healthcare Research and Quality's Evidence-Based Practice Centers, among others. Any process for seeking clinical expertise and stakeholder input would need to be carefully designed to avoid conflicts of interest, give the public and stakeholders adequate notice and opportunity for comment, and allow for decisions to be reconsidered as clinical evidence evolved.

Restructuring the competitive acquisition program

Medicare implemented a voluntary competitive acquisition program (CAP) for Part B drugs from June 2006 to December 2008. The goal was to remove physicians from the business of buying and billing for drugs and eliminate any financial incentives for prescribing drugs. Under the program, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program instead of paying the physicians directly for the drugs they administer. The program was viewed as unsuccessful largely because physician enrollment was low, the vendor had little leverage to negotiate discounts, and Medicare paid the vendor more than ASP + 6 percent for the drugs. The CAP has been suspended since the end of 2008, when the first CAP contract period expired. In 2008, CMS put a second CAP contract out to bid for the period from 2009 to 2011. CMS reported receiving several qualified bids, but because of contractual issues with the successful bidders CMS suspended the program at the end of 2008.[29] Although Medicare's original experience with the CAP faced challenges, the concept underlying the program—to eliminate financial incentives physicians face when prescribing Part B drugs—continues to have appeal. We explore ways to restructure the CAP to address the challenges it faced, particularly to increase physician enrollment and provide the vendor with tools to negotiate more favorable discounts and support high-quality care. A carefully reconstructed CAP with population-based incentives for quality and cost would be consistent with other efforts underway more broadly in the Medicare program to move toward delivery system and payment reform.

Background on Medicare's CAP

Under the CAP, physician practices chose whether to join the program and receive drugs from the CAP vendor or continue to buy and bill drugs under the ASP payment system. Before a patient's visit to the doctor for a drug administration, the patient's physician would place an order with the CAP vendor to deliver drugs specifically for that individual patient. If the physician needed the drug urgently for a beneficiary and had not ordered it, the physician was permitted to administer the drug from his or her own inventory and the CAP vendor would replenish the physician's inventory afterwards. More than 45 percent of drugs furnished by the CAP vendor in 2006 and 2007 were provided through this emergency restocking provision. After the physician administered the drug, the physician would submit a claim to Medicare for the drug administration services (but not for the drug itself). Medicare would pay the CAP vendor for the drug, and the vendor would bill the beneficiary for the drug cost sharing.

CMS conducted a bidding process to select organizations to become CAP vendors. CMS offered contracts to several organizations but only one organization, BioScrip, chose to sign a contract and became the national CAP vendor.

CMS selected the drugs for inclusion in the program. Roughly 180 individually coded Part B drugs were included in the program, with CMS focusing on drugs administered by oncologists, rheumatologists, ophthalmologists, and psychiatrists. For drugs not included in the program, physicians participating in the CAP continued to bill Medicare for the drugs under the ASP payment system.

Roughly 1,000 physician practices participated in the CAP each of the 3 years it was in operation (with some practices leaving and new practices entering over this period). Among drugs furnished by the CAP vendor, rheumatology drugs were overrepresented and oncology drugs were underrepresented, suggesting that rheumatologists were more likely to enroll than oncologists. Physicians who participated in the program reported being generally satisfied with it (Drozd et al. 2009). However, roughly 50 percent of practices that participated in the program one year chose not to participate the next year. Beneficiaries who received drugs through the program reported few problems with access to drugs or cost-sharing billing by the CAP vendor.

An evaluation of the program by a CMS contractor, RTI International, found that the aggregate price Medicare paid the CAP vendor for Part B drugs exceeded ASP + 6 percent (roughly 3 percent higher in aggregate through 2007) (Drozd et al. 2009). Several factors contributed to CAP payments exceeding ASP + 6 percent. While CMS limited the vendor's bid in aggregate to no greater than ASP + 6 percent, the aggregate bid was calculated as a weighted average across all billing codes using historic

utilization data for the weights. The relative utilization of drugs furnished by the CAP vendor was different from the historic claims data, which contributed to the aggregate payments being higher than ASP + 6 percent. In addition, CMS updated the bid prices based on the producer price index for drugs. According to RTI, this index grew more quickly than the ASP for some drugs, leading to payments that exceeded ASP + 6 percent. Beyond these issues, there were broader challenges with this model that made it difficult to generate price savings. The CAP vendor was required to offer all biologics and single-source drugs and was not permitted to create a formulary, giving the vendor little leverage to obtain favorable prices from manufacturers.

Restructuring the CAP

To restructure the CAP, two key challenges identified during the original program need to be addressed: increasing physician enrollment in the program and enhancing the vendor's leverage to obtain favorable prices.

Encouraging physician enrollment For the CAP to be successful, physician enrollment in the program would need to increase. Two general approaches could be considered: (1) a voluntary program with incentives for participation or (2) a mandatory program with all physicians required to participate. A mandatory program would have the advantage of ensuring that the population for which the vendor was negotiating drug prices would be large, increasing the vendor's leverage. However, there would likely be resistance to a mandatory program, both because some physicians may not want to be dependent on a Medicare-selected vendor and because some physicians earn substantial profits from Part B drugs under the current reimbursement structure.

A voluntary program in which physicians are given incentives to participate in the CAP is another option. At least two types of incentives could be considered. Physicians who enrolled in the program could be given the opportunity to share in any savings achieved, creating a positive incentive for participation. At the same time, the Medicare add-on payment to ASP (6 percent or any future modification) in the traditional buy-and-bill payment system could be reduced or eliminated, creating an incentive for physicians to move away from that system and enroll in the CAP.

There may be additional ways to encourage enrollment in the program. Experience with Medicare's CAP showed that some physicians did not want to obtain drugs from the CAP vendor. One concern they expressed involved the administrative burden of having to place an order with the CAP vendor for each Medicare patient in advance of the patient's office visit and having to keep track of the vendor-supplied drugs for each patient. In fact, nearly half of drugs furnished by the CAP vendor were not done so in advance of the patient's visit, as the design of the CAP had envisioned. Instead, physicians furnished the drug to the patient from their own supply under the emergency provision and the vendor restocked the drug afterwards. To address this design issue, the CAP could be restructured to be a stock-replacement model.

Under a stock-replacement model, physicians would estimate the type and quantity of drugs they require for all of their Medicare patients for a week (or some other short time period). The vendor would supply the drugs. When a drug was used, the physician would notify the vendor, and the vendor would then bill Medicare and the beneficiary for the drug and send the physician practice a replacement for the administered drug. This model would reduce the administrative burden on physicians and vendors. Physicians would not have to send the vendor in advance a separate prescription for each patient and would not have to separate inventory by patient (although they would still need to keep drugs for Medicare beneficiaries separate from drugs for their other patients). This model would also maintain the vendor's role in collecting beneficiary cost sharing, something that some physicians found to be an attractive feature of the CAP.

Another structure that could be considered is a group purchasing organization (GPO) model. Under a GPO approach, the vendor would negotiate the price at which participating physicians would acquire drugs but not supply the drugs directly to physicians. Instead, physicians would acquire drugs from wholesalers and distributors in the marketplace as they normally would, but at a price negotiated by the vendor, and Medicare would pay physicians the negotiated rate for the drugs. This arrangement would effectively eliminate any profit or loss the physician would otherwise make on the drug. Since physicians would not know at the time they purchased a supply of drugs how much would be used for Medicare patients versus other patients, there would need to be a retroactive reconciliation process to ensure that the appropriate price was charged for the units of the drug administered to Medicare beneficiaries.

Formulary authority In the original CAP, the vendor was required to offer all drugs specified by CMS (with

the exception of generics, from which the vendor could choose one product among a group of generics). This requirement gave the vendor little leverage to negotiate favorable prices. To give the vendor more leverage, the vendor could be permitted to create a formulary (i.e., a list of covered or preferred drugs).

A formulary would give the vendor leverage to negotiate more favorable prices in situations where multiple drugs with the same health effects exist. If the vendor had the ability to steer physicians toward using a preferred drug over its competitors, with sufficient volume for the preferred drug, the vendor would have leverage to obtain price concessions on the drug. For drugs without therapeutic alternatives, formulary authority would do little to increase the vendor's leverage. If the CAP were restructured to permit the vendor to create a formulary, decisions would have to be made about what constitutes an acceptable formulary and how the formulary would be developed.

A range of potential formulary structures exists. Under one approach, the vendor is able to exclude drugs if it can offer another drug with similar health effects for a lower price. Under another approach, the vendor is required to offer all drugs, but the vendor is able to designate lower cost drugs as preferred and can encourage physicians to use preferred drugs through shared savings opportunities. Depending on how the formulary was structured, an exceptions process and appeals process could be needed (particularly if the vendor was permitted to exclude drugs from the formulary or if the vendor had prior authorization functions).[30]

In addition, under a formulary approach, requirements would need to be established regarding the vendor's process to develop the formulary and regarding the clinical or other experts participating in that process. In addition, criteria governing conflicts of interest would be needed to prevent participation of physicians or other experts who might have a financial stake in a particular pharmaceutical product. Decisions would also have to be made about how much oversight CMS would have over the formulary.

An important factor in building acceptance of a formulary would be to involve physicians who treat Medicare beneficiaries in the formulary's development, possibly through a collaborative process between the vendor and leading physicians in the relevant clinical specialties. There is some evidence from integrated delivery systems that when physicians participate in formulary development, they are more likely to adhere to the formulary. The combination of physician involvement in the formulary development process and shared savings opportunities for physicians would strengthen the vendor's negotiating leverage.

Illustrative CAP To illustrate how a restructured vendor program could be designed and what issues would have to be considered in operating such a program, we considered the following features:

- Physician enrollment in CAP remains voluntary.
- The CAP uses a formulary with shared savings opportunities for beneficiaries, physicians, and the vendor.
- The add-on payment to ASP under the traditional buy-and-bill system is reduced or eliminated.
- The CAP would be a stock-replacement model.

The illustrative CAP described above would maintain the voluntary nature of the CAP. It would encourage physician participation by a combination of offering physicians a shared savings opportunity under the CAP, reducing the ASP add-on payment in the traditional buy-and-bill system, and making the CAP simpler for physicians by restructuring it into a stock-replacement model. Physicians would have an incentive to use preferred drugs through a shared savings opportunity. Under a CAP with these features, if physician enrollment was sizable and physicians generally adhered to the formulary, the vendor would have enhanced leverage to negotiate discounts on drugs with therapeutic substitutes.

An important design issue would be how to pay the vendor. As with the original CAP, the amount Medicare paid the vendor for each drug could be determined based on the vendor's bid price to supply the drug, with one or more organizations selected to be vendors through a competitive bidding process. The original CAP had problems updating the bids over time using the producer price index because it was not a good proxy for price changes at the individual drug level. To avoid this problem, the vendor could be required to structure its bid for each drug as a percentage of ASP, which would ensure that the price Medicare paid the vendor for drugs tracked trends in ASP.

Another important design issue would be how to measure and apportion savings. Savings could be shared with the beneficiary by basing the beneficiary's cost sharing on the vendor's price. If the vendor's price were lower than

TABLE 5–8 **Current Part B drug dispensing and supplying fees**

Dispensing and supplying fees	Current payment rate
Inhalation drug dispensing fee:	
Initial one-time fee	$57
30-day supply	$33
90-day supply	$66
Immunosuppressive, oral anticancer, and oral antiemetic drug supplying fee:	
Initial one-time fee for immunosuppressives	$50
First drug in a 30-day period	$24
Subsequent drug in the same 30-day period	$16

Source: CMS Manual System Pub 100–04 Medicare Claims Processing, Transmittal 754, "Supplying Fee and Inhalation Drug Dispensing Fee Revisions and Clarifications." November 10, 2005.

the price paid by the traditional Medicare program, the beneficiary would save.

Offering physicians shared savings opportunities under a CAP would engage physicians in managing the total Medicare cost of Part B drugs (i.e., choice of agent, price, duration of treatment, and appropriateness of treatment). Such an approach has the potential to offer more robust incentives for efficient, high-quality care than what currently exist under the ASP payment system. To that end, it would be important that a restructured CAP measure savings in a way that takes into account how total spending has changed, reflecting both price and utilization changes. In contrast, it would not be beneficial for a savings measure under a restructured CAP to focus only on price since that approach could create unintended incentives for use of more expensive drugs. For example, hypothetically, if an expensive drug could be purchased for $700 (30 percent below its $1,000 ASP) and a cheaper alternative could be purchased for $100 (100 percent of its ASP), Medicare would not want to create incentives for the provider and vendor to use the $700 drug (because of potentially $300 shared savings) over the $100 drug (with potentially no shared shavings). Estimating savings (or costs) from a restructured CAP based on changes in the total cost of Part B drugs would avoid these concerns about unintended incentives.

To measure the effect of the CAP on total spending, policymakers would have to identify the spending benchmark against which CAP spending would be compared. For example, should the spending benchmark be based on a historical estimate of drug spending updated for inflation or on a comparison of drug spending trends for CAP-participating physicians and for nonparticipating physicians? In addition, should spending be measured at the aggregate level across all drugs and all patients or across patient groups with certain conditions? Since drug prices at the product level move in a variety of directions, applying a broad inflation measure to aggregate drug spending might not be a good proxy for spending growth in the absence of the program. Comparing spending growth for participating and nonparticipating physicians would be a better indicator of performance. One approach could be to identify patient groups with certain conditions for which several drug therapeutic alternatives exist and compare drug spending for these patient groups over time for CAP-participating physicians and nonparticipating physicians. The apportionment of shared savings among the CAP's participating physicians raises other design questions. Would all physicians who participate receive a portion of any overall savings, or would savings be apportioned based on performance at the practice level? Measuring any savings at the practice level would create stronger incentives for use of preferred drugs. However, a sufficiently large number of patients would be needed to measure savings for an individual practice. To address measurement challenges for small practices, approaches could be considered to aggregate performance data across a number of small practices or to measure performance for an individual practice using multiple years of data.

Overall, we would expect a restructured CAP with the features we identified to generate savings because the ASP add-on in the buy-and-bill system would be reduced or eliminated. Whether such a program would be able to achieve additional savings beyond those generated by the reduced add-on would depend on a number of factors, including how much leverage the vendor had to negotiate price discounts, which would depend on how many physicians enrolled in the program and the extent to which these physicians used the preferred drugs over more expensive alternatives. The ability to achieve additional savings would also depend on what share of Part B spending is accounted for by drugs that have substitutes and thus offer savings potential, something that is currently unknown. Also, any savings through reduced prices or shifts in utilization would be netted against the vendor's operating costs—those associated with

developing a formulary, negotiating prices, accepting drug orders from physicians, shipping, billing, collecting cost sharing, auditing, and quality assurance.

The original CAP applied across a wide range of drugs, covering 180 drug billing codes. A restructured CAP raises the question of whether the program should be applied broadly or should focus on certain specialties or certain drugs across specialties for which opportunities for savings appear greatest. Since Part B drug spending is fairly concentrated among a small group of drugs (the top 30 billing codes account for more than 70 percent of spending) and since some drugs do not have therapeutic alternatives, there could be benefits to focusing the program, at least initially, on those areas where it has the best chance of success. For example, this approach could be tested for one specialty for which spending is substantial enough to make it worthwhile. Alternatively, the program could focus on high-expenditure drugs that have therapeutic alternatives (including biosimilars or products not biosimilar but considered by clinicians to have similar health effects).

Part B drugs furnished by suppliers

Medicare Part B pays dispensing and supplying fees for certain drugs furnished by suppliers. Medicare pays dispensing fees for inhalation drugs furnished by durable medical equipment suppliers, in addition to paying ASP + 6 percent for the drugs. Beneficiaries are liable for 20 percent cost sharing on these fees, similar to other Part B services. In 2014, Medicare and beneficiaries paid inhalation drug suppliers about $800 million in ASP + 6 percent payments and $120 million in dispensing fees for inhalation drugs. Medicare also pays supplying fees for Part B–covered immunosuppressive, oral anticancer, and oral antiemetic drugs furnished by pharmacies. In 2014, Medicare and beneficiaries paid suppliers $700 million in ASP + 6 percent payments and $35 million in supplying fees for these drugs.

The inhalation drug dispensing fee is $33 per 30-day supply of drugs, with higher fees for 90-day supplies and for the first supply a beneficiary receives (Table 5-8). The supplying fees for immunosuppressive, oral anticancer, and oral antiemetics drugs are $24 for the first prescription and $16 for each subsequent prescription in a 30-day period, with a higher amount for the first immunosuppressive prescription ever.

Under the statute, CMS has discretion to pay a dispensing fee for Part B drugs furnished by pharmacies, but the statute does not specify what the dispensing fee is intended to cover.[31] In regulation, CMS has not precisely defined the scope of the dispensing fee but has described it as including shipping, handling, and pharmacy services necessary to get the drugs to the beneficiary and has said it does not include pharmacy care management services (Centers for Medicare & Medicaid Services 2005).[32] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 gave the Secretary the authority to pay a supplying fee for immunosuppressive, oral anticancer, and oral antiemetic drugs. Although referred to as a supplying fee, it is similar to a pharmacy dispensing fee. CMS has said that the lack of online claims adjudication for Part B drugs means that pharmacies face higher costs when billing Part B compared with other payers. CMS has said it is appropriate for the supplying fee to be higher than other payers' dispensing fees because of the lack of online claims adjudication, but not for other reasons (Centers for Medicare & Medicaid Services 2005).

OIG has reported that the Part B dispensing and supplying fees are substantially higher than dispensing fees paid by Part D plans and Medicaid, and it recommended that Medicare's Part B fees be lowered to a level similar to other payers (Office of Inspector General 2014b). OIG found that in 2011, Medicare Part D plans paid a dispensing fee of about $4.60 for inhalation drugs and about $1.80 for immunosuppressive, oral anticancer, and oral antiemetic drugs; Medicaid paid about $4.60 per prescription across these different types of drugs.

RECOMMENDATION 5

The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

RATIONALE 5

Medicare Part B pays dispensing fees for inhalation drugs and supplying fees for oral anticancer, oral antiemetic, and immunosuppressive drugs that are substantially higher than the rates paid by Medicare Part D plans and Medicaid. These fee levels have been in effect since 2006, and the data on which the fees were based were quite limited. We believe that Medicare should not pay a dispensing fee higher than other payers. Reducing the dispensing and supplying fees to the level of other payers (e.g., $5 per prescription) would generate savings for the Medicare program and beneficiaries.

IMPLICATIONS 5

Spending

- Reducing the Part B drug dispensing and supplying fees would decrease federal program spending by between $50 million and $250 million over one year and by less than $1 billion over five years.

Beneficiary and provider

- Reducing the Part B drug dispensing and supplying fees would generate savings for beneficiaries through lower cost sharing. Reducing these fees would represent a reduction in suppliers' total Medicare revenues of less than 5 percent. We would not expect this recommendation to have adverse effects on beneficiaries' access to care or suppliers' willingness or ability to furnish these drugs to Medicare beneficiaries.

Improving the efficiency of oncology care in fee-for-service Medicare

Medicare spending for anticancer drugs is substantial; in 2014, anticancer drugs accounted for about 55 percent of the nearly $21 billion spent on Part B drugs paid under the ASP methodology in physician office and HOPD settings. Anticancer drugs include chemotherapy and supportive drugs (such as pegfilgrastim and darbepoetin alfa), which address the side effects of cancer treatment, including nausea and vomiting, low white blood cell counts, and anemia. In the Commission's June 2015 report to the Congress, we explored episode-of-care and bundled-payment approaches as mechanisms to heighten providers' sensitivity to the cost of Part B medications used in a cancer care treatment regimen (Medicare Payment Advisory Commission 2015). Specifically, we examined Medicare spending in the six-month period following the first oncology drug administration and reviewed issues in designing oncology bundling, such as what triggers an episode and the services included in the bundle. With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area amenable to payment bundling.

In this section, we continue to examine episode-of-care and other approaches that seek to improve the efficiency of oncology services while improving care quality. Keeping in mind Medicare's coverage and payment policies for Part B anticancer drugs and their administration, we examined factors that can influence clinicians' prescribing of anticancer drugs. In addition, we examined four examples of narrower versus broader approaches designed to improve the efficiency of oncology care in Medicare and non-Medicare populations. The two narrower approaches—risk sharing and oncology clinical pathways—attempt to improve the value of drug spending:

- Risk-sharing agreements made between product manufacturers and payers link payment for a drug to patient outcomes, such as a clinical measure (e.g., laboratory value) or an event (inpatient hospital admission). Product manufacturers and commercial payers have implemented these agreements in the United States and internationally.
- Oncology clinical pathways consist of treatment protocols adopted by commercial payers and providers (hospitals and clinicians) to standardize drug treatment, reduce unnecessary variation, improve quality of care, and reduce costs. Some payers and providers have implemented various approaches that link compliance to clinical pathways to financial incentives.

By contrast, the two other, broader approaches—medical homes and episode-of-care approaches—take a more holistic view of cancer care, seeking to improve care management and coordination:

- The oncology medical home is built on the concept of patient-centered care; the expectation is that enhanced services, such as team-based care, will expand patient access and education and that clinical practices will improve health outcomes and reduce cost. The Center for Medicare & Medicaid Innovation (CMMI) funded an oncology medical home under a three-year grant, which ended in 2015. Commercial payers also have implemented oncology medical homes.
- Bundling Part B oncology drugs with non-oncology services holds providers accountable for the total cost of services across an episode of care. UnitedHealthcare implemented such an approach under which practices were paid ASP for chemotherapy drugs (instead of ASP plus a negotiated add-on amount), an episode fee (based on the contracted drug add-on amount to ASP), and fee-for-service (FFS) contractual amounts for most other services. Practices were eligible for shared savings if quality improved or total costs decreased.

How Medicare covers and pays for Part B anticancer drugs and administration (infusion) services

Medicare Part B covers infusible and injectable drugs, including anticancer drugs, administered by clinicians in physician offices and HOPDs if the treatment is reasonable and necessary for the diagnosis or treatment of an illness or injury. In addition, Medicare Part B covers certain oral anticancer and oral antiemetic products. The Omnibus Budget Reconciliation Act of 1993 (Section 1861(s)(2)(Q) of the statute) provides Part B coverage for FDA-approved oral anticancer drugs prescribed as chemotherapeutic agents if they have the same active ingredients and are used for the same indications as chemotherapeutic agents that would be covered if they were not self-administered and were furnished incident to a clinician's service. The Balance Budget Act of 1997 (Section 1861(s)(2)(T) of the statute) provides Part B coverage for FDA-approved oral drugs prescribed as acute antiemetic (antinausea) products that are used as part of a chemotherapeutic regimen if the drug is prescribed for use immediately before, at, or within 48 hours after the time of the administration of the chemotherapeutic regimen and as a full replacement for the antiemetic therapy that would otherwise be administered intravenously.

Specific to anticancer drugs, the statute (Section 1861(t)) requires that Medicare cover any drug used in an "anticancer chemotherapeutic regimen," as long as the use is "for a medically accepted indication," which includes indications for uses listed on the product's label (written by its manufacturer for FDA approval) and off-label uses reported in one of several drug compendia and in peer-reviewed medical literature. The statute recognizes several compendia and gives the Secretary authority to revise the list as appropriate for identifying medically accepted indications for drugs. Medicare recently expanded its list of approved compendia to set coverage policies for off-label anticancer drugs.[33]

Part B spending (program payments and beneficiary cost sharing) for anticancer drugs paid under ASP in the office and HOPD settings and to suppliers was $11.5 billion, accounting for 55 percent of all drugs paid under ASP in 2014.[34] Anticancer drugs accounted for 7 of 10 leading drugs as measured by Part B ASP spending. In paying for anticancer and related drugs under Part B using ASP methodology, Medicare makes an additional separate payment for administration of the drug under the PFS or OPPS. In 2014, we estimate that Part B spending on the infusion (administration) of chemotherapy drugs was roughly $1.0 billion; about 60 percent of this total was associated with administration services furnished in HOPDs.[35]

Anticancer drugs and the associated administration services account for a substantial portion of gross Medicare revenue for oncology practices. Together, Medicare-allowed charges for anticancer drugs and their administration accounted for nearly 60 percent of total Medicare-allowed charges billed by clinicians specializing in oncology. A Commission analysis found that for an oncology episode—defined as 180 days following the administration of an anticancer drug paid under Part B for beneficiaries newly diagnosed with breast, colon, or lung cancer in 2011 or 2012—nearly half of total Part A and Part B spending was associated with spending for anticancer drugs and their administration services (Medicare Payment Advisory Commission 2015).

Variation in the use of anticancer drug regimens

Researchers have found variation in clinicians' anticancer drug utilization and that various factors affect clinicians' prescribing decisions, including their choice among therapeutic alternatives. For example, drugs may vary in their effectiveness in treating patients with certain conditions or comorbidities, and they can have different side effects. Decisions can also take into account whether a drug is on label or off label for a patient's condition, or whether a drug is compounded.

Patients' preferences and demographic and clinical characteristics also affect use and choice of anticancer regimens. Researchers reported that age, comorbidities, and cancer stage were the primary determinants of chemotherapy use among Medicare beneficiaries with newly diagnosed ovarian cancer who received chemotherapy within one year of diagnosis (Polsky et al. 2006). These researchers found that (1) race, income, and geography (hospital referral region) also were significant in predicting chemotherapy use, although less so than age, cancer stage, and comorbidities; and (2) the presence of more hospitals with oncology facilities in a market predicted greater use of chemotherapy. Other researchers found that Medicare beneficiaries in the oldest age groups were less likely to receive chemotherapy than younger beneficiaries (Schrag et al. 2001, Sundararajan et al. 2002).

Researchers found substantial variation in FFS Medicare in 2011 and 2012 across medical oncology practices in

the use of anticancer drug regimens, advanced imaging, and acute medical inpatient admissions (as measured by Medicare spending per beneficiary after adjustment for demographic and clinical characteristics) (Clough et al. 2015). Overall, the study reported that the ratio of the mean spending per beneficiary between the highest spending practices (in the 75th percentile of practice costs) and the lowest spending practices (in the 25th percentile of practice costs) ranged from 1.2 to 1.4 for anticancer drugs, imaging, and medical admissions. Supportive care drugs (pegfilgrastim, darbepoetin alfa, and palonosetron), bevacizumab, and positron-emission tomography accounted for the greatest share of variation between the highest spending and lowest spending practices.

In addition, the researchers found significant practice-level variation in mean spending per beneficiary for the leading 10 anticancer drugs by cancer type. For example, the ratio of the mean beneficiary spending for the highest spending practices and the lowest spending practices for treatment of lung, breast, and colorectal cancers was:

- 2.8 for pegfilgrastim, 2.8 for bevacizumab, 1.6 for pemetrexed per lung cancer beneficiary;
- 2.2 for pegfilgrastim, 2.0 for bevacizumab, and 1.6 for trastuzumab per breast cancer beneficiary; and
- 4.4 for pegfilgrastim, 1.8 for bevacizumab, 1.4 for cetuximab, and 1.3 for oxaliplatin per colorectal cancer beneficiary (Clough et al. 2015).

The researchers also found an association between increasing practice size and increased use of chemotherapy and imaging (as measured by Medicare spending) (Clough et al. 2015). Practice-level factors that could influence use of services included treatment protocols, information technology, staffing patterns, access to ancillary services, and hours of operation.

Other research examined the variation in mean total FFS Medicare spending between 2004 and 2006 for beneficiaries in the one year after they underwent surgical resection for colorectal cancer (i.e., the index hospitalization). Spending was analyzed across hospitals, which were ranked from lowest to highest based on the index surgical hospitalization. The ratio of mean total payments between hospitals in the highest spending quintile compared with hospitals in the lowest spending quintile was greatest for chemotherapy drugs (4.2), followed by physician services (2.0), post-acute services (1.8), and hospital readmissions (1.4) (Abdelsattar et al. 2015a). The payments associated with the index surgical hospitalization, which had the largest share of total payments, did not vary substantially between hospitals in the lowest spending and highest spending quintiles; post-acute services had the second largest share of mean total payments and accounted for much of the variation in mean total spending.

In addition, two studies discussed in the prior section suggested that anticancer drug choice may to some degree be influenced by the higher add-on payment to ASP (Jacobson et al. 2010, Office of Inspector General 2012).

Last, clinician prescribing can be influenced by Medicare's local and national coverage determinations. Medicare claims processing contractors and CMS sometimes develop coverage determinations based on the presence of certain clinical conditions, prerequisite treatments, and other factors. Each coverage policy addresses a clinical topic and one or more types of service, including drugs and biologics. Contractors issue local coverage determinations that apply to the states in their jurisdictions. CMS develops national coverage determinations that apply to all beneficiaries across the country. Notably, Medicare coverage exists for most items and services without the need for individual coverage determinations (Office of Inspector General 2014a). Instead, most services are paid through CMS's prospective payment mechanisms, under which providers serve as the purchaser and make decisions about which items and services are furnished in the payment bundle.

Options for improving the efficiency of oncology services

CMS; the Institute of Medicine (IOM), now known as the Health and Medicine Division (a division of the National Academies of Sciences, Engineering, and Medicine); and others have discussed the need to improve health outcomes for patients with cancer, improve the quality of cancer care, and reduce spending for treatment. The current FFS payment systems in general can have the following undesirable effects on aspects of cancer care:

- *Encourage the selection of more costly drugs and discourage the use of lower cost products, even when clinical results are similar (Newcomer 2012)*—Bach (2007) contends that FFS payment incentives have promoted a culture of buying and selling cancer drugs at the expense of other aspects of cancer care. According to the American Society of Clinical Oncology (2015), "many patients are receiving

expensive drugs that increase the costs of care for both patients and payers without providing benefits to the patients." Studies of Medicare beneficiary populations receiving chemotherapy report statistically significant practice-level and regional variation (Clough et al. 2015, Polsky et al. 2006).

- *Encourage the use of more costly types of radiation therapy with limited evidence to support clinical superiority compared with less costly alternatives*—For example, some contend that financial incentives may be one of the factors for the rapid adoption of intensity-modulated radiotherapy compared with three-dimensional conformal radiation therapy for localized prostate cancer treatment (Balogh et al. 2013, Carreyrou and Tamman 2010, Institute of Medicine 2013, Jacobs et al. 2012).

- *Lead to the overuse of oncology-related interventions*—According to the IOM, use of chemotherapy near the end of life is an example of overuse (Institute of Medicine 2013). Researchers reported that nearly 11 percent of FFS Medicare decedents in 2010 with cancer (and older than 65 years) received chemotherapy in the last 30 days of life (Bekelman et al. 2016).

- *Inhibit integrated care, which can lead to duplication of care and result in patient complications*—This lack of integration is particularly problematic for patients who have comorbidities that should be managed both by the cancer care and other specialist care teams (Institute of Medicine 2013).

- *Lack tools to promote care coordination, which can result in potentially avoidable emergency department (ED) visits and hospitalizations*—Researchers found that nearly 20 percent of hospital admissions in patients with gastrointestinal cancer were potentially avoidable (Brooks et al. 2014). Some researchers contend that improvements in the management of cancer patients, such as after-hours access to clinicians, may lead to reductions in hospitalizations and ED visits (American Society of Clinical Oncology 2015, Institute of Medicine 2013, Pyenson and Fitch 2010, Sanghavi et al. 2014).

As part of the Choosing Wisely campaign, the American Society of Clinical Oncology (ASCO) and the Quality Oncology Practice Initiative identified 10 opportunities for reducing waste through the appropriate use of cancer services. See online Appendix 5-A, available at http://www.medpac.gov, for the 10 tests and treatments that ASCO identified (ABIM Foundation 2013).

Seeking alternatives to Medicare's current FFS payment system, we examined four case studies of approaches designed to introduce value to oncology care payment (Table 5-9, p. 144). These are approaches that CMS and other payers and providers have tested or implemented.

Risk-sharing agreements

As discussed in our June 2010 report to the Congress, risk-sharing agreements link payment of a drug to patient outcomes through risk sharing with product developers (Medicare Payment Advisory Commission 2010). The reward tied to the outcome could be a higher price, while the penalty for undesirable results could be a lower price (through rebates, adjustments, or refunds).

Risk-sharing agreements are more commonly used in Europe than in the United States (Garrison et al. 2015). An example of an agreement for an oncology drug is the risk-sharing agreement between Johnson & Johnson and the National Health Service in the United Kingdom under which the manufacturer assumes the cost of bortezomib if testing indicates that a patient receiving the product is not responding (Young 2015). (Bortezomib is used to treat multiple myeloma.[36]) According to Neumann and colleagues (2011), this approach involves an after-the-fact refund by the manufacturer to the government, covering the first four months of treatment for patients who do not respond to therapy. Response is based on a biomarker for disease progression. Tasks that the payer (the National Health Service) is responsible for include collecting evidence on patients' outcomes, analyzing clinical data, and submitting claims (within 60 days) to the product developer for patients who do not respond (National Institute for Health and Care Excellence 2016, University of Washington 2016). For nonresponders, the manufacturer provides a complete refund or provision of the drug for another patient free of charge. Because the National Health Service pays for the drug only for those patients who respond to therapy, this agreement effectively gives the government a sizable discount. The agreement, however, differs from a pure discount because the manufacturer has a strong incentive to maximize the number of patients who respond, not merely the number treated or doses sold. In return, the manufacturer gains market access and maintains its list price. The government reduces drug budget risks, although it adds the burden of maintaining a tracking system to determine whether patients are responding to the drug.

TABLE 5–9

Summary of four case-study approaches illustrating strategies to improve the efficiency of oncology services

Payer or provider	Design summary
National Health Service, United Kingdom risk-sharing agreements (underway since 2007)	An agreement between payer and pharmaceutical manufacturers that links payment of a drug to patient outcomes.
Oncology clinical pathways implemented by and ongoing with various commercial payers and providers	Evidence-based treatment protocols that are intended to standardize drug treatment, reduce unnecessary variation, and improve quality of care.
Oncology medical home tested by CMS (completed summer 2015)	CMMI provided a grant to seven community-based oncology practices to test an oncology medical home, COME HOME. The COME HOME model included patients with seven cancer types, and practices were required to provide enhanced services including patient education, enhanced access through triage pathways, and extended night and weekend office hours.
UnitedHealthcare pilot with five physician practices (completed December 2012)	Five participating practices paid FFS for nondrug services, ASP (no add-on) for anticancer drugs, and an initial episode payment for case management. Length of episode varied for lung, colon, and breast cancer. Performance-based payment was based on reducing total spending and meeting quality metrics.

Note: CMMI (Center for Medicare & Medicaid Innovation), COME HOME (Community Oncology Medical Home), FFS (fee-for-service), ASP (average sales price).

For product manufacturers, risk sharing offers the potential to secure reimbursement for technologies whose treatment effects are uncertain, especially if the alternative is noncoverage. From a drug company's perspective, the model offers predictability of pricing and the prospect of future financial rewards during the time when additional data are being collected. Risk sharing also allows companies to emphasize outcomes and can help differentiate their products from those of competitors. Moreover, it enables companies to offer certain payers discounts without lowering published or "list" prices.

A key implementation issue is selecting and specifying the outcome measured in risk-sharing agreements. According to Neumann and colleagues (2011), the outcome should be objective, clearly defined, reliable, easily measured, and not confounded by patients' characteristics, and it must assess the selected treatment effect. According to these researchers, clinical outcomes (e.g., hospital admission) are preferable to surrogate endpoints (e.g., measures that rely on laboratory values), unless those endpoints are associated with positive patient outcomes (Neumann et al. 2011). Agreements with outcomes that are assessed during shorter time horizons have an advantage over longer term agreements, which may be difficult to execute (Neumann et al. 2011). Other issues and obstacles in establishing such agreements, identified in an online survey of stakeholders, include (1) the significant administrative burden and time investment incurred by the payer and the drug manufacturer to establish the infrastructure, (2) the development of the data infrastructure to track patients' outcomes, (3) the significant resources to adjudicate such agreements, and (4) the effect on Medicaid best-price calculations if the risk-sharing agreement links a drug's performance to a price discount (Garrison et al. 2015).

According to the National Health Service in the United Kingdom, bortezomib lends itself to such a scheme because a protein marker exists that indicates whether a patient has responded to the drug or not (National Institute for Health and Care Excellence 2007). Given predicted response rates, the payer expected that the product developer would rebate at least 15 percent of the cost of bortezomib under the arrangement (National Institute for Health and Care Excellence 2016). Because risk-based arrangements between the payer and the product developer are proprietary, the results (e.g., actual rebates or quantity of replacement product) are typically not published. A survey of oncology pharmacists who implemented this arrangement reported issues with tracking patients and ensuring that claims were submitted (within the allotted time frame) to the product developer for patients who did not respond to treatment (Williamson 2009).

There is an increased interest in establishing risk-sharing agreements in the United States by manufacturers and payers (ISPOR Issues Panel 2014). For example, Novartis established separate performance-based agreements for its recently approved oral drug for the treatment of heart failure (sacubitril/valsartan) with Cigna and Aetna (Humer 2016).[37] Amgen and Harvard Pilgrim Health Care established a pay-for-performance plan for a recently approved oral drug for the treatment of hypercholesterolemia (evolocumab) (Appel 2015).[38]

Oncology clinical pathways

Oncology clinical pathways are evidence-based treatment protocols that payers and providers are adopting to standardize drug treatment, reduce unnecessary variation, and improve quality of care (DeMartino and Larsen 2012).[39] Oncology pathways are based on and generally consistent with publicly available clinical guidelines, such as the National Comprehensive Cancer Network guidelines. In contrast to guidelines, oncology pathways may narrow treatment options and suggest when these options are appropriate, may be more prescriptive than guidelines, and may provide specific guidance on the sequencing of care steps and the time line of interventions. Most pathways begin by focusing on chemotherapy, but some have broadened to include other oncology-related services (e.g., radiation oncology services) (DeMartino and Larsen 2012). Oncology pathways typically evaluate competing regimens for a given condition based on efficacy, side effects (toxicity), strength of national guideline recommendations, and cost. One payer explicitly states that in selecting a particular therapy as a pathway, cost is considered only after consideration of all other factors (Anthem 2014).

Oncology clinical pathways are used by some commercial payers and providers in furnishing oncology care. One survey estimated that over half of responding practices used clinical pathways, and about 90 percent used guidelines (Barr and Towle 2011). Various companies (including eviti, New Century Health, Cardinal Health, US Oncology, McKesson Specialty Health, Kew Group, and Via Oncology) have developed pathways (DeMartino and Larsen 2012). In addition, some clinician practices and large cancer centers have developed their own pathways. There are two common business models for pathway development (DeMartino and Larsen 2012). In the first model, a payer sponsors a company to develop pathways and provides incentives to the payer's oncologists to use the pathways. In the second model, oncologists work directly with vendors to develop pathways (Sanghavi et al. 2014); the payers and the oncologists who bill them work together to develop incentives for oncologists to follow the pathways.

Payers and providers have implemented various approaches that link compliance with clinical pathways to financial incentives, including providers receiving a higher reimbursement rate on drugs or other services (e.g., evaluation and management services), an add-on per patient, and a lower risk of denied or delayed reimbursement (DeMartino and Larsen 2012). Under these approaches, providers typically have to meet a certain level of pathway compliance but can go "off pathway" to accommodate patient preferences and variation in disease development. For example, one commercial payer increases the add-on to the drug payment rate if clinicians meet a 60 percent compliance threshold (*Oncology Business Review* 2008). Another commercial payer makes additional payments for each patient who receives treatment as specified by the pathways for breast, lung, and colorectal cancer. If a practice follows the pathways, it receives a $350 one-time fee at the onset of treatment and payments of $350 per patient per month while the patient is actively in therapy and treated in compliance with a pathway (Anthem 2014). These arrangements are based on the premise that the additional payments will offset the amount of revenue the practice could gain from administering more costly drugs (Nelson 2013).

Compared with episode-of-care and bundled approaches, payment for pathway adherence may limit flexibility and (depending on the design) may not remove the incentive for some clinicians to furnish higher priced products when therapeutic equivalents exist. Compared with bundling approaches that require providers to be accountable for a wide range of care, use of pathways may not necessarily lead to more coordinated care or enhanced access for beneficiaries. In addition, there is the concern that some clinical pathways are not available to patients and others. In many instances, pathways are proprietary; that is, they are available only to the payers or providers who develop and use them. Applicable to both guidelines and pathways, there is also the concern that more evidence is needed (1) about the clinical effectiveness of a treatment (e.g., drug regimen) compared with its alternatives and (2) about a treatment's effect as measured by clinical outcomes (e.g., patient survival) rather than surrogate endpoints (e.g., tumor response rate).

Some clinicians and a physician specialty organization (i.e., ASCO) have raised the following issues about

the manner in which oncology pathways are currently developed and used:

- There is a lack of transparency and consistency in the design of some pathways.
- Some clinical pathways lack adequate grounding in the clinical literature.
- Some oncology practices experience increased administrative costs because commercial payers use different pathways for the same type and stage of cancer (Zon et al. 2016).

Likewise, some clinicians have raised concerns about the quality of oncology clinical guidelines that are used to develop some clinical pathways. For example:

- He and colleagues (2015) used the Appraisal of Guidelines and Research and Evaluation instrument to examine the quality of clinical practice guidelines for pancreatic cancer.[40] The researchers gave low scores to the following domains: "rigor of development" (the process used to gather and synthesize the evidence and the methods used to formulate the recommendations and update them), "stakeholder involvement" (the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended), "applicability" (the barriers to and facilitators of implementation, strategies to improve uptake, and cost implications of applying the guidelines), and "editorial independence" (recommendations not being unduly biased with competing interests) (He et al. 2015).
- Abdelsattar and colleagues (2015b) found the quality of the processes used to develop clinical practice guidelines for rectal cancer was variable and found differences in the guidelines' treatment recommendations. Using the Appraisal of Guidelines and Research and Evaluation instrument, the researchers gave low scores to the "applicability" and the "rigor of development" domains (Abdelsattar et al. 2015b).
- Reames and colleagues (2013) found that none of the clinical practice guidelines for lung, breast, prostate, and colorectal cancers met the eight standards that the IOM set forth for developing clinical practice guidelines.[41] The researchers found that less than half of the guidelines were based on systematic literature reviews, only half addressed conflicts of interest, and most did not comply with standards for inclusion of patient and public involvement in the review process and did not specify their process for updating (Reames et al. 2013).

Oncology medical homes

The medical home builds on the concept of patient-centered care under which a designated provider is responsible for complying with requirements for integrated or coordinated care, evidence-based medicine and performance measurement to assure quality and safety, and enhanced access. In 2010, the first oncology practice was recognized by the National Committee for Quality Assurance as a Level III patient-centered medical home (Sprandio 2012). The adoption of an oncology medical home by providers and payers appears to have been increasing over the past five years (Aetna 2013, Fox 2013).

Between 2012 and 2015, CMMI provided a grant for seven oncology practices to implement a three-year oncology patient-centered medical home. The Community Oncology Medical Home (COME HOME) model offered enhanced services to Medicare and Medicaid beneficiaries and commercially insured patients with one of seven cancer types (breast, lung, colon, pancreas, thyroid, melanoma, and lymphoma). These services included patient education and medication management counseling, team-based care, and enhanced practice access through triage pathways to manage patient symptoms on a 24/7 basis through a triage phone line, extended night and weekend office hours, and on-call providers. CMMI provided a $19.8 million grant to the participating practices to fund the enhanced services; the grant funding could not be used for services billed with an evaluation and management service (to ensure that CMS would not be paying twice for the same service) (Centers for Medicare & Medicaid Services 2015). Medicare paid participating practices according to existing Medicare coverage determinations and FFS payment policies. This demonstration concluded in 2015.

In the grant's announcement, CMS said that the oncology medical home model would improve the timeliness and appropriateness of care, reduce unnecessary testing, and reduce hospitalizations and ED visits. At the time of the grant's award, the grantee projected net total Medicare savings of $13.76 million (or projected net savings of $1,715 per beneficiary per year, assuming Medicare enrollment of 8,022 patients over 3 years) due primarily to reductions in hospital admissions and ED visits (McAneny 2012).

At the time this report went to press, the final evaluation of the COME HOME model on total costs, hospital admissions, and ED visits was not available. The initial evaluation conducted by CMS's contractor included Medicare beneficiaries enrolled in the demonstration only in 2013; a comparison group was not included (NORC at the University of Chicago 2014). The initial evaluation examined whether there was an association between length of enrollment in COME HOME and all-cause hospitalizations, hospitalizations for ambulatory care–sensitive conditions, ED visits, and total cost of care.

The contractor reported that the average total cost of care per beneficiary was progressively lower across three-quarters of enrollment in 2013 after adjusting for other beneficiary covariates. The average total cost of care for beneficiaries enrolled for two or three calendar quarters in 2013 was significantly lower compared with care for beneficiaries enrolled in the model for one calendar quarter in 2013. A similar trend was reported for all-cause hospital admissions, with the number of all-cause admissions significantly decreasing as beneficiaries were enrolled in the model for two or three calendar quarters compared with one quarter in 2013. The contractor did not find a statistically significant relationship between length of beneficiary enrollment and rates of ambulatory care–sensitive hospitalizations and ED visits. The contractor could not determine whether the reduction in cost and all-cause admissions over greater lengths of program enrollment was a consequence of the model.

Episode-of-care approach for oncology and non-oncology services

Between October 2009 and December 2012, UnitedHealthcare implemented the initial phase of an oncology payment pilot with 19 distinct types of clinical episodes. The five participating practices were paid ASP instead of ASP plus the negotiated add-on amount for chemotherapy drugs, an episode fee at the initial visit that was based on the contracted drug add-on amount to ASP, and FFS contractual amounts for most other services (including physician services, chemotherapy administration, and diagnostic radiology). The five participating practices were eligible for shared savings if, compared with physician practices in a national payer registry, quality (as measured by survival) improved or total episode costs decreased (or both). The pilot's objectives were to decrease total medical costs by aligning financial incentives supported by use and quality data and remove the link between drug selection and medical oncology income (Newcomer et al. 2014).

The pilot included 810 patients with breast, colon, and lung cancer. The episodes varied based on type of cancer, clinical stage (Stage 0 through Stage IV), and tumor histology. The duration of an episode varied by cancer type and spanned from 4 months to 12 months. At the time of the initial patient presentation, participating practices reported clinical information—such as clinical stage, histology, and intent of treatment (curative or palliative)—to the payer to determine the correct episode.

To arrive at the episode payment for each of the 19 cancer episodes, the national drug margin for each episode was calculated by subtracting the aggregate ASP from the aggregate amount paid for chemotherapy drugs and dividing by the total number of patients in each episode. The episode payment (intended to cover physician hospital care and hospice management) also included a small fee for case management (Newcomer et al. 2014). To compensate providers for furnishing palliative care services, the episode payments continued every four months for patients with metastatic disease who were no longer receiving chemotherapy or were enrolled in hospice (Newcomer et al. 2014).

The participating practices collaborated with the payer to develop quality, cost, and use measures, and the practices met annually to review their outcomes. These outcomes included total cost of care; rates of emergency room and hospitalization use; use of laboratory, diagnostic radiology, durable medical equipment, and surgical services; time to first progression for relapsed patients; hospice days for patients who died; days from last chemotherapy to death; and rate of febrile neutropenia occurrence. During the meeting, providers discussed potential solutions for variation in performance (e.g., in rates of hospital admission and use of diagnostic radiology).

UnitedHealthcare found that their overall spending declined during the pilot while drug spending increased. Specifically, Newcomer and colleagues (2014) reported a 34 percent reduction in actual total spending compared with predicted total spending ($64.8 million and $98.1 million, respectively) and a 179 percent increase in actual drug spending compared with predicted drug spending ($21.0 million versus $7.5 million, respectively). The authors did not provide information about the changes in the specific components of drug spending and the factors that might have affected any changes. UnitedHealthcare redistributed one-third of the savings to the practices by increasing their episode payments in the second round of the pilot (Appleby 2015).

Although the Newcomer and colleagues (2014) analysis was not designed to determine the drivers of the differences in total medical spending, a subset analysis demonstrated a statistically valid decrease in hospitalization and therapeutic radiology usage for the episode model. Most quality outcomes had insufficient numbers for statistical analysis, but Kaplan-Meier survival curves were monitored for all patients with metastatic disease; lung cancer survivors were the only evaluable subgroup, and there was no significant survival difference between the episode and registry patients (Newcomer et al. 2014).

Since its completion, UnitedHealthcare expanded its model to include additional oncology practices (Appleby 2015). A press report stated that the continuation of the episode model includes five additional practices and that the design is the same as the pilot's, including its inclusion of patients with breast, colon, and lung cancer (Maas 2015).

In addition, in 2015, UnitedHealthcare announced a program for oncologists that offers real-time decision support and a fast-track drug approval program based on the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. UnitedHealthcare automatically approves treatments that fall under the top three categories of this guideline (1, 2A, and 2B) (Maas 2015).

Under CMMI's authority, Medicare is testing an oncology episode-of-care approach, the Oncology Care Model, which is expected to start in 2016 and last for five years. An episode will last for six months and will begin when the patient receives chemotherapy administration for cancer under Part B or Part D. Current FFS payment policies and coverage determinations will apply to participating practices. Unlike the UnitedHealthcare pilot, practices will continue to be paid the 6 percent add-on to the drug payment's ASP. Practices will be paid an additional $160 per beneficiary per month for furnishing enhanced services, such as 24/7 access to clinicians with real-time access to medical records. Under the model, risk sharing includes a one-sided arrangement for the first two years and an optional two-sided arrangement for the last three years. Performance-based payment will be based on reducing total spending and meeting quality metrics.

Conclusions

This chapter has focused on two broad issues: potential modifications of the way Medicare Part B pays for drugs, in general, and approaches to improve the quality and efficiency of oncology care. To examine potential modifications of the way Medicare Part B pays for drugs, we focused on three aspects of Medicare's payment methodology for Part B drugs. First, we explored whether there is a better way to structure the add-on payment to ASP. Second, we examined whether there are payment policies that could be considered to promote more price competition among Part B drugs and put downward pressure on ASP. Third, the Commission recommended reducing the dispensing and supplying fees for certain Part B drugs furnished by inhalation drug suppliers and pharmacies to levels similar to those paid by other payers.

Chapter 5 also considered approaches to improve the quality and efficiency of oncology care since more than half of Medicare Part B drug spending is associated with anticancer drugs. For this chapter, we examined four examples of narrower and broader approaches designed to improve the efficiency of oncology care. The two narrower approaches—oncology clinical pathways and risk-sharing agreements—attempt to improve the value of drug spending. By contrast, the two broader approaches—oncology medical homes and bundling Part B oncology drugs with non-oncology services—take a more holistic view of cancer care by improving care management and coordination. ■

Endnotes

1 Section 1861(t)(1) requires payment for drugs or biologicals only if the product is included in the United States Pharmacopoeia National Formulary, the United States Pharmacopoeia Drug Information, or the American Dental Association Guide to Dental Therapeutics.

2 Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent. Our work in this chapter excludes these products, unless otherwise noted.

3 At the time of publication, CMS had issued a notice of proposed rulemaking that seeks to test changes to the ASP add-on and other value-based approaches to payment for Part B drugs. A few of the topics in this chapter overlap with, but are not identical to, some of the areas CMS focuses on in its proposals.

4 Under the OPPS, in most cases, Medicare pays separately for drugs that have an estimated average cost per day that exceeds a packaging threshold. That threshold ($100 in 2016) was $90 in 2014, the period of our data analysis. Payment for drugs with an estimated average cost per day less than the threshold are packaged into payment for other separately payable services on the claim (e.g., drug administration). Beginning in 2014, drugs used as part of diagnostic tests or as supplies in surgical procedures are packaged regardless of their cost.

5 The sequester reduces payments providers receive for Part B–covered drugs by 1.6 percent, which results in a net payment equivalent to ASP + 4.3 percent. Unless otherwise noted, our analysis focuses on the pre-sequester ASP + 6 percent payment rate because that is the rate specified in the Medicare statute for most Part B–covered drugs provided by physicians and suppliers.

6 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. (See Chapter 5 of the Commission's June 2009 report for more detail.)

7 In 2014, we estimate that Medicare and its beneficiaries paid roughly $3 billion for drug administration services. This estimate includes therapeutic, prophylactic, and diagnostic injections and infusion of chemotherapy and nonchemotherapy drugs, but excludes certain types of injections such as intravitreal injections.

8 Total Part B drug spending for physicians, outpatient hospitals, and suppliers—without any adjustments for the changes in packaging or payment formulas—grew at an average rate of about 9 percent per year between 2009 and 2013.

9 Nonprofit hospitals with high shares of Medicaid and low-income Medicare patients (about one-third of all prospective payment system hospitals) qualify for the 340B Drug Pricing Program.

10 For example, the manufacturer submits its first-quarter ASP data within 30 days after the close of a quarter. CMS then has 60 days to calculate the new payment rates and update the claims processing systems so that the new payment rates can be effective in the third quarter.

11 By *margin*, we mean the difference between Medicare's ASP + 6 percent payment rate and the amount the provider pays to acquire the drug (taking into account all rebates, discounts, and price concessions the provider may receive).

12 Other aspects of the ASP methodology (e.g., how lagged price concessions and bundled price concessions are reflected in ASP) can increase or decrease providers' margins on a drug.

13 IMS obtains acquisition price data (i.e., the prices at which pharmaceuticals are sold by manufacturers, wholesalers, and chain warehouses to retail pharmacies, hospitals, and certain other classes of trade) from a subset of the manufacturers, wholesalers, and chains that supply other data to IMS. This subset represents approximately 65 percent to 70 percent of all transaction volume within the audited nonretail classes of trade. IMS-audited sales account for approximately 90 percent of all sales in the nonretail channel.

14 If a drug has more than one national drug code (NDC), we used the data for the NDC with the greatest volume sold.

15 To construct this measure, we calculate the ratio of the 75th percentile invoice prices to ASP for each of the 34 drugs for a quarter. Then we calculate the median of that ratio across the 34 drugs for that quarter.

16 Since prices as a percentage of ASP fluctuate on a quarterly basis, we tried to be conservative by selecting the first quarter of 2015. Over the most recent four quarters for which we have data, the first quarter of 2015 had higher invoice prices as a percentage of ASP than the other quarters.

17 Medicare's payment rate for bevacizumab for wet AMD is not based on ASP + 6 percent, but is instead contractor priced. The reason is that bevacizumab comes in vial sizes intended for cancer patients. Ophthalmologists often rely on compounding pharmacies to repackage the product into syringes for use in the eye. Medicare pays for compounded drugs through contractor pricing rather than 106 percent of the ASP for the FDA-approved product.

18 For drugs provided by HOPDs, some portion of the drug payment amount is intended to cover pharmacy overhead. Specifically, with respect to payment for separately paid drugs under the OPPS, CMS has stated that the drug payment rate (currently ASP + 6 percent; in prior years, as low as ASP + 4 percent) includes payment for drug acquisition costs and pharmacy overhead (Centers for Medicare & Medicaid Services 2012).

19 In our June 2015 report, we explored two budget-neutral options to restructure the 6 percent add-on to ASP. Those options were 100 percent of ASP + $24 per drug per day and 102.5 percent of ASP + $14 per drug per day. The Commission estimated those options to be budget neutral relative to the 6 percent add-on to ASP using 2013 claims data and assuming no utilization changes. The modeling work done in this chapter is based on the more recently available 2014 claims data.

20 The policy option we modeled includes a flat fee per drug administered per day by a provider. In this option, if the beneficiary received two drugs from a particular provider on a specific day, that provider would receive a flat fee of $10 (2 × $5) for the drugs provided to that beneficiary that day. The flat fee is unaffected by the dosage size or the number of units of the drug furnished in a day. For example, the flat fee for a drug in a day would be $5 regardless of whether the beneficiary received a 100-mg infusion or 500-mg infusion of that drug.

21 In our modeling, we assume the policy option would not apply to low-cost drugs furnished under the OPPS that are packaged into payment for other services.

22 The add-on payment under current policy and the add-on payment under the policy option is the same for a drug with an ASP per administration of $200 (6 percent of $200 equals $12 and 3.5 percent of $200 + $5 equals $12). For a drug with an ASP per administration greater than $200, the 6 percent add-on is larger than the policy option add-on of 3.5 percent plus $5 per drug per day; for drugs with an ASP per administration less than $200, it is the reverse.

23 Hospitals benefit from the increase in the add-on payments for low-priced drugs, but to a lesser extent than physicians. Under the policy option, add-on payments increase for drugs with an ASP per administration of less than $200. Under the OPPS, drugs with an estimated cost per day of less than $100 are packaged into payment for other services and would be unaffected by the policy option. Thus, OPPS hospitals would see an increase in add-on payments for drugs with an average ASP per administration in the range of $100 to $200.

24 On a percentage basis, neurologists would also see a decline in Part B drug revenues in this range (–1.7 percent). The effect on neurologists' total revenues (–0.4 percent) is lower because drug revenues account for roughly 20 percent of neurologists' total Medicare revenues.

25 The purpose of this example is to illustrate how the policy option to restructure the add-on would reduce, but not eliminate, the difference in add-on payments for two differently priced products with a similar use. However, we note that some stakeholders point out that patients frequently get both of these products over the course of their treatment because they become resistant to one and switch to the other.

26 Some may argue a constraint on ASP growth would make payment for Part B drugs more consistent with payment for other Part A– and Part B–covered services (Centers for Medicare & Medicaid Services 2012).

27 The Medicaid inflation rebate historically has applied to single-source drugs, but the Bipartisan Budget Act of 2015 extended the Medicaid inflation rebate to generic drugs.

28 Medicaid rebates are not included in the ASP calculation. If a manufacturer rebate to Medicare was modeled on the Medicaid rebate, these rebates would not be included in the ASP calculation.

29 The organization that served as the CAP vendor (Bioscrip) reported that it declined to renew the contract to continue as the CAP vendor for 2009 because of concerns about its organization's short-term and long-term profitability under the CAP.

30 It would be important that any exceptions or appeals processes be timely and incorporate input from clinical experts.

31 Before 2005, Medicare paid a dispensing fee of $5 per monthly supply of inhalation drugs. With implementation of the ASP payment system, CMS increased the inhalation drug dispensing fee substantially in 2005, cut the dispensing fee slightly in 2006, and has maintained the dispensing fee at the same level since 2006.

32 To set the dispensing fee, CMS relied on a 2004 industry report on costs for inhalation drug suppliers by category of activity. CMS based the fee on industry-reported costs for establishing or revising the plan of care, delivery of services, refill calls and compliance monitoring, billing and collections, ''other'' direct costs, and indirect costs (excluding sales, marketing, bad debt, and profit). CMS excluded industry-reported costs for patient education, caregiver training, care coordination, and in-home visits. CMS also noted that the durable medical equipment supplier is responsible for educating the beneficiary on proper use of the nebulizer equipment or ensuring that another party has done so.

33 The statute also requires that no compendium be included on the list unless it has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

34 The spending associated with drugs that have both oncology and non-oncology indications is included in the estimate of Medicare spending for anticancer drugs.

35 This estimate is based on chemotherapy administration codes 96401–96459, which may also include the administration of antineoplastic drugs for treatment of noncancer diagnoses.

36 Bortezomib is administered through intravenous injection, covered by Medicare, and paid under Part B according to its ASP.

37 According to Cigna, its agreement with Novartis ties the financial terms to how well the drug improves the relative health of Cigna's customers. The primary metric is reduction in the proportion of customers with heart failure hospitalizations (Cigna 2016).

38 Under this agreement, the health plan (1) receives a discount for "preferring" the drug, (2) receives a rebate if the drug does not lower cholesterol levels in members to the degree indicated by the drug's clinical trials, and (3) receives a rebate if more members use the drug than was anticipated during negotiations (Appel 2015).

39 Clinical pathways are also referred to as care pathways, patient pathways, and treatment pathways. The concept goes as far back as the 1980s to formalize patterns of care in the inpatient hospital setting. In addition to oncology, clinical pathways are also used in other clinical areas, including cardiology, gastroenterology, and immunology.

40 The Appraisal of Guidelines and Research and Evaluation instrument was developed to assess the variability in guideline quality and includes the following six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.

41 In 2011, the IOM issued eight standards that it viewed as essential elements in the development of trustworthy and high-quality clinical guidelines. The eight standards call for (1) a transparent process to develop and fund guidelines, (2) the disclosure of conflict of interest, (3) a development group that is multidisciplinary and includes patients, (4) a systematic evidence review process, (5) a clear explanation of the reasoning underlying treatment recommendations and rating recommendations, (6) recommendations communicated in a standardized form, (7) an external review process, and (8) an updating process.

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CHAPTER 6

Improving Medicare Part D

RECOMMENDATIONS

6-1 The Congress should change Part D to:

- transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,
- exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and
- eliminate enrollee cost sharing above the out-of-pocket threshold.

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

6-2 The Congress should change Part D's low-income subsidy to:

- modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;
- direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and
- direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

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

6-3 The Secretary should change Part D to:

- remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,
- streamline the process for formulary changes,
- require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and
- permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

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

CHAPTER 6

Improving Medicare Part D

Chapter summary

In 2015, more than 39 million Medicare beneficiaries received outpatient prescription drug coverage through Part D. A key goal for the Part D program is to ensure that beneficiaries have access to appropriate medications, while keeping the program financially sustainable to taxpayers. Under Part D, Medicare subsidizes 74.5 percent of the cost of basic drug benefits, and enrollees pay the remaining 25.5 percent through premiums. Medicare pays plan sponsors the 74.5 percent subsidy in two forms: (1) capitated direct-subsidy payments that are based on plan bids and (2) open-ended reinsurance on individual enrollees that covers 80 percent of drug spending above Part D's out-of-pocket (OOP) threshold (which occurs at an estimated average of $7,515 in total drug spending for 2016). Medicare also pays plans for some or all premiums and cost sharing on behalf of about 12 million beneficiaries who qualify for and enroll in the program's low-income subsidy (LIS).

The current structure of Part D reflects a system of federal subsidies and regulations that was designed to encourage broad participation of Medicare beneficiaries and private plan sponsors in a new program. However, since the launch of the program in 2006, the market for Medicare Advantage–Prescription Drug plans has grown substantially, and the market for stand-alone prescription drug plans is firmly established, so it is appropriate to consider whether the program's incentives need to be restructured to better ensure financial sustainability.

In this chapter

Financial sustainability is a growing concern because of sizable increases in program expenditures for high-cost enrollees (those who reach Part D's OOP threshold), which have been driven by increases in the numbers of non-LIS enrollees reaching the OOP threshold and increases in the average price of prescriptions they fill (which reflect both growth in drug prices and changes in the mix of drugs used). Going forward, many new biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, even when the drugs have therapeutic competitors. This trend will exert strong upward pressure on premiums, beneficiary cost sharing, and program costs.

In keeping with the program's market-based approach, the Commission recommends improvements intended to prepare Medicare's prescription drug program for the future. Collectively, the recommendations make up a package of interrelated steps. One set of changes would give plan sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees. Medicare's overall subsidy of basic Part D benefits would remain unchanged at 74.5 percent, but plan sponsors would receive more of that subsidy through capitated payments rather than open-ended reinsurance. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above Part D's OOP threshold to 20 percent. When combined with the Commission's recommendation to provide greater OOP protection, the insurance risk that plan sponsors shoulder for catastrophic spending would rise commensurately from 15 percent to 80 percent. At the same time, plan sponsors would be given greater flexibility to use formulary tools to manage benefits. Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection to all non-LIS enrollees through a real OOP cap (although some enrollees would incur higher OOP costs than they do today). The recommended improvements would also moderately increase financial incentives for LIS enrollees to use lower cost drugs and biologics.

Under the combined recommendations, Part D's set of risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk adjustment system. Similarly, because plans would have greater flexibility to use management tools, CMS would need to continue monitoring plan operations, such as reviewing formularies and pharmacy networks, to ensure beneficiary access. The agency would also need to ensure that the appeals and grievance procedures under Part D function effectively.

The net impact of the Commission's recommendations restrains overall drug costs and makes the benefit more affordable for beneficiaries and taxpayers in the long

run. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendations would also expose some beneficiaries to higher cost sharing in the coverage gap. To the extent that the adoption of this combined set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS beneficiaries facing high cost-sharing burdens. ■

Introduction

Part D began in 2006, and by many measures, this program for providing Medicare beneficiaries with access to outpatient prescription drugs has been a success. Using a market-based approach, Part D expanded access to medicines for the Medicare population. Part D uses competing private plans to deliver benefits. That competition has given beneficiaries a broad choice of plans while generally keeping down growth in enrollee premiums. Repeated surveys indicate that 85 percent or more of enrollees are satisfied with their coverage.

However, the environment in which Part D operates has changed. Part D was launched when patents on many widely used brand-name drugs were expiring. Plan sponsors have used formularies, pharmacy networks, and differential cost sharing to encourage enrollees to use lower cost drugs. These practices, combined with the fortuitous timing of patent expirations, have led to a dramatic shift toward the use of generics. At the same time, increases in program expenditures have been driven by spending for high-cost enrollees (those who reach Part D's out-of-pocket (OOP) threshold). Since the enactment of the Patient Protection and Affordable Care Act of 2010 (PPACA), changes in what counts as the enrollee's own OOP spending have led to more enrollees reaching the OOP threshold. Concurrently, the average price of prescriptions filled by high-cost enrollees has increased sharply (affected by changes in both the price and mix of drugs). For the future, many biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, which will exert upward pressure on premiums and program costs.

In 2014, Medicare spent almost $78 billion on its Part D benefit covering outpatient prescription drugs.[1] The program finances drug benefits for individuals enrolled in private stand-alone prescription drug plans (PDPs), in Medicare Advantage–Prescription Drug plans (MA–PDs), and in employer plans that receive Part D's retiree drug subsidy (RDS). In 2015, 39 million Medicare beneficiaries (70 percent) were enrolled in Part D plans; over three-fifths were in PDPs, with the remainder in MA–PDs (Medicare Payment Advisory Commission 2016). Medicare also pays Part D plans for some or all premiums and cost sharing on behalf of about 12 million beneficiaries who qualify for and enroll in the program's low-income subsidy (LIS), including those dually eligible for Medicare and Medicaid. In 2015, 30 percent of Part D enrollees received the LIS, and 70 percent of LIS enrollees were in PDPs (Medicare Payment Advisory Commission 2016).

A defined standard benefit

Part D's defined standard basic benefit has a structure that, for 2016, includes a $360 deductible and 25 percent coinsurance until the enrollee reaches $3,310 in total covered drug spending, called the initial coverage limit (Figure 6-1, p. 162). Enrollees with spending higher than the initial coverage limit face higher cost sharing (45 percent for brand-name drugs and 58 percent for generic drugs)—commonly called the coverage gap—up to a threshold of $4,850 in OOP spending (at an estimated average of $7,515 in total drug spending). That threshold is also known as a "true OOP" cap because it excludes cost sharing paid on behalf of a beneficiary by most sources of supplemental coverage such as employer-sponsored policies and enhanced benefits provided by Part D plans. An exception to the true OOP approach relates to a 50 percent manufacturer discount on brand-name drugs purchased in the coverage gap. Under PPACA, manufacturers must provide that discount as a condition for Part D to cover their drugs, and the 50 percent discount is added to the enrollee's own spending for purposes of determining whether the enrollee has reached the OOP threshold. Part D's basic benefit is scheduled to become more generous in 2020, when enrollees will pay 25 percent cost sharing until they reach the OOP threshold. Above that threshold, enrollees will pay the greater of 5 percent coinsurance or $2.95 to $7.40 per prescription.

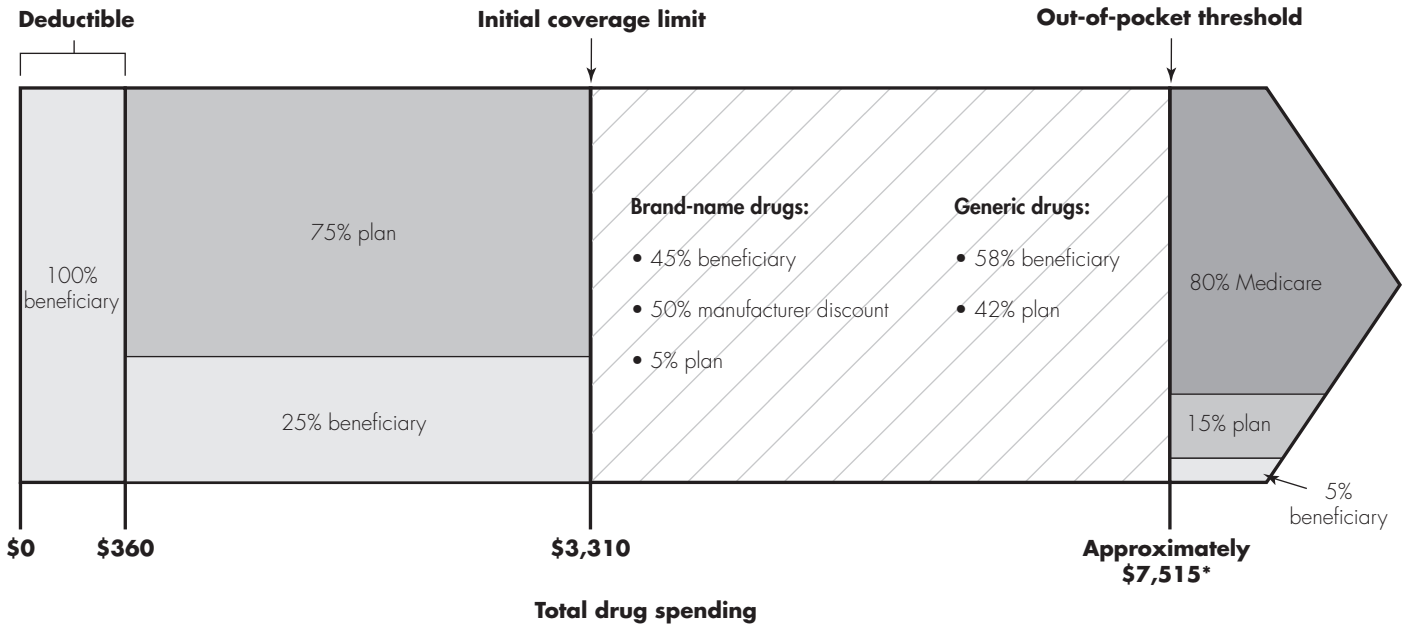
Less than 1 percent of Part D enrollees are in plans that use this defined standard benefit; the rest are in plans that are actuarially equivalent to the standard benefit or are enhanced in some way (Medicare Payment Advisory Commission 2016). Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure; for example, they may use tiered copayments that can be higher or lower for a given drug compared with the 25 percent coinsurance. Enhanced plans have a higher average benefit value, but Medicare does not subsidize the value of benefits above the average of the defined standard benefit; enrollees pay the full premium for additional benefits.

Medicare's payments to plans and mechanisms for sharing risk

Medicare pays Part D plans capitated amounts based on competitive bids, and the program pays more open-ended subsidies for enrollees with high drug spending.

FIGURE 6–1

Part D's defined standard benefit in 2016



Notes: Dollar amounts and benefits between the initial coverage limit and the out-of-pocket (OOP) threshold (also known as the coverage gap) reflect Part D's basic benefit structure in 2016.
*Total covered drug spending at the annual OOP threshold depends on each enrollee's mix of brand-name and generic drugs filled during the coverage gap. This amount is for an individual who does not receive Part D's low-income subsidy, has no other supplemental coverage, and has the average mix of generic and brand-name drug spending.

Source: MedPAC based on information from CMS, Office of the Actuary.

Combined, these payments subsidize premiums by about 74.5 percent; enrollees pay the remaining 25.5 percent in monthly premiums. To arrive at the amount of capitated payments, sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering basic drug benefits to an enrollee of average health. After reviewing bids, CMS applies a statutory formula to determine Medicare's per member per month prospective payment to plans (called the *direct subsidy*), which reduces premiums for all Part D enrollees. Because Medicare pays a fixed dollar amount, plan sponsors risk losing money if their enrollees' drug spending is higher than the combination of direct-subsidy payments and enrollee premiums.

However, plan sponsors do not bear all the risk; Medicare shares risk with sponsors through three mechanisms (Medicare Payment Advisory Commission 2015a). CMS risk adjusts direct-subsidy payments to keep sponsors from avoiding enrollees who use more drugs. Medicare pays plans individual reinsurance equal to 80 percent of covered spending above Part D's OOP threshold. Part D uses risk corridors that limit each plan's overall losses or profits if actual benefit spending is much higher or lower than the plan sponsor anticipated.

A plan's share of LIS enrollees is important because LIS enrollees tend to have higher than average drug spending, and plan sponsors have fewer tools to manage that spending. Unlike other enrollees whose cost-sharing amounts are set by sponsors as a part of plans' benefit design, maximum cost-sharing amounts for LIS enrollees are set by law at nominal amounts. Similarly, under law, LIS enrollees face no coverage gap and no cost sharing above Part D's OOP threshold. Part D's risk adjustment system helps to mitigate the incentive to avoid LIS enrollees, who tend to have higher benefit spending. Plan sponsors also receive monthly prospective payments from Medicare for the plan's expected amount of cost-sharing liability for LIS enrollees based on estimates that sponsors submit with their bids and that CMS later reconciles with plans based on actual prescriptions filled.

Risk adjustment

CMS risk adjusts Medicare's direct-subsidy payments to plans to reflect the expected costliness of each enrollee. Risk adjustment is prospective in that each enrollee's diagnoses from a base year are used to predict Part D benefit spending for the subsequent payment year. Diagnosis codes are taken from medical visits (i.e., physician, hospital outpatient, and hospital inpatient) using information from both fee-for-service claims and Medicare Advantage (MA) data.

The prescription drug hierarchical condition category (RxHCC) model predicts only the Part D benefit spending that a plan sponsor would cover (called *plan liability*) rather than total drug spending. Specifically, the predicted spending excludes the value of Medicare's individual reinsurance subsidies for high-cost enrollees because that risk is borne by Medicare rather than by the plan.

In past years, the Commission raised questions about an earlier version of the RxHCC model—whether risk scores were effective at overcoming incentives to avoid LIS enrollees (Hsu et al. 2010, Hsu et al. 2009, Medicare Payment Advisory Commission 2009b). However, beginning in 2011, CMS refined its model to better capture differences in the mix of prescription drugs taken by categories of enrollees.[2] For example, among younger disabled enrollees who receive the LIS, there is generally a greater prevalence of conditions treated with multiple drugs, such as HIV/AIDS and mental illness compared with older nondisabled enrollees, and their drug spending may be costlier on average.

In 2014 and 2015, Commission staff interviewed plan and consulting actuaries about the performance of the current RxHCC model. All interviewees responded that the newer model is much improved for equalizing remuneration between LIS and non-LIS enrollees. However, several actuaries also said that the risk adjusters tend to undercompensate for enrollees who use high-cost specialty drugs.[3] When a widely used, high-priced drug enters the market, CMS may need to modify certain RxHCCs to recognize lags that can occur between the entrance of new high-cost drugs and the point at which claims data become available to recalibrate risk adjustment models. At the same time, if Medicare were to base plan payments on risk-adjusted amounts that predict actual spending too closely, the result would differ little from using a system of cost-based reimbursement rather than one of prospective payment.

In general, any changes to Part D's benefit structure that affect plan liability would be accompanied by a recalibration of the RxHCC model. Most recently, CMS recalibrated the RxHCC model in preparation for the 2017 benefit year. The agency re-estimated model coefficients to reflect a more recent year of Part D claims data (2014) and diagnosis information (2013). CMS also estimated how the gradual phaseout of Part D's coverage gap would affect plan liability. For example, in 2017, plan liability for non-LIS beneficiaries in the coverage gap is 49 percent for generic drugs and 10 percent for brand-name drugs (compared with 42 percent and 5 percent, respectively, in 2016). In some years, CMS also conducts a clinical review of condition categories, dropping some and adding others to use groupings that better reflect predictors of current costs. For example, for 2016, a new condition category was created for high-cost, secondary metastatic cancers and liver cancer. Another category was created for hepatitis C, separating it from other types of chronic viral hepatitis.

For 2016, CMS uses a risk adjustment model that was calibrated to prescription claims data from 2013—before the introduction of newer hepatitis C medications. To account for the higher cost of those treatments, CMS made a manual adjustment to reflect what the coefficient for chronic hepatitis C would have been if the newer drugs had existed in 2013. CMS noted that the hepatitis C situation is unusual, and the agency does not expect to make similar adjustments routinely (Centers for Medicare & Medicaid Services 2015a). For its 2017 payments, the agency will use a coefficient for hepatitis C drugs estimated from claims and diagnoses data that is lower than the factor used for 2016 payments (Centers for Medicare & Medicaid Services 2016b).

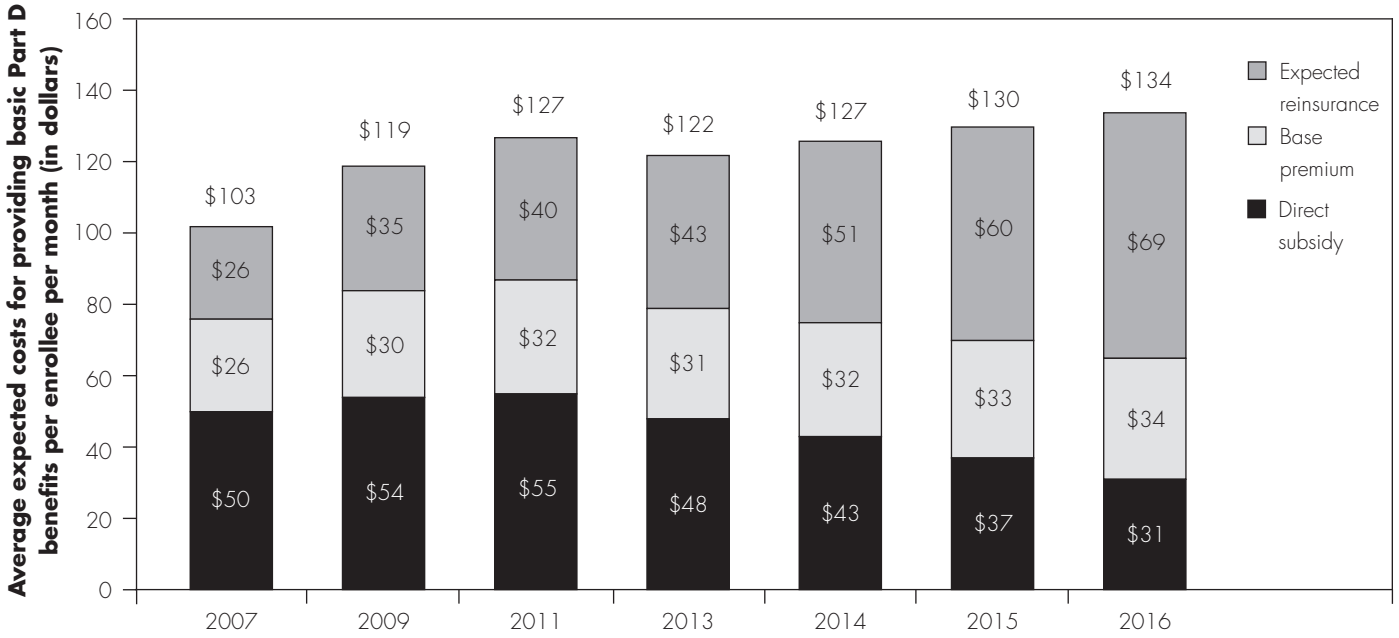
Individual reinsurance for high-cost enrollees

Medicare also subsidizes the Part D benefit and shares risk with plans through reinsurance. For individual enrollees with very high drug spending, Medicare pays plan sponsors 80 percent of covered benefits above Part D's OOP threshold (Figure 6-1). The remaining benefit spending is divided between the plan (15 percent) and the enrollee (5 percent). As with risk adjustment, individual reinsurance tempers the incentives for plans to avoid high-cost enrollees.

When plan sponsors submit their bids to CMS, they include an estimate of how much individual reinsurance the plan expects its enrollees will accrue. CMS uses this information to set prospective reinsurance payments to

FIGURE 6–2

Individual reinsurance has grown over time as a share of Part D's average expected monthly cost of providing basic benefits



Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

the plan, which the agency reconciles with the plan after the end of the benefit year. The proportion of the average basic benefit cost made up by individual reinsurance has grown each year since the start of Part D (Figure 6-2). In 2007, expected reinsurance made up about 26 percent of the average costs of providing basic benefits ($26 of $103). By 2016, this share grew to about 52 percent of the average benefit costs ($69 out of $134).

Risk corridors

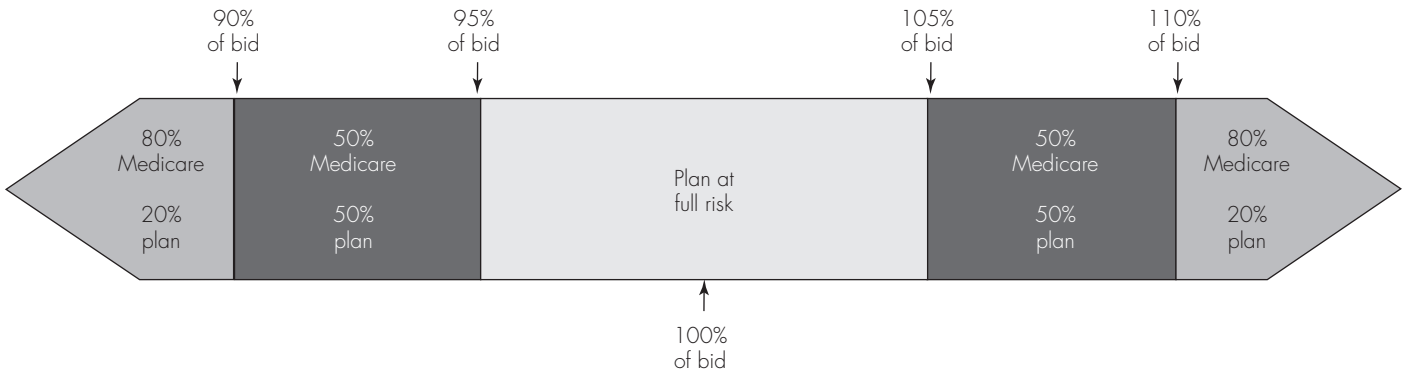
A third mechanism by which Medicare shares risk with Part D plans is risk corridors, which limit a plan's overall losses across all its enrollees when actual spending for basic benefits is higher than predicted spending. Since Part D's risk corridors are symmetric, they also limit a plan's unanticipated profits. Administrative costs and supplemental benefits are not part of the Part D risk corridor calculation.

In contrast to Medicare's reinsurance that protects plans against unexpectedly high costs incurred by individual enrollees, risk corridors provide a cushion at a plan level in the event of unforeseen high drug spending. For example, if use of an expensive new medication affected a plan more widely than the sponsor had anticipated, resulting in sizable losses, Medicare would share some of those losses. Plan sponsors submit their bids seven months before the start of a Part D benefit year. If circumstances change between when a sponsor submits its bid and when it delivers benefits, risk corridors provide a safety net.

Plan sponsors are at full risk for average monthly benefits within the range of 95 percent to 105 percent of the plan bid (Figure 6-3). If actual benefit spending is either between 105 percent and 110 percent of the bid or between 90 percent and 95 percent of the bid, then Medicare splits the difference (between the bid and actual benefit spending) with the plan sponsor 50–50. Beyond 110 percent or below 90 percent, Medicare covers 80 percent of excess benefit costs (or recoups excess profits). Since 2012, the Secretary of Health and Human Services has had authority to change the structure of Part D's risk

FIGURE 6–3

Risk corridors are in place for each Part D plan



Source: MedPAC depiction of Part D risk corridors as set by law.

corridors as long as she keeps at least the same amount of plan risk as in 2011 (i.e., widen risk corridors by adjusting the threshold percentages). Medicare recoups any amounts owed by withholding them from future monthly payments.

In our 2015 report to the Congress, the Commission discussed whether Part D's risk corridors were still necessary (Medicare Payment Advisory Commission 2015a). Initially, the corridors were put in place to encourage the creation of a market for stand-alone PDPs. The year 2016 marks Part D's 11th year, and the market for PDPs is now firmly established. Arguably, risk corridors are no longer needed. At the same time, each year between 2006 and 2014, the majority of Part D plan sponsors have made risk-corridor payments to Medicare because they earned substantially higher profits than they had built into their plan bids. Keeping Part D's risk corridors in place, at least temporarily, would limit excess plan profits.[4] Given changes the Commission is recommending to increase the share of risk assumed by plan sponsors and the uncertainty sponsors face associated with prices and spending on new specialty and biologic products, the Commission does not contemplate changes to the risk corridors at this time.[5]

Goals for Part D and the case for change

A key goal for the Part D program is to ensure that Medicare beneficiaries have access to appropriate medications while it remains financially sustainable to taxpayers. That goal involves managing medication therapies—that is, finding a balance between encouraging adherence to appropriate medicines while mitigating concerns that may arise with polypharmacy (see text box on adherence and polypharmacy, pp. 166–167). The current structure of Part D still reflects a system of federal subsidies and regulations that was designed to encourage broad participation of Medicare beneficiaries and private plan sponsors in a new program. Now that the market for MA–PDs has expanded and the market for stand-alone PDPs is in place, it is appropriate to consider whether the program's incentives need to be restructured to better ensure financial sustainability.

Recent trends in program spending are unsustainable

Evidence on program spending gives a mixed picture about the success of Part D plans at containing costs. Spending for the competitively derived direct-subsidy payments on which sponsors bear the most insurance risk has grown slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides 80 percent reinsurance) has grown much faster (Medicare Payment Advisory Commission 2016).

From 2007 through 2014, Part D spending increased from $46 billion to $73 billion, a nearly 60 percent increase and

Balancing concerns about adherence and polypharmacy

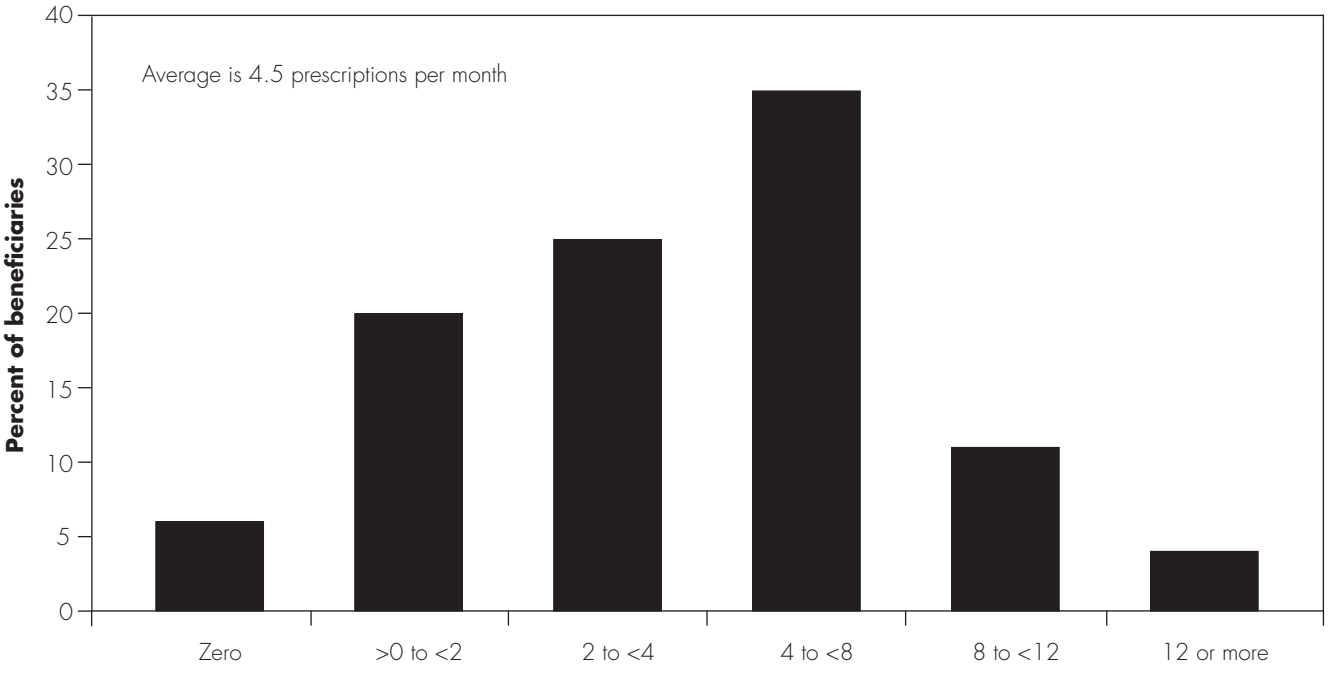
Access to medications is an important tool for treating disease. Because most Medicare beneficiaries have chronic conditions—often multiple ones—typically, they need to use medication over time to ensure its therapeutic value (Lorgunpai et al. 2014).

Medication adherence refers to the degree to which a patient follows a prescriber's recommendations for a drug therapy. By some estimates, 20 percent to 30 percent of prescriptions are never filled, and in 50 percent of cases, patients do not take a medication as prescribed (Brown and Bussell 2011, Ho et al. 2009). Public health officials and health literature report that poor medication adherence is associated with avoidable hospitalizations, sizable nondrug medical costs, and mortality. Because of the therapeutic importance of certain classes of drugs (e.g., those used to treat cardiovascular diseases), measures of medication adherence are included among Part C (private plans that deliver medical benefits) and Part D quality measures and are a factor in the star ratings.

Within the Medicare population, the relative benefits and risks of drug therapies are less clear because of the risk of polypharmacy—the use of multiple medications (Lorincz et al. 2011).[6] Clinical trials that evaluate the safety and effectiveness of new drugs rarely have patient populations that look like the Medicare population. For example, trials may use participant inclusion criteria such as having some minimum remaining life expectancy or exclusion criteria associated with history of other diseases. Medicare beneficiaries are elderly or disabled and typically receive treatment for multiple

(continued next page)

FIGURE 6–4 **Number of prescriptions filled per month by Part D enrollees, 2013**



Note: Number of prescriptions is standardized to a 30-day supply. Average number of prescriptions filled per month is estimated by taking the annual total prescriptions filled by Part D enrollees who were enrolled in the program for the full year in 2013. Percentages may not sum to 100 due to rounding.

Source: MedPAC analysis of Part D prescription drug event data.

Balancing concerns about adherence and polypharmacy (cont.)

chronic conditions—often through multiple prescribers. Our analysis of claims from 2013 shows that nearly three-quarters of Part D enrollees filled two or more prescriptions per month, and about half of enrollees filled four or more per month (Figure 6-4). A recent study found that in 2011, 15 percent of older adults were at potential risk of major interactions among their prescription drugs, over-the-counter medications, and dietary supplements compared with 8 percent in 2005 (Qato et al. 2016). Part D plans are required to have medication therapy management (MTM) programs to improve quality of pharmaceutical care for high-risk beneficiaries, but the Commission has been concerned about their effectiveness (Medicare Payment Advisory Commission 2016). Beginning in 2017, CMS will test whether prescription drug plan payment incentives and regulatory flexibility can lead to more effective MTM interventions.

Some Medicare beneficiaries have medical problems caused or exacerbated by polypharmacy. Adverse effects of polypharmacy can occur when a patient is prescribed more drugs than are clinically warranted or when all the prescribed medications are appropriate, but the total is too many for the patient to ingest or manage safely (Haque 2009). Individuals ages 65 and older are at high risk for adverse drug events associated with polypharmacy, yet there are few clinical guidelines pertinent to prescribing and managing multiple medications for this population (Lorgunpai et al. 2014). A literature review of 16 studies (based on Medicare data) found polypharmacy to be a statistically significant predictor of hospitalization, nursing home placement, death, hypoglycemia, fractures, decreased mobility, pneumonia, and malnutrition (Frazier 2005). Polypharmacy among Medicare beneficiaries has also been associated with cognitive decline, falls, and urinary incontinence (Maher et al. 2014). One study of an elderly, community-dwelling population found no adverse events or deaths from systematically discontinuing many of their medications, and 88 percent of study subjects reported global improvements in their health (Garfinkel and Mangin 2010).

Because of the potential risks of polypharmacy, the relationship between medication adherence and health spending for individuals who are treated with multiple medications can differ from that for relatively healthier individuals. For example, adhering to multiple drug regimens could result in drug–drug interactions that affect a patient's medical condition and lead to additional physician visits, emergency department visits, and hospitalizations. In its June 2014 report, the Commission examined the effects of medication adherence on health spending for the Medicare population (Medicare Payment Advisory Commission 2014b). We found that the effects of adherence vary by medical condition and range from modest savings to increased costs. We also found it difficult to control for all the factors that can influence this relationship. ■

an average annual growth rate of about 6.8 percent (Table 6-1, p. 168).[7] Medicare's direct-subsidy payments to plans grew slowly between 2007 and 2014, at an average annual rate of 1.5 percent. Over the same period, Medicare's reinsurance payments to plans for the catastrophic spending of high-cost enrollees grew by an average annual rate of 19.5 percent. In 2014, Medicare's reinsurance payments surpassed program spending for the LIS to become the single largest component of Part D spending.

We estimate that in 2014, nearly 70 percent of Medicare's total program spending for Part D plans was on behalf of the 30 percent of Part D enrollees who receive the LIS. Specifically, in addition to the LIS itself ($24.3 billion), about 30 percent of Medicare's direct-subsidy payments to plans ($5.9 billion, or 30 percent of $19.6 billion) and about 70 percent of individual reinsurance payments ($19.5 billion, or 70 percent of $27.8 billion) were for LIS enrollees. Disproportionate spending for this population reflects, in part, the policy goal of reducing the hurdle of OOP spending for low-income individuals. In addition, LIS enrollees tend, on average, to be in poorer health and use more medications than other enrollees.

In 2014, Part D program payments increased by nearly 15 percent over 2013 payments, much of that due to spending for new hepatitis C drugs (Boards of Trustees 2015). On a per capita basis, the Medicare Trustees observed faster

TABLE 6–1

Medicare's reimbursement amounts for Part D

	Calendar year						Cumulative growth 2007–2014	Average annual growth rate 2007–2014
	2007	2009	2011	2012	2013	2014		
Reimbursement amount (in billions):								
Direct subsidy*	$17.6	$18.2	$19.2	$19.7	$19.6	$19.6	11.4%	1.5%
Reinsurance	8.0	10.1	13.7	15.5	19.2	27.8	247.5	19.5
Low-income subsidy	16.7	19.6	22.2	22.5	23.2	24.3	45.5	5.5
Retiree drug subsidy	3.9	3.9	3.6	3.0	1.8	1.6	–59.0	–12.0
Total	46.2	51.8	58.7	60.7	63.8	73.3	58.7	6.8

Note: Numbers above reflect reconciliation. Most enrollees paid premiums directly to plans, and those amounts are not included. On a cash basis, the Board of Trustees estimates that premiums paid by enrollees were $4.1 billion in 2007, $5.0 billion in 2008, $6.1 billion in 2009, $6.7 billion in 2010, $7.3 billion in 2011, $7.8 billion in 2012, $9.3 billion in 2013, and $10.5 billion in 2014. Components may not sum to stated totals due to rounding.
*Net of risk-sharing payments using Part D's risk corridors.

Source: MedPAC analysis based on Table IV.B10 of the 2015 annual report of the Boards of Trustees of the Medicare trust funds.

than historical rates of growth in Part D spending in 2014, which they attributed to price increases for both brand-name and generic drugs. The Trustees expected even faster rates of increase in 2015 because of growth in the use of specialty drugs. Going forward, the Medicare Trustees project that between 2015 and 2024, per capita costs for Part D will grow by 5.6 percent per year. This rate is faster than projected per capita spending growth rates for Part A and Part B services because it reflects continued slowing in the use of generics and continued increases in the use and prices of specialty drugs. Because of the size of the baby-boom population entering Medicare, the Trustees project that aggregate program spending for Part D (net of enrollee premiums) will grow by 8.8 percent annually between 2015 and 2024, from $76.9 billion to $164.7 billion.

In each year since 2009, more than half of the FDA's approvals of new drugs have been for specialty drugs (Long 2015). New specialty drugs are often launched at high prices. Specialty drugs in the development pipeline are concentrated in drug classes that treat conditions such as rheumatoid arthritis and inflammatory diseases, multiple sclerosis, cancer, and HIV, which are more prevalent within the Medicare population. Major pharmacy benefit managers (PBMs), insurers, and other organizations project that growth in prices of brand-name drugs and in the use of specialty drugs will continue to drive trends in spending (CVS Health 2016, Express Scripts Lab 2016, IMS Institute for Healthcare Informatics 2015).

High-priced specialty drugs pose a particular challenge for Part D. As more expensive therapies become available, larger numbers of beneficiaries could reach the catastrophic phase of benefit, when Medicare pays for 80 percent of the costs through individual reinsurance. Some of this trend has already happened with biologic products. Between 2009 and 2013, the share of high-cost enrollees who filled at least one prescription for a biologic product grew from 8 percent to 12 percent.[8] During the same period, the share of gross Part D spending accounted for by biologic products grew from 6 percent to 10 percent.

The growing role of high-cost non-LIS enrollees

Recent growth in Part D program spending reflects two underlying trends. First, patent expirations on widely used brand-name drugs and plans' use of tiered copayments have led to a dramatic shift toward use of generics. From 2007 through 2013, generic drugs' share of all Part D prescriptions rose from 61 percent to 84 percent. Were this trend the only one, we would expect the shift toward generics to lead to lower growth in program spending—and though it has, in the sense that direct-subsidy payments and average enrollee premiums grew slowly between 2007 and 2014, other factors are changing that dynamic. Going forward, however, opportunities for further generic use are expected to diminish (Keehan et al. 2015).

TABLE 6–2 **Growth in enrollment and spending for high-cost enrollees, 2007–2013**

				Average annual growth (in percent)	
	2007	2010	2013	2007–2010	2010–2013
Number of enrollees (in millions)					
All Part D	26.1	29.7	37.8	4.4%	8.4%
High-cost enrollees					
LIS	1.9	2.0	2.1	1.3	3.0
Non-LIS	0.4	0.4	0.7	–1.9	21.8
Total high-cost enrollees	2.3	2.4	2.9	0.7	6.7
High-cost enrollees as a share of all Part D	*8.8%*	*7.9%*	*7.6%*	*N/A*	*N/A*
Gross spending (in billions of dollars)					
All Part D	$62.1	$77.6	$103.7	7.7%	10.1%
High-cost enrollees					
LIS	19.7	25.5	33.4	8.9	9.5
Non-LIS	4.3	5.7	14.9	9.9	37.9
Total high-cost enrollees	24.0	31.2	48.4	9.1	15.8
High-cost enrollees as a share of all Part D	*38.7%*	*40.1%*	*46.6%*	*N/A*	*N/A*

Note: LIS (low-income subsidy), N/A (not applicable). Components may not sum to totals due to rounding. "High-cost enrollees" refers to enrollees with annual drug spending high enough to reach Part D's out-of-pocket threshold. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Between 2010 and 2013, about half of the growth in the number of high-cost, non-LIS enrollees was due to growth in Part D employer group waiver plans (EGWPs). Largely because of changes in the Patient Protection and Affordable Care Act of 2010, employers that had previously provided primary drug coverage to their former workers and received Medicare's retiree drug subsidy (RDS) instead set up Part D EGWPs for their retirees. Employers were motivated to make this shift because the law changed the tax treatment of the RDS and made the Part D benefit more generous through the phased closure of the coverage gap and the provision of brand discounts. (See the Commission's March 2016 report to the Congress for more about enrollment growth in EGWPs.) The provision of a 50 percent discount on brand-name drugs from manufacturers and exclusion of that discount from Part D's true out-of-pocket provision likely contributed to the growth in the number of high-cost, non-LIS enrollees among beneficiaries enrolled in EGWPs and other plans.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

A second trend is that spending for high-cost enrollees—particularly those individuals who do not receive the LIS—has started to drive overall Part D program spending. From 2010 to 2013, the number of Part D enrollees increased as baby boomers began to retire and employers that had previously provided primary drug coverage to their former workers shifted their retirees to Part D by setting up employer group waiver plans. In addition, changes in the Patient Protection and Affordable Care Act of 2010 allowed manufacturers' discounts on brand-name drugs to count toward an enrollee's OOP spending in meeting the true OOP threshold, resulting in more beneficiaries reaching the OOP threshold. All of these factors have contributed to rapid growth (about 22 percent) in the number of non-LIS enrollees with high costs (Table 6-2). Meanwhile, between 2010 and 2013, gross spending for non-LIS enrollees with high costs grew from $5.7 billion to $14.9 billion—a nearly 38 percent increase. Between 2007 and 2010, the share of gross drug spending accounted for by high-cost enrollees grew slowly from nearly 39 percent to slightly more than 40 percent and then jumped to nearly 47 percent by 2013.

Sharp increases in the average price of prescriptions filled by high-cost non-LIS enrollees have also contributed to growth in their gross spending. That growth may reflect increases in the prices of their medications, greater need for higher priced drugs, and other changes in the mix of medications they were prescribed. Between 2010 and 2013, the average price per standardized, 30-day prescription grew by 12.9 percent for high-cost non-LIS enrollees (Table 6-3, p. 170). By comparison, the average price per prescription for high-cost LIS enrollees grew by 4.3 percent and fell by 4.8 percent for Part D enrollees who did not reach the OOP threshold. The quantity of prescriptions used grew by a modest 2.2 percent across all Part D enrollees, but grew by just 0.2 percent for high-cost non-LIS enrollees. Overall, between 2010 and 2013, gross spending for all high-cost enrollees grew by 15.8 percent

TABLE 6–3 **Growth in the number of high-cost enrollees and in the average price of prescriptions they use has driven much of Part D's spending growth in recent years**

	Breakdown of average annual spending growth, 2010–2013				
	Per enrollee amounts				
	Average price per prescription	Number of prescriptions	Spending	Numbers of enrollees	Gross spending
High-cost enrollees					
LIS	4.3%	1.9%	6.2%	3.0%	9.5%
Non-LIS	12.9	0.2	13.2	21.8	37.9
Total high-cost enrollees	7.2	1.2	8.5	6.7	15.8
Not high-cost enrollees	–4.8	2.7	–2.3	8.5	6.0
All Part D enrollees	–0.6	2.2	1.6	8.4	10.1

Note: LIS (low-income subsidy). "High-cost enrollees" refers to enrollees with annual drug spending high enough to reach Part D's out-of-pocket threshold. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Numbers of prescriptions are standardized to a 30-day supply. Between 2010 and 2013, about half of the growth in the number of high-cost, non-LIS enrollees was due to growth in Part D employer group waiver plans (EGWPs). Largely because of changes in the Patient Protection and Affordable Care Act of 2010, employers that had previously provided primary drug coverage to their former workers and received Medicare's retiree drug subsidy (RDS) instead set up Part D EGWPs for their retirees. Employers were motivated to make this shift because the law changed the tax treatment of the RDS and made the Part D benefit more generous through the phased closure of the coverage gap and the provision of brand discounts. (See the Commission's March 2016 report to the Congress for more about enrollment growth in EGWPs.) The provision of a 50 percent discount on brand-name drugs from manufacturers, and exclusion of that discount from Part D's true out-of-pocket provision, likely contributed to the growth in the number of high-cost, non-LIS enrollees among beneficiaries enrolled in EGWPs and other plans.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

compared with 6.0 percent growth in gross spending for enrollees who did not reach the OOP threshold.

Patterns of spending differ between high-cost enrollees with and without the LIS

In 2013, Part D had about 2.9 million high-cost enrollees (7.6 percent) (Table 6-4). About 2.1 million, or three-quarters of high-cost enrollees, received Part D's LIS, and 0.3 million resided in long-term care institutions.[9] Because most LIS enrollees remained covered under traditional Medicare rather than under Medicare Advantage plans, 78 percent of high-cost enrollees were in PDPs (data not shown). High-cost enrollees were much more likely to be disabled beneficiaries (under age 65) and African American compared with all Part D enrollees.

In 2013, all Part D enrollees filled an average of 50 prescriptions during the year (or more than 4 per month) at an average price of $54 per standardized 30-day prescription, for average annual spending of $2,741. By comparison, high-cost enrollees filled an average of more than twice as many prescriptions (116, or 9.7 per month) at an average price per prescription that is more than two and a half times higher ($145), for average annual spending of $16,914 per person.

Patterns of drug spending among high-cost enrollees vary depending on LIS status. High-cost LIS enrollees tend to fill a somewhat larger number of prescriptions (averaging 121, or 10.1 per month) compared with high-cost enrollees without the LIS (103 prescriptions, or about 8.6 per month). High-cost enrollees who resided in long-term care institutions (90 percent of whom received the LIS) had the highest use, at an annual average of 165 prescriptions (13.8 prescriptions per month).

High-cost enrollees without the LIS are more likely to use specialty drugs and biologics. For example, in 2013, of the 20 therapeutic classes that accounted for about 80 percent of spending by high-cost LIS enrollees, only four classes (e.g., antineoplastics and multiple sclerosis agents) were often associated with specialty tier drugs or biologic products. Spending for drugs in those four classes accounted for less than 8 percent of high-cost LIS enrollees' total spending compared with nearly 30 percent of spending by high-cost enrollees without the LIS (data not shown). This pattern is reflected in the higher average

TABLE 6–4 **High-cost enrollees and their prescription use and spending, 2013**

	All Part D enrollees	High-cost enrollees			
			LIS status		
		All	LIS	Non-LIS	Long-term institutionalized
Numbers of enrollees in millions	37.8	2.9	2.1	0.7	0.3
Percent of enrollees in category with high costs	N/A	7.6%	17.3%	2.8%	21.4%
As a percent of high-cost enrollees	N/A	100%	75%	25%	10%
Gender (in percent within category)					
Male	42%	40%	38%	46%	33%
Female	58	60	62	54	67
Age (in percent within category)					
Less than 65	20%	44%	54%	17%	19%
Between 65 and 80	57	40	33	63	38
80 and above	23	16	14	21	43
Race/ethnicity (in percent within category)					
White, non-Hispanic	74%	69%	63%	86%	75%
African American, non-Hispanic	11	15	18	5	15
Hispanic	10	11	12	5	7
Asian	3	4	5	1	2
Other	2	2	2	2	1
Total gross spending, in billions of dollars	$103.7	$48.4	$33.4	$14.9	$3.5
Percent of total for high-cost enrollees	N/A	100%	69%	31%	7%
Total numbers of prescriptions, in millions	1,910	333	259	74	46
Percent of total for high-cost enrollees	N/A	100%	78%	22%	14%
Gross annual spending per enrollee, in dollars	$2,741	$16,914	$15,599	$20,847	$12,730
Annual number of prescriptions per enrollee	50	116	121	103	165
Average price per prescription, in dollars	$54	$145	$129	$202	$77
Average annual OOP spending per enrollee	$365	$773	$127	$2,706	$192

Note: LIS (low-income subsidy), N/A (not applicable), OOP (out of pocket). Components may not sum to totals due to rounding. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Individuals are classified as "long-term institutionalized" if they resided more than 90 days in an institution at some point during the year. Numbers of prescriptions are standardized to a 30-day supply.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

spending by high-cost enrollees without the LIS: $202 per prescription and $20,847 per year compared with $129 per prescription and $15,599 per year for high-cost enrollees with the LIS (Table 6-4).

In 2013, high-cost LIS enrollees paid substantially lower cost sharing out of pocket than high-cost non-LIS enrollees. Average annual OOP cost-sharing amounts for high-cost LIS enrollees were $127, compared with $2,706 among non-LIS enrollees. One might expect average annual OOP spending for high-cost non-LIS enrollees to be higher than $4,750, which was Part D's OOP threshold in 2013. The average amount is lower primarily because those enrollees received credit that counted as OOP spending for the 50 percent discount provided by brand-name manufacturers in the coverage gap. By comparison, all Part D enrollees averaged $365 in annual OOP cost sharing.

Generic use among high-cost enrollees

Patterns of Part D claims suggest that certain policy changes would allow plan sponsors to better manage

TABLE 6–5

Top 10 therapeutic classes by spending for high-cost enrollees who receive the low-income subsidy, 2013

Therapeutic classes	Gross spending (in billions of dollars)	Generic dispensing rate			
		High-cost LIS	High-cost non-LIS*	All non-high-cost	All Part D
Antipsychotics (neuroleptics)	$4.1	58%	54%	93%	78%
Diabetic therapy	3.3	39	36	73	65
Antivirals	3.2	20	30	83	47
Asthma/COPD therapy agents	2.2	23	20	25	24
Analgesic, anti-inflammatory or antipyretic—non-narcotic	1.4	69	44	86	82
Analgesics—narcotic	1.4	90	85	97	96
Anticonvulsants	1.3	82	76	93	90
Antidepressants	1.2	80	76	94	91
Peptic ulcer therapy	1.2	68	71	89	85
Antihyperlipidemics	1.1	69	63	86	84
All therapeutic classes	33.4	71	67	86	84

Note: LIS (low-income subsidy), COPD (chronic obstructive pulmonary disease). Therapeutic classification based on the First DataBank Enhanced Therapeutic Classification System 1.0.
*For comparison, the top 10 therapeutic classes used by high-cost non-LIS enrollees in 2013 were antineoplastic—systemic enzyme inhibitors ($1.6 billion); diabetic therapy ($1.3 billion); antineoplastic—immunomodulators ($1.1 billion); analgesic, anti-inflammatory or antipyretic—non-narcotic ($1.0 billion); antivirals ($0.8 billion); antihypertensive therapy agents ($0.8 billion); asthma/COPD therapy agents ($0.6 billion); multiple sclerosis agents ($0.6 billion); antineoplastic—hormone/hormone antagonist agents ($0.6 billion); and antihyperlipidemics ($0.5 billion).

Source: MedPAC analysis of Medicare Part D prescription drug event data from CMS.

drug benefits for high-cost enrollees. Past research by the Commission has shown that plan sponsors are less successful at encouraging LIS enrollees to use generics. If plans were more successful, greater use of generics could reduce the number of individuals who reach the OOP threshold and moderate Medicare's reinsurance payments to plans.

Consistent with our previous work, we find that having high costs is correlated with using more brand-name drugs (Medicare Payment Advisory Commission 2012). For example, in 2013, the average generic dispensing rate (GDR) among high-cost LIS enrollees was 71 percent, while the overall Part D average was 84 percent. High-cost non-LIS enrollees had a GDR that was even lower, at 67 percent (Table 6-5). Some of the difference reflects situations in which brand-name medications are the dominant standard of care for a therapeutic drug class, especially classes for newer specialty drugs. However, in other therapeutic classes such as diabetic therapy and antihyperlipidemics, many of the drugs taken by high-cost enrollees are also used heavily by all Part D enrollees.

Across certain therapeutic classes, notable differences exist between high-cost enrollees and enrollees with lower drug spending. For example, among prescriptions for antipsychotics filled by high-cost enrollees in 2013—observed separately with and without the LIS—about 58 percent and 54 percent, respectively, were generics, compared with 93 percent for Part D enrollees who did not reach the OOP threshold (were not high cost) (Table 6-5). In the category of peptic ulcer therapies, the GDRs of high-cost enrollees with and without the LIS were 68 percent and 71 percent, respectively, compared with 89 percent among Part D enrollees with lower costs.

Multiple factors likely contribute to the higher or lower GDRs among groups of beneficiaries. For example, differences in health status may limit the opportunity for clinically appropriate therapeutic substitutions for some beneficiaries. For certain conditions, such as multiple sclerosis, rheumatoid arthritis, certain cancers, asthma,

and chronic obstructive pulmonary disease, prescribers predominantly treat patients with branded products. There can be geographic differences in prescribing behavior among physicians as well as differences between prescribers who are part of certain managed care settings and those who are not. Another factor may be the difference in financial incentives faced by LIS and non-LIS enrollees.

Patterns of Medicare payments and bidding incentives

In the Commission's June 2015 report to the Congress, we noted regular patterns in Medicare's reconciliation payments with plans (Medicare Payment Advisory Commission 2015a). First, many plan sponsors bid too low on the amount of benefit spending they expect above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. Second, plan sponsors bid too high on benefit spending other than catastrophic benefits. Between 2009 and 2013, about three-fourths of parent organizations returned a portion of their prospective payments to Medicare through risk corridors. Actuaries interviewed by Commission staff suggested that there is significant uncertainty behind the assumptions they make when projecting drug spending for their bids. At the same time, we suggested that Part D's risk-sharing mechanisms could provide incentives to bid too low on catastrophic spending and too high on spending for the remainder of the Part D benefit. When plan sponsors underbid on the amount of individual reinsurance they will ultimately receive, Medicare pays an overall Part D subsidy higher than the 74.5 percent specified in law, which helps plan sponsors keep their premiums low. We estimate this higher subsidy occurred in most years from 2007 through 2014.

In their 2015 report, the Medicare Trustees projected that, because of higher than anticipated spending on new hepatitis C therapies in 2014, most plans would receive risk-corridor payments from Medicare in 2015 rather than return overpayments (Boards of Trustees 2015). However, the projection was not fully accurate. For benefits delivered in 2014, 81 percent of plan sponsors received additional individual reinsurance payments from Medicare at reconciliation, much of which was due to hepatitis C spending. Ultimately, however, 62 percent of Part D plan sponsors made risk-corridor payments to Medicare (rather than receiving payments from Medicare) for 2014 benefits. In aggregate, those payments totaled less than $100 million, much lower than risk-corridor payments from plan sponsors to Medicare in recent years.

Potential improvements to Part D

The Commission recommends improvements to the Part D program that are interrelated changes. Sponsors of Part D plans would shoulder more insurance risk but would also have greater flexibility to use formulary tools. The Commission's recommendations would modify what would count toward Part D's OOP spending threshold, would provide greater protection to all non-LIS enrollees through a real OOP cap, and would increase financial incentives for enrollees who receive the LIS to use lower cost drugs and biologics. At the same time, these changes would need to be accompanied by a recalibrated risk adjustment system, regular monitoring of beneficiary access, and well-functioning appeals and grievance procedures.

The net impact of the Commission's recommendations restrains overall drug costs and makes the benefit more affordable for beneficiaries and taxpayers in the long run. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendations would also expose some beneficiaries to higher cost sharing in the coverage gap. To the extent that the adoption of this combined set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS beneficiaries facing high cost-sharing burdens.

Changes related to Part D's OOP spending threshold

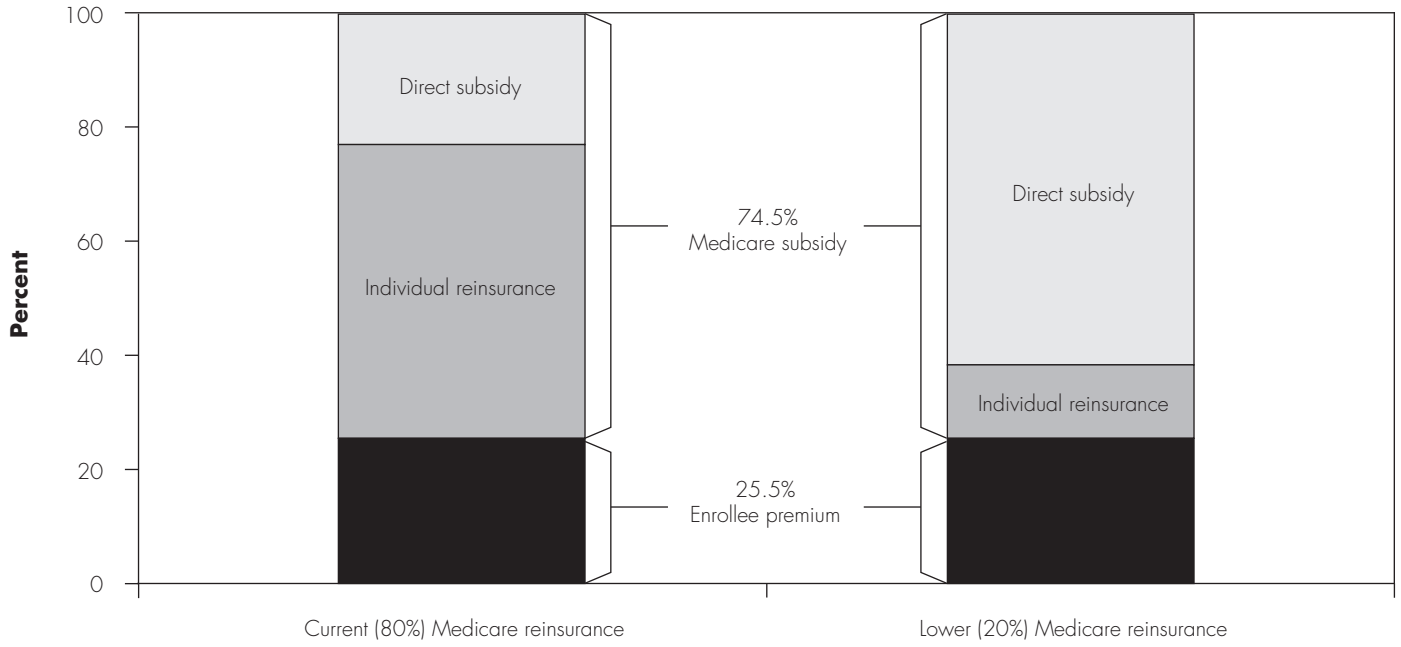
The Commission recommends changes that would reduce Medicare's individual reinsurance, discontinue counting brand-name discounts as enrollees' own "true OOP" spending, and eliminate enrollee cost sharing above Part D's OOP threshold.

A larger portion of Medicare's subsidy through capitated payments

One step toward better managing Part D spending would be for Medicare to pay a larger portion of its prescription drug subsidy through capitated payments. Currently, Medicare subsidizes 74.5 percent of the expected cost of basic drug benefits, with enrollees paying the remainder through premiums. Medicare's subsidy share is made up of two components: monthly direct-subsidy payments and expected individual reinsurance payments to plans, in which Medicare pays 80 percent of catastrophic spending. Under the recommendation (described on pp. 183–184),

FIGURE 6–5

Recommended change in how Medicare provides its 74.5 percent subsidy to Part D plans



Note: Medicare subsidizes about 74.5 percent of the cost of basic Part D benefits through a combination of monthly capitated payments and individual reinsurance payments to plans. Enrollees pay the remainder (about 25.5 percent) in premiums. As one component of Medicare's subsidy, the program currently pays 80 percent of each high-cost enrollee's spending above Part D's out-of-pocket threshold as individual reinsurance. Under the recommendation, Medicare would lower its reinsurance to 20 percent of catastrophic spending but also increase capitated payments to keep the combined Medicare subsidy at 74.5 percent. Medicare payments and enrollee premium shown assume no behavioral changes.

Medicare would keep its subsidy of Part D at 74.5 percent of basic benefits, but the structure of individual reinsurance would be changed so that plans included more of the costs of catastrophic spending in their covered benefits. In other words, Medicare would provide more of the 74.5 percent subsidy through capitated payments and less of the subsidy through open-ended individual reinsurance.

Discussions with plan executives and academic economists suggest that the current structure of Medicare's reinsurance subsidy takes away the urgency for sponsors to manage prescription use among high-cost enrollees. One commenter pointed out that the rebates sponsors receive from manufacturers for brand-name drugs dispensed to enrollees who reach Part D's OOP threshold (including rebates in the coverage-gap phase) can more than offset plans' 15 percent share of payments for spending that exceeds the OOP threshold. Requiring plans to pay a share larger than 15 percent would provide greater incentive for sponsors to negotiate larger rebates with manufacturers or design formularies in ways that encourage greater use of lower cost drugs.

Under the Commission's recommendation, Medicare's overall subsidy would remain at 74.5 percent, but the share of that subsidy provided through individual reinsurance would be reduced over a transition period, and the dollar amount of capitated direct-subsidy payments would increase (Figure 6-5). (Medicare's reinsurance subsidy, currently 80 percent of catastrophic spending, is notionally different from the program's overall 74.5 percent subsidy. Medicare pays reinsurance only for individuals who reach the OOP threshold, and the reinsurance subsidy is one component of the overall 74.5 percent subsidy.) At the end of the transition period and after implementation of a real catastrophic cap (described in the section about limiting enrollee cost sharing above the OOP threshold), ultimately

plan sponsors would be at risk for 80 percent of the spending above the OOP limit rather than 15 percent as they are today. Medicare would pay 20 percent reinsurance instead of the current 80 percent. The Commission's recommendation would retain 20 percent reinsurance through Medicare as a complement to risk adjustment, to protect plans against the consequences of an individual enrollee's unpredictably high benefit spending. The recommendation would also retain Part D's risk corridors as currently structured to provide sponsors with overall protection at the plan level.

Because the overall subsidy rate of 74.5 percent would remain the same, the recommendation might not affect enrollee premiums—assuming no behavioral changes. However, because more of Medicare's subsidy would take the form of a capitated payment rather than open-ended reinsurance, plan sponsors would be at risk for more of covered benefits than they are today. Assuming greater risk for high-spending enrollees would likely require plans to reevaluate their overall bidding and operational strategy. For example, plan sponsors might bargain more aggressively with drug manufacturers over rebates and prices. This approach would also give sponsors more incentive to move high-cost enrollees to lower cost drugs (such as generics) when available, or to encourage them to use lower cost pharmacies.

One question to consider relates to the growing influence of higher priced specialty drugs. Even if Medicare required plan sponsors to bear more risk in Part D, would sponsors have sufficient market power to negotiate larger price discounts with pharmaceutical manufacturers? For some drug therapies that are the first in a class with a new mechanism of action or breakthrough therapies, and those with few or limited substitutes, the answer may be no. For these situations, Part D's risk adjusters would be recalibrated to reflect the higher spending of enrollees who fill prescriptions for those drugs, and the program's risk corridors would protect sponsors from unexpectedly large losses at the plan level. However, for other drug therapies, even the prospect of potential competitors in the development pipeline can give plan sponsors and their pharmacy benefit managers bargaining leverage with manufacturers. For example, in our discussions with plan actuaries, some noted that they were able to obtain rebates on Sovaldi even when it was the only hepatitis C treatment of its kind on the market because of the leverage provided by other therapies that were about to receive FDA approval.

Other behavioral changes could result in higher plan costs for providing the benefit. For example, because they would bear more risk, plan sponsors might build in a larger risk premium (that is, compensation required by insurers for bearing a given level of risk) or decide to purchase private reinsurance to protect themselves from large losses (called stop-loss coverage). The cost of any risk premium or private reinsurance would be reflected in a higher bid. However, plans that purchased private reinsurance could be subject to the practice of "lasering," in which reinsurers do not cover (or provide less coverage for) plan enrollees with predictably high levels of spending (see text box about lasering, pp. 176–177).

How much reinsurance should Medicare provide? A key consideration is the level of uncertainty inherent in predicting catastrophic spending. In 2013, among the 2.9 million beneficiaries who reached Part D's OOP threshold, 1.8 million, or 65 percent, also had high costs in 2012 (Table 6-6, p. 178). In 2013, those 1.8 million individuals accounted for about 70 percent of gross Part D spending and 76 percent of the gross spending above the OOP threshold.

Plan sponsors often use predictive modeling that incorporates information about enrollees' diagnoses and past claims to estimate future spending. Given the predictability of drug spending, perhaps a larger uncertainty for insurers is how much catastrophic spending would be incurred by enrollees without a history of high costs. If the goal of Medicare's reinsurance is to protect plan sponsors from unpredictably high drug spending, then providing sponsors with reinsurance substantially lower than 80 percent would appear to still offer adequate protection. At the same time, it would be prudent to phase down Medicare's reinsurance subsidy over a few years so that plan sponsors could adjust to higher levels of risk and CMS could recalibrate Part D's risk adjusters.

Under the recommendations, Part D's risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk adjustment system. Recalibrating Part D's risk adjusters to reflect the higher plan liability is notionally similar to the adjustments CMS has made to the RxHCC model since 2010 to reflect the phased closure of Part D's coverage gap. Since 2011, CMS has had to adjust the expenditure data used for estimating the model coefficients to reflect a different benefit structure as the phaseout of the coverage gap increases the share of drug spending for which plans

Persistence of high drug costs and the practice of "lasering" in private reinsurance

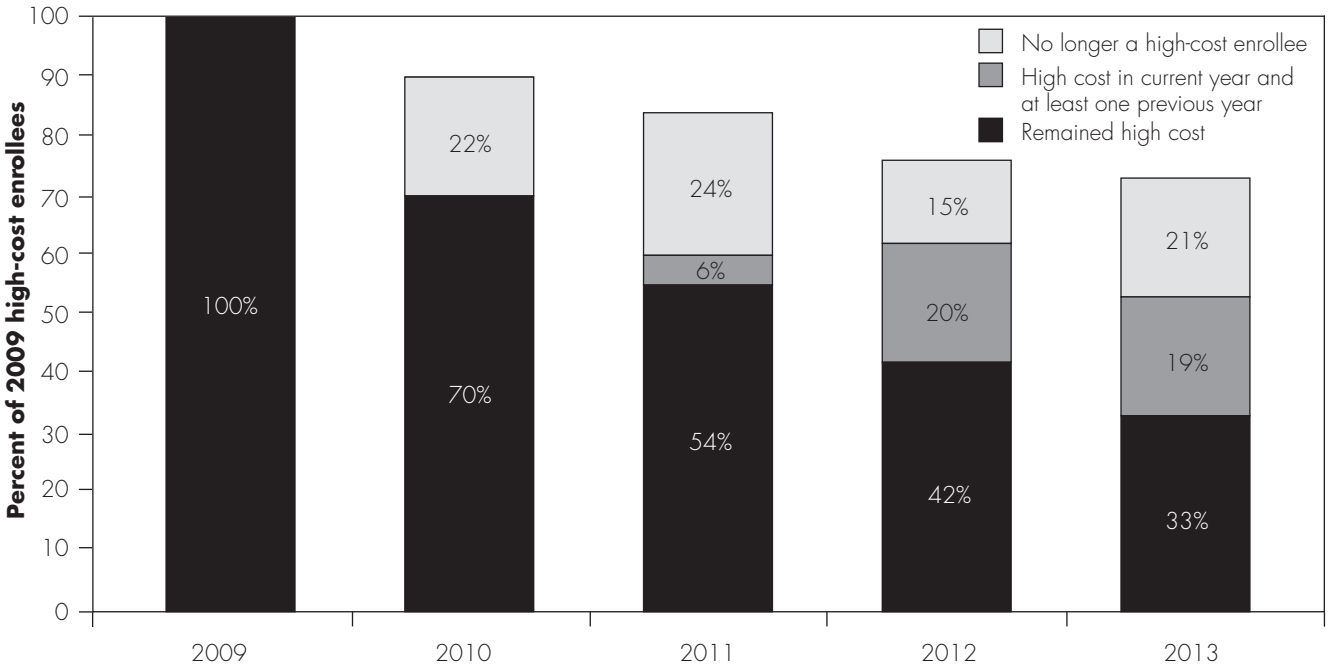
Medicare beneficiaries often have multiple chronic conditions treated with medications, and their drug-spending patterns can be highly predictable (Boccuti and Moon 2003). For this reason, plan sponsors and reinsurers may have particularly strong information with which to identify individuals who have persistently high costs.

To understand the persistence of high costs in Part D, we examined the spending patterns of enrollees who reached the out-of-pocket (OOP) threshold between 2009 and 2013 (Figure 6-6). We found that Part D spending for high-cost individuals tended to persist over time. By the end of the five-year period, more than one-quarter of the original 2009 cohort had died.

(continued next page)

FIGURE 6–6

Persistence of high spending and mortality in the cohort of enrollees who reached Part D's out-of-pocket threshold in 2009



Note: "High-cost enrollees" refers to enrollees with annual drug spending high enough to reach Part D's out-of-pocket threshold. The denominator of the percentage is the number of individuals who reached the out-of-pocket threshold in 2009. The declining height of the bars reflects enrollees who died. "Remained high cost" means the individual had high costs in each year. Shares of enrollees who remained high cost or were "high cost in current year and at least one previous year" would be higher if decedents were excluded from the calculation.

Source: MedPAC analysis of Part D prescription drug event data.

are responsible. CMS could similarly adjust upward the portion of claims for which plans would be liable if there were lower reinsurance. In addition, because spending in the catastrophic phase of the benefit is large and likely concentrated among beneficiaries with certain conditions, CMS would need to review condition categories.

Even though Medicare would continue to risk adjust payments and retain risk corridors, plan sponsors may include a larger risk premium in their bids or purchase private reinsurance. However, most Part D enrollees are in plans sponsored by large insurers. By virtue of having larger risk pools, these plan sponsors would likely be able

Persistence of high drug costs and the practice of "lasering" in private reinsurance (cont.)

Just over 20 percent of the 2009 cohort did not reach the OOP threshold in 2013 ("no longer a high-cost enrollee"), about 19 percent incurred high spending in two to four of the years, and more than 30 percent incurred high spending in all five years ("remained high cost"). The shares of individuals with persistently high spending would be larger if decedents were omitted from the calculations.

When a beneficiary has predictably high drug spending, private reinsurance companies may require modifications to stop-loss agreements with plan sponsors. For example, the reinsurer might exclude the beneficiary from future coverage. Alternatively, the reinsurer might agree to cover the beneficiary only at a higher stop-loss amount. Such modifications apply only to the individual enrollee; that is, the lower stop-loss threshold continues to apply for the rest of the covered population. This practice of pinpointing high-risk individuals is known as "lasering." Reinsurers' rationale behind lasering is that, because some enrollees have predictably higher spending, the sponsor should build those costs into the plan's premiums rather than rely on reinsurance to cover the higher expected benefit costs.

Conceptually, the same lasering notion should apply in Part D, but the current structure of Medicare's individual reinsurance payments carves out predictable costs of high-cost enrollees from plan bids. If Medicare paid plans a lower share of individual reinsurance, then plans with higher concentrations of high-cost enrollees would have higher bids. It is very important for CMS to recalibrate the prescription drug hierarchical condition category risk adjustment system to reflect plans' higher benefit spending and to discourage plan sponsors from avoiding such beneficiaries. ■

to shoulder more of their enrollees' insurance risk. In 2013, some parent organizations offered only PDPs, others offered only MA–PDs, but many offered both. Among the 63 parent organizations that sponsored PDPs, only about 1 percent of Part D enrollees were in PDPs operated by parent organizations that had enrollment totaling less than 30,000. Conversely, 95 percent of PDP enrollees were in plans offered by parent organizations with enrollment totaling 125,000 or more. By comparison, larger numbers of sponsors had MA–PDs with smaller enrollment: 134 parent organizations had 5,000 or fewer MA–PD enrollees, and 57 parent organizations had between 5,000 and 30,000 enrollees. Nonetheless, total enrollment in MA–PDs was still fairly concentrated: 71 percent of enrollees were in plans sponsored by parent organizations with MA–PD enrollment totaling 125,000 or more.

Large plan sponsors also participate in other major insurance markets, covering, for example, MA plans' medical benefits, employer health plans, and the health insurance exchanges. In the case of MA, Medicare does not provide any individual reinsurance, and some plan sponsors already purchase private reinsurance. In interviews, private reinsurers suggested that existing reinsurance contracts with MA plans could be modified to include drug spending and medical benefits. Consulting actuaries also suggested that large insurance companies would have sufficient capital and cash flow on hand to set up systems of cross-subsidies among their business lines to reinsure themselves. However, smaller plan sponsors would likely need to purchase private reinsurance, which could affect their decision to enter or exit the Part D market.[10]

Manufacturers' discounts on brand-name drugs and Part D's OOP threshold

Although Part D's defined standard benefit currently includes a coverage gap, in 2020, the Part D benefit will become more generous so that drug spending now in the coverage gap will have the same 25 percent cost sharing that applies to the benefit's initial coverage phase. From 2006 to 2010, non-LIS enrollees exceeding the initial coverage limit were responsible for paying the full price of covered drugs up to the annual OOP threshold (Figure 6-7, p. 179). In 2016, the coverage gap has been partially phased out. Non-LIS enrollees in the coverage gap pay 45 percent of their brand-name drug costs and 58 percent of

TABLE 6–6

More than three-quarters of Part D's catastrophic spending in 2013 was for enrollees who also had high costs in 2012

	Enrollees		Total gross spending		Gross spending above Part D's out-of-pocket limit	
	In millions	In percent	In billions	In percent	In billions	In percent
Enrollees with high costs in 2013						
High cost in 2012	1.8	65%	$34.0	70%	$21.1	76%
Not high cost in 2012	1.0	35	14.4	30	6.6	24
Total	2.9	100	48.4	100	27.7	100

Note: Components may not sum to totals due to rounding.

Source: MedPAC analysis of Part D prescription drug event data.

their generic drug costs, while the Part D benefit covers 5 percent of their brand-name drug costs and 42 percent of their generic drug costs. Manufacturers provide a 50 percent discount that covers the remaining costs for brand-name drugs. In 2020 and thereafter, the Part D benefit will cover 25 percent of covered brand-name drug spending in what is now the coverage gap, the enrollee will pay 25 percent cost sharing, and brand manufacturers will continue to provide a 50 percent discount on price.

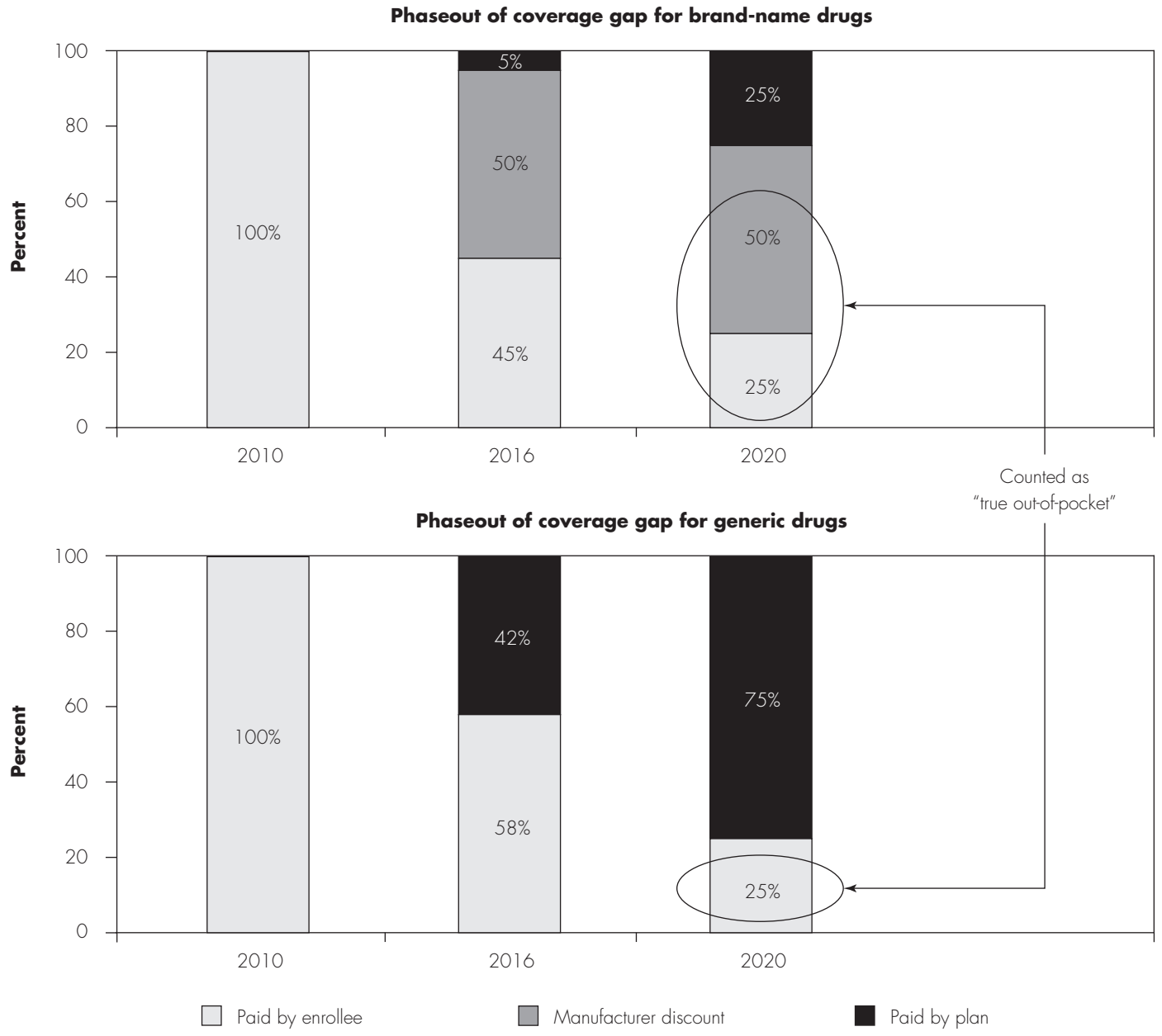
Generally, only cost sharing paid by the enrollee counts toward the OOP threshold. However, under PPACA, brand-name discounts are also counted toward the OOP spending threshold of non-LIS enrollees.[11] By comparison, Part D does not count most other sources of supplemental drug coverage toward an enrollee's OOP threshold ("true OOP" provision).[12] For example, for a plan enrollee with retiree drug coverage or enhanced benefits that wrap around his or her Part D plan benefit (e.g., paying the deductible or covering some cost sharing in the coverage gap), Medicare counts only the beneficiary's own OOP spending toward the threshold. This feature of the benefit ensures that, if a beneficiary has supplemental coverage, no part of that supplemental benefit would be replaced or subsidized by Part D. Under PPACA, manufacturer discounts for brand-name drugs are exempted from this "true OOP" provision so that those amounts are treated as though the beneficiary had paid them.

Brand-name discounts lower relative prices for brand-name drugs. For therapeutic classes in which an enrollee has a choice of both brand-name and generic alternatives, the policy makes brand-name drugs appear less expensive than they would otherwise.[13] Because manufacturers' discounts are counted as the enrollee's own spending, the exemption of discounts from the true OOP provision allows the enrollee who fills brand-name drugs to reach the OOP threshold more quickly (i.e., at a lower level of drug spending) (see text box on beneficiary spending at the OOP threshold, p. 180). In turn, this exemption quickens the pace at which Medicare begins paying for 80 percent of enrollees' benefits through reinsurance. Meanwhile, plan sponsors may not be as motivated to encourage use of generics as much as they might otherwise because the plan's responsibility for benefit spending is lowered by the brand discount and the plan sponsor receives rebates for brand-name drugs from manufacturers. Ultimately, program spending is greater because Medicare pays for 80 percent of spending above the OOP threshold. (Plan incentives and effects on program spending could change significantly under the Commission's recommendation to reduce Medicare's reinsurance and increase plan risk for catastrophic benefits.)

In 2010, about 400,000 non-LIS enrollees reached the OOP threshold. After PPACA was enacted, that number grew to about 700,000 by 2013—more than 80 percent higher. Among those 700,000 enrollees, total drug spending averaged $20,847. Of that total, these enrollees paid average cost sharing of $2,706, and less than 10 percent paid $4,750 from their OOP spending alone ($4,750 was Part D's OOP threshold in 2013). Under the current approach, from the enrollees' perspective, manufacturer discounts may have an effect similar to copayment coupons offered by manufacturers of brand-

FIGURE 6–7

Brand-name drugs are treated differently from generics in the coverage gap



Source: MedPAC based on Kaiser Family Foundation 2010.

name drugs; that is, by replacing their cost-sharing liability, the discounts may provide greater incentive to use brand-name drugs when lower cost options are available (Maggs and Kesselheim 2014). This discrepancy could be mitigated in 2020, when the same 25 percent coinsurance will apply to both brand-name drugs and generics. If manufacturer discounts had not been counted toward the OOP threshold, most individuals likely would not have reached Part D's catastrophic phase as quickly, and some would not have reached it at all. Meanwhile, enrollees who used generic medications alone would need to pay more out of their own pocket before reaching the OOP threshold, since they would not receive manufacturers' discounts.

Individual enrollees' level of drug spending at the OOP threshold depends on mix of brand-name and generic prescriptions

In Part D's coverage gap, the share of drug spending counted toward the out-of-pocket (OOP) threshold differs between brand-name and generic drugs. For example, consider two beneficiaries who, by the middle of 2016, have already accumulated $3,310 in drug spending, which marks the start of the coverage gap. Here we consider each beneficiary's next $100 of spending for either a generic or brand-name prescription, but bear in mind that in 2013, the average retail price of a brand-name prescription under Part D was 13 times more expensive than a generic ($242 per standardized 30-day supply of a brand-name drug compared with $18 for a generic). The first beneficiary pays $100 toward a generic prescription. Her plan covers 42 percent ($42); she pays 58 percent and receives $58 credit toward her true OOP threshold. A second beneficiary also pays $100, but toward a brand-name prescription. The pharmacy reduces the price by $50 because of the brand-name discount, the enrollee pays 45 percent ($45), and his plan pays 5 percent ($5). Under current policy, the second enrollee is credited with $95 of true OOP spending—$45 out of his own pocket and $50 from the brand manufacturer. Even though both beneficiaries spent the same amount ($100), the second enrollee is $37 closer to reaching his $4,850 OOP threshold ($95 minus $58) than the first enrollee because he used a brand-name drug.

This example shows how spending at the OOP threshold varies across individuals depending on the mix of brand-name and generic drugs they use. Enrollees are credited with relatively more OOP spending when they use brand-name drugs than when they use generics. A beneficiary using only brand-name drugs would reach Part D's $4,850 OOP threshold at $7,260 in total spending. By comparison, an enrollee who used only generic drugs would reach the OOP threshold at $9,780 in total spending. ■

Limit enrollee cost sharing above the OOP threshold

Prices of some specialty drugs have reached levels around $100,000 or more per regimen before rebates. Plans often require enrollees to pay 25 percent to 33 percent cost sharing for these drugs and higher cost sharing in the coverage gap until the patient reaches Part D's OOP threshold, after which the patient pays 5 percent of the price. Part D enrollees are not permitted to use manufacturers' coupons to reduce their cost sharing because such arrangements are considered an inducement.[14] Beneficiaries who do not receive the LIS but who do have a condition for which specialty drugs are prescribed can face significant financial challenges to pay cost sharing before they reach Part D's OOP limit. Even after they reach that threshold, 5 percent of the price of each prescription can be substantial. For some specialty drugs, an enrollee could potentially pay one-third to more than half of all their out-of-pocket costs above Part D's OOP threshold (Hoadley et al. 2015).

To analyze the extent of this burden, we examined the average cost-sharing amounts paid out of pocket by non-LIS enrollees once they entered the catastrophic phase of the benefit. In 2013, OOP spending averaged $2,706 among the roughly 700,000 non-LIS enrollees who reached the OOP threshold (Table 6-7). That amount is less than the $4,750 threshold amount in Part D's benefit structure for 2013 because manufacturer discounts averaging $2,293 were counted as true OOP spending. Of the $2,706 paid by the enrollee, about $814 (30 percent) was for cost sharing paid in the catastrophic phase of the benefit. However, many beneficiaries paid less.

Three-quarters of the 700,000 enrollees paid $664 or less in cost sharing above the OOP threshold (Table 6-7). Those enrollees reached Part D's OOP threshold at an average of $8,966 in total drug spending. Of that amount, manufacturers' discounts contributed an average of $2,372 and enrollees paid an average of $1,983 themselves, or 22 percent of the total spending below the OOP threshold. Above the OOP threshold, those enrollees paid on average an additional $221, or 10 percent of their combined OOP spending. The effective average coinsurance rate in the benefit's catastrophic phase was 4 percent for this group of enrollees. Altogether, in 2013, these high-cost enrollees

TABLE 6–7

Average drug spending and cost sharing paid OOP among non-LIS enrollees who incurred high costs in 2013

	Benefit phases			
	All benefit phases	Below OOP threshold	Above OOP threshold	Percent above OOP threshold
All enrollees				
Total drug spending	$20,847	$8,647	$12,200	59%
Cost sharing paid OOP	2,706	1,892	814	30
Manufacturer discounts	2,293	2,293	N/A	N/A
Percent of drug spending paid OOP	13%	22%	7%	
Enrollees with OOP costs in catastrophic phase at or below 75th percentile ($664)				
Total drug spending	$14,372	$8,966	$5,406	38%
Cost sharing paid OOP	2,204	1,983	221	10
Manufacturer discounts	2,372	2,372	N/A	N/A
Percent of drug spending paid OOP	15%	22%	4%	
Enrollees with OOP costs in catastrophic phase above 75th percentile ($664)				
Total drug spending	$40,273	$7,692	$32,581	81%
Cost sharing paid OOP	4,213	1,618	2,596	62
Manufacturer discounts	2,054	2,054	N/A	N/A
Percent of drug spending paid OOP	10%	21%	8%	

Note: OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable).

Source: MedPAC analysis of Part D prescription drug event data.

spent $14,372 on drugs, about 16 percent of which paid for generic drugs (data not shown).

The remaining 25 percent of high-cost, non-LIS enrollees had OOP spending greater than $664 in 2013. Those enrollees reached their OOP threshold at an average of $7,692 in drug spending, but their overall drug spending averaged more than $40,000 so that 81 percent of their spending was incurred in the benefit's catastrophic phase. On average, about 8 percent of their spending paid for generic drugs (data not shown). Manufacturers' discounts for brand-name drugs averaged $2,054, and enrollees paid an average of $1,618 themselves, or 21 percent. Because so much of their total drug spending was in the catastrophic phase of the benefit, those enrollees paid much higher amounts themselves, averaging $2,596, which accounted for 62 percent of their total OOP spending ($4,213).

There are pros and cons associated with providing more complete OOP protection than Part D provides today. High amounts of cost sharing may discourage beneficiaries from using appropriate therapies. Further, the current benefit structure appears to provide greater OOP protection to individuals with mid-to-low drug spending, with no limit on cost sharing for those with the highest spending. Enrollees in MA plans already have a hard OOP limit on spending for their Part A and Part B benefits. Some analysts contend that prescribers (more than enrollees) establish patterns of prescription therapy long before the beneficiary reaches the OOP threshold, and cost sharing above the cap would be punitive rather than provide incentives to use lower cost medicines. However, it is not

always clear that some high-priced drug therapies improve clinical outcomes for patients. The absence of cost sharing may result in higher necessary and unnecessary use of both high-priced and other therapies.

Potential effects of changes related to the OOP threshold

The Commission recommends three changes related to Part D's OOP threshold: (1) reduce Medicare's individual reinsurance from 80 percent to 20 percent; (2) exclude manufacturer discounts on brand-name drugs from counting toward enrollees' OOP spending; and (3) provide Part D enrollees with an absolute, or "hard," OOP cap once they reach the catastrophic threshold.

Analyzing the effects of these policy changes is challenging for several reasons. Part D's defined benefit structure has multiple cost-sharing phases, and the level of drug spending needed to reach the catastrophic phase of the benefit varies across individuals depending on their mix of brand-name and generic drugs. Part D plans use different benefit designs, sometimes with enhanced (supplemental) benefits. For example, it appears that enrollees with high spending may seek out enhanced benefits. Claims data show that among the non-LIS enrollees with high costs in 2013, enhanced benefits through Part D plans covered an average of $540 of their drug spending.

The gradual phaseout of the coverage gap means that Part D's benefit will become more generous each year until 2020. In turn, that new benefit structure could affect the share of Part D enrollees who reach the OOP cap. However, we did not try to model effects of the policy changes in 2020 because of the large amount of uncertainty in the future distribution of drug spending. Projecting future drug spending would involve predicting the entry dates of new drugs and biologics into the market and the prices at which they would be launched, the degree to which physicians would prescribe new drugs to patients, price trends for drugs already on the market, plans' success at encouraging use of lower cost drugs, and enrollment levels in Part D, among other factors.

Combined effects of applying the true OOP provision to manufacturer discounts and eliminating cost sharing on spending above the OOP threshold If the true OOP provision had applied to manufacturer discounts in 2013, then beneficiaries would have had to spend higher amounts themselves to reach the OOP threshold because manufacturer discounts would no longer have been counted as the enrollee's OOP spending. At the same time, eliminating cost sharing above the OOP threshold would provide better protection to all enrollees in the sense that Part D would offer true insurance. Based on our analysis of the Part D claims data for 2013, we estimate the two policy changes would have the following combined effects:[15]

- At the 2013 rates of coinsurance, on average, all of the 700,000 non-LIS enrollees would remain in the coverage gap longer and would each pay about $1,000 more in cost sharing.
- Manufacturers of brand-name drugs would pay an average additional $1,000 per enrollee because they would be offering brand discounts throughout a longer coverage-gap phase.
- About half of the 700,000 non-LIS enrollees who reached the OOP threshold in 2013 would no longer reach that threshold.
- The remaining 350,000 non-LIS enrollees would still have OOP spending high enough to reach the benefit's catastrophic phase, but the hard OOP cap would provide an upper limit on their spending. On average, individuals who reached the hard OOP cap would pay about $1,000 less in catastrophic cost sharing. Combining the hard OOP cap with the change in the treatment of manufacturer discounts would result in better financial protection for individuals with the highest costs.
- Because fewer enrollees would reach the OOP threshold, Medicare's subsidy payments for spending above the threshold would also be lower. In 2013, that reduction would have totaled about $1 billion.
- Part D enrollees would experience little or no change to their monthly premiums. On its own, the exclusion of manufacturer discounts from the true OOP provision would lower premiums slightly (less than $1 per month) because there would be fewer enrollees reaching the OOP threshold. Likewise, on its own, a hard OOP cap would lead to slightly higher monthly premiums for all enrollees (also less than $1) because the Part D benefit would be more generous. Because these premium changes are of about the same magnitude, there would be little or no net change in monthly premiums paid by Part D enrollees.
- From Medicare's perspective, the increase in the benefit costs resulting from the expanded benefit

would be offset almost entirely by reductions in the program's subsidy payments for low-income cost sharing. In other words, Medicare had formerly paid for the 5 percent cost sharing on behalf of LIS enrollees; however, under the proposed change, that amount would now be part of Part D's basic benefit.

Estimated effects and future uncertainties A caution about estimating the effects of proposed changes is that many factors could influence the outcome. For 2013, the number of non-LIS enrollees who reached the OOP threshold was still fairly small—about 700,000 individuals—but their numbers are growing (Medicare Payment Advisory Commission 2016). In addition, the Medicare Trustees expect that use of and prices for biologics and specialty drugs will increase faster than other components of health care spending (Boards of Trustees 2015). Those factors could push the costs of a hard cap on OOP spending considerably higher. Scheduled changes to Part D's benefit structure and other changes to the underlying distribution of drug spending will also factor into the effects of changes to the true OOP provision by 2020.

The effects described above assume no behavioral change on the part of plan sponsors or enrollees, but behavioral changes would be likely. For example, eliminating all cost sharing above Part D's OOP threshold could lead some enrollees to fill more prescriptions. Also, the exclusion of the manufacturer discount from the true OOP spending could affect beneficiaries' decisions about choosing generic alternatives when available by changing the relative price of brand-name and generic drugs.

Finally, to the extent that the policy increases the amount of discounts paid by brand manufacturers, it may result in lower manufacturer rebates. At the same time, because plan sponsors would be assuming greater risk under the policy, they may negotiate more aggressively with drug manufacturers over prices and rebates. Thus, it is not clear how the increase in manufacturer discounts would affect the size of manufacturer rebates that plan sponsors would be able to negotiate under the policy.

RECOMMENDATION 6-1

The Commission's first recommendation has three parts. The first would provide more of Medicare's subsidies through capitated payments rather than through individual reinsurance. Under the second part, manufacturer discounts on brand-name drugs would be excluded from true OOP spending. Under the third part, Part D would provide more complete insurance protection against high OOP spending. Specifically, the Commission recommends:

The Congress should change Part D to:

- **transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,**
- **exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and**
- **eliminate enrollee cost sharing above the out-of-pocket threshold.**

RATIONALE 6-1

Since Part D began, individual reinsurance payments rather than capitated payments have assumed a growing share of Medicare's subsidy of enrollees' Part D spending, and the taxpayers' share of the benefit costs has been somewhat greater than the 74.5 percent specified in law. The original intent behind Part D's market-based approach was for private plans to negotiate with pharmaceutical manufacturers and pharmacies over drug prices and to use formularies and differential cost sharing to encourage enrollees to use lower cost medicines. However, the current structure of Medicare's reinsurance subsidy removes the urgency for plan sponsors to manage prescription use of high-cost enrollees and negotiate lower drug prices. The recommendation would give plan sponsors stronger incentives to manage overall benefit spending while retaining the risk protection afforded to plan sponsors through risk corridors. The reduction of Medicare's rate of reinsurance payments over a transition period and the retention of risk corridors would limit the financial impact of the policy on any individual Part D plan sponsor.

The second part of the recommendation relates to the types of expenditures that count toward Part D's OOP threshold for enrollees who do not receive the LIS. (Because LIS enrollees pay comparatively low cost-sharing amounts, these enrollees' OOP spending does not reach Part D's OOP threshold.) Under changes enacted in 2010, pharmaceutical manufacturers of brand-name drugs must provide a 50 percent discount to enrollees beginning at the coverage-gap phase of the benefit, and those discounts are credited toward an enrollees' OOP spending threshold, as if the enrollee paid that amount out of pocket. That policy both lowers the price of brand-name drugs relative to generic drugs and quickens the pace at which an enrollee reaches the OOP threshold (the point at which Medicare currently begins paying for 80 percent of

benefits through reinsurance). Under the current policy's treatment of the brand discount, enrollees who use more generics pay more OOP than those who use brand-name drugs. The second part of the recommendation excludes the manufacturers' discount from what counts toward an enrollee's OOP spending threshold. The change would equalize the treatment of brand-name drugs and generic drugs in the coverage gap. Because the recommendation affects only brand-name drugs, it would have less effect on enrollees with higher use of generic drugs and would not affect enrollees who use only generic drugs during the coverage-gap phase.

The recommendation's third part would provide more complete OOP protection to Part D enrollees by removing any cost sharing above the benefit's OOP threshold. Currently, high-cost enrollees who do not receive the LIS must pay 5 percent of the price of their prescriptions after they reach the threshold. Specialty medicines for certain conditions are priced at thousands of dollars per prescription, so 5 percent cost sharing can be a considerable expense on top of an OOP threshold that, in 2016, reaches $4,850. The recommendation would remove cost sharing above Part D's OOP threshold.

IMPLICATIONS 6-1

Spending

- The Congressional Budget Office estimates that the combination of the Commission's three recommendations would lead to one-year program savings of more than $2 billion relative to baseline spending and more than $10 billion in savings over five years. Separate estimates for each recommendation are not available.

Beneficiaries and providers

- Because this recommendation's first part would provide more of Medicare's 74.5 percent subsidy through capitated payments, plan sponsors would bear more insurance risk for their enrollees' benefit spending. To the extent that sponsors charged a larger risk premium to reflect greater insurance risk or purchased private reinsurance, the policy could increase plans' costs of doing business and put upward pressure on enrollee premiums. However, larger insurers, better positioned to shoulder more insurance risk independently and reinsure themselves, account for the vast majority of Part D enrollment. Plan sponsors with smaller numbers of enrollees could be more likely to purchase private reinsurance. Most parent organizations with smaller Part D enrollment are MA–PDs, some of which already purchase private reinsurance to cover unexpectedly high medical spending. Our discussions with private reinsurers suggest that those types of contracts could be modified to include drug benefits.
- The need for larger risk premiums or private reinsurance could be offset if more of Medicare's subsidy was provided through capitated payments; that is, plan sponsors would have greater motivation to better manage benefits of high-cost enrollees and negotiate larger discounts with pharmaceutical manufacturers and pharmacies. However, the net result of those two opposing forces (potentially higher costs of private reinsurance vs. greater motivation to manage benefits) is uncertain.
- This recommendation's second part would keep the current 50 percent manufacturers' discount on brand-name drugs that begins in the Part D benefit's coverage gap. However, because those discounts would no longer count as an enrollee's OOP spending, fewer non-LIS enrollees would reach Part D's OOP threshold. We estimate that in 2013, this situation would have applied to about 350,000 enrollees. However, to the extent that the policy change would encourage greater use of lower cost drugs, it could lead to lower OOP spending for those enrollees. The policy change would have less effect on enrollees with higher use of generic drugs and would not affect enrollees who use only generic drugs during the coverage gap phase. The recommendation would expose some beneficiaries to higher cost sharing in the coverage gap. We estimate that in 2013, all of the 700,000 non-LIS enrollees who reached the coverage gap would remain in the gap phase longer and would each pay, on average, about $1,000 more in cost sharing.
- We estimate that the third part of this recommendation, when combined with the second part, would have eliminated cost sharing above Part D's OOP threshold for approximately 350,000 enrollees in 2013. On average, beneficiaries who reach the OOP threshold would have an average of $1,000 less in cost sharing above the OOP threshold because of the new cap.

Greater financial incentives for enrollees with the low-income subsidy to use lower cost medicines

In 2015, Part D's LIS provided nearly 12 million low-income beneficiaries with help paying their premiums and cost sharing. Of these individuals, more than 7

million were dually eligible for Medicare and Medicaid. Another 4.6 million qualified for the LIS either because they received benefits through the Medicare Savings Programs or the Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. LIS enrollees are more likely than other Part D enrollees to be female; African American, Hispanic, or Asian American; and under age 65. They also tend to have poorer health status and higher risk scores. In 2015, about 70 percent of LIS enrollees were in PDPs, and 30 percent were enrolled in MA–PDs.

The maximum amounts of cost sharing that LIS enrollees pay out of pocket are set in law, and Part D plan sponsors cannot vary those amounts. In 2016, beneficiaries who are dually eligible for Medicare and Medicaid and other beneficiaries with incomes less than 100 percent of the federal poverty level (FPL) pay up to $1.20 to fill a generic prescription, up to $3.60 for brand-name drugs, and zero above Part D's OOP threshold. Other beneficiaries with incomes between 100 percent and 150 percent of the FPL (who meet certain asset tests) pay $2.95 for generic prescriptions and $7.40 for brand-name drugs.[16] Most LIS enrollees do not face a coverage gap. However, a small number of individuals with a partial LIS must pay a $74 deductible before paying reduced copayments and then 15 percent coinsurance in the coverage gap. Beneficiaries with the LIS who reside in long-term care institutions or who receive home and community-based services pay no cost sharing.

Differential cost sharing across formulary tiers is a fundamental tool used by plan sponsors to manage their enrollees' drug spending (Medicare Payment Advisory Commission 2016). This approach provides financial incentives to enrollees to use lower cost drugs. However, those financial incentives do not apply to LIS enrollees because the maximum OOP cost-sharing amounts for them are set by law. For example, if a full-benefit dual-eligible beneficiary filled a prescription through her PDP that used a benefit design that charged $3 for a preferred generic drug and $10 for other generics, the LIS enrollee would pay $1.20, even if her prescription was not for a preferred generic. Part D's low-income cost-sharing subsidy would pay for the $8.80 difference ($10 minus $1.20). Likewise, if the plan's benefit design charged $35 for a preferred brand-name drug and $85 for a nonpreferred brand, the LIS enrollee would pay $3.60 out of pocket for a nonpreferred brand prescription and Medicare's low-income cost-sharing subsidy would pay $81.40.

The amounts of cost sharing that Medicare pays on behalf of LIS enrollees are substantial. For example, in 2013, Medicare's low-income cost-sharing subsidy totaled $19.5 billion—an amount much larger than the approximate $5 billion Medicare paid for premiums on behalf of LIS enrollees. An analysis by Acumen LLC of the average percentage of cost sharing for LIS enrollees at different intervals of annual total spending helped us compare what LIS enrollees pay out of pocket with what Medicare pays on their behalf for cost sharing.

Table 6-8 (p. 186) shows cost-sharing amounts for LIS beneficiaries with annual total drug spending that occurred at different phases of the benefit.[17] Cost-sharing amounts shown are for an enrollee with average annual spending in each spending range based on actual spending in 2013. For example, about 15 percent of LIS enrollees had total drug spending between $1 and $324 in 2013. Because many LIS enrollees were in plans with a deductible, the average cost sharing charged by plans for these enrollees was 85 percent of the total drug costs. However, most LIS enrollees paid nominal copayments out of pocket, and Medicare's low-income cost-sharing subsidy paid most of the deductible on their behalf. As a result, LIS enrollees with spending between $1 and $324 paid 13 percent of their drug costs, while Medicare's low-income cost-sharing subsidy paid 72 percent.

Twenty-one percent of LIS enrollees had drug spending between $2,970 and $6,954.51, which is the range of spending in which non-LIS enrollees face a coverage gap. However, LIS enrollees do not face a coverage gap; most continue to pay nominal copayments for each prescription, with Medicare paying the remaining cost-sharing amounts charged by their plans. Seventeen percent of LIS enrollees had spending high enough to reach Part D's OOP threshold (7 percent with spending between $6,954.52 and $9,999, plus 10 percent with spending of $10,000 or more).

In its March 2012 report, the Commission recommended that the Congress give the Secretary authority to provide stronger financial incentives for LIS enrollees to use lower cost generics when available (Medicare Payment Advisory Commission 2012). At the time, a key rationale for the recommendation was that LIS enrollees made up the majority of beneficiaries who reached the catastrophic phase of the benefit. This rationale continues to be true; in 2013, LIS enrollees made up 75 percent of high-cost enrollees. Encouraging LIS enrollees to use lower cost generics could reduce the number of individuals who

TABLE 6–8

Cost-sharing amounts paid by LIS enrollees and by Medicare's low-income cost-sharing subsidy in 2013

			Average percent paid in cost sharing			Average dollars paid in cost sharing		
Gross drug spending per beneficiary	Percent of LIS enrollees	Average spending per LIS enrollee*	LIS enrollees' OOP cost sharing	LIS enrollees' OOP combined with LICS	LICS	LIS enrollees' OOP cost sharing	LIS enrollees' OOP combined with LICS	LICS
$0	8%	$0	N/A	N/A	N/A	N/A	N/A	N/A
$1–$324	15	146	13%	85%	72%	$19	$124	$105
$325–$2,969	39	1,276	5	45	40	68	573	505
$2,970–$6,954.51	21	4,426	3	55	52	130	2,429	2,299
$6,954.52–$9,999	7	8,272	2	58	56	148	4,805	4,658
≥$10,000	10	22,073	0.5	25	25	113	5,619	5,506

Note: LIS (low-income subsidy), OOP (out-of-pocket), LICS (low-income cost-sharing subsidy), N/A (not applicable). Beneficiary OOP includes all payments made by or for a beneficiary (excluding low-income cost sharing) that would be treated as OOP for the purpose of determining when he or she has reached the catastrophic phase of the benefit.
*Average across all LIS enrollees with total (gross) annual spending that falls within the spending ranges.

Source: MedPAC based on Acumen LLC analysis for MedPAC.

reach the catastrophic phase of the benefit and thereby reduce the amount Medicare pays to plans in individual reinsurance. It could also reduce Medicare's spending for low-income cost sharing.

The President's budget proposals for 2016 and 2017 included similar modifications to Part D's LIS copayment amounts. Specifically, the proposals would lower LIS copayments for generic drugs and double them for brand-name drugs. To protect beneficiaries, the Secretary would have authority to select only therapeutic classes with generic alternatives for which generic substitution would be clinically appropriate. She would also have authority to exclude brand-name drugs from this policy in therapeutic classes for which she determines that therapeutic substitution is not appropriate or for which no generics are available (Department of Health and Human Services 2016, Department of Health and Human Services 2015). Institutionalized LIS enrollees would continue to pay zero cost sharing, and LIS enrollees with a partial subsidy would pay the new copayment amounts above Part D's OOP threshold. For the President's 2017 budget proposal, the Congressional Budget Office estimated that this policy would reduce Medicare spending by $7.2 billion over 5 years and by $18.3 billion over 10 years (Congressional Budget Office 2016).

Some empirical research supports the idea that zero-dollar copayments could encourage greater use of generics and may improve medication adherence. One study based on 2008 Part D claims for statins that excluded LIS enrollees found that having a zero copayment for generic statins was associated with an especially large effect on generic use (Hoadley et al. 2012). More recently, CMS researchers examined the generic substitution rates of LIS enrollees and non-LIS enrollees in Part D plans that charged no copayment for generic drugs. (If an LIS enrollee's plan benefit design charges no copayment, the beneficiary pays nothing rather than the statutory amount.) The study found that in 2012, about 21 percent of plans had a generic tier with no copayment, and those plans enrolled about 11 percent of all Part D enrollees. Average rates of generic substitution were 1 percentage point to 3 percentage points higher for LIS enrollees and non-LIS enrollees (estimated separately) in plans that charged no generic copays (Centers for Medicare & Medicaid Services 2015b).

In discussions last year between plan sponsors and Commission staff, plan representatives were highly supportive of giving LIS enrollees stronger financial incentives to use lower cost options. Many of the individuals noted the lower use of generics by LIS enrollees, and some voiced frustration with plans' inability

to use differential cost sharing to a greater degree. Many plan sponsors noted that because of the statutorily set copayments, their plans that enroll higher shares of LIS enrollees use "leaner" formularies that cover fewer drugs, and they apply utilization management tools more frequently.

When Commission staff spoke with beneficiary advocates, they supported the idea of charging zero copayments for generics, but had strong concerns about any increases to LIS copayments for brand-name drugs. Given the limited incomes and poorer health status of the LIS population, beneficiary advocates believe the policy would be burdensome or that low-income beneficiaries would not fill prescriptions for needed medications (Leadership Council of Aging Organizations 2014). Advocates believe that a better approach would be for plans to contact prescribers directly about medically appropriate substitutions.

Since 2012, when the Commission last examined the issue of LIS cost sharing, the Food and Drug Administration (FDA) has approved the first biosimilar product, and other biosimilar products are under review.[18] The current LIS copayment structure does not distinguish between biosimilars and their reference products; LIS enrollees would pay the same brand-name copayment in either case. The introduction of biosimilars may lead to lower prices over time, so Medicare may want to encourage their use when clinically appropriate to help keep the Part D program financially sustainable.

With that consideration in mind, a second recommendation would slightly modify the Commission's recommendation on LIS cost sharing from 2012. The recommendation would have the Secretary consider moderately increasing financial incentives for LIS enrollees to use lower cost medicines, including generic drugs, preferred multisource drugs, and biosimilars. To protect beneficiaries, the Secretary would have authority to select therapeutic classes to which this policy would apply—classes that have generics or biosimilars available and for which substitution would be clinically appropriate. Plan sponsors would need to ensure that their prior authorization and their appeals and grievance processes allowed access to needed medications in cases where therapeutic substitution was not clinically appropriate.

RECOMMENDATION 6-2

The Commission's second recommendation slightly modifies its 2012 recommendation on statutory copayment amounts for Part D enrollees who receive the LIS. Specifically, the Commission recommends that:

The Congress should change Part D's low-income subsidy to:

- **modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;**
- **direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and**
- **direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.**

RATIONALE 6-2

Plan sponsors routinely use differential cost sharing to make generics and lower cost drugs and biologics more attractive to enrollees. However, since maximum cost sharing for LIS enrollees is set by law and plans cannot modify those amounts, sponsors have limited ability to manage drug spending for this population. Current LIS copayments provide much weaker financial incentives than those faced by non-LIS enrollees. This recommendation would give the Secretary flexibility to determine clinically appropriate therapeutic classes and cost-sharing amounts, which would strengthen financial incentives to use lower cost drugs and biosimilars while ensuring affordability of medicines for LIS enrollees. By directing the Secretary to review the therapeutic classes at least every three years, the recommendation would ensure that the latest clinical evidence could be used to determine the appropriate therapeutic classes for applying this policy.

IMPLICATIONS 6-2

Spending

- The Congressional Budget Office estimates that the combination of this chapter's three recommendations would lead to one-year program savings of more than $2 billion relative to baseline spending and more than $10 billion in savings over five years. Separate estimates for each recommendation are not available.

Beneficiaries and providers

- Lower copayments for generics, preferred multisource drugs, and biosimilars would reduce OOP costs for beneficiaries on generic, preferred

multisource, or biosimilar medications and for beneficiaries who switched from brand-name drugs and reference biologics. This change could increase beneficiaries' access to medications and improve adherence to therapies. Some plan sponsors could experience a decrease in the costs of providing the benefit if their LIS enrollees switched from brand-name drugs and reference biologics to generic and other preferred multisource drugs and biosimilars. Those lower costs would tend to decrease premiums for all enrollees and reduce subsidy payments from Medicare to Part D plans.

Increased flexibility to use formulary tools

If Part D plans were required to take on more risk, they would have stronger incentives to manage enrollees' drug spending. However, plan sponsors also need stronger tools to carry out that management, particularly in how they operate their drug formularies.

Formulary design is the key tool used by plans to manage drug benefits. Plan sponsors must decide which drugs to include on the formulary, which cost-sharing tier is appropriate for each drug, and whether a drug will be subject to prior authorization or other forms of utilization management. Those decisions, in turn, require that plan sponsors strike a balance between providing access to medications while encouraging enrollees to use lower cost therapies. Decisions about formulary design also affect plan sponsors' bargaining leverage with pharmacies and pharmaceutical manufacturers over drug prices and rebates.

Part D regulations and policy guidance were designed to ensure that Medicare beneficiaries, with their higher disease burden, have access to medications. The regulations limit how Part D plan sponsors operate their formularies compared with how the same sponsors manage formularies for their commercial populations. We first provide an overview of Part D formulary requirements and coverage determinations and then describe specific areas for recommended change.

Part D formulary requirements and coverage determinations

Law and regulations lay out specific requirements for Part D plan formularies. Plans 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 addition to considering drug prices, rebates, and cost effectiveness, P&T committees base decisions about plan coverage and formulary design on the strength of scientific evidence and standards of practice.

Part D plans must provide an adequate formulary. In that regard, CMS must review and approve each plan's formulary to ensure that it would not substantially discourage enrollment by any group of eligible individuals such as those with certain conditions. Under a "safe harbor" provision in regulation, many plan sponsors choose to avoid a rigorous review of their drug categories and classes by adopting model guidelines for therapeutic classes established by the U.S. Pharmacopeia.[19] Plans must include coverage of the types of drugs most commonly needed by Part D enrollees as recognized in national treatment guidelines. For most drug classes, plans must cover at least 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. Because of these provisions, some analysts have noted that Medicare "limits the freedom of Part D plans to control their formularies" (Outterson and Kesselheim 2009).

As with commercial plans, Part D plans must allow formulary exceptions—coverage of a nonformulary drug under certain circumstances such as a patient's potential for an adverse reaction to the formulary drug or prior experience that the drug was ineffective for the patient. However, unlike commercial plans, Part D plans must also allow tiering exceptions—requests for the enrollee to pay lower preferred cost-sharing amounts for nonpreferred drugs. (Tiering exceptions do not apply to specialty tiers or to LIS copays, which are specified by law rather than part of a plan's benefit design and formulary structure.)

Medicare requires plan sponsors to establish coverage determination and appeals processes with the explicit goal of ensuring that plan formularies do not impede access to needed medications. The burden associated with navigating these processes varies from plan to plan. Part D law also requires sponsors to have a transition process to ensure that new enrollees, as well as current members

whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.[20] The transition-fill policy is intended to give enrollees time either to find an alternative that is on the plan's formulary or to initiate an exception request.

If an enrollee's prescription claim is rejected at the point of sale, the pharmacy is required to provide the enrollee with written information about how to obtain a detailed written notice from the enrollee's plan about why the benefit was denied and their right to an appeal. However, the enrollee must contact the plan to find the reason for the refusal and must initiate a request for a coverage determination with supporting justification from the prescriber.

Part D requires quicker adjudication time frames than for Medicare Advantage 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). Plan sponsors must make a decision about exceptions and coverage determination within 72 hours of a request or within 24 hours for expedited requests. If the plan contacts the prescriber but is not able to obtain the supporting information needed to make a coverage determination within the allotted time, the plan must issue a denial and then process any subsequent information it receives as a redetermination.

In our discussions, stakeholders—beneficiary advocates, prescribers, plan sponsors, and CMS—have all noted frustrations with Part D coverage determinations, exceptions, and appeals (see text box about these processes, p. 190). A more efficient approach would be to resolve such issues at the point of prescribing through e-prescribing and electronic prior authorization rather than at the pharmacy counter. Such tools could reduce the need for coverage determinations and appeals and could increase the likelihood that beneficiaries receive an appropriate medicine at the pharmacy. Automated processes could also lower administrative burden and lead to a more uniform approach for beneficiaries, prescribers, and plans (American Medical Association 2015). Part D plan sponsors are required to support electronic prescribing, but e-prescribing is optional for physicians and pharmacies.[21] While beneficiary advocates are generally supportive of such steps, some contend that they would not be sufficient to address persistent challenges (Medicare Rights Center 2016).

Revisit the protected classes

The "protected class" policy was intended to ensure access to medications in classes for which access cannot be adequately ensured through existing beneficiary protections. Plan sponsors are permitted to place protected-class drugs on preferred and nonpreferred cost-sharing tiers, but they cannot remove a drug altogether from their formulary, which limits their leverage in price negotiations. Because the policy requires open coverage of drugs in those classes, CMS noted in a 2014 proposed rule that the policy "presents both patient welfare concerns and financial disadvantages for the Part D program as a result of increased drug prices and overutilization." The agency also noted that protected status may "substantially limit Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes" (Centers for Medicare & Medicaid Services 2014).

Part D restricts how plan sponsors may apply utilization management tools such as prior authorization for drugs in the protected classes. In the case of an enrollee just starting to take a protected-class drug, Part D guidance permits sponsors to apply utilization management tools. However, for enrollees who are already using a protected-class medication, plan sponsors may not use prior authorization or step therapy to steer the enrollee toward preferred alternatives.

In its 2014 proposed rule, CMS suggested applying a two-step test to determine which drug classes are of sufficient clinical concern to merit protection. The criteria included the following:

- hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration of a drug in the category or class does not occur within seven days of the date the prescription was presented to the pharmacy to be filled; and
- more specific CMS formulary requirements will not suffice to meet the universe of clinical drug-specific and disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

In other words, a drug class would not be given protected status unless a delay in obtaining a medication would likely result in serious health consequences and the clinical

Part D's exceptions and appeals process

The Part D appeals process is complex, involving multiple levels. After examining Part D's exceptions and appeals process, we found insufficient data to evaluate how well the process is working for beneficiaries to gain access to needed medications (Medicare Payment Advisory Commission 2015b, Medicare Payment Advisory Commission 2014c). We also found that the process can be time consuming and frustrating and may be burdensome for some individuals (Hargrave et al. 2015, Hargrave et al. 2012). Similarly, CMS audits continue to find that plans have difficulties in the areas of Part D coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2015c). These findings suggest a need for increased transparency and streamlining of the coverage determination process so that beneficiaries and prescribers are not discouraged from seeking exceptions for needed medications.

At the same time, exceptions and appeals that routinely overturn plans' coverage decisions could undermine plans' efforts to manage drug spending. A representative of one plan sponsor we spoke with described the sponsor's experience in which the plan's negative coverage decisions of nonformulary drugs were routinely overturned (reversed) by an independent review entity (IRE). The plan sponsor was generally not successful in appealing IRE decisions, which were typically denied on the grounds that supporting statements provided by prescribers proved the medical necessity for the drug—even when those statements were extremely general such as, "this is the right drug for the patient." Because a Part D plan's star rating includes how often its coverage decisions are overturned by the IRE, such cases can have a chilling effect on a plan's willingness to use formulary tools—including on-formulary or off-formulary status to manage the use of expensive medications. That situation, in turn, can affect the rebate negotiations with pharmaceutical manufacturers.

CMS has expressed repeated concerns that some Part D sponsors reject claims inappropriately and are not fully compliant with transition-fill requirements (Centers for Medicare & Medicaid Services 2015c, Centers for Medicare & Medicaid Services 2012, Centers for Medicare & Medicaid Services 2010b). Recently, CMS applied civil and monetary sanctions against several Part D plan sponsors for failure to comply with regulations in areas such as formulary requirements, coverage determinations, and exceptions and appeals processes (Centers for Medicare & Medicaid Services 2016c).

In 2015, CMS conducted a "point-of-sale pilot" with four Part D plan sponsors to identify alternatives to beneficiaries having to request coverage determinations from their plans. Each sponsor took a somewhat different approach in identifying which drugs to focus on and how to communicate with prescribers and pharmacies. The pilot had mixed results in terms of helping beneficiaries to obtain an appropriate medication from the pharmacy. Plans that participated in the pilot found the process to be labor intensive, and the key difficulty appeared to be engaging prescribers (Centers for Medicare & Medicaid Services 2016d). Several participants suggested that more fruitful approaches would include promotion of e-prescribing, better real-time queries about formulary coverage at the point of prescribing, and broader use of electronic prior authorization. ■

needs of patients treated with one or more medications in that drug class cannot be met unless all Part D drugs in that class were included on a plan formulary. After reviewing medications in the six protected classes, in 2014, CMS proposed removing antidepressants and immunosuppressants for transplant rejection from protected status.[22] (CMS also found that antipsychotics did not meet the two-part test. However, the agency did not propose removing antipsychotics from protected-class status because of the clinical risk associated with untreated psychotic illness.) The Commission noted in comments to CMS that it was generally supportive of applying objective criteria in determining classes of clinical concern while balancing the goals of beneficiary access and welfare with Part D plans' tools to manage the drug benefit and appropriately constrain costs (Medicare Payment Advisory

Commission 2014a). Ultimately, however, CMS never adopted its proposed changes to the protected classes because of stakeholder concerns.

The Commission continues to support CMS's proposal to remove antidepressants and immunosuppressants for transplant rejection from protected status. The two classes have a number of generic versions of drugs available. In the case of antidepressants, a patient may need to use several drugs before finding effective treatment. Among commercial plans that are not subject to CMS's formulary requirements, our cursory review of several commercial formularies suggests that plans already include a number of generic drugs, each with different molecular structures, as therapeutic alternatives.

In the Commission's March 2016 report to the Congress, we noted that, when measured by individual national drug codes, prices for protected-class drugs showed a trend between 2006 and 2013 similar to that for all Part D drugs, rising by a cumulative 38 percent. However, when protected-class drugs were grouped to take generic substitution into account, their prices declined by a cumulative 16 percent over the same period (Medicare Payment Advisory Commission 2016). For this reason, the degree to which plans could achieve additional savings is unclear. To the extent that enrollees still use brand-name drugs in the antidepressant and immunosuppressant classes, the recommendation could give plan sponsors additional bargaining leverage with manufacturers.[23]

Formulary changes

Continuity of a plan's formulary is very important for beneficiaries, allowing them to maintain access to the medications that were offered by their plan at the time they enrolled. However, there may be circumstances in which new clinical information about a drug or the entrance of a new competing therapy may warrant changes to a formulary in the middle of a benefit year. CMS's rules regarding formulary changes warrant examination.

CMS reviews two sets of formularies for each plan: (1) one set for the upcoming year and (2) proposed formulary changes that would be effective during the current (ongoing) benefit year (referred to as "midyear changes"). In both situations, plan representatives discussed streamlining CMS's process for reviewing applications.

In setting the formulary for the upcoming year, plan sponsors have limited time to ask CMS to change their formularies in response to changing market conditions or new clinical information. To address this problem, CMS could consider offering one or more additional update opportunities. Plan sponsors submit their proposed formularies to CMS for the upcoming year no later than June as part of their bids.[24] CMS allows plans to submit limited types of proposed changes typically in July, but sponsors have no other opportunity to request changes until January of the new benefit year, for an effective date of March 1. Such a long gap can lead to difficulties in formulary administration, such as delays in adding drugs approved by the FDA late in the year or updating utilization management criteria in response to new FDA-approved indications.

There are also opportunities to streamline the process for midyear formulary changes, especially of the type that Part D guidance says CMS would generally approve. Part D regulations classify midyear formulary changes as either "enhancements" or "negative" changes. Adding a drug to the formulary or removing utilization management is an enhancement, while removing a drug from a formulary or setting new utilization management requirements is a negative change. Plan sponsors can implement enhancements to formularies at any time and are not required to seek CMS approval. However, plan sponsors must request and receive CMS approval before carrying out most negative changes (Government Accountability Office 2011). Plans must also give affected enrollees 60 days' notice before the change.

Part D guidance notes that the vast majority of negative changes to formularies are "maintenance changes" that CMS would generally approve. Examples of maintenance changes include (1) the plan sponsor's desire to remove a brand-name drug and substitute a new generic drug after the generic's entry in the market or after the publication of new clinical guidelines and (2) the plan's P&T committee recommendation to put a drug on a higher tier or to apply prior authorization. For maintenance changes, plan sponsors can send enrollees notification as soon as they submit their request to CMS. Part D guidance states that, if the plan has not heard from CMS within 30 days, it can assume that the change was approved. However, some plan sponsors wait for approval to avoid the risk of sending notifications on a change that CMS disapproves.

"Nonmaintenance changes" occur when a sponsor removes a drug from its formulary, moves a drug to a nonpreferred tier, or adds utilization management edits. Part D guidance states that plan sponsors must obtain

approval from CMS before carrying out nonmaintenance changes, and CMS officials have noted that it would tend to approve such situations only under extraordinary circumstances. When CMS approves such a change, enrollees currently taking the affected drug must be exempt from the formulary change for the remainder of the benefit year. Plan representatives told Commission staff that they recognize the need for CMS to evaluate nonmaintenance formulary changes. However, in their experience, CMS's criteria for approval or denial can be unclear, and some plan sponsors believe they have not had an opportunity to share information with CMS about why their P&T committee chose to propose such a change. In the case of nonmaintenance changes, sponsors may not send enrollees notice of the change until they have received formal approval from CMS. Plan sponsors report that the process of seeking approval for and implementing a maintenance change can sometimes take three to six months, and for this reason, some sponsors believe there is no value in submitting requests in the last one or two quarters of the benefit year.[25]

Ideally, Medicare's review process would continue to guard against negative changes that affect beneficiaries' access to needed medications but would expedite midyear changes that CMS would generally approve. CMS could provide plan sponsors with greater flexibility to make certain maintenance changes, such as adding a generic drug and removing the brand-name version, without first receiving agency approval. Under that approach, the plan would still be required to file the change with CMS, and the plan sponsor would be subject to enforcement actions if it had not provided plan enrollees with timely access to the medication.

Rationalizing the exceptions process

Plan sponsors use utilization management tools such as quantity limits, step therapy, and prior authorization for expensive drugs to encourage use of lower cost therapies or to ensure appropriate use of an otherwise high-risk medication or medications that have a high likelihood of abuse. Plans also use prior authorization to help verify that a drug is being used for a covered Part D indication.

When an enrollee applies for a formulary exception, Part D guidance requires that the application be accompanied by a written or oral supporting justification from the prescriber that the medication is medically necessary. If the plan denies coverage, the beneficiary can appeal the decision. However, some plans have indicated that, unlike in the commercial sector, in Part D, the expectations for justifications requesting coverage exceptions are not rigorous, resulting in approval of almost all requests. This situation can render utilization management tools ineffective. It can also undermine sponsors' efforts to negotiate rebates with pharmaceutical manufacturers. Plan sponsors note that the ease of formulary exceptions is a particular challenge with respect to "high-risk medications" that could pose serious side effects or increase risk of falls for elderly patients.

Instead, CMS could require standardized supporting justifications that provide more clinical information when requesting exceptions. Under a standardized approach, the process that plans use to obtain prescriber input needs to be not only specific and accurate but also relatively simple for prescribers, to reduce administrative burden.

Standardizing the type of clinical information that prescribers must submit in supporting justifications could improve the exceptions process and could help ensure that beneficiaries receive clinically appropriate drug therapies. Setting clear expectations for supporting justifications could also make the process more predictable for prescribers, thereby reducing their administrative burden. For example, CMS could develop a checklist of information needed related to the patient's requested medication, such as diagnosis, drug allergies, and rationale. Currently, when the pharmacy or plan contacts the prescriber but cannot receive a justification in a timely manner, the plan must issue a denial and the beneficiary must initiate the appeals process. However, a standardized approach could simplify the process of justifying a formulary exception for the prescriber, thereby reducing the delay associated with a beneficiary's efforts to file an appeal.

Ideas for managing the use of specialty products

Specialty drugs sometimes offer advances in patient care, and beneficiaries should be provided appropriate access to them. Because of their high prices, however, waste and inappropriate use of specialty drugs can have large consequences for spending. Greater use of tools to manage the use of specialty drugs could improve the quality of services for beneficiaries and provide plan sponsors with greater leverage in negotiations with drug manufacturers. Some approaches used by plans in the commercial sector include:

- using "split fills" (initial supplies that cover fewer days than is typical, e.g., 15 days rather than 30 days) to reduce waste, accompanied by a program to

improve the quality of patient care, such as monitoring for side effects and improving adherence.

- using two specialty tiers (preferred and nonpreferred), with more utilization management tools applied to products listed on the nonpreferred specialty tier. Such a tier structure, could, if used appropriately, reduce the need for nonformulary exceptions (because more expensive options could be placed on the nonpreferred tier rather than excluded from the formulary). This tier structure could also encourage competition among existing specialty drugs that are therapeutic substitutes. As more biosimilar products gain FDA approval, an additional specialty tier could also be effective at encouraging beneficiaries to consider substituting biosimilar products for reference products.

Another strategy most commercial health plans have adopted to manage the use of specialty drugs is to require that enrollees fill prescriptions through a limited network of specialty pharmacies. Specialty pharmacies often (but not always) deliver prescriptions by mail and offer additional support services to beneficiaries. Pharmacy benefit managers (PBMs) and health plans contend that specialty pharmacies can lead to better patient education and improved adherence. Specialty pharmacies can help prescribers navigate the clinical documentation needed to meet prior authorization requirements. The largest specialty pharmacies are owned by PBMs, and in some cases, they may be able to negotiate lower prices with drug manufacturers. However, a variety of business models fall under the term "specialty pharmacy," and the interests served by some specialty pharmacies may not be aligned with those of payers or patients.

Unlike the commercial sector, Medicare guidance prohibits Part D plan sponsors from limiting where beneficiaries fill their prescriptions, so long as the pharmacy selected by the enrollee is in the plan's network.[26] Many pharmacies would like to participate in the market for dispensing specialty drugs, especially in light of predictions about future growth in spending for those medications. The Commission intends to study specialty pharmacies further to identify ways to benefit from their management approach while ensuring appropriate access and healthy competition among pharmacies.

Other changes to the rules related to Part D's formulary and benefit design would increase the ability of plan sponsors to manage drug use or bargain more effectively with pharmaceutical manufacturers. In general, providing plan sponsors greater flexibility to manage drug use and spending has the potential to improve the financial outlook of the program. However, CMS will need to be vigilant to ensure that plan sponsors are using management tools to prevent inappropriate prescribing rather than to limit access to needed medications.

RECOMMENDATION 6-3

The Commission's third recommendation relates to the use of formulary tools for managing Part D drug benefits. Current Medicare regulations and guidance limit plan sponsors from controlling their formularies to the degree they do for their commercial populations. This recommendation retains most conditions on Part D formularies such as requiring coverage of at least two drugs per therapeutic class, allowing enrollees to request coverage of nonformulary drugs, and allowing requests for an enrollee to pay the lower cost sharing of a preferred tier for a nonpreferred drug. However, the recommendation would allow for certain new flexibilities to meet changing market conditions while ensuring that beneficiaries maintain access to needed medications. Specifically, the Commission recommends that:

The Secretary should change Part D to:

- **remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,**
- **streamline the process for formulary changes,**
- **require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and**
- **permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.**

RATIONALE 6-3

This third recommendation would provide plan sponsors with stronger formulary tools with which to manage their enrollees' drug spending. It would complement the Commission's first recommendation in that the combination of greater incentives (more of Medicare's subsidy through capitated payments) and stronger tools (more formulary flexibility) could lead plan sponsors to manage overall prescription drug spending more effectively.

The first part of this recommendation generally supports an approach CMS proposed in 2014 to apply objective criteria for determining which drug classes merit

protection. The intent behind the "protected classes" policy was to prevent sponsors from discouraging beneficiaries who are reliant on certain drugs from enrolling in certain plans and to mitigate the risk of interrupting therapy. However, because the policy requires plan sponsors to cover all drugs in the six classes, it limits the ability of plan sponsors to negotiate price concessions for those drugs. In 2014, CMS proposed objective criteria that evaluated the health consequences for beneficiaries of more limited access to medications. After applying those criteria to the six protected classes and noting the wide availability of generics in some of those classes, CMS proposed removing antidepressants and immunosuppressants for transplant rejection from protected status. CMS's approach and its proposal to remove the two drug classes from protected status reached a balance between ensuring that beneficiaries have access to needed medications while giving plan sponsors greater room to negotiate price discounts.

Continuity of a plan's formulary is very important for beneficiaries. However, there are circumstances in which negative changes (such as removing a drug from the formulary or adding a prior authorization requirement) are warranted. The second part of this recommendation would give plan sponsors one or more additional opportunities to modify their formulary before the start of an annual open enrollment period for a new benefit year. It also proposes to expedite midyear changes that CMS would generally approve. Plan sponsors would still be required to notify enrollees before making the change, but sponsors would no longer need prior CMS approval. CMS would verify the change after the fact, and plan sponsors would be subject to enforcement action if the change did not meet clear criteria for permissible changes.

Under the third part of this recommendation, CMS would require a standardized approach for prescribers to submit supporting justifications to plan sponsors to obtain a formulary exception for patients. Currently, requests for exceptions accompanied by a prescriber justification are typically approved, even if that statement is extremely general. By using a standardized approach, prescribers would have a more predictable process that could lead to less administrative burden. A standardized approach to providing clinical justifications for exceptions could also help ensure that beneficiaries receive clinically appropriate medicines.

The fourth part of this recommendation would direct CMS to develop guidance on using new tools for specialty drugs. That guidance would have the intent of balancing beneficiaries' access to needed medications with measures to limit the very expensive consequences of waste or inappropriate use of specialty products. For example, currently prescribers write prescriptions for a 30-day supply of medications, and the Part D plan must fill that prescription as written. However, many specialty medications such as oral oncology agents are changed or stopped early, and a portion goes unused. Under this part of the recommendation, CMS would develop guidance for plan sponsors to use an initial 15-day supply of a specialty drug to ensure that the patient has not abandoned treatment. CMS could also consider revising Part D guidance to allow for two specialty tiers, including a preferred one that offers lower cost sharing to encourage the use of lower cost biosimilars.

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Spending

- The Congressional Budget Office estimates that the combination of the Commission's three recommendations would lead to one-year program savings of more than $2 billion relative to baseline spending and to more than $10 billion in savings over five years. Separate estimates for each recommendation are not available.

Beneficiaries and providers

- Several parts of this recommendation could affect beneficiaries who take certain antidepressants and immunosuppressants if their plan were to no longer cover their current drug. However, these classes contain a wide variety of therapy options, including many generics. Plans would continue to cover at least two drugs in those drug classes, and affected beneficiaries might find that they could switch medications. By including fewer drugs in those classes on their formulary, plan sponsors may be able to negotiate larger price discounts, which would lead to lower premiums and cost sharing for enrollees. If a patient's clinical situation did not warrant switching drugs, the patient could apply for a formulary exception to obtain coverage of the original medicine. In this circumstance, the patient's prescriber would need to submit a supporting statement with the clinical rationale for needing the original medicine.
- More extensive use of formulary changes when warranted would allow plan sponsors to respond more quickly to new clinical information and changing market conditions. In turn, this flexibility could give

sponsors more leverage in their price negotiations with manufacturers, potentially leading to lower enrollee premiums and cost sharing. Affected enrollees would continue to receive a 60-day written notice before the formulary change, including the rationale for the change, alternative treatments in the same therapeutic class, and instructions for pursuing a coverage determination. As with the protected classes policy change, midyear formulary changes would mean that some beneficiaries would need to switch medications or seek exceptions. Prescribers would need to submit a supporting statement if their patient had clinical reasons for continuing with their original therapy.

- Requiring that prescribers provide standardized justifications for a formulary exception could reduce unnecessary benefit costs and, in some cases, improve quality for the patient. To the extent that prescribers had to submit more rigorous clinical evidence in their supporting justifications than they do currently, that change could increase their workload. However, by instituting a standardized approach and allowing prescribers to submit the information in writing or orally, the relative amount of that burden would be lessened. ■

Endnotes

1 This amount includes reconciliation payments made during 2014 between Medicare and plan sponsors for benefits delivered in previous years. In 2014, incurred program spending totaled $73.3 billion.

2 CMS assigns risk scores to enrollees based on demographic information and RxHCCs. Beginning in 2011, CMS replaced a single RxHCC model with five sets of model coefficients for long-term institutional enrollees, aged low-income enrollees, aged non-low-income enrollees, disabled low-income enrollees, and disabled non-low-income enrollees (Centers for Medicare & Medicaid Services 2010a). CMS uses regression analysis to determine dollar coefficients for each factor in the RxHCC model. CMS then creates relative factors for each demographic factor and condition category by dividing the coefficient by average predicted per capita spending so that the average risk score for all Part D enrollees is 1.0. CMS applies a normalization factor to risk scores used to predict spending in years after the calibration year to reflect changes in the population and in coding of diagnoses. CMS then calculates each enrollee's risk score by adding the relative risk factors applicable to the individual enrollee.

3 The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost (e.g., Medicare defines specialty drugs based on the average price for a one-month supply; for 2016, the threshold is $600 or more per month) and are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs. See http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-PharmacyIs-it-Sustainable.

4 Starting in 2014, Part D contracts are subject to "medical loss ratio" requirements that require them to spend at least 85 percent of revenues on benefit costs and quality-improving activities. That policy also constrains plan profits.

5 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. See Chapter 5 of the Commission's *Report to the Congress: Improving Incentives in the Medicare Program* (Medicare Payment Advisory Commission 2009a) for more detail.

6 The Commission examined this issue more closely in its June 2015 report within the context of prescription opioid use (Medicare Payment Advisory Commission 2015a).

7 The incurred amount of $73 billion for 2014 differs from the $78 billion described earlier because the larger amount includes reconciliation payments between Medicare and plan sponsors for benefits delivered in previous years.

8 These calculations for biologic products exclude insulin.

9 About 90 percent of long-term institutionalized Part D enrollees receive the LIS.

10 Private reinsurers and consulting actuaries that staff members interviewed for the Commissions' June 2015 report noted that they structure reinsurance contracts differently from Medicare's risk-sharing arrangements. They tend to use a higher dollar threshold than Part D's OOP limit before providing reinsurance coverage. For example, a private contract for specific stop loss might cover only the top 1 percent or 2 percent of enrollees as ranked by spending. By comparison, in 2013, about 8 percent of Part D enrollees reached the OOP limit. Interviewees said that the premium for such coverage would incorporate administrative costs and profits on the order of about 20 percent to 25 percent of covered benefits. However, such spending covered by private reinsurance would be considerably smaller than the amount of risk sharing Medicare provides currently (Medicare Payment Advisory Commission 2015a).

11 Because most LIS enrollees pay nominal copay amounts and face no coverage gap, they are not eligible for the brand-name discount and their OOP spending does not reach as high as the OOP threshold.

12 Examples of exceptions to this policy include cost sharing paid by individuals on behalf of the enrollee and payments by state pharmaceutical assistance programs. Medigap policies are prohibited from including drug coverage for Part D enrollees.

13 In 2020 and thereafter, enrollees will pay 25 percent cost sharing for both generics and brand-name drugs; to the enrollee, the manufacturer discount will no longer make the price of brand-name drugs appear relatively less expensive. However, because Part D plans must cover only 25 percent of the price of brand-name drugs but 75 percent of the price of generics, from a plan's perspective, the manufacturer discount will still lower relative prices for brand-name drugs.

14 However, the enrollee may apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. Guidance from the Department of Health and Human Services

Office of Inspector General states that independent charity PAPs must provide assistance to broad rather than narrow disease groups, manufacturers must not exert direct or indirect control over the charity, and the PAP must not limit assistance to a subset of available products (Office of Inspector General 2014).

15 For this analysis, we assumed that each enrollee's entire incremental spending in the coverage gap was for brand-name drugs. Among enrollees who reached the coverage gap, in 2013, on the order of 80 percent of their spending was for brand-name drugs and 20 percent for generics. By assuming instead that all of their coverage-gap spending was used for brands, we provide an estimate of the maximum numbers of enrollees who would remain in the coverage gap rather than reach the OOP threshold. We also tend to overstate the average increase in manufacturer discount under the policy change.

16 For 2016, an individual is eligible to receive the low-income subsidy if his or her annual income is below $17,820 (or $24,030 for a married couple) and if the assets are below $13,640 (or $27,250 for a married couple).

17 We took the share of drug costs that were paid by beneficiaries (OOP share) by annual spending levels in $100 increments estimated by Acumen LLC and multiplied those amounts by the average spending by benefit phase, calculated using 2013 data on drug spending.

18 A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/).

19 U.S. Pharmacopeia is a scientific nonprofit organization with the primary mission of setting standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements.

20 The transition fill is a temporary one-time supply of up to 30 days of medication provided during the first 90 days in a plan for new enrollees and during the first 90 days of the new contract year for the existing enrollees. For individuals living in long-term care facilities, the temporary supply may be for up to 31 days and may be renewed as necessary during the entire length of the 90-day transition period.

21 The exception is New York, which mandates electronic prescribing.

22 CMS's review panel found that antidepressants did not meet the first criterion: a seven-day delay in start of therapy would not put a patient at risk of hospitalization, incapacity, or death. For immunosuppressants, the panel found that while they met the first criteria, they did not meet the second one. CMS noted that "because widely accepted treatment guidelines recommend subclasses of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies" (Centers for Medicare & Medicaid Services 2013).

23 While the share of prescriptions accounted for by generic drugs in classes with generic alternatives can be high, often exceeding 80 percent, the share of spending accounted for by brand-name drugs still may account for a large share of spending. For example, in 2013, 80 percent of the prescriptions for antidepressants were for generics, but spending for brand antidepressants accounted for 60 percent of total spending for that class.

24 Sponsors submit formulary information to CMS on a formulary reference file (FRF)—a list of drugs that may be included on Part D plan formularies. CMS developed the FRF to have a normalized approach for reviewing and comparing plan formularies and to ensure that the same information can be uploaded to Medicare's Plan Finder website. To maintain up-to-date FRFs, CMS coordinates with the Food and Drug Administration (which provides supporting files about which drugs have marketing approval), the National Library of Medicine (which provides normalized names and unique identifiers for drugs), and other contractors (for example, to update the Plan Finder with biweekly price information).

25 CMS estimates that in 2015, the agency took an average of 15 days to review and respond to maintenance changes and approximately 37 days to review and respond to nonmaintenance changes. In addition to CMS's review time, plan sponsors also include time required for new additions to the formulary reference file (described in endnote 24) as well as for notification of affected beneficiaries.

26 CMS regulation states that Part D plans may not restrict access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections of Section 1860D–4(b)(1)(C) of the Social Security Act and 42 CFR Section 423.120(a). An exception is if a *manufacturer* of a specialty medication has limited the distribution of its product to certain authorized pharmacies. In this situation, the Part D enrollee would be able to fill that prescription only at one of the designated (specialty) pharmacies.

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CHAPTER 7

Improving efficiency and preserving access to emergency care in rural areas

CHAPTER 7

Improving efficiency and preserving access to emergency care in rural areas

Chapter summary

Efficiently providing access to inpatient and emergency services is a growing challenge in sparsely populated rural areas. Declining populations can lead to fewer admissions, greater inefficiencies, and increased financial difficulties. For example, it is difficult to efficiently staff a hospital that has less than one admission per day. Low inpatient volume may also make it hard for clinicians at rural hospitals to have enough experience with different types of patients and clinical situations to provide outcomes equal to neighboring higher volume facilities.

Most rural hospitals are critical access hospitals (CAHs), which receive cost-based payment for Medicare inpatient and outpatient services. However, cost-based models have three limitations. First, cost-based payments favor hospitals with high cost structures over hospitals in poorer communities that are forced to have lower cost structures. Second, they favor the expansion of services with high shares of Medicare and privately insured patients rather than emergency services, which often have higher shares of uninsured patients. Third, cost-based payments reduce the incentive to control costs.

At most CAHs, cost-based payments are well above the rates the hospital would otherwise receive if it were paid under Medicare's prospective payment systems (PPSs). Among CAHs that closed in 2014, the median aggregate Medicare payments for acute and post-acute inpatient services

In this chapter

were $500,000 above PPS rates in aggregate. Despite the relatively high Medicare payment rates, these facilities were not able to stay open. The question is whether the existing Medicare supplemental payments (the $500,000) could preserve access and generate more value for the beneficiary if the supplemental dollars were used to preserve access to emergency services rather than being used to support inpatient services.

New options for rural communities

The purpose of this chapter is to discuss giving isolated rural hospitals the option of converting to an outpatient-only model that would be sustainable in a community with declining inpatient volumes. The objectives of a new outpatient-only option would be to:

- ***Ensure access***—Allow isolated hospitals (CAHs and PPS hospitals) that are not financially viable to convert to outpatient-only facilities that would preserve access to outpatient and emergency care in their community.
- ***Promote efficiency***—Allow isolated hospitals the option of converting to an outpatient model if they believe that model would create more value for their community without increasing the overall cost of care.

The chapter outlines two potential outpatient-only options for communities that lack the population to support efficient high-quality inpatient services: a 24/7 emergency department (ED) model and a clinic with ambulance services model.

Model 1: 24/7 emergency department

Under the first outpatient-only model, if an isolated rural hospital chooses to give up acute inpatient services and cost-based payment, Medicare would give the facility an annual grant or fixed payment to help cover the standby costs of 24/7 emergency services. The facility would also continue to receive Medicare outpatient hospital PPS rates for outpatient services (including emergency care, radiology services, lab services, and telehealth services). The facility would receive Medicare skilled nursing facility (SNF) PPS rates if it chooses to convert inpatient beds to post-acute SNF beds. In short, the supplemental payments hospitals currently receive for maintaining CAH inpatient services could be redirected to support stable access to emergency care. Only isolated providers that do not have competing nearby hospitals with a 24/7 ED would be eligible for a supplemental fixed payment under this model.

Model 2: Clinic and ambulance

The second model is for communities that cannot support a 24/7 ED and may have to rely on an ambulance service to stabilize and transfer patients. These

communities could opt to convert their existing inpatient facilities into a primary care clinic with an affiliated ambulance service. Similar to the federally qualified health center model, Medicare could provide prospective rates for primary care visits and ambulance transports, but also provide grant funds or other fixed payment to support the fixed costs of having a primary care practice, the standby costs of the ambulance service, and uncompensated care costs. Compared with the model in which a hospital becomes a stand-alone emergency facility, the clinic and ambulance model may be more problematic to execute. It will be more challenging to describe exactly what level of primary care and ambulance access is required. In addition, there could be a large number of isolated communities with primary care practices and ambulance services that do not have a hospital. These communities may feel they should also receive a fixed payment similar to the payment given to clinics in communities where a hospital is closing. The pressure to expand the program to include areas without a hospital closure could cause Medicare to "buy out the base" (i.e., support the primary care infrastructure across a large number of rural communities), which would raise the cost of this policy.

Why create one more special payment program for rural providers?

Medicare has several special payment models for rural hospitals. About 60 percent of rural hospitals are CAHs (1,300), and most are expected to remain in the CAH program. This chapter is not about changing the CAH program. However, the CAH model—which requires a hospital to maintain acute inpatient services—is not the best solution for all rural communities. Many small towns do not have the population to support efficient, high-quality inpatient services. However, they may be reluctant to cease inpatient services because doing so would also mean giving up the higher payment rates that they receive through the CAH cost-based payment model. The two options discussed in this chapter would allow facilities to shift to an outpatient-only model while maintaining some supplemental Medicare funding that could keep them financially viable and able to continue to serve the community.

Why limit eligibility to isolated hospitals?

As the Commission has maintained in previous reports, supplemental payments beyond the standard PPS rates should be targeted to isolated rural providers. Thirty-four percent of rural hospitals are 25 or more miles from other hospitals. Some are more than an hour from other hospitals. The emergency access provided by these hospitals needs to be preserved in some form. However, there is great diversity among rural hospitals. Many rural hospitals—including CAHs—are 2, 5, or 10 miles from another acute care hospital. Keeping an ED open that is 2 or 10 miles away from a competitor is not the same public policy priority as keeping a hospital

open that is 30 or 60 miles away from all other providers. Therefore, a new program to support stand-alone EDs in rural areas could be limited to facilities that would be at least some minimum number of road miles from the nearest hospital, meaning the Medicare program would not provide special support to EDs that are, for example, 5 or 10 road miles from a hospital. ■

Introduction

Rural and urban beneficiaries receive similar volumes of care

In our 2012 mandated report on rural health care, we found significant regional variation in the overall volume of services used by rural beneficiaries. Medicare beneficiaries with similar health status had significantly higher use of certain services in some states than in other states. Despite differences in practice patterns among states, we found little difference in service use between isolated rural beneficiaries and urban beneficiaries in the same state. In states where service use was high for urban beneficiaries, service use also tended to be high for rural beneficiaries. Similarly, in states where urban beneficiaries used fewer services, rural beneficiaries also used fewer services. This pattern suggests that rural patients in communities with few local providers traveled for their care, resulting in rural and urban patients having similar volumes of physician visits, hospital admissions, skilled nursing facility (SNF) days, and prescription fills (Medicare Payment Advisory Commission 2012). Our 2012 report examined data through 2010. Since 2010, large changes have not occurred in Medicare payment policy or in the level of spending per beneficiary in rural or urban areas.

Quality of care and hospital volume

As the populations in rural communities decline and the remaining patients often bypass their local rural hospitals, inpatient volumes in those hospitals decline. 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). Declining volume is a concern because low-volume rural hospitals tend to have worse mortality metrics and worse performance on some process measures (Durairaj et al. 2005, Institute of Medicine 2000, Joynt et al. 2013, Joynt et al. 2011a, Joynt et al. 2011b, Medicare Payment Advisory Commission 2012, Ross et al. 2010, Silber et al. 2010). Given the research on volume and outcomes, there may be value for beneficiaries in maintaining local emergency access while giving rural communities the option of consolidating inpatient services at a subset of existing rural hospitals.

There is also a concern that smaller rural hospitals have been left out of national efforts in quality reporting and improvement. Unlike prospective payment system (PPS) hospitals, critical access hospitals (CAHs) are not required to publicly report their outcomes data on Hospital Compare, though a significant share voluntarily report some data. In 2015, a panel of providers and other rural advocates was convened by the National Quality Forum to address quality improvement in rural areas. The panel recommended requiring CAHs to track their quality metrics and start participating in a limited set of CMS quality measures within two to four years (National Quality Forum 2015). These measures could focus on services frequently provided in small rural hospitals; for example, they could focus on heart failure patients' outcomes rather than acute myocardial infarction (AMI) outcomes because AMI patients are often helicoptered to larger hospitals with cardiac catheterization labs. To help overcome the issue of low case volume in pay-for-performance models, the panel also considered encouraging groups of hospitals to pool their data to generate a large enough volume of cases to evaluate performance. While the movement of small hospitals into the CMS quality improvement programs may help measure performance, concerns remain regarding patient outcomes at low-volume facilities where the staff does not have the benefit of experiencing a large number of similar clinical situations.

Declining rural hospital volume and workforce changes

While the overall volume of care received and total per capita spending remain similar for rural and urban beneficiaries, rural beneficiaries' care patterns have changed in two ways. First, rural hospitals' volume of inpatient admissions has declined at a faster rate than urban hospitals. Between 2013 and 2014, the volume of Medicare discharges from rural hospitals with fewer than 50 beds declined by 8.4 percent compared with a 3.9 percent decline at urban hospitals (Medicare Payment Advisory Commission 2016). This decline reflects a shift in care from inpatient to outpatient services and an increase in the share of patients who bypass rural hospitals and use urban hospitals for care. Between 2006 and 2014, occupancy at small rural hospitals declined from 47 percent to 37 percent. In 2014, on average, urban hospital occupancy was 64 percent compared with 37 percent at small rural hospitals and 41 percent for all rural hospitals (Medicare Payment Advisory Commission 2016).

The second change has been the greater specialization of the rural clinical workforce. Historically, primary

care physicians in rural communities had a broad scope of practice, seeing patients in their office, covering the emergency department (ED), and seeing patients in the hospital. In more recent years, rural clinicians have become more specialized. From 2005 to 2009, the share of rural hospitals using hospitalists increased from 19.8 percent to 41.2 percent (Casey and Moscovice 2012). Our site visits and interviews with rural hospital administrators suggest that this trend has accelerated since 2009. Interviewees report that increasingly fewer clinicians want the lifestyle associated with having an office-based clinical practice, covering the ED, and covering inpatient concerns at night. Some larger CAHs employ physicians just to cover the ED, hospitalist physicians to cover inpatient services, and clinicians to cover services provided in outpatient settings. The pool of clinicians now includes more physician assistants (PAs) and nurse practitioners (NPs). However, even with the lower cost of NPs and PAs, it can be difficult for smaller CAHs to finance separate clinicians for inpatient, outpatient, and emergency care as patient volumes decline. Therefore, low-volume CAHs have the difficult job of competing with each other for a shrinking pool of clinicians who want the lifestyle of operating an outpatient practice during the day, covering inpatient issues that arise at night, and covering the emergency department.

Medicare's special payments to rural hospitals

The Medicare program has several payment programs designed to preserve access to 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 to over 300 SCHs. The Medicare-Dependent Hospital (MDH) Program increases inpatient payments by about $100 million 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 inpatient prospective payment system (IPPS) payments 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. Some closures reflect excess capacity, but in other instances, the closed hospitals were the sole provider of emergency services in the area. From 2013 through March 2016, 43 rural hospitals closed (55 if we include rural areas of metropolitan counties).[1] Among the closures were 21 CAHs (Young 2016). While 27 of the closures were less than 20 miles from the nearest hospital, 13 were 20 to 30 miles from the nearest hospital and 3 were over 30 miles from the nearest hospital. Given that 16 of the 41 closures were more than 20 miles from the nearest acute care hospital, some have questioned whether Medicare's current rural payment models are effective in preserving access to emergency services. In particular, there is an interest in payment models that are focused on preserving outpatient access rather than maintaining inpatient services (Thompson 2015).

Different payment models for rural hospitals have been debated since the start of the prospective payment system (PPS) (Christianson et al. 1990). The Congress created the SCH program before the start of the PPS in 1983. The SCH program provides higher prospective inpatient operating payments to rural hospitals that historically had high inpatient operating costs. Originally, the SCH program was limited to rural hospitals that were more than 35 miles from another acute care hospital (or 25 miles in special circumstances). However, currently, SCHs are allowed to be any distance from CAHs, meaning the program is less targeted at isolated hospitals than it was in the 1980s. Similar to the SCH program, the Congress instituted the MDH program in 1989; it provided a blended payment that was equal to 50 percent of PPS operating payment rates and 50 percent of the hospital's historic inpatient operating costs trended forward.[2] Qualifying hospitals are required to be small and rural and to have a high share of Medicare patients, but they do not need to be isolated. In the 1980s, the Congress also authorized the Rural Primary Care Hospital (RPCH) Program, and the Montana Medical Assistance Facility (MAF) Program was started. The RPCH and MAF programs provided cost-based payment to small hospitals that agreed to not keep patients for more than three or four days. The inpatient focus of these payment programs reflects the dominance of inpatient services in the financing of hospitals in the 1980s. In 2011, the Congress reinforced the inpatient focus of Medicare payment by enacting a generous low-volume add-on payment for inpatient care at hospitals with fewer than 1,600 Medicare discharges that are more than 15 miles away from another PPS hospital (Medicare Payment Advisory Commission 2012). Under current policy, hospitals receiving SCH and MDH payments can also receive a low-volume adjustment.

In the 1990s, the Congress expanded special payments beyond inpatient services. In 1997, the RPCH program was transformed into the CAH program. CAHs receive cost-based payments for inpatient and outpatient services. The program was later expanded to include cost-based payment for post-acute care in swing beds, on-call payments, and a 15 percent add-on to physician-fee-schedule payments (Medicare Payment Advisory Commission 2005). To qualify for CAH status, a hospital must have 25 or fewer acute care beds, maintain inpatient services, maintain an emergency department (with clinicians available within 30 minutes), and have an average length of stay of 96 hours or less.

Unlike the MAF program, the Congress initially did not require that CAHs be 35 or more miles from another hospital. The Congress permitted states to designate hospitals as "necessary providers" to make them eligible for the program and let the states determine whether a small hospital was rural or urban. The Congress later eliminated the "necessary provider" exception but grandfathered in about 800 hospitals that entered the program through the "necessary provider" exception. Given the program's initial lack of targeting, 1,300 small rural hospitals eventually entered the program and received Medicare payment equal to 101 percent of operating and capital costs for inpatient, outpatient, laboratory, and swing bed skilled nursing post-acute services. As a result, CAHs received about $9 billion in payments in 2012, which was about $2 billion more than these hospitals would have received under PPS rates (Medicare Payment Advisory Commission 2012). The additional Medicare dollars helped many rural communities build new hospitals, and it almost eliminated rural hospital closures for several years. However, limitations of the CAH financing mechanism have become apparent in recent years.

Six CAHs closed in 2013, and another seven closed in 2014, despite having received cost-based Medicare payment. The financial challenges faced by CAHs can include factors such as declining populations, declining patient volume from commercial insurers, continued 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 2014, the median number of annual all-payer discharges among CAHs fell from over 600 to under 400, and 10 percent of CAHs had 86 or fewer discharges in 2014 (Figure 7-1, p. 210). Despite having 25 or fewer beds per CAH, the average CAH occupancy rate (including post-acute swing bed patients) fell to 35 percent in 2014.

When CAHs face a decline in the number of patients with commercial insurance, they can face financial difficulties despite receiving cost-based payments from Medicare. Medicare pays CAHs roughly their costs for Medicare patients, and Medicaid also pays costs in many states. As a result, CAHs need to make enough profit on commercially insured patients or receive enough local government support to cover losses on the uninsured and bad debts. The current Medicare inpatient-centric payment models, in which hospitals must rely on cross-subsidizing uncompensated care costs with profits from commercially insured patients, may not work in all rural communities.

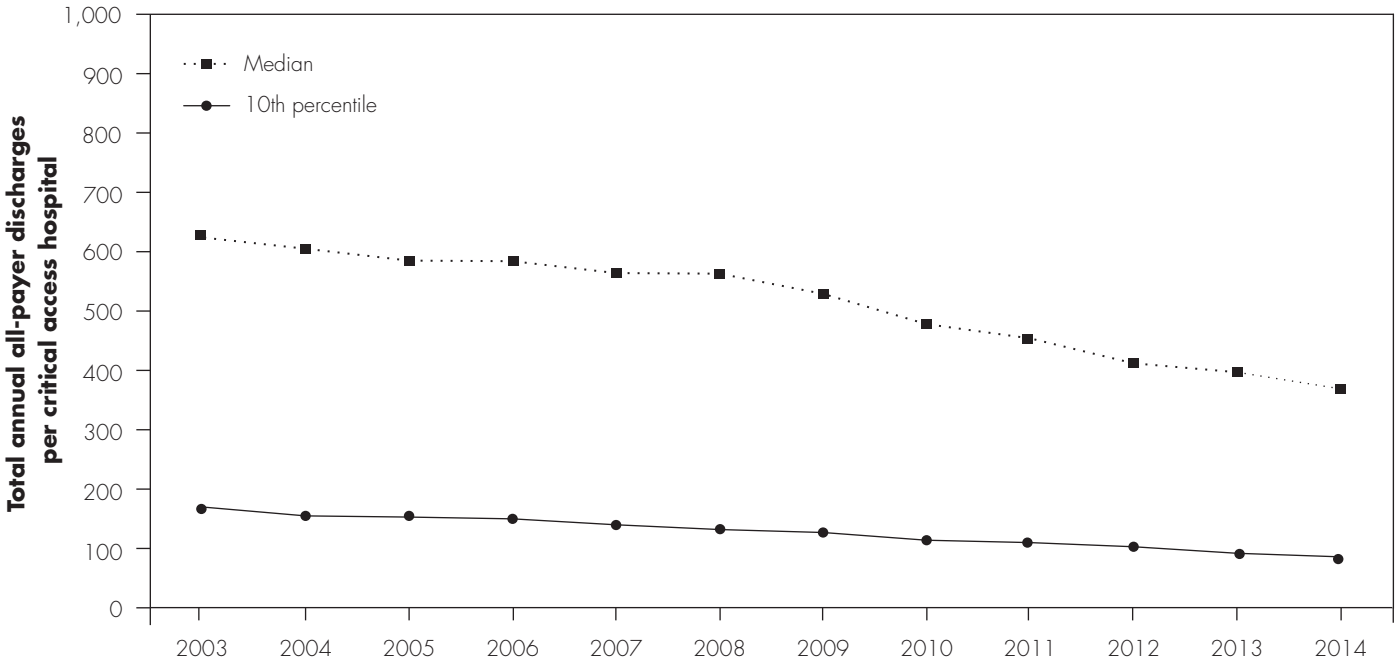
Inefficiency of inpatient-centric models

To qualify for the special payments in the SCH program, the MDH program, or the CAH program, a hospital must provide inpatient services. In the SCH and MDH programs, the amount of supplemental dollars received depends on the hospital's volume of Medicare inpatient discharges. In the CAH program, supplemental dollars increase with the volumes of Medicare admissions, post-acute days in swing beds, and other Medicare services. Medicare will pay its share of costs (no matter how high those costs go), but the hospital must keep costs low enough so that profits on privately insured patients (plus local government and charitable contributions) cover the costs of uncompensated care. To keep unit costs sufficiently below private insurer prices, hospitals need to have a certain volume of paying cases. A fundamental problem is that costs per inpatient day rise as CAH volume falls, which results in higher losses per uninsured day and lower profits per privately insured day. For example, it is difficult to efficiently staff a hospital with an average census of two patients, especially if a hospital has a census of four inpatients one day and zero the next.

A key question is whether a rural hospital could stop providing inpatient services and still generate enough outpatient revenue to maintain an ED. This approach has been successful in some communities, but they are generally rural communities with a fairly high ED volume and payer mixes that include a large share of privately insured patients. Operators of stand-alone emergency facilities have told us that these facilities can be profitable in markets with 20 or more ED visits per day when most patients have private insurance (see text box, pp. 212–213,

FIGURE 7–1

Declining inpatient use of critical access hospitals



Source: MedPAC analysis of cost report data from CMS.

for a discussion of urban stand-alone EDs). Some rural communities will have too few ED patients and too few private-pay patients to make the stand-alone ED model work without some federal or local support. For example, after three rural Georgia hospitals closed, Georgia legislators discussed operating them as stand-alone emergency facilities. However, a committee formed by the state concluded that the facilities would not have enough volume to be viable without additional financial support (Rural Hospital Stabilization Committee 2015).

The threat of closure is not the only reason a hospital would prefer an outpatient-only care model. Some financially viable hospitals may only keep their inpatient service open to qualify for CAH status and the associated higher post-acute and outpatient payment rates. If those hospitals could remain financially viable under a new outpatient-only model, they could choose to eliminate their inpatient services (and the associated costs).

Community concerns regarding the loss of local inpatient services

Discontinuing local inpatient services would be a difficult process for rural communities that have long been served by hospitals that focused on inpatient care. Care patterns could change, and some local hospital employees would have to find work with other health care providers. While a recent study suggests that most closures do not have significant effects on the health of the community, some more isolated communities would be concerned about access to emergency services if their hospital closed (Joynt et al. 2015). Communities are also concerned about the economic effects of a closure (Thomas et al. 2015). Data on past closures show a small negative economic effect when the only hospital in a county closes, but no material economic effect when one of two hospitals in a county closes (Holmes et al. 2006). The combination of discomfort with changing care delivery patterns and concerns about the local economy (even if unfounded) can make the closure of a rural hospital a difficult decision for a rural hospital board. These hospital boards may be more receptive to adopting outpatient-only payment models of care that allow hospitals to convert into outpatient facilities with emergency capabilities.

Hospital boards may be more likely to convert to an outpatient-only facility if, for a limited number of years, they had the option of converting back to CAH status.

While all converting facilities that are more than 35 miles away from another hospital could convert back to CAH status under current regulations, most CAHs were grandfathered into the program and do not meet the 35-mile criteria. These converting facilities that are less than 35 miles from another hospital would need a special waiver of CAH rules to convert back to CAH status. The Congress could give them a limited time frame (e.g., five years) to convert back to CAH status (or SCH or MDH status if they are PPS hospitals). That option would make conversion an easier decision for the board but would still place some limit on a facility's ability to convert back to CAH status when a competing hospital is located in a neighboring town.

Three ways cost-based payment models misdirect Medicare dollars

While the CAH program has helped many hospitals and has strong support among rural providers, it uses a cost-based model that has three main limitations. First, cost-based payments fail to direct payments toward isolated hospitals having the greatest financial difficulty. Instead, hospitals in high-income areas with higher non-Medicare margins tend to have higher costs and thus receive higher Medicare payments. Second, cost-based payments encourage providers to expand service lines with high Medicare and private-payer shares rather than primarily focus on services that are needed on an emergency basis. Thus, cost-based services can lead, for example, to expansion of post-acute swing bed services and outpatient services (e.g., mobile MRI services) that are not needed on an emergency basis. Third, cost-based models reduce the incentive for hospitals to control their costs and can lead to unnecessary growth in capital costs, despite declining volumes. Before we discuss alternatives to cost-based reimbursement, we will review how cost-based reimbursement under the CAH program helps wealthier hospitals, affects service offerings at small rural hospitals, affects hospital cost structures, and preserves some hospitals but fails to preserve others.

Problem 1: Cost-based payment favors hospitals that can afford high cost structures

Cost-based payments do less to help poor communities with low cost structures than communities with high cost structures. Poor communities tend to have fewer private-pay patients and more uninsured patients, and the profits derived from privately insured patients may not be enough to cover the costs of those who are uninsured.[3] These hospitals may not remain financially viable even if they break even on Medicare because payments from private insurers are insufficient to offset their uncompensated care costs. For this reason, some hospitals we visited in poorer Alabama communities chose not to become CAHs. They needed to keep their costs below PPS rates and generate profits on Medicare patients to help fund the costs of the uninsured.

In contrast, wealthier communities tend to have more privately insured patients and fewer uninsured patients, which results in higher revenues for hospitals in wealthier areas. Higher revenues allow the hospital to incur higher costs. Higher costs then result in high cost-based payments relative to PPS rates. We can see this relationship between non-Medicare profit margins and costs by examining costs per day of post-acute care (PAC) in CAH swing beds.[4] We use post-acute costs per day because post-acute services are similar across CAHs and are provided by almost all CAHs. We found that in 2013, CAHs with higher non-Medicare margins had higher costs per post-acute day. On average, the resulting Medicare cost-based payment rate per day for PAC in these hospitals was roughly $200 higher than at hospitals that historically suffered losses on their non-Medicare patients.[5] In other words, Medicare paid higher rates to CAHs that were under less financial pressure than it paid to CAHs that were under greater financial pressure to constrain their costs. This finding—that hospitals under financial pressure have lower costs—is consistent with prior findings for PPS hospitals (Medicare Payment Advisory Commission 2015b, White and Wu 2014).

Problem 2: Cost-based payments fail to prioritize emergency access

All payment systems may create incentives to provide certain services and avoid providing others, by making some services relatively more profitable than others. For CAHs, cost-based payments often fail to create an incentive to focus on ED services because EDs tend to have a higher share of uncompensated care, fewer Medicare beneficiaries (which are paid at cost), and fewer privately insured patients (which pay more than cost) compared with other departments such as PAC or imaging services. Because Medicare beneficiaries comprise a smaller share of ED patients (fee-for-service (FFS) Medicare represents less than 30 percent of the average CAH's ED charges), a dollar of additional spending by the hospital in the ED will not result in as much additional

Stand-alone emergency departments in urban areas

A small but growing share of urban emergency department (ED) facilities are stand-alone facilities located off the primary hospital campus. These facilities are of two types, both of which are growing in number: hospital-affiliated off-campus emergency departments (OCEDs) and independent freestanding emergency centers (IFECs).

Hospital-affiliated off-campus emergency departments

In 2015, 387 OCEDs were operating in the United States. These facilities are affiliated with 323 hospitals. About 6 percent of hospitals have at least one OCED; these hospitals tend to be urban, affiliated with a health system, and relatively large facilities. Most of these hospitals operate a single OCED, but 30 hospitals (8 percent) have multiple OCEDs (between 2 and 7 OCEDs). Between 2008 and 2015, the number of hospitals with an OCED increased 76 percent.

OCEDs are able to bill Medicare if they are deemed provider-based facilities. To be deemed a Medicare provider-based facility, OCEDs must be in compliance with the standard hospital and 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 hospital. OCEDs can bill Medicare under the outpatient prospective payment system (OPPS) for a beneficiary's ED visit and any ancillary services (e.g., imaging and lab services), while the clinician can bill under the Medicare fee schedule for physicians and other health professionals just as in an on-campus ED.[6] Most other insurers pay OCEDs a facility fee and generally consider OCEDs in-network facilities.

The vast majority of OCEDs offer ED services 24 hours per day; basic imaging services such as X-rays, computed tomography (CT) scans, and ultrasounds; and on-site lab services for basic diagnostic analysis. They do not typically provide trauma services (e.g., patients coming from car accidents or with gunshot wounds), and most receive ambulance transports less frequently than do hospital EDs. OCEDs range in size, with larger facilities serving as many as 100 patients per day and the smallest facilities serving 20 patients per day. Larger OCEDs may also offer MRI and primary care and house physician specialists' offices, and they tend to take more ambulance transports than smaller OCEDs. OCEDs have one or more physicians on-site at all times, and physicians are typically contract employees. OCEDs often advertise that they are open longer (24 hours per day) than urgent care centers and serve higher acuity medical conditions such as respiratory distress, head injuries, dehydration, infection, orthopedic injuries and fractures, and abdominal pain.

(continued next page)

Medicare revenue as a dollar of additional spending by the hospital in a more Medicare-focused department such as post-acute care or cardiac therapy. For example, if 25 percent of a hospital's ED patients are Medicare patients, Medicare will increase payments by $25 for every $100 in additional expenses within the department. In contrast, if Medicare beneficiaries represent 80 percent of its post-acute swing bed days, the Medicare program will increase payments by $80 for every additional $100 spent on post-acute care.

CAHs tended to expand services that became relatively more profitable after transitioning to cost-based Medicare payments. Between 2003 and 2013, revenue for post-acute care rose from roughly 10 percent to 50 percent of CAHs' acute inpatient revenue. While CAHs constitute a relatively small share of PAC providers, they have gained market share. In 2003, post-acute payments to hospitals that became CAHs accounted for 3 percent of Medicare's SNF payments (urban and rural). By 2013, they accounted for 5 percent of SNF payments. In 2013, post-acute swing bed payments to CAHs totaled $1.5 billion. The higher payment level for PAC services (above PPS rates) represented a material share of the more than $2 billion in payments above PPS rates received by CAHs. This trend illustrates how cost-based payments can direct resources toward profitable services rather than the services needed for emergency access.

Stand-alone emergency departments in urban areas (cont.)

OCEDs are permitted in most states, but in certain metropolitan areas such as Seattle, Dallas, Houston, and Denver, more have opened in recent years. OCEDs are typically located within 5 to 10 miles of the affiliated hospital and are typically located in areas with rapid population growth—not always in communities with access deficiencies, such as communities with recently closed hospitals. In some cases, OCEDs are built outside the hospital because hospitals have exhausted the capacity of their architectural footprint. In other cases, OCEDs are built strategically near other hospitals to capture market share from competitors.

Independent freestanding emergency centers

IFECs are a relatively new phenomenon in the health care industry and have grown rapidly. We have identified 172 IFECs; the vast majority are in Texas, where the number increased from zero in June 2010 (when state licensure of IFECs began) to 156 facilities in May 2015. Colorado and Arizona also have IFECs. IFECs are located in urban and suburban communities and tend to locate in areas with rapid population growth that are relatively affluent and have a well-insured population. They tend to offer services similar to smaller OCEDs, such as X-rays, CT scans, and basic lab services.

IFECs cannot currently bill the Medicare program for ED services because they are not considered provider-based facilities. Therefore, their patient mix tends to have higher shares of privately insured patients and smaller shares of Medicare and Medicaid patients. Private insurers often do not contract with these facilities, and they are often treated as out-of-network providers. Several IFECs have made efforts recently to partner with hospitals to obtain Medicare provider–based status and to begin billing Medicare under the hospital OPPS.

Regulations of OCEDs in rural and urban areas

Due to Medicare's 35-mile restriction associated with provider-based facilities, many isolated rural hospitals cannot become OCEDs. As a result, there are currently very few rural OCEDs. Therefore, the IFEC model would require new legislation allowing isolated stand-alone EDs to bill Medicare.

Currently, Medicare cannot distinguish OCED claims from on-campus hospital ED claims. To better understand what patients are being served by OCEDs, Medicare could consider tracking OCED claims. CMS currently has the regulatory authority to require OCEDs to bill with a special modifier so that their claims can be tracked. ■

Cost-based payments (coupled with high private-payer rates) can also encourage providers to expand outpatient services that are not needed on an emergency basis and cannot be delivered for a competitive price in the community. For example, by 2013, 81 percent of CAHs were billing for MRIs (Briggs et al. 2016). Some CAHs own MRI machines, but many others use mobile units that come to the CAH. In 2013, the estimated cost of an MRI at CAHs was $633 per MRI. This rate is significantly above outpatient PPS rates for MRIs. While local emergency services are necessary, certain CAH services such as mobile MRI services are generally not used in emergency situations.

Problem 3: Cost-based payments reduce the incentive for cost control

Paying a hospital 100 percent of its costs reduces the incentive for cost control, and paying a hospital more than 100 percent of its costs for its Medicare patients could significantly reduce the incentive for cost control. To illustrate, consider the extreme example of a hospital that is paid more than 100 percent of its Medicare costs. Assume that a hospital is paid 115 percent of its Medicare and Medicaid costs. A payment of 115 percent of costs would be a significant concern if certain hospital departments had very high shares of Medicare patients. For example, suppose the hospital served an aging rural

community and 90 percent of the hospital's cardiac patients were Medicare beneficiaries or Medicaid patients. Also assume that Medicaid paid the CAH cost-based reimbursement as it does in many states. In this extreme case, the incentive for cost control would be eliminated, as follows:

Medicare payment = 115 percent × all department costs × Medicare share of department charges

Or, consider the implications given a cardiology department where 90 percent of patients are Medicare beneficiaries:

Medicare payment = 115 percent × all cardiac department costs × 90 percent = 104 percent of all cardiac department costs

In the example above, the hospital's revenue would increase by $104 for every extra $100 of expenses in the cardiac department. Under this payment, the incentive to control costs would be eliminated.

Consider a more realistic and common example. Under current Medicare law, CAHs are paid roughly 100 percent of their costs; many state Medicaid programs also pay CAHs cost-based payments. If the CAH's cardiac department had 50 percent of its patients on Medicare and 10 percent on Medicaid, the CAH would receive cost-based reimbursement for 60 percent of its patients. Under this payment system, if purchasing a new piece of equipment increased costs in the department by $100,000, it would receive $60,000 in additional cost-based reimbursement ($100,000 × 60 percent). Therefore, if a $100,000 expenditure brought more than $40,000 of private revenue and other value to the community, the hospital would have an incentive to take on that additional $100,000 expenditure. The incentive to control costs is not eliminated, but it is reduced. We can see some evidence of this reduced incentive for cost control by examining capital expenditures at CAHs. We examined 557 hospitals that were CAHs in 2003 and in 2013. We found that their capital costs increased faster (125 percent over 10 years) than PPS hospitals' capital costs (38 percent over 10 years). While not all CAHs were updated, a significant number of CAHs were remodeled or replaced with new buildings. From 2003 to 2013, CAHs' capital costs (which include depreciation, lease, and interest costs) increased from 5.7 percent of total revenue to 7.1 percent of total revenue (Table 7-1). Some CAHs' facilities and equipment may have needed replacement, but it is questionable whether the updates to inpatient facilities were always needed, given the decline in discharges at CAHs. In comparison, PPS hospitals' capital costs rose slower than their revenue and were 5.6 percent of total revenue in 2013. The combination of growing capital costs and declining admissions illustrates how the incentives in the cost-based payment system are misdirected.

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

To evaluate the level of supplemental payments (above PPS rates) that CAHs received before their closure, we examined inpatient payments for both post-acute and acute care. Of the seven CAHs that closed in 2014, we found that, before closure, all seven received Medicare cost-based payments of $900 or more per day for post-acute care in swing beds; six of the seven received aggregate Medicare payments for post-acute care in swing beds that were at least $400,000 above SNF PPS rates (Table 7-2, p. 216).

For acute inpatient services, we compared the cost-based payments CAHs received for acute inpatient services with how much they would have received under the PPS system.[7] We found that, on average, cost-based rates and IPPS rates (including special rural payments) in 2013 were about equal for the average CAH, which is an artifact of CAH cost accounting (Table 7-2, p. 216). CAHs typically allocate a disproportionate share of their costs to post-acute care days because of Medicare regulations. (See online Appendix 7-A, available at http://www.medpac.gov.) The combination of CAHs allocating a smaller share of their costs to acute inpatient care along with special payments for rural inpatient care (i.e., SCH, MDH, and low-volume adjustments) resulted in cost-based payments for acute inpatient services being close to the PPS rates with the rural add-ons. Combining the supplemental payments for both post-acute care and acute inpatient care, the median CAH received $800,000 in supplementary payments above PPS rates in 2013 (Table 7-2). Among the seven closed hospitals, the median CAH received $500,000 in payments above the comparable PPS payments.[8] These extra payments for inpatient care were

TABLE 7–1 **Critical access hospital cost growth**

	Critical access hospitals	PPS hospitals
Number of hospitals*	557	2,646
Mean number of total discharges		
2003	492	9,749
2013	361	9,873
Growth, 2003–2013	*–27%*	*1%*
Mean number of Medicare swing bed days		
2003	673	102
2013	709	67
Growth, 2003–2013	*5%*	*–34%*
Medicare FFS revenue		
2003 (in millions)	$2.8	$40.8
2013 (in millions)	6.2	56.3
Growth, 2003–2013	*125%*	*38%*
Total all-payer revenue		
2003 (in millions)	$10.6	$146
2013 (in millions)	18.4	253
Growth, 2003–2013	*74%*	*73%*
Capital cost		
Capital cost		
2003 (in millions)	$0.6	$9.1
2013 (in millions)	$1.3	14.2
Growth, 2003–2013	*125%*	*56%*
Capital cost as a share of total all-payer revenue		
2003	5.7%	6.2%
2013	7.1%	5.6%

Note: PPS (prospective payment system), FFS (fee-for-service). Reported swing bed days in the Commission's analysis are days in beds that can be used for either inpatient acute or post-acute care. "Medicare FFS revenue" refers to inpatient, outpatient, and post-acute revenue for which CAHs receive cost-based reimbursement. It does not include physician fee income (which is included in "Total all-payer revenue"). In some cases, physician fee income may grow due to CAHs taking on the billing of physician services, which would not accurately reflect an actual change in Medicare payments. Medicare FFS revenue also does not include Medicare Advantage revenue.
*The critical access hospital (CAH) data are limited to hospitals that were in the CAH program continuously from 2003 to 2013. We limited the CAH sample to prevent the trend in revenue from reflecting the change from PPS to CAH rates. The hospitals that entered the CAH program before 2003 have slightly lower revenue on average than newer CAHs. Across all CAHs in 2013, Medicare payments averaged about $7 million per CAH, or roughly $9 billion dollars in aggregate, which is about 5 percent of all Medicare hospital payments.

Source: MedPAC analysis of hospitals that had cost reports in 2003 and 2013.

not sufficient to keep these hospitals open because the extra payments were absorbed by the high inpatient costs per day of care at these hospitals. 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.

Are cost-based rates higher than PPS rates for CAH outpatient care?

Another question is whether Medicare program payments for outpatient services would decline if hospitals shift from CAH status to outpatient 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

TABLE 7–2

Despite total inpatient payments above PPS rates in the year before closure, seven CAHs closed in 2014

	2013							
Location of the seven CAHs that closed in 2014	**Total (all payer) discharges**	**Medicare discharges**	**Acute inpatient Medicare revenue**	**Annual acute inpatient payments above PPS rates**	**Medicare post-acute swing bed days**	**Payment per post-acute day**	**Annual post-acute payments above SNF PPS rates**	**Total inpatient acute and post-acute payments above PPS**
Georgia	609	300	$1,500,000	$–600,000*	107	$900	$50,000	$–550,000*
Kentucky	314	163	900,000	0	438	1,300	400,000	400,000
Nebraska	52	42	400,000	200,000	498	2,400	1,000,000	1,200,000
North Carolina	458	313	2,000,000	–100,000	356	1,800	500,000	400,000
Ohio	303	155	1,300,000	500,000	672	1,900	1,000,000	1,500,000
Pennsylvania	358	203	1,000,000	–150,000	2,051	1,200	1,600,000	1,450,000
Texas	356	222	1,000,000	–50,000	470	1,600	550,000	500,000
Closed CAHs								
Median	314	203	1,000,000	–50,000	438	1,600	550,000	500,000
All CAHs								
Median	443	230	1,700,000	50,000	528	1,800	750,000	800,000
Mean	556	278	2,300,000	50,000	681	2,000	900,000	950,000

Note: PPS (prospective payment system), CAH (critical access hospital), SNF (skilled nursing facility). SNF PPS payment rates were estimated at the national average of roughly $400 per day. The additional post-acute payments are equal to the hospital's cost-based payment rate per day less $400, times the number of post-acute Medicare swing bed days at the CAH. Hospital inpatient PPS payments were estimated using claims and cost report data for each CAH and the Commission's 2013 inpatient PPS payment model (for details, see endnote 7). The additional acute inpatient payments are equal to 1.01 times the hospital's reported Medicare inpatient costs from its 2013 cost report less estimated inpatient acute care payments from the payment model for all Medicare inpatient acute care claims for patients discharged during the same 2013 cost reporting period. The extra payments are primarily paid for post-acute care rather than for acute inpatient services, due in part to the cost-accounting issues discussed in online Appendix 7-A (available at http://www.medpac.gov).
*The Georgia hospital had relatively low costs per day of $900 (not shown). They would have received higher inpatient payments under the PPS because of their low costs and the high payment rates provided under the current low-volume adjustment offered to certain hospitals. However, it is not clear whether their overall payments would have been higher under the PPS due to differences in outpatient rates and reimbursement that CAHs receive for the cost of on-call physicians. The example does illustrate how lower cost facilities benefit less from cost-based reimbursement.

Source: MedPAC analysis of 2013 Medicare claims data and cost reports.

to the program's share of PPS rates (Medicare Payment Advisory Commission 2012). Therefore, we would not expect significant program savings from shifting from CAH program payments for outpatient services to PPS rates. However, beneficiary cost sharing is substantially higher under the CAH program than it would be under the outpatient PPS. Beneficiaries' coinsurance at CAHs is set at 20 percent of charges, which is roughly half of the cost-based payment (Medicare Payment Advisory Commission 2011). Therefore, Medicare beneficiaries would see the substantial savings from shifting from cost-based to outpatient PPS rates.

Coinsurance at critical access hospitals

Medicare patients (or their medigap plans) pay CAHs coinsurance equal to 20 percent of charges for many outpatient services. Paying 20 percent of charges was originally the coinsurance policy used for PPS hospitals, but after a 1995 recommendation by one of the Commission's predecessor agencies, the Congress shifted the coinsurance policy used for PPS hospitals from coinsurance based on charges to coinsurance equal to 20 percent of the PPS amount (Prospective Payment Assessment Commission 1995). CAH coinsurance remained at 20 percent of charges. Because charges are

TABLE 7–3 **Coinsurance at critical access hospitals has grown as charges have grown**

Year	Coinsurance as a share of cost of care	
	All outpatient services including lab	Only outpatient services that require coinsurance
2005/2006	33%	44%
2008/2009	35	47
2012/2013	37	49

Note: The second column excludes lab and other services such as flu shots that are not subject to coinsurance. This column is more representative of the average coinsurance paid by beneficiaries when coinsurance is due.

Source: RTI analysis of Medicare outpatient claims data; Briggs et al. 2016; Medicare Payment Advisory Commission 2011.

greater than costs, CAH patients pay more than 20 percent of costs as coinsurance. In 2006, the average Medicare patient at a CAH paid 44 percent of costs as coinsurance for services for which coinsurance is required (Medicare Payment Advisory Commission 2011). However, charges are growing faster than costs (markups are increasing), which has caused an increase in patient coinsurance relative to the cost of care. Between 2006 and 2013, coinsurance as a share of cost rose from 44 percent to 49 percent (Table 7-3). Similarly, the Office of Inspector General found that, in 2012, coinsurance was 47 percent on average for services at CAHs that required coinsurance (Office of Inspector General 2014).

Table 7-3 shows the average share of CAH outpatient costs paid as coinsurance, but coinsurance can vary widely across hospitals and across services due to wide variations in hospitals' charging practices. For services with lower markups, such as ED visits, coinsurance in 2013 was usually 20 percent to 50 percent of costs. For computed tomography (CT) scans, a higher markup service, the coinsurance that year was usually over 50 percent of costs, and over 100 percent of costs for a fourth of CT scan patients. In these cases, the CAH collects 20 percent of charges (which is more than the cost of the service) from the beneficiaries (or their supplemental insurer); then at year-end Medicare settlement, the hospital has to pay the Medicare program a portion of that coinsurance because the patient's coinsurance exceeded the full payment due to the hospital (the cost-based payment rate). Coinsurance for CAH outpatient services can be substantial for the 19 percent of FFS beneficiaries without supplemental insurance (Medicare Payment Advisory Commission 2015a). In fact, for some high-markup services such as CT scans, it may be less expensive for a beneficiary to negotiate a cash price rather than pay the Medicare coinsurance for the CAH-provided service.

A shift in the payment model away from cost-based reimbursement to a new model that gives the provider a fixed payment or grant for overhead services and pays the provider PPS rates would lower beneficiaries' cost sharing to approximately 20 percent of outpatient PPS rates.[9] It would also eliminate the current incentive that beneficiaries without supplemental insurance have to bypass their local CAH for facilities with lower coinsurance for outpatient services.

Medicare may achieve greater efficiency and financial stability at some rural hospitals by subsidizing emergency services rather than inpatient care

Although cost-based payment covers a provider's Medicare costs, it does not generate profits to cover significant uncompensated care costs from treating uninsured patients or ED patients who have high-deductible private insurance policies. In the end, the inpatient focus and the cost-based focus both present barriers to preserving access for at least two reasons:

- The inpatient models (including the CAH model) provide higher inpatient payments, but the payments are largely accounted for by high inpatient costs. Few financial resources may be left to invest in providing emergency care.

- Cost-based Medicare reimbursement does little for hospitals with very low volumes of private-payer patients and high levels of uncompensated care. Medicare and Medicaid pay roughly the cost of their patients' care, but if hospitals do not achieve profits on privately insured patients or local government funding, the hospital will not be able to cover uncompensated care and bad debt. The hospital can fail, and beneficiaries' access may be compromised if there is not an alternative in the area.

New Option 1: A 24/7 emergency department model

There is a growing interest in trying to preserve access to 24-hour emergency services in rural areas without having the hospital encumbered by the need to provide inpatient services (Morse 2015). This interest in part stems from the significant decrease in rural hospital admissions over the past decade, with occupancy at small rural hospitals falling to 37 percent (Medicare Payment Advisory Commission 2015b). Under a 24/7 ED model, the strategy is to redirect funds away from inpatient acute and post-acute care and toward maintaining emergency services.

Under the 24/7 ED model, Medicare would pay the facility standard hospital outpatient rates plus a fixed payment to partially cover overhead services. 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 standby costs of the emergency department and other services that help preserve access such as telehealth services (see Chapter 8 for a description of telehealth services). The new outpatient facility could also provide outpatient observation services, paid at the outpatient PPS rate.

A few rural facilities currently operate stand-alone EDs with an attached outpatient clinic. A study by the University of North Carolina suggests 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 accountants and ED operators support estimates at this general level. To make the model available to poorer communities that have limited taxpayer support, the Medicare program could provide some fixed level of financial support. For isolated hospitals willing to close inpatient services, the program could provide a fixed payment (e.g., $500,000) and pay for outpatient services using outpatient PPS rates. The rationale for this approach is that if standby emergency and primary care capacity are the desired services, then Medicare should pay for standby emergency capacity and primary care capacity directly with the fixed payment rather than indirectly through increasing payments per inpatient day. This approach would help rural communities where the volume of services and the payer mix is insufficient to support a traditional hospital with an inpatient department.

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 will not materially shift with volume changes. It would also differ from cost-based models in that the hospital would no longer have an incentive to offer services for which their costs are not competitive (e.g., post-acute services or MRI services) because additional volume would not lead to increases in supplemental Medicare payments.

We would expect the new Option 1 to change the financing and delivery of care in several ways:

- Hospitals could choose to eliminate acute inpatient services.
- Hospitals choosing to eliminate acute inpatient services and accept PPS rates would receive a fixed supplemental payment from Medicare. The inpatient volume would flow to neighboring hospitals, potentially improving the neighboring hospitals' financial condition.
- Some hospitals may convert their hospital beds to SNF beds, for which they would receive SNF PPS rates.
- Outpatient facilities would place a priority on emergency care and would have the additional fixed payments to fund that care. We would expect outpatient clinics (e.g., federally qualified health centers and freestanding rural health clinics) to continue operating.
- The facilities would have greater flexibility to use telehealth consultations. The facility would still receive the telehealth fee that hospitals currently receive, but could also use the fixed payment to help support telehealth. (See Chapter 8 for a more lengthy

description of telehealth consultations in emergency and nonemergency situations.)

- Without inpatient services and nonemergency outpatient services such as MRI, the hospital's cost of delivering care would be substantially lower than under the current inpatient models.

While hospitals that eliminated their inpatient departments would see a decline in Medicare revenue, revenues would not decline as much as costs due to retaining a fixed payment. In many cases, we expect that the PPS payments plus the fixed payment would exceed the new lower levels of Medicare costs. Under these circumstances, Medicare would explicitly be covering more than its share of standby capacity costs to preserve access for Medicare beneficiaries.

The facility would also have the option of aligning with larger hospitals in the area to help 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. The idea is that the new outpatient-only facility would work cooperatively with other health care providers to give members of the community continuity of care across settings.

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

A hospital that eliminates inpatient services (acute and post-acute swing services) and accepts outpatient PPS rates could receive the fixed payment. To ensure that the funds are 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.

It is not clear how many providers would choose to convert from a PPS hospital or CAH status to an outpatient facility under the new program. How many would convert would in part be determined by the size of the fixed payment and how the program was targeted. Ideally, the fixed-payment model would target isolated providers only; *isolated* could be defined as a certain driving distance from other EDs.[10]

New Option 2: A clinic and ambulance model in towns too small to support a 24-hour emergency department

The smallest communities—generally unable to support an ED open 24 hours per day, 7 days per week—would likely have to rely on an ambulance service to stabilize and transfer patients. However, the low population density would also make it difficult to retain primary care providers and support an ambulance service. An alternative for these communities could be a primary care facility with an affiliated ambulance service. Similar to the federally qualified health center (FQHC) model, Medicare could provide prospective rates for primary care visits and ambulance transports and could make a fixed payment or grant to support the capital costs of having a primary care practice, the standby costs of the ambulance service, and uncompensated care costs. There could also be a requirement for some local matching funding, such as hospital district funding that is now in place in many parts of the country for small rural hospitals. Medicare could also require that the eligible clinics be some distance away from hospitals to prevent duplicative capacity.

The Kansas Hospital Association (KHA) is evaluating two options: a 12-hour Primary Health Center Model (similar to the new Option 2 model of clinic plus ambulance) and a 24/7 model where an emergency department would be available 24 hours a day (similar to the new Option 1 model discussed (Morse 2015, Thompson 2015, Washington State Hospital Association 2015). The 12-hour model discussed by the KHA would differ from a traditional FQHC in that it would be open 365 days a year and have additional emergency stabilization-and-transfer ability. Despite being open 365 days a year, some communities may be reluctant to give up 24-hour emergency access.

From a payment policy perspective, the clinic and ambulance model will be more challenging to define than the 24/7 stand-alone ED model. In the 24-hour ED model, an existing hospital's organization is in place, including a governing board that could accept the annual fixed payment from CMS after they close their inpatient capacity. In addition, in the 24-hour model, the fixed payment will also be contingent on providing a specific product, namely an ED that is staffed 24 hours a day. By contrast, in the clinic with ambulance model, it is less clear what entity would receive the fixed payment, and it may be more problematic to execute. It will be more challenging to describe exactly what level of primary care and timely ambulance access is required to receive the fixed payment from the Medicare program. In addition, there could be a large number of existing small-town primary care practices and ambulance services that may argue that they should receive a fixed payment equal to those received by providers in towns that lost a hospital. This situation could

result in Medicare "buying-out the base" (i.e., supporting the entire primary care infrastructure of large numbers of communities, including those not losing a hospital) and thus raising the cost of this policy.

Limiting the fixed payment to isolated providers

Rural hospitals, including CAHs, are widely diverse. About a third of rural hospitals are 25 or more miles from other hospitals. Some are more than an hour from other hospitals. However, other hospitals (including CAHs) are 2, 5, or 10 miles from a competing hospital. The value of keeping open a hospital that is 5 miles from a competitor is less than the value of keeping open a hospital that is 60 miles from the next hospital. The emergency access that isolated hospitals provide needs to be preserved, and in certain circumstances, preserving this access will involve Medicare payment rates that are higher than standard PPS rates.

In the Commission's 2012 report on rural health care, we stated that special rural payments should be targeted to isolated low-volume providers that are at least a certain distance from other providers (Medicare Payment Advisory Commission 2012). A distance requirement would encourage two neighboring low-volume hospitals to consolidate into one higher volume facility. There is a substantial body of literature showing a relationship between volume and outcomes, including hospital mortality, suggesting that a merger of nearby facilities would reduce mortality rates in rural areas (Durairaj et al. 2005, Institute of Medicine 2000, Joynt et al. 2013, Joynt et al. 2011a, Joynt et al. 2011b, Medicare Payment Advisory Commission 2012, Ross et al. 2010, Silber et al. 2010). However, isolated providers would need to be preserved to retain beneficiaries' access to emergency care.

Isolated providers could be targeted through the new models if qualifying hospitals were limited to hospitals that were closing their inpatient units and were located a certain travel distance (road miles) from another hospital. This approach would help increase patient volume at remaining inpatient facilities. In addition, merging neighboring low-volume hospitals could help physician recruitment because physicians' on-call burden would be reduced when a small area's EDs were reduced from two to one. Any consolidation of hospitals would be difficult but could yield material benefits in terms of improved patient outcomes and physician recruitment.

Require local government contributions?

To provide some assurance that the local community values the local provider, policymakers could consider requiring the local community to provide some matching funding to the new entity under the new Option 1 or Option 2 models. For example, if the Medicare program contributed a $500,000 fixed payment, the local community could be required to contribute a percentage matching contribution (e.g., $250,000 annual contribution). By limiting the supplemental fixed payments to markets where the local hospital district, county, or city government was willing to put a tangible value on the provider of emergency access, greater assurance would be provided that the federal dollars were being appropriately targeted. However, there are some reasons why policymakers may choose not to require a matching payment from local sources. For example, it may be more difficult for the poorest communities to approve local funds or county funds to support the hospital, or it may be difficult for communities to make multiyear commitments to provide matching funds.

Conclusion

We have discussed some limitations of the current rural payment models. Specifically, they can promote inefficiencies and, despite cost-based Medicare payments, do not always result in financially viable hospitals. Therefore, there may be a need for a new rural payment option that could promote greater efficiency and better maintain access to care.

For hospitals that choose to participate, the combination of a Medicare fixed payment or grant and potentially local support could help pay for 24-hour standby emergency capacity in small rural communities. Buying a defined set of services, such as standby emergency capacity, would make this program easier to administer than giving rural hospitals a global budget for all services.[11]

Implementing a 24/7 ED model would require action by the Congress and the boards of rural hospitals. The Congress would have to enact new payment model options. Hospital boards in small communities would have to accept giving up inpatient services to preserve emergency access. Giving up inpatient services would be a difficult decision even if a hospital board thought that their current model was not sustainable or did not deliver

adequate value to their community. To reduce hospital boards' possible concerns over substantial changes to care delivery in their communities, CMS could allow the facilities to revert to CAH status within 5 years (even if they do not meet the 35-mile distance requirement) if conditions changed and a board determined that local inpatient services were needed. Similarly, if a PPS hospital was an SCH or an MDH before conversion to an outpatient-only facility, they would have the option to revert back to that special status within five years.

The end goal is to preserve access to emergency services in isolated rural areas where there are no alternatives. The mechanism for achieving this goal efficiently is to shift from providing supplemental funds for low-volume inpatient services to a fixed payment model that funds 24/7 emergency access. The fixed payment would help fund the cost of ED standby capacity and the cost of indigent patients using the facility. In the long run, given the current funding situation of the Medicare program, there is the broader question of what share of the cost of preserving access for all patients should be borne by Medicare. ■

Endnotes

1 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 that is often used by the Federal Office of Rural Health Policy.

2 The MDH program was later changed so that MDHs receive the higher of (a) payments based on 75 percent of their case-mix-adjusted historical inpatient operating costs per case trended forward and 25 percent based on operating PPS rates or (b) 100 percent of operating PPS rates.

3 In fact, because of the way cost-based reimbursement works, Medicare reimbursement is reduced for every uninsured patient served. For example, assume that two CAHs were both committed to serving all of the indigent patients in their communities. Assume the two hospitals had identical levels of fixed costs, identical numbers of Medicare patients, and identical mixes of cases among their paying patients. The only difference was that one of the two hospitals had one additional indigent patient. The hospital with the one additional indigent patient would have that patient's variable costs allocated to that additional patient. However, its fixed costs would be averaged over more patients, resulting in lower costs per discharge (i.e., same fixed costs, one more patient). The lower fixed cost per patient would result in lower CAH cost-based Medicare payments per discharge and lower Medicare payments in aggregate. This example illustrates how serving additional indigent patients can reduce the Medicare share and result in lower payments under a cost-based model.

4 Swing beds are beds in small rural hospitals that can be used for acute or post-acute care. PPS hospitals are paid SNF rates for swing bed services, but CAHs are paid cost-based payment for swing bed services. For these services, the median payment was $1,800 per day in 2013. This payment compares with the $300 per day that an average PPS hospital receives for swing bed care and the $400 per day that SNFs receive on average for post-acute care. See online Appendix 7-A (available at http://www.medpac.gov) for a description of how the cost accounting for swing beds can overallocate costs to swing beds and how high swing bed payments reduce the extra payments hospitals receive for acute inpatient services.

5 We looked at the relationship between historic non-Medicare (private, Medicaid, and uncompensated care) margins and Medicare payments per post-acute day in two ways. Both methods suggest that CAHs with higher profits on their non-Medicare business receive higher post-acute care payments from Medicare. Medicare's post-acute care payments per day at these high-margin hospitals were about $200 more per day, on average, than at low-margin CAHs when the hospitals have similar volumes of total inpatient days. In both methods, we started with a sample of 862 CAHs that had valid cost report data and a material number of inpatient days (over 700 combined inpatient acute and swing bed days). We then divided the sample CAHs into three groups based on their median margins on their non-Medicare business during the three years from 2010 to 2012: 300 CAHs with median non-Medicare margins over 5 percent; 233 with medians between 0 percent and 5 percent; and 329 with medians below zero. We then conducted a Tukey mean separation test to examine differences in payments per post-acute day across the three groups. The historically high-profit hospitals had Medicare payments that were $250 per day higher than the hospitals that historically had losses. The difference is statistically significant ($p < 0.05$). We also estimated ordinary least squares regressions where the log of Medicare payments per post-acute day is modeled as a function of the log of inpatient volume (number of all-payer inpatient days) and historic margins. The implication of the regression coefficients is that the typical hospital in the high-profit group would have payments of roughly $200 per day more than a typical hospital in the low-profit group. In various versions of the regression model (e.g., with and without log transformation of costs, with and without controlling for county income), the coefficient on historical non-Medicare margins was always significant at the $p < 0.001$ level.

6 Under the OPPS, Medicare maintains different payment rates for hospital EDs that are open 24 hours a day and 7 days per week (Type A visits) and for those that are open less than 24/7 (Type B visits). In general, payment amounts for Type A visits are higher than payment amounts for Type B visits because facilities that are open 24/7 have higher facility and labor costs. OCEDs largely bill for Type A visits because they are open 24/7.

7 CAH's cost reports record their Medicare costs, payments, discharges, and other information for their annual cost reporting periods, which vary among CAHs and often overlap portions of two federal fiscal years. Our goal was to estimate what each CAH would have been paid under the inpatient hospital PPS for its 2013 cost reporting period. We first identified all the claims from Medicare's inpatient hospital claims files with discharge dates in each CAH's 2013 cost reporting period. We then used the fiscal year 2013 version of our PPS payment model to estimate PPS payments for each CAH using the matched claims. To do this calculation, we had to fill certain gaps in CAH reporting. For example,

to calculate disproportionate share payments, we estimated each hospital's share of Medicare inpatient days for Medicare beneficiaries who received Supplemental Security Income payments during the hospital's 2013 cost reporting period. To determine whether each CAH would have been eligible for the SCH program, we used a hospital geo-location file to estimate distances between each CAH and other nearby acute care hospitals. We then identified CAHs that would have qualified for the SCH program in 2013 because they were located more than 25 miles from the nearest acute care hospital. For each SCH-eligible CAH, we used matched Medicare claims and cost data for its 2006 cost reporting period to estimate its 2006 base-year, case-mix-adjusted operating costs per case. Then we updated the base-year amount to 2013, as it would have been updated if the hospital had been paid under the PPS. The payment model uses this amount to calculate whether and how much supplemental operating payments each CAH/SCH would have received in 2013. To calculate PPS base operating and capital payments, we also calculated weighted average 2013 operating standardized payment amounts and capital federal payment rates for each CAH. These base rates were designed to reflect the distribution of each CAH's matched claims for fiscal years 2012, 2013, and 2014. We also used each CAH's operating and capital cost-to-charge ratios (CCRs) from its 2013 cost report; these CCRs were needed to estimate outlier payments in the PPS model. For outlier payment estimates, we used the national fixed-loss amount for fiscal year 2013. We also made an estimate of the low-volume adjustment that hospitals would receive if they met the distance requirement. Using these inputs, the PPS model provided an estimate of total PPS payments for each CAH's 2013 cost reporting period that was comparable with what it was actually paid in cost-based payments for Medicare acute care inpatient services.

8 Because there are cost allocation issues between post-acute and acute stays, the most accurate way to examine the higher PPS payments going to hospitals for inpatient stays is to add together the higher payments for Medicare inpatient acute and post-acute care stays. See online Appendix 7-A (available at http://www.medpac.gov) for more information on the cost-accounting issue.

9 The Commission recognizes that the term *grant* may carry certain connotations within the context of federal funding. Our use of the term in describing funding for the options discussed in this chapter does not imply the endorsement of any or all of the administrative apparatus typically associated with federal grant funding. We *do* use the term, however, to distinguish how the new entities under these models would be funded in contrast to alternative funding constructs. In the Commission's view, Medicare would give fixed sums to qualifying providers who agree to convert to one of the models and discontinue providing inpatient hospital services.

10 As has always been the case with Medicare policy, the minimum distance would be calculated using road miles. The Department of Veterans Affairs has also recently switched to using road miles (rather than "as the crow flies" miles) to compute distance (Department of Veterans Affairs 2015).

11 Fixed budgets for a broader scope of services (e.g., all outpatient services) would be more problematic because a substantial and variable share of rural patients bypasses their local hospital for many services, including those locally available. The share of services provided locally would change over time and vary widely across providers. The additional problem with broader bundles is that providers deemed the highest quality providers could see increased volume and those with lower quality would see decreases in volume. For this reason, the proposal here to buy a specific service (fixed standby capacity) should be easier to administer than other systems, such as the Maryland system that provides for global budgets for rural providers.

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CHAPTER 8

Telehealth services and the Medicare program

CHAPTER 8

Telehealth services and the Medicare program

Chapter summary

The Commission's analysis of telehealth services—a multidimensional set of health care services delivered through a range of online, video, and telephone communication—is intended to be informational for policymakers as they consider how telehealth services fit into the Medicare program in the future. The Commission finds that telehealth services are currently covered to a limited extent by Medicare, commercial insurers, the Department of Veterans Affairs (VA), and Medicaid programs. The efficacy of telehealth services—in terms of access, quality of care, and cost—is mixed, with the exception of a small number of services. The Commission raises issues for policymakers to consider in addressing the question of expanding telehealth services under the Medicare Advantage program, under bundled and accountable care payment models, and under the fee-for-service model.

Commercial insurers, health systems, employers, Medicaid programs, the VA, patients, and technology vendors have recently demonstrated increased interest in telehealth services. Entities asserting their rationale for using telehealth hope that it will expand access to care, create greater convenience for patients, improve the quality of care, and reduce the costs of care. For example, telehealth may improve access to care in rural areas that have difficulty staffing a full-service hospital (see Chapter 7). A separate impetus for the use of telehealth services stems from recent advancements

In this chapter

in telecommunications technology, such as improving the quality and availability of two-way video. With regard to evaluating the capacity of telehealth services to reduce costs, an important question is whether telehealth services are a supplement to or a substitute for existing services (Congressional Budget Office 2015). In addition, policymakers must consider the potential for more convenient services to generate new utilization.

In 2015 and 2016, the Commission conducted several analyses related to telehealth services and found the following:

- ***Telehealth services fall into six categories:***

  1. basic medical care and consultations between the patient at home and a distant clinician,
  2. basic medical care and consultations between a patient in the presence of a clinician and a distant clinician,
  3. basic medical care and consultations between two clinicians without the patient present,
  4. remote monitoring of a patient in a hospital or other facility,
  5. remote monitoring of a patient at home, and
  6. secure asynchronous electronic transfer (e.g., e-mail) of patient information (e.g., an image or lab results) to a clinician.

- ***Medicare's coverage of telehealth covers a certain set of services under the traditional fee-for-service (FFS) program's fee schedule for physicians and other health professionals (also referred to as the physician fee schedule, or PFS).*** Coverage is limited to certain providers and to care provided in rural locations. Medicare Advantage (MA) plans must cover telehealth services that are covered under FFS Medicare and can provide telehealth services that are adjunct to delivering services covered under FFS Medicare. In addition, MA's coverage can include telehealth services that are extra benefits beyond Medicare FFS coverage, if approved by CMS. These extra benefits must be financed either through a plan's rebate dollars or by charging Medicare enrollees a supplemental premium. Medicare also permits providers participating in certain special programs run by the Center for Medicare & Medicaid Innovation to provide telehealth benefits beyond those covered under FFS Medicare.

- ***Medicare telehealth use is low but has grown rapidly in recent years.*** In 2014, approximately 68,000 beneficiaries used telehealth services under the PFS, but from 2008 to 2014, the number of telehealth visits grew by over 500 percent. Medicare beneficiaries using telehealth services tend to be young, to

be disabled, to be dually eligible for Medicare and Medicaid, and to reside in rural areas. Beneficiaries use telehealth services for basic medical care as well as psychiatric care.

- ***Interest in telehealth services outside of the Medicare program has grown in recent years, but the use of these services is not widespread.*** Several insurers cover telehealth services to expand access and convenience to primary care. Their rationale for doing so is to have their enrollees use telehealth services instead of receiving care at more expensive urgent care centers and emergency departments (EDs). Some health systems have developed and are marketing telehealth services for the hospital setting as well as for ambulatory and behavioral health care. Their intention is to improve quality and create staffing efficiencies within their systems and to market these benefits to other payers and providers. A growing share of large employers provide telehealth services as a convenience to their employees and to reduce their health care spending. The VA implemented telehealth programs several years ago and in 2015 provided telehealth services to 736,000 of their patients. Initially, the VA implemented these programs to provide clinicians with capabilities they requested and to improve quality and reduce costs.

- ***Most state Medicaid programs cover telehealth services to some degree.*** Some cover telehealth in urban areas and from patients' homes, and others limit coverage to certain types of services and certain types of clinicians or restrict coverage to rural areas.

- ***Evidence is mixed about the efficacy of telehealth services to expand access and create convenience, improve quality and outcomes, and reduce costs.*** Evidence that certain telehealth services improve access and create convenience is much stronger than evidence regarding quality improvement or cost reduction. In general, telehealth for patients with chronic conditions has shown some positive quality and cost results. Telestroke services (the use of two-way video to connect stroke patients in the hospital ED with neurologists in distant locations for evaluation and monitoring) may be the best example of positive results. Given the inconsistency in the academic literature, it appears that more targeted research isolating specific telehealth interventions for specific patient populations is needed.

- ***If policymakers consider expanding telehealth services in the Medicare program, they should differentiate between the financial incentives that exist under Medicare's payment models.*** In MA, many bundled payment models, and accountable care organizations, the financial risk of providing such services

falls to the insurers or providers. By contrast, under traditional FFS Medicare, the additional cost for telehealth services would be borne by the Medicare program, unless such services were substitutes for traditional face-to-face clinical services. ■

Introduction

This chapter summarizes information concerning telehealth services that the Commission considered from July 2015 through April 2016. We describe how telehealth services are used within the Medicare program and in non-Medicare settings, such as by commercial insurers, health systems, the Department of Veterans Affairs (VA), and others. We report our review of recent academic literature addressing the efficacy of telehealth services in terms of access, quality, and costs. This analysis has grown out of interest by MedPAC Commissioners and the Congress.

The definition of telehealth—also referred to as telemedicine—is multidimensional and continues to evolve.[1] The American Telemedicine Association (ATA) defines telehealth services broadly as medical information exchanged from one site to another by means of electronic communications to improve a patient's clinical health status (American Telemedicine Association 2016b). Telehealth is provided in several modalities by numerous types of clinicians and facilities for various types of patients. Telehealth services are used for basic medical care (primary care), patient monitoring, behavioral health, case management, patient education, and off-site interpretation of medical images. Telehealth is provided in various modalities, such as online two-way video, telephone, smart phone, e-mail, text, or other online monitoring systems. While a wide range of clinicians use telehealth services, telehealth represents a relatively small share of all the care provided in the United States.

Interest in using telehealth services has rapidly increased in recent years. For many years, telehealth was considered a tool for improving access to care, primarily in the rural setting. Commercial insurers, health systems, hospitals, skilled nursing facilities (SNFs), clinicians, employers, patients, and telehealth vendors have all demonstrated growing interest in telehealth services as advancements have occurred in electronic health records, data analytics, and communication technology (Alliance of Community Health Plans 2015, Bashshur et al. 2014). The Healthcare Information and Management Systems Society found that between 2014 and 2015, the number of vendors selling telehealth technologies increased from 69 to 85 different vendors, an increase of 23 percent (Healthcare Information and Management Systems Society 2015). Researchers estimate that approximately 40 percent of hospitals had telehealth capability in 2012 (Adler-Milstein et al. 2014).

A variety of interested parties assert that telehealth has the potential to expand access and convenience, improve the quality of care, and reduce costs. Some researchers have noted that telehealth may substitute for some traditional in-person visits and reduce the use of high-cost care such as emergency department (ED) visits, hospitalizations, home health services, and skilled nursing care (Baker et al. 2011, Cryer et al. 2012). Other researchers, citing the potential benefits of telehealth services, caution policymakers that telehealth could also drive increases in health care spending by increasing utilization or unnecessary use (Mehrotra 2014, Schwamm 2014). Some government agencies and researchers have stated that telehealth has the potential to keep patients in more consistent contact with providers, reduce the number of acute or major illnesses for high-risk patients with chronic conditions, and improve access to care by making it more convenient, particularly for patients in isolated rural locations (Dixon et al. 2008, National Advisory Committee on Rural Health and Human Services 2015, President's Council of Advisors on Science and Technology 2016). Similarly, telehealth services may help ensure access to specialized care in isolated rural areas facing difficulties in maintaining and staffing full-service hospitals (see Chapter 7). However, to date, the available research offers a mixed picture of telehealth's benefits. For example, a draft report released for comment by the Agency for Healthcare Research and Quality (AHRQ) in December 2015 concluded, based on the 44 studies they reviewed, that telehealth interventions aimed at patients with chronic conditions and behavioral health needs produced some success in improving quality and reducing costs (Agency for Healthcare Research and Quality 2015). However, AHRQ also concluded that more studies are necessary to determine the efficacy of telehealth interventions aimed at hospitalizations, pediatrics, primary care, and payment models where risk is shared between providers and payers.

The recent push to expand telehealth services may be the result of changes in technology, telehealth vendors' interest, and the growth of new payment models. Advancements in the quality of and access to communication technology within the last decade, such as online two-way video, have improved lines of interpersonal communication. It has been only in the last few years that a large share of the population has become comfortable enough with these new technologies to consider their applicability in a clinical setting. Several vendors have developed technologies, software, systems, and services that rely on these advancements. In addition, the growth of new payment models such as accountable

care organizations (ACOs) and bundled payment may have increased the willingness of payers to cover telehealth services.

There are investment costs associated with implementing telehealth for facilities, health systems, clinicians, and patients. For facilities such as hospitals and SNFs, wiring patient rooms with telehealth capacity can cost several thousand dollars per room, not including ongoing maintenance and labor costs. For health systems, installing a centralized telehealth control center can cost roughly a million dollars. These costs are small relative to these organizations' overall budgets, but the investment can be material. For clinicians' offices and patients, telehealth investments are more modest, including computers, cell phones, monitoring equipment, and Internet connectivity. For beneficiaries on fixed incomes, these investments could be more of a burden.

In assessing the impact of telehealth services on the cost of care, the calculations must consider whether telehealth is a substitute for traditional services or a supplement, whether telehealth might induce new utilization, whether telehealth would shift the site of care to a less costly setting, and how the payment model under which telehealth services are paid can impact costs. The Congressional Budget Office (CBO) concluded that when telehealth services clearly substitute for traditional in-person services, there is potential for reducing Medicare program costs. On the other hand, when telehealth services supplement traditional services, there is potential to increase program costs (Congressional Budget Office 2015). Another key factor in estimating potential telehealth spending is the extent to which beneficiaries would be interested in using these services. Research has found that easily accessible retail clinics induce new utilization (Ashwood et al. 2016). This finding may offer some insight into whether easily accessible telehealth services would also induce new utilization. The system under which telehealth services are paid could also alter cost projections. For example, under fee-for-service (FFS) Medicare, the program could theoretically be expected to pay for each video, e-mail, or telephone interaction between a patient and a clinician (if e-mail and telephone were also permitted under Medicare), which could increase costs. However, under a capitated or bundled payment system, the program could pay a flat rate for a period of time or episode of care that includes multiple services. Under this payment model, the problem of unnecessary use of telehealth services could be mitigated because the provider would be at financial risk if total spending exceeded a target.

Analysis of telehealth services

To evaluate the use of telehealth services we:

- analyzed the forms of telehealth services;
- examined Medicare payment policy;
- analyzed trends in Medicare volume and spending;
- reviewed literature on the impact of telehealth services on access, quality, and costs;
- conducted semi-structured interviews with commercial insurers, health systems, ACOs, and the VA;
- evaluated state laws and Medicaid programs;
- visited a health system known to its peers as a leader in telehealth; and
- met with telehealth vendors, advocates, and other interested parties.

Telehealth services come in a variety of forms

Telehealth services encompass a large, multidimensional group of services, modalities, clinicians, settings, and types of patients. The ATA loosely categorizes telehealth services into four types of clinical services and four modalities.[2] In practice, telehealth services are used for primary care, specialty consultations, behavioral health, hospital care (e.g., emergency departments, intensive care units, and inpatient departments), SNF care, and other clinical applications. Telehealth services can be delivered using common technologies such as telephone, e-mail, and text, or more sophisticated technologies that have recently become more widely available, such as online two-way video conferencing and online remote monitoring systems that record and send vital patient statistics to clinicians. These recent advancements have enabled broader availability of telehealth.

Based on the ATA's categorizations and our own observations, we group telehealth services into six categories. Three categories involve basic medical care and consultations:

- ***Patient at home connecting to a clinician***—The patient receives basic medical care or consultation while at home or another location, using two-way video, e-mail, text, or telephone. The clinician is located in his or her office or facility.

- ***Patient in the presence of a clinician connecting to a second clinician***—The patient receives basic medical care or consultation while at a clinician's place of service, connecting with a second clinician at a different place of service using two-way video.
- ***Clinician connecting to a second clinician***—Two clinicians consult without the patient present, using two-way video, e-mail, or telephone. A common example is a clinician communicating with a pharmacist to reconcile a patient's medication portfolio—referred to as telepharmacy.

Two telehealth service categories involve the remote monitoring of patients:

- ***Remote hospital-based monitoring***—Clinicians monitor a patient during a hospital stay from a remote location using two-way video and electronic monitoring systems. Examples include diagnosing and evaluating stroke patients in the ED using monitoring equipment—referred to as telestroke—and assisting hospital staff with the monitoring of patients in the intensive care unit (ICU) or inpatient beds—referred to as tele–ICU and telehospitalist care.
- ***Remote patient monitoring (RPM)***—A patient at home is monitored continuously or intermittently from a remote location using two-way video or electronic monitoring technology that automatically transmits data from the patient's home to the clinician.

The sixth service category involves the transmission of data:

- ***Asynchronous store-and-forward data transmission***—A health care provider transfers saved patient information (e.g., photographs or video) to a clinician using e-mail or other modalities, such as cloud-based technologies. Examples include transferring patient images using teledermatology and teleradiology.

Medicare payment for telehealth services

The Medicare program currently covers telehealth services under three different statutory provisions. Section 1834(m) of the Social Security Act specifies that under the fee schedule for physicians and other health professionals (also referred to as the physician fee schedule, or PFS), Medicare covers a limited set of telehealth services, modalities, and providers, and only in rural locations.[3] Medicare also covers services under the PFS that meet a broader definition than what is defined in statute as telehealth services, such as remote interpretation of diagnostic tests and the remote monitoring of patients with implantable cardiac devices. Under the Medicare Advantage (MA) program, MA plans must cover telehealth services covered as a part of the Medicare FFS (Part B) benefit and have some flexibility to cover other forms of telehealth. CMS's Center for Medicare & Medicaid Innovation (CMMI) is also testing expanded coverage of telehealth services through several payment models.[4]

Payment for telehealth services under the Medicare fee schedule for physicians and other health professionals

Medicare coverage of telehealth services under the PFS began in 2001 with the enactment of the Balanced Budget Act of 1997 (BBA) and has evolved since then. Since the BBA, the Congress expanded telehealth coverage by increasing the list of approved providers, modifying the payment structure, and expanding the definition of rural areas. Through regulation, CMS has increased the number of permissible telehealth services by increasing the number of billing codes.

Three pieces of legislation have altered Medicare telehealth coverage under the PFS: BBA; the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA); and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

- BBA's original mandate was that (1) Medicare begin coverage of telehealth services through the fee schedule, (2) a clinician must be present with the beneficiary at the location where the service originates (the originating site), (3) a clinician must be present at the distant end of the connection (the distant site), and (4) the two clinicians must split the appropriate fee schedule payment rate (25 percent for the originating site and 75 percent for the distant site). BBA also limited Medicare telehealth coverage to originating sites located in health professional shortage areas (HPSAs) (i.e., rural areas) at physician offices, hospitals, critical access hospitals (CAHs), rural health clinics, and federally qualified health centers (FQHCs).
- BIPA expanded Medicare telehealth coverage by removing the requirements that a clinician be present at the originating site and by broadening the scope of originating sites to include those in all rural areas (all counties outside of a metropolitan statistical area

TABLE 8–1 **Medicare coverage of telehealth services, 2015**

Characteristic	Description
Medicare payment	Distant site receives the full PFS rate, subject to standard Part B cost-sharing rules
	Originating site receives a fixed telehealth facility fee of about $25, subject to standard Part B cost-sharing rules
Geographic requirement of originating sites	Rural locations (rural health professional shortage area or a county outside of a metropolitan statistical area)
Types of permitted originating sites	Hospitals, critical access hospitals, physician offices, federally qualified health centers, rural health centers, skilled nursing facilities, community mental health centers, and hospital-based dialysis centers
Types of permitted distant sites	Physicians and other health professionals and critical access hospitals
Services covered	General services: evaluation and management visits, subsequent care in the hospital or skilled nursing facility, annual wellness visits, general consultations (inpatient, emergency department, or outpatient setting), transitional care management
	Kidney disease: kidney disease education (individual and group), diabetes self-management training (individual and group), ESRD-related services
	Behavioral health: health and behavior assessment and interventions, psychotherapy (individual and family), psychoanalysis, psychiatric diagnostic interviews, depression screening, neurobehavioral status exams, behavioral counseling to prevent sexually transmitted infection
	Substance abuse: assessments and interventions, alcohol misuse screening and counseling, smoking cessation
	Nutrition therapy (individual and group)
	Pharmacological management
	Cardiovascular disease behavioral therapy
	Obesity counseling
Modality of telehealth	Two-way video conferencing (all states) Asynchronous store-and-forward technology (only in Alaska and Hawaii)

Note: PFS (fee schedule for physicians and other health professionals), ESRD (end-stage renal disease).

Source: CMS. Medicare claims processing manual: Chapter 12.

(MSA). The Act also added to the list of permitted telehealth services and altered reimbursement so that the originating site receives a fixed payment of about $25 (referred to as the telehealth facility fee). The telehealth facility fee is a coded service paid under the PFS to physicians' offices and certain defined facilities. In addition, the clinician at the distant site receives the full PFS rate.[5]

- MIPPA slightly expanded the scope of permitted telehealth services and expanded the types of eligible originating sites to include community mental health centers, SNFs, and renal dialysis centers based in a hospital.

Currently, the originating site receives the $25 PFS telehealth facility fee payment, and the clinician (or CAH) at the distant site receives the full PFS rate (Table 8-1). Originating sites are required to be in rural areas, defined as those in a HPSA or a county outside of an MSA, and they can only be physician offices, hospitals, CAHs, rural health clinics, FQHCs, community mental health centers,

or hospital-based dialysis facilities. Medicare sometimes permits entities participating in a federal telehealth demonstration project to bill as an originating site regardless of their geographic location, even in urban areas. In addition, clinicians are not required to be present at the originating site with the beneficiary unless it is medically necessary. Physicians and other health professionals (and CAHs) are permitted to bill Medicare for telehealth distant site services under the fee schedule.[6] Clinicians must be present at the distant site during the visit.

Coverage is limited by service type and modality (Table 8-1). The list of telehealth services Medicare covers has been increasing incrementally for several years (Centers for Medicare & Medicaid Services 2016c). Most telehealth services are covered under statute, but CMS has also expanded coverage to some services through regulation. The services currently covered include certain general health care services (e.g., evaluation and management visits and annual wellness visits) and those related to kidney disease, behavioral health, substance abuse, smoking cessation, nutrition therapy, pharmacological management, and cardiovascular disease behavioral therapy. The most recent CMS additions include annual depression screenings, obesity counseling, and behavioral counseling to prevent sexually transmitted infections.[7] The statute limits the modality of Medicare telehealth coverage to live two-way video; asynchronous store-and-forward technology (e.g., e-mailing of a saved diagnostic image or video) is permitted only in Alaska and Hawaii.

Beneficiary cost-sharing responsibilities for telehealth services are identical to other Part B services, and the same rules apply to both the originating and distant site components of the encounter. Therefore, beneficiaries must pay 20 percent of the Medicare-allowed originating site amount and 20 percent of the Medicare-allowed distant site amount after meeting the deductible. For example, a beneficiary who had an individual psychotherapy visit using two-way video between a rural hospital (originating site) and a psychologist's office (distant site) is responsible for 20 percent of the $25 originating site facility fee, or $5, plus 20 percent of the $115 distant site PFS amount ($23), for a combined total of $28 for the encounter. However, because most Medicare beneficiaries have supplemental coverage, they are likely shielded from these cost-sharing responsibilities.

Telehealth services are not separately payable under the inpatient, outpatient, home health, or hospice payment systems. Under the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS), telehealth services are permitted but not separately reimbursable services. Therefore, a telehealth visit or consultation can occur during an inpatient or outpatient stay, but the hospital cannot be reimbursed for that telehealth service separately. While the hospital cannot bill for the originating site facility fee, the clinician at the distant site can bill for the visit through the PFS, provided the patient was at a rural originating site. In addition, hospitals can include costs related to telehealth services on their CMS cost reports as allowable (or reimbursable) costs. As a result, if hospitals report these costs, Medicare builds them into the inpatient Medicare severity–diagnosis related groups (MS–DRGs). Under the Medicare home health and hospice payment systems, providers are not prevented from using telehealth services, but these services are not considered equivalent home health or hospice visits for the purposes of payment. Therefore, Medicare does not pay for telehealth visits separately under these two systems.

Coverage of remote interpretation of tests and cardiac monitoring under the fee schedule

Medicare covers many services under the PFS that involve a practitioner's remote interpretation of a diagnostic test and some services that involve remote monitoring of a patient, although CMS does not define these services as telehealth. Medicare covers diagnostic tests in which a practitioner reviews and interprets a visual image (e.g., X-ray, MRI) related to the patient's condition, even if the practitioner performs this service in a location different from the patient's location (Centers for Medicare & Medicaid Services 2016d). For example, a hospital can perform an imaging study on a patient and transmit the images electronically to a radiologist, who interprets the images in his or her office. To receive reimbursement, these services must be provided within the United States and the practitioner must be licensed in the state in which the patient is located. Because these services are billed using the same codes as in-person interpretation services, we were not able to examine how frequently remote test interpretations are provided.

Medicare also covers remote cardiac monitoring services and remote monitoring of implantable cardiac devices. For example, Medicare covers mobile cardiac telemetry, in which a device records a patient's electrocardiographic rhythm and transmits this information to a remote surveillance location using a phone signal. A physician reviews the data and prepares a report. In 2014, Medicare spent $119 million on remote cardiac monitoring services for 265,000 beneficiaries (beneficiaries' cost sharing was

an additional $34 million). In the same year, Medicare spent $70 million for 639,000 beneficiaries (beneficiaries' cost sharing was an additional $29 million) to remotely monitor patients' heart rhythms through implantable cardiac devices (e.g., pacemakers) and to evaluate the function of these devices.

Telehealth services under Medicare Advantage

Medicare beneficiaries can receive telehealth services through an MA plan. As a part of the basic Medicare FFS benefit, MA plans must cover the same telehealth services that are covered in FFS Medicare under the PFS. In addition, MA plans may provide telehealth services beyond what is covered under FFS Medicare. As part of that requirement, MA plans can use telehealth services adjunct to the delivery of the broad range of services covered under FFS Medicare. Such activities are considered to be within the scope of Medicare-covered services. In describing these adjunct services, CMS's MA manual uses the example of e-mail communication between physicians and patients, stating that these services are "part of the basic FFS benefit" (Centers for Medicare & Medicaid Services 2016a).[8] For example, if a beneficiary discusses lab test results with a clinician by e-mail or telephone, the fact that the patient could have gone to the physician in person to discuss the results does not mean that the call or video is substituting for an in-person visit. Instead, this transaction may be viewed as communication that complements the range of services covered under FFS Medicare.

When MA plans submit their annual Medicare Part A and Part B bid amounts to CMS, they must include the costs of telehealth services specifically covered under FFS Medicare as well as the telehealth services adjunct to the delivery of services covered under FFS Medicare. For example, MA plans would include the costs of covering individual psychotherapy visits for Medicare enrollees in rural areas that are conducted through two-way video in their bid amounts because this service is specifically covered as a part of FFS Medicare. Similarly, MA plans must include the costs of telehealth services adjunct to Medicare FFS services (such as the lab test example above) in their bid amounts. Under this construct, the benefits available to Medicare beneficiaries are the same under FFS Medicare and the MA program.

In contrast to telehealth services that are covered and provided as part of the MA plan's bid amount, MA plans that wish to offer extra telehealth benefits (defined by CMS as "supplemental benefits") beyond Medicare FFS benefits may do so after gaining CMS approval. The costs of these extra telehealth benefits are not included in plan bid amounts. The CMS approval process for extra benefits requires that extra telehealth benefits not substitute for services included in the Medicare FFS benefit and are optional for beneficiaries. In addition, MA plans must continue to meet CMS's network adequacy standards, and providers furnishing extra telehealth benefits do so within their state's licensure laws (Centers for Medicare & Medicaid Services 2014). For example, a plan may choose to offer its enrollees with multiple chronic conditions an extra benefit in which clinicians track an enrollee's vital signs using remote patient monitoring services. This benefit is not covered under FFS Medicare, and the costs of this monitoring would not be included in the plan's bid amount. Some MA plans are offering extra telehealth benefits in 2016. For plan year 2016, CMS reports that 200 MA plans (8 percent of plans) chose to include remote patient monitoring—defined earlier as the monitoring of patients in their homes—and 1,900 plans (73 percent of plans) chose to offer "remote access technologies"—a broad category of services CMS defines as services including e-mail, two-way video, and nurse call-in telephone lines (Centers for Medicare & Medicaid Services 2016b).

To finance the cost of this extra benefit, MA plans can use rebate dollars when its bid is below its regional benchmark. Rebate dollars are equal to the difference between a plan's bid amount and the plan's benchmark, minus a portion of the amount retained by the Medicare program. However, if a plan's bid is at or exceeds its benchmark, it must charge beneficiaries a supplemental premium to cover the expected costs of these extra benefits. For example, an MA plan offering its enrollees' remote patient monitoring as an extra benefit can either finance the cost of this extra benefit by paying for it using rebate dollars or charge beneficiaries a supplemental premium.

Several Medicare CMMI models allow expanded use of telehealth services

Several of the innovative care delivery and payment models currently being tested by CMMI allow expanded use of telehealth services in Medicare, particularly among models in which providers bear significant financial risk.[9] CMS has the authority to waive certain requirements, including restrictions on telehealth, to test new models of providing care. Models that allow greater use of telehealth include the Comprehensive Care for Joint Replacement (CJR) Model, the Next Generation Accountable Care

Organization (ACO) model, the Bundled Payment for Care Improvement Initiative (BPCI), and the Health Care Innovation Awards (HCIA) program.

The CJR model—which began on April 1, 2016—tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements. The model is intended to encourage quality improvement and care coordination by hospitals, physicians, and post-acute care providers. Participating hospitals are held financially accountable for the cost and quality of a joint replacement episode. They are at risk for episode spending above a spending target but can receive bonus payments if spending is below the target and quality thresholds are met. Hospitals paid under the IPPS—generally, acute care hospitals—and located in 1 of 67 geographic areas are required to participate in the CJR model. For services included in the joint replacement episode, this model waives the requirements that the originating site for a telehealth service must be in a rural area and be a specified facility (e.g., a physician's office, hospital, or CAH) (Centers for Medicare & Medicaid Services 2015d). In other words, under this model, patients living not only in rural but also urban areas can receive telehealth services in their homes or places of residence. If the telehealth service is provided in a patient's home, only the distant site provider is paid. All other Medicare coverage and payment criteria for telehealth services apply. CMS believes that this waiver will support care coordination and timely access to quality care for beneficiaries recovering at home following joint replacement surgery (Centers for Medicare & Medicaid Services 2015d).

The Next Generation ACO model, which began in January 2016, includes ACOs that have experience coordinating care for populations of patients and are ready to assume higher levels of financial risk and reward compared with ACOs in other initiatives (i.e., the Pioneer Model or Medicare Shared Savings Program) (Centers for Medicare & Medicaid Services 2016e). Next Generation ACOs may assume up to 100 percent financial risk. CMS waives the same telehealth requirements for Next Generation ACOs that it waives for the CJR model, permitting urban and home telehealth services.

BPCI, which began in 2013, is a voluntary program that tests whether bundled payments can reduce Medicare spending while maintaining or improving quality of care. Organizations that participate in BPCI assume financial and performance accountability for episodes of care that are triggered by a hospital admission. These organizations can choose from several waivers of Medicare requirements, including a waiver from the requirement that the originating site for a telehealth service must be in a rural area (Lewin Group 2015). However, the other coverage requirements for telehealth services (e.g., the originating site may not be the patient's home) may not be waived. There is no information yet on how many organizations have used these waivers or how they have affected spending and quality.

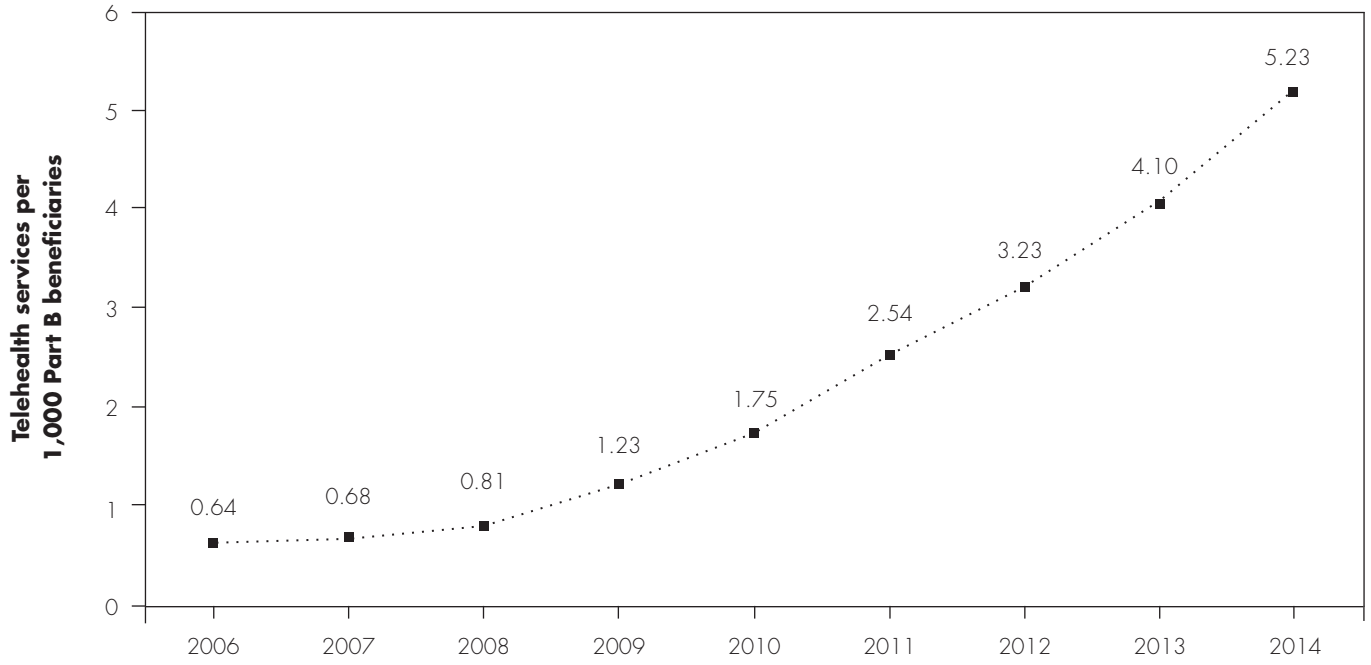
The HCIA program, which began in 2012, provides awards to organizations to test innovative payment and delivery models designed to deliver better care and lower costs for people enrolled in Medicare, Medicaid, or Children's Health Insurance Program. Eight of the various HCIA projects include telehealth services (Centers for Medicare & Medicaid Services 2015b):

- The University of Southern California tests telepharmacy applications as a part of a larger program.
- The Wyoming Institute of Population Health tests telepharmacy and various telehealth applications as parts of a larger program.
- Emory University uses telemonitoring for rural intensive care unit patients.
- George Washington University incorporates telemonitoring in its program for urban patients with end-stage renal disease.
- The Ochsner Clinic Foundation focuses on telemedicine-enabled inpatient care coordination and postdischarge telemonitoring of stroke patients.
- Upper San Juan Health Systems uses telemedicine to screen and treat patients with cardiovascular disease.
- HealthLinkNow uses telehealth to provide mental health care services to rural patients.
- The University of Miami uses telehealth video conferencing to provide nutrition counseling, mental health visits, primary care, and other services to urban school health clinics throughout the city of Miami.

Medicare telehealth volume is low but increasing

Utilization of telehealth visits under the Medicare program remains relatively low, but has increased rapidly in recent years. In 2014, Medicare claims data indicated that slightly more than 68,000 Medicare beneficiaries used telehealth

FIGURE 8–1 **Utilization of Medicare telehealth visits per 1,000 Part B beneficiaries, 2006 to 2014**



Source: MedPAC analysis of Medicare carrier file claims data.

services, or 0.2 percent of Medicare Part B beneficiaries. Telehealth volume increased rapidly between 2008 and 2014, growing by more than 500 percent per Part B beneficiary. In 2008, there were 0.81 telehealth visits per 1,000 beneficiaries, which increased to 5.23 visits per 1,000 beneficiaries in 2014 (Figure 8-1).[10] Between 2001—when coverage of telehealth service began—and 2008, the volume of service use was relatively flat (data not shown).

Growth in the number of claims and spending for telehealth visits increased at a similar rate. From 2008 through 2014, telehealth claims filed by distant site providers increased from 26,000 claims to 175,000 claims. During that period, originating site claims increased from 8,000 to 68,000.[11] Combining claims from distant and originating sites, spending on telehealth visits increased from approximately $2 million in 2008 to nearly $14 million in 2014.

Types of services

The most common types of telehealth services in 2014 were evaluation and management (E&M) or other outpatient visits and psychiatric visits (individual psychotherapy and psychiatric diagnostic interview examinations) (Table 8-2). E&M accounted for 66 percent of all telehealth services, and psychiatric visits accounted for about 19 percent of all telehealth visits. Other services included inpatient-discharge follow-ups, ED consultations, pharmacological management, and visits related to end-stage renal disease.

Providers and clinicians

A relatively small group of providers billed Medicare for telehealth services in 2014, both for originating site claims and distant site claims. That year, some 1,400 unique originating sites and 3,300 unique distant sites billed Medicare for a telehealth service. Physician offices were the most common type of originating and distant sites. Of the originating sites, 82 percent were physician offices, 15 percent were outpatient hospital departments (including the ED), and 2 percent were community health centers (none were nursing facilities). E&M were the most commonly provided services in conjunction with telehealth services at originating site physician offices and community health centers. By contrast,

TABLE 8–2 **Frequency of telehealth visits at distant sites by service type, 2014**

Type of service	Number of visits	Share of visits
Evaluation and management visits	115,430	66.0%
Individual psychotherapy	19,914	11.4
Psychiatric diagnostic interview examination	12,952	7.4
Follow-up inpatient telehealth consultations	7,642	4.4
Telehealth consultations, emergency department or initial outpatient	7,626	4.4
Subsequent hospital care services	4,902	2.8
Subsequent nursing care services	3,341	1.9
Pharmacological management	1,766	1.0
End-stage renal disease–related services	1,078	0.6
Other	347	0.2
Total	174,998	100.0

Note: Components may not sum to totals due to rounding.

Source: CMS carrier file.

group psychotherapy and basic blood work were the most commonly provided services in conjunction with telehealth services at originating site hospitals.

Distant sites were more varied in type than originating sites. Of the distant sites in 2014, 61 percent were physician offices, 12 percent were community health centers, 9 percent were inpatient hospital departments, 6 percent were nursing facilities, 6 percent were hospital outpatient departments, and 3 percent were inpatient psychiatric hospitals. E&M were the most commonly provided services in conjunction with telehealth services at distant-site physician offices and community health centers. By contrast, postdischarge follow-up care, E&M services, and ED consultations were the most common services at distant site hospitals. For nursing facilities, the most common services with telehealth were postdischarge follow-up care; for inpatient psychiatric hospitals, the most common telehealth service was psychiatric diagnostic evaluation.

The most common types of clinicians associated with telehealth visits in 2014 were physicians and nurse practitioners. At the originating site, 52 percent of clinicians were physicians. Other clinicians associated with originating site telehealth claims were nurse practitioners (15 percent), clinical psychologists (7 percent), physician assistants (2 percent), social workers (1 percent), and other (23 percent). Based on our observations from site visits, the "other" category most likely consisted of nonclinical hospital staff who assist the patient with operating the telehealth equipment at the originating site. Among all clinicians associated with the originating site in 2014, 57 percent could be classified as behavioral health clinicians.[12] At the distant site, 67 percent of clinicians were physicians; other clinicians included nurse practitioners (17 percent), clinical psychologists (6 percent), nurses (2 percent), social workers (2 percent), and physician assistants (1 percent). Among all the clinicians associated with the distant site, 62 percent could be classified as behavioral health clinicians.

The provision of telehealth services was concentrated in a small group of clinicians in 2014, with very few providing these services more than once per day. Among clinicians providing telehealth services from the originating site, 10 percent accounted for almost two-thirds of telehealth claims. Four percent of clinicians (50 clinicians) provided one or more originating site telehealth claims per day.[13] This group accounted for 40 percent of originating site claims; 80 percent of the beneficiaries they served were rural (a larger share of rural than most other providers). Among clinicians providing telehealth services from distant sites, 10 percent accounted for 69 percent of all telehealth claims. Three percent of clinicians (100 clinicians) provided one or more distant site telehealth claims per day. This group accounted for 42 percent of distant site claims; 67 percent of the beneficiaries they served were rural (a larger share of rural than most other providers). Clinicians using the most telehealth services, at both originating and distant sites, tended to specialize

TABLE 8–3 States with the highest and lowest use of Medicare telehealth services, 2014

State	Number of distant site services per 1,000 FFS beneficiaries (2014)	Percent change in distant site services per 1,000 FFS beneficiaries (2013 to 2014)	Number of distant site services (2014)	Share of all distant site services (2014)
Top 10				
South Dakota	33.7	23%	4,067	2%
Iowa	29.8	47	13,902	8
North Dakota	24.5	25	2,309	1
Wyoming	18.7	80	1,603	1
Nebraska	15.5	84	3,963	2
Minnesota	15.2	10	5,804	3
Missouri	14.7	3	11,369	6
Montana	11.8	23	1,826	1
Texas	11.5	21	26,115	15
Oklahoma	10.5	–25	5,583	3
Top 10	14.9	19	76,541	42
Bottom 10				
Indiana	1.2	28	1,002	1
District of Columbia	0.9	0	55	0
Washington	0.8	48	623	0
Utah	0.6	8	114	0
Maryland	0.5	568	344	0
Massachusetts	0.2	–10	189	0
New Jersey	0.2	–36	234	0
Delaware	0.1	0	12	0
Connecticut	0.1	–40	29	0
Rhode Island	0.1	–95	7	0
Bottom 10	0.5	22	2,609	1

Note: FFS (fee-for-service).

Source: CMS carrier file and Geographic Variation Public Use File.

in internal medicine, psychiatry, and psychology, or were nurse practitioners.

Geographic characteristics

In 2014, telehealth visits occurred in all 50 states and the District of Columbia, but recent growth was more pronounced in certain states with large rural populations. Use was highest in South Dakota, Iowa, and North Dakota, where more than 20 telehealth services were provided per 1,000 beneficiaries (Table 8-3). The 10 states with the highest use of telehealth services collectively used nearly 15 services per 1,000 beneficiaries and accounted for 42 percent of all Medicare telehealth services. By contrast, the 10 states with the lowest use of telehealth services collectively used less than 1 telehealth service per 1,000 beneficiaries and accounted for 1 percent of all Medicare telehealth services. The rate of growth in telehealth services between 2013 and 2014 has been similar for high-use states (19 percent) and low-use states (22 percent), but the net increase in number of telehealth services was larger in high-use (12,000 additional telehealth services) than low-use states (500 additional telehealth services) (data not shown in table).

A small share of Medicare telehealth visits crossed state lines. Among the telehealth visits we identified

by matching originating and distant site claims (65,000 visits), 94 percent occurred at originating and distant sites in the same state, and 6 percent (3,900 visits) occurred in different states. Twelve pairs of states accounted for 75 percent of this cross-state volume. Northern and central Midwestern states that are contiguous, such as Wisconsin and Minnesota or Missouri and Iowa, were more likely to have telehealth visits that crossed state lines. However, noncontiguous state pairings, such as Iowa and Pennsylvania, also occurred. The volume of telehealth visits crossing state lines could have been low because of state-level medical licensure requirements (see text box discussing state-level licensure, pp. 244–245).

Beneficiary characteristics

Overall, in 2014, 68,000 beneficiaries (0.2 percent) used telehealth services at a rate of 3 visits per person per year, amounting to an average of $182 per person per year. Beneficiaries using telehealth services that year tended to be younger and eligible for Medicare through disability; 62 percent of telehealth visits were for beneficiaries younger than 65 years old, 19 percent were for beneficiaries ages 65 to 74, and 19 percent were for beneficiaries 75 years or older. By contrast, 17 percent of Medicare beneficiaries are under age 65 (Centers for Medicare & Medicaid Services 2015c). Similarly, 61 percent of beneficiaries using telehealth services were eligible for Medicare through disability, just 38 percent were eligible through age, and 1 percent were eligible through end-stage renal disease.

In 2014, 61 percent (42,055) of beneficiaries who used telehealth services were dually eligible for Medicare and Medicaid.[14] Dually eligible beneficiaries were only 20 percent of the Medicare population but accounted for 67 percent of telehealth claims (139,613). In addition, 58 percent of telehealth users resided in rural locations, and 42 percent resided in urban locations. By contrast, 77 percent of Medicare FFS beneficiaries resided in urban locations. Among the rural beneficiaries, 59 percent (23,234) were dually eligible. Among the urban beneficiaries, 66 percent (18,662) were dually eligible. Because telehealth coverage is permitted only in rural areas, the share of urban beneficiaries using telehealth services (in particular, urban and dually eligible beneficiaries) suggests that many telehealth visits are associated with CMS dual-eligible demonstrations or could reflect inappropriate use of these services. The average number of telehealth claims per beneficiary and the average associated Medicare payments were comparable between the dually eligible and other Medicare beneficiaries.

In 2014, the use of telehealth services was concentrated among a small group of beneficiaries. One percent of the telehealth users (about 700 beneficiaries) accounted for 11 percent of telehealth visits. The 100 most frequent users of telehealth services accounted for 4 percent of telehealth visits. These frequent users had between 50 and 189 telehealth visits each, and the average Medicare payment was $3,800 per user. Of the high users, 78 percent were dually eligible for Medicare and Medicaid and 80 percent were rural. In addition, these high users were served by just 14 providers, and in each case, the services high users received were a mix of E&M services and individual psychotherapy services.

Telehealth episodes without originating site claims

Among the 175,000 telehealth claims from distant sites, 95,000 (55 percent) were without an originating site claim. This discrepancy could be due to providers not bothering to bill for the $25 facility fee, or it could be that some services inappropriately originated from a patient's home, as other research has suggested (Gilman and Stensland 2013). Among the distant site telehealth claims without an originating site claim, 56 percent (53,000 visits) were associated with rural beneficiaries and 44 percent (41,000 visits) were associated with urban beneficiaries. Both claims groups suggest that beneficiaries could be inappropriately receiving telehealth services from home or another unapproved location that did not file an originating site claim. The urban claims are also potentially problematic because they could be occurring in urban originating sites, which is inconsistent with Medicare statute.

2015 Medicare claims data

Preliminary 2015 Medicare claims data suggest that many of the trends observed in telehealth services continued into 2015. These data suggest a 20 percent increase in the number of telehealth claims, users, and providers between 2014 and 2015. This growth is on par with growth in the last several years, but overall levels remain low. In 2015, there were 100,000 originating site claims and 210,000 distant site claims. Between 2014 and 2015, the number of users increased from 68,000 beneficiaries to 80,000 beneficiaries, but use per beneficiary remained unchanged at 3 visits per year. The number of providers using telehealth increased to 1,700 originating sites and 3,700 distant sites. In general, in 2015, we also observed

State-level licensure of clinicians poses barriers to providing care across state lines

Strict state-level licensing rules for physicians and nurses are a barrier to working in telehealth programs that aim to operate across state lines. Across all states, clinicians must be licensed in the state in which the patient they are treating is located. Each state has its own licensure requirements that typically do not permit partial or temporary licensure. In general, state medical licensure boards for physicians and nurses are protective of their state's medical standards and licensure requirements. Both the standards and licensure requirements vary from state to state.

In recent years, federal legislation has been proposed that would permit full portability of medical licensure for physicians and nurses. Some of these proposals have sought portability through the Medicare program. The American Medical Association, the Federation of State Medical Boards, and the National Council of State Boards of Nursing have opposed this legislation but support the physician Interstate Medical Licensure Compact (IMLC) and the Nurse Licensure Compact (NLC). The IMLC and NLC facilitate the portability of licensure across state lines by creating an administrative body and process through which states negotiate differences in licensing standards. Despite these agreements, under the IMLC, physicians must still apply to each state medical board individually, but through a somewhat expedited process. By contrast, under the NLC, nurses can use their home-state license to operate in all states participating in the NLC. To date, 20 states do not participate in either the IMLC or NLC, 18 participate in the NLC, 6 participate in both the IMLC and NLCs, and 6 participate in just the IMLC (Figure 8-2).

Several telehealth vendors, providers, and insurers assert that one of the barriers to further expansion of telehealth services is the prohibition on physicians and nurses providing care across state lines in states where they are not licensed. In some cases, this prohibition has prevented large employers or insurers from allowing their employees or enrollees to use centralized telehealth call centers and from leveraging excess clinician supply in some states with excess demand for clinicians in other states. The lack of reciprocal state licensure can be burdensome. One clinician we interviewed asserted that he individually maintains 23 state licenses to practice tele–ICU in 23 states. To maintain licensure, this clinician must keep up with changing standards in each state. The subject of reciprocal state licensure has gained the attention of some policymakers. In March 2016, the President's Council of Advisors on Science and Technology recommended the Department of Health and Human Services convene the Federation of State Medical Boards and the National Governors Association to accelerate reciprocal state licensure policies (President's Council of Advisors on Science and Technology 2016).

Opponents of the IMLC, NLC, and broader federal medical licensure assert that individual states should not be required to change their medical standards or licensure requirements. Some believe doing so could reduce the quality of health care in their state. Others are concerned that the IMLC, NLC, and federal licensure concepts will blur the lines of authority in cases where it may be appropriate to take legal action against a clinician.

(continued next page)

that psychotherapy visits accounted for a larger share of telehealth visits, clinical psychologists and nurse practitioners accounted for larger shares of clinicians located at distant sites, nonclinicians accounted for a larger share of those involved at originating sites, and clinicians at SNFs accounted for a larger share of the distant sites.

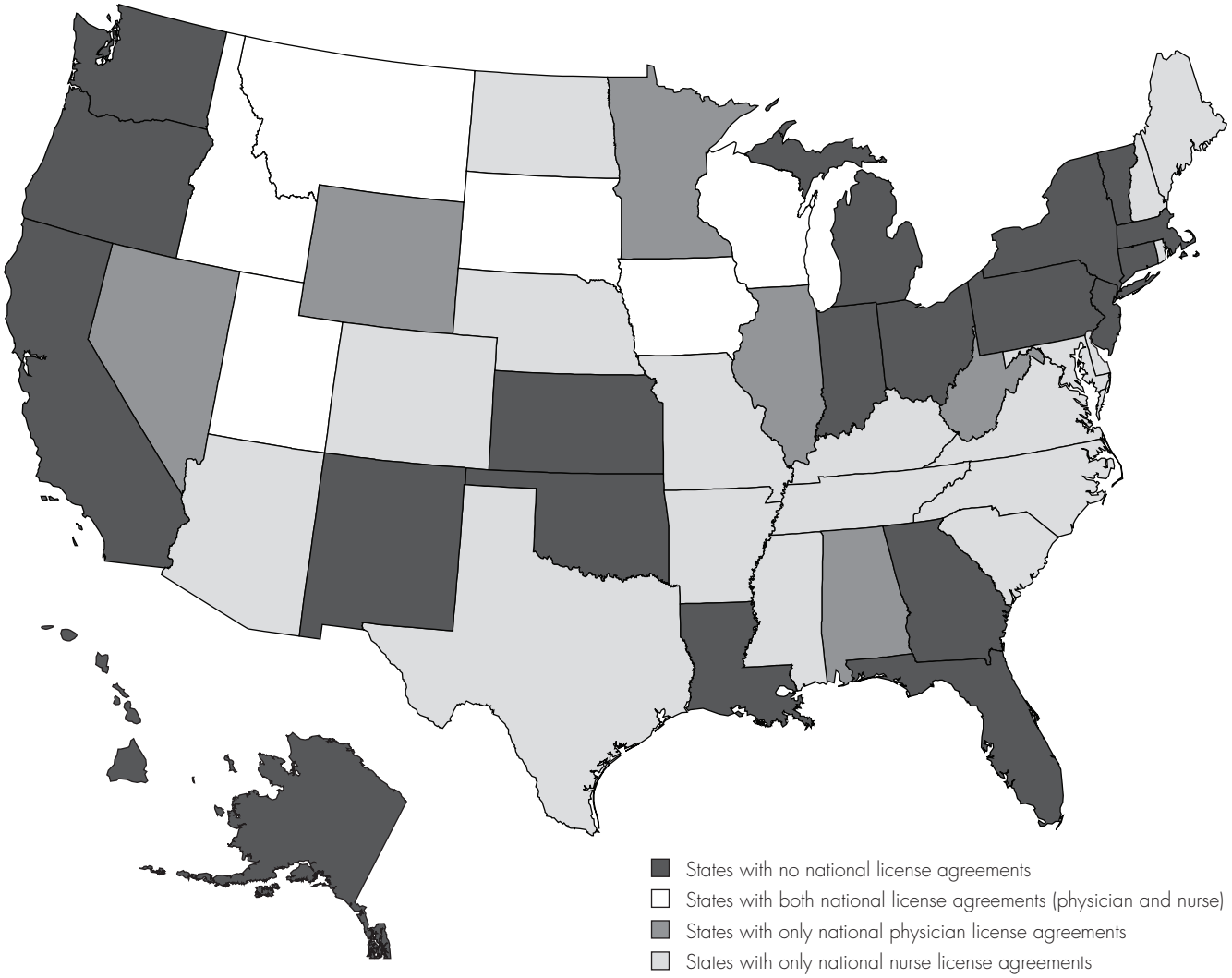
Numerous insurers and providers have implemented telehealth services, but overall use appears to remain low

Telehealth services have been implemented by many insurers and providers across the United States. Despite this widespread use of telehealth, these services still account for a relatively small share of all health care.

State-level licensure of clinicians poses barriers to providing care across state lines (cont.)

FIGURE 8–2

State participation in the physician Interstate Medical Licensure Compact and Nurse Licensure Compact as of April 2016



Source: National Council of State Boards of Nursing and the Federation of State Medical Boards.

Between August 2015 and March 2016, the Commission worked with researchers at the University of Minnesota to conduct semi-structured interviews with 13 commercial insurers, 3 health systems, and the VA to assess their use of telehealth services. We visited one health system in Missouri, known as an industry leader in the use of telehealth. We selected organizations to interview based on their reported involvement with telehealth or prominence in their respective markets. These organizations vary in size and geographic location. Information from these interviews is summarized in the following sections.

Commercial insurers that cover telehealth are focused on primary care

Several commercial insurers, including some of the largest insurers in the United States, have been using telehealth services more regularly in recent years. Insurers stated that their rationale for implementing telehealth services was multifaceted. Some insurers sought to improve quality, expand access and convenience, and reduce costs, particularly for underserved areas. Some also stated that clinicians were requesting the ability to use telehealth. In addition, several insurers contended that telehealth services are more compatible with capitated payment models because capitation controls the risk of overuse.

In recent years, several sources—including those in our own interviews—have suggested that commercial insurers are expanding their coverage of telehealth services, but to date there has been little evidence of an increase in telehealth utilization in insurers' claims data. In an analysis of claims data from Aetna, Humana, Kaiser Permanente, and United Healthcare, the Health Care Cost Institute (HCCI) concluded that the use of telehealth services was extremely low from 2009 to 2013 (Wilson et al. 2016). For example, for 2013, HCCI identified just 2,558 telehealth claims for primary care, compared with approximately 19 million nontelehealth primary care claims.

In general, insurers tend to focus their coverage of telehealth on basic medical care, especially after-hours care. Some refer to these services as tele–primary care and tele–psychiatric care. Tele–primary care is the delivery of basic primary care services using telehealth modalities, such as e-mail, video, or store-and-forward technology. These services are delivered by physicians and nurses, just as they would be in face-to-face encounters, and are conducted in a variety of settings. Most importantly, they can be conducted from the patient's home or remotely by cell phone or e-mail. Tele–psychiatric care is the delivery of behavioral health services in which clinicians (psychiatrists, psychologists, social workers, and nurses) conduct diagnostic evaluations and individual and group psychotherapy visits with patients using two-way video. These services are conducted between a number of settings, such as hospitals, health clinics, physicians' offices, and patients' homes.

There are various benefits and drawbacks to both tele–primary care and tele–psychiatric care. Patients gain greater convenience and access to their clinicians, particularly patients with chronic conditions, patients with disabilities, and patients who live in isolated areas. For clinicians, these services also offer greater convenience by leveraging their time and broadening their reach. In addition, these services may have particular value for follow-up visits and medication management visits, in which the clinician is aware of the patient's history. However, the benefits these services offer to clinicians likely vary by the type of clinician. Clinicians with full schedules may view logging into two-way video visits as a burden. In addition, it is unclear how these services will impact long-term patient spending. In general, these services are easy to use and therefore at higher risk for unnecessary use.

In general, insurers asserted that the use of telehealth for inexpensive primary care services is likely to keep their enrollees out of the ED, the urgent care setting, and other expensive settings (Alliance of Community Health Plans 2015). Therefore, some insurers we interviewed view telehealth services for basic primary care functions as a potential replacement for face-to-face services. Others stated that while the impact of these services on costs is currently inconclusive, they anticipate that the use of some services (such as behavioral health) could increase when delivered through telehealth. Several insurers cover telehealth access to specialty care, particularly behavioral health and oncology care. They believe telehealth services are a good match for these specialties because the follow-up visits for these patients do not typically require a physical exam. In addition, insurers are covering telehealth for dermatology, as images of the skin can be transmitted using store-and-forward images or two-way video. Some insurers cover in-hospital physician consultations using telehealth technologies.

To provide basic primary care services, many insurers contract with telehealth vendors to provide 24-hour access to physicians and nurse practitioners, hire health systems, or staff their own clinician call centers for their members. In general, insurers have a variety of vendors to choose from. The Healthcare Information and Management Systems Society found that between 2014 and 2015, the number of vendors selling telehealth services increased from 69 to 85, an increase of 23 percent (Healthcare Information and Management Systems Society 2015).

With regard to primary care, insurers generally allow patients to initiate contact with clinicians from their homes or remotely. Several insurers stated that because their goal is to expand access and convenience to basic primary care, they rarely limit telehealth use by geographic location

(urban vs. rural) or by the originating site of the patient (home, work, or mobile location).

Insurers generally pay providers for telehealth services at the same base rate as face-to-face visits, but enrollee cost sharing varies. Many insurers we interviewed do not pay for telehealth services differently from face-to-face visits because they want to give providers the incentive to offer these services. In some cases, state law requires equivalent payment for telehealth and in-person services. In other cases, insurers that are staff-model HMOs, which employ their own clinicians, treat many telehealth services as equivalent to in-person services. However, one insurer we interviewed disliked state payment parity laws for telehealth services. That insurer stated that it would prefer to not pay the cost of office overhead when clinicians do all their business through telehealth without a traditional office setting.

Cost-sharing levels vary by insurer. Some insurers, particularly those that use direct-to-consumer telehealth vendors, such as Teledoc and AmericanWell, pass the vendor's fees along to their enrollees as cost sharing, charging a copayment of $40 to $50 per primary care visit. A few insurers offer their enrollees no copayment, or a lower copayment, for opting to use telehealth services over face-to-face services. Other insurers differentiate cost-sharing levels by telehealth modality, with higher copayments for two-way video visits than for e-mail visits.

Insurers have implemented different methods for curtailing unnecessary use of primary care telehealth services. Insurers asserted that the unnecessary use of telehealth services, particularly for basic primary care services, is not a major concern for them because these are low-cost services, but they have taken some moderate measures to limit unnecessary use. First, they rely on plan networks to limit use to only trusted providers. Second, they often instruct patients and providers that telehealth services should be limited to basic primary care services or common conditions such as flu, gastrointestinal symptoms, colds, sinus infections, and headaches. Third, they exclude certain types of medication, such as pain medications and lifestyle drugs (e.g., Viagra), from being prescribed through telehealth visits.

Several health systems have developed telehealth services

Several large health systems are advancing the growth in telehealth services by developing products that they distribute within their own systems and market to other entities. These systems assert that their goal is to expand access, improve quality, and reduce costs. Many systems have implemented hospital-based telehealth services because they intend to link their various facilities, clinics, and physician groups with one another to share resources. Other systems include services such as primary care, behavioral health, and case management. While the efficacy of these approaches remains unclear, health systems typically market these telehealth services to subscribers as having the potential to reduce hospital length of stay and create staffing efficiencies. In addition, health systems assert that their telehealth services may be more compatible with capitated payment models.

The three most common forms of telehealth services in use at the health systems we interviewed were telestroke, tele–ICU, and telehospitalist care.

- Telestroke care is the use of two-way video to connect patients in the hospital ED with neurologists in distant locations. The neurologist evaluates the patient from afar to determine whether the patient has suffered a stroke and whether that stroke is ischemic (blood clot) or hemorrhagic (brain bleed), and to assist with the treatment of the patient. Central to the concept of telestroke is the need for timely treatment of ischemic strokes, which, if caught in time, can be treated with tissue plasminogen activator (tPA), a clot-busting drug that has the potential to reduce disability resulting from the ischemic stroke. However, administration of tPA must occur in the first few hours after the stroke to be effective (Grotta 2014).

- Tele–ICU is the use of two-way video to connect patients in the ICU with clinicians outside the hospital. The patient is monitored remotely by clinicians who are available to on-site clinicians through two-way video to assist with the patient's treatment. To monitor patients, tele–ICU programs also use real-time data integration, electronic health record access, and specialized surveillance applications.

- Telehospitalist care is the use of two-way video to connect patients in inpatient rooms with clinicians outside the hospital. Similar to tele–ICU, this service is focused on patient monitoring and providing assistance to on-site clinical staff, especially on nights and weekends. Telehospitalist care offers on-site clinicians assistance with issues such as medication management, pain control, blood sugar levels, and the monitoring of patient vitals.

The benefits and drawbacks of these three hospital-based telehealth services are similar. They expand access to expert clinicians such as neurologists, hospitalists, physician intensivists, and expert nursing staff to areas or facilities that lack a sufficient supply of these clinicians, rural and small hospitals in particular. These services also offer hospitals greater efficiency by enabling them to reduce labor costs associated with staffing the ED with a neurologist or the ICU with an intensivist. In addition, having the capacity to offer stroke care, an ICU, and high-quality inpatient services allows rural and small hospitals to retain more of the patients that they might otherwise transfer to larger facilities. Retaining patients at rural or small hospitals may also benefit larger facilities with high occupancy rates and overcrowded EDs. For beneficiaries, these services could improve the quality of care by reducing the time between stroke and tPA administration or by providing access to clinicians around the clock. Beneficiaries could also benefit from the broader availability of these services by being able to stay closer to their homes and reduce their driving times.

Health systems representatives stated in interviews that the most significant drawback to developing telehealth networks was the requirement of capital investment. For example, the telehealth hardware and software that act as the network's foundation cost $1 million or more. This cost varies considerably based on the size of the system and does not include the cost of the clinicians and technical staff needed to operate the call-in center or the telehealth stations in the system's hospitals, clinics, and physician offices. Health systems and vendors told us that the cost of outfitting a single hospital inpatient or ICU room with the capacity to conduct two-way video and share clinical information electronically with the call-in center can be as much as $10,000. Alternatively, a single mobile telehealth cart that can move from room to room can cost the hospital as much as $20,000. In both cases, there are also ongoing costs to maintain these technologies. The capital investment required to build telehealth systems into SNFs is thought to be similar to those of hospitals (Grabowski and O'Malley 2014). Health systems and vendors also stated that for clinics or physician offices, the capital investment required for a basic single telehealth station can cost as much as $2,500. For patients receiving telehealth services at home, the telehealth capital investment is typically lower because they can connect with clinicians through their home/work computer, tablet, or cell phone.

Health systems market their telehealth subscription services to providers and insurers outside of their systems, but they also sell subscription services to facilities within their own systems. These systems typically purchase hardware and software from manufacturers that are designed specifically for telehealth and then add their own clinical expertise (e.g., physicians, nurses, and case managers) in the form of call centers. The telehealth services typically come in two forms: hospital-based (largely specialty care) and basic medical care. Hospital-based services include telestroke, tele–ICU, telehospitalist, telecardiology, and tele–psychiatric care. Basic care services include telehealth behavioral health care, primary care, and case management, which are largely sold to insurers, employers, and physician practices.

Health systems and hospitals indicated that hospitals seeking to develop their telehealth infrastructure have been able to receive federal grants in recent years to finance their costs. The United States Department of Agriculture (USDA) and the Department of Health and Human Services have awarded millions of dollars in grants and loans for use in developing rural health care. These funds are still being expanded. For example, in November 2015, the USDA added $23.4 million in additional funding for 75 telehealth projects across 31 states (United States Department of Agriculture 2015). The Federal Communications Commission has also contributed millions of dollars to developing broadband infrastructure and access across the country with a focus on rural populations (Federal Communications Commission 2016).

Employers seeking telehealth services

Employers have contributed to growth in the use of telehealth services by developing their own services for their employees or hiring commercial insurers and health systems to provide these services. Many of the insurers and providers we interviewed stated that employers in their markets have become increasingly interested in telehealth services and are requesting that telehealth be built into their benefit packages. Insurers and health systems assert that employers hope to create convenience for their employees, reduce employee absences, or lower the organizations' health care costs by keeping employees out of EDs and urgent care centers.

Walmart, the largest employer in the United States, has chosen to implement its own telehealth services for its employees. In many of their stores, Walmart has built health clinics that rely on two-way video to connect patients with clinicians remotely. These clinics serve

not only Walmart employees and their families, but also Walmart customers. Walmart employees enrolled in the Walmart employee health plan pay a copayment of $4 per visit, and Walmart customers are charged a $40 fee. Walmart contends that this solution enables timely access to clinicians and increases the quality of health care service for their employees.

Evidence that telehealth services are included in employer health insurance plans has grown in recent years. The Kaiser Family Foundation, in partnership with the Health Research & Educational Trust, concluded that based on their survey of employer-sponsored health benefits in 2015, 27 percent of large firms (200 or more employees) offered telehealth coverage (Kaiser Family Foundation and Health Research & Educational Trust 2015). Based on a similar survey of employers, Towers Watson concluded that employers' coverage of telehealth will increase in future years, projecting that 56 percent of employers would cover telehealth in 2016 and over 80 percent would in 2018 (Towers Watson 2015). The National Business Group on Health's 2015 report corroborates these findings, concluding that 74 percent of employers plan to offer some form of telehealth to employees in 2016, up from 48 percent who planned to offer telehealth in 2015 (National Business Group on Health 2015).

Department of Veterans Affairs has been using telehealth for several years

The VA has had telehealth programs in place for over a decade. In fiscal year 2015, the VA's telehealth programs served more than 736,000 veterans through more than 2 million online visits. In fiscal year 2014, 55 percent of VA telehealth visits were for veterans living in rural areas and 45 percent were for veterans living in urban areas (Department of Veterans Affairs 2014).

The VA currently has three categories of telehealth programs: clinical video telehealth (CVT), home telehealth (HT), and store-and-forward telehealth (SFT).

- CVT programs are real-time video consultations covering 44 clinical specialties, including intensive care, primary care, mental health, amputation care, cardiology, neurology, audiology, and remote nursing home consultations. The VA's CVT programs link the various facilities within the VA's integrated system, including the 150 VA medical centers and 1,400 VA community-based outpatient clinics. CVT programs served nearly 282,000 patients in fiscal year 2015.
- HT programs are case management programs for patients with chronic conditions, such as diabetes, congestive heart failure (CHF), hypertension, obesity, head injury, and depression. HT programs served nearly 156,000 patients in fiscal year 2015. The VA asserts that the HT program has resulted in declines in hospital bed days used and hospital admissions in general.
- SFT programs enable clinical images to be acquired at sites close to the patient and the interpretation and reporting of these images to occur remotely and asynchronously. The SFTs are used for retinal imaging, dermatology, pathology, wound care, spirometry, and cardiology. The VA's SFT program served nearly 298,000 patients in fiscal year 2015.

VA staff members said they decided to implement telehealth programs in two stages. The first stage involved individual clinicians convincing their respective VA medical centers to invest in telehealth technologies; soon the use of these technologies grew across the VA network of facilities. The technology adopted by the VA was driven by which areas the VA clinicians identified as being suitable for telehealth use. The second stage involved the VA leadership's development of a system-wide centralized telehealth center to prevent the duplication of each VA medical center operating its own telehealth system.

VA staff asserted that the telehealth programs they implemented were possible under the VA system, in part, because of the VA's unique characteristics. The VA is the largest integrated health care system in the United States and is organized into 21 geographically defined Veterans Integrated Service Networks (VISNs) that include a network of medical centers, clinics, and veterans centers (Veterans Health Administration 2016). The VA provides each VISN with a capitated annual budget to use toward health care planning and resource allocation for the facilities and veterans within their geographic area (Oliver 2007). Also, the VA requires patients to pay either the same copayment for telehealth visits as face-to-face visits or no copayment, depending on the service. Therefore, under these circumstances, the misuse of these services—otherwise incentivized under FFS payment—is mitigated and patients are not financially penalized for using telehealth services. Additionally, because VA clinicians are allowed to practice across state lines, state-level medical licensure requirements are not barriers to overcome. Across all their telehealth services, VA staff members contend that the quality of care has increased and that veterans have

better access to, and receive, more timely care. However, more peer-reviewed studies are needed to confirm these claims.

State-level telehealth parity laws and Medicaid coverage vary

States' policies related to the parity of telehealth services with in-person services, as well as their Medicaid coverage of telehealth, vary considerably across states. In 2016, 28 states plus the District of Columbia have telehealth parity laws mandating that private insurers cover telehealth services as they would face-to-face services. This number doubled over the last four years (American Telemedicine Association 2016a).

Almost all Medicaid programs cover some form of telehealth service in 2016, but there is wide variation in the extent to which telehealth is covered. Of the 51 Medicaid programs, 49 cover telehealth services to some degree.

- *Originating sites:* 43 programs cover telehealth services without geographic limitations (urban vs. rural); 36 programs recognize the patient's home as an originating site.
- *Reimbursement:* 29 programs reimburse the originating site for the service; all reimburse the distant site.
- *Services:* 9 programs do not have restrictions on the types of medical services that can be used for telehealth; 40 programs have restrictions. Services that are most commonly covered by these programs include physician office visits, specialist consultations, mental health assessments, psychotherapy, and pharmacological management (Center for Connected Health Policy 2015).
- *Provider types:* 34 programs restrict the types of providers that are permitted to provide telehealth services.
- *Modality:* 48 programs offer some type of two-way video reimbursement, and 9 programs reimburse for store-and-forward telehealth. California permits the use of store-and-forward telehealth for dermatology, ophthalmology, and dentistry. Remote patient monitoring (RPM) is permitted by 16 state Medicaid programs but is commonly limited to certain types of providers and clinical conditions. For example, some programs permit only RPM by home health agencies; Colorado permits RPM for one of four conditions (CHF, chronic obstructive pulmonary disease (COPD), asthma, or diabetes) (Center for Connected Health Policy 2015).

Among states with more inclusive Medicaid telehealth coverage, the following stand out:

- Maine has no limit on originating sites geographically (urban or rural), covered services, or eligible providers.
- New Mexico has no limit on originating sites geographically, allows a wide array of providers to deliver telehealth services, and is one of eight states to issue telehealth licenses to providers from other states who meet certain requirements.
- Virginia is participating in a CMS demonstration for dually eligible Medicare and Medicaid beneficiaries that uses capitated reimbursement for providers, waives Medicare's urban telehealth limitation, permits store-and-forward technology, and permits RPM.

Among states with more restrictive Medicaid telehealth coverage are:

- Connecticut and Rhode Island, which do not cover telehealth under their state Medicaid programs and do not have telehealth parity laws.
- Idaho, which limits telehealth coverage to behavioral health services, permits only physicians to provide telehealth services, and requires written informed consent to cover telehealth services.
- Florida and Montana, which limit reimbursement for telehealth to only physicians.

Evidence of the efficacy of telehealth in existing literature is mixed

To date within academic research, evidence of the efficacy of telehealth services is mixed. Several studies conclude that many telehealth services expand access and convenience. However, other studies assessing telehealth's impact on quality and costs demonstrate mixed results. Two large-scale literature reviews conducted in recent years demonstrate mixed results for telehealth services in general and for most telehealth services individually. Smaller scale studies of telehealth interventions have found positive and negative outcomes.

Access to care and convenience

A wide array of research on telehealth interventions demonstrates, in general, that these services improve

patients' access to care and convenience in acquiring care. The level of improvement can vary, depending on the telehealth service provided and the settings in which it is provided.

- *Basic medical care:* Among recent studies with positive findings, one found that telehealth services permitted patients without prior connection to a provider to contact clinicians from home or remotely (Uscher-Pines and Mehrotra 2014). However, this study also found that most of the patients using these services were not in more disadvantaged communities. Another study found that two-way video provided patients residing in nursing homes with convenient access to physician services (Grabowski and O'Malley 2014).
- *Remote patient monitoring:* Several studies reported that monitoring patients at home expanded their access to health care services (Baker et al. 2011, Chaudhry et al. 2010, Maeng et al. 2014, Takahashi et al. 2012).
- *Time-sensitive medical care:* Studies found that telestroke services in EDs diminished geographic disparities for patients needing acute stroke care (Demaerschalk et al. 2012, Nelson et al. 2011, Switzer et al. 2013) and that tele–ICU interventions have provided access to intensive care physicians, particularly at rural hospitals and hospitals within hospital systems (Boots et al. 2011, Sapirstein et al. 2009).
- *Store-and-forward telehealth services:* One study demonstrated that these services increased access to retinal screening for patients with diabetes (Kirkizlar et al. 2013). The VA has used teleretinal screening for several years to provide access to retinal specialists at the VA's medical centers and clinics.

Quality and patient outcomes

Research is mixed on whether telehealth services, in general, improve the quality of patient care and outcomes. Some research demonstrates that telehealth services can improve quality, using certain interventions in certain settings. However, other studies conclude that telehealth interventions can have negligible or negative outcomes for patients.

In December 2015, the Agency for Healthcare Research and Quality (AHRQ) released a draft report providing a review of academic literature evaluating the effect of telehealth services on quality. AHRQ's literature review is based on 44 published studies, drawn from a field of over 1,000 studies using a strict set of inclusion criteria aimed at identifying the most rigorous and reliable systematic reviews. AHRQ's analysis noted that of the numerous studies reporting that telehealth interventions produced positive results, not a single study definitively demonstrated the efficacy of telehealth services in general or of individual services in particular. AHRQ also concluded:

- Telehealth services can improve outcomes (e.g., mortality, utilization) when used for communication and counseling, monitoring, and management for patients with several chronic conditions and for patients requiring behavioral health care.
- There needs to be additional research to better understand telehealth interventions involving physician consults, acute care, maternal and child health, urgent and primary care, the management of serious pediatric conditions, and the integration of behavioral and physical health.

Overall, AHRQ concluded that future telehealth research should be designed to evaluate (1) specific interventions rather than multiple telehealth and nontelehealth interventions combined and (2) their use under different payment models.

A second literature review, published in 2014 in partnership with the industry group the Alliance for Connected Health, also found mixed results related to quality (Bashshur et al. 2014). The authors assessed more than 70 studies published between 2000 and 2014 that were related to telehealth interventions in the management of chronic diseases. Their focus was on telehealth interventions for patients with CHF, stroke, and COPD, and most of the interventions they evaluated involved remote patient monitoring. This study concluded that telehealth interventions, in general, can reduce hospitalizations and ED visits, which can result in improved health outcomes. However, other outcomes were more mixed. They found that telehealth intervention for stroke care was feasible and reliable and improved health outcomes better than other telehealth services, while interventions for CHF and COPD patients had mixed results. Some CHF and COPD studies they evaluated demonstrated declines in hospital admissions, mortality, and improvement in long-term survival and social functioning. However, other studies demonstrated increases in admissions and mortality, or no change in service use. The authors also suggested that future research

on telehealth be more targeted by clinical diagnosis and specific intervention.

Certain individual studies have demonstrated quality improvements resulting from specific telehealth interventions such as telemonitoring, basic medical care delivered in nursing homes, tele–ICU programs, and teledermatology. One study concluded that the use of telemonitoring as part of a larger care management program for Medicare beneficiaries with certain chronic conditions (CHF, COPD, or diabetes) was associated with improvements in mortality rates (Baker et al. 2011). Specifically, in the second year of the intervention, the mortality rates for patients receiving telemonitoring were lower (9.7 percent) than for patients who did not receive telemonitoring (12.2 percent). Another study concluded that the use of two-way video physician visits for patients in nursing homes reduced hospitalizations and generated savings (Grabowski and O'Malley 2014). These telehealth services were implemented for urgent calls on weeknights and weekends.

By contrast, some studies concluded that telemonitoring programs can have negligible or negative outcomes for patients. One study found that mortality rates were higher for patients who received telemonitoring services at home (Takahashi et al. 2012). Specifically, this study was a randomized controlled trial of adults over the age of 60 with multiple health problems who received telemonitoring services. The authors found that mortality was higher (14.7 percent) for patients who had been in the telemonitoring group than patients who had received usual care (3.9 percent). In addition, this study concluded that the use of telemonitoring did not yield lower hospitalizations or ED visits. A different randomized controlled study concluded that telemonitoring of patients who had recently been hospitalized for heart failure had mortality rates similar to those of patients who did not use telemonitoring (Chaudhry et al. 2010).

A limited set of studies demonstrates that tele–ICU and teledermatology interventions can improve quality, but this body of research is not comprehensive. One study concluded that tele–ICU reduced mortality and length of stay when patients were in the ICU, but found no improvement in patient mortality or length of stay once the patient left the ICU for the standard inpatient department (Young et al. 2011). Another study provides evidence that tele–ICU programs can improve best practices and lower rates of preventable complications (Lilly et al. 2011). In addition, there is some evidence that teledermatology can be an effective and reliable approach for routine management of patient referrals for basic dermatological care (Moreno-Ramirez et al. 2007).

Costs of care

Research is mixed on whether telehealth services, in general, reduce the costs of care. A large volume of research conducted on cost implications of telemonitoring interventions and outcomes has produced mixed results. There has been less research on the cost implications of telestroke care and teleretinal scanning, but the results have been more positive. In addition, a recent study shows the potential for telehealth services to increase costs by incentivizing new utilization.

The literature review published in 2014 in partnership with the Alliance for Connected Health (referred to earlier) demonstrated that telehealth interventions can have variable effects on costs. Some studies included in this analysis found that telemonitoring interventions for CHF and COPD patients showed reductions in hospitalizations, and other studies found increased hospitalizations, which would have corresponding implications for costs. In addition, this analysis found that telestroke care can improve patient outcomes for acute stroke patients.

Some studies demonstrate that telemonitoring interventions can reduce costs. For example, the 2011 Baker study concluded that the telemonitoring of Medicare beneficiaries with certain chronic conditions was associated with spending reductions of 8 percent to 13 percent per beneficiary (Baker et al. 2011). Similarly, a study of Geisinger Health Plan's (GHP's) telemonitoring program for Medicare Advantage members with heart failure resulted in reduced admissions, 30-day and 90-day readmissions, and cost of care (Maeng et al. 2014). The GHP program reduced costs by 11 percent per year, and GHP's estimated return on investment was 3.3 times the investment. GHP estimated savings by comparing expected expenses and observed expenses over five years.

By contrast, some research demonstrates that telemonitoring services do not reduce costs. The Chaudhry study (referred to earlier) concluded that the costs of patients who had telemonitoring did not differ from similar patients who had not had telemonitoring (Chaudhry et al. 2010). These patients had similar numbers of subsequent readmissions and numbers of days in the hospital. A different study of patients with a recent hospitalization for COPD, who were randomized to receive daily home telemonitoring, had similar rates of future admissions

and days in the hospital as patients who had not received telemonitoring (Pinnock et al. 2013).

There is some initial evidence of cost savings for telestroke and store-and-forward teleretinal screening. Studies pertaining to telestroke cases suggest telestroke care may generate cost savings for either the payer or the provider. One study concluded that telestroke networks could increase the number of patients discharged home and reduce the costs borne by the stroke-network hospitals (Switzer et al. 2013). The study compared a telestroke network consisting of a hub hospital with 7 spoke hospitals and about 1,100 acute stroke patients with hospitals without a hub-and-spoke telestroke network. As a result of the telestroke network, six more patients per year were discharged home, more patients received clot-busting medication (tPA), and the hospital network was expected to achieve an estimated $360,000 per year in cost savings, or $45,000 per year per spoke hospital. Also, the Nelson study (referred to earlier) concluded that when a lifetime perspective is taken, telestroke appears cost effective compared with usual care because telestroke costs are up front and the benefits—the lifelong health status of the patient—occur over time (Nelson et al. 2011).

With regard to store-and-forward telehealth and teleretinal screening, one study concluded that the use of this service is cost effective for the VA for patients younger than 80 years and at VA medical facilities with a population of more than 3,500 veterans (Kirkizlar et al. 2013). Cost efficiency was generated from the early detection and prevention of blindness, the eventual result of retinopathy. However, some researchers caution policymakers that in addition to the benefits telehealth services can produce, these services can also drive increases in health care spending by increasing utilization (Mehrotra 2014).

International studies of telehealth demonstrate similarly mixed results

Outside of the United States, evidence of telehealth's efficacy also appears to be mixed. Much like studies conducted in the United States, international studies demonstrate a wide range of methods, study a broad assortment of telehealth interventions and patient populations, and produce varying outcomes. Studies conducted in Australia have concluded that telehealth interventions have expanded access to cancer care in rural areas (Sabesan et al. 2012, Sabesan et al. 2009). Studies of telestroke in the United Kingdom and Australia identified long-term cost savings, quality improvements, and the reliability of this service, but health outcomes were not always definitive (Audebert et al. 2009, Nagao et al. 2012). Studies of telemonitoring of patients at home in the United Kingdom, Argentina, and Canada found reductions in hospital admissions and ED use, as well as quality improvements (Ferrante et al. 2010, Steventon et al. 2012, Stickland et al. 2011). However, studies of patients in Germany and Italy demonstrated no change in either patient utilization or quality; the studies showed mixed outcomes such as lower risk of hospitalization but longer hospital stays once admitted (Koehler et al. 2011, Pedone et al. 2013).

Policy issues for telehealth coverage expansion under Medicare

Policymakers have several issues to consider regarding the expansion of telehealth coverage under Medicare. Our discussion covers three payment and delivery systems that exist in Medicare: Medicare Advantage, bundled payment and ACOs, and FFS. Each system currently incorporates some degree of coverage of telehealth services; however, they have different financial incentives for insurers, providers, and beneficiaries. The Commission believes policymakers should consider each system's unique incentives in making future policy related to the coverage of telehealth services.

Medicare Advantage

MA plans must cover any telehealth services that are covered as a part of FFS Medicare (under the PFS). As a part of this requirement, CMS allows plans to provide other telehealth services that are adjunct to the provision of Medicare FFS benefits. MA plans include the costs associated with these telehealth services in their bid amounts. Under this construct, the benefits available to Medicare beneficiaries are the same under FFS Medicare and MA. In addition, MA plans may cover telehealth services beyond what is covered under FFS Medicare as an extra benefit ("supplemental benefit"), but these extra benefits are not included in the plan's bid amount.

In CMS's MA manual, the definition of services adjunct to the provision of FFS benefits is ambiguous and subject to interpretation. The manual indicates that some communication between a patient and physician (e.g., e-mail) may be considered "part of the basic FFS benefit." (Centers for Medicare & Medicaid Services 2016a). CMS states that such communication may be viewed as complementary to the physicians' or plans' responsibilities to provide the services covered under FFS Medicare. In our view, the difference between telehealth services that

are complementary to the delivery of services covered under FFS Medicare and telehealth services CMS defines as extra benefits needs to be clarified. Some plans interpret any telehealth service as an extra benefit, and in doing so, prohibit clinicians from providing services that are complementary to the delivery of services covered under FFS Medicare, such as making follow-up phone calls to patients about lab test results. By contrast, other plans interpret any and all telehealth services as complementary. Clarification of this issue could enable greater consistency in practice across plans. We believe that CMS has the statutory authority to clarify this definition.

Another policy consideration relates to MA's financing of extra benefits. Remote patient monitoring using telehealth, for example, is not a covered service under FFS Medicare, and is one service CMS would define as an extra benefit. MA plans must finance the cost of extra benefits either through their rebates or by charging Medicare enrollees a supplemental premium. If MA plans bidding below their benchmark wanted full Medicare payment for the cost of extra benefits, a change in law would be required. Policymakers could consider allowing MA plans to build the costs associated with extra telehealth benefits into their bid amounts. This policy is included in the President's Budget for Fiscal Year 2017. Permitting this action would simplify the financing of extra benefits but would come with several complications, including inequity between the benefits covered under FFS Medicare and MA. This policy could also increase program spending if plan bid amounts increased and could result in MA plans narrowing their networks of providers.

Bundled payment and accountable care organizations

Three CMMI models involving bundled payment and ACOs currently include coverage of telehealth services broader than the standard Medicare benefit. CMS could consider expanding coverage for telehealth services either in existing CMMI programs or in new programs with this targeted focus.

For three models, CMMI has exercised its authority to waive the requirement that benefits offered in these programs be equivalent to the standard benefit. Organizations participating in the CJR and BPCI programs accept bundled payment rates for the care of individual patients for an entire episode of care. Under bundled payment, providers have the incentive to use any service that they believe can reduce the costs of providing care during the episode or improve quality. For the CJR, originating sites are permitted to be in urban areas (not just rural areas) and can be beneficiaries' homes (not just medical facilities). Under BPCI, originating sites are permitted to be in urban areas, not just rural areas, but they may not be a patient's home. CMMI's Next Generation ACO model permits telehealth services that exceed the standard Medicare benefit by allowing originating sites to be in urban areas and patients' homes.

CMS could consider whether the waivers for these three CMMI programs should be expanded to include a broader range of telehealth services. For example, CMS could expand the use of telehealth services under the CJR and Next Generation ACO programs to telehealth services that are not included in the standard Medicare benefit, such as allowing patients to obtain basic medical care remotely (outside of their homes) or expanding the use of store-and-forward telehealth.

Fee-for-service

Telehealth services are currently covered to a limited degree as a part of the Medicare FFS benefit under the PFS. Many insurers, providers, and telehealth experts assert that covering telehealth services under FFS payment could risk unnecessary use of services. Paying separately for each telehealth encounter could increase spending. If policymakers were to expand the coverage of telehealth services under FFS, they would need to consider doing so in a targeted manner that reduces risk of unnecessary use. For example, telestroke programs appear to offer greater access to specialists in certain markets, target a specific set of severely ill patients in need of timely care, and have minimal risk of unnecessary use. There is evidence to suggest that telestroke care can improve patient outcomes and may reduce long-term disability-related costs when there is no access to in-person neurology consultations. Telestroke care is currently permitted in rural settings, but policymakers may wish to consider expansion of this service to urban settings.

As with other services paid through FFS Medicare, providers have an incentive to increase the use of services, regardless of the impact on total spending. In addition, the Congressional Budget Office has asserted that greater use of telehealth services could increase or decrease spending, depending on whether telehealth services supplemented or substituted for in-person care. For example, policymakers could expand all telehealth services currently included under the PFS to urban settings or expand the current definition of an originating site to include beneficiaries' homes. Both of these options represent considerable

expansions that incorporate greater risk of unnecessary use and increased spending.

With regard to telehealth services involving basic medical care and remote patient monitoring of patients in their homes, policymakers could consider partial capitation payment models, such as per member per month payments for primary care. Some commercial insurers believe telehealth can assist in providing basic medical care. However, evidence of the efficacy of telehealth services for basic medical care, both in terms of quality and cost savings, is mixed. Similarly, the use of remote patient monitoring in patients' homes has become more common in recent years, but the evidence of its efficacy is mixed. Because of the lack of clear evidence, policymakers could consider allowing clinicians to provide telehealth services to patients under a primary care partial capitation payment model that pays a fixed monthly payment to clinicians rather than paying separately for each encounter.

The Commission has discussed a model in which primary care providers would be paid for primary care on a monthly partial capitation basis plus FFS at a reduced rate. All other services would be paid at full FFS rates. The objective of this model is to give providers more flexibility to structure their practice and promote efficient, high-quality care. Providers could choose to use this partial capitation amount to offer telehealth services. Conceptually, this might be similar to the monthly chronic care management (CCM) code that exists in the Medicare PFS. As a part of CCM, practitioners can bill Medicare for monthly care management of patients with more than one chronic condition, but they must ensure round-the-clock access to care management services and provide enhanced opportunities for patients to communicate with the practitioner through telephone, messaging, Internet, or other methods (Centers for Medicare & Medicaid Services 2015a).[15]

If policymakers decide to expand telehealth services under FFS Medicare, it would be important to consider how beneficiary cost sharing would be structured. For example, if cost sharing for telehealth services were less than for in-person visits, beneficiaries would have a greater incentive to use telehealth. The opposite would be true if cost sharing for telehealth were higher than for in-person visits. In addition, policymakers should consider the role that supplemental plans play in sheltering beneficiaries from cost-sharing implications. For example, beneficiaries might not respond to cost-sharing incentives if supplemental plans covered their cost-sharing liability. Policymakers would also need to be aware that any changes to the Medicare FFS setting, in terms of expanding telehealth coverage, would in turn be included in the basic Medicare benefit and therefore, by statute, be included in MA plans' bid amounts. ■

Endnotes

1 The terms *telehealth* and *telemedicine* are used as synonyms by many sources, but differ slightly. *Telehealth* tends to be used in describing a broad range of health care services that are delivered through a number of electronic modalities. *Telemedicine* is often used to describe basic medical services delivered by physicians or nurses through electronic modalities.

2 The ATA's four types of telehealth services include primary care and specialist referral services, remote patient monitoring, telepharmacy, and off-site analysis of imaging or tests. The ATA also categorizes telehealth services in four different modalities: networked programs, point-to-point connections, monitoring center links, and web-based e-health patient service sites (American Telemedicine Association, http://www.americantelemed.org).

3 Section 1834(m) of the Social Security Act specifies the law pertaining to telehealth coverage under FFS Medicare and the fee schedule for physicians and other clinicians (the PFS). The law specifies the permitted originating sites, authorized practitioners, and geographical restrictions to patients in rural areas for telehealth services. CMS is permitted to make regulatory changes to PFS telehealth policy that include adding, removing, or revising codes under the PFS; CMS cannot expand telehealth to urban areas or to new types of facilities.

4 In addition to the areas of the Medicare program mentioned here, there is limited coverage of telehealth services under Medicare Part D. Section 10328 of the Patient Protection and Affordable Care Act of 2010 requires prescription drug plan sponsors to offer, at a minimum, an annual comprehensive medication review that may be furnished person to person or through telehealth technologies. E-prescribing is also common and permitted within the Medicare program, which some consider a form of telehealth service.

5 The originating site facility fee is a separately billable Part B payment under the PFS, and like other Part B services, beneficiaries are responsible for the amount of any unmet deductible and applicable coinsurance that occurs at the originating and distant site. The PFS program payment amount paid to the originating site is the lesser of 80 percent of the actual charge or 80 percent of the originating site facility fee (about $25), except for CAHs. When a CAH is the originating site, the facility fee payment amount is 80 percent of the originating site facility fee. Regardless of the type of provider, the beneficiary is responsible for the remaining 20 percent of the originating site facility fee.

6 CAHs are permitted to bill Medicare for their fee schedule claims if the practitioner has reassigned his or her benefits to the CAHs. In these cases, Medicare will make the payment for telehealth services provided by the CAH's physicians or practitioners at 80 percent of the fee schedule amount for the distant site, and not as a cost-based payment. The beneficiary is responsible for the remaining 20 percent of the distant site payment amount.

7 In 2013, CMS created two billing codes (S9109 and S9110) that enable physicians to monitor patients remotely in their homes using any necessary monitoring equipment. Billable on a monthly basis, these codes reimburse providers for the cost of all necessary equipment and time involved with remote monitoring. The codes originated from the Medicare Care Management for High-Cost Beneficiaries demonstration that took place from 2006 through January 2012. However, these codes are not currently covered under Medicare, but they have been adopted for use by some state Medicaid programs.

8 CMS's MA manual indicates that some communication between a patient and physician (e.g., e-mail) may be considered part of the basic Medicare FFS benefits that MA plans must provide; therefore, these services are not regarded as services beyond the basic Medicare FFS benefit.

9 The CMS Center for Medicare & Medicaid Innovation was established by Section 1115A of the Social Security Act (as added by Section 3021 of the Patient Protection and Affordable Care Act of 2010). The Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. The Congress provided the Secretary of Health and Human Services with the authority to expand the scope and duration of a model being tested through rulemaking, including the option of testing on a nationwide basis. For the Secretary to exercise this authority, a model must either reduce spending without reducing the quality of care or improve the quality of care without increasing spending and must not deny or limit the coverage or provision of any benefits. These determinations are made based on evaluations performed by CMS and the certification of CMS's Chief Actuary with respect to spending.

10 By contrast, Medicare beneficiaries used approximately 200 inpatient stays per 1,000 Part A beneficiaries and more than 800 outpatient evaluation and management visits per 1,000 Part B beneficiaries.

11 The disparity between the number of originating and distant site claims is discussed in more detail (p. 243).

12 We defined *behavioral health clinicians* as physicians and other health professionals who bill Medicare and fall into one of the following Medicare-defined specialist categories: psychiatrists, psychiatrist/neurologists, neuropsychiatrists, clinical psychologists, and other psychologists.

13 The Commission's March 2016 report to the Congress determined that approximately 900,000 clinicians (physicians, nurses, physician assistants, and other clinicians) in 2014 each served 15 or more unique Medicare beneficiaries.

14 While there is overlap between dual-eligible beneficiaries and beneficiaries who qualify for Medicare through disability, not all disabled beneficiaries are also dual-eligible beneficiaries. In fact, less than half of the Medicare under-65 disabled population is dually eligible.

15 Under the CCM, practitioners receive approximately $40 per month for care management services but must obtain consent from the patient and must provide at least 20 minutes of clinical staff time per month. In 2015, providers billed for over 840,000 CCM services for 270,000 unique beneficiaries. Less than 1 percent of CCM users in 2015 were also telehealth users.

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CHAPTER 9

Issues affecting dual-eligible beneficiaries: CMS's financial alignment demonstration and the Medicare Savings Programs

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Issues affecting dual-eligible beneficiaries: CMS's financial alignment demonstration and the Medicare Savings Programs

Chapter summary

About 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, home health care, physician services, durable medical equipment, and prescription drugs. The federal–state Medicaid program covers a variety of long-term services and supports (such as nursing home care or community-based care) and wraparound services, and it provides assistance with Medicare premiums and cost sharing.

Policymakers have long been concerned that dual-eligible beneficiaries may receive fragmented or ineffective care because they are generally in poorer health than other Medicare beneficiaries and must obtain care from two distinct programs, which can make coordinating their care more difficult. These concerns also reflect the high costs of caring for dual-eligible beneficiaries. In 2011, the most recent year of data available, dual eligibles represented about 20 percent of Medicare beneficiaries but accounted for about 35 percent of Medicare spending. For Medicaid, dual eligibles represented about 14 percent of enrollment and about 33 percent of total spending.

The Commission has examined numerous issues related to dual-eligible beneficiaries in recent years. This work organizes broadly into two areas of interest: (1) the development of new models of care that could improve quality

In this chapter

and reduce costs for dual eligibles and (2) the eligibility rules for these low-income beneficiaries and how their care is financed. This chapter continues our work in both areas by providing a status report on the "financial alignment" demonstration project, an initiative by CMS and states to test new models of care for dual eligibles, and by examining the potential cost of three illustrative scenarios for expanding the Medicare Savings Programs (MSPs), which are Medicaid programs that provide assistance with Medicare premiums and cost sharing to certain low-income Medicare beneficiaries.

Under the financial alignment initiative, CMS has approved 14 demonstrations in 13 states. CMS does not expect any additional states to join the demonstration. As of March 2016, 12 of the demonstrations were operational, and the other 2 are expected to start later this year. Most demonstrations will operate for five years. About 450,000 dual eligibles are currently enrolled, making this demonstration one of the largest that CMS has ever conducted related to dual eligibles.

Most demonstrations (11 of 14) are testing a "capitated" model, which uses health plans known as Medicare–Medicaid Plans (MMPs) to provide all Medicare benefits and all or most Medicaid benefits to dual eligibles. Enrollment in the MMPs has been much lower than some expected because many beneficiaries have declined to participate, or "opted out." Based on interviews with stakeholders in several demonstration states, beneficiaries have opted out because they are satisfied with their existing care or are uncertain about how the demonstration would affect them. Stakeholders also agreed that provider resistance to the demonstration has contributed to the low participation rates.

Under the demonstration, states can "passively" (that is, automatically) enroll dual eligibles in MMPs to help ensure that the plans have enough enrollment to justify up-front investments in care coordination activities. Passive enrollment has helped generate sufficient enrollment for most MMPs, but our interviews found broad agreement that its use could be improved in the future. In particular, stakeholders said that passive enrollment should have been implemented more slowly to give MMPs more time to assess the health of new enrollees within the required time frames and that beneficiaries and providers needed to be better educated about the demonstration before passive enrollment began.

MMPs are distinctive because they are required to provide extensive care coordination for their enrollees, including individual health assessments, individual plans of care, and the use of interdisciplinary teams of providers. Several MMPs we interviewed said they have not been able to complete assessments for 20 percent to 30 percent of their enrollees, partly because of outdated contact information. More

broadly, MMPs vary in how they provide care coordination and are still trying to refine and improve their approaches.

As of now, there is no data available on the quality of care provided by MMPs or their ability to improve patterns of service use, such as reducing inpatient stays or nursing home placements. In our interviews, MMPs indicated that their efforts to reshape utilization patterns may not begin to pay off until the second or third year of the demonstration. More information will become available in the future as CMS releases preliminary evaluation reports on each demonstration.

MMPs are paid using a blended capitation rate that has separate components for Medicare Part A and Part B services, Part D drugs, and Medicaid benefits. Each component is risk adjusted to account for the beneficiary's health status. However, six MMPs have left the demonstration since it began, and some have cited inadequate payment rates as one factor. CMS recently increased the payment rate for Part A and Part B services, based on research that the existing risk adjustment model tends to underestimate costs for full-benefit dual eligibles.

Two states (Colorado and Washington) are testing a "managed fee-for-service" (FFS) model, under which the state provides additional care coordination for dual eligibles with FFS coverage in both programs. Interviews with stakeholders in Washington indicate that only 10 percent to 15 percent of those enrolled in its demonstration have used the additional care coordination services, in part because of difficulties with locating and engaging beneficiaries. CMS recently issued a preliminary report finding that Washington's demonstration had reduced Medicare spending by $22 million (or 6 percent) in its first 18 months, but savings of that magnitude do not seem plausible given the low number of people served.

This chapter also summarizes MSP eligibility rules and assistance and examines the potential effects of expanding MSP eligibility under three illustrative scenarios. The scenarios highlight some of the key issues that policymakers would need to consider as part of an MSP expansion, such as the relationship between the eligibility rules for MSPs and those for the Part D low-income subsidy, how much Medicare cost-sharing assistance MSPs should provide (and in particular, whether states can continue to limit their payments for cost sharing), and whether MSPs should be federalized in some fashion. ■

Introduction

About 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, home health 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 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.

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 partial federal financing. Each program is complex, with its own distinct rules for eligibility, covered services, and administrative processes. Medicaid also differs from state to state because states have some flexibility in deciding which individuals and which benefits to cover. The two programs sometimes overlap in ways that are confusing for dual eligibles and providers. For example, Medicare and Medicaid have different rules for covering durable medical equipment and home health and different ways of processing grievances and appeals (Kruse and Philip 2015, Verdier et al. 2014).

More broadly, Medicare and Medicaid do not have strong financial incentives to engage in activities that might benefit the other program. For example, Medicaid covers long-term nursing home care, and Medicare covers inpatient care. States have relatively little incentive to reduce the use of inpatient care by nursing home residents because doing so increases Medicaid spending, while Medicare realizes savings when beneficiaries spend more time in the nursing home and less time in the hospital. Similarly, Medicare has little incentive to prevent dual eligibles from going into nursing homes, where Medicaid pays for most of their care.

How individuals become dual-eligible beneficiaries

Individuals must separately qualify for both Medicare and Medicaid coverage to become dual-eligible beneficiaries. Medicare is a national program, and its eligibility rules and benefits are the same in every state. Individuals typically qualify for coverage if they have a sufficient work history and are either aged (65 or older) or have been disabled for at least 24 months, are a dependent or survivor of an aged or disabled beneficiary, or have end-stage renal disease. For those who qualify, Medicare covers a wide range of primary, acute, and post-acute services, as well as prescription drugs. Medicare also acts as the primary payer for any services that are covered by both programs.

Many dual-eligible beneficiaries qualify for Medicare because they are disabled. Based on linked Medicare–Medicaid eligibility data for 2011, about 41 percent of dual eligibles were under the age of 65, and 51 percent of dual eligibles originally qualified on the basis of disability (including beneficiaries who are now over age 65 but first qualified for Medicare because they were disabled). The corresponding figure for Medicare beneficiaries who are not dual eligibles is much lower: Only 17 percent originally qualified for Medicare because of disability (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2016).

Medicaid's eligibility rules and benefits are more complex because states have some flexibility in deciding which individuals and which benefits to cover. Dual-eligible beneficiaries divide into two broad groups—"full benefit" and "partial benefit"—based on the Medicaid benefits they receive. Full-benefit dual-eligible beneficiaries qualify for the full range of Medicaid services covered in their state, which generally includes a broad array of primary and acute care services, nursing home care, and other long-term services and supports. In contrast, partial-benefit dual-eligible beneficiaries receive assistance only with Medicare premiums and, in most cases, assistance with cost sharing.

There were 9.9 million dual eligibles in 2014—7.1 million who were full benefit and 2.8 million who were partial benefit. Together, they represented about 20 percent of all Medicare beneficiaries.[1] Using linked Medicare–Medicaid eligibility data for 2011, we found that almost all full-benefit dual eligibles qualify for Medicaid in one of four ways:[2]

- ***Eligibility for Supplemental Security Income (SSI) benefits.*** The federal SSI program provides monthly cash payments to elderly and disabled individuals whose income is below about 75 percent of the federal poverty level. SSI recipients are automatically eligible for Medicaid in 41 states and the District of Columbia. The other nine states must allow SSI recipients to

TABLE 9–1

Service use and per user spending for full-benefit dual eligibles, 2011

	Percent using service	Per user spending for each service	Percent of Total Medicare spending	Percent of Total Medicaid spending
Medicare-covered services				
Inpatient hospital	28%	$18,708	28%	N/A
Skilled nursing facility	11	19,467	11	N/A
Home health	14	5,906	5	N/A
Other outpatient	94	5,904	30	N/A
Part D drugs	92	4,976	24	N/A
Medicaid-covered services				
Inpatient hospital	14	2,115	N/A	2%
Outpatient	87	2,390	N/A	12
Institutional LTSS	21	41,789	N/A	50
HCBS state plan	14	10,020	N/A	8
HCBS waiver	14	29,511	N/A	23

Note: N/A (not applicable), LTSS (long-term services and supports), HCBS (home- and community-based services). Figures are based on full-benefit dual eligibles who had fee-for-service coverage in both programs and do not include individuals with end-stage renal disease. (The dual eligibles who met these criteria represented about 63 percent of the overall total.) The figures for percentage of total spending do not sum to 100 because spending is shown only for selected services. Medicaid spending on inpatient hospital and outpatient services reflects payments for Medicare cost sharing and for services that Medicare does not cover, such as dental benefits. The percentage of dual eligibles using Medicaid-covered inpatient hospital services is lower than the corresponding percentage for Medicare-covered inpatient hospital services because some inpatient hospital services do not result in Medicaid spending. For example, the Medicare inpatient deductible may not apply, or states may not cover any of the deductible. A similar logic applies to outpatient services. "HCBS state plan" refers to services that states provide as a regular benefit under their Medicaid plan, such as home health or personal care. "HCBS waiver" refers to services that states only provide through waiver programs, such as those authorized under Section 1915(c) of the Social Security Act.

Source: Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2016.

"spend down" to Medicaid eligibility if needed, which means that they can qualify if their medical spending is high enough that their remaining income falls below an eligibility threshold set by the state. The SSI group accounts for about 49 percent of full-benefit dual eligibles.

- ***Special income limit.*** States can provide coverage to individuals who have income as high as 300 percent of the SSI benefit rate (or about 225 percent of the federal poverty level) and need the level of care provided in a nursing home. A total of 42 states and the District of Columbia use this eligibility pathway, which accounts for about 24 percent of full-benefit dual eligibles.
- ***Poverty-related eligibility.*** States can provide coverage to individuals who are either aged or disabled and have income that exceeds the SSI eligibility limit but is below the federal poverty level. A total of 23 states and the District of Columbia use this eligibility pathway, which accounts for about 15 percent of full-benefit dual eligibles.
- ***Medically needy program.*** States can provide coverage to individuals who have higher income but also have high medical expenses. Under this pathway, individuals qualify for Medicaid by "spending down" their income on medical expenses until their remaining income falls below an eligibility threshold set by the state. A total of 33 states and the District of Columbia use this eligibility pathway, which accounts for about 12 percent of full-benefit dual eligibles.

Partial-benefit dual eligibles do not meet the eligibility criteria for full Medicaid benefits under any of the

pathways outlined above, but instead qualify for partial Medicaid benefits through the Medicare Savings Programs (MSPs), which require states to provide low-income Medicare beneficiaries assistance with Part A and Part B premiums and cost sharing. Under MSPs, beneficiaries with income below 135 percent of the federal poverty level receive assistance with the Part B premium, and individuals with income below 100 percent of the federal poverty level also receive assistance with Part A and Part B cost sharing (and the Part A premium, if necessary).

Characteristics of dual-eligible beneficiaries

Given the importance that factors such as disability, the need for nursing home care (or an equivalent level of care provided in the community), and high medical expenses play in becoming a dual-eligible beneficiary, it is not surprising that dual eligibles, as a group, tend to be in poorer health and have higher spending than other Medicare beneficiaries.

Dual eligibles are more likely than other Medicare beneficiaries to have three or more chronic conditions (19 percent vs. 9 percent) or be diagnosed with a mental illness (30 percent vs. 11 percent) (Congressional Budget Office 2013). Dual eligibles are also more likely to need help performing activities of daily living (ADLs), such as bathing or getting dressed.[3] According to survey data, dual eligibles compared with other Medicare beneficiaries had higher rates of needing help with at least one ADL (55 percent vs. 26 percent) and needing help with three or more ADLs (32 percent vs. 9 percent) (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2016).

About 18 percent of full-benefit dual eligibles have Alzheimer's disease or a related dementia. (That figure is higher—23 percent—for full-benefit dual eligibles who are over the age of 65.) In 2009, average Medicare and Medicaid spending for full-benefit dual eligibles with Alzheimer's disease or a related dementia was nearly twice as high as average spending for full-benefit dual eligibles who did not have those conditions ($61,944 vs. $29,185) (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2013).

Table 9-1 summarizes the major types of Medicare and Medicaid services used by full-benefit dual eligibles.[4] (These figures are based on individuals who had fee-for-service (FFS) coverage in both programs in 2011 and exclude those with end-stage renal disease.[5]) For Medicare, dual eligibles were more likely than other Medicare beneficiaries, who are not shown in the table, to have an inpatient stay (28 percent vs. 17 percent) and use post-acute services, such as skilled nursing facility care (11 percent vs. 4 percent) and home health care (14 percent vs. 9 percent). Furthermore, Medicare's average spending for those three services—when measured on a per user basis—was 21 percent to 32 percent higher for dual eligibles than for other beneficiaries, indicating that users who are dual eligibles receive more of a particular service, receive a more intensive level of care, or some combination of the two. Almost all dual eligibles used outpatient services and Part D–covered prescription drugs. Outpatient services (30 percent), inpatient hospital care (28 percent), and Part D drugs (24 percent) accounted for most of Medicare's total spending for dual eligibles.

Across all services, average Medicare spending for dual eligibles—measured on a per capita basis—was about $17,960 in 2011, more than two times higher than the average spending of $8,460 for other Medicare beneficiaries (data not shown).

As for Medicaid, spending on LTSS, which includes institutional forms of care as well as home- and community-based services, accounts for more than 80 percent of total program spending. However, less than half of dual eligibles use those services.[6] For those who do, per user spending is high, particularly for institutional LTSS, such as nursing home care ($41,789), or care provided through a home- and community-based services waiver program ($29,511).

In aggregate, dual-eligible beneficiaries represented about 20 percent of Medicare enrollees in 2011 (the most recent year of linked Medicare and Medicaid enrollment and spending data available) but accounted for about 35 percent of total Medicare spending. They are costly for Medicaid as well, representing about 14 percent of enrollment and about 33 percent of total spending in that program.

Recent Commission work related to dual-eligible beneficiaries

The Commission has examined several issues in recent years that directly affect dual-eligible beneficiaries. Broadly speaking, the Commission's work has centered on two key areas of interest: (1) developing new models of care that could improve the quality of care and lower costs for dual eligibles and (2) assessing the eligibility rules and financing of care for dual eligibles.

New models of care

Given the challenges involved with coordinating Medicare and Medicaid services for dual-eligible beneficiaries, the Commission has a long-standing interest in developing new models of care, or expanding the use of existing models of care, that would give providers stronger incentives to coordinate care for dual eligibles. Several of these models involve the use of managed care.

In 2012, the Commission examined the Program of All-Inclusive Care for the Elderly (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 most enrollees are dual-eligible beneficiaries. The central feature of this model of care is the PACE provider, which is usually an adult day-care center that is staffed by an interdisciplinary team and provides therapy and medical services. For dual eligibles, Medicare and Medicaid make separate monthly capitation payments to the PACE provider, and the PACE provider can blend those payments and use them to deliver the full range of Medicare-covered and Medicaid-covered services. The program thus 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, with about 33,000 Medicare beneficiaries currently enrolled. 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 Medicare Advantage (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).[7]

In 2013, the Commission examined the role of MA special needs plans (SNPs), which can limit their enrollment to one of three specified groups: dual-eligible beneficiaries (in plans known as D–SNPs), beneficiaries who need the level of care provided in a long-term care institution (in plans known as I–SNPs), or beneficiaries with certain chronic conditions (in plans known as C–SNPs). Dual eligibles account for almost all enrollees in D–SNPs and a substantial share of those enrolled in I–SNPs and C–SNPs. At the time, SNPs were authorized only through the end of 2014; the Congress has since authorized them through the end of 2018.

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 all I–SNPs, certain D–SNPs (those that are highly integrated with Medicaid), and certain C–SNPs (those that focus on certain chronic conditions—such as end-stage renal disease, HIV/AIDS, and severe mental illness—for which a distinct MA benefit package is most warranted). Authority would be allowed to expire for D–SNPs that did not integrate with Medicaid or C–SNPs that focused on other chronic conditions. The Commission also recommended letting MA plans enhance their benefit designs so that benefits could vary based on the medical needs of individuals with certain chronic or disabling conditions (Medicare Payment Advisory Commission 2013).

Eligibility rules and financing

In 2008, the Commission made recommendations that would increase the number of Medicare beneficiaries who are partial-benefit dual eligibles. The Commission examined beneficiaries' participation in MSPs, which provide assistance with Part A and Part B premiums and cost sharing, and the Part D low-income drug subsidy (LIS), which provides assistance with premiums and cost sharing for the Medicare prescription drug benefit. Although MSPs and the LIS provide valuable financial assistance, the research available at the time suggested that participation rates in the programs were relatively low, due to such factors as beneficiaries' lack of knowledge about the programs and the complexity of the application process.

The Commission concluded that participation rates would increase if MSP eligibility rules and application processes were better aligned with the LIS. The LIS has higher eligibility limits than MSPs, and the Commission recommended that the Congress raise the income and asset limits for MSPs to LIS levels. As part of this change, beneficiaries with income between 135 percent and 150 percent of the federal poverty level would become eligible for assistance with the Part B premium, but the cost of that assistance would be paid entirely by the federal government to minimize the impact on state Medicaid budgets.

The Commission also recommended that the Congress require the Social Security Administration, which determines LIS eligibility for most applicants, to also determine whether applicants are eligible for MSPs and enroll them in both programs if they qualify (Medicare Payment Advisory Commission 2008).

In 2012, the Commission recommended making a number of changes to Medicare's cost-sharing rules that could affect low-income Medicare beneficiaries. Those changes included placing an annual limit on beneficiary out-of-pocket spending, establishing a uniform deductible for Part A and Part B that would be higher than the current Part B deductible, replacing coinsurance with copayments that could vary by type of service and provider, and imposing an additional charge on premiums for supplemental insurance coverage, such as medigap plans. However, there would be no change in beneficiaries' aggregate cost-sharing liability. Since Medicaid pays for Part A and Part B cost sharing for many dual-eligible beneficiaries, those changes would increase Medicaid spending for some dual eligibles (such as those who use largely Part B services and would face a higher deductible) while reducing spending for other dual eligibles (such as those with high out-of-pocket spending) (Medicare Payment Advisory Commission 2012b).

Status report on the financial alignment demonstration

Since 2011, CMS has worked with states to conduct a financial alignment demonstration that tests new models of care for full-benefit dual-eligible beneficiaries. (Partial-benefit dual eligibles cannot participate in the demonstration.) These new models seek to improve the coordination of Medicare and Medicaid for dual eligibles, improve the quality of their care, and lower costs. Thirteen states are currently conducting or preparing to conduct demonstrations, and about 450,000 dual-eligible beneficiaries are enrolled in them. Collectively, they represent one of the largest demonstration projects that CMS has ever conducted related to dual eligibles.

For this report, we reviewed a wide range of CMS guidance related to the demonstration, made site visits to three states with demonstrations (California, Illinois, and Massachusetts), and conducted phone interviews with stakeholders in a fourth demonstration state (Washington). Our site visits and phone interviews took place between November 2015 and February 2016. In all, we conducted over 40 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.

Development of the financial alignment demonstration

CMS began developing the financial alignment demonstration in April 2011, when it awarded 15 states up to $1 million apiece to help them design new approaches for coordinating care for dual eligibles (Department of Health and Human Services 2011). A few months later, in July, CMS announced that states could test two models of care as part of the financial alignment demonstration—a *capitated* model and a *managed fee-for-service* model:

- Under the capitated model, a single managed care plan (known as a Medicare–Medicaid Plan, or MMP) provides the full range of Medicare and Medicaid benefits to dual eligibles. The MMP receives a blended Medicare–Medicaid payment rate that is reduced to reflect expected savings from the demonstration. This model builds on previous efforts to use managed care to better integrate Medicare and Medicaid, such as PACE and Medicare Advantage D–SNPs.[8]
- 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. This model builds on broader state efforts to improve the FFS delivery system that involve other reforms such as accountable care organizations and health homes (Centers for Medicare & Medicaid Services 2011).

Many states initially expressed interest in the financial alignment demonstration, but the number of states that are actually participating is much smaller. After CMS's announcement in 2011, a total of 37 states and the District of Columbia indicated their interest in participating, and 26 states ultimately submitted proposals to CMS (Medicaid and CHIP Payment and Access Commission 2015a).

As of March 2016, CMS had approved 14 demonstrations in 13 states. CMS does not expect to approve any more demonstrations; the other states that submitted proposals

The Commission's July 2012 letter to CMS about the financial alignment demonstration

In its letter to CMS, the Commission underscored its support for the goals of the financial alignment demonstration, noting that dual eligibles were often in poor health and vulnerable to receiving uncoordinated care. However, the Commission highlighted five key areas of concern about the demonstration, which at the time was still being developed:

1. ***Scope of the demonstration***—At the time, CMS 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 true demonstration. The Commission believed that the two new models of care should be tested on a smaller scale before being used more broadly.

2. ***Passive enrollment***—The Commission supported the demonstration's use of passive enrollment—that is, the automatic enrollment of beneficiaries—but suggested that it be accompanied by a number of beneficiary protections, such as allowing beneficiaries to opt out at multiple points in the process, conducting extensive outreach and education before passive enrollment, and assessing beneficiaries' care needs shortly after their enrollment.

3. ***Plan requirements***—The Commission suggested that CMS use existing requirements for Medicare Advantage plans as a minimum standard for plans participating in the demonstration.

4. ***Monitoring and evaluation***—The Commission suggested that CMS collect a core set of measures from all states to monitor access to care and quality, as well as a core set of outcome measures. The Commission also recommended that the evaluation of the demonstration should measure Medicare and Medicaid costs and savings separately, so that policymakers would know where savings were actually achieved.

5. ***Program costs and ensuring savings***—The Commission suggested that the demonstration first aim to improve quality and care coordination for dual eligibles, and only after that to reduce Medicare and Medicaid spending. For the participating managed care plans, CMS planned to lower the blended Medicare–Medicaid capitation rate so that the federal government and states would realize savings, and to use the same percentage to reduce both the Medicare and Medicaid components of the blended rate. The Commission disagreed with this approach, arguing that it was unlikely that both programs would see similar savings. The Commission also 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).

Some elements of the demonstration as it has been implemented are in line with the Commission's comments, while others are not. The demonstration is much smaller than many observers expected because fewer states are participating, CMS reduced the size of the demonstrations in some states, and many beneficiaries have chosen to opt out. Nevertheless, the demonstration is still larger than needed to test its new models of care. The requirements for the demonstration in the areas of passive enrollment, plan requirements, and monitoring and evaluation are generally in line with the Commission's comments. However, the methodology that CMS is using to pay the health plans participating in the demonstration is generally not aligned with the Commission's comments. For example, CMS has continued to apply a uniform savings estimate to both the Medicare and Medicaid components of plan payment rates, rather than developing separate assumptions for each component. ■

have either formally withdrawn them or are no longer actively discussing them with CMS (Centers for Medicare & Medicaid Services 2016c). States that were initially interested in the demonstration but ultimately did not participate cited a number of reasons for their decision, such as concerns about low payment rates for participating plans and less state flexibility than initially expected in designing the demonstration. A number of these states have chosen instead to pursue Medicare–Medicaid integration through the use of D–SNPs.

TABLE 9–2

Overview of the financial alignment demonstrations

State	Model type	Eligible population	MOU date	Start/end dates	March 2016 enrollment
California	Capitated	Aged and disabled	March 2013	April 2014 to 2017	127,349
Colorado	Managed FFS	Aged and disabled	February 2014	September 2014 to 2017	25,611
Illinois	Capitated	Aged and disabled	February 2013	March 2014 to 2017	49,171
Massachusetts	Capitated	Disabled only	August 2012	October 2013 to 2016	12,642
Michigan	Capitated	Aged and disabled	April 2014	March 2015 to 2018	34,684
Minnesota	Alternative	Aged only	September 2013	September 2013 to 2016	36,052
New York (1)	Capitated	Aged and disabled	August 2013	January 2015 to 2017	6,005
New York (2)	Capitated	Aged and disabled	November 2015	April 2016 to 2020	—
Ohio	Capitated	Aged and disabled	December 2012	May 2014 to 2017	63,112
Rhode Island	Capitated	Aged and disabled	July 2015	mid-2016 to 2018	—
South Carolina	Capitated	Aged only	October 2013	February 2015 to 2018	1,838
Texas	Capitated	Aged and disabled	May 2014	March 2015 to 2018	49,010
Virginia	Capitated	Aged and disabled	May 2013	April 2014 to 2017	28,249
Washington	Managed FFS	Aged and disabled	October 2012	April 2013 to 2016	21,870

Note: MOU (memorandum of understanding), FFS (fee-for-service). Enrollment figures for Washington are for December 2015. All states use additional eligibility criteria beyond age and disability. New York is conducting two distinct demonstrations: The first targets individuals who use certain kinds of long-term services and supports, while the second targets individuals with intellectual and developmental disabilities. All demonstrations are scheduled to end on December 31 of the indicated calendar year. End dates do not account for the optional two-year extension that CMS announced in July 2015.

Source: MedPAC analysis of state MOUs, CMS demonstration guidance, and Medicare Advantage enrollment data for March 2016; personal communication from L. Barnette at CMS.

In July 2012, after states had submitted their proposals but before CMS had approved any demonstrations, the Commission sent a letter to CMS outlining five key areas of concern with the demonstration (see text box).

Table 9-2 provides a high-level overview of the 14 demonstrations that CMS has approved. Most of them are testing the capitated model; only Colorado and Washington are testing the managed FFS model, while Minnesota is testing an alternative model.[9] Most of the demonstrations are open to both disabled and aged dual eligibles, although one state (Massachusetts) is targeting only disabled beneficiaries, and two states (Minnesota and South Carolina) are targeting only aged beneficiaries.

CMS has 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 (Table 9-2). Most of the demonstrations started enrolling beneficiaries about a year after the signing of the MOU. As of March 2016, 12 of the 14 demonstrations were underway, with the last two (Rhode Island and New York's second demonstration) expected to start later this year.

CMS initially planned for the demonstrations to last for three years, but announced in July 2015 that states could extend them for an additional two years.[10] CMS offered the extension because the first detailed evaluations of the demonstrations will not be ready until the end of their second year, and states would need to start their planning process for fiscal years beyond the original three-year period before then (Centers for Medicare & Medicaid Services 2015f). All participating states expressed interest in the extension, but Virginia now plans to end its demonstration in 2017, as originally scheduled

(Gutman 2015a, Virginia Department of Medical Assistance Services 2015).[11] California may also end its demonstration in 2017 if it is not found to be cost effective (State of California 2016). CMS expects to approve the extensions later this year (Centers for Medicare & Medicaid Services 2016c).

About 450,000 dual eligibles were enrolled in the financial alignment demonstrations as of March 2016. California's demonstration is by far the largest, with almost 130,000 enrollees (about 30 percent of the national total), followed by Ohio, Illinois, and Texas.

Demonstrations using the capitated model

As shown in Table 9-2 (p. 273), nine states are currently working with CMS to test the capitated model, which relies on health plans to provide the full range of Medicare and Medicaid benefits to dual eligibles. About 372,000 dual eligibles were enrolled in those demonstrations in March 2016. Two more demonstrations using the model, in Rhode Island and New York, are planning to start later this year.

The centerpiece of the capitated model is the Medicare–Medicaid Plan (MMP), a health plan that provides all Medicare-covered and all or most Medicaid-covered services to dual eligibles. MMPs are required to provide a high level of care coordination for their enrollees; they receive a blended capitation rate that combines Medicare Part A, Part B, and Part D and Medicaid payments. CMS and the states hope that the integration of Medicare and Medicaid financing, combined with extensive requirements for care coordination, will lead to better care for dual eligibles and reduce Medicare and Medicaid spending.

This section covers eight key areas for the capitated demonstrations: beneficiary eligibility, health plan participation, beneficiary participation, the use of passive enrollment, care coordination, quality of care, service use, and payment adequacy. For this status report, we focus in particular on the use of passive enrollment and care coordination, two areas where we have enough information to offer some initial impressions. In many other areas, there is still relatively little information available.

Beneficiary eligibility

CMS has limited the financial alignment demonstration's eligibility 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 all states testing the capitated model have done so. These additional eligibility criteria vary across states, but there are some common elements:

- Disabled (under 65) and aged (65 and older) beneficiaries both can enroll in most of the demonstrations. The exceptions are Massachusetts (disabled only) and South Carolina (aged only).
- Most demonstrations operate only in certain parts of the state. South Carolina has the only fully statewide demonstration for the capitated model.[12] The other states limit eligibility to certain counties or regions, usually around large metropolitan areas. For example, Texas is conducting its demonstration in six counties around Dallas, El Paso, Fort Worth, Houston, McAllen, and San Antonio.
- Beneficiaries enrolled in PACE cannot participate unless they first leave the PACE program. These individuals are already served by a program that fully integrates Medicare and Medicaid for dual eligibles.
- Six demonstrations do not allow beneficiaries to participate if they have other forms of health insurance coverage, such as employer-sponsored coverage.
- Seven demonstrations exclude beneficiaries enrolled in certain Medicaid home- and community-based waiver programs. The excluded waiver programs usually serve individuals with intellectual or developmental disabilities.
- Seven demonstrations restrict eligibility for individuals who qualify for Medicaid through "medically needy" programs for people with high medical expenses. Many of these individuals qualify for Medicaid for only a limited time.

As of March 2016, about 1.3 million dual eligibles were eligible to participate in the capitated demonstrations (Centers for Medicare & Medicaid Services 2016b).[13] That number represents about 35 percent of the dual eligibles in the nine states testing the capitated model and between 15 percent and 20 percent of all dual eligibles in the country. While the size of the eligible population is in line with CMS's interest in enrolling up to 1 million to 2 million dual eligibles in the demonstration, enrollment has been much lower than some expected.

Since eligibility for the demonstration uses both Medicare and Medicaid criteria, states have had to integrate their

TABLE 9–3

Largest MMP sponsors as of March 2016

Plan sponsor	Sponsor type	States	Enrollment	Percent of total
Molina	For profit	CA, IL, MI, OH, SC, TX	52,077	14.0%
Centene	For profit	CA, IL, MI, OH, SC, TX	48,338	13.0
Anthem	For profit	CA, TX, VA	36,251	9.7
Aetna	For profit	IL, MI, NY, OH	26,577	7.1
Inland Empire Health Plan	Nonprofit	CA	22,101	5.9
Orange County Health Authority	Nonprofit	CA	18,726	5.0
UnitedHealth Group	For profit	OH, TX	18,462	5.0
Humana	For profit	IL, VA	17,072	4.6
CareSource	Nonprofit	OH	16,076	4.3
Health Care Service Corporation	Nonprofit	IL	14,052	3.8
Total, top 10 sponsors			269,732	72.5

Note: MMP (Medicare–Medicaid Plan). The figures for Centene reflect its acquisition of Health Net, which took effect in March 2016. Anthem has announced plans to acquire Cigna (not shown in this table), and Aetna has announced plans to acquire Humana, but those acquisitions had not received regulatory approval as of the time of this report. If they were approved without any changes, the four largest sponsors would account for just over half of MMP enrollment. Components may not sum to totals due to rounding.

Source: Medicare Advantage enrollment data for March 2016.

enrollment systems with Medicare's, which has often proven difficult (Chepaitis et al. 2015). Some stakeholders also raised this issue during our site visits, noting that MMPs and providers sometimes have had difficulty obtaining accurate enrollment information.

Health plan participation

As of March 2016, 60 MMPs were operating in the 9 states that had begun testing the capitated model. Two new MMPs intend to begin operating later this year—Rhode Island's demonstration and New York's second demonstration (both will use only one MMP). Six other MMPs have left the demonstration since it started—four in New York's first demonstration and one apiece in Illinois and Massachusetts. The MMPs that left the demonstration either had very low enrollment or cited inadequate payment rates.

Each MMP signs a three-way contract with CMS and the state that specifies its requirements under the demonstration. States initially select the plans for the demonstration and can limit the number of plans that participate. Some states have chosen from among their Medicaid managed care plans, while others have issued a separate procurement. Plans must also 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 2015a).

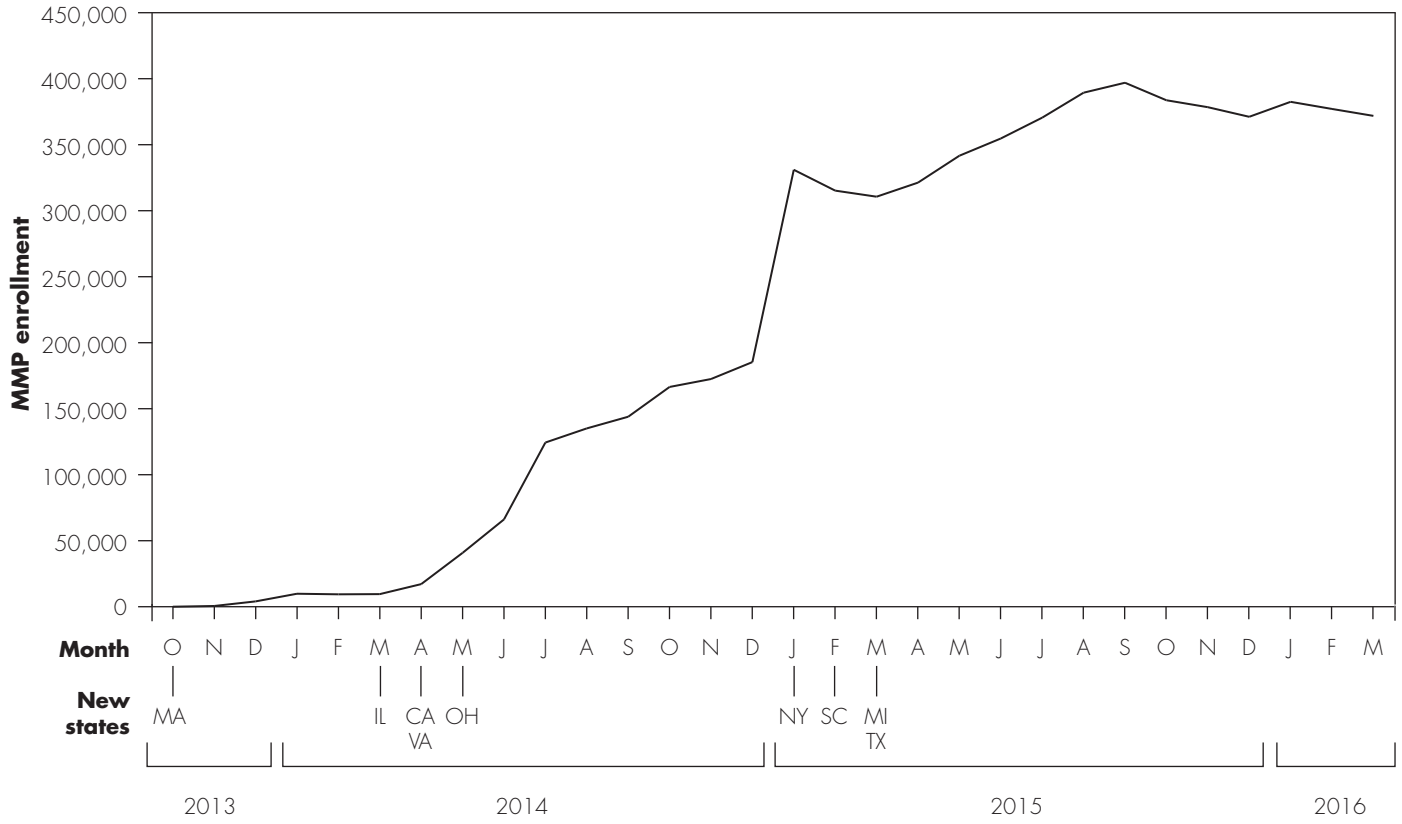
The number of MMPs in each state varies. All states currently have between 2 and 7 plans, except for California (10 plans) and New York (17 plans in its first demonstration). As noted earlier, many demonstrations are being conducted only in certain parts of the state, and many MMPs serve only part of the demonstration area. For example, Ohio is conducting its demonstration in seven regions. The state has five MMPs, but only two or three operate in each region.

Most MMPs are sponsored by organizations with prior experience in MA, Medicaid managed care, or both. One study found that 52 of the 67 MMPs in the demonstration had prior experience in MA, either by offering D–SNPs or regular MA plans.[14] On the Medicaid side, 45 MMPs had prior experience serving dual eligibles in the state in some fashion (Weiser and Gold 2015). However, some of these MMPs did not have prior experience with LTSS, and some reported that working in that area has been challenging (Chepaitis et al. 2015).

A relatively small number of plan sponsors account for most MMP enrollment. Table 9-3 shows the 10 plan sponsors with the most MMP enrollees, as of March

FIGURE 9–1

Total MMP enrollment, by month, October 2013–March 2016



Note: MMP (Medicare–Medicaid Plan).

Source: MedPAC analysis of monthly Medicare Advantage enrollment data from CMS.

2016. As a group, these sponsors account for over 70 percent of MMP enrollment. The four biggest sponsors—Molina, Centene, Anthem, and Aetna—are for-profit companies that offer MMPs in several states, and together they account for about 44 percent of MMP enrollment. Although the largest sponsors are primarily for-profit companies across all participating states, regional or local nonprofit MMPs have a significant presence in many individual states.

Beneficiary participation

Total enrollment in MMPs has grown gradually because the individual state demonstrations have started at different times and many have been implemented in stages (Figure 9-1). Overall enrollment has grown from about 4,000 at the end of 2013 (when there was 1 active demonstration), to 185,000 at the end of 2014 (5 active demonstrations), and to 370,000 at the end of 2015 (9 active demonstrations). Total enrollment peaked in September 2015, at almost 400,000, and has declined somewhat since then. As of March 2016, about 372,000 beneficiaries were enrolled in MMPs.

Enrollment in MMPs has been much lower than many observers expected. When CMS first unveiled the demonstration in 2011, it was interested in enrolling up to 1 million to 2 million beneficiaries (Centers for Medicare & Medicaid Services 2011). Table 9-4 shows, as of March 2016, each state's MMP enrollment, the number of beneficiaries eligible to participate in the demonstration, and MMP participation rate. Participation rates vary widely across states. Ohio has had the highest participation rate, at 68 percent, followed by five states—California, Illinois, Michigan, Texas, and Virginia—with participation rates of roughly 30 percent to 40 percent. On the low end, three states—Massachusetts, New York, and South

TABLE 9–4

MMP participation rates, March 2016

State	MMP enrollment	Eligible beneficiaries	Participation rate
California	127,349	424,000	30%
Illinois	49,171	154,000	32
Massachusetts	12,642	101,000	13
Michigan	34,684	105,000	33
New York	6,005	100,000	6
Ohio	63,112	93,000	68
South Carolina	1,838	50,000	4
Texas	49,010	165,000	30
Virginia	28,249	67,000	42
Total	372,060	1,259,000	30

Note: MMP (Medicare–Medicaid Plan). All of these demonstrations have completed their initial round of passive enrollment except New York and South Carolina. New York stopped using passive enrollment in December 2015, after it had attempted to passively enroll about 50,000 beneficiaries. South Carolina has used only voluntary enrollment so far and is planning to begin passive enrollment later this year. This table does not include Rhode Island's demonstration or New York's second demonstration, both starting later this year.

Source: Medicare Advantage enrollment data for March 2016, personal communication from L. Barnette at CMS.

Carolina—have participation rates below 15 percent.[15] Across all participating states, only about 30 percent of eligible beneficiaries are enrolled in MMPs.

Participation rates for the MMPs have been relatively low because many beneficiaries have chosen not to participate. Under the demonstration, states can passively enroll dual eligibles in MMPs, but beneficiaries can "opt out" before their enrollment takes effect, and MMP enrollees can subsequently disenroll at any time.

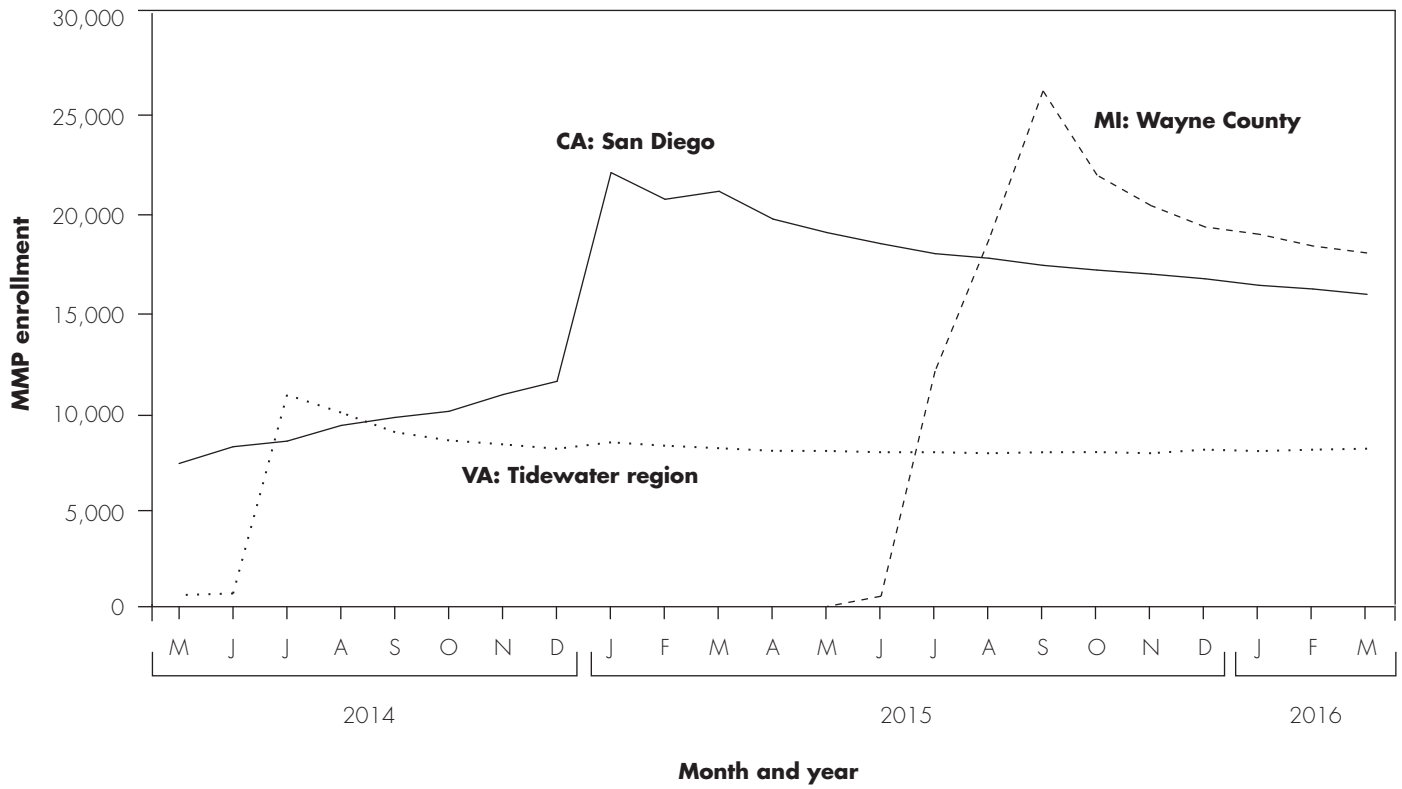
The three states we visited—California, Illinois, and Massachusetts—have experienced high opt-out rates. Stakeholders in those states said that beneficiaries declined to participate in the demonstration for a number of reasons:

- ***Satisfaction with existing care.*** Some beneficiaries are happy with their current providers and do not think that they will benefit by enrolling in an MMP. They are also concerned that enrolling in an MMP could threaten access to their current providers, such as specialists, who may not participate in the plans' provider networks.
- ***Fear of the unknown.*** Many stakeholders indicated that beneficiaries often did not receive a clear explanation of the demonstration or how it would affect them. State educational materials were sometimes difficult to understand and could prove unreliable. For example, many states had to delay the start of their demonstrations because of implementation challenges, which led to delays in expected enrollment dates. Stakeholders also said that explaining "care coordination" and its benefits for dual eligibles could be difficult. Given the uncertainties, many beneficiaries decided that opting out was the safer course of action.
- ***Resistance from providers.*** Stakeholders in these states indicated that some providers in their state opposed the demonstration and refused to participate in the MMPs' provider networks or advised their dual-eligible patients not to participate.[16] These states' demonstrations largely involved moving FFS beneficiaries into managed care, and provider resistance seemed largely driven by a preference for the existing FFS system and an unwillingness to interact with managed care plans. The types of providers that resisted the demonstration varied across states but included primary care physicians, specialists, physicians in solo or small group practices, and nursing homes.

Although the high opt-out rates have received significant attention, disenrollment (leaving an MMP after being enrolled) has also been an issue. Many states have had

FIGURE 9–2

Attrition in MMP enrollment



Note: MMP (Medicare–Medicaid Plan).

Source: MedPAC analysis of monthly Medicare Advantage enrollment data from CMS.

similar experiences. Figure 9-2 shows MMP enrollment in three regions that conducted passive enrollment at different times. Once passive enrollment has concluded, MMP enrollment often falls by roughly 10 percent to 30 percent in the following two to three months. After that, enrollment usually continues to decline, but at a slower rate. The decline in enrollment has stopped in some states (Illinois, Massachusetts, Ohio, and Virginia), and MMP enrollment there now appears to be stable. Other states continue to experience gradual declines in their MMP enrollment.

The variation in participation rates also appears to stem partly from structural differences among the individual state demonstrations. For example, Ohio's high participation rate may be partly because the state effectively moved its dual eligibles into MMPs in two stages—first for Medicaid benefits and then for Medicare benefits. In the first stage, which took place in May 2014, the state required all dual eligibles in counties that were part of the demonstration to enroll in managed care plans for their Medicaid benefits, including LTSS. In the second stage, which took place in January 2015, the state transferred these dual eligibles into companion MMPs offered by the same parent companies. This two-step process may have helped reduce resistance from LTSS providers to the demonstration (because they now had to operate in a managed care environment regardless) and may have given beneficiaries time to become more comfortable with managed care.

Conversely, the low participation rate in New York's first demonstration may be partly due to requirements for care coordination that were unusually prescriptive. In particular, the demonstration required primary care physicians to complete training on the process that would be used to prepare each enrollee's individual care plan, and it required all members of the interdisciplinary provider team (plus the enrollee) to participate in planning

meetings. These requirements were difficult for MMPs to administer and generated strong resistance from providers and high opt-out levels. To date, over 61,000 dual eligibles have opted out of the demonstration, and only about 6,000 were enrolled as of March 2016 (New York State Department of Health 2016). In response, the state suspended the use of passive enrollment in late 2015 and made a series of changes to give MMPs and providers greater flexibility in providing care coordination (New York State Department of Health 2015).

Despite relatively low participation rates, overall MMP enrollment is still substantial at 372,000 beneficiaries and represents a noticeable shift from FFS to managed care for the dual-eligible population. For comparison, the number of full-benefit dual eligibles enrolled in MA plans, which are much more widely available, was about 1.7 million at the end of 2014, with 1.2 million enrolled in SNPs. Enrollment in MMPs is now much higher than in the other forms of managed care that significantly integrate Medicare and Medicaid: fully integrated dual-eligible (FIDE) SNPs (39 plans and about 123,000 enrollees in March 2016) and PACE plans (238 plans and about 35,000 enrollees).[17] Enrollment in most demonstrations appears to be sufficient to properly test the capitated model, with the possible exception of New York, where many MMPs have very low enrollment.

The use of passive enrollment

As part of the capitated model, CMS allows states to use a passive enrollment process to enroll eligible beneficiaries in MMPs. With passive enrollment, states' enrollment of beneficiaries in MMPs is automatic, unless beneficiaries actively indicate that they do not want to enroll in an MMP, which is known as opting out. Beneficiaries who opt out keep their existing form of Medicare coverage.

The use of passive enrollment is a departure from Medicare's usual rules, where the FFS program is the default form of Part A and Part B coverage for new Medicare beneficiaries, and any subsequent changes, such as enrolling in a Medicare Advantage plan or Part D prescription drug plan, are voluntary. However, CMS uses passive enrollment under certain circumstances, most notably to assign certain beneficiaries who receive the Part D low-income subsidy to new prescription drug plans (see text box, pp. 280–281).

CMS authorized the use of passive enrollment in the demonstration to encourage health plans to participate and to ensure that there was enough enrollment to conduct a robust evaluation. Many health plans believed that they would need to make significant upfront investments to provide the level of care coordination required for MMPs. CMS and the states were concerned that some plans would be unwilling to participate without some assurance that they would have enough enrollment to justify those initial investments. Passive enrollment would result in higher enrollment levels than a purely voluntary system, at least in the short term, and would help ensure that MMP enrollment would be sufficient.

The MMPs we visited largely confirmed these assertions. All indicated that they had made substantial investments to participate in the demonstration, such as developing new information technology systems and hiring and training care coordinators, often months before the demonstration started. Most indicated that passive enrollment was an important factor in their decision to participate in the demonstration.

The use of passive enrollment has been a key feature of the demonstration. Every state that is testing the capitated model has used it in some fashion, and passive enrollment has accounted for the vast majority of overall MMP enrollment.[18]

Requirements for MMPs to qualify for passive enrollment Under the demonstration, MMPs must satisfy two key requirements before they can receive beneficiaries through passive enrollment. First, all states follow a "two-plan" rule that limits their use of passive enrollment to areas where at least two MMPs are operating. CMS requires states to follow this rule if they require Medicaid beneficiaries to enroll in managed care (four demonstration states currently do), but the other participating states have chosen to use it as well. This requirement is borrowed from the Medicaid program, where the two-plan rule is used to ensure that beneficiaries have some degree of choice when states require them to enroll in a Medicaid managed care plan. There are exceptions to the two-plan rule for rural areas and counties in California with a county organized health system (Centers for Medicare & Medicaid Services 2013d).[19] Three demonstration regions—Michigan's Upper Peninsula (a rural area) and California's San Mateo County and Orange County (which have county organized health systems)—qualify for an exception and have used passive enrollment despite having only one MMP. All other demonstration regions are subject to the two-plan rule. States can only use voluntary, or "opt-in," enrollment in regions that do not satisfy the two-plan rule. However,

Other uses of passive enrollment in Medicare and Medicaid

While the financial alignment demonstration has been noteworthy for its use of passive enrollment, Medicare and Medicaid regularly use passive (automatic) enrollment in other situations.

Medicare Part D

Since Medicare's prescription drug benefit does not have a fee-for-service option, CMS passively enrolls beneficiaries in stand-alone Part D plans in certain situations to ensure that they have prescription drug coverage. CMS categorizes some of these actions as "auto-enrollment" or "facilitated enrollment" instead of passive enrollment, but in each instance CMS selects a Part D plan for a beneficiary, and that selection takes effect unless the beneficiary takes some action to change it.

CMS most commonly uses passive enrollment for beneficiaries who qualify for Part D's low-income subsidy (LIS). All dual eligibles qualify automatically for the LIS. If beneficiaries do not select a Part D plan when they first qualify for the LIS, CMS randomly assigns them to a plan where the LIS fully covers the plan's Part D premium, known as a zero-premium plan. Part D also allows LIS beneficiaries to pick a new Part D plan at any time, with their selection taking effect the following month, or to opt out of passive enrollment entirely. This automatic enrollment is particularly important for dual eligibles who qualify for Medicaid before they qualify for Medicare. When those individuals qualify for Medicare, they lose their Medicaid drug coverage and must enroll in a Part D plan to maintain prescription drug coverage.

CMS also uses passive enrollment to ensure that LIS beneficiaries remain enrolled in zero-premium plans. Part D plans qualify as zero-premium plans if their premiums are below a benchmark amount, and exactly which plans qualify changes from year to year because of changes in plans' Part D bids. If a plan's premium exceeds the benchmark by more than a minimal amount, LIS beneficiaries must pay the difference. When LIS beneficiaries are in plans that no longer qualify as zero-premium plans in the following year, CMS reassigns them at the start of the following year to another zero-premium plan to ensure that they do not have to start paying a premium. CMS does not reassign LIS beneficiaries who have selected a Part D plan on their own, including beneficiaries enrolled in Medicare Advantage plans that include drug coverage (Centers for Medicare & Medicaid Services 2015c). One study found that only 42 percent of LIS enrollees in 2010 had selected their own plan and that 90 percent of those who had been automatically reassigned accepted their new plan (Hoadley et al. 2015).

Finally, CMS uses passive enrollment when a plan's participation in Part D is terminating immediately and its enrollees' coverage would otherwise be disrupted. In these cases, CMS reassigns the beneficiaries in the terminating plan to a new plan and gives them a chance to pick a new plan.[20] CMS also reassigns beneficiaries when a Medicare Advantage (MA) plan that includes Part D coverage terminates immediately; the beneficiaries in that plan are either transferred to another MA plan with Part D coverage or placed in the fee-for-service (FFS) program and passively enrolled in a Part D plan.

Medicare Advantage

Health insurance companies typically offer plans in multiple lines of business, such as MA, commercial

(continued next page)

when an MMP plan sponsor also offers an MA plan or Medicaid managed care plan, states can transfer eligible beneficiaries from these plans to the sponsor's MMP—a process sometimes referred to as "crosswalking"—even if that is the only MMP available in an area.

Several states have had difficulty getting enough plans to participate in their demonstration projects, either because fewer plans agreed to participate at the outset or because some MMPs have dropped out during the demonstration. Because of the two-plan rule, there have been several instances in which low plan participation has significantly limited states' ability to use passive enrollment:

- Illinois no longer uses passive enrollment in its Central Illinois region after one of the two MMPs there withdrew from the demonstration at the end of 2015.

Other uses of passive enrollment in Medicare and Medicaid (cont.)

insurance, or Medicaid managed care. Sponsors of MA plans may take individuals who have been enrolled in one of their non-Medicare health plans and passively enroll them in one of their MA plans when those individuals first become eligible for Medicare. This process is optional for plan sponsors and is known as "seamless conversion." CMS requires sponsors to notify affected beneficiaries at least 60 days before they become eligible for Medicare and allow them to opt out of seamless conversion (Centers for Medicare & Medicaid Services 2014a). CMS has not indicated how many plan sponsors offer seamless conversion or how many beneficiaries are affected.

One-time opportunity for certain special needs plans

In 2006, a number of Medicaid managed care plans that served dual eligibles decided to begin offering special needs plans (SNPs) as well. CMS gave 42 SNPs in 13 states a one-time opportunity to passively enroll the dual eligibles from their Medicaid managed care plans in their new companion SNPs. Beneficiaries could opt out and stay enrolled in FFS Medicare, but most accepted their new coverage, which led to a substantial increase in SNP enrollment (Milligan and Woodcock 2008). CMS passively enrolled about 213,000 beneficiaries in SNPs through this process (Schmitz et al. 2008).

This use of passive enrollment in SNPs had mixed results. Implementation in many areas went relatively smoothly, but SNPs in Pennsylvania had problems coordinating Medicare and Medicaid benefits, which ultimately prompted a class-action lawsuit and a settlement stopping the use of passive enrollment in the state (Saucier et al. 2009). In California, opt-out rates varied significantly: Only one-third of beneficiaries who were passively enrolled in San Mateo County chose to opt out, compared with about 80 percent of beneficiaries in Orange County (Gold et al. 2013).[21]

Medicaid

One notable difference between Medicare and Medicaid is that states can require many categories of Medicaid beneficiaries to enroll in a managed care plan in order to receive their Medicaid benefits. States that require beneficiaries to enroll in managed care must generally offer them a choice of at least two plans and passively enroll them in a plan if they do not pick one on their own. When states conduct these passive enrollments, they must try to maintain beneficiaries' existing relationships with health care providers. In addition, when beneficiaries first enroll in Medicaid managed care, many states allow them to switch plans for any reason within a certain period of time. Once that period ends, many states have "lock-in" provisions that prevent beneficiaries from switching plans, usually for 6 to 12 months (Medicaid and CHIP Payment and Access Commission 2011).

In most states, mandatory enrollment in Medicaid managed care is now the norm for low-income children and adults who are not disabled or elderly. Medicaid prohibits states from requiring dual eligibles to enroll in managed care unless they obtain a waiver from CMS, and enrollment in Medicaid managed care has traditionally been lower for dual eligibles than for other Medicaid beneficiaries. However, the number of states that require dual eligibles to enroll in Medicaid managed care has grown significantly in recent years, particularly due to state interest in using managed care plans to deliver long-term services and supports (Saucier and Burwell 2015). ■

- Massachusetts originally planned to operate its demonstration throughout the state, but has been able to operate it in only 9 of the state's 15 counties because of limited interest from health plans. Only four of those counties initially satisfied the two-plan requirement, which meant that the state could use passive enrollment for only about half of the eligible beneficiaries. One of the state's three MMPs later withdrew from the demonstration in September 2015, and currently only two counties, with about 30 percent of the eligible beneficiaries, are eligible for passive enrollment (Barry et al. 2015, Massachusetts Executive Office of Health and Human Services 2015).
- Texas has not been able to use passive enrollment in Tarrant County (Fort Worth) because only one MMP has received approval to operate there. However, the

state has crosswalked beneficiaries into the MMP from the plan sponsor's Medicaid managed care plan.

- Virginia has been able to use passive enrollment only in parts of its Northern Virginia region because some areas there have only one MMP. One area that has not met the two-plan rule is Fairfax County, the state's most populous county and home to about 20 percent of the state's eligible beneficiaries.

Second, CMS has limited the extent to which parent organizations with poor performance in the Medicare Advantage or Part D programs can participate in the demonstrations. Parent organizations that are under any kind of Medicare enrollment or marketing sanction are prohibited from participating in the demonstrations; organizations that are sanctioned after the demonstration has already started cannot enroll any new members until the sanction has been lifted. Parent organizations that are considered outliers based on their past performance or designated "consistently low performing" in Medicare's star ratings for MA and Part D plans are allowed to participate in the demonstration, but they cannot receive passively enrolled beneficiaries while their low-performance designation remains in effect (Centers for Medicare & Medicaid Services 2013d). Both of these requirements delayed the start of the demonstration project in parts of California (Weiser and Gold 2015), and an MMP in Illinois was barred for a period of time from receiving passively enrolled beneficiaries.

Beneficiary protections Once states have a sufficient number of qualified MMPs and are able to conduct passive enrollment, they must meet a number of CMS requirements intended to limit disruptions to beneficiaries' coverage and ensure that affected beneficiaries are adequately informed about the coming changes in their Medicare and Medicaid coverage and their ability to opt out.

Certain groups of beneficiaries are exempt from passive enrollment and can participate in the demonstration only on a voluntary basis. The three major exemptions are:

- Beneficiaries enrolled in PACE, which provides Medicare and Medicaid benefits to frail individuals who are 55 or older and live in the community. PACE enrollees already receive fully integrated care and may not benefit from enrolling in an MMP.
- Beneficiaries with retiree health coverage from a former employer or union; these individuals may inadvertently lose their retiree coverage if they enroll in an MMP.
- Beneficiaries who opt out of passive enrollment.

Some states exempt other groups from passive enrollment in their demonstration projects. In particular, states differ on using passive enrollment for beneficiaries in MA plans. Two states exclude all MA enrollees from passive enrollment, one state excludes only those enrolled in employer-sponsored MA plans, three states use passive enrollment only to crosswalk beneficiaries from MA plans to MMPs offered by the same plan sponsor, and three states include all MA enrollees in passive enrollment.

Under the passive enrollment process, states must send beneficiaries two advance notices. The first notice must be sent at least 60 days before enrollment takes effect. It tells beneficiaries that they will be enrolled in an MMP if they take no further action, indicates which MMP they will be enrolled in, and tells them how they can opt out. The second notice is a reminder and must be sent at least 30 days before enrollment takes effect. Beneficiaries can opt out by contacting the state or calling 1-800-MEDICARE and can opt out as late as the day before their enrollment is scheduled to take effect. Beneficiaries who opt out cannot be passively enrolled in an MMP at any other point during the demonstration, although they can later enroll voluntarily, as long as they remain eligible to participate (Centers for Medicare & Medicaid Services 2013b).[22]

After beneficiaries have been passively enrolled, they can leave their MMP at any time, with their new coverage taking effect at the beginning of the next month. This is consistent with long-standing Medicare rules that allow dual eligibles to switch MA or Part D plans on a month-to-month basis. Beneficiaries can disenroll by enrolling in another MMP, an MA plan, or a stand-alone Part D plan. They can also disenroll without selecting a new form of Medicare coverage; if they do so, they are placed in FFS Medicare and passively enrolled in a stand-alone Part D plan. As for Medicaid, beneficiaries who disenroll are either returned to FFS Medicaid or are required to enroll in a Medicaid managed care plan, depending on the state.[23]

Many stakeholders we interviewed said that some beneficiaries do not read the 60-day and 30-day notices and do not realize that they have been passively enrolled in an MMP until they visit their doctor or try to fill a prescription. At that point, some of these beneficiaries disenroll from the MMP, which may help explain the

initial drop in enrollment that many states experienced after conducting passive enrollment (Figure 9-2, p. 278).

States must also try to assign beneficiaries to the MMP that best meets their needs by using recent Medicare and Medicaid claims data to identify each beneficiary's key providers, such as a primary care physician, and assigning the beneficiary to the plan that includes those providers in its network (Centers for Medicare & Medicaid Services 2013b). However, stakeholders on our site visits indicated that this assignment process does not always work well. For example, states may have difficulty obtaining current claims data, and their information about which providers participate in each MMP's network can sometimes be incomplete or out of date. States also assign many beneficiaries to MMPs based on their primary care provider, but other providers, such as behavioral health providers or Medicaid personal care attendants, may be more important for certain groups of beneficiaries.

For the financial alignment demonstration, CMS has stated that beneficiaries can be passively enrolled only once each year, and that limit applies across both Part D plans and MMPs. States with demonstrations have thus had to coordinate their passive enrollment schedules with Part D's schedule, in which passive enrollments take effect in January. For example, a state that conducted passive enrollment for its MMPs in mid-2015 could not immediately enroll any beneficiaries that had been assigned to a new Part D plan in January 2015; the state would instead have had to wait until January 2016 before enrolling them in an MMP (Centers for Medicare & Medicaid Services 2013b).[24] While this requirement may reduce disruptions in coverage for affected beneficiaries, it can also limit states' ability to gradually enroll beneficiaries in their MMPs. As a result, some states had to make many of their passive enrollments effective in January, and this clustering can make it difficult for MMPs to complete health assessments for new enrollees in the required time frames.[25]

Finally, all states use third-party brokers to process voluntary MMP enrollments. Unlike MA plans, plan sponsors cannot directly market to beneficiaries or enroll them in their MMPs. However, now that the demonstration's initial round of passive enrollment is largely over and many eligible beneficiaries have not enrolled, some stakeholders we interviewed were exploring new ways to inform beneficiaries about the demonstration. For example, companies that sponsor both a Medicaid managed care plan and an MMP could send information about their MMP product to those enrolled in the Medicaid plan. One state was considering a nonbranded campaign (i.e., not specific to any particular MMP) that would advertise the benefits of the demonstration. Finally, some MMPs said they would like to be able to market directly to beneficiaries; they noted that beneficiaries often have very specific questions when deciding whether to enroll (for example, whether their doctors are in the plan's network) and that individual MMPs can best provide that information.

How states have used passive enrollment Except for the beneficiary protections described above, states have considerable flexibility in deciding how to conduct passive enrollment. CMS has urged states to phase in the use of passive enrollment, and most have done so, using a variety of approaches (Centers for Medicare & Medicaid Services 2013b). Some states with multiple demonstration regions have started passive enrollment at different times for each region, depending on when the MMPs there were ready. Many states have conducted passive enrollment over several months, splitting their dual eligibles into cohorts using variables like birth month, zip codes, Medicaid case numbers, or Medicaid renewal dates. Some states have also distinguished dual eligibles based on their LTSS use, with LTSS users often being enrolled later. Some states have numeric limits on the number of dual eligibles that can be passively enrolled in a plan in a given month, while other states factor in each plan's capacity to accept new enrollees. Many states have used some combination of these approaches.

One key issue is whether states passively enroll beneficiaries who first become dual eligibles after the start of the demonstration. The composition of the dual-eligible population changes noticeably over time, largely because dual eligibles are typically in poorer health than other Medicare beneficiaries and are more likely to die in a given year. For example, we identified beneficiaries who were dual eligibles in January 2011, using national data, and followed them over time. The share of the cohort that was still both alive and dually eligible declined to 86 percent after one year, 79 percent after two years, and 72 percent after three years. Among the 28 percent that were no longer dual eligibles after three years, 20 percent had died, 3 percent had switched from being full-benefit dual eligibles to partial-benefit dual eligibles, and 5 percent were no longer eligible for Medicaid.

When states have conducted passive enrollment, they have initially limited their efforts to beneficiaries who

were eligible for the demonstration at the time it started. Since mortality rates for the dual-eligible population are relatively high, this one-time approach will likely result in declining MMP enrollment over time (even if there were no disenrollment, which has not been the case), unless the declines are offset by growth in voluntary MMP enrollment. States can passively enroll beneficiaries who have newly become dual eligibles but must navigate some operational challenges before doing so.[26] However, using passive enrollment on an ongoing basis can help stabilize MMP enrollment. Three states (Illinois, Ohio, and Virginia) currently conduct passive enrollment each month for their new dual eligibles, and MMP enrollment in those states appears to be stable. Two other states (Michigan and Texas) are planning to begin passively enrolling their new dual eligibles later this year.

Perspectives from site visits Most (but not all) of the stakeholders we interviewed on our site visits supported the use of passive enrollment, and some MMPs said that passive enrollment had been an important factor in their decision to participate in the demonstration. However, stakeholders broadly agreed that its implementation had been problematic, and they had numerous suggestions for how it could be better used in the future.

Although the three states we visited conducted passive enrollment in stages, the most common sentiment was that passive enrollment should have been implemented more slowly. MMPs had difficulty contacting a significant number of enrollees and struggled to meet their deadlines for completing initial health assessments for all enrollees. (In this respect, the low participation rates have been beneficial, by relieving some of the workload for the MMPs.) Stakeholders suggested passively enrolling beneficiaries in smaller monthly increments or separating each "wave" of passive enrollment by a month or two to give MMPs time to contact and assess new enrollees. In this regard, CMS could make it easier for states to stretch out the implementation of passive enrollment by modifying its policy that beneficiaries cannot be passively enrolled in both a stand-alone Part D plan and an MMP in the same year.

Stakeholders also frequently said that passive enrollment should have been preceded by a more robust outreach and education campaign, for both beneficiaries and providers. States often sent numerous mailings about the demonstration to beneficiaries before passive enrollment, but those materials were sometimes difficult to understand (many states have revised their mailings during the demonstration) and sometimes turned out to be inaccurate, particularly when states had to delay the start of their demonstrations. One stakeholder indicated that face-to-face outreach efforts, such as presentations in nursing homes, would be most effective, especially if state officials and MMP representatives both participated.

Some stakeholders, mainly from MMPs, said that states should be allowed to use "lock-in periods" that limit when beneficiaries can disenroll. States often have lock-in periods for their Medicaid managed care plans, and about half of the states testing the capitated model had some sort of lock-in period in their original demonstration proposal. The MA and Part D programs also have lock-in periods; most beneficiaries can leave their plan only during the annual open enrollment period. However, CMS has always allowed dual eligibles to leave MA and Part D plans at any time and decided to apply the same policy to MMPs. Stakeholders argued that lock-in periods could help compensate for poor beneficiary outreach and education by giving beneficiaries sufficient time to become familiar with the MMP and its benefits. In concept, a lock-in period could be used for all beneficiaries who are passively enrolled (eliminating their ability to opt out) or applied only once beneficiaries are actually enrolled in an MMP. The stakeholders who supported the use of lock-in periods appeared to be primarily interested in the latter, more limited approach.

Care coordination

Under the demonstration, MMPs are required to provide extensive care coordination to their enrollees, which CMS and states hope will improve their quality of care and reduce spending relative to the FFS Medicare and Medicaid programs.

Key elements of the MMP care coordination model The care coordination requirements for MMPs have three key elements: the completion of an initial health assessment for all enrollees, the development of individual plans of care by interdisciplinary teams of providers, and the use of care coordinators to help dual eligibles obtain and manage their care.[27]

All beneficiaries must receive an initial health assessment when they first enroll in an MMP. The assessment is supposed to be comprehensive, covering such areas as physical health, behavioral health, ability to perform activities of daily living, and cognitive status (Medicaid and CHIP Payment and Access Commission 2015a). Each state has its own deadlines for completing the assessments;

in the states we visited, they generally had to be completed within two to three months of enrollment. MMPs must also periodically update their assessments, usually at least once a year.

MMPs must also develop individual care plans for each enrollee, based in part on the results of the initial health assessment. Like the assessment, the care plan is intended to be comprehensive and cover the full range of a beneficiary's care needs. The plan must be formulated by an interdisciplinary team: Each state has its own membership requirements, but the teams normally include the enrollee's care coordinator, primary care physician, LTSS providers, relevant specialists (such as behavioral health providers), as well as the enrollee.[28]

Finally, MMPs are required to assign a care coordinator to each enrollee. The care coordinator often takes the lead in developing an enrollee's care plan and provides ongoing help in finding and obtaining necessary care (Medicaid and CHIP Payment and Access Commission 2015a).

Findings from site visits Based on our site visits to California, Illinois, and Massachusetts, care coordination is very much a work in progress. Many MMPs we interviewed had confronted similar challenges in trying to coordinate care for their enrollees, but each had developed a care coordination model that was unique in some respects, even among MMPs in the same state. Plans were also continuing to develop and refine their care coordination models as they gained more experience with their enrollees.

Most MMPs, as well as many other stakeholders, said that the completion of the initial health assessments had been a significant challenge. Part of the problem was the sheer number of new enrollees who needed assessments. Despite state efforts to phase in passive enrollment, many MMPs still had months in which they received more than a thousand new enrollees, often followed a month later by another wave of passive enrollment. Some MMPs also found it difficult to staff properly for the assessments because the share of beneficiaries who opted out varied from one wave of passive enrollment to the next (so while the state may have included the same number of beneficiaries in each wave, the number who ultimately enrolled varied).

The MMPs we interviewed also said that the enrollee contact information they received from the state was often outdated and that it had been very difficult to contact some enrollees to conduct their assessments. (Several MMPs, in different states, indicated that 20 percent to 30 percent of their enrollees had been unreachable.) Plans have sometimes taken unorthodox measures to locate enrollees, such as asking pharmacies where enrollees had filled prescriptions for contact information, sending care coordinators to the hospital when they learned that enrollees were in the emergency room, or going to enrollees' last known addresses and asking people in the community for any information on their whereabouts.

MMPs have largely used nurses to complete the assessments because they require clinical expertise. The assessments are either done in person, usually at the enrollee's home or a doctor's office, or over the phone, depending on the beneficiary's health needs. Some plans have used in-house staff to conduct the assessments, while other plans have used outside contractors to conduct most of them (with some plans turning to contractors only after they realized that they needed additional help to complete the assessments on time). Even where plans use in-house staff for the assessments, the person who conducts the assessment is usually different from the care coordinator.

Each MMP we interviewed said that it had made significant investments to get ready for the demonstration. Most plans had hired dozens of care coordinators; CMS has estimated that the MMPs with active enrollment as of the end of 2014 had hired about 2,500 care coordinators in all (Centers for Medicare & Medicaid Services 2015f). Plans often hired coordinators several months before the start of the demonstration to train them. Many plans had also made changes to their information technology systems; for example, they modified their electronic health record systems to accommodate LTSS providers and better track interactions between care coordinators and enrollees.

Most care coordinators have backgrounds in social work, with plans using more highly trained staff (such as nurse practitioners, licensed clinical social workers, or mental health counselors) to provide additional expertise when needed. The care coordinators are usually assigned to the enrollees in a specified geographic region, and their caseloads vary depending on the health needs of the enrollees.[29] The coordinators we interviewed spent most of their time either on the phone (making appointments for beneficiaries, answering questions from beneficiaries, helping beneficiaries obtain approval for services such as durable medical equipment, and so on) or meeting with beneficiaries in person (for example, checking on beneficiaries' living arrangements or accompanying them

Caring for dual eligibles with behavioral health needs

Dual-eligible beneficiaries are much more likely than other Medicare beneficiaries to have a behavioral health condition, meaning some form of mental illness or substance abuse disorder. Researchers use different methods to identify beneficiaries with behavioral health conditions, so prevalence estimates vary. As one example, the Congressional Budget Office found that in 2009, 30 percent of dual eligibles had been diagnosed with a mental illness, compared with 11 percent of Medicare-only beneficiaries (Congressional Budget Office 2013). Since so many dual eligibles have behavioral health needs, we asked stakeholders during our site visits about the challenges involved with caring for this population.

The Medicare–Medicaid Plans (MMPs) we interviewed recognized the importance of behavioral health care under the financial alignment demonstration. As part of the demonstration, most plans had hired staff that specializes in behavioral health; these individuals often helped to oversee the work of the care coordinators and the development of individual care plans for enrollees with behavioral health conditions. Some MMPs had also contracted with community mental health providers to furnish care coordination for plan enrollees, particularly those considered high risk. Some plans said that it had been harder to complete the initial health assessments for enrollees with behavioral health needs and that it was particularly important for care coordinators to develop trusting relationships with these enrollees to be effective. Plans also noted that some beneficiaries with behavioral health conditions are either homeless or lack stable housing arrangements and that finding adequate housing was often the biggest challenge for their care coordinators.

Several stakeholders said that there was a general shortage of providers of outpatient mental health services in their areas and that this shortage made it more difficult for MMPs to reduce inpatient admissions related to behavioral health. Some stakeholders hoped that the MMPs would provide a

(continued next page)

to appointments). Often, care coordinators also spent time helping beneficiaries obtain assistance from a range of social service programs, such as those providing housing assistance.

Some plans found it difficult to hire or retain care coordinators, especially in the early stages of the demonstration when other MMPs in the area were also staffing up. (In one case, an MMP lost all its care coordinators after the state delayed the start of the demonstration and the coordinators had nothing to do. The plan later had to hire an entirely new group of care coordinators.) Many plans try to hire people from local social service agencies because their employees have experience working with disabled and aged individuals and are familiar with the various social services available in the community.

Depending on the plan, care coordinators can be direct employees of the plan, employees of one of the plan's subcontractors, or a mix of the two. Most care coordinators in Massachusetts and Illinois worked directly for the MMP, while most in California were employed by plan subcontractors.[30] However, these arrangements were evolving as plans gained experience and tested new approaches. We saw movement in both directions: One plan that largely used internal employees as care coordinators was experimenting with using primary care practices and social service agencies to provide care coordination, while another plan that largely relied on subcontractors was considering moving some care coordination in-house, particularly for high-risk or high-cost beneficiaries.

All MMPs that we interviewed tried to focus their care coordination efforts on enrollees with the greatest care needs. (The text box describes some of the specific challenges involved with one particularly important subset of dual eligibles—those with behavioral health conditions.) Some states were more prescriptive than others in this area. For example, Illinois requires its MMPs to classify beneficiaries receiving home- or community-based LTSS as either medium or high risk, but MMPs appeared to have a fair amount of latitude in classifying enrollees. High-risk

Caring for dual eligibles with behavioral health needs (cont.)

new source of funding for outpatient mental health providers and help support them. We interviewed one mental health provider who reported being able to hire more staff as a result of the demonstration.

Behavioral health has been a particularly important issue in Massachusetts, which has the only demonstration limited to beneficiaries with disabilities. One of the state's MMPs has gone to unusual lengths to expand the availability of care outside of inpatient hospitals by opening and operating two crisis stabilization centers. The centers provide 24-hour care to enrollees who have behavioral health needs that are not acute enough to require inpatient hospital care. The centers are staffed by a combination of psychiatric nurse practitioners, licensed clinical social workers, and nurse managers and provide counseling and addiction treatment. The plan says that the cost of caring for beneficiaries in the centers is much lower than the cost of inpatient care ($600 per day vs. $1,100 per day) (McCluskey 2015a). Some stakeholders also said that peer specialists—individuals who have personal experience managing their own behavioral health conditions—provide an effective way to engage enrollees with behavioral health needs, but they are in short supply because they take time to train.

Multiple stakeholders also said that it had been challenging to provide care coordination and use interdisciplinary teams of providers for beneficiaries with behavioral health needs while also adhering to federal laws and regulations (particularly those in Title 42, Part 2, of the Code of Federal Regulations) that limit the disclosure of patient information related to substance abuse. Stakeholders in Los Angeles have responded by developing a universal consent form that authorizes the disclosure of enrollees' patient information and will be used by all MMPs and providers in the city. There was widespread agreement that the form will make it easier to coordinate care for these beneficiaries while still providing adequate privacy safeguards. ■

enrollees receive the most extensive care coordination, such as regular calls from their care coordinators and in-person meetings or assistance. Care coordination for low-risk enrollees is much more limited; in one MMP, low-risk enrollees receive calls only periodically (less than monthly) from their care coordinators and have little or no in-person contact. MMPs said that they provide greater care coordination as needed (for example, after an inpatient stay), but some beneficiary advocates said that plans' efforts to classify enrollees were not always accurate and that some enrollees who were considered low risk would benefit from greater care coordination.

In each state we visited, beneficiary advocates and providers reported some level of confusion about the MMPs' care coordination efforts. Some beneficiaries did not know who their care coordinators were or how to contact them, which could be partly due to turnover among care coordinators. The responsiveness of the individual care coordinators also appeared to vary. LTSS providers that had coordinated care for enrollees before the demonstration as part of Medicaid home- and community-based waiver programs were also uncertain about their role once MMPs became the locus for care coordination.

Quality of care

Improving the quality of care for dual eligibles is one of the primary goals of the demonstration. MMPs are required to collect and report the same quality data as MA plans. CMS and the states also require MMPs to regularly submit a wide range of additional quality data as part of their efforts to oversee the demonstration and evaluate its impact. Some requirements are modeled after the MA and Part D programs (dealing with issues like grievances, coverage determinations and reconsiderations, and pharmacy access), while others were developed specifically for MMPs.

The MMP-specific measures are a mix of process and structure measures (such as completing health assessments and reassessments 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 2015g). CMS and states use these measures partly to determine MMP payment rates. Quality data are not yet available for MMPs, but CMS plans to release this information when it becomes available.

In November 2015, CMS announced plans to develop a star rating system for MMPs. This rating system will differ from the one used for MA plans because MMPs provide a much broader range of services. CMS tentatively proposed that ratings for MMPs be based on their performance in six areas: The provision of LTSS and management of chronic conditions would each count for 25 percent of the rating; prevention, safety of care, member experience, and plan performance on administrative measures would each count for 12.5 percent of the rating.

CMS does not plan to have the rating system ready until after the end of the demonstration, but has begun working on it now in case the demonstration succeeds and the use of the capitated model is expanded. CMS noted that there is a shortage of accepted quality measures for LTSS, in particular, and that the time frame for developing them "is likely to be long" (Centers for Medicare & Medicaid Services 2015h). Other observers have also noted the current lack of quality measures for LTSS and argued that it will be difficult to compare performance across MMPs without them (Zainulbhai et al. 2014).

Service use

We chose California, Illinois, and Massachusetts for our site visits because they were among the first states to begin their demonstrations. At the time of our visits, the Massachusetts demonstration had been underway for about 2 years; Illinois and California, about 18 months. We hoped that this experience would enable stakeholders to provide insights into whether MMPs have been able to better manage service use and improve the quality of care for dual eligibles. However, the representatives from the MMPs that we interviewed said that it was unrealistic to expect plans to produce savings in the first few years of the demonstration. Other stakeholders had the same view, and the plans themselves said that they had not yet seen noticeable changes in service use for their enrollees. The plans said that several factors made savings unlikely in the near term, such as the gradual implementation of passive enrollment, the challenges that many plans faced in completing the initial health assessments, and continuity-of-care requirements.[31] More broadly, most MMP enrollees had come from the FFS environment, and plan representatives said they would need time to build relationships with the enrollees before they could modify certain enrollee behaviors, such as using emergency rooms to obtain primary care.

The delivery of LTSS appeared to have been a particular challenge for many MMPs we interviewed. Most had little prior experience managing these services and had to acquaint themselves with entirely new types of providers and services. In the early stages of the demonstration, the delivery of LTSS seemed to differ little from the prior FFS Medicaid system, with plans often deferring to the judgment of LTSS providers about which services were appropriate. However, as the MMPs gained experience, they began to take a more active role in LTSS delivery (for example, reviewing care needs for enrollees who had been approved for skilled nursing visits).

As part of the demonstration, MMPs have flexibility to experiment with new forms of service delivery and care coordination. For example, one MMP was testing the idea of paying monthly stipends to enrollees' personal care attendants in return for regular updates on the enrollees' overall health and functioning, while another MMP opened a pair of crisis stabilization centers to serve enrollees with behavioral health needs (see text box, pp. 286–287).

However, this flexibility has limits. Several stakeholders said that help with housing was the most pressing need for some MMP enrollees, but that plans generally could not use their funds for permanent housing assistance. Instead, care coordinators tried to help these enrollees obtain housing through existing social service programs.

CMS intends to examine changes in beneficiaries' service use as part of its overall evaluation of the demonstration, which is expected to include annual reports and a final report for each state. However, no annual reports have yet been released for states testing the capitated model.

Payment adequacy

Under the capitated model, MMPs provide all Part A, Part B, and Part D benefits to their enrollees, as well as all or most of the state's Medicaid-covered services.[32] MMPs are accordingly paid a monthly capitation rate with three distinct components: one for Medicare Part A and Part B services, one for Part D drugs, and one for Medicaid services. However, the payment methodology for MMPs differs from those used in the MA and Part D programs in several respects.

For Part A and Part B benefits, MMPs are paid using a county-level base rate that is adjusted for differences in

beneficiaries' health status. CMS determines the base rate using historical FFS and MA spending data 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 base rate is primarily based on historical FFS experience. The base rates are also standardized to reflect costs for a beneficiary of average health status and are updated annually based on FFS per capita spending growth. Unlike MA plans, MMPs do not submit bids for the cost of providing Part A and Part B benefits. CMS adjusts for differences in beneficiaries' health status using the hierarchical condition category (HCC) risk adjustment model that Medicare uses to pay MA plans.[33]

MMPs also do not submit bids for the cost of providing Part D drugs. Instead, CMS pays MMPs 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 LIS, which all dual eligibles receive. The direct subsidy payment is adjusted for differences in beneficiaries' health status using the prescription drug HCC risk adjustment model used for Part D plans.

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 home- and community-based LTSS somewhere in between.

CMS and states also make two other adjustments to produce the final MMP payment rates. Both adjustments apply only to the Part A and Part B and Medicaid components. First, part of the payment rate is withheld (known as the "quality withhold") and later paid to the plan if it performs sufficiently well on a range of quality measures, such as completing initial health assessments on time. For almost all states, the quality withhold equals 1 percent of the rate in the first year of the demonstration, 2 percent in the second year, and 3 percent in the third year. Second, rates are reduced by a certain percentage to reflect savings that CMS and states assume MMPs will be able to produce under the demonstration (Centers for Medicare & Medicaid Services 2013a). The savings percentages vary by state but are generally around 1 percent in the first year of the demonstration, 2 percent in the second year, and 3 percent to 5 percent in the third year (Medicaid and CHIP Payment and Access Commission 2015a).

CMS has made a number of changes to its payment methodology during the demonstration. Most notably, the agency increased payment rates for 2016 for the Part A and Part B component based on an analysis that found that the HCC risk adjustment model underestimated costs for full-benefit dual eligibles (Centers for Medicare & Medicaid Services 2015i). The increase is between 5 percent and 10 percent for most MMPs. CMS has also raised Part A and Part B and Medicaid payment rates for MMPs in Massachusetts and Virginia by reducing some of the savings percentages and quality withholds. Finally, CMS increased certain Part D payments for MMPs in Massachusetts (Centers for Medicare & Medicaid Services 2016b).[34]

Stakeholder views on the adequacy of the payment rates varied greatly among states. Some MMPs in Massachusetts have experienced substantial financial losses, which stakeholders attributed to the challenges of serving a population that is composed entirely of disabled beneficiaries and, in their view, often has unmet needs. These difficulties led one MMP to leave the demonstration at the end of September 2015 and prompted CMS and the state to increase payment rates (Gutman 2015b, McCluskey 2015b). In our interviews, stakeholders said that the initial savings assumptions had proven unrealistic, and they believed that the higher rates would help stabilize the demonstration's financing.

In contrast, stakeholders in Chicago and Los Angeles did not express any significant concerns about the payment rates. One MMP said that it had lost money so far on the demonstration but did not find that surprising given the challenges of developing a new and complex managed care product. Another MMP indicated that it had managed to break even so far. Stakeholders appreciated CMS's plans to increase payment rates for Part A and Part B services and generally believed that the higher savings assumed to occur later in the demonstration were achievable.

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—are testing the managed FFS model, and about 47,000 dual eligibles were enrolled in their demonstrations as of March 2016 (Table 9-2, p. 273). Both demonstrations are part of broader state efforts to provide more care coordination in FFS Medicaid.

Under the managed FFS model, the state passively enrolls dual eligibles that have both FFS Medicare and FFS Medicaid in a Medicaid-funded entity that is responsible for providing care coordination. (In Colorado, the entities are called Regional Care Collaborative Organizations. In Washington, they are called health homes.) 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.

At the end of each year, the state 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.

Findings on the demonstration in Washington State

In Washington State, dual-eligible beneficiaries are eligible for the demonstration if they have one chronic condition and are at risk of developing another (which is one of Medicaid's eligibility criteria for health homes). They must also be considered high risk based on an analysis of their Medicare and Medicaid claims, and the subset of dual eligibles who have been enrolled in the demonstration have substantially higher average risk scores than the broader population of dual eligibles who meet only the chronic condition criteria (2.4 vs. 2.0) (Walsh et al. 2016). The demonstration operates in all parts of the state except two counties around Seattle.[35]

Under the demonstration, the state approves "lead organizations" in six regions to oversee the delivery of care coordination. There can be multiple lead organizations in a region. The lead organizations are a mix of health insurers, provider-sponsored consortia, and area agencies on aging. The lead organizations, in turn, contract with care coordination organizations (CCOs), which are responsible for most of the ground-level care coordination.[36] CCOs are typically entities such as area agencies on aging, mental health clinics, and community health centers. CCOs contact beneficiaries who have been passively enrolled in the demonstration, develop individual care plans known as health action plans (HAPs), and provide ongoing care coordination.

The stakeholders that we interviewed said that only 10 percent to 15 percent of the dual eligibles who had been assigned to a health home had completed a HAP, which is the first care coordination service that the state pays for under the demonstration. As a result, the number of people who actually receive care coordination is much lower than the enrollment figures for the demonstration might suggest. (Beneficiaries are considered enrollees once the state has referred them to the lead organizations.) The completion rate varies widely across CCOs, ranging from 15 percent to 80 percent for one lead organization. The completion rate can also vary significantly over time for the same CCO.

As with the capitated model, stakeholders in Washington reported that they often had difficulty contacting enrollees, partly due to outdated contact information from the state. Even when CCOs had good contact information, many beneficiaries were unfamiliar with the program and saw little or no benefit in participating. Some stakeholders also said that the number of new enrollees they received had varied significantly from month to month, which made it difficult for CCOs to staff appropriately and could contribute to the low participation rate.

Several stakeholders from lead organizations and CCOs also expressed concern with the adequacy of the payment rates for care coordination. The state makes three types of payments under the demonstration: a one-time initial payment of $253 for the completion of a HAP, followed by monthly rates of either $173 for intensive care coordination or $68 for low-level care coordination.[37] Stakeholders were particularly concerned that the initial payment was not made until a HAP was completed, which they argued did not adequately compensate CCOs for the time they spend dealing with beneficiaries who do not complete a HAP. It was unclear whether the state's payment methodology was a factor in the low participation rate.

In January, CMS released a report that estimated that the demonstration reduced Medicare spending by 6 percent in its first 18 months of operation (July 2013 to December 2014) and generated about $22 million in savings. CMS

produced its estimate by comparing per capita spending growth for the enrollees in the demonstration (7 percent) with the growth for a comparison group of dual eligibles in Arkansas, Georgia, and West Virginia (13 percent). The report notes that its findings are preliminary and do not account for any changes in Medicaid spending. CMS plans to update the savings estimate using more rigorous analytic methods as part of its final evaluation of the demonstration (Walsh et al. 2016). While we understand that the report is preliminary, we do not think that savings of that magnitude are plausible because the number of people who actually received care coordination during that period was relatively small (about 1,700) and they received care coordination for a relatively short amount of time (about 5 months, on average).

Expanding the Medicare Savings Programs

Eligibility rules and the financing of care for dual-eligible beneficiaries have been abiding concerns for policymakers. Changes in these areas offer another way to correct or lessen some of the programmatic shortcomings that dual eligibles face. Such changes are not mutually exclusive with changes to models of care. One area of focus has been the Medicare Savings Programs (MSPs).

MSPs play an important role in defining which Medicare beneficiaries can become dual eligibles and what benefits Medicaid is required to provide to them. Under MSPs, Medicaid requires states to provide assistance with Medicare Part A and Part B premiums and cost sharing to four categories of low-income Medicare beneficiaries. Each category is considered a distinct MSP. Although the Part D LIS provides analogous assistance with Part D premiums and cost sharing, the LIS is part of the Medicare drug benefit and is not considered an MSP.

Eligibility and benefits

MSPs require individuals to have both limited income and limited assets to qualify for benefits. States are required to exclude certain items when calculating an individual's income and assets, and eligibility is determined based on the remaining "countable" income and assets. For example, countable income does not include the first $20 in monthly income (such as wages or Social Security benefits) or half of any earned income, and countable assets do not include the value of a primary residence.[38] The Part D LIS uses similar rules.

The eligibility rules and benefits for the three primary MSPs are summarized in Table 9-5 (p. 292), which includes information for the Part D LIS for comparison.[39] Taken together, the MSP and LIS eligibility rules divide low-income Medicare beneficiaries into four categories based on income levels: up to 100 percent of the federal poverty level, between 100 percent and 120 percent of the federal poverty level, between 120 percent and 135 percent of the federal poverty level, and between 135 percent and 150 percent of the federal poverty level. The three MSP categories use the same asset limit ($7,280 for an individual in 2016), while the Part D LIS has a higher asset limit ($13,640 for an individual in 2016). The level of assistance provided varies across these groups:

- ***Beneficiaries with income up to 100 percent of the federal poverty level***—These beneficiaries are eligible for the qualified Medicare beneficiary (QMB) program, which has the most generous benefits of any MSP and covers Part A and Part B premiums, deductibles, and coinsurance. The cost of QMB benefits are paid for by the federal government and the states, with their respective shares determined by the federal Medicaid match rate.[40] QMBs are also the largest MSP category: In 2014, about 6.5 million beneficiaries—12 percent of all Medicare beneficiaries—were enrolled in the QMB program (Table 9-6, p. 293). Under the Part D LIS, most beneficiaries in this income range do not pay a Part D premium or deductible and pay nominal copayments (in 2016, $1.20 for generic drugs and $3.60 for brand-name drugs).
- ***Beneficiaries with income between 100 percent and 120 percent of the federal poverty level***—These beneficiaries are eligible for the specified low-income Medicare beneficiary (SLMB) program, which covers the Part B premium. Like the QMB program, the costs of these benefits are paid for by the federal government and the states, with their respective shares determined by the federal Medicaid match rate. SLMBs are the second-largest MSP category: In 2014, about 1.2 million beneficiaries (2 percent of all Medicare beneficiaries) were SLMBs (Table 9-6, p. 293). Under the Part D LIS, most beneficiaries in this income range do not pay a Part D premium or deductible and pay reduced copayments (in 2016, $2.95 for generic drugs and $7.40 for brand-name drugs).

TABLE 9–5

Medicare premium and cost-sharing assistance, by beneficiary income, 2016

	Income			
	Up to 100% FPL	**100–120% FPL**	**120–135% FPL**	**135–150% FPL[a]**
Income limit	Up to $11,880	$11,880 to $14,260	$14,260 to $16,040	$16,040 to $17,820
Medicare Part A and Part B				
MSP category	QMB	SLMB	QI	Not covered
Part A premium	X			
Part B premium	X	X	X	
Deductibles	X			
Coinsurance	X			
Asset limit	$7,280	$7,280	$7,280	
Financing	Federal/state	Federal/state	Federal	
Medicare Part D LIS				
Premium	X	X	X	X[b]
Deductible[c]	X	X	X	X
Copayments	X	X	X	X
Asset limit	$13,640	$13,640	$13,640	$13,640
Financing	Federal	Federal	Federal	Federal

Note: FPL (federal poverty level), MSP (Medicare Savings Program), QMB (qualified Medicare beneficiary), SLMB (specified low-income Medicare beneficiary), QI (qualifying individual), LIS (low-income drug subsidy). Income and asset limits are for an unmarried individual; couples are subject to higher limits. Most Medicare beneficiaries do not pay the Part A premium because they have worked at least 40 quarters and paid Medicare taxes while working (or are the dependent or survivor of such a person). The table does not include the qualified disabled working individual MSP category or other full-benefit dual-eligible beneficiaries who are not eligible for one of the MSPs.

[a] Some Medicare beneficiaries with income above 135 percent of the federal poverty level can meet their state's eligibility rules for full Medicaid benefits. These beneficiaries are not enrolled in the MSPs, however, because they do not meet the MSP eligibility criteria. States may cover Medicare cost sharing for these beneficiaries, but they are not required to do so.

[b] These beneficiaries receive a partial Part D premium subsidy based on a sliding scale.

[c] Beneficiaries who have income below 135 percent of the federal poverty level and assets between the MSP limit and the LIS limit, as well as all beneficiaries with income between 135 and 150 percent of the federal poverty level, receive a reduced deductible.

Source: Centers for Medicare & Medicaid Services 2016a, Centers for Medicare & Medicaid Services 2016d, Centers for Medicare & Medicaid Services 2015b, Centers for Medicare & Medicaid Services 2014b, Office of the Assistant Secretary for Planning and Evaluation 2016b.

- ***Beneficiaries with income between 120 percent and 135 percent of the federal poverty level***—These beneficiaries are eligible for the qualifying individual (QI) program, which, like the SLMB program, covers the Part B premium. Aside from the higher eligibility limit, the only difference between the QI and SLMB programs is their method of financing. The costs of the QI program are paid for entirely by the federal government from the Part B trust fund, and the total amount of federal funding for each state is subject to an annual cap. QIs are the smallest of the three MSP categories: In 2014, about 500,000 beneficiaries—1 percent of all Medicare beneficiaries—were enrolled in the QI program (Table 9-6). Under the Part D LIS, most beneficiaries in this income range do not pay a Part D premium or deductible and pay reduced copayments (in 2016, $2.95 for generic drugs and $7.40 for brand-name drugs).
- ***Beneficiaries with income between 135 percent and 150 percent of the federal poverty level***—These beneficiaries are not eligible for MSPs but are eligible for the Part D LIS. These beneficiaries get a partial Part D premium subsidy based on a sliding scale, a reduced deductible ($74 in 2016, instead of $360), reduced coinsurance up to the out-of-pocket (OOP) threshold (the lower of 15 percent coinsurance or the plan's copayment), and reduced copayments after

the OOP threshold (in 2016, $2.95 for generic drugs, $7.40 for brand-name drugs).

Medicaid allows states to disregard larger amounts of income or assets when they determine eligibility for the MSPs. States that use more generous income or asset disregards effectively have more generous eligibility rules. In 2010, two states and the District of Columbia had higher income limits than the federal standards, and nine states and the District of Columbia had higher asset limits (Kaiser Commission on Medicaid and the Uninsured 2010). For example, Connecticut and Maine use additional income disregards to raise the eligibility limit for the QMB program, which is normally 100 percent of the federal poverty level, to 200 percent and 140 percent, respectively, and both states disregard all assets when determining MSP eligibility (Medicare Payment Advisory Commission 2014).

In addition to the MSPs, states have separate eligibility rules for full Medicaid benefits, which include coverage of Medicare wraparound services and LTSS, such as nursing home care and community-based care. The eligibility rules for MSP benefits differ from the eligibility rules for full Medicaid benefits; as a result, some individuals are eligible for MSP benefits only, some qualify for both MSP and full Medicaid benefits, and some are eligible for full Medicaid benefits only. In 2014, 1.3 million enrollees in the QMB program and about 900,000 enrollees in the SLMB program were eligible only for MSP benefits and are sometimes known as QMB-only or SLMB-only enrollees. The remaining QMB and SLMB enrollees (about 5.2 million and 250,000 people, respectively) also qualified for full Medicaid benefits and are sometimes known as QMB-plus or SLMB-plus beneficiaries. Another 1.7 million Medicare beneficiaries were not eligible for MSPs but received full Medicaid benefits.[41]

Participation rates and application process

Medicare beneficiaries must apply with their state's Medicaid office to become eligible for MSP benefits, and many beneficiaries who are eligible for benefits do not enroll. The low participation rates have been attributed to such factors as complex eligibility rules and a lack of awareness that the programs exist (Medicare Payment Advisory Commission 2008).[42]

Under current law, all dual-eligible beneficiaries, including those enrolled in the MSPs, are automatically enrolled in the Part D LIS. All other Medicare beneficiaries must apply for LIS coverage and can do so through their Medicaid program or through the Social Security Administration (SSA). In practice, almost all beneficiaries who apply for LIS coverage do so through the SSA, which is familiar to virtually all beneficiaries through their dealings with the Social Security program and does not have Medicaid's welfare stigma. Although beneficiaries who qualify for an MSP are automatically enrolled in the LIS, the reverse is not true, even though many LIS enrollees likely also qualify for MSP benefits (Medicare Payment Advisory Commission 2008).

TABLE 9–6 **Medicare beneficiaries enrolled in the MSPs, 2014**

MSP category	Number of beneficiaries (in millions)	Percent of all Medicare beneficiaries
QMB	6.5	12%
SLMB	1.2	2
QI	0.5	1

Note: MSP (Medicare Savings Program), QMB (qualified Medicare beneficiary), SLMB (specified low-income Medicare beneficiary), QI (qualifying individual). The table includes fee-for-service and Medicare Advantage enrollees.

Source: MedPAC analysis of July 2014 enrollment data.

State payment of Medicare cost sharing for QMBs

As noted above, the QMB program covers all deductibles, copayments, and coinsurance for Part A and Part B services. However, states have considerable flexibility in determining how much of that cost sharing they actually cover because of a provision in the Balanced Budget Act of 1997 (BBA) that gave states the option of using their Medicaid rates, which are often lower than Medicare rates, to determine the amount of cost sharing they will pay for QMBs.[43]

As an example, consider a beneficiary who is enrolled in the QMB program, has already met the Part B deductible, and has an office visit with her physician. If Medicare's payment rate for the visit were $100, Medicare would pay $80 to the provider and the state would be responsible for $20 in coinsurance. The state has the option of using Medicare rates to determine its cost-sharing payment. Under this approach, which is sometimes called a "full-payment" policy, the state would pay the entire $20 in coinsurance.

However, the state could instead choose to base its cost-sharing payment on the lower of the Medicare rate or the state's Medicaid rate for the same service. Under this approach, which is sometimes called a "lesser-of" policy, if the Medicaid rate was $85, the state would only pay the difference between that amount and Medicare's payment of $80, which would result in the state paying $5 of the coinsurance. If the state's Medicaid rate for the service was less than $80, the state would not pay any of the coinsurance. When states do not pay the full amount of Medicare cost sharing, Medicaid prohibits providers from billing the beneficiary for the remaining unpaid amount. As a result, while lesser-of policies reduce Medicaid spending, they also reduce overall payments for providers who serve QMBs.

States can use a full-payment policy for certain services and a lesser-of policy for other services, and they can adopt other approaches as well, such as paying a fixed percentage of Medicare cost sharing (Centers for Medicare & Medicaid Services 2015a, Medicaid and CHIP Payment and Access Commission 2013).

Most states use lesser-of policies for at least some services. The Medicaid and CHIP Payment and Access Commission (MACPAC) examined state policies on payment of cost sharing for QMBs for four major types of service—inpatient hospital, outpatient hospital, skilled nursing facility, and physician services—and found that 45 states and the District of Columbia used a lesser-of policy in 2015 for at least 1 type of service (Medicaid and CHIP Payment and Access Commission 2015d). The number of states that use lesser-of policies grew rapidly in the late 1990s after BBA was enacted (Medicaid and CHIP Payment and Access Commission 2013).

Recent research suggests that lesser-of policies reduce access to care for QMBs. MACPAC estimated the share of Medicare cost sharing that states paid for certain outpatient services that can serve as indicators of access to care (office-based and outpatient evaluation and management services, preventive services, services provided by federally qualified health centers (FQHCs) and rural health clinics (RHCs), and psychotherapy services) and examined how utilization rates for QMBs compared with rates for Medicare-only beneficiaries across states. MACPAC found that when states paid a larger share of the Medicare cost sharing, QMBs were more likely to receive office-based and outpatient evaluation and management services, preventive services, and psychotherapy services, and less likely to receive services from an FQHC or RHC. These findings suggest that lesser-of policies make it more difficult for QMBs to obtain care in traditional office-based settings and increase their reliance on safety-net providers (Medicaid and CHIP Payment and Access Commission 2015c).

CMS recently conducted a similar analysis, with broadly similar results. CMS also studied the impact of lesser-of policies on the use of inpatient hospital services and skilled nursing facility (SNF) care and found that lesser-of policies had no significant impact on inpatient hospital use and ambiguous results for SNF care (Centers for Medicare & Medicaid Services 2015a).

CMS has also found that providers in states with lesser-of policies sometimes bill QMBs for their unpaid cost sharing, even though Medicare and Medicaid both prohibit this practice. Many QMBs appear to pay these bills from their providers, either because they are unaware that Medicaid protects them from being balance-billed in this way or because they do not want to endanger their relationship with the provider (Centers for Medicare & Medicaid Services 2015a, Centers for Medicare & Medicaid Services 2013e).

Illustrative scenarios for expanding MSPs

A variety of researchers, policymakers, and beneficiary advocates have expressed interest over the years in expanding MSPs—by making additional beneficiaries eligible for the programs, by providing more generous benefits (such as extending coverage of Part A and Part B cost sharing to some beneficiaries with income above the federal poverty level), by federalizing MSPs in some fashion, or by employing a combination of these strategies.

Supporters make several arguments in favor of expanding MSPs. They contend that "near-poor" Medicare beneficiaries—those with income somewhere between 100 percent and 200 percent of the federal poverty level—spend a relatively large share of their income, on average, on health care costs (Families USA 2014). They cite evidence that states' use of lesser-of policies has reduced access to care for QMBs and that some providers appear to bill QMBs for unpaid cost sharing, despite the statutory prohibition against doing so (Burke and Prindiville 2011). They also argue that federalizing MSPs would lead more beneficiaries to participate in the programs and provide budgetary relief to states (Moon et al. 1996).

Given the numerous policy issues that would need to be addressed, proposals to expand MSPs would vary significantly in their budgetary and programmatic effects. To demonstrate the range of possible outcomes, the Commission developed three illustrative scenarios for expanding MSPs and used analyses prepared by the Urban Institute to estimate their potential costs.[44] These costs should be viewed as approximations and not a substitute for the budgetary estimates that the Congressional Budget Office prepares for the Congress as part of the legislative process.

The three illustrative scenarios are listed in order from least to most expensive:

- ***Scenario 1—Raise eligibility for the QI program to 150 percent of the federal poverty level.*** This scenario is a reprise of the Commission's recommendation from 2008. The eligibility limit for the QI program, which provides assistance with the Part B premium, would be raised from the current 135 percent of the federal poverty level to 150 percent. The QI program would continue to be funded entirely by the federal government, but its annual funding cap would be increased to reflect its higher eligibility limit.
- ***Scenario 2—Raise eligibility for the QMB program to 150 percent of the federal poverty level.*** This scenario would increase the eligibility limit for the QMB program—which provides assistance with Part A and Part B premiums and cost sharing—from the current 100 percent of the federal poverty level to 150 percent. The SLMB and QI programs would be eliminated. Like the existing program, the expanded QMB program would be funded jointly by the federal government and the states based on regular Medicaid match rates. States would remain able to use lesser-of policies to limit their spending on Medicare cost sharing.
- ***Scenario 3—Raise eligibility for the QMB program to 150 percent of the federal poverty level and federalize the program.*** As with the second scenario, the eligibility limit for the QMB program would be increased from the current 100 percent of the federal poverty level to 150 percent, and the SLMB and QI programs would be eliminated. However, the QMB program would be federalized and become part of the Medicare program, which would pay the full amount of any cost sharing for QMBs. As part of this scenario, states would be required to make maintenance-of-effort payments based on their historical spending on MSP benefits.

Each scenario outlined above would also make two related changes to MSPs. First, the asset limit for the MSPs would be increased to match the level used for the Part D LIS. Second, since the MSP and LIS eligibility criteria would be aligned, the Social Security Administration would be required to determine eligibility for both programs at the same time and would enroll applicants in both programs if they were eligible.

The effects of each scenario on MSP participation, federal spending, and state spending are shown in Table 9-7 (p. 296). The participation figures are for 2012. The estimated costs are for 2016 to 2025; the Commission generated these figures by adjusting the estimated 2012 costs for expected growth in Medicare enrollment and per capita spending, using data from the 2015 Medicare Trustees' report.

Under current law, about 17.6 million Medicare beneficiaries are eligible for MSPs. (This figure does not include beneficiaries whose income is low enough to qualify for MSPs but whose assets exceed the limits.) This number would increase under all three scenarios because the MSP income and asset limits would be raised to the higher Part D LIS levels.

Enrollment in MSPs would increase by about 2 million beneficiaries under all three scenarios, from 9.1 million under current law to between 11.0 and 11.5 million. The higher enrollment would be due largely to beneficiaries who are now enrolled only in the LIS but also would qualify to be automatically enrolled in an MSP. Medicare enrollment data indicates that about 1.4 million people enrolled in the LIS are not in an MSP.

MSP participation rates are assumed to rise also, from the current rate of 51 percent to 56 percent under the first scenario and to 59 percent under the second and third scenarios.[45] Participation rates for the second and third scenarios would be higher because beneficiaries with income between 100 percent and 150 percent of the federal poverty level would be eligible for more generous benefits (assistance with Part A and Part B cost sharing, in addition to the Part B premium), and thus more eligible beneficiaries would enroll.

The estimated 10-year federal cost of the 3 scenarios would vary significantly, ranging from $38 billion for the first scenario to $74 billion for the second scenario

TABLE 9–7

Illustrative scenarios for expanding the MSPs

		Scenario		
	Current	**1**	**2**	**3**
Eligibility limits (as percent of federal poverty level)				
Part B premiums	135%	150%	150%	150%
Part A and Part B cost sharing*	100%	100%	150%	150%
Are MSPs federalized?	QI only	QI only	No	Yes
Eligible beneficiaries, 2012 (in millions)	17.6	19.6	19.6	19.6
Total enrollees, 2012 (in millions)	9.1	11.0	11.5	11.5
Current MSP enrollees		9.1	9.1	9.1
Current LIS-only enrollees		1.4	1.4	1.4
Truly new enrollees		0.5	1.0	1.0
Participation rate	51%	56%	59%	59%
Estimated cost, 2016–2025 (in billions)				
Federal		$38	$74	$296
State		$8	$38	$0
Total		$46	$111	$296
Breakdown of federal costs, 2016–2025 (in billions)				
Current MSP enrollees		$0	$10	$162
Current LIS-only enrollees		$19	$23	$61
Truly new enrollees		$19	$41	$73

Note: MSP (Medicare Savings Program), QI (qualifying individual), LIS (low-income subsidy). All scenarios assume that the MSP asset limit would be raised to the limit used for the Part D LIS and that the Social Security Administration would be required to screen LIS applicants for MSP eligibility as well. The Social Security Administration would also enroll those who qualify in both programs. Scenario 3 assumes that Medicare pays the full amount of cost sharing for MSP enrollees and that states would be required to make maintenance-of-effort payments. Components may not sum to totals due to rounding.
* Includes coverage of Part A premiums for beneficiaries who do not qualify for premium-free Part A coverage.

Source: MedPAC analysis of estimates prepared by the Urban Institute.

and $296 billion for the third scenario. The variation in the expected cost of the three scenarios is due largely to differences in how each scenario provides assistance with Part A and Part B cost sharing. (All three scenarios extend assistance with the Part B premium to beneficiaries with income between 135 percent and 150 percent of the federal poverty level.) The first scenario (raise the income level for QI eligibility) does not expand eligibility for assistance with cost sharing, although some of the LIS enrollees who would become automatically eligible for MSP benefits would receive assistance with cost sharing. In contrast, the second scenario (raise the income level for QMB eligibility) expands assistance with cost sharing to beneficiaries with income between 100 percent and 150 percent of the federal poverty level. However, states would still be able to use lesser-of policies to limit how much cost sharing they cover, which would reduce the expected cost. The third scenario (raise the income level for QMB eligibility and federalize the program) is the most expensive because it both expands eligibility for assistance with cost sharing to 150 percent of the federal poverty level and requires Medicare to pay the full amount of any cost sharing for those enrolled in MSPs. In aggregate, the analyses prepared by the Urban Institute indicate that states pay only about 35 percent of the cost-sharing liability for QMBs now. The difference in the cost of the

second and third scenarios is largely due to Medicare's liability for the 65 percent of cost sharing that states do not cover. (As shown in Table 9-7, a majority of the costs for the third scenario are for existing rather than new MSP enrollees.) The additional costs to Medicare under the third scenario would be partly offset by lower spending on bad-debt payments; those savings are included in the estimate for the third scenario.[46]

The impact on state budgets would also vary significantly, depending on the scenario. Under the first, expanding QI eligibility, the cost to the states would total about $8 billion over 10 years. While the cost of the assistance with the Part B premium for beneficiaries with income between 135 percent and 150 percent of the federal poverty level would be paid entirely by the federal government, states would still see higher Medicaid costs because some LIS enrollees would become automatically eligible for QMB or SLMB benefits, which are partly financed by states. Under the second scenario, expanding QMB eligibility, the cost to the states would total about $38 billion over 10 years because states would bear part of the cost for the additional MSP benefits provided to beneficiaries with income between 100 percent and 150 percent of the federal poverty level. Under the third scenario, expanding QMB eligibility and federalizing the program, the impact for states would be negligible. States would ordinarily see significant savings from federalizing MSPs, but under this scenario, states would be required to make maintenance-of-effort payments to the federal government that equal what the states would have spent on MSPs under current law, which would largely eliminate any savings for states.[47] Without a maintenance-of-effort requirement, federal costs under the third scenario would be much higher.

The amount of cost sharing that states currently pay for QMBs varies considerably, and the maintenance-of-effort requirement under the third scenario would create inequities across states. Health care providers and beneficiaries in states that currently pay a relatively small percentage of the cost sharing for QMBs would benefit more under this scenario. The providers in those states would see a larger increase in their overall revenues (once Medicare started covering the cost sharing that states currently do not pay), and the QMBs themselves would see a bigger improvement in their access to care, while the states' maintenance-of-effort payments would be relatively limited. Conversely, states that now pay a larger percentage of the cost sharing for QMBs would benefit less: the additional revenues for providers in those states would be smaller, as would any improvements in access to care for the QMBs themselves, and the states' maintenance-of-effort payments would be larger.

To illustrate how the third scenario's impact could vary by state, consider two states that had similar cost-sharing liability in 2012 for their QMBs—$105 million and $98 million, respectively. The first state paid about 36 percent of its cost-sharing liability (or $37 million), and the state's share of those payments, based on its Medicaid match rate, was about $14 million. In contrast, the second state paid about 71 percent of its cost-sharing liability ($70 million), and the state's share of those payments was about $22 million. Under the third scenario, providers in both states would now be fully paid for the cost sharing; the additional revenue would be about $68 million in the first state and about $28 million in the second state. However, the first state would have to make smaller maintenance-of-effort payments ($14 million vs. $22 million).

Conclusion

The financial alignment demonstration is one the largest demonstrations that CMS has ever conducted related to dual eligibles and will have a significant impact on dual eligibles, the federal government, and the states, regardless of its ultimate success or failure. The demonstrations in most states are now well underway. While enrollment has been much lower than anticipated, it is nonetheless substantial and should be sufficient to test the capitated and managed FFS models.

The implementation of the demonstration has consistently proven to be more difficult than first expected, and our site visits to three states suggest that these challenges continue. The MMP representatives that we interviewed widely agreed that at least one to two years would be needed to begin reshaping their enrollees' patterns of care and that the expected savings from the demonstration were unrealistic, at least initially. Correspondingly, many stakeholders viewed improving the quality of care for dual eligibles as the primary goal of the demonstration. Plans are still developing their care coordination models and revising them as they gain more experience under the demonstration.

Given these continuing challenges, the results from the demonstration at the end of its original three-year lifespan could be less definitive than policymakers would like. We support CMS's offer to extend the

demonstration for another two years and hope that most states agree to it because the additional time may yield valuable information about the ultimate effectiveness of the two models. The Commission continues to support the overall goals of the demonstration—although we remain concerned about its ultimate impact on Medicare spending—and will monitor its progress with interest. In particular, we will continue to monitor the development of the demonstration's care coordination models and their impact on the quality of care received by dual eligibles.

As for MSPs, they are a good example of the challenges that policymakers confront in deciding what roles Medicare and Medicaid should play in caring for dual-eligible beneficiaries. Although MSPs play an important role in protecting low-income Medicare beneficiaries against high out-of-pocket spending on premiums and cost sharing, participation is relatively low, in part because the MSP eligibility rules differ from those used by the Part D LIS and the two programs use separate enrollment processes. Since MSPs are part of Medicaid, states play an important role in paying for their costs, but their ability to use lesser-of policies to limit spending on cost sharing for QMBs ultimately reduces payments to the health care providers that serve QMBs and could impede access to care.

Policymakers could expand MSPs in a variety of ways, and the three illustrative scenarios we examined suggest that the resulting impact on beneficiaries, federal spending, and state spending would depend on the approach used. The scenarios we examined suggest that efforts to expand or federalize MSPs would affect a relatively small number of Medicare beneficiaries, could result in substantial new federal costs, and would have an uneven impact across states. ■

Endnotes

1 Annual enrollment figures for dual-eligible beneficiaries are usually calculated using one of two methods: (1) a "point-in-time" method that counts all beneficiaries who were dual eligibles at a specific point during the year or (2) an "ever-enrolled" method that counts all beneficiaries who were dual eligibles at any point during the year. The two methods produce somewhat different results because some individuals are dual eligibles for only part of the year. (There are also individuals who are full-benefit dual eligibles for part of the year and partial-benefit dual eligibles for part of the year. Those individuals are counted in both categories under the ever-enrolled method unless some sort of hierarchy is applied, such as assigning them to their most recent type of dual eligibility.) The 20 percent figure is based on the ever-enrolled method; the point-in-time figure would be a few percentage points lower.

2 The descriptions of the Medicaid eligibility categories and the number of states using them are based on work done by the Medicaid and CHIP Payment and Access Commission (Medicaid and CHIP Payment and Access Commission 2015b, Medicaid and CHIP Payment and Access Commission 2013).

3 Other 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.

4 The rest of the figures in this section are taken from the data book on dual-eligible beneficiaries that the Commission produced with the Medicaid and CHIP Access and Payment Commission (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2016).

5 About 63 percent of all full-benefit dual eligibles in 2011 met these criteria. The share of dual eligibles enrolled in FFS has likely declined since then due to growth in the number of dual eligibles enrolled in various forms of managed care (Medicare Advantage plans, Medicaid managed care, or Medicare–Medicaid Plans under the financial alignment demonstration).

6 The service categories in Table 9-1 (p. 268) are not mutually exclusive; some beneficiaries used more than one type of service. About 44 percent of full-benefit dual eligibles used at least one type of LTSS.

7 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. In November 2015, the Congress enacted legislation that authorizes CMS to test the use of PACE on people younger than 55.

8 PACE serves individuals who live in the community but are at risk of entering a nursing home and fully integrates Medicare and Medicaid financing. D–SNPs must have a contract with the state to coordinate Medicare and Medicaid benefits for their enrollees, but the degree to which they integrate the two programs varies widely and is generally much lower than the degree of integration provided by MMPs.

9 Since the late 1990s, Minnesota has operated a program known as Minnesota Senior Health Options (MSHO) that uses health plans to integrate Medicare and Medicaid for beneficiaries who are 65 or older. MSHO plans contract with the state as Medicaid managed care plans and with CMS as D–SNPs. Under the demonstration, the state will test new ways to integrate Medicare and Medicaid administrative functions in its MSHO plans (for example, in areas such as beneficiary notices and appeals). The MSHO program is otherwise unchanged (Centers for Medicare & Medicaid Services 2013c).

10 New York's second demonstration is scheduled to last for four years. CMS and the state signed the MOU for this demonstration after CMS's July 2015 announcement, and its end date implicitly reflects an extension.

11 Virginia will enroll all Medicaid beneficiaries who use long-term services and supports in managed LTSS (MLTSS) plans starting in 2017. The state has decided to use the MLTSS plans as its platform for integrating Medicare and Medicaid and will require the sponsors of the MLTSS plans to offer companion Medicare D–SNP products also. The dual eligibles in the demonstration will be moved into MLTSS plans once the demonstration ends. CMS has not indicated what will happen to their Medicare coverage—they could be passively enrolled in the companion D–SNPs on a one-time basis (see text box, pp. 280–281) or placed in FFS Medicare. The role of D–SNPs in integrating Medicare and Medicaid for dual eligibles is a broader question that policymakers may want to consider based on the results of the demonstrations using the capitated model.

12 Although the demonstration is statewide, no MMPs are currently operating in 5 of the state's 46 counties because they have not been able to meet network adequacy requirements in those areas. Rhode Island's demonstration, expected to start later this year, will also be statewide.

13 This figure does not include Rhode Island's demonstration or New York's second demonstration, which had not started

as of March 2016. About 30,000 and 20,000 dual eligibles, respectively, will be eligible for those demonstrations (Centers for Medicare & Medicaid Services 2015d, Centers for Medicare & Medicaid Services 2015e).

14 The 67 MMPs examined in the study are the 60 plans that are still participating in the demonstration, the 6 plans that left the demonstration after it started, and 1 plan in New York that dropped out of the demonstration before any beneficiaries were enrolled.

15 South Carolina has not yet conducted passive enrollment in its demonstration. Its participation rate is likely to increase once that occurs later this year.

16 There have been numerous reports of provider resistance in other states also.

17 The figures for the FIDE SNPs include the plans in the Minnesota Senior Health Options program, which are part of the alternative model that the state is testing in the financial alignment demonstration.

18 South Carolina has used voluntary enrollment only since launching its demonstration in February 2015, but it plans to conduct passive enrollment in 2016. Rhode Island will launch its demonstration later this year and plans to use passive enrollment for some beneficiaries. As noted earlier, New York used passive enrollment during the initial year of its first demonstration but stopped using it in December 2015. The state will not use passive enrollment in its second demonstration, scheduled to begin later this year.

19 California lets its counties decide how to use managed care to serve residents who are enrolled in the state's Medicaid program, known as Medi-Cal. Counties can choose one of six models. Under one model, the county creates and runs its own health plan, which is known as a county organized health system (COHS), and all Medi-Cal beneficiaries in the county receive services through the COHS (California Department of Health Care Services 2014).

20 For example, CMS took these steps when it terminated its Part D contract with Fox Insurance Company in 2010 (Centers for Medicare & Medicaid Services 2010).

21 California's experience with its demonstration project has echoed that earlier episode: MMP participation rates in February 2016 were 77 percent in San Mateo County and 47 percent in Orange County (California Department of Health Care Services 2016). Provider resistance to managed care appears to have been a significant factor in both 2006 and the current demonstration, particularly in Orange County.

22 Some states provide additional notices. For example, California sends beneficiaries an initial notice 90 days before their passive enrollment will take effect, followed by the required 60-day and 30-day notices (California Department of Health Care Services 2016).

23 Four demonstration states—California, Ohio, New York, and Texas—currently require dual eligibles to enroll in managed care for their Medicaid benefits, including LTSS. These states typically contract with the same insurers for their MMPs and their Medicaid plans. As a result, beneficiaries who disenroll from MMPs in these states are usually enrolled in a Medicaid managed care plan sponsored by the same company.

24 In some situations, this requirement might work the other way and lead states to passively enroll beneficiaries sooner than they would otherwise. For example, if a state initially plans to passively enroll beneficiaries in an MMP in February or March of a given year and determines that some of those beneficiaries will be assigned to a new Part D plan in January of that year, it can either move up the MMP enrollment to January (to trump the Part D reassignment) or delay the MMP enrollment until the following January.

25 This issue has been more significant for some demonstrations than others. The number of passive enrollments in Part D is determined by the year-to-year change in plans that qualify to offer zero-premium plans to beneficiaries who receive the low-income subsidy. The extent of the year-to-year change varies over time and across states. For example, if the lineup of zero-premium plans in a particular state changed little from 2014 to 2015, the number of Part D enrollees who were assigned to new plans in January 2015 would be relatively low, and the state would have more flexibility to passively enroll beneficiaries in its MMPs during 2015.

26 For example, states must develop the ability to process passive enrollments more than two months before beneficiaries actually gain dual eligibility to supersede CMS actions to passively enroll those beneficiaries in Part D plans. States must also develop systems that can communicate with the Social Security Administration so that they can identify which disabled Medicaid beneficiaries also receive Social Security disability benefits and will become eligible for Medicare after a two-year waiting period.

27 Some states use different names for these elements, such as "care manager" or "case manager" instead of "care coordinator."

28 The MMPs are not required to pay providers for the time they spend engaged in this activity. Some MMPs that we interviewed during our site visits indicated that low participation by primary care physicians had been an obstacle to developing individual care plans and that the MMPs had started paying physicians to participate.

29 Caseloads varied widely across the MMPs we interviewed, ranging from about 50 (all high-risk enrollees) to about 500 (all low-risk enrollees). However, most care coordinators appeared to have caseloads of 75 to 125 enrollees.

30 Managed care plans in California often make capitated payments of their own to large physician groups that assume risk for providing services to plan enrollees. This arrangement is sometimes referred to as "subcapitation" or the "delegated model." The MMPs we interviewed in California use the delegated model for many services and contract with the delegated entity to provide much of the care coordination.

31 All demonstrations require MMPs to allow new enrollees to use their existing providers for a certain period of time, even if the providers are not in the MMP's provider network. This transition period often lasts for at least 90 days and, in some cases, can last for 6 months or a year (Musumeci 2014).

32 Several states have "carved out" certain benefits from the demonstration and continue to provide them through FFS arrangements (Medicaid and CHIP Payment and Access Commission 2015a). For example, California has carved out certain services for beneficiaries with serious behavioral health needs.

33 Since 2010, CMS has applied an across-the-board reduction to HCC risk scores to compensate for the higher reporting of diagnoses for MA enrollees compared with those in FFS. This reduction is often referred to as the "coding intensity adjustment" and equals 5.41 percent in 2016. This adjustment also applies to MMPs but is being phased in over time and will not be fully implemented until the second or third year of the demonstration.

34 CMS increased its prospective payments for reinsurance for beneficiaries with high drug costs and for cost sharing covered by the LIS. Both types of payments are estimated amounts and are later adjusted based on plans' actual experience, so this change does not increase overall program spending. The MMPs that we interviewed in Massachusetts indicated that their costs for reinsurance and LIS cost sharing had been much higher than the initial payment rates. Although CMS reimburses plans for any additional costs in these areas, this reconciliation does not take place until the following year, and this delay led to cash-flow problems for the MMPs.

35 The state originally planned to conduct a second demonstration in King and Snohomish counties using the capitated model. The state signed an MOU with CMS in November 2013 for the second demonstration but later canceled it when one of the two health plans that had agreed to participate decided to drop out.

36 The distinction between lead organizations and CCOs can quickly get confusing because each lead organization may contract with multiple CCOs, each CCO may contract with multiple lead organizations, and some entities serve as lead organizations in some regions and as CCOs in other regions.

37 Health homes must first complete a HAP before they can bill the state for providing intensive or low-level care coordination. In addition, the state makes payments for intensive or low-level care coordination only for months in which the beneficiary received care coordination services.

38 Medicaid requires states to determine the countable income and assets of MSP applicants using the same rules as the Supplemental Security Income program.

39 The fourth MSP category is the qualified disabled working individual (QDWI) program, which requires Medicaid to pay the Part A premium for certain disabled individuals who have income below 200 percent of the federal poverty level but are no longer eligible for Medicare Part A because they have returned to work. In 2014, fewer than 100 people were enrolled in the QDWI program.

40 The federal Medicaid match rate, known as the federal medical assistance percentage, or FMAP, determines what share of Medicaid spending is paid by the federal government. The FMAP varies from state to state and is determined by a formula that compares each state's per capita income with the national average. States with higher per capita income have lower FMAPs and vice versa, although each state's FMAP cannot be lower than 50 percent or higher than 83 percent. FMAPs for fiscal year 2016 range from 50 percent in 13 states to 74.17 percent in Mississippi (Office of the Assistant Secretary for Planning and Evaluation 2016a).

41 Many of those 1.7 million beneficiaries either require long-term care and reside in nursing homes or live in the community and have high medical expenses. States have the option of covering Medicare cost sharing for these beneficiaries, but Medicaid does not require them to do so. States can also cover the Part B premium for these beneficiaries, but they can receive federal Medicaid matching funds only for beneficiaries who receive some sort of cash assistance payment, such as a state supplementary payment (Medicaid and CHIP Payment and Access Commission 2015c).

42 Researchers have found it challenging to estimate participation rates for the MSPs because doing so requires detailed information about the income and assets of low-income individuals (to determine which individuals are eligible) and their Medicaid enrollment status (to determine which individuals are already enrolled in the MSPs). Researchers usually base their estimates on statistical surveys such as the Medicare Current Beneficiary Survey or the Survey of Income and Program Participation, but each survey has limitations.

43 The Congress first required states to cover QMBs in 1988. CMS, then known as the Health Care Financing Administration, issued guidance in 1991 that allowed states to use Medicaid rates to determine their obligation to pay cost sharing for QMBs. However, health care providers filed multiple lawsuits on the issue, arguing that the statutory language for the QMB program required states to use Medicare rates. Federal courts had issued mixed rulings on the issue, and the Congress resolved the disagreement by explicitly giving states the authority to use Medicaid rates (Medicaid and CHIP Payment and Access Commission 2013).

44 The Urban Institute used data from the American Community Survey, the Survey of Income and Program Participation, and the Medicare Beneficiary Summary File to produce its analyses.

45 These participation rates are higher than the ones included in the Commission's March 2008 report, which stated that participation rates for the QMB and SLMB programs were about 33 percent and 13 percent, respectively. These figures come from a 2004 study by the Congressional Budget Office (CBO) that examined the impact of the recently enacted Medicare drug benefit (Congressional Budget Office 2004). The CBO figures do not include full-benefit dual eligibles and thus cannot be directly compared with the figures shown here (which do include them) and are also now somewhat dated.

46 Medicare currently makes payments to most institutional providers (such as hospitals and skilled nursing facilities) that cover a portion of their Medicare "bad debt," which is cost sharing not paid by FFS enrollees. This bad debt includes amounts that providers cannot collect because states do not pay the full amount of cost sharing for QMBs. Since under the third scenario Medicare would pay the full amount of any cost sharing for beneficiaries with income below 150 percent of the federal poverty level, Medicare payments to providers for bad debt would decrease.

47 These payments would be similar in nature to the so-called clawback payments that states make as part of the Medicare Part D drug benefit. The creation of the Part D program shifted the responsibility for providing drug coverage for dual-eligible beneficiaries from Medicaid to Medicare and thus lowered state Medicaid spending. However, states are required to make payments to the federal government that are equal to 75 percent of their estimated Medicaid savings, thus allowing the federal government to "claw back" most of the states' savings.

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APPENDIX A

Commissioners' voting on recommendations

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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: Using competitive pricing to set beneficiary premiums in Medicare

No recommendations

Chapter 2: Medicare's new framework for paying clinicians

No recommendations

Chapter 3: Mandated report: Developing a unified payment system for post-acute care

The Commission has voted to forward to the Congress the report on the unified post-acute care payment system required by the Improving Medicare Post-Acute Care Transformation Act of 2014.

Yes: *Armstrong, Baicker, Buto, Christianson, Coombs, Crosson, Gradison, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Thompson, Uccello*

Chapter 4: Medicare drug spending in its broader context

No recommendations

Chapter 5: Medicare Part B drug and oncology payment policy issues

The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

Yes: *Armstrong, Baicker, Buto, Christianson, Coombs, Crosson, Gradison, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Thompson, Uccello*

Chapter 6: Improving Medicare Part D

6-1 The Congress should change Part D to:

- transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,
- exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and
- eliminate enrollee cost sharing above the out-of-pocket threshold.

Yes: *Armstrong, Baicker, Buto, Christianson, Coombs, Crosson, Gradison, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Thompson, Uccello*

6-2 The Congress should change Part D's low-income subsidy to:

- modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;
- direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and
- direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

Yes: *Armstrong, Baicker, Buto, Christianson, Coombs, Crosson, Gradison, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Thompson, Uccello*

6-3 The Secretary should change Part D to:

- remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,
- streamline the process for formulary changes,
- require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and
- permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

Yes: *Armstrong, Baicker, Buto, Christianson, Coombs, Crosson, Gradison, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Thompson, Uccello*

Chapter 7: Improving efficiency and preserving access to emergency care in rural areas

No recommendations

Chapter 8: Telehealth services and the Medicare program

No recommendations

Chapter 9: Issues affecting dual-eligible beneficiaries: CMS's financial alignment demonstration and the Medicare Savings Programs

No recommendations

Acronyms

Acronyms

ACO	accountable care organization
ADL	activity of daily living
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
AMD	age-related macular degeneration
AMI	acute myocardial infarction
AMP	average manufacturer price
APM	alternative payment model
APR–DRG	all-patient refined–diagnosis related group
ASCO	American Society of Clinical Oncology
ASP	average sales price
ASP + 6 percent	average sales price plus 6 percent
ATA	American Telemedicine Association
BBA	Balanced Budget Act of 1997
BPCI	Bundled Payments for Care Improvement
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
BPC	Bipartisan Policy Center
CAD	coronary artery disease
CAH	critical access hospital
CAHPS®	Consumer Assessment of Healthcare Providers and Systems®
CAP	competitive acquisition program
CBO	Congressional Budget Office
CBSA	core-based statistical area
CCI	chronically critically ill
CCM	Chronic Care Management
CCO	care coordination organization
CCR	cost-to-charge ratio
CHF	congestive heart failure
CHIP	Children's Health Insurance Program
CJR	Comprehensive Care for Joint Replacement
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CNS	clinical nurse specialist
COHS	county organized health system
COME HOME	Community Oncology Medical Home
COPD	chronic obstructive pulmonary disease
CPC+	Comprehensive Primary Care Plus
CPCI	Comprehensive Primary Care Initiative
CPI–U	consumer price index for all urban consumers
CRNA	certified registered nurse anesthetist
C–SNP	chronic condition special needs plan
CT	computed tomography
CVT	clinical video telehealth
CY	calendar year
DME	durable medical equipment
DRG	diagnosis related group
D–SNP	dual-eligible special needs plan
E&M	evaluation and management
EAPE	eligible alternative payment entity
ED	emergency department
EGWP	employer group waiver plan
EHR	electronic health record
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FFS	fee-for-service
FIDE	fully integrated dual eligible
FIDE–SNP	fully integrated dual-eligible special needs plan
FMAP	federal medical assistance percentage
FPL	federal poverty level
FQHC	federally qualified health center
FRF	formulary reference file
GDR	generic dispensing rate
GHP	Geisinger Health Plan
GPO	group purchasing organization
HAP	health action plan
H–CAHPS®	Hospital Consumer Assessment of Healthcare Providers and Systems®
HCBS	home- and community-based services
HCC	hierarchical condition category
HCCI	Health Care Cost Institute
HCIA	Health Care Innovation Awards
HCPCS	Healthcare Common Procedure Coding System
HHA	home health agency
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HMO	health maintenance organization
HOPD	hospital outpatient department
HPSA	health professional shortage area
HSA	health service area
HT	home telehealth
IAH	Independence at Home
ICD–9	International Classification of Diseases, Ninth Revision

ICU	intensive care unit
IFEC	independent freestanding emergency center
IMLC	Interstate Medical Licensure Compact
IMPACT	Improving Medicare Post-Acute Care Transformation Act of 2014
IOM	Institute of Medicine
IPPS	inpatient prospective payment system
IRE	independent review entity
IRF	inpatient rehabilitation facility
I–SNP	institutional special needs plan
KFF	Kaiser Family Foundation
KHA	Kansas Hospital Association
LICS	low-income cost sharing
LIS	low-income [drug] subsidy
LLC	limited liability corporation
LTCH	long-term care hospital
LTSS	long-term care services and supports
MA	Medicare Advantage
MACPAC	Medicaid and CHIP Payment and Access Commission
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MAF	medical assistance facility
MAPCP	Multi-payer advanced primary care practice
MA–PD	Medicare Advantage–Prescription Drug [plan]
MDC	major diagnostic category
MDH	Medicare-dependent hospital
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MIPS	Merit-based Incentive Payment System
MLTSS	managed long-term care services and supports
MMP	Medicare–Medicaid Plan
MOU	memorandum of understanding
MSA	metropolitan statistical area
MS–DRG	Medicare severity–diagnosis related group
MSHO	Minnesota Senior Health Options
MSP	Medicare Savings Program
MSPB	Medicare spending per beneficiary
MSPB–PAC	Medicare spending per beneficiary–post-acute care
MSSP	Medicare Shared Savings Program
MTM	medication therapy management
N/A	not applicable
NDC	national drug code
NLC	Nurse Licensure Compact
NORC	(formerly) National Opinion Research Center
NP	nurse practitioner
NTA	nontherapy ancillary
OCED	off-campus emergency department
OIG	Office of Inspector General
OOP	out-of-pocket
OP	outpatient
OPPS	outpatient prospective payment system
P&T	pharmacy and therapeutics
PA	physician assistant
PAC	post-acute care
PAC–PRD	Post-Acute Care Payment Reform Demonstration
PACE	Program of All-Inclusive Care for the Elderly
PAP	patient assistance program
PBM	pharmacy benefit manager
PDP	prescription drug plan
PFS	physician fee schedule
PPACA	Patient Protection and Affordable Care Act of 2010
PPS	prospective payment system
PQRS	Physician Quality Reporting System
PTAC	Physician-Focused Payment Model Technical Advisory Committee
QDWI	qualified disabled working individual
QI	qualifying individual
QMB	qualified Medicare beneficiary
RA	rheumatoid arthritis
RAC	recovery audit contractor
RDS	retiree drug subsidy
RHC	rural health clinic
RPCH	rural primary care hospital
RPM	remote patient monitoring
RxHCC	prescription drug hierarchical condition category
SCH	sole community hospital
SCHIP	State Children's Health Insurance Program
SFT	store-and-forward telehealth
SGR	sustainable growth rate
SHIP	State Health Insurance Assistance Program
SLMB	specified low-income Medicare beneficiary
SNF	skilled nursing facility
SNP	special needs plan
SOI	severity of illness
SSA	Social Security Administration
SSI	Supplemental Security Income
tele–ICU	tele–intensive care unit

tPA	tissue plasminogen activator
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs
VBP	value-based purchasing [program]
VISN	Veterans Integrated Service Network
VM	value-based payment modifier (value modifier)

More about MedPAC

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Commissioners' biographies

Scott Armstrong, M.B.A., F.A.C.H.E., is president and chief executive officer (CEO) of Group Health Cooperative, a consumer-governed health system serving 650,000 enrollees through coordinated care plans for groups and individuals and for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. He has worked at Group Health since 1986, serving in positions ranging from assistant hospital administrator to chief operating officer; he became president and CEO in 2005. Before joining Group Health, Mr. Armstrong was assistant vice president for hospital operations at Miami Valley Hospital in Dayton, OH. Mr. Armstrong is a member of the board of the Alliance of Community Health Plans and board member of America's Health Insurance Plans and the Seattle Chamber of Commerce. He is also immediate past chair of the Board of the Pacific Science Center and a fellow of the American College of Healthcare Executives. He received his bachelor's degree from Hamilton College in New York and a master's degree in business with a concentration in hospital administration from the University of Wisconsin–Madison.

Katherine Baicker, Ph.D., is C. Boyden Gray Professor of Health Economics and chair of the Department of Health Policy and Management at the Harvard T. H. Chan School of Public Health, where her research focuses on health insurance finance and the effect of reforms on the distribution and quality of care. From 2005 to 2007, Professor Baicker served as a Senate-confirmed member of the President's Council of Economic Advisers. She is a research associate at the National Bureau of Economic Research and the Jameel Poverty Action Lab, serves on the Congressional Budget Office's Panel of Health Advisers, is a director of Eli Lilly, chairs the Group Insurance Commission of Massachusetts, and is an elected member of the Institute of Medicine. She also served as chair of AcademyHealth and on the faculty of the Economics Department at Dartmouth College. She received her B.A. in economics from Yale University and her Ph.D. in economics from Harvard University.

Kathy Buto, M.P.A., is an expert in U.S. and international health policy. She has recently been involved in a range of volunteer professional engagements with, among others, the Arlington Free Clinic, the National Academy of Social Insurance, the Robert Wood Johnson Foundation's Healthcare Legacy Forum, and the National Science Foundation's Study of Women in Policy Making. 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 serves on the Institute of Medicine's Board on Health Care Services and on the editorial board of the *American Journal of Managed Care*. He recently served on the Institute of Medicine's Committee on Geographic Adjustment Factors in Medicare Payment and has chaired AcademyHealth's annual research meeting. 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 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 "Jay" Crosson, M.D., spent 35 years as a physician and physician executive at Kaiser Permanente. In 1997 he founded and then 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.

Bill Gradison, Jr., M.B.A., D.C.S., was a scholar in residence in the Health Sector Management Program at Duke's Fuqua School of Business. He was a member of the U.S. Congress (1975–1993) where he served on the House Budget Committee and the Health Subcommittee of the Committee on Ways and Means. Mr. Gradison was a founding board member of the Public Company Accounting Oversight Board and was vice chairman of the U.S. Bipartisan Commission on Comprehensive Health Care ("Pepper Commission"). Prior positions also include assistant to the Secretary of Health, Education, and Welfare; president of the Health Insurance Association of America; and vice chair of the Commonwealth Fund Task Force on Academic Health Centers. Mr. Gradison received his B.A. from Yale University and an M.B.A. and doctorate from Harvard Business School.

William J. Hall, M.D., M.A.C.P., is a geriatrician and professor of medicine at the University of Rochester School of Medicine where he directs the Highland Hospital Center for Healthy Aging. He previously served as a member of the board of directors of AARP. His career has focused on systems of health care for older adults. He was instrumental in establishing the Program of All-Inclusive Care for the Elderly and developing many senior prevention and wellness programs. Dr. Hall's prior service and positions include president of the American College of Physicians and leadership positions in the American Geriatrics Society. He received his bachelor's degree from the College of the Holy Cross and his medical degree from the University of Michigan Medical School and pursued postdoctoral training at Yale University School of Medicine.

Jack Hoadley, Ph.D., is research professor 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); pharmacoeconomics and prescription drug benefit programs; and private sector insurance coverage. Dr. Hoadley has published widely on health care financing and pharmacoeconomics and has provided testimony to government panels.

Herb B. Kuhn is current president and chief executive officer of the Missouri Hospital Association (MHA), the trade association serving the state's 176 hospitals and health systems. Before joining MHA, Mr. Kuhn served in multiple roles at the Centers for Medicare & Medicaid Services, including deputy administrator from 2006 to 2009 and director of the Center for Medicare Management from 2004 to 2006. From 2000 to 2004, Mr. Kuhn served as corporate vice president for the Premier Hospital Alliance, serving 1,600 institutional members. From 1987 through 2000, Mr. Kuhn worked in federal relations with the American Hospital Association. Mr. Kuhn received his bachelor of science in business from Emporia State University.

Mary Naylor, Ph.D., R.N., F.A.A.N., is the Marian S. Ware Professor in Gerontology and director of the NewCourtland Center for Transitions and Health at the University of Pennsylvania School of Nursing. For the past two decades, Dr. Naylor has led an interdisciplinary program of research designed to improve the quality of care, decrease unnecessary hospitalizations, and reduce health care costs for vulnerable community-based elders. For the past eight years, Dr. Naylor served as the national program director for the Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative, which was aimed at generating, disseminating, and translating research to understand how nurses contribute to quality patient care. She was elected to the

National Academy of Medicine in 2005, is a member of the Leadership Consortium on Value and Science-Driven Health Care, and co-chairs the Care Culture and Decision-Making Innovation Collaborative. Dr. Naylor is also a member of the ABIM Foundation Board of Trustees, the RAND Health Board of Advisors, and the Agency for Healthcare Research and Quality National Advisory Council. She recently completed her term on the National Quality Forum Board of Directors.

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*.

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.

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 the Centers for Medicare & Medicaid Services' 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 the 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's 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. Previously, she was chief executive officer of UnityPoint Health–Fort Dodge health system in Iowa, which serves a predominantly rural and aging population and includes a medical center, a sole community hospital, a clinic, a primary care and multispecialty physician group, management contracts with critical access hospitals throughout the region, and a Pioneer Accountable Care Organization. She previously served in successive clinical and management positions at Trinity Regional Medical Center, including 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 bachelor of science in nursing and her master of science in health services management from Clarkson College in Omaha, NE.

Cori E. Uccello, F.S.A., M.A.A.A., M.P.P., is senior health fellow of the American Academy of Actuaries, serving as the actuarial profession's chief public policy liaison on health issues. Ms. Uccello focuses on issues related to health insurance financing, coverage and market reforms, and risk-sharing mechanisms. She served as a member of the 2010–2011 Technical Review Panel on the Medicare Trustees' report. Before joining the academy in 2001, she was a senior research associate at the Urban Institute where she focused on health insurance and retirement policy issues. She previously held the position of actuarial fellow at the John Hancock Life Insurance Company. Ms. Uccello is a fellow of the Society of Actuaries and a member of the American Academy of Actuaries. She received an undergraduate degree in mathematics and biology from Boston College and a master's degree in public policy from Georgetown University.

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