JUNE 2017

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.

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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
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June 15, 2017

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

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

Dear Mr. President and Mr. Speaker:

I am pleased to submit the Medicare Payment Advisory Commission's June 2017 *Report to the Congress: Medicare and the Health Care Delivery System*. This report fulfills the Commission's legislative mandate to evaluate Medicare payment issues and to make recommendations to the Congress.

In the 10 chapters of this report, we consider:

- implementing a unified payment system for post-acute care.
- Medicare Part B drug payment policy issues.
- using premium support in Medicare.
- the relationship between physician and other health professional services and other Medicare services (mandated report).
- redesigning the Merit-based Incentive Payment System and strengthening advanced alternative payment models.
- payments from drug and device manufacturers to physicians and teaching hospitals in 2015.
- an overview of the medical device industry.
- stand-alone emergency departments.

- hospital and skilled nursing facility use by Medicare beneficiaries who reside in nursing facilities.
- provider consolidation—the role of Medicare policy.

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

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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 issues affecting the Medicare program, including broader changes in health care delivery and the market for health care services. In the 10 chapters of this report, we consider:

- ***Implementing a unified payment system for post-acute care (PAC).*** Although the types of patients treated in the four main PAC settings overlap, Medicare's payments for similar patients can differ substantially. The Commission recommends moving to a unified PAC prospective payment system (PPS) that spans the four settings—with payments based on patient characteristics rather than the site of service—and supports the implementation of a PAC PPS in the near term.
- ***Medicare Part B drug payment policy issues.*** The Medicare payment system for Part B drugs raises a number of concerns, including the overall price Medicare Part B pays for drugs, the lack of price competition among drugs with similar health effects, and the rapid growth in spending. The Commission recommends a series of regulatory and market-based reforms—both short and long term—to improve Medicare payment for Part B drugs.
- ***Using premium support in Medicare.*** Under a premium support model, the government would pay a fixed dollar amount for each beneficiary's Medicare coverage. As a result, beneficiaries' premiums would reflect the choices they make to receive the Medicare benefit package through the fee-for-service (FFS) program or a managed care plan. Although the Commission makes no recommendations, we examine some of the key issues that policymakers would want to resolve if they decide to use premium support in Medicare.
- ***The relationship between physician and other health professional services and other Medicare services.*** The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directs the Commission to submit a report to the Congress on the relationship between the use of and expenditures for services provided by clinicians and the total service use and expenditures under Part A, Part B, and Part D of Medicare. We do not find any strong relationships; that is, our findings suggest that clinician services and other services are neither clear complements nor clear substitutes.
- ***Redesigning the Merit-based Incentive Payment System (MIPS) and strengthening advanced alternative payment models (A–APMs).*** MIPS as presently designed is unlikely to help beneficiaries choose clinicians, help clinicians change practice patterns to improve value, or help the Medicare program reward clinicians based on value. Therefore, we discuss a possible alternative construct for MIPS. We also discuss two policies to encourage clinicians to form and participate in A–APMs.
- ***Payments from drug and device manufacturers to physicians and teaching hospitals in 2015.*** Under the Open Payments program, drug and device manufacturers and group purchasing organizations (GPOs) report information to CMS about payments they make to physicians and teaching hospitals (those payments totaled over $7 billion in 2015). This program has increased the transparency of financial interactions between manufacturers and physicians and teaching hospitals and should be expanded to include other providers and organizations that receive industry payments.
- ***An overview of the medical device industry.*** The medical device industry makes a wide range of products—from surgical gloves to artificial joints to imaging equipment—and plays an important role in developing new medical technologies. We provide an introduction to the industry, discuss its role in the Medicare program, and provide possible directions for policy.
- ***Stand-alone emergency departments (EDs).*** The number of health care facilities devoted primarily to ED services and located apart from hospitals—referred to as stand-alone EDs—has grown rapidly in recent years. We discuss three policies that could be considered in response to this trend.
- ***Hospital and skilled nursing facility (SNF) use by Medicare beneficiaries who reside in nursing facilities.*** Transferring Medicare beneficiaries who are long-stay nursing facility (NF) residents to a hospital for conditions that could have been prevented

or treated by the NF exposes beneficiaries to health risks and unnecessarily increases Medicare program spending. We found wide variation across facilities in their risk-adjusted rates of hospital use, which suggests opportunities for reductions in unnecessary Medicare spending.

- ***Provider consolidation: The role of Medicare policy.*** We discuss the implications for the Medicare program of consolidation in the health care industry. We find that consolidation among and between hospitals and physicians has increased prices without any increase in quality. The Commission has made several recommendations to address those issues. In addition, we discuss consolidation of provider functions and insurer functions by accountable care organizations (ACOs) or Medicare Advantage (MA) plans and its implication for the Medicare program.

Implementing a unified payment system for post-acute care

In Chapter 1, the Commission recommends a unified payment system for PAC services. Although the types of cases treated in the four main PAC settings (SNFs, home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs)) overlap, Medicare's payments for similar patients can differ substantially, in part because Medicare uses separate PPSs to pay for stays in each setting. The supply and use of PAC providers vary considerably across the country, and evidence-based criteria do not exist to guide decisions about which patients require PAC, which PAC setting is most appropriate for a given patient, and how much care is needed. These factors undermine clear policies to guide PAC placement decisions.

Given the overlap among PAC settings in the patients they treat, the Commission has long promoted the idea of moving to a unified PAC PPS that spans the four settings, with payments based on patient characteristics rather than the site of service. In a report mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT), in June 2016, the Commission set out the necessary features of a PAC PPS and considered the effects on payments of moving to such a system. Using readily available data on patient characteristics (such as age, reason to treat, and comorbidities), the Commission's PAC PPS design accurately predicted the costs of stays for most patient groups, although functional assessment information—uniform across settings—would further align payments with the cost of certain types of stays. This PAC PPS design is conceptually consistent with past Commission recommendations to revise the SNF and HHA PPSs.

A PAC PPS would redistribute payments among types of stays and settings. Payments would decrease for rehabilitation care unrelated to patient characteristics (for example, for patients recovering from hip surgery who receive high amounts of rehabilitation therapy services regardless of their care needs) and increase for medically complex care (for example, for patients with comorbidities that involve multiple body systems). The redistribution of payments is consistent with what would result from past Commission recommendations to revise the SNF and HHA PPSs. Equity in payments would increase across types of patients and the providers that treat them because the relative profitability across types of stays would become more uniform. Therefore, providers would have less incentive to selectively admit certain types of patients over others.

The Commission supports the implementation of a PAC PPS sooner than the timetable outlined in IMPACT. The Act does not require the implementation of a PAC PPS—only recommendations for a design. Further, the Act's schedule would make it unlikely that a new payment system would be proposed before 2024, and implementation would follow even later. The Commission recommends that a new PAC PPS begin implementation in 2021, with a three-year transition. The Commission finds that Medicare payments exceed providers' costs by 14 percent across the PAC settings and recommends that the aggregate level of payments be lowered by 5 percent to more closely align payments with the cost of care. The Secretary of the Department of Health and Human Services should begin aligning the setting-specific regulations when the PPS is implemented to level the playing field among providers—an area the Commission will begin working on as well. In addition, the Secretary would need the authority to revise and rebase PAC PPS payments over time to keep payments aligned with the cost of care. Providers could be given the option to bypass the transition and be paid full PAC PPS payments. While this option would raise program spending during the transition, it would more quickly base payments on patient characteristics and make them more equitable.

Medicare Part B drug payment policy issues

Chapter 2 presents the Commission's recommendation to improve Medicare payment for Part B drugs. Medicare Part B covers drugs administered by infusion or injection in physician offices and hospital outpatient departments. It also covers certain drugs furnished by suppliers. In 2015, Medicare and its beneficiaries paid about $26 billion for Part B–covered drugs and biologics, two-thirds of which was accounted for by biologics. Since 2009, Medicare Part B drug spending has grown at an average rate of about 9 percent per year.

The Commission is concerned about the overall price Medicare pays for Part B–covered drugs, the lack of price competition among drugs with similar health effects, and the rapid growth in Part B drug spending. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). It also assigns generic drugs and their associated brand products to a single billing code, which creates price competition. By contrast, it pays for most single-source drugs and biologics under separate billing codes—which does not create price competition among products with similar health effects. In addition, the 6 percent add-on to ASP may create incentives for providers to choose higher priced drugs over lower priced drugs.

The Commission's recommendation improves the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system. In the short term, we recommend:

- *Improving ASP data reporting.* CMS relies on manufacturers to submit their sales data in order to calculate ASPs for Part B drugs, but not all manufacturers are required to do so. A policy requiring all Part B drug manufacturers to report ASP data and giving the Secretary the authority to enforce penalties on manufacturers who do not report required data would improve the accuracy of ASP payments.
- *Modifying payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC).* Medicare generally reimburses new, single-source Part B drugs at 106 percent of WAC when ASP data are not available. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. A policy reducing the payment rate for drugs currently paid at 106 percent of WAC to 103 percent of WAC would help reduce excessive payments for these drugs.
- *Establishing an ASP inflation rebate.* 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. An ASP inflation rebate policy would protect the Medicare program and beneficiaries from rapid price increases for individual products.
- *Establishing consolidated billing codes.* The structure of the ASP payment system—with the reference biologic drug assigned to one billing code and its biosimilar drugs assigned to a different billing code—does not spur price competition among these products. A policy requiring use of consolidated billing codes to group a reference biologic drug with its biosimilar drugs would encourage price competition among these Part B drugs.

Over the longer term, the Commission recommends Medicare develop an alternative program—which we refer to as the Part B Drug Value Program (DVP)—that would allow providers to voluntarily enroll and would use private vendors to negotiate drug prices with manufacturers. The DVP would be informed by Medicare's experience with the competitive acquisition program (CAP) for Part B drugs (in effect between 2006 and 2008), but it would be structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the DVP, a small number of vendors would negotiate prices for Part B drugs, but, unlike the CAP, vendors would not ship product to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries, through lower cost sharing, as well as with DVP vendors and Medicare.

The Commission's recommendation takes a balanced approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Medicare payment for Part B drugs, through both a regulatory approach and a market-based approach, and policies that would achieve savings not just by modifying provider payment incentives but also by creating pressure for drug manufacturers to reduce or slow the growth of drugs prices.

Using premium support in Medicare

Medicare finances Part A and Part B using a combination of government funding and beneficiary premiums. Most beneficiaries are not required to pay a premium for Part A coverage. For Part B coverage, most beneficiaries pay a standard premium regardless of whether they are enrolled in the FFS program or an MA plan. As a result, beneficiary premiums do not reflect any differences in the underlying cost to Medicare of providing the Medicare benefit package through the FFS program or through an MA plan.

Under a premium support model, the amount that the government pays for each beneficiary's Medicare coverage in a given market area could be changed to a fixed dollar amount that would remain the same whether the beneficiary enrolled in the FFS program or in a managed care plan. Beneficiaries would pay premiums that equal the difference between the overall cost of providing the Medicare benefit package and the government contribution. As a result, premiums for FFS coverage and managed care plans would vary based on the underlying differences in their overall costs. Plans with lower overall costs would charge lower premiums, while plans with higher overall costs would charge higher premiums. Premium support has been used in the Part D program since its inception.

The Commission makes no recommendation on whether premium support should be used in the Medicare program. Given the Congress's interest in premium support and the Commission's role in providing analysis and guidance on Medicare issues, Chapter 3 examines some of the key issues that policymakers may want to resolve if they decide to use premium support in Medicare and discusses some of the potential consequences of taking particular approaches on a number of issues. Because of the complexity of this topic, this chapter does not examine all of the issues raised by premium support. The key issues discussed in this chapter are as follows.

What would be the role of the FFS program, which covers about 70 percent of all Medicare beneficiaries? Under many premium support proposals, the FFS program would be maintained and would be treated as a competing plan when calculating beneficiary premiums. Under this approach, Medicare would develop a "bid" for FFS that, together with managed care plan bids, would determine the Medicare contribution and beneficiary premium for each coverage option. This approach has several advantages:

- Beneficiary premiums would accurately reflect the relative cost of providing the Medicare benefit package through FFS compared with managed care plans.
- Beneficiaries who live in areas of the country where no managed care plans are available would have access to coverage.
- The continued presence of FFS and its payment rates would protect the Medicare program and managed care plans from paying higher commercial rates for Medicare beneficiaries.

Under this approach, beneficiaries would be free to select the type of coverage that best meets their preferences, but beneficiaries who choose more expensive coverage would pay the incremental cost.

How much should the coverage offered by the FFS program and managed care plans be standardized under a premium support system? Standardizing coverage would help ensure that beneficiaries have adequate coverage, would make it easier for beneficiaries to understand and compare their coverage options, would make bidding more competitive, and would facilitate Medicare's evaluation of plan bids. The FFS program and all plans could offer a standard package of benefits. The FFS benefit package could be changed in ways such as adding a cap on beneficiary out-of-pocket spending that would make it more comparable with plans' benefit packages. Managed care plans could have the flexibility to offer alternative forms of cost sharing that are actuarially equivalent, as MA plans can now. Plans could offer additional benefits if they wished, but plan enrollees would not be required to purchase them, and those who did would pay an additional premium that reflected the full cost of the additional benefits. Beneficiary premiums would also need to be standardized to reflect costs for a beneficiary of average health to ensure that premiums reflected differences in the underlying efficiency of each

coverage option instead of differences in the health of the beneficiaries enrolled. Finally, beneficiaries would need to have access to robust decision support tools that help them understand their coverage options and select the one that best meets their needs.

What method would be used to calculate the Medicare contribution and beneficiary premiums? The method would involve setting a "benchmark" consisting of two components: the Medicare contribution and a base beneficiary premium. The Medicare contribution would be the same for each coverage option, while the amount that beneficiaries would pay for each option would equal the base beneficiary premium plus or minus any difference between the plan's bid and the benchmark.

Many premium support proposals would use competitive bidding to determine benchmarks. Bids would need to be risk adjusted to reflect costs for a beneficiary of average health. The bidding process could also use geographic regions that reflect local health care markets. The use of local market areas would likely result in benchmarks that vary across areas (given the geographic variation in Medicare spending and service use that now exists) and would help protect beneficiaries who live in high-cost areas from paying much higher premiums.

One issue in premium support is how the Medicare contribution and the base beneficiary premium would grow over time. Limiting the growth of the Medicare contribution could reduce government spending but could also result in higher beneficiary premiums if spending growth exceeds the limit. An alternate approach would be to have the Medicare contribution and base beneficiary premium grow in tandem with plan bids and rely on competition among managed care plans to achieve savings.

How would high-quality care be rewarded under premium support? Under a premium support system, quality of care could be measured by comparing the performance of managed care plans and the FFS program on a set of population-based measures with a common, market area–level standard. Quality could be rewarded in two ways. In the first option, the government would require all plans to meet minimum standards and publicly release quality data, but it would not adjust the Medicare contribution based on quality. In the second option, the government would also require plans to meet minimum standards and publicly release quality data, but plans with higher quality scores would receive a higher Medicare contribution, which would allow them to charge lower beneficiary premiums.

What steps could be taken to mitigate or delay the impact of potentially higher premiums and protect low-income beneficiaries? The impact of a premium support system on beneficiaries' premiums would vary across market areas: In areas where FFS is less expensive than managed care, plan enrollees could face higher premiums; in areas where managed care is less expensive than FFS, FFS enrollees could face higher premiums. Some steps to mitigate or delay these effects include phasing in higher premiums over time or limiting the extent to which premiums for the different coverage options could vary. In addition, low-income beneficiaries would need to receive premium subsidies to ensure that they could obtain coverage.

The use of premium support could have significant effects on beneficiaries and managed care plans. Research on relevant issues such as the sensitivity of beneficiaries to changes in premiums provides some indication of potential effects. However, given the substantial number of actors and design choices (which go well beyond the issues raised in this chapter), there is no way to predict with certainty how premium support would play out. Experience in the MA and Part D programs indicates that beneficiaries respond to higher premiums by switching plans, but most beneficiaries keep their existing plan when premiums increase, and many beneficiaries who would benefit from changing plans do not switch. However, the changes in premiums could be larger under premium support than they have been in MA and Part D, which makes it difficult to estimate how many beneficiaries might switch coverage. Beneficiaries also consider factors other than premiums when selecting a health plan, such as provider networks. Health care plans would likely reassess which markets they serve and submit lower bids than they do currently because of the greater emphasis on price competition. On balance, the use of premium support would likely increase the number of beneficiaries enrolled in health care plans and reduce the number enrolled in FFS.

Mandated report: Relationship between physician and other health professional services and other Medicare services

Section 101(a)(3) of MACRA directs the Commission to submit a report to the Congress on the relationship between the use of and expenditures for services provided by physicians and other health professionals (whom we

refer to collectively as "clinicians") and total service use and expenditures under Part A, Part B, and Part D of Medicare. Chapter 4 fulfills that mandate. A positive correlation between services provided by clinicians and all other services would suggest that the services might be complements. Alternatively, a negative correlation would suggest clinician services and all other services could be substitutes for one another. Our findings suggest that clinician services and other services are neither clear complements nor clear substitutes.

Comparisons of service use (which adjust Medicare program spending for differences in Medicare prices and for beneficiary demographics and health status) are more meaningful than comparisons of spending. Our analysis of service use found that, in the aggregate, use of clinician services as a share of all Part A and Part B services increased from 24.4 percent in 2008 to 26.3 percent in 2013. In addition, across geographic areas, there was a moderately positive correlation in 2013 between use of clinician services and use of all Part A and Part B services. However, when we removed clinician services from use of all Part A and Part B services, we found a weak relationship between percentage change in clinician services and percentage change in all other Part A and Part B services. This finding implies that increasing clinician services had little or no effect on use of all other services.

Our analysis for the years 2008 and 2013 of a subset of FFS beneficiaries who received their drug coverage through the Part D program found a weak to modest positive correlation between the level of clinician and Part D service use. The regression models explained very little of the variation observed across geographic areas.

Redesigning the Merit-based Incentive Payment System and strengthening advanced alternative payment models

MACRA repealed the sustainable growth rate (SGR) system and established a new approach to updating payments to clinicians. It established two paths—a path for clinicians who participate in A–APMs and a path for other clinicians (MIPS). Beginning in 2019 and continuing through 2024, clinicians will receive a 5 percent incentive payment if they have sufficient participation in an A–APM. From 2026 on, clinicians meeting the criteria for participation in an A–APM will receive a higher update than other clinicians.

As CMS has begun to implement these two paths, it is becoming apparent that there are some serious challenges, some of which follow from basic issues in MACRA. Although MACRA repealed the SGR and addresses some of its shortcomings, it sets up a complex system in which some signals to improve value may not be well aligned. It is always difficult mid-implementation to judge what sort of program will eventually result, but the Commission is concerned by the direction the program is taking. Therefore, although we have not made any recommendations as yet, we have started to discuss ideas for improvement and present some of these ideas in Chapter 5.

There are four categories in MIPS; performance in those categories will determine whether clinicians in MIPS receive a bonus or a penalty on their Medicare FFS payments. MIPS as presently designed is unlikely to help beneficiaries choose clinicians, help clinicians change practice patterns to improve value, or help the Medicare program reward clinicians based on value. In part, this result is likely because the MIPS quality category allows clinicians to choose six measures from a large set of process measures, and if they choose measures that are "topped out" (everyone does very well on them), they will have high scores. Two other MIPS categories rely on clinician attestation that they are engaged in certain activities; clinicians will likely score high on them also. (The fourth category, cost, has been given a zero weight for 2019.) As a result, although MIPS will mechanically identify clinicians as being high or low "value," that distinction may not reflect any true differences among clinicians. This outcome will not be helpful to achieve the aims of MIPS, and it will impose a considerable reporting burden on clinicians.

Chapter 5 discusses an alternative model for MIPS, which would start with the institution of a quality withhold for all services under the physician fee schedule (PFS) (i.e., payment rates are reduced by a set percentage and then returned or not, depending on performance on quality). It would eliminate the current set of MIPS measures and instead would rely on population-based outcome measures. (Fundamentally, it may not be possible for the national Medicare program to accurately judge individual clinicians on quality because there are too few cases per clinician for measures to be reliable.) The proposed outcome measures would be calculated from claims or surveys, and thus would not require burdensome clinician reporting. Under this alternative model, clinicians could choose to join an A–APM, join a group of clinicians that

they define, be measured in a group of clinicians that Medicare defines, or elect not to be measured at all. If they choose to be associated with a group, that group would need to care for a population of beneficiaries of sufficient size for the measures to be reliable.

If the clinicians chose not to be measured at all, they would lose the MIPS quality withhold. If they were in an A–APM, the withhold would be returned to them. If they were in either a self-defined group or a Medicare-defined group, the group's performance would determine how much of the withhold is returned or whether a quality bonus in excess of the withhold would be given.

MACRA includes a 5 percent incentive payment for clinicians who have a sufficient amount of their FFS revenues coming through A–APM entities. Currently, clinicians must reach a threshold of revenue through an A–APM (e.g., 25 percent, 50 percent) to be eligible for the 5 percent incentive payment, but the incentive payment is then applied to all of their PFS revenue—whether or not it comes through the A–APM. Instead, we discuss making the reward related solely to the revenue coming through an A–APM. There would be no threshold; instead, the incentive payment would be proportional to A–APM involvement: Any PFS payment coming through an A–APM would get the 5 percent incentive payment added to it. This design would create greater certainty of payment, be more equitable, and would create an incentive for clinicians to move their services to A–APMs.

MACRA creates a fund of $500 million per year for MIPS (from 2019 to 2024) to reward clinicians with "exceptional performance" on their MIPS scores. Moving this fund from MIPS to A–APMs would shift clinician incentives toward A–APMs by making MIPS less attractive. We discuss using this money to fund an asymmetric risk corridor for two-sided-risk ACOs that qualify as A–APM entities. Also, we discuss a possible design for an A–APM that might be more attractive to a small practice that is reluctant to take on a large amount of risk relative to its revenue.

We recognize that these alternative constructs are a departure from the current design of MIPS and the planned application of the 5 percent A–APM incentive payment. The alternative models are meant to inform further policy discussions and to start to address the inherent difficulties in assessing clinician performance and the challenges of moving clinicians toward reformed payment and delivery systems.

Payments from drug and device manufacturers to physicians and teaching hospitals in 2015

Under the Open Payments program, drug and device manufacturers and GPOs report information to CMS about payments to physicians and teaching hospitals. This program has shed significant light on industry ties to these providers; we discuss its 2015 results in Chapter 6.

The Open Payments database contains information on financial interactions that were worth $7.3 billion in 2015. Payments for research accounted for just over half of the total; general payments (e.g., royalties and speaking fees) accounted for 35 percent; and physician ownership or investment interests accounted for 11 percent. The data include payments from 1,455 companies to about 618,000 physicians and 1,111 teaching hospitals. Physicians accounted for just over 80 percent of the payments and other transfers of value ($6.0 billion); teaching hospitals accounted for almost 20 percent ($1.3 billion).

Of note:

- The distribution of general payments to physicians was highly skewed. The top 5 percent of physicians accounted for 86 percent of the dollars; each of these physicians received about $56,000 in payments, on average. Likewise, the distribution of general payments to teaching hospitals was highly concentrated: 51 percent of the value of these payments went to a single hospital.
- Royalty or license payments to physicians totaled $527 million and had the highest average amount per physician: about $233,000. About 2,300 physicians received one of these payments.
- Compensation for services other than consulting (e.g., promotional speaking fees) amounted to $509 million and went to about 31,000 physicians.
- The physician specialties with the highest amount of general payments were internal medicine ($420 million) and orthopedic surgery ($410 million).

Although the Open Payments program has increased the transparency of financial interactions between manufacturers and physicians and teaching hospitals, it should be expanded. In 2009, the Commission recommended that financial ties between manufacturers and a broad range of providers and other entities (e.g.,

physicians and other prescribers, pharmacy benefit managers, hospitals, medical schools, organizations that sponsor continuing medical education, patient organizations, professional organizations) be publicly reported. We are especially concerned that manufacturers have financial relationships with many advanced practice registered nurses, physician assistants, and patient organizations, but these relationships are not reported. In addition, the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans. Finally, CMS should require companies to report whether they are GPOs or manufacturers, what type of products they make, whether they are physician-owned distributors (PODs), and the portion of a research payment that is related to physician compensation.

An overview of the medical device industry

The medical device industry makes a wide range of products—from surgical gloves to artificial joints to imaging equipment—and plays an important role in developing new medical technologies. Chapter 7 provides a brief introduction to the industry and its role in the Medicare program. The industry has a relatively small number of large, diversified companies and a large number of smaller companies that are mainly engaged in research and development of new devices for specific therapeutic areas. The industry is distinctive for its tendency to make frequent, incremental changes to its products and for its extensive ties with physicians. Large medical device companies are consistently profitable and typically have profit margins of 20 percent to 30 percent.

Like prescription drugs, medical devices are regulated by the Food and Drug Administration (FDA). However, the regulatory framework that the Congress has established for medical devices is less stringent in many respects. For example, most devices that are low risk can be marketed without FDA review.

The market dynamics for medical devices can vary greatly. Markets for conventional devices like routine surgical supplies are competitive; companies compete heavily on price and often need high sales volumes to be profitable. In contrast, markets for advanced products like implantable medical devices involve opaque pricing and are less competitive, which allows device companies to charge higher prices and earn substantial profits.

Medicare does not pay for medical devices directly. Instead, the average cost of medical devices is bundled into Medicare's overall payment rate for many services, giving hospitals, for example, an incentive to use lower cost devices. However, physicians' incentives may run in the opposite direction because they are generally not financially responsible for the cost of the device and may have financial connections to the device industry. Medicare cost report data indicate that hospitals spent about $14 billion on implantable devices and $10 billion on medical supplies (e.g., handheld surgical instruments) for Medicare-covered services in 2014.

Future changes to improve the quality of medical devices and reduce their associated costs could focus on improving the availability of device- and provider-specific information and aligning provider incentives. Such improvements could include adding more device-specific information to administrative claims, improving reporting by PODs under the Open Payments program, limiting the number of PODs, and more broadly allowing initiatives that encourage hospital–physician collaboration to reduce device costs.

Stand-alone emergency departments

The number of health care facilities devoted primarily to ED services and located apart from hospitals—referred to as "stand-alone EDs"—has grown rapidly in recent years. In Chapter 8, we look at some salient aspects of this phenomenon.

The majority of stand-alone EDs have opened since 2010. This growth has been driven by payment systems that reward treating lower severity cases in the higher paying ED setting, competition for patient market share, and an exemption in law that allows stand-alone EDs to receive higher hospital outpatient payments for non-ED services. Although, potentially, stand-alone EDs could expand access to ED services in underserved areas, very few stand-alone EDs are in fact located in rural areas. In 2016, almost all of the 566 stand-alone EDs were located in metropolitan areas that have existing ED capacity. They also tended to be located in more affluent ZIP codes, with higher household incomes and higher shares of privately insured patients.

Stand-alone EDs come in two forms: (1) off-campus emergency departments (OCEDs), which are affiliated with a hospital and therefore reimbursed by Medicare; and (2) independent freestanding emergency centers (IFECs), which, until recently, were not typically affiliated with a hospital and therefore not eligible for Medicare reimbursement. However, in recent years, many IFECs

have chosen to affiliate with hospitals to enable them to bill Medicare. Medicare pays OCEDs the same rates as on-campus hospital EDs, although available data suggest that stand-alone EDs tend to serve lower severity patients who are more similar to patients treated at urgent care centers than at on-campus hospital EDs.

In our June 2016 report to the Congress, the Commission discussed stand-alone EDs in the context of rural areas and suggested that rural stand-alone EDs could have a role in the Medicare program. In our March 2017 report, in response to the concern about a lack of Medicare claims data specific to stand-alone EDs, the Commission recommended that the Secretary require hospitals to add a modifier on claims for all services provided at stand-alone EDs. In the future, policymakers could consider reducing payment rates for OCEDs; encouraging the development of stand-alone EDs in areas with inadequate access to ED services; and eliminating policy exceptions to site-neutral payment for ambulatory (i.e., hospital outpatient and physician) services.

Hospital and SNF use by Medicare beneficiaries who reside in nursing facilities

Transferring Medicare beneficiaries who are long-stay NF residents to a hospital for conditions that could have been prevented or treated by the NF exposes beneficiaries to health risks and unnecessarily increases Medicare program spending. Although Medicare does not pay for the long-term portion of NF care, it does pay for hospital use by long-stay NF residents. High rates of hospital use may indicate poor care coordination between the NF staff and physicians or poor quality of care provided within the NF. In addition, transferring long-stay residents to the hospital may result in a higher paid Medicare SNF stay following hospital discharge. In response to Medicare's Hospital Readmission Reduction Program, some hospitals have begun to pressure NFs to adopt strategies to reduce hospital use, such as increased staff communication, staff training, medication review, and advance care planning.

In Chapter 9, we consider the use of hospitals by long-stay NF residents. The Commission developed facility-level measures to track use of hospitals by long-stay NF residents, including all-cause hospital admissions, potentially avoidable hospital admissions, and a combined measure of emergency department visits and observation stays. We also developed a measure of long-stay beneficiaries' use of Medicare-paid SNF care following discharge from the hospital.

We found wide variation in the rates of hospital and SNF use across facilities. Several facility-level characteristics helped to explain the variation in the measures of hospital use, including the frequency of physician visits and access to on-site X-ray capabilities. Differences in state Medicaid policies may explain some of the variation observed across states, but we also observed high within-state variation. This variation indicates potential disparities in quality across facilities and suggests opportunities for reductions in hospital and SNF use for long-stay NF residents, which would reduce potential harm to beneficiaries and unnecessary Medicare spending.

CMS and the Congress could evaluate policies regarding hospital and SNF use by long-stay NF beneficiaries. CMS could consider developing measures of hospital and SNF use to incorporate into the NFs' public reporting requirements; if successful, the Congress could consider expanding the SNF value-based purchasing program to include additional measures such as a long-stay NF resident–hospital admission measure. CMS could also consider focusing on aberrant patterns of hospital and SNF use as part of the agency's program integrity efforts.

Provider consolidation: The role of Medicare policy

In Chapter 10, we discuss the implications for the Medicare program of consolidation in the health care industry. We first discuss the current level of provider consolidation and its effect on prices and quality. Next, we discuss vertical consolidation of provider functions and insurer functions by ACOs or MA plans.

Arguments in favor of consolidation include economies of scale, consolidating services into centers of excellence, access to capital, improved coordination, relieving physicians of practice management duties and regulatory burdens, elimination of duplicative services through common electronic medical records, and improved quality of care. However, the literature finds weak evidence that financial consolidation consistently leads to lower cost or higher quality.

- Hospitals have been consolidating horizontally for the past 30 years. The resulting increased market power has contributed to a growing divergence between the prices Medicare pays hospitals and the prices commercial insurers pay hospitals. Commercial prices average about 50 percent higher than hospital costs and often far more than 50 percent above Medicare prices. The result is that hospitals' all-payer profit

margins reached a 30-year high in 2014, averaging 7.3 percent nationwide.

- Physician horizontal consolidation can also lead to higher prices. Commercial prices tend to be higher in more concentrated markets and tend to increase after physicians integrate with hospitals. We also show that providers with greater domination within a given market tend to receive higher prices than others in the market.
- Vertical physician–hospital consolidation increases both commercial and Medicare prices paid for physician services. Commercial physician prices may increase because of the market power of the hospitals owning the practices. Medicare prices increase because of the Medicare program paying hospital facility fees. For example, the Commission estimated that the Medicare program would have spent $1.6 billion less in 2015 if prices for evaluation and management office visits in hospital outpatient departments were the same as freestanding office prices.

The effect of insurer–provider consolidation on costs and competitiveness is less clear. Some vertically integrated organizations have been profitable and have strong reputations, but in other cases, integrated entities with strong reputations have divested their insurance organizations. In the case of Medicare, there is a growing movement of patients into MA plans, some of which integrate care of patients in a group- or staff-model HMO and some of which contract with otherwise unaffiliated providers. While some MA plans (in particular some HMOs) can control service use, this ability has not translated into program savings because of the way MA benchmarks are set and the way the program adjusts for coding.

In response to horizontal consolidation, the Commission has recommended restraining Medicare prices rather than following increases in commercial prices. As a result of Medicare price restraints, from 2007 to 2016, the cost of Part A, Part B, and Part D benefits per FFS beneficiary increased by about 23 percent. By comparison, employer-sponsored HMO and preferred provider organization commercial premiums grew by about 50 percent over the same period. In response to vertical provider consolidation, the Commission has recommended imposing site-neutral pricing. By creating true "site-neutral" payments, the Medicare program could be further insulated from the cost of physician–hospital consolidation. Integration that improves care and generates efficiencies would still occur, but consolidation that is driven primarily by capturing new facility fees would not.

In response to consolidation of provider and insurance functions, the Commission has discussed synchronizing payments across MA plans, ACOs, and FFS so that they could compete on a level playing field. We have found that MA, traditional FFS, and ACOs all have the potential to be the low-cost option in some markets. Because no one model is dominant, one policy option is to make Medicare contributions financially neutral among MA, traditional FFS, and ACOs, enabling market forces to illuminate the model that is most efficient given particular market conditions. ■

CHAPTER 1

Implementing a unified payment system for post-acute care

RECOMMENDATION

The Congress should direct the Secretary to:

- implement a prospective payment system for post-acute care beginning in 2021 with a three-year transition;
- lower aggregate payments by 5 percent, absent prior reductions to the level of payments;
- concurrently, begin to align setting-specific regulatory requirements; and
- periodically revise and rebase payments, as needed, to keep payments aligned with the cost of care.

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

CHAPTER 1

Implementing a unified payment system for post-acute care

Chapter summary

In 2015, Medicare spending on post-acute care (PAC) services totaled $60 billion. Although the types of cases treated in the four main PAC settings (skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs)) overlap, Medicare's payments for similar patients can differ substantially, in part because Medicare uses separate prospective payment systems (PPSs) to pay for stays in each setting. There is considerable variation in the supply and use of PAC providers across the country as well as an absence of evidence-based criteria guiding decisions about which patients require PAC, which PAC setting is most appropriate for a given patient, and how much care is needed. These factors undermine clear policies to guide PAC placement decisions.

Given the overlap between PAC settings in the patients they treat, the Commission has long promoted the idea of moving to a unified PAC PPS that spans the four settings, with payments based on patient characteristics rather than the site of service. As required by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT), the Commission, in June 2016, recommended the necessary features of a PAC PPS and considered the effects on payments of moving to such a system. Using readily available data on patient characteristics (such as age, reason to treat, and comorbidities), the Commission's PAC PPS design accurately predicted the costs of stays for most patient groups, although functional assessment information—uniform

In this chapter

across settings—would further align payments with the cost of certain types of stays. This PAC PPS design is conceptually consistent with past Commission recommendations to revise the SNF and HHA PPSs.

A PAC PPS would redistribute payments among types of stays and settings. Payments would decrease for rehabilitation care unrelated to patient characteristics (for example, for patients recovering from hip surgery who receive high amounts of rehabilitation therapy services regardless of their care needs) and would increase for medically complex care (for example, for patients with comorbidities that involve multiple body systems). The redistribution of payments is consistent with those estimated by the Commission in its recommended redesigns of the PPSs for HHAs and SNFs. The equity in payments would increase across different types of patients, and the providers that treat them, because the relative profitability across types of stays would be narrower. Therefore, providers would have less incentive to admit certain types of patients over others.

The Commission supports the implementation of a PAC PPS sooner than the timetable outlined in IMPACT. On the Act's schedule of required reports on a design, it is unlikely that a new payment system would be proposed before 2024 for implementation sometime later. And while the Act requires recommendations for a design, it does not require the implementation specifically of a PAC PPS. The Commission believes that the implementation could begin as early as 2021, assuming some regulatory alignment is underway that would begin to standardize requirements across the settings. The implementation could begin with a design using readily available data and be refined when uniform assessment data become available.

This year, we return to our analysis of the PAC PPS design to explore three implementation issues. First, we examine whether the implementation should include a transition during which providers would be paid a blend of current (setting-specific) rates and a PAC PPS rate. A multiyear transition would extend the inequities in the current PPSs and delay the much-needed redistribution of payments. However, it would give providers time to adjust their costs and patient mix to the new payment system. Although the PAC PPS would change payments for many providers, the Commission concludes that, because the majority of those that would experience decreases in payments had above-average profitability, the transition period could be short.

Policymakers could allow providers the option to bypass the transition and move immediately to full PAC PPS rates. However, because providers whose payments are likely to increase under a full PAC PPS would be more likely to exercise

this early option, allowing providers to bypass the transition would likely raise aggregate spending above current levels during the transition period. This additional cost could be mitigated by lowering the level of PAC payments.

A second implementation issue is whether the Congress should consider lowering the level of total PAC payments when the PPS is implemented so that payments more closely align with the cost of stays. In aggregate, we estimate that current payments to PAC providers exceed the cost of stays by 14 percent, with some variation across the patient groups. In its March 2017 report to the Congress, the Commission discussed the high level of FFS payments relative to the costs of care in PAC and recommended lowering payments to HHAs and IRFs and freezing payments to SNFs and LTCHs. Our analyses indicate that, even if payments were lowered by 5 percent, the average payments across all stays and for the 30 clinical groups we examined would remain well above the average cost of stays.

Finally, if it mandates the implementation of a PAC PPS, the Congress should provide the Secretary with the authority to perform the ongoing maintenance that is required in any payment system to keep payments and costs aligned. Medicare's experience with major payment policy changes has shown that providers will modify their costs and practices in response to such changes, thereby enabling them to maintain profitability. The Secretary will need to make regular refinements in response to changes in costs and practices to ensure that relative payments across different types of stays remain accurate. The Secretary also would need the authority to rebase payments if costs change significantly. Without this authority, over time, aggregate program payments could be too high or too low relative to the cost of stays.

The Commission's recommendation states that a PAC PPS be implemented beginning in 2021 with a three-year transition. The aggregate level of payments should be lowered by 5 percent to more closely align payments to the cost of care. To level the playing field among providers, the Secretary would need to begin aligning the setting-specific regulations when the PPS is implemented. The Secretary would also need the authority to revise and rebase PAC PPS payments over time to keep payments aligned with the cost of care.

In its discussion of the recommendation, the Commission calls for taking the 5 percent reduction at the beginning of the transition for several reasons. First, the level of payments is high. Second, a multiyear transition would phase in the impacts of the new payment system, thereby lessening its immediate effect. Third, providers are likely to change their costs, patient mix, and practices to maintain their payments well above the cost of care. Last, providers whose payments would

increase under a PAC PPS are likely to bypass the transition and be paid full PAC PPS payments, if given the option. The Commission notes that, while this option would raise program spending during the transition, overall the proposal would reduce spending and would redistribute payments toward stays for medical conditions and away from stays with therapy services unrelated to a patient's condition. ■

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 important recuperation and rehabilitation services to Medicare beneficiaries. In 2015, Medicare fee-for-service (FFS) spending on these services totaled $60 billion. Although the types of cases treated in the four settings overlap, Medicare's payments can differ substantially, in part because Medicare uses separate prospective payment systems (PPSs) to pay for stays in each setting. Two of those PPSs (for HHAs and SNFs) encourage the provision of therapy services over medically complex care. Some of the difference in payments reflects the considerably different regulatory and statutory requirements for each setting (see online Appendix 3-B from the Commission's June 2016 report to the Congress, available at http://www.medpac.gov). At the same time, there is an absence of evidence-based criteria guiding decisions about where patients should receive PAC and how much care they should receive. The only study to compare outcomes across the settings for a broad range of clinical conditions did not find consistent differences in rates of readmission to hospitals or in improvement in mobility or self-care (Gage et al. 2012). These factors contribute to considerable variation in the supply and use of PAC providers across the country. Given the overlap between settings for treating similar patients, the Commission has long promoted the idea of moving to a unified PAC PPS that spans the four settings, with payments based on patient characteristics, not the site of service (Medicare Payment Advisory Commission 2016).

As required by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT), the Commission, in June 2016, recommended necessary features of a PAC PPS and considered the impacts of moving to such a system. A second Commission report outlining the details of a prototype design is due in 2023, after the Secretary of the Department of Health and Human Services has collected and analyzed common patient assessment information and submitted a report to the Congress in 2022 recommending a PAC PPS. On this timetable, it is unlikely that CMS will propose a PAC PPS before 2024, with implementation occurring sometime after that, assuming that the Congress has granted it the authority to do so. IMPACT does not require the Secretary to implement a PAC PPS.

In its June 2016 report to the Congress, the Commission reported that a unified PPS is feasible using readily available data and that such a system would correct distortions that are present in the setting-specific PPSs. The Commission found that an initial PAC PPS design could be based on existing administrative data and therefore could be implemented earlier than the current timetable. However, because functional assessment data would improve the accuracy of payments for some patient groups, the Secretary should incorporate this dimension into the risk adjustment method when uniform patient assessment becomes available. We also found that payments in 2013 (the year of data we used for the analysis) far exceeded the cost of care.

This year, we return to our analysis of the PAC PPS design. We begin by reviewing the key findings from our June 2016 report and then consider three aspects of implementation. First, we discuss a transition policy that would phase in the implementation over multiple years and whether providers should have the option to bypass it and immediately be paid full PAC PPS payments. Second, we assess whether the Congress should lower aggregate payments so that they are more closely aligned with the cost of care. Last, we discuss the regular maintenance and rebasing that the Secretary will need to conduct to keep payments and costs aligned.

Review of June 2016 key findings

In June 2016, we reported that a PAC PPS is within reach. It is possible to design a payment system for a uniform unit of service (a stay in a PAC setting) and to adjust payments using a uniform set of patient and stay characteristics (such as clinical conditions) that do not include the amount of service furnished to a patient. The design includes a common unit of service (a stay) and risk adjustment method based on patient characteristics and considers PAC stays with and without a prior hospitalization (consistent with the current PAC PPSs) (Table 1-1, p. 8).[1] We confirmed that a PAC PPS is feasible, but the Commission fully expects that the Secretary would consider our conclusions as a starting point for the design of a unified PAC PPS.

Under this design, payments to HHAs would be adjusted to reflect this setting's considerably lower costs.[2] This adjustment would need to be set so that it does not interfere with clinical decision making; that is, it would neither financially encourage nor discourage the use

TABLE 1–1 **Commission's key recommended design features of a PAC PPS**

Design feature
• A common unit of service (e.g., institutional stay or home health stay)
• A common method of risk adjustment that relies on administrative data on patient characteristics and incorporates functional status as these data become available
• Two payment models (one for routine and therapy services, another one for nontherapy ancillary services) to reflect differences in benefits across settings; sum of the two payments establish the total payment amount for the stay
• Adjustment of payments for home health stays to prevent considerable overpayment
• A high-cost outlier policy to protect providers from incurring large losses and help ensure beneficiary access to care
• A short-stay outlier policy to prevent large overpayments for unusually short stays
• Uniform application of any payment adjusters across all providers

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

Source: Medicare Payment Advisory Commission 2016.

of home health care. The design would need to include two outlier policies: one for unusually short stays and one for unusually high-cost stays. To help compensate for inaccurate payments for high-cost stays during the transition period, the design could include a large outlier pool that would get smaller over time as assessment data and refinements were incorporated into the PAC PPS.

We found that models could accurately predict the average costs of most stays.[3] We "stress tested" the models by examining the accuracy of predicted costs for more than 30 different patient groups, including 4 definitions of medically complex stays. For patient groups with predicted costs that differed substantially from the stays' actual costs, current practices (such as the provision of therapy services unrelated to patient characteristics) or the cost structures of high-cost settings explained the results.

We compared the accuracy of designs with and without functional assessment data and confirmed that designs using readily available administrative data were accurate for most of the patient groups. However, patient assessment data would increase the accuracy of payments for certain types of stays (for example, patients with low or high functional status). The Commission noted that the Secretary could implement a PAC PPS sooner than the time frames outlined in IMPACT, by beginning with a design that does not rely on patient assessment data and refining the payment system over time as those data become available. Providers are required to begin collecting certain uniform patient assessment information (including functional status) in October 2018 for institutional PAC providers and in January 2019 for HHAs, with other items to be added later.

Payment implications of a PAC PPS

We estimated the payment implications of a PAC PPS, assuming no changes in provider behavior. A PAC PPS would redistribute payments among types of stays and settings and correct some of the distortions in current payment systems. Payments would decrease for rehabilitation care unrelated to patient characteristics (for example, for patients recovering from hip surgery who receive high amounts of rehabilitation therapy services regardless of their clinical condition) and increase for medically complex care (for example, patients with comorbidities that involve multiple body systems). The equity in payments across different types of patients, and across the providers that treat them, would increase because the relative profitability across types of stays would be narrower. Therefore, providers would have less incentive to admit certain types of patients over others. The shifts in payments and the increases in the equity of payments across types of stays would be consistent with the goals of the Commission's recommendations to revise the SNF and HHA PPSs.

Many of the various types of PAC stays are treated in all four settings, so payments based on the average cost

across settings would be considerably lower than current payments for the high-cost (and lower volume) settings, namely LTCHs and IRFs, while payments would be higher for the lower cost SNF setting. Because the objective of a PAC PPS is to base payments on patient characteristics, not setting, a redistribution of payments would be expected. A high-cost outlier policy and a multiyear transition would give providers time to adjust their costs and practice patterns to match the PAC PPS payments.

The Commission found that the average level of payment for PAC was considerably higher than the average cost of stays. Our impact analyses assumed that the PAC PPS was implemented on a budget-neutral basis (i.e., that the level of payments in aggregate would be the same as the current level). However, the Commission noted that the Secretary would need to consider lowering aggregate spending to more closely align Medicare's payments with providers' costs. Lowering aggregate spending on PAC would be consistent with the Commission's recommendations for many years regarding updates to FFS payments to SNFs, HHAs, IRFs, and LTCHs.

If past provider responses to other changes in payment policy are any guide, we would expect providers to change their costs and mix of patients in reaction to a PAC PPS. If they did, the impact on providers' payments would differ from our estimates. Over time, a PAC PPS would need to be updated to incorporate changes in practice, mix of patients, and absolute and relative costs of stays. Because Medicare's payment reforms—including accountable care organizations, bundled payment initiatives, the joint replacement demonstration, cardiac bundles, and Medicare Advantage plans—are based on the FFS payment model, a PAC PPS would influence payments under these alternative payment models. Reciprocally, these payment alternatives would likely influence FFS practices by, for example, encouraging shorter SNF stays and shifts in placement to lower cost PAC settings. When possible, some patients currently treated in IRFs and LTCHs would be shifted to SNFs, while some patients currently treated in SNFs would be discharged to home health care, without compromising patient outcomes. The lower costs associated with these shifts and shorter stays would be incorporated into the PAC PPS as payments are periodically recalibrated.

Conforming regulatory requirements

When Medicare begins to pay PAC providers under a single payment system, it will need to give providers more flexibility to offer services that span the PAC continuum of care. If certain regulations are waived or modified, providers can change their cost structures to more closely align them with PAC PPS payments. A more flexible structure would give providers the option to consolidate separate PAC operations into a single, larger institutional PAC unit to achieve greater economies of scale. Likewise, low-occupancy hospitals or PAC providers would have the flexibility to convert unused capacity to become an institutional PAC provider serving a broader mix of patients. Either scenario could create a higher volume of patients in one location that might encourage greater physician presence if the dispersion of PAC patients across multiple locations discourages physicians from conducting rounds on them.

The Commission discussed a two-part strategy to even out the different regulatory requirements across settings. In the near term, the Secretary could waive or modify select setting-specific requirements, such as the 25-day length of stay requirement for LTCHs and the 60 percent rule and intensive therapy requirements for IRFs. The Secretary currently has this authority for some setting-specific requirements (such as requiring intensive therapy for IRF patients) but would need to be granted the authority for others (such as the 25-day length of stay requirement for LTCHs). Note that revised regulatory requirements could, in some cases, result in more stringent requirements that raise the cost of care for some providers. For example, PAC providers could be required to have a registered nurse available 24 hours a day, 7 days a week—a level that is higher than the current 8-hour per day requirement for SNFs.

The Commission has proposed that, over the longer term, a common core set of conditions of participation be developed for all PAC providers, with additional requirements specified for providers that opt to treat patients who require specialized resources. Requirements would thus shift from being based on setting to being defined by the care needs of different types of patients. For example, additional requirements could be specified for patients requiring ventilator care, intensive rehabilitation therapy, and care management for severe wounds.

The effect of waiving requirements could be limited by state licensure, certificate of need, or other regulations that providers must meet. For example, providers that are certified for both Medicaid and Medicare and located in states with minimum staffing requirements for nursing homes would have less flexibility to change their staffing mix (and the accompanying costs) compared with

providers in other states. Because Medicare does not have the authority to change state requirements, providers would continue to meet state requirements, just as they do now when state and federal requirements differ.

The Commission also noted that, as Medicare moves toward uniform payment for PAC, the program would need to standardize its cost-sharing requirements, which currently vary by setting. This standardization would result in more rational PAC use for those beneficiaries who select a PAC setting based at least in part on cost-sharing requirements. Over the coming year, the Commission will examine this issue.

Companion policies to dampen FFS incentives

The Commission also discussed companion policies to dampen the underlying incentives of FFS payment design—that is, incentives to generate unnecessary volume or provide low-quality care if it is less costly. Companion policies include a readmission policy to prevent unnecessary hospital readmissions and a value-based purchasing program to protect beneficiaries against stinting and the program against unnecessary services. In addition to these policies, CMS would need to monitor provider behavior to detect inappropriate responses, including stinting on care that could result in poor outcomes; selecting patients who are likely to be relatively more profitable; generating unnecessary PAC stays; and delaying care that shifts, but does not lower, program spending. As unintended consequences are documented, the Secretary would need to revise the PAC PPS accordingly.

Options for transitioning to a PAC PPS

Given the accuracy of payments using readily available data, the Commission urges the implementation of a PAC PPS sooner than outlined in IMPACT. Policymakers will need to consider whether to include a transition policy that phases in the new PAC PPS over multiple years. A transition would extend the current inequities of the HHA and SNF PPSs and delay the redistribution of payments toward medical and medically complex cases (and away from stays with therapy services that appear unrelated to patients' characteristics). However, it would give providers time to adjust their costs and mix of patients. The Commission's impact analyses showing substantial changes in payment for many PAC stays and providers suggest the need for a transition. However, because, in general, providers that would incur the largest decreases in payments under the PAC PPS are also currently the most profitable, the Commission concludes that the transition should be short. By blending current and "new" payments, a transition would dampen the effects of the new payment system during the phase-in period. Policymakers could consider allowing providers the choice to bypass the transition altogether and move directly to full PAC PPS payments.

Year to begin the implementation

Our analyses indicate that the initial design of a PAC PPS could be based on administrative data, with refinements to the risk adjustment method to incorporate the uniform functional data when they become available. Under such a design, the Commission believes the Secretary could implement a PAC PPS as early as 2021, assuming some regulatory alignment is underway. The start date of a PAC PPS would depend on whether and how quickly the Secretary could waive or modify certain regulatory requirements now in place that raise the costs of care in some settings. To help compensate for inaccurate payments for high-cost stays during the transition period, the initial design could include a large pool of funds to pay for high-cost outlier cases, with the size of the pool decreasing over time as refinements improve the new PPS's accuracy. A high-cost outlier policy would help moderate the financial impacts of the new PPS on providers, especially as high-cost providers modify their cost structures and mix of patients.

Before implementation, the Secretary must complete a list of activities that is, admittedly, long but we believe achievable since CMS has deep experience with prior payment systems that have required identical actions. These activities include:

- Develop and validate the design of the payment system—such as its case-mix groupings, payment adjusters, and outlier policies. To expedite this process, the Secretary could begin using the Commission's work as a readily implementable starting point in identifying factors that should be considered in a case-mix system and other aspects of the PPS design. The Secretary may wish to use a more recent year of PAC stays in establishing the base year and PPS design.

- Identify (1) the regulatory and statutory requirements that need to be aligned before the beginning of the

transition and (2) begin to develop a common set of requirements for all PAC providers and additional requirements for providers opting to treat patients with special care needs.

- Identify measures to monitor and develop the systems that will track provider performance. Sample measures are described in Table 1-7 (p. 24).
- Revise and test the claims processing and other systems to pay providers, monitor quality, and track beneficiary cost sharing.
- Consider provider input through the Secretary's rule-making process.

Definition and rationale for a transition

A transition policy blends current policy payments with payments under a new policy, weighting current payments more heavily in the early years and new payments more heavily in later years, until current payments are phased out. The blending of current and new payments would temper the impact of the PAC PPS in the early years. Policymakers would need to decide the number of years over which to blend old and new payments and how to weight the blend of payments in each year. For example, a three-year transition could consider a one-third blend of new PAC PPS rates during the first year, a two-thirds PAC PPS blend during the second year, and full PAC PPS rates beginning the third year.

A transition begins the much-needed shift of payments toward medically complex care and away from therapy-based care that may be unrelated to a patient's condition. Further, by moving to a new payment system gradually in one-year increments, a transition would likely make it easier to gain provider support. In addition, a transition period would give providers time to adjust their costs and mix of patients, thereby protecting themselves from large payment reductions that could impede some beneficiaries' access to care. SNFs would transition from a day-based PPS to stay-based payments, thereby aligning their unit of service with that of other PAC providers. The high level of aggregate payments dampens the concern that payment reductions will affect access or threaten many providers' financial viability. However, a transition would extend the current inequities of the current HHA and SNF payment systems, thereby delaying the narrowing of differences in profitability across different types of stays. A long transition could run the risk that industry pressure would further delay or halt entirely the implementation of the new payment system.

Wide range in the effects of a fully implemented PAC PPS on payments suggests the need for a transition

To consider the need for a transition, we updated the results included in our June 2016 report based on 8.9 million PAC stays in 2013; the updated results reflect changes in costs and payments between 2013 and 2017 (see online Appendix 1-A, available at http://www.medpac.gov, for a description of the methodology). This update provides a more accurate picture of the need for a transition and the current misalignment between payments and costs. The estimated costs and payments in 2017 for these PAC stays are the starting point for all analyses included in this chapter. Consistent with past analyses, we have not modeled provider responses to the PAC PPS. Although changes in the mix of patients and cost per stay are likely, the analyses presented do not attempt to simulate the size of such changes or their likely effects. The analyses of the transition assume aggregate payments remain the same (the section on the level of payments, page 20, estimates the impacts of various reductions to total payments).

We confirmed that the model accurately predicts the costs of most of the more than 30 patient-stay groups we examined, including medically complex groups (Wissoker 2017). Differences in the relative profitability of PAC payments across patient groups would narrow considerably under a PAC PPS, so providers would have less incentive than they do now to admit some types of patients over others. A PAC PPS would redistribute payments from stays that include high amounts of therapy care not predicted by patients' clinical characteristics (for example, orthopedic stays with unusually high amounts of therapy care) to medical stays (such as severe wound or ventilator care). However, the design would not lower payments indiscriminately for rehabilitation care. Payments would be above average for patients with clinical characteristics and impairments indicating higher than average care needs. The resulting redistribution of payments would be consistent with the Commission's recommended changes to the SNF and HHA PPSs (Medicare Payment Advisory Commission 2011, Medicare Payment Advisory Commission 2008).

Policymakers can evaluate the need for a transition by considering the estimated impact of the PAC PPS on different conditions and types of providers. The effects of

TABLE 1–2

A fully implemented PAC PPS would affect payments differently by types of stay and setting, based on 2013 PAC stays' payments and costs updated to 2017 (continued next page)

Reporting group	Percent change in payments between PAC PPS payments and current payments	Ratio of average payment under a PAC PPS to average cost of stays	Percent of stays	Mix of stays by setting			
				HHA	SNF	IRF	LTCH
All stays	0%	1.14	100%	69%	25%	4%	2%
Cardiovascular medical	0	1.15	14	81	17	1	0
Orthopedic medical	–6	1.15	10	83	15	2	0
Orthopedic surgical	–3	1.14	10	44	44	12	0
Respiratory medical	5	1.15	9	62	34	2	2
Other neurology medical	–6	1.15	8	80	17	3	0
Serious mental illness	0	1.15	5	57	36	4	3
Severe wound	10	1.15	5	71	15	4	10
Skin medical	3	1.14	4	87	12	1	0
Cardiovascular surgical	7	1.14	3	53	36	10	2
Infection medical	1	1.14	3	35	57	4	4
Stroke	–2	1.13	2	30	41	28	1
Hematology medical	4	1.11	2	80	18	1	0
Ventilator	9	1.17	<1	6	14	1	79
Least frail	–4	1.15	7	92	8	0	0
Most frail	1	1.13	11	38	49	9	4
Cognitively impaired	–4	1.14	20	57	38	3	2
Multiple body system diagnoses	3	1.14	5	0	76	10	14
Chronically critically ill	8	1.14	5	31	46	10	13
Severely ill (SOI = Level 4)	6	1.13	4	0	71	12	17

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), SOI (severity of illness), I–PAC (intitutional post-acute care), ESRD (end-stage renal disease). Percent of stays do not total 100 percent because many of the groups overlap.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. "LTCH-qualifying" stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

a fully implemented PAC PPS on payments would vary considerably across the condition groups and providers we examined, even if aggregate PAC PPS payments were set equal to aggregate payments under current policy (i.e., even if, on net, there were no change in total payments) (Table 1-2).[4] For example, across the clinical conditions we examined, payment changes under a PAC PPS would range from a 10 percent increase for severe wound cases to a 6 percent decrease for orthopedic medical stays and for other neurology medical stays (excluding stroke).

We expected and found that payments for stays with low and high shares of therapy costs would change considerably under a PAC PPS. For patients who receive high amounts of therapy, payments would decline substantially because the amount of therapy (and the associated costs) furnished during many HHA and SNF

TABLE 1–2

A fully implemented PAC PPS would affect payments differently by types of stay and setting, based on 2013 PAC stays' payments and costs updated to 2017 (continued)

Reporting group	Percent change in payments between PAC PPS payments and current payments	Ratio of average payment under a PAC PPS to average cost of stays	Percent of stays	Mix of stays by setting			
				HHA	SNF	IRF	LTCH
No therapy costs for HHA stays	25	1.94	29	100	0	0	0
Lowest therapy costs for I–PAC stays	18	1.11	8	0	68	13	19
Highest therapy costs for HHA stays	–24	0.83	17	100	0	0	0
Highest therapy costs for I–PAC stays	–16	1.11	8	0	94	6	0
Community admitted	–4	1.16	50	94	5	1	0
Stays with prior hospital stay	1	1.14	50	44	46	7	3
Disabled	1	1.15	26	72	22	4	2
Dual eligible	–3	1.14	32	71	24	3	2
ESRD	2	1.14	4	62	30	5	4
Very old (age 85+ years)	–2	1.14	30	67	29	3	1
HHA	–1	1.16	69				
SNF	7	1.22	25				
IRF	–15	1.00	4				
LTCH: All stays	–15	0.89	2				
LTCH-qualifying stays	–9	0.95	1				
Nonprofit	9	1.09	22	65	26	9	1
For profit	–3	1.17	75	70	25	3	2
Hospital based	11	0.94	11	64	15	20	0
Freestanding	–1	1.18	89	69	27	2	2
Urban	–1	1.14	84	69	25	5	2
Rural	3	1.15	16	69	29	2	0
Frontier	10	1.13	<1	71	28	0	0

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), SOI (severity of illness), I–PAC (intitutional post-acute care), ESRD (end-stage renal disease). Percent of stays do not total 100 percent because many of the groups overlap.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. "LTCH-qualifying" stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

stays under the current PPS designs is unrelated to a patient's clinical conditions. Conversely, payments for stays with low therapy costs (for example, medical cases with multiple comorbidities) would increase substantially because the PAC PPS would base payments on the clinical conditions and complexity of the patient. Over time, under a PAC PPS, we would expect providers to change their therapy practices to match patients' characteristics.

As we expected, the impact on the high-cost settings (IRFs and LTCHs) would be large because most providers in these settings treat the types of cases that are also admitted

TABLE 1–3

Distribution of the changes in payments under a fully implemented PAC PPS, based on 2013 PAC stays' payments and costs updated to 2017 (continued next page)

	Decrease in payment			About the same	Increase in payment		
Stay or provider group	**>25%**	**10% to 25%**	**1% to 10%**	**−1% to +1%**	**1% to 10%**	**10% to 25%**	**>25%**
Reporting groups: Stays							
All stays (*N* = 8.9 million)	20%	12%	8%	2%	8%	12%	39%
Cardiovascular medical	16	10	9	2	10	15	38
Orthopedic medical	25	15	7	1	6	10	34
Orthopedic surgical	25	17	8	2	7	8	32
Respiratory medical	18	10	7	2	8	12	42
Other neurology medical	25	13	7	2	7	12	36
Serious mental illness	20	10	6	1	7	11	45
Severe wound	10	8	5	1	6	13	56
Skin medical	13	9	8	2	13	20	34
Cardiovascular surgical	16	11	7	2	8	12	43
Infection medical	22	10	6	1	6	9	46
Stroke	21	13	7	2	6	9	42
Hematology medical	13	10	8	2	8	13	45
Ventilator	18	17	8	2	6	8	41
Least frail	20	15	10	2	9	13	30
Most frail	21	11	6	1	6	9	44
Cognitively impaired	23	11	7	2	7	11	40
Multiple body system diagnoses	24	10	5	1	4	6	50
Chronically critically ill	18	11	6	1	6	9	47
Severely ill (SOI = Level 4)	22	10	5	1	5	6	51

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The percentages in each row may not sum to 100 because of rounding. The stay-level reporting groups show the distribution of the change in payments for the stays in the each group. The provider-level analysis shows the distribution of the change in the average payment for the providers in the group.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. The provider reporting groups include providers with at least 20 stays.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

to lower cost (and higher volume) settings. Payments to IRFs and LTCHs would decrease by 15 percent, while payments to SNFs would increase 7 percent.[5] On average, nonprofit, hospital-based, and frontier providers would experience fairly large increases in payments (9 percent, 11 percent, and 10 percent, respectively), while for-profit, freestanding, and urban providers would experience small decreases. The magnitude of these changes, especially for LTCHs and IRFs, suggests that a transition is desirable.

We also found that if a PAC PPS were implemented to maintain aggregate PAC payments at the current level, the level of PAC payments would remain well above the cost of stays. We estimate that the average PAC PPS payment would be 14 percent higher than the current average cost of PAC stays.

The predicted redistribution of payments *within* each type of stay and provider category further supports

TABLE 1–3

Distribution of the changes in payments under a fully implemented PAC PPS, based on 2013 PAC stays' payments and costs updated to 2017 (continued)

	Decrease in payment			About the same	Increase in payment		
Stay or provider group	**>25%**	**10% to 25%**	**1% to 10%**	**–1% to +1%**	**1% to 10%**	**10% to 25%**	**>25%**
No therapy costs for HHA stays	2%	3%	6%	2%	11%	20%	56%
Lowest therapy costs for I–PAC stays	16	7	4	1	3	5	64
Highest therapy costs for HHA stays	47	25	10	2	6	5	5
Highest therapy costs for I–PAC stays	33	11	6	1	5	8	35
Community admitted	19	12	8	2	9	14	36
Stays with prior hospital stay	21	12	7	2	7	10	42
Disabled	18	11	8	2	8	13	40
Dual eligible	20	11	7	2	8	12	40
ESRD	19	11	8	2	8	11	41
Very old (age 85+ years)	21	12	7	2	8	12	39
Reporting groups: Providers							
All providers (*N* = 24,225)	7	19	18	4	17	19	16
HHA	6	16	20	5	22	22	9
SNF	7	18	15	4	15	18	23
IRF	9	55	28	3	5	1	0
LTCH	12	53	24	2	8	1	0
Nonprofit	2	14	14	3	16	20	29
For profit	8	21	19	4	18	18	12
Hospital based	2	19	15	3	13	17	31
Freestanding	7	19	18	4	17	19	15
Urban	7	20	19	4	17	19	15
Rural	6	18	15	4	17	20	21
Frontier	7	11	9	2	16	18	35

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The percentages in each row may not sum to 100 because of rounding. The stay-level reporting groups show the distribution of the change in payments for the stays in the each group. The provider-level analysis shows the distribution of the change in the average payment for the providers in the group.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. The provider reporting groups include providers with at least 20 stays.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

incorporating a transition period into the implementation of a PAC PPS. Within each reporting group, there would be considerable variation in the payment changes that result from a PAC PPS (Table 1-3). Although aggregate payments across all stays would remain unchanged (assuming implementation to be budget neutral), we estimate that payments would decrease by more than 25 percent for one-fifth of stays and would increase by

TABLE 1–4

For many providers, changes in payments would be inversely related to current relative Medicare profitability

Relative profitability	Provider count	Decrease in average payment >25%	Decrease in average payment 10% to 25%	Decrease in average payment 1% to 10%	About the same –1% to +1%	Increase in average payment 1% to 10%	Increase in average payment 10% to 25%	Increase in average payment >25%
Below average								
<0.75 (lowest)	2,720	4	100	189	45	357	715	1,310
0.75 to 0.90	4,586	91	533	762	189	910	1,127	974
About average								
(0.9 to 1.1)	10,105	402	2,086	2,078	465	1,902	1,879	1,293
Above average								
1.1 to 1.25	4,265	497	1,248	861	186	679	518	276
>1.25 (highest)	2,549	620	737	410	70	295	315	102
Provider count	24,225	1,614	4,704	4,300	955	4,143	4,554	3,955

Note: Relative profitability is a ratio of the provider's profitability (the ratio of the provider's average payment under current policy to the average stay cost) to the setting's average profitability. Ratios below 1.0 indicate below-average profitability; ratios above 1.0 indicate above-average profitability. Only providers with at least 20 stays were included in the analysis (*N* = 24,225).

Source: Analysis of 8.9 million 2013 post-acute care stays with costs and payments updated to 2017 (Wissoker 2017).

more than 25 percent for over one-third (39 percent) of stays. Analysis of the estimated payment changes reveals a wide range even for types of stays that would, on average, experience modest change in payments. For example, though we estimate that the average payment for cardiovascular medical stays would not change (as shown in Table 1-2, pp. 12–13), payments for over half of these stays would decrease or increase by more than 25 percent.

The estimated distribution of changes reflects in part the settings where patients are treated. Almost one-third of stays were treated in settings that we estimated would experience sizable changes in payments: There would be a 7 percent increase in average payments for stays treated in SNFs and a 15 percent reduction for stays treated in IRFs and LTCHs, as shown in Table 1-2 (pp. 12–13). Thus, even for types of stays that would experience a large average increase in payment—such as the ventilator group, which would see a 9 percent increase—payments would decrease for many stays (43 percent), in part because the majority of these patients were treated in LTCHs. Similarly, the average payment for severe wound stays would increase 10 percent (Table 1-2) and for more than half of these stays (56 percent), payments would increase by more than 25 percent. Yet, even for this group, 18 percent of severe wound stays would see payments fall by 10 percent or more (Table 1-3). This difference would occur because a sizable share (14 percent) of severe wound stays was treated in IRFs and LTCHs, where payments on average are estimated to decrease (Table 1-2, pp. 12–13).

At the provider level, the distribution of payment changes would not be as wide as at the stay level because payment changes at the stay level would be averaged across all of a provider's stays, thereby offsetting some of the increases and decreases for individual stays. For example, though our analysis found that 20 percent of PAC stays would experience payment decreases of more than 25 percent, we estimate that a much smaller share (7 percent) of providers would experience payments decreases of that magnitude (Table 1-3, pp. 14–15). The majority of providers would experience more moderate changes in payments. Nevertheless, the distribution of the changes further supports the need for a transition to full implementation of the PAC PPS.

Estimated changes in payments would be inversely related to current provider profitability, suggesting viability of a short transition

The relationship between payment changes and provider profitability also informs the decision to include a transition and how long it should be. Two findings argue for a transition of short duration. First, the providers predicted to experience the largest payment reductions have relatively high profitability. Those providers' current profits would allow them to absorb at least some of the payment reductions while remaining profitable. Second, average payments are expected to increase the most for relatively low-profit providers, so it would be desirable to move quickly to the PAC PPS, with a short transition (or none at all).

To explore the relationship between payments and profitability under the PAC PPS, we measured current relative profitability using the ratio of the provider's average current payment (under its setting's PPS) to its average per stay costs and compared the facility's payment-to-cost ratio (PCR) with the average PCR for that setting. For example, we compared each IRF's PCR with the average PCR for all IRFs to control for the different cost structures across settings.

In general, we found that expected payment changes under a PAC PPS were inversely related to providers' relative profitability (Table 1-4). Of the 2,720 providers with well-below-average profitability (a PCR that was more than 25 percent below the setting average), most (2,382) would experience increases in their average payment, and almost half (1,310) would experience payment increases of at least 25 percent. Fewer than 300 providers with low profitability (11 percent) would experience decreases in their average payment. Only four providers with well-below-average profitability would experience large (greater than 25 percent) reductions in their average payment.

Low-profitability providers that would experience large payment increases were disproportionately nonprofit and had lower therapy costs as a share of the stay's total cost. These results suggest that many providers would not need a long transition to a PAC PPS.

Conversely, of the 2,549 providers with well-above-average profitability (a PCR that was more than 25 percent higher than the setting average), the majority (1,767) would experience reductions in their average payment, and almost one-quarter (620) would have payment reductions of more than 25 percent. High-profitability providers that would experience large decreases in their average payments had high therapy costs as a share of total stay costs. Four percent (102) of providers with high PCRs would see large increases (greater than 25 percent) in payments.

We also looked at relative profitability for providers experiencing the largest changes in payment. Among providers expected to experience payment increases of 25 percent or more, more than half had below-average profitability; one-third had the lowest relative profitability (relative PCR of less than 0.75). Among providers expected to experience payment decreases of more than 25 percent, more than two-thirds had above-average profitability; 38 percent had the highest relative profitability (relative PCR of greater than 1.25). The PAC PPS would thus shift payments from high-profitability providers (disproportionately for profit and freestanding) to low-profitability providers (disproportionately nonprofit and hospital based), in part reflecting their mix of patients and current therapy practices. A long transition would delay this redistribution, thus perpetuating current payment system inequities.

PAC PPS payment changes would be moderated during a transition

By blending current setting-specific payments with those under a PAC PPS, a transition would dampen the immediate impact of a full PAC PPS. Changes in the distribution of payments—the shift of payments to medically complex care from therapy-driven care—would be phased in over the transition period.

We illustrate the moderated impact on providers during a three-year transition and show payments during the first year based on a one-third blend of PAC PPS payments and a two-thirds blend of current payments (Table 1-5, pp. 18–19). Compared with the impact of full PAC PPS payments, the change in payments would be proportionally smaller during the first year of the transition. For example, under full PAC PPS implementation versus first year of transition: stays with severe wounds would experience a 10 percent payment increase versus a 3 percent payment increase; orthopedic medical stays would experience a 6 percent payment reduction in payments versus a 2 percent payment reduction.

Similarly, a transition would dampen the initial effects of the PAC PPS on IRFs and LTCHs, which would experience a 5 percent reduction in payments in the first year, compared with a 15 percent reduction under a fully implemented PAC PPS (Table 1-5, pp. 18–19). A multiyear

TABLE 1–5

A three-year transition would reduce the first-year impact of a PAC PPS, based on 2013 PAC stays' payments and costs updated to 2017 (continued next page)

Reporting groups	Current policy: Ratio of average payment to average cost of stays	Impact of full PAC PPS		First year impact of a 3-year transition (33% PAC PPS)	
		Percent change in payment from current payments	Ratio of average payment to average cost of stays	Percent change in payment from current payments	Ratio of average payment to average cost of stays
All stays	1.14	0%	1.14	0%	1.14
Cardiovascular medical	1.15	0	1.15	0	1.15
Orthopedic medical	1.22	–6	1.15	–2	1.20
Orthopedic surgical	1.18	–3	1.14	–1	1.17
Respiratory medical	1.09	5	1.15	2	1.11
Other neurology medical	1.22	–6	1.15	–2	1.20
Serious mental illness	1.14	0	1.15	0	1.14
Severe wound	1.05	10	1.15	3	1.08
Skin medical	1.11	3	1.14	1	1.12
Cardiovascular surgical	1.06	7	1.14	2	1.09
Infection medical	1.13	1	1.14	0	1.13
Stroke	1.15	–2	1.13	–1	1.14
Hematology medical	1.07	4	1.11	1	1.08
Ventilator	1.07	9	1.17	3	1.10
Least frail	1.20	–4	1.15	–1	1.18
Most frail	1.12	1	1.13	0	1.12
Cognitively impaired	1.19	–4	1.14	–1	1.17
Multiple body system diagnoses	1.10	3	1.14	1	1.11
Chronically critically ill	1.06	8	1.14	3	1.09
Severely ill (SOI = Level 4)	1.07	6	1.13	2	1.09

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The impact of the first year was modeled using a blend of one-third PAC PPS payments and two-thirds setting-specific PPS payments.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. LTCH-qualifying stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

transition would therefore give high-cost providers time to restructure their costs and practices, but it would also delay redistributing payments to medical stays.

A transition would also temper the *distribution* of increases and decreases in payments during a transition. Using the same three-year example, many fewer stays and providers would experience large changes in payments (data not shown). During the first year, no stays would experience reductions of 25 percent or more (compared with 20 percent of stays under the full PAC PPS rates). We see similar moderation in the impact of a transition on providers. In the first year of a three-year transition,

TABLE 1–5

A three-year transition would reduce the first-year impact of a PAC PPS, based on 2013 PAC stays' payments and costs updated to 2017 (continued)

Reporting groups	Current policy: Ratio of average payment to average cost of stays	Impact of full PAC PPS		First year impact of a 3-year transition (33% PAC PPS)	
		Percent change in payment from current payments	Ratio of average payment to average cost of stays	Percent change in payment from current payments	Ratio of average payment to average cost of stays
No therapy costs for HHA stays	1.55	25	1.94	8	1.68
Lowest therapy costs for I–PAC stays	0.94	18	1.11	6	0.99
Highest therapy costs for HHA stays	1.09	–24	0.83	–8	1.00
Highest therapy costs for I–PAC stays	1.32	–16	1.11	–5	1.25
Community admitted	1.21	–4	1.16	–1	1.19
Stays with prior hospital stay	1.12	1	1.14	0	1.13
Disabled	1.13	1	1.15	0	1.14
Dual eligible	1.17	–3	1.14	–1	1.16
ESRD	1.12	2	1.14	1	1.13
Very old (age 85+ years)	1.17	–2	1.14	–1	1.16
HHA	1.17	–1	1.16	0	1.16
SNF	1.14	7	1.22	2	1.17
IRF	1.18	–15	1.00	–5	1.12
LTCH: All stays	1.05	–15	0.89	–5	1.00
LTCH-qualifying stays	1.05	–9	0.95	–3	1.01
Nonprofit	1.00	9	1.09	3	1.03
For profit	1.20	–3	1.17	–1	1.19
Hospital based	0.85	11	0.94	4	0.88
Freestanding	1.19	–1	1.18	0	1.19
Urban	1.15	–1	1.14	0	1.15
Rural	1.11	3	1.15	1	1.12
Frontier	1.03	10	1.13	3	1.06

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). The impact of the first year was modeled using a blend of one-third PAC PPS payments and two-thirds setting-specific PPS payments.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" includes patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. LTCH-qualifying stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

no provider would experience decreases of 25 percent or more (compared with 7 percent of providers under a fully implemented PAC PPS), while 3 percent of providers would experience increases of 25 percent or more (compared with 16 percent of providers under a fully implemented PAC PPS). Under a transition, the payment changes would be more moderate: Most providers (84 percent) would have increases or decreases of 10 percent or less (compared with 39 percent of providers under a fully implemented PAC PPS).

Allowing providers to bypass the transition

Policymakers may want to consider giving providers the option to bypass the transition and move directly to full PAC PPS rates. Experience with the implementation of the setting-specific PPSs suggests that many providers whose payments would increase under the PAC PPS would elect to do so if given the option. The implementation of the SNF, IRF, and LTCH PPSs included multiyear transitions with blended rates but allowed providers to bypass the transition and receive full PPS rates, which many providers did.[6]

Allowing providers to bypass the transition would have benefits and drawbacks. A key advantage of allowing providers to bypass the transition is the quicker shift to a payment system that will base payments on patient care needs and be more equitable across different types of stays and providers. One indicator of how many providers might opt to bypass the transition is the share of providers whose payments would increase substantially. We estimate that average payments would increase by at least 10 percent for about 35 percent of providers (Table 1-3, pp. 14–15). One reason to allow "early adopters" is to create momentum for the new payment system and make it less likely to delay full implementation. The key disadvantage of the bypass option is that it will raise total spending during the transition. Providers that expect their payments to increase under the PAC PPS will likely opt to bypass the transition, while those that expect their payments to decline will not. Some policymakers may question why program spending has to increase to implement a more equitable payment system. The Secretary could mitigate this added cost by lowering the aggregate level of spending as part of the transition.

Because the impact of the PAC PPS will vary considerably across settings and providers, we expect providers' interest in bypassing the transition will differ substantially. Many providers in lower cost settings (HHAs and SNFs) are likely to experience increases in their payments under a PAC PPS and may be interested in transitioning quickly to a full PAC PPS payment. In addition, in discussions with the Commission's staff, administrators of some integrated systems have indicated their interest in moving quickly to a PAC PPS so they have a uniform set of payment rules and incentives and greater flexibility in the mix of patients their providers treat. Conversely, high-cost providers (for example, many IRFs and LTCHs) are likely to face lower payments under a PAC PPS. Many of them will likely prefer to adhere to the transition schedule, gaining extra time to restructure their costs and payments.

A transition would require CMS to maintain parallel payment systems, during which CMS would calculate rates under the "old" setting-specific system and under the "new" system; CMS would then apply a blend of the two to arrive at the final payment. This approach is typically taken by CMS when transitioning from one payment system to another (for example, the implementation of the IRF PPS and the implementation of site-neutral payments for LTCHs). Because both systems would use administratively available data that are currently submitted to CMS, providers would not be required to collect and submit new data.

Assessing the level of aggregate payment

In implementing a PAC PPS, the Secretary will need to evaluate the level of aggregate payments. The analyses conducted thus far have assumed that the PAC PPS would be implemented to be budget neutral relative to the current level of aggregate PAC payments. However, this approach would maintain average payments that we estimate would be 14 percent higher than the average costs of care in 2017. The Commission has repeatedly recommended reductions or freezes to payments to PAC providers to bring Medicare's payments in closer alignment with providers' costs. This year, the Commission recommended that the Congress lower payments to HHAs and IRFs by 5 percent and freeze payment rates for SNFs and LTCHs (Medicare Payment Advisory Commission 2017). The Commission's payment update recommendations made in March 2017 would result in about a 2 percent reduction in aggregate spending, lowering program spending by about $1.2 billion.

If the Congress has not made setting-specific payment reductions by the time the Secretary implements the PAC PPS, the Congress should lower payments to align them with the cost of stays, consistent with the Commission's recommendations regarding payment updates to PAC providers. This policy is separate from the need for the Secretary to have the authority to rebase payments periodically. Lowering the initial level of payments would bring payments more in line with the current cost of stays, while the authority to rebase payments acknowledges that

changes in the costs of care may warrant future payment realignment.

We modeled several reductions to overall payments, ranging from 2 percent to 5 percent, and compared the resulting average payments with the average cost of PAC stays. All scenarios assume no changes in providers' costs or practices. However, experience with other payment policy changes suggests that, under a PAC PPS, many providers are likely to lower their costs and change the mix of their patients relatively quickly. The limited evidence comparing PAC use by beneficiaries in accountable care organizations and Medicare Advantage with PAC use by beneficiaries in FFS Medicare may offer some insights into the type of changes providers may make. Although the incentives differ, alternative payment models appear to prompt shorter and less therapy-intensive stays and increase the use of relatively lower cost PAC settings (Colla et al. 2016, Huckfeldt et al. 2017, McWilliams et al. 2016). Because the PAC PPS would narrow the differences in payments across settings, it would dampen the incentive to shift where patients are treated, but the incentive to lower costs would remain.

Under all of the options we modeled, average payments would remain higher than the average cost of all stays and higher than the average cost for most of the patient groups (Table 1-6, pp. 22–23). For example, if payments were lowered by 5 percent, the average payment for all stays would remain 9 percent higher than the average cost of stays and between 8 percent and 9 percent higher for most of the patient groups. As we reported in June 2016, compared with current policy, the ratios of payments to costs across the various patient groups would be much narrower, so providers would have less incentive to admit certain types of patients over others.

The ratios of payments to costs are less than 1.0 for the higher cost providers (such as IRFs, LTCHs, and hospital-based providers) because the PAC PPS considers the costs of the lower cost providers and lower cost settings in determining the payments across all stays with similar characteristics. By averaging the costs of all similar stays (regardless of setting), the payments made to the high-cost settings and high-cost providers are lowered. Under the PAC PPS, payments would be below the cost of stays for HHA stays with high therapy costs (even before reductions to the aggregate level of payment are considered), most likely because payments would be based on patient characteristics, in contrast to current HHA costs that include the provision of therapy services that are of questionable value. This finding is an expected result of a PAC PPS based on patient characteristics rather than the amount of care furnished to a patient. If a patient had clinical characteristics and impairments indicating above-average care needs, payments for the stay would be above average.

A transition would temper the impact of the changes in payments under a PAC PPS, but these changes could be further moderated by taking the reduction in increments throughout the transition. Given that PAC payments are relatively high and there may be a transition to full PAC PPS rates, the Commission supports taking the reduction in one action at the beginning of implementation. This approach makes it less likely that reductions are halted partway through the transition, before the full realignment of payment to the costs of care.

The Secretary would consider the aggregate reduction separately from each year's update; providers would continue to receive payment updates, as appropriate, during the transition. After full implementation, the Secretary would need to evaluate whether further alignment of payments with costs was warranted. Continued monitoring of beneficiary access, provider performance, and Medicare margins would provide indicators of the need for future refinements.

Periodic refinements needed to maintain the accuracy of the PAC PPS

Under a new PAC PPS, practice patterns will change as high-cost providers lower their costs and all providers evaluate and possibly shift their mix of patients and services furnished. These changes could compromise the quality of care furnished and, if payments are inaccurate, beneficiaries' access to care. The Secretary must carefully monitor provider behavior, including the level of quality furnished, the types of stays admitted, and the adequacy of payments. If aberrant patterns or unintended provider responses occur, the Secretary will need to make revisions to counter this behavior. As with any payment system, the Secretary would need to revise and rebase the PAC PPS, when warranted, to maintain the accuracy of payments over time.

Monitor provider responses to the PAC PPS

In June 2016, the Commission discussed possible measures to monitor quality, patient selection, unnecessary

TABLE 1–6

Lowering payments by 2 percent to 5 percent would still cover the average cost of stays for most patient groups (continued next page)

		Ratio of average payment to average cost of stays					
			Payments reduced under PAC PPS by:				
Reporting group	Percent of stays	Current policy	0%	2%	3%	4%	5%
All stays	100%	1.14	1.14	1.12	1.11	1.10	1.09
Cardiovascular medical	14	1.15	1.15	1.13	1.12	1.10	1.09
Orthopedic medical	10	1.22	1.15	1.13	1.11	1.10	1.09
Orthopedic surgical	10	1.18	1.14	1.12	1.11	1.10	1.08
Respiratory medical	9	1.09	1.15	1.12	1.11	1.10	1.09
Other neurology medical	8	1.22	1.15	1.13	1.12	1.11	1.10
Serious mental illness	5	1.14	1.15	1.12	1.11	1.10	1.09
Severe wound	5	1.05	1.15	1.13	1.12	1.11	1.09
Skin medical	4	1.11	1.14	1.12	1.11	1.10	1.09
Cardiovascular surgical	3	1.06	1.14	1.11	1.10	1.09	1.08
Infection medical	3	1.13	1.14	1.12	1.11	1.09	1.08
Stroke	2	1.15	1.13	1.10	1.09	1.08	1.07
Hematology medical	2	1.07	1.11	1.08	1.07	1.06	1.05
Ventilator	<1	1.07	1.17	1.15	1.13	1.12	1.11
Least frail	7	1.20	1.15	1.13	1.11	1.10	1.09
Most frail	11	1.12	1.13	1.11	1.10	1.09	1.08
Cognitively impaired	20	1.19	1.14	1.12	1.11	1.10	1.09
Multiple body system diagnoses	5	1.10	1.14	1.12	1.11	1.09	1.08
Chronically critically ill	5	1.06	1.14	1.12	1.11	1.10	1.08
Severely ill (SOI = Level 4)	4	1.07	1.13	1.11	1.10	1.09	1.08

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). Percent of stays does not total 100 percent because many of the groups overlap.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" include patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. LTCH-qualifying stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

PAC use, and the adequacy of payments (Table 1-7, p. 24). Observed changes in PAC use under the new PAC PPS could reflect a change in payment incentives. Certain types of patients might be more or less preferable to admit than they were under the previous payment systems. Such changes in PAC use may be desirable or may indicate the need for payment revisions. Although the relative profitability across patient conditions will be considerably narrower than under current policy, there will continue to be some variation that could make certain types of conditions more attractive for providers to treat. As part of his ongoing evaluation, the Secretary should monitor PAC provision for these conditions and for particularly vulnerable patients, such as the sickest and frailest patients. Observed increases in the length of stay of preceding hospitalizations could reflect delays in PAC placement, which could indicate that PAC providers are reluctant to admit less profitable patients. Changes in the distribution of the lengths of PAC stays (such as a concentration of discharges just after a short-stay threshold) could indicate that revisions to the short-stay outlier policy are needed.

TABLE 1–6

Lowering payments by 2 percent to 5 percent would still cover the average cost of stays for most patient groups (continued)

		Ratio of average payment to average cost of stays					
			Payments reduced under PAC PPS by:				
Reporting group	Percent of stays	Current policy	0%	2%	3%	4%	5%
No therapy costs for HHA stays	29	1.55	1.94	1.91	1.89	1.87	1.85
Lowest therapy costs for I–PAC stays	8	0.94	1.11	1.08	1.07	1.06	1.05
Highest therapy costs for HHA stays	17	1.09	0.83	0.82	0.81	0.80	0.79
Highest therapy costs for I–PAC stays	8	1.32	1.11	1.09	1.08	1.07	1.06
Community admitted	50	1.21	1.16	1.14	1.13	1.12	1.10
Stays with prior hospital stay	50	1.12	1.14	1.12	1.10	1.09	1.08
Disabled	26	1.13	1.15	1.12	1.11	1.10	1.09
Dual eligible	32	1.17	1.14	1.12	1.11	1.10	1.09
ESRD	4	1.12	1.14	1.12	1.11	1.10	1.08
Very old (age 85+ years)	30	1.17	1.14	1.12	1.11	1.09	1.08
HHA	69	1.17	1.16	1.13	1.12	1.11	1.10
SNF	25	1.14	1.22	1.19	1.18	1.17	1.16
IRF	4	1.18	1.00	0.98	0.97	0.96	0.95
LTCH: All stays	2	1.05	0.89	0.87	0.87	0.86	0.85
LTCH-qualifying stays	1	1.05	0.95	0.93	0.92	0.91	0.90
Nonprofit	22	1.00	1.09	1.07	1.06	1.05	1.04
For profit	75	1.20	1.17	1.15	1.13	1.12	1.11
Hospital based	11	0.85	0.94	0.92	0.91	0.90	0.90
Freestanding	89	1.19	1.18	1.15	1.14	1.13	1.12
Urban	84	1.15	1.14	1.12	1.11	1.10	1.09
Rural	16	1.11	1.15	1.12	1.11	1.10	1.09
Frontier	<1	1.03	1.13	1.10	1.09	1.08	1.07

Note: PAC (post-acute care), PPS (prospective payment system), SOI (severity of illness), HHA (home health agency), I–PAC (institutional–post-acute care), ESRD (end-stage renal disease), SNF (skilled nursing facility), IRF (inpatient rehabilitation facility), LTCH (long-term care hospital). Percent of stays does not total 100 percent because many of the groups overlap.
"Other neurology medical" excludes stroke. "Serious mental illness" includes beneficiaries with schizophrenia, bipolar disorders, or severe depression. Patients' level of frailty was determined using a frailty index. "Multiple body system diagnoses" include patients treated in I–PAC with diagnoses involving five or more body systems. "Chronically critically ill" 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 treated in I–PAC who were categorized as SOI Level 4 during the immediately preceding hospital stay (or simulated for patients admitted from the community). "Lowest therapy costs" and "highest therapy costs" refer to those stays in the lowest and highest quartile, respectively, of therapy costs as a share of total stay costs. For home health stays, the low group includes only stays with no therapy. Institutional PAC includes SNFs, IRFs, and LTCHs. LTCH-qualifying stays are those that would meet the patient-specific criteria to qualify for LTCH PPS payments.

Source: Analysis of 8.9 million 2013 PAC stays with costs and payments updated to 2017 (Wissoker 2017).

Other possible provider responses will also warrant monitoring. For example, a large increase in second PAC stays following initial PAC use could indicate that providers are unbundling care—for example, IRFs could discharge a higher proportion of patients to SNFs as a way for IRFs to avoid treatment costs. Although second PAC use can be appropriate, large changes in its use could indicate unintended provider responses and would increase Medicare spending, as well as expose beneficiaries to unnecessary care transitions.

Medicare margins and cost growth are good barometers of the adequacy of Medicare's payments. When payments are more than adequate, providers have less incentive to control their costs, and cost growth may be high. However, high cost growth could also reflect providers making

TABLE 1–7 **Measures to monitor provider responses to a PAC PPS**

Dimension	Measure
Quality of care	• Potentially avoidable readmissions
	• Potentially avoidable admissions (for community admissions)
	• Changes in patient function
	• Length of PAC stay
	• Potentially avoidable complication rates
	• Potentially avoidable emergency department visits and observation stays
	• Days elapsed between discharge from PAC and follow-up appointment with a clinician
	• Beneficiary experience
Patient selection	• PAC use by condition/reason to treat
	• Mix of patients across settings and providers
	• Length of stay of preceding hospital stay
PAC use	• PAC use following a hospital stay, which could detect over- or underuse
	• Subsequent PAC use following an initial PAC stay, which could detect over- and underuse
Adequacy of payments	• Medicare margins
	• Cost growth

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

investments in staffing and equipment to treat a more complex mix of patients.

The Commission has been clear that providers should be accountable for the quality of care they furnish and for a period after discharge. The first helps protect beneficiaries from providers stinting on services if doing so lowers their costs. The second encourages providers to coordinate care with the patient's next provider (or the caregiver at home) so that the patient has a safe transition. The Commission's PAC measures of quality (and CMS's hospital readmission rates) include 30 days after discharge. Tracking measures over longer periods of time, such as 60 or 90 days, would hold providers accountable for a longer recovery period but could include events unrelated to the initial reason for PAC.

Maintain alignment of payments and costs

Experience with prior payment policy changes indicates that providers will change their costs, patient mix, and practice patterns to maintain or increase their profitability. The Secretary should therefore periodically evaluate the need to make refinements to the PAC payment system. Such refinements fall into two broad categories. The first involves revisions to the classification system—the case-mix groups and their relative weights—to help maintain the equity and accuracy of payments across different types of stays. The second involves rebasing payments to keep them aligned with the cost of stays. Both types of refinements are part of the ongoing maintenance of any PPS.

The Secretary should periodically evaluate the need to revise the PPS to help ensure that Medicare's payments capture changes in the relative costs of stays. For example, if admitting practices change, the relative and absolute costs of different types of stays may change. Further, standards of care may change, affecting the costs of some types of stays relative to others. This ongoing maintenance would include revisions to the case-mix adjustment system (such as the adding or collapsing of case-mix groups) and

the relative weights that adjust payments up or down for each type of case.

The Secretary should also have the authority to rebase payments periodically if payment changes outpace cost changes. Because coding practices are likely to change (as they typically do when new payment systems are implemented), payments are likely to increase, even when patients' resource needs remain the same. PAC providers are likely to adjust to this new payment system just as they have consistently done to other payment policy changes by changing their costs, mix of patients, and practices. With the implementation of each setting's PPS, providers relatively quickly adjusted their practices, and Medicare margins increased substantially. After the HHA PPS was implemented, HHA margins in 2003 were the highest they have ever been (23 percent). Between 1999 and 2000, the year CMS implemented the SNF PPS, SNF Medicare margins rose from 2.0 percent to 10.1 percent. Between 2001 and 2002, the year CMS implemented the IRF PPS, IRF margins increased from 1.5 percent to 10.8 percent. Between 2002 and 2003, the year the LTCH PPS was implemented, LTCH margins grew from –0.1 percent to 5.2 percent. 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.

Recommendation regarding the implementation of a PAC PPS

In June 2016, the Commission recommended to the Congress the design features of a PAC PPS and estimated the impact of the new system on payments. The design features include a uniform unit of service (a stay) and risk adjustment method using patient characteristics rather than the site of service or the amount of therapy a patient received, outlier payments for unusually short or unusually high-cost stays, and a downward adjustment for home health stays to reflect this setting's considerably lower cost compared with institutional PAC.

IMPACT does not require the implementation of a PAC PPS by an explicit date, but its report requirements suggest that a unified PPS would not be proposed before 2024 for implementation some time later. However, the Commission contends that a PAC PPS should be implemented sooner than contemplated by IMPACT, beginning in 2021, with a design that relies on readily available data and is revised over time to include functional status as a risk adjuster when these data become available. This implementation timetable assumes that the Secretary will have begun to waive or modify certain setting-specific regulatory requirements. Because some of the regulatory requirements are in statute, the Congress will need to grant authority to the Secretary to take these actions. Given the range in impacts, the implementation should include a transition, but because providers with the largest decreases in payments tend to be those with above-average profitability, the phase-in period should be short.

Regarding the level of payments, if the Congress has not already done so by the beginning of the implementation, the aggregate level of spending on PAC should be lowered to more closely align payments with the costs of care. Concurrently, the Secretary would need to begin to align the regulatory requirements across PAC providers so they face similar costs in furnishing care to beneficiaries. In addition, the Congress should give the Secretary the authority to periodically revise and rebase the PAC PPS to keep payments aligned with the cost of care.

RECOMMENDATION

The Congress should direct the Secretary to:

- **implement a prospective payment system for post-acute care beginning in 2021 with a three-year transition;**
- **lower aggregate payments by 5 percent, absent prior reductions to the level of payments;**
- **concurrently, begin to align setting-specific regulatory requirements; and**
- **periodically revise and rebase payments, as needed, to keep payments aligned with the cost of care.**

RATIONALE

The Commission found that payments based on a design that used currently available administrative data were accurate for most types of stays. The Commission concluded that a PAC PPS could be implemented in 2021 using administrative data and be revised over time to incorporate information on patient function into the risk adjustment of payment when these data become available.

A PAC PPS will have widely varying effects on payments for stays and on providers. Therefore, the Commission concludes that the new payment system should be

implemented with a transition that blends current setting-specific payments with PAC PPS payments. However, the transition should be relatively short because it delays the redistribution of payments toward medical and medically complex stays. Implementing a PAC PPS with a short transition balances the desire to redistribute payments quickly and the need to give high-cost providers time to modify their costs and practices. Furthermore, this recommendation puts the PAC industry on notice about the type of changes they will need to make, giving them effectively a six-year transition to fully implemented PAC PPS payments. Providers could begin to change their cost structures and therapy practices in anticipation of the changes encouraged by the PAC PPS.

The Commission recommends that when the PAC PPS is implemented, the aggregate level of PAC payments be lowered by 5 percent. This reduction assumes that the Congress has not already acted to lower PAC spending. If the Congress has already lowered the level of payments to PAC providers, it should compare the impact of those reductions with the Commission's recommendation and make additional adjustments if necessary to reach the recommended reduction.

The Secretary could give providers the option to bypass the transition and be paid full PAC PPS payments. While this option would raise program spending during the transition, it would begin to shift payments to being more equitable and based on patient characteristics compared with the current designs of the HHA and SNF payment systems.

The Commission's recommendation to lower payments is consistent with the payment update recommendations the Commission has made for many years concerning PAC providers, most recently in March 2017. Compared with these recommendations, the Commission recommends a larger reduction for two reasons. First, if providers respond to the PAC PPS as they have to previous payment system changes—by altering their mix of patients, costs, and coding—their margins could increase substantially under the PAC PPS. Second, prior experience suggests that providers whose payments will increase under the PAC PPS are likely to opt to bypass the transition and receive full PAC PPS payments. Because this possibility will raise aggregate PAC spending during the transition, a larger reduction helps mitigate the increased spending. However, even with a 5 percent reduction, the average payment would remain substantially above the average cost of stays for all stays and for the 30 patient groups we examined.

The Commission believes the reduction should be taken in one action at the beginning of the implementation because the level of PAC payments is high; there would be a transition to full PAC PPS rates; providers may have the option to bypass the transition (which would raise program spending); and providers are likely to respond by changing their patient mix, costs, and treatment practice.

The recommendation explicitly ties the implementation of a unified payment system to the start of the alignment of setting-specific regulatory requirements. Without alignment, some providers will continue to face differing regulatory requirements that may raise their costs. The Secretary will need the authority to waive or modify regulatory requirements that are in statute. Eventually, the Secretary should develop regulations that delineate a core set of requirements all providers must meet and a separate set of requirements for those providers opting to treat patients with special care needs. The Commission plans to focus on this issue over the coming year.

Finally, the Secretary must have the authority to periodically revise and rebase PAC PPS payments. Revisions to the PAC PPS (such as changes to the patient classification system and the risk adjustment method) will help ensure that Medicare's payments capture changes in the relative cost of stays. Rebasing will help ensure that the aggregate level of Medicare's payments reflects the costs of care. Throughout the implementation, the Commission will continue to monitor the level and alignment of payments with the cost of care and make recommendations as needed.

IMPLICATIONS

Spending

- The one-year spending will not change relative to current law because the recommendation does not affect payments until 2021 (or year 4). Over five years, spending will be lower by between $5 billion and $10 billion. These estimates assume no behavioral changes by providers. In addition, savings will depend in part on whether providers are allowed to bypass the transition, and if so, how many will exercise this option. Providers that expect their payments to increase under the PAC PPS may opt to bypass the transition, raising spending during the transition, while those whose payments will decrease are likely to adhere to the three-year transition. The net change will depend on how many providers opt to move directly to full PAC PPS rates.

Beneficiary and provider

- We do not expect this recommendation to have adverse effects on beneficiaries. On the contrary, payments based on patient characteristics will make providers more willing to admit and treat medical patients and medically complex patients. With a transition that phases in the impacts of the new payment system, providers will be protected from large changes in payments that otherwise could adversely affect beneficiaries.The PAC PPS will redistribute payments from high-cost settings and providers to lower cost settings and providers. Further, by basing payments on patient characteristics rather than the amount of service furnished, the new payment system will shift payments to medically complex patients and away from patients who receive high-intensity rehabilitation that appears unrelated to their clinical condition. Thus, the PAC PPS will narrow disparities in the profitability of Medicare patients and increase the equity of Medicare's payments to providers. The impact on providers will vary considerably and will depend on how quickly providers can adjust their cost structures, treatment practices, and mix of patients to align with payments under the PAC PPS. ■

Endnotes

1 A stay is defined as the days spent in a PAC provider between admission and discharge or, in the case of home health care, the end of the 60-day episode. A SNF stay followed by a HHA episode would count as two PAC stays.

2 Because the costs of HHAs are so much lower than the costs of the three institutional PAC settings, payments for stays in HHAs would need to be adjusted to avoid exceptionally high payments relative to the cost of these stays. In our analyses, we included a home-health indicator in the model predicting the cost of stays as one way to account for the very different costs in this setting. The indicator keeps the predicted cost of HHA stays aligned with their actual costs and preserves the relative differences in costs between institutional and HHA stays.

3 The cost of stays was predicted using Poisson regression models and the following patient information: age and disability status, primary reason to treat, diagnoses and comorbidities, severity, impairments, cognitive status, and use of high-cost service items (ventilator care, tracheostomy care, and continuous positive airflow pressure). We developed one model to predict the routine and therapy costs per stay and another for the nontherapy ancillary (NTA) costs per stay (such as drug costs) because the costs and payments for stays in HHAs do not include NTA services. We combined the results of the two models and compared their results with the actual costs of stays. The predicted costs would form the basis of payments under a PAC PPS. In this analysis, we assumed total payments under a PAC PPS would equal total actual payments to providers across the four settings.

4 Aggregate payments under the PAC PPS were set to be budget neutral to current *aggregate* payments, not budget neutral by setting.

5 Our estimate of the impact of the PAC PPS on LTCHs assumes that the number and types of cases admitted to LTCHs in 2017 will be the same as in 2013. However, substantial changes in LTCH payment policy, which began in fiscal year 2016, will likely alter the admission patterns, volume, and cost structures of these providers.

6 Within two years of the five-year transition to the LTCH PPS, almost all LTCHs had transitioned; most IRFs opted to bypass the two-year transition to the IRF PPS. The HHA PPS did not include a transition.

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CHAPTER 2

Medicare Part B drug payment policy issues

RECOMMENDATION

The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:

(1) Modify the average sales price (ASP) system in 2018 to:

- require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.
- reduce wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent.
- require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.
- require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:

- Medicare contracts with a small number of private vendors to negotiate prices for Part B products.
- Providers purchase all DVP products at the price negotiated by their selected DVP vendor.
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.
- Beneficiaries pay lower cost sharing.
- Medicare payments under the DVP cannot exceed 100 percent of ASP.
- Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.

(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

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

CHAPTER 2

Medicare Part B drug payment policy issues

Chapter summary

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. In 2015, Medicare and its beneficiaries paid about $26 billion dollars for Part B–covered drugs and biologics. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). Since 2009, Medicare Part B drug spending has grown at an average rate of about 9 percent per year. About half of the growth in Part B drug spending from 2009 to 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs (Medicare Payment Advisory Commission 2015b).

Medicare Part B drug spending has been growing rapidly. Concern exists about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. Among the 10 products that account for the most Medicare Part B drug expenditures, 8 of those products have an annual cost per user that ranges from roughly $10,000 to $30,000 per year. In addition, some Part B drugs used by small numbers of beneficiaries have annual costs per user of more than $75,000 per year. The current ASP payment system spurs price competition among generic drugs and their associated brand products by assigning these products to a single billing code. By contrast, the current ASP payment system—with most single-

In this chapter

source drugs and biologics each paid under separate billing codes—does not spur price competition among products with similar health effects. There is also concern about the financial incentives providers face under the ASP + 6 percent payment system. In particular, the 6 percent add-on to ASP may create incentives for providers to choose higher priced drugs over lower priced drugs.

The Commission's recommendation includes a set of policies that seeks to improve the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system. This alternative program—which we refer to as the Part B Drug Value Program (DVP)—would allow providers to voluntarily enroll and would use private vendors to negotiate drug prices with manufacturers. The DVP would be informed by Medicare's experience with the competitive acquisition program (CAP) for Part B drugs (in effect between 2006 and 2008) but structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

It would take several years to develop and implement the DVP, but immediate action could be taken to improve the existing ASP payment system. These shorter term steps would apply to all providers and would remain in place for those providers that chose not to enroll in the DVP. Specifically, the recommended short-term actions would:

- ***Improve ASP data reporting.*** CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. Payment rates based on incompletely reported ASP data might not accurately reflect average prices. A policy requiring all Part B drug manufacturers to report ASP data and giving the Secretary the authority to apply penalties to manufacturers who do not report required data would improve the accuracy of the ASP payments.
- ***Modify payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC)***. Medicare generally reimburses new single-source Part B drugs at 106 percent of WAC when ASP data are not available. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. A policy reducing the payment rate for drugs currently paid at 106 percent to 103 percent of WAC would reduce excessive payments for these drugs.
- ***Establish an ASP inflation rebate.*** 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. An ASP inflation rebate policy would protect the Medicare program and beneficiaries from the potential for rapid price increases for individual products.

- ***Establish consolidated billing codes.*** The structure of the ASP payment system—with the reference biologic assigned to one billing code and its biosimilars assigned to a different billing code—does not spur price competition among these products. A policy permitting use of consolidated billing codes to group a reference biologic with its biosimilars would spur price competition among these Part B drugs.

Over the longer term, the Commission recommends that Medicare develop the DVP as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but in contrast to the CAP, vendors would not ship products to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

The Commission's recommendation seeks to take a balanced, multipronged approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Part B drug payment through a regulatory approach (by making reforms to the ASP payment system) and through a market-based approach (by developing a voluntary alternative DVP). The Commission's recommendation also seeks balance by including policies that would achieve savings for taxpayers and beneficiaries not just by modifying provider payment rates but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices (e.g., through consolidated billing codes, an ASP inflation rebate, and DVP vendor tools such as a formulary and binding arbitration). ■

Introduction

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs).[1] Medicare Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs). In 2015, Medicare and its beneficiaries paid about $26 billion dollars for Part B–covered drugs and biologics.

In accordance 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] 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 bundled, or "packaged," into payment for other services under the OPPS instead of being paid separately.[3] Like other Medicare services, Part B–covered drugs are subject to the budget sequester effective April 1, 2013, through 2025.[4] In this chapter, we use the term *drug* to refer to both drugs and biologics (unless otherwise noted).[5]

In addition to a payment of ASP + 6 percent for a Part B–covered drug, Medicare makes a separate payment under the physician fee schedule or OPPS to the physician or hospital administering the drug (that is, for the act of injecting or infusing the product into the patient). We estimate that, in 2015, Medicare and its beneficiaries paid about $3.6 billion for drug administration services.[6] Medicare also pays a dispensing or supplying fee to suppliers (typically 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. In June 2016, the Commission recommended that CMS reduce the dispensing and supplying fees paid to pharmacies to be similar to those of other payers. This chapter includes data only on the ASP + 6 percent payments and not on drug administration payments or supplying and dispensing fees (unless otherwise noted).

Medicare spending on Part B drugs is substantial and has grown rapidly in recent years. In 2015, total Part B drug spending amounted to about $26 billion, with about $21 billion in program payments and $5 billion in beneficiary cost sharing.[7] Of that spending, physician offices accounted for about $15 billion; HOPDs, about $9 billion; and suppliers, about $2 billion. In 2015, Medicare spending on Part B–covered drugs increased 13 percent over the prior year.[8] Since 2009, Medicare Part B drug spending grew at an average rate of about 9 percent per year. About half of that growth in Part B drug spending between 2009 and 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs (Medicare Payment Advisory Commission 2016a).

In recent years, total Medicare Part B drug spending has grown more rapidly in HOPDs compared with physician offices and suppliers. Between 2009 and 2015, average annual growth was roughly 16 percent for HOPDs and 7 percent for physicians. Over half of the Medicare Part B drug spending in HOPDs in 2015 was attributable to hospitals that participate in the 340B Drug Pricing Program. Nonprofit hospitals that qualify for the 340B Drug Pricing Program receive substantial discounts on Part B drugs.[9]

Medicare Part B covers a wide range of drugs. Some of the most commonly used Part B drugs like corticosteroids, saline, and vitamin B-12 are inexpensive, with an ASP per administration of less than $10. In contrast, the top 10 drugs that accounted for the largest share of Part B spending in 2015 are more expensive, ranging from roughly $1,000 to $6,000 per administration and from roughly $2,000 to $32,000 per beneficiary per year (Table 2-1, p. 38). Among these top 10 products in 2015, 8 were biologics and none faced biosimilar or generic competition. Beyond these products, additional Part B drugs that have annual costs of more than $75,000 per year are used by small numbers of beneficiaries. In 2015, biological products (not including vaccines) accounted for the majority of Part B drug spending (65 percent). Small-molecule drugs accounted for about 24 percent of Part B drug spending, with roughly half of that spending on single-source drugs without generic competition (15 percent) and on drugs with generic competition (10 percent). The remainder of Part B drug spending is accounted for by vaccines, radiopharmaceuticals, products that are regulated as devices (e.g., certain injections for knee pain), and products billed under not-otherwise-classified codes.

TABLE 2–1

Top 10 Part B–covered drugs paid based on ASP by total expenditures and by number of beneficiaries who used the drug, 2015

HCPCS code	Drug name	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
J0178	Aflibercept	Macular degeneration	$1.8	180	$2,100	$10,000
J9310	Rituximab	Cancer, RA	1.6	68	5,800	22,800
J2505	Pegfilgrastim	Cancer supportive	1.3	97	3,600	12,800
J1745	Infliximab	RA	1.2	58	3,700	21,200
J2778	Ranibizumab	Macular degeneration	1.2	120	2,000	9,500
J9035	Bevacizumab	Cancer, macular degeneration	1.1	208	1,100	4,100
J0897	Denosumab	Osteoporosis, cancer supportive	0.9	354	1,200	2,400
J9355	Trastuzumab	Cancer	0.6	20	3,200	32,400
J9305	Pemetrexed	Cancer	0.5	22	5,500	24,900
J9041	Bortezomib	Cancer	0.5	21	1,500	24,000

Note: ASP (average sales price), HCPCS (Healthcare Common Procedure Coding System), RA (rheumatoid arthritis). Eight of these top 10 high-expenditure products are biologics; pemetrexed and bortezomib are the only drugs 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 other hospitals not paid under the outpatient prospective payment system are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Vaccines paid 95 percent of the average wholesale price are also excluded (e.g., Prevnar 13, a pneumococcal vaccine, for which Medicare paid about $0.9 billion in 2015).

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

Medicare's payment methodology for Part B drugs

Medicare pays for most Part B–covered drugs based on ASP + 6 percent. The ASP for a drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions.[10] Medicare pays providers ASP + 6 percent for the drug regardless of the price a provider pays for the drug. Manufacturers report ASP data to CMS. The Medicare Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set ASP + 6 percent payment rates.

Payments for single-source drugs and biologics, multiple-source drugs, and biosimilars are set differently. Each single-source drug and biologic is paid under its own billing code at a rate equal to 106 percent of its own ASP. For multiple-source drugs, both the brand and generic versions are paid under a single billing code at the same rate (i.e., 106 percent of the weighted average ASP for all products assigned to that code). All biosimilars associated with the same reference product are paid under a single billing code at the same rate (i.e., 100 percent of the weighted average ASP for the biosimilars plus 6 percent of the reference biologic's ASP). The reference biologic remains under its own billing code and is paid 106 percent of its own ASP.

An individual provider may purchase a drug for more or less than ASP for a number of reasons. ASP is the average price from the manufacturer's perspective. Generally, some purchasers pay more than ASP and some pay less. For example, prices can vary across purchasers of different sizes (e.g., due to volume discounts) or across types of purchasers (e.g., physicians, hospitals, and pharmacies). In addition, the two-quarter lag in ASP data can result in the average provider acquisition cost for a drug being different from the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that price change is reflected in the ASP data used to pay providers.[11]

In our June 2016 report to the Congress, we analyzed proprietary data from IMS Health Incorporated on invoice prices for 34 high-expenditure drugs for clinic purchasers to get a sense of how providers' acquisition costs for drugs compare with ASP.[12] This analysis found that, for two-thirds of the 34 drugs, at least 75 percent of the volume was sold to clinics at an invoice price of less than 102 percent of ASP in the first quarter of 2015 (Medicare Payment Advisory Commission 2016a). The analysis also found that the median across the 34 drugs of the 75th percentile invoice price as a percent of ASP declined in the second quarter of 2013 when the sequester went into effect (from around 103 percent of ASP in the first quarter of 2012 through the first quarter of 2013 to about 101.5 percent of ASP in the second quarter of 2013 through the second quarter of 2015). 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 for some providers (Medicare Payment Advisory Commission 2016a).

Broader context affecting Medicare Part B drug spending

The Part B drug payment system is based on the manufacturer's ASP for drugs, a manufacturer price that reflects sales to many purchasers and encompasses patients with many types of insurance. It is important to recognize that Medicare exists within a U.S. 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 have a significant influence on the prices Medicare pays for drugs.

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 and data and marketing "exclusivity" for a period during which generic drugs and biosimilars are unable to enter the market. 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) lay 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 small-molecule drugs, a 12-year period for biologics, and a 7-year period for drugs and biologics receiving orphan drug designation for specific indications. 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.

Law and FDA regulations 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 affect the number of medicines available on the market, as do whether and how many therapeutic substitutes and generics are available within a drug class. With respect to biosimilars, FDA guidance on a range of issues (including standards for FDA approval of biosimilars, the naming convention for biosimilars, and proposed standards for demonstrating interchangeability) has implications for the resources involved in obtaining FDA approval, the availability of biosimilars, and clinician attitudes about the safety and efficacy of these products, which in turn can affect the competitive environment and pricing of these products.

Other external factors that can affect Medicare drug spending include biomedical research and development and the policies of other government programs. For example, biomedical research and development funding through the National Institutes of Health and government tax credits for drug research and experimentation can affect the amount of new drug products available and the diseases they target. The Medicaid "best price" policy, which requires makers of innovator drugs to provide a rebate equal to the greater of 23.1 percent of the average manufacturer price (AMP) or the difference between AMP and the manufacturer's "best price" to any customer (with certain exceptions), can increase costs to other payers, including Medicare (Congressional Budget Office 1996).

When the Commission considers payment adequacy for most types of services, it uses a framework that includes looking at providers' profit margins. Drug manufacturers are not Medicare providers since Medicare does not pay them directly for drugs. Nonetheless, drug manufacturers'

financial performance provides broader context when considering payment changes for Part B drugs. According to an analysis by Pembroke Consulting, the 11 U.S. drug manufacturers with revenues large enough to be on the 2016 Fortune 500 list had a profit margin as a share of revenues of 22.3 percent on average and 17.3 percent at the median (Fein 2016).[13] These margins reflect net revenues after expenses on research and development, general administration and marketing, and income taxes. Another measure of profitability is return on assets (ROA), which is profit margin as a share of average total assets. Pembroke Consulting estimated that for the same group of drug manufacturers, the ROA was 10.7 percent on average and 7.8 percent at the median.[14] The level of drug prices and profits needed to fund an appropriate amount of drug research and development is a controversial issue. On the one hand, some argue that the riskiness and cost of the drug development process necessitates substantial profit margins to draw in capital investment and spur innovation. Some stakeholders point to a report by Deloitte indicating that the projected rate of return on new drugs and biologics in the late-stage pipeline for 12 large drug manufacturers has declined in recent years (Deloitte 2016). On the other hand, the Deloitte report also suggests that some inefficiencies exist in the research and development process and states that "opportunities to reduce costs exist, in clinical trials, during discovery and in other areas of development…." The Deloitte report also concludes that companies "can improve R&D [research and development] efficiency, regardless of scale." In addition, a recent analysis by Yu and colleagues (2017) disputes the contention made by drug manufacturers that higher prices in the United States compared with other countries are necessary to fund drug research and development. For a group of manufacturers, Yu and colleagues estimate that the additional revenue generated by the difference in prices between the United States and other countries substantially exceeds global research and development spending.[15]

Policy options to improve payment for Part B drugs

Medicare's ASP + 6 percent payment methodology for Part B drugs has raised several concerns. There is concern about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. There is also concern about the financial incentives providers face under the ASP payment system. In particular, the 6 percent add-on to ASP may create incentives for providers to choose higher priced drugs over lower priced drugs.[16]

This chapter discusses policies that seek to improve payment for Part B drugs. The recommendation's set of policies would improve the current ASP payment system in the short-term while developing an alternative voluntary program that providers could choose to enroll in instead of remaining in the ASP system. (See Figure 2-1 for an overview of the set of recommended policies.) This alternative program—which we refer to as the Part B Drug Value Program (DVP)—would be informed by Medicare's past experience with the competitive acquisition program (CAP) for Part B drugs, but structured differently to encourage provider enrollment; give vendors greater negotiating leverage with manufacturers; and allow for providers, beneficiaries, vendors, and Medicare to share in savings achieved by the program.

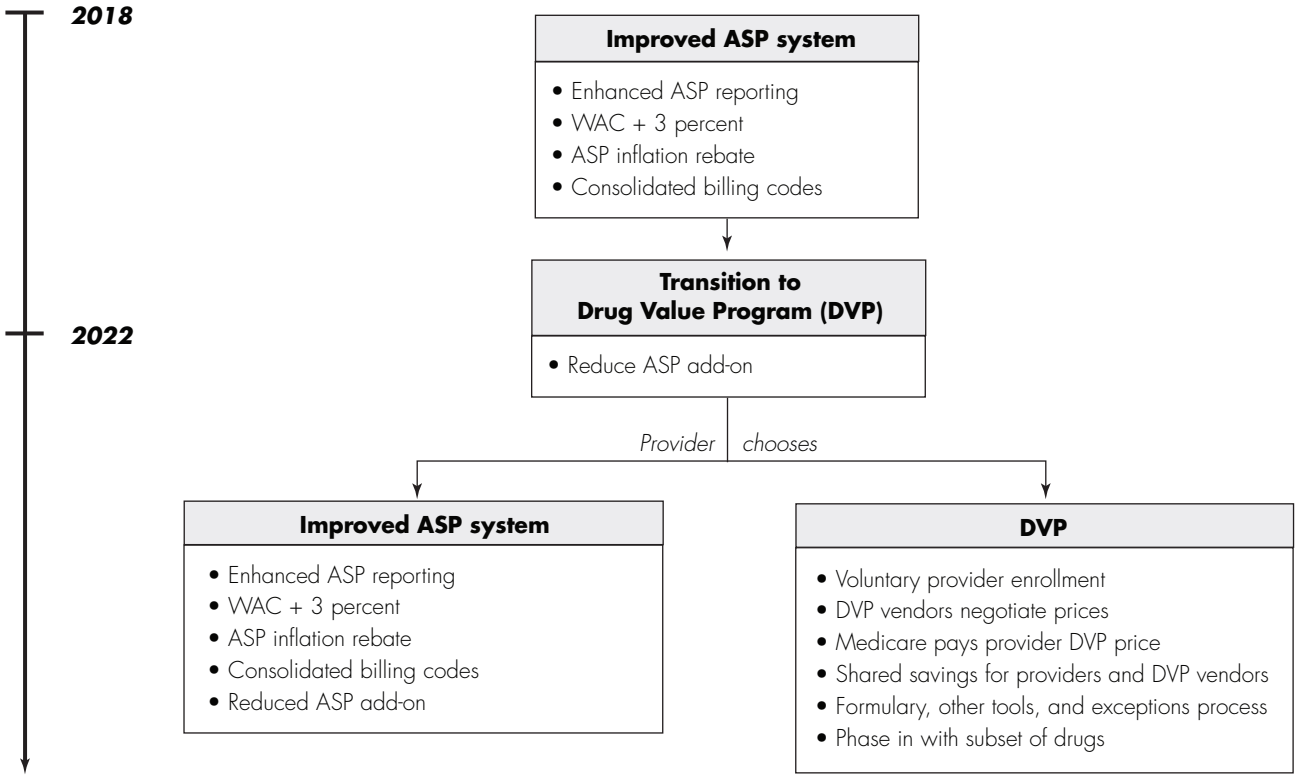
While it would take several years for the DVP to be developed and operationalized, immediate action could improve the existing ASP payment system. These payment policy improvements would apply in the short run to all providers and would remain in place for those providers that chose not to enroll in the DVP once that program became operational. Our recommendation includes the following actions:

- improve ASP data reporting by requiring all manufacturers of Part B drugs to report ASP data and impose civil monetary penalties for failure to report;
- modify payment rates for drugs currently paid at 106 percent of wholesale acquisition cost (WAC) to 103 percent of WAC to reduce overpayments;
- implement an ASP inflation rebate as protection against the potential for rapid price increases by manufacturers; and
- use consolidated billing codes to pay for Part B products with a reference biologic and its associated biosimilars to spur price competition.

The DVP would be a voluntary, market-based alternative to the ASP payment system for physicians and HOPDs. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary) to negotiate with manufacturers and improve incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but vendors would not ship product to providers.

FIGURE 2–1

Set of Commission's recommended policies for Part B drugs



Note: ASP (average sales price), WAC (wholesale acquisition cost).

Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

We note that some stakeholders raise concerns that one or more of these policies aimed at reducing Medicare spending for Part B drugs would reduce incentives for innovation. While arguments can be made that any effort to reduce drug prices lessens incentives for innovation, there is an inherent need to strike a balance between incentives for innovation and affordability and access. A presumption of arguments against reducing drug prices is that current prices strike the appropriate balance. However, others argue that the current level of prices for some products adversely affect affordability and access and exceed what is necessary to provide appropriate incentives for innovation (Nichols 2015).

Improving ASP data reporting

ASP data reporting could be improved by requiring all manufacturers of Part B drugs to report ASP data and by imposing civil monetary penalties for failure to report. Such actions could help ensure the accuracy of CMS's drug prices. CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. Specifically, Section 1927(b)(3) of the Social Security Act requires manufacturers with Medicaid rebate agreements in place to report the ASP and number of units sold for each of their Part B drugs on a quarterly basis. If manufacturers covered by this section do not report data

within 30 days after the end of the quarter, they face civil monetary penalties of up to $10,000 for each day the data are not provided and, after 90 days of the deadline imposed, suspension of their rebate agreements. However, because not all manufacturers of Part B drugs have Medicaid rebate agreements in place, not all manufacturers that sell Part B drugs are required to submit ASP data.

The Health and Human Services Office of Inspector General (OIG) has found that a number of Part B drug manufacturers are not required to report their ASP data. For example, OIG found that at least 45 manufacturers were not required to report ASPs for 443 Part B national drug codes (NDCs) in the third quarter of 2012 (Office of Inspector General 2014). In that quarter, only about half (22) of these manufacturers voluntarily reported ASP data. OIG noted multiple reasons why a manufacturer might not have a Medicaid rebate agreement in place and, therefore, not be required to submit ASP data. For example, manufacturers of Part B drugs that are considered devices by Medicaid and the FDA (e.g., certain injections for knee pain) typically do not have rebate agreements. Many repackagers—entities that purchase drugs from manufacturers and resell the drugs in smaller package sizes—also do not have Medicaid rebate agreements.

OIG has also reported that some manufacturers that are required to submit ASP data fail to do so. For example, OIG found that at least 207 manufacturers of Part B drugs had a Medicaid rebate in place in the third quarter of 2012 and that at least 74 of these manufacturers did not report ASPs for at least one of their Part B NDCs (Office of Inspector General 2014). While most manufacturers failed to submit data for a small share of their NDCs or a small number of NDCs, OIG has initiated actions against certain manufacturers that failed to satisfy their submission requirements. These findings suggest the importance not only of requiring manufacturers to report ASP data but also of giving the Secretary the necessary authority to enforce compliance.

Failing to report ASPs can impact prices for Part B drugs in several ways. For drugs with partially complete ASP data—that is, drugs for which some manufacturers report ASPs but others do not—payment rates based on only the reported ASP data might not reflect average prices of all manufacturers accurately. For drugs with no ASP data—that is, drugs for which no manufacturer reports ASPs—CMS might resort to pricing drugs using alternative and potentially inflated measures of price such as WACs.

Requiring that all manufacturers of Part B drugs report ASP data would improve the accuracy of CMS's drug prices and help prevent CMS from relying on other, less appropriate prices, such as WACs.[17,18] Enhancing the monetary penalty for failing to report ASP data—for instance, from $10,000 to $50,000 per day—and maintaining the ability to exclude a drug from coverage after 90 days of failing to report could help improve the timeliness of ASP data. Repackagers could be excluded from the reporting requirement. This exclusion would reduce the administrative burden of this policy (since many repackagers currently do not report ASP data), avoid double-counting sales (since the same drug can be sold multiple times as it moves through the supply chain), and provide an incentive for manufacturers to find the most efficient way for their drugs to reach consumers (since any mark-up by repackagers would not be included in the ASP).[19]

While this policy requires enhanced reporting of ASP data, it does not call for additional checks on the data that manufacturers report. Ensuring the quality of ASP data is important because lapses in the quality of the data, such as inappropriately included or excluded costs, can affect the accuracy of CMS's drug prices. For example, variation in what manufacturers consider bona fide service fees could affect ASPs. The Secretary could consider providing additional guidance to clarify reporting requirements and enhanced oversight of data submissions to ensure proper compliance. The Commission could also consider examining this issue in the future.

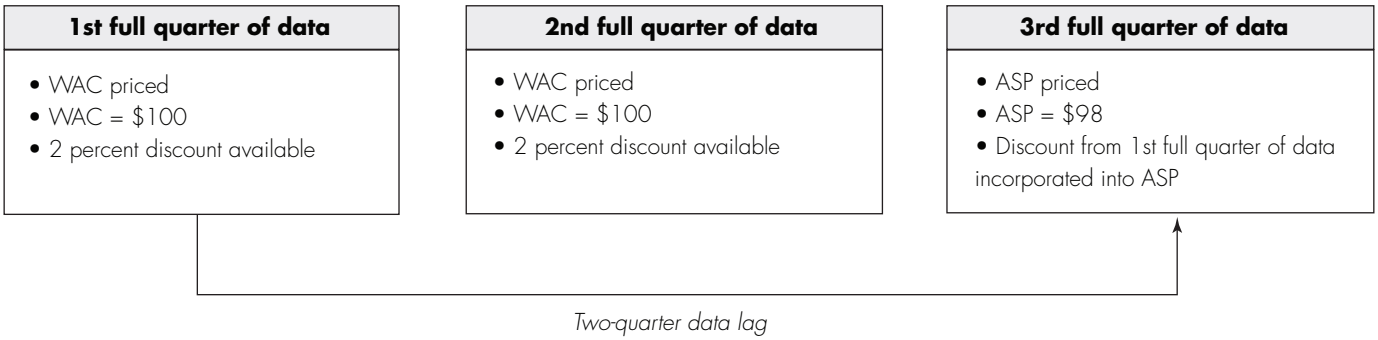
Modifying payment rates for drugs paid at 106 percent of wholesale acquisition cost

The Commission supports reducing the payment rate for drugs currently paid at 106 percent of WAC to 103 percent of WAC. The intent is to reduce the excessive payments made when a drug is priced based on its WAC since the same drug is often paid at a higher rate when WAC priced compared with ASP priced because discounts are not incorporated into WAC-based prices.

The Commission has questioned whether Medicare should pay for certain Part B drugs at 106 percent of WAC. Medicare generally reimburses Part B drugs at 106 percent of WAC when ASP data are not available.[20] For example, when a new, single-source drug or the first biosimilar to a reference product enters the market, an ASP may not be available for nearly three calendar quarters in order to allow time for manufacturers to report sales data and CMS

FIGURE 2–2

Illustrative example of how a 2 percent discount available while a drug is WAC priced is incorporated into its ASP



Note: WAC (wholesale acquisition cost), ASP (average sales price).

Source: MedPAC analysis of CMS payment policies.

to calculate an ASP. For new drugs, an ASP is calculated based on the first full quarter of data available, with a two-quarter lag. For example, if a new drug was first sold in February, the first full quarter would be that year's second quarter (April through June). The data for this quarter would then be used to calculate the rates for the fourth quarter, beginning October 1. In this example, providers would be paid at 106 percent of WAC from February through the end of September.

The WAC is the manufacturer's list price for a drug paid by wholesalers or direct purchasers in the United States. While manufacturers might be influenced by various outside factors—such as physician preference, the price of similar drugs, or potentially negative public reactions—setting a drug's WAC is ultimately controlled by the manufacturer. Unlike an ASP, a drug's WAC does not incorporate prompt-pay or other discounts. Prompt-pay discounts have been reported by industry stakeholders to be in the range of 1 percent to 2 percent of the drug's purchase price. If discounts are available on drugs reimbursed by Medicare at 106 percent of WAC, then Medicare is paying more for drugs than it otherwise would under the ASP-based formula. Furthermore, because beneficiaries are liable for 20 percent cost sharing on Part B drugs, beneficiaries incur these extra costs also.

Because the data used to set ASPs have a two-quarter lag, a drug's initial ASP is based on sales data from when a drug was reimbursed using its WAC. Therefore, a drop in price from when a drug was priced using its WAC to when a drug was priced using its ASP could indicate the presence of discounts that were not reflected in its WAC (Figure 2-2). To examine the extent of discounts on drugs reimbursed at 106 percent of WAC, we tracked the price of eight new, high-expenditure Part B drugs before and after the drugs were priced using ASPs.[21] Specifically, we identified a drug's WAC using First Databank and compared that price with the price CMS posted on the agency's quarterly ASP drug pricing files for a year after the drug first appeared on the pricing files.[22] Observing drugs over this period allows time for rebates, to the extent there were any, to begin to be incorporated into a drug's ASP since certain rebates can be lagged.

We found that drugs' ASPs one year after appearing on CMS's drug pricing files were generally lower than their WACs, suggesting that drug purchasers received discounts that were not incorporated into WACs. Namely, the ASP one year after appearing on CMS's drug pricing files was lower than the WAC for seven out of the eight drugs we examined, with aflibercept's price experiencing no movement. For these seven drugs, the price declines ranged from 0.7 percent to 2.7 percent (Table 2-2, p. 44).

While the differences between WAC and ASP payment rates for the cohort of new, high-expenditure drugs appear to be modest during our study period, larger differences occur in other instances in which WAC-based payment rates are used. First, CMS may revert to pricing drugs

TABLE 2–2

Price declines from drugs' initial WACs to ASPs suggest modest discounts commonly available while drugs are WAC priced

Drug	Percentage change in price
Abatacept	–2.1%
Aflibercept	0.0
Bendamustine	–2.7
Denosumab	–0.7
Ipilimumab	–1.6
Natalizumab	–2.7
Paclitaxel protein bound	–1.2
Ranibizumab	–1.8

Note: WAC (wholesale acquisition cost), ASP (average sales price). Percentage change in price determined from a drug's initial WAC to its ASP one year after being listed in CMS's ASP drug pricing files. Although initially approved by the Food and Drug Administration (FDA) in November 2004, natalizumab's manufacturer suspended marketing of the drug in 2005. In June 2006, the FDA approved an application for resumed marketing of the drug. For the purposes of calculating the change in price, we treat natalizumab as though it were approved in June 2006.

Source: MedPAC analysis of data from Medicare claims, CMS's ASP drug pricing files, and First Databank.

based on WACs instead of ASPs in instances when manufacturers do not report data or when other data issues exist. In a 2014 report, OIG found three instances in the first quarter of 2013 in which CMS priced a Part B drug using WACs because of such issues (Office of Inspector General 2014). While the ASP for these drugs was not known, OIG found that WACs often do not reflect actual market prices for drugs.[23] Second, while the number of biosimilars is limited, early patterns suggest that large discounts on biosimilars may be available while those drugs are WAC priced.[24] For example, applying the same methodology used to examine our cohort of new, high-expenditure drugs, we found that the price of Zarxio, the first biosimilar approved in the United States, declined by approximately 16 percent within one year of being listed on CMS's drug pricing files in the fourth quarter of 2015.

Based on industry statements regarding the magnitude of prompt-pay discounts, our analysis of a small group of new drugs, and previous OIG research, the Commission supports reducing the payment rate for drugs currently paid at 106 percent of WAC by 3 percentage points—roughly the high end of the discounts we observed. In doing so, many new, WAC-priced drugs would be paid the same or less than if they were ASP priced, assuming that manufacturers would not substantially increase discounts in the future. Further, to maintain parity between WAC-priced and ASP-priced drugs, the payment rate for WAC-priced drugs could be further reduced if changes were made to ASP-priced drugs. For example, if the payment rate for ASP-priced drugs were reduced by 3 percentage points, the payment rate for WAC-priced drugs could be reduced to 100 percent of WAC (i.e., 103 percent minus 3 percentage points). Both the initial reduction of 3 percentage points and further reducing the add-on if the ASP add-on is reduced would help maintain parity between ASP-based prices and WAC-based prices and would be consistent with the Commission's policy of paying similar rates for similar care.

This policy does not address drugs for which WACs substantially exceed ASPs, such as biosimilars and drugs for which CMS substitutes WAC-based prices for ASP-based prices because of a lack of data. Other policies the Commission supports—consolidated billing codes for biosimilars and reference products and improved ASP data reporting—could help address these issues.

ASP inflation limit

To protect taxpayers and Medicare beneficiaries from substantial price increases over time for individual drug products, the Commission supports requiring drug manufacturers to pay Medicare a rebate when a Part B drug product's ASP grows faster than an inflation benchmark. Elements of such a policy would include tying beneficiary cost sharing and provider add-on payments to the inflation-adjusted ASP and exempting low-cost drugs and certain utilization from rebates. While the Commission has pursued a rebate approach, we also discuss an alternative approach that could be used to limit growth in Medicare's ASP + 6 percent payment rates.

Under Medicare's ASP payment system, growth in Medicare's ASP + 6 percent payment rates for individual drugs is driven by manufacturer pricing policies.[25] 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 2-3 shows ASP growth between January 2005 and January 2017 for the 20 Part B drugs with the highest 2015 expenditures. Among these 20 high-expenditure drugs, the median ASP growth rate was slightly below inflation as measured by the consumer

TABLE 2–3

Growth in ASP for the 20 highest expenditure Part B drugs, 2005–2017

HCPCS code	Drug name	Total Medicare payments in 2015 (in billions)	Average annual ASP growth, from January to January of each year				Earliest year of ASP data if not 2005
			2005–2017	2005–2010	2010–2016	2016–2017	
J0178	Aflibercept	$1.8	0.0%*	N/A	0.0%*	0.0%	2013
J9310	Rituximab	1.6	5.3	5.0%	5.3	6.4	
J2505	Pegfilgrastim	1.3	5.1	0.8	8.4	7.6	
J1745	Infliximab	1.2	3.7	2.0	5.3	2.9	
J2778	Ranibizumab	1.2	–0.7*	–0.2*	–0.7	–1.9	2008
J9035	Bevacizumab	1.1	2.2	0.1	3.6	4.1	
J0897	Denosumab	0.9	2.7*	N/A	1.8*	6.6	2012
J9355	Trastuzumab	0.6	4.9	4.1	5.5	5.6	
J9305	Pemetrexed	0.5	3.9	4.5	3.4	3.3	
J9041	Bortezomib	0.5	4.2	6.1	3.4	–1.2	
J0129	Abatacept	0.5	9.4*	1.4*	12.4	16.3	2007
J2353	Octreotide depot	0.4	6.1	4.9	6.6	10.0	
J9033	Bendamustine	0.3	5.2*	–0.6*	4.8	13.8	2009
J0881	Darbepoetin alfa	0.3	0.7	–4.4	6.6	–7.2	
J0885	Epoetin alfa	0.3	1.3	–2.1	4.4	–0.1	
J2323	Natalizumab	0.3	10.7*	4.7*	12.9	10.3	2008
J1561	Gamunex-C and Gammaked	0.3	1.1*	7.0*	1.8	–12.7	2008
J9264	Paclitaxel protein bound	0.3	2.0*	3.0*	1.1	3.2	2006
J9217	Leuprolide acetate	0.3	–1.1	–4.0	3.4	–12.5	
J2357	Omalizumab	0.3	6.4	4.6	7.7	8.0	
Median average annual ASP growth across top 20 drugs			3.8	2.5	4.6	3.7	
Consumer price index for urban consumers			2.0	2.6	1.5	2.5	

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 and exclude critical access hospitals and other hospitals not paid under the outpatient prospective payment system. Vaccines paid 95 percent of the average wholesale price are also excluded (e.g., Prevnar 13, a pneumococcal vaccine, for which Medicare paid about $0.9 billion in 2015).
*Indicates that ASP payment rates were not available for the full period listed, and the average annual growth rate was calculated based on the earliest January for which data were available.

Source: MedPAC analysis of CMS ASP pricing files and consumer price index for all urban consumers data from the Bureau of Labor Statistics and Medicare claims data for physicians, outpatient hospitals, and suppliers.

price index for urban consumers (CPI–U) from 2005 to 2010 and 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 2017), ASPs for several high-expenditure drugs have grown at an average annual rate of roughly 5 percent or more (i.e., natalizumab, abatacept, omalizumab, octreotide depot, rituximab, bendamustine, pegfilgrastim, and trastuzumab). In the last year (January 2016 to January 2017), 9 of the top 20 high-expenditure drugs had ASP growth of 5 percent or more, and 4 of the products had ASP growth of 10 percent or more.

Among products outside the top 20 highest expenditure drugs, a number of Part B drugs experienced substantial price increases. For products with at least $5 million in Medicare spending in 2015, 17 products experienced an increase in their ASP of 100 percent or more between

January 2010 and January 2017.[26] For example, over this period, several products—injectable cyclophosphamide, vitamin B-12, mitomycin, and pegloticase—had very large ASP increases ranging from 500 percent to 1,400 percent, and one product—edetate calcium disodium—had an ASP increase of over 6,000 percent. A variety of factors may contribute to price increases. For example, with some of these products, price increases occurred when only one manufacturer made the product, when the product changed ownership, when a competing product experienced a shortage, or when the product itself was in short supply due to production problems or difficulty obtaining raw ingredients.

A policy could be instituted to limit the amount that Medicare's ASP + 6 percent payment for a product can grow over time. Such a limit would protect the Medicare program and beneficiaries from the possibility that a manufacturer could institute a dramatic price increase and would generate savings for existing drugs that experience ASP growth higher than a specified inflation threshold. It would not, however, address the issue of high launch prices for new products, and it might spur some manufacturers to set higher launch prices.

Some argue that an administrative constraint on price growth is contrary to letting market conditions and competitive forces drive payments for Part B drugs; however, in many instances, a competitive market does not exist for Part B drugs. The federal government grants temporary monopolies to pharmaceutical companies in the form of patents as well as data and marketing "exclusivity" for a period of time. During these periods, manufacturers have substantial market power to set prices without the potential for another company to enter the market and sell the same product at a lower price. Although, in some cases, drugs with patent protection may face competition from other brand drugs in the same therapeutic class, price competition between such products may be limited because the Part B drug payment system is not structured to facilitate competition among brand products with similar health effects. In addition, demand for pharmaceutical products may be relatively unresponsive to price changes since many patients do not bear the full cost of the product because of third-party insurance and because these products could serve clinical needs for which alternative treatments do not exist. Because competitive markets for these products are often lacking, placing a constraint on how much Medicare's ASP + 6 percent payment rate can increase over time would be a safeguard for the Medicare program and beneficiaries to ensure that Medicare payment rates for existing Part B drugs do not grow rapidly. In addition, some contend that a limit on growth in Medicare's ASP + 6 percent payment rates would make payment for Part B drugs more consistent with payment for other Part A–covered and Part B–covered services.

At least two approaches exist for implementing an ASP inflation limit: a manufacturer rebate and a limit on provider payment rates. These two approaches differ in terms of which entity bears financial risk for price increases. Under a rebate approach, the manufacturer bears the financial liability if the price of its drug rises higher than an inflation benchmark. Under the payment-limit approach, providers would bear the financial liability for ASP growth greater than inflation. The two approaches also differ in the administrative work required of CMS to implement the policy. A provider payment limit would require fewer administrative resources than a rebate because CMS would not have to calculate and collect rebate payments. Although both approaches have merit, the Commission has chosen to focus on a rebate approach because it results in the manufacturer rather than the provider assuming financial risk for price increases.

The structure of an ASP inflation rebate would include the following elements. A manufacturer of a Part B drug would be required to pay Medicare a rebate if its drug's ASP (weighted across all NDCs for the manufacturer's drug) exceeded the inflation-adjusted ASP for the billing code.[27,28,29] For each unit of Medicare use of the manufacturer's product, the manufacturer would pay Medicare a rebate that equals the difference between the manufacturer's actual ASP and the inflation-adjusted ASP for the billing code.[30]

Rebates would be shared with beneficiaries by reducing beneficiary cost sharing for drugs that triggered a rebate. The cost-sharing amount for a drug billing code would be reduced when the ASP increased faster than inflation (to the level it would have been if ASP had grown at the same rate as inflation). This cost-sharing reduction would occur up front, with Medicare increasing its payment to the provider to make up the difference. The Medicare program would then receive rebates from the manufacturer afterward and keep the full amount of the rebate. The net result would be that the beneficiary would realize roughly 20 percent of the rebate through lower cost sharing and the program would realize 80 percent (i.e., total rebates minus the additional amount the program paid the provider to make up for the reduced beneficiary cost sharing).[31]

The provider's add-on payment (the 6 percent) would also be based on the inflation-adjusted ASP. Under this approach, the provider's payment for a drug that triggers a rebate would be 100 percent of the actual ASP plus 6 percent of the inflation-adjusted ASP. This policy would be a safeguard to ensure that rapid price increases for a particular product do not translate into large increases in provider add-on payments.

A Medicare inflation rebate policy would exempt certain Part B drugs and certain Medicare use from the rebate. Low-cost drugs—those with an annual cost per user of less than a specified threshold (e.g., $100)—would be exempt from the rebate policy. With a low-cost drug, a significant percentage increase would be of less concern because it would constitute a relatively small price increase in dollar terms (e.g., a 10 percent increase in ASP for a $20 drug is $2). Excluding low-cost products from the policy would also reduce CMS's administrative work and target the policy toward products for which rapid price increases would have the largest impact.[32] Large price increases have occurred among some low-cost generic drugs, so low-cost drugs would be exempt from the ASP inflation rebate policy only as long as they continued to remain low cost.

Manufacturers would also be exempt from paying an ASP inflation rebate on Medicare Part B utilization that is already subject to an inflation discount. Under the Medicaid rebate program and the 340B program, manufacturers pay rebates to states and offer discounted prices to 340B hospitals that incorporate an inflation rebate. To ensure that manufacturers did not pay multiple inflation discounts on the same utilization, manufacturers would be exempt from paying a Medicare inflation rebate on use subject to a Medicaid rebate or 340B discount. This exemption would be similar to current policy in which the same utilization cannot be subject to both a Medicaid rebate and a 340B discount under those two programs.

Some stakeholders have expressed concern that an ASP inflation limit might lead manufacturers to leave the market because they would not be able to increase the price of their product substantially for the portion of their business covered by Medicare Part B, resulting in a product shortage. This potential concern might be most applicable to low-cost drugs where a manufacturer might decide it is not worth it to make the product any longer for a low price. The exemption of low-cost drugs from the Medicare inflation rebate should alleviate such concerns. Some stakeholders have also expressed concern that an ASP inflation rebate might adversely affect a manufacturer of a drug in short supply (for reasons such as production problems, for example) if a manufacturer wished to increase the price in conjunction with bringing more product to market. The exemption of low-cost drugs from the rebate policy would alleviate this concern for those drugs. With respect to higher cost drugs that are in short supply, policymakers could consider creating a process to permit the Secretary to exempt such products from the ASP inflation rebate on a case-by-case basis. In developing an exceptions process, it would be important to prescribe the limited circumstances under which an exception could be granted so that the policy did not create unintended incentives for shortages.

To operationalize an inflation rebate policy, an inflation benchmark would need to be selected. One option is to use the same inflation benchmark used in the Medicaid rebate program, which is the CPI–U. Other benchmarks could also be evaluated. There are several inflation benchmarks related to drugs (e.g., consumer price index for prescription drugs and producer price index for pharmaceutical preparations); however, these indexes largely capture trends in drug prices established by manufacturers, so it would undermine the policy objective to use them to limit ASP growth. Another option would be to use a producer price index for wholesale distribution of nondrug medical supplies, with smoothing to address volatility that may be present with this type of index. In choosing a benchmark, one principle that could be considered is that the inflation benchmark for Part B drug manufacturers be no greater than the typical payment updates received by other providers in the Medicare program, particularly physicians and hospitals that purchase these drugs.

Reduced spending from an inflation limit would likely come mostly from existing products, while manufacturers of new products that launched after the policy was implemented might respond by increasing their launch prices to partly or fully offset the inflation-limit policy affecting their products. The extent to which manufacturers of new products would be able to fully offset the inflation limit for their products by setting a higher launch price would depend on competitive dynamics. For example, a new breakthrough product might be able to increase its launch price with minimal constraints. In contrast, the manufacturer of a drug with available alternatives might take into account how its launch price would be viewed relative to competitor products already on the market and might be less inclined to raise the launch price to fully offset the inflation limit policy.

Consolidated billing codes for a reference biologic and its associated biosimilars

To spur price competition and pay similar rates for similar products, the Commission supports giving the Secretary the authority to create consolidated billing codes that would assign a reference biologic and its biosimilars to the same billing code. Elements of such a policy would include using the FDA's approval process for biosimilars established by the Biologic and Price Competition and Innovation Act of 2009 to determine what products to group together. The Commission is also interested in the use of broader consolidated billing to spur competition among products with similar health effects.

Within the current ASP payment system, competition is maximized when products that result in similar health effects are assigned to the same billing code—a consolidated billing code—and paid according to the volume-weighted ASP of all products assigned to the code. The current ASP payment system assigns consolidated billing codes to:

- generic drugs along with their associated brand drug. 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).
- all biosimilar products associated with a given reference biologic. However, unlike generic drugs, biosimilars are not assigned the same code as the reference biologic.

The current ASP payment system does not spur price competition between the reference biologic and its associated biosimilars because the reference product is assigned to one billing code and its biosimilars are assigned to a different billing code. CMS has stated its lack of statutory authority to group the reference biologic and its biosimilars in a single billing code (Centers for Medicare & Medicaid Services 2015). Likewise, the structure of the ASP payment system—with most single-source drugs and most biologics (excluding biosimilars) each being paid under its own ASP rate under separate billing codes—does not promote price competition among products with similar health effects.

The Commission has held that Medicare should pay similar rates for similar care. With respect to the reference biologic and its biosimilars, this principle warrants that Medicare use a consolidated billing code when paying for these products. The pricing behavior exhibited by the manufacturers of currently available reference biologics and biosimilar products—the ASPs for the two currently available reference biologics have increased despite the availability of their biosimilars, and Medicare's initial payment rate for one of the biosimilars was higher than the reference biologic's rate—suggests consolidated billing codes would spur price competition among these products.

Beyond grouping a reference biologic with its biosimilars, the Commission is interested in the use of broader consolidated billing within the current ASP payment system to maximize competition among products with similar health effects. The text box (pp. 54–55) provides two case studies demonstrating greater competition when Medicare has assigned drugs with similar health effects to a single billing code compared with payment for these drugs when each was under its own separate billing code. Some issues associated with using such a policy more broadly for groups of drugs with similar health effects and groups of biologics with similar health effects are discussed in the text box (pp. 50–52). We encourage the Secretary to conduct research that examines the potential for these broader groupings of Part B products with similar health effects.

Creating consolidated billing codes that group a reference biologic with its biosimilars

Under this policy, the Secretary would have the authority to assign a common billing code to group a reference biologic and its biosimilars, resulting in a single rate paid for all products billed under that code. By contrast, under current ASP policy, the reference biologic has its own billing code and is paid 106 percent of its own ASP. All biosimilar products associated with a particular reference product are grouped together in a single billing code (separate from the reference biologic) 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.[33,34]

Grouping the reference biologic and its biosimilars together under one billing code and paying all of them the same rate would be expected to generate greater price competition than using 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

TABLE 2–4 **Use of Zarxio, the biosimilar for Neupogen, has increased since its launch**

		Share of total spending			Share of total units	
	Total Medicare payments (in millions)	Neupogen (reference biologic)	Zarxio (biosimilar)	Total units furnished (in millions)	Neupogen (reference biologic)	Zarxio (biosimilar)
2014						
q1	$36.0	100%	N/A	37.3	100%	N/A
q2	38.0	100	N/A	38.9	100	N/A
q3	36.8	100	N/A	37.7	100	N/A
q4	33.9	100	N/A	35.0	100	N/A
2015						
q1	32.3	100	N/A	33.2	100	N/A
q2	33.4	100	N/A	34.5	100	N/A
q3	32.3	99.9	0.1%	33.0	99.9	0.1%
q4	30.7	97.3	2.7	31.5	97.2	2.8
2016						
q1	30.1	89.5	10.5	30.8	89.1	10.9
q2	30.7	76.7	23.3	31.4	76.0	24.0
q3*	29.0	68.4	31.6	31.0	65.4	34.6

Note: N/A (not available). "Total Medicare payments" includes beneficiary cost sharing and deductibles.
*Spending and utilization for the third quarter of 2016 is preliminary based on Medicare claims available week 9 of 2017.

Source: Acumen analysis of 100 percent Medicare claims data for physicians, suppliers, and outpatient hospitals.

and exclusivity periods elapse, competitive biosimilar manufacturers are able to enter the market and produce a similar product at lower development cost compared with the reference biologic. Under a single payment rate, the reference product and its biosimilars 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 assigning each product a separate billing code (Congressional Budget Office 2008).

Since 2015, manufacturers have launched two biosimilars in the United States. The first biosimilar is Zarxio (filgrastim-bflm), a granulocyte-colony stimulating factor used to manage certain side effects of chemotherapy, including infection and neutropenic (low white blood cell) fevers. It was launched in September 2015 after the FDA approved it in March 2015 for all of the indications (at that time) of its reference biologic, Neupogen (filgrastim).[35] Table 2-4 shows that since its launch, use of Zarxio among Medicare beneficiaries has increased. As a share of total units furnished, use of Zarxio increased between the fourth quarter of 2015 and the third quarter of 2016 from about 3 percent to nearly 35 percent.[36]

The second biosimilar is Inflectra (infliximab-dyyb), a targeted immune modulator used to treat certain autoimmune diseases including rheumatoid arthritis. Inflectra was launched in the United States in late November 2016 after the FDA approved it in April 2016 for all of the indications of its reference biologic, Remicade (infliximab). Medicare claims data are not yet available to quantify Medicare beneficiaries' use of Inflectra.

Price competition under a consolidated billing code would likely increase as the number of available

Creating consolidated billing codes for single-source products with similar health effects

Broader consolidated billing (beyond a reference biologic and its biosimilars) for single-source products (i.e., single-source drugs and reference biologics) with similar health effects could improve competition and thus achieve lower prices for Part B products. Because Medicare pays for each of these products under its own billing code based on its own average sales price (ASP), there is less pressure for price competition among these products. According to researchers, competition between two or more brand-name manufacturers marketing drugs in the same class does not usually result in substantial price reductions (Kesselheim et al. 2016). Like the combined billing code for a reference biologic and its biosimilars, combining single-source products under a single payment code essentially would set the payment amount based on the volume-weighted ASP for all products included in the single payment code.[37]

Presented below are examples of groups of competing products, with each product paid under a separate billing code based on its separate ASP. Five of the products listed below are among the top 10 Part B drugs as measured by total 2015 expenditures (Table 2-1, p. 38).[38] For each group, we have highlighted the three leading products as measured by total 2015 Part B expenditures and the changes in each product's ASP during the most recent five-year period for which data are available (April 2012 through April 2017). The ASPs for nearly all of the products listed below have either remained the same or increased during this five-year period.

- Erythropoiesis-stimulating agents (ESAs) are biologics used to stimulate production of red blood cells. In 2015, Part B spending for these products totaled nearly $600 million. The products in this group include epoetin alfa (Procrit/Epogen) and darbepoetin alfa (Aranesp). Between April 2012 and April 2017 (the most recent five-year period data are available), the ASPs for Procrit/Epogen and Aranesp increased at an average annual rate of 6.9 percent and 3.4 percent, respectively. In 2015, mean annual payment per beneficiary for Procrit/Epogen and Aranesp was $3,200 and $4,800, respectively. The launch of a new single-source ESA, epoetin beta (Mircera), in 2015 has resulted in increased competition and shifts in the use of ESAs covered under the dialysis prospective payment system.[39]

- Anti-vascular endothelial growth factor (anti-VEGF) agents are biologics used to treat wet age-related macular degeneration and certain other eye conditions. In 2015, Part B spending for these products totaled nearly $3 billion. The products in this group include ranibizumab (Lucentis) and aflibercept (Eyelea). Price competition between Lucentis and Eyelea has been very limited: Between April 2012 (when ASP data became available for Eyelea) and April 2017, Eyelea's ASP has remained essentially unchanged (from $980.50 per unit to $980.14 per unit, respectively) while Lucentis's ASP has declined modestly (1.3 percent per year). In 2015, mean annual payment per beneficiary for Lucentis and Eyelea was $9,500 and $10,000, respectively.

- Targeted immune modulators are biologics used to treat immunologic diseases including rheumatoid arthritis, Crohn's disease, and certain other conditions. In 2015, Part B spending for these products totaled $2.5 billion. Products in this group include infliximab (Remicade) and its biosimilar (Inflectra), abatacept (Orencia), and rituximab (Rituxan). Between April 2012 and April 2017, the ASPs for Rituxan, Remicade, and Orencia increased by 5.0 percent, 6.1 percent, and 16.7 percent per year, respectively. In 2015, mean annual payment per beneficiary for these three products ranged from $21,200 to $22,800.

- Leukocyte growth factors (LGFs) are biologics that stimulate the proliferation and differentiation of normal white blood cells. In 2015, Part B spending for these products totaled $1.4 billion. The products in this group include filgrastim (Neupogen) and its biosimilar (Zarxio), pegfilgrastim (Neulasta), and tbo-filgrastim (Granix). Between April 2012 and April 2017, the ASPs for filgrastim and

(continued next page)

Creating consolidated billing codes for single-source products with similar health effects (cont.)

pegfilgrastim (the LGFs that have been available since 2012) increased at an average annual rate of 3.0 percent and 8.4 percent, respectively. In 2015, mean annual payment per beneficiary for Granix, Neupogen, and Neulasta was $2,000, $3,000, and $12,800, respectively.

- Immune globulins are for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. In 2015, Part B spending for these products totaled $1.3 billion. The products in this group include Gamunex-C/Gammaked, Gammagard liquid injection, and IVIG Privigen. Between April 2012 and April 2017, the ASP for Gamunex-C/Gammaked decreased by 2.0 percent per year, while the ASPs for the remaining products increased by 0.1 percent and 2.1 percent, respectively. In 2015, mean annual payment per beneficiary for these products ranged from $20,200 to $26,000.

Among the products that are not in the group of the Part B highest expenditure products are additional examples of products that are competitors and are each paid under separate billing codes based on their separate ASPs:

- Luteinizing hormone-releasing hormone agonists for prostate cancer. In 2015, Part B spending for these products totaled $302 million. The products in this group include luprolide acetate suspension (Lupron), goserelin acetate implant (Zoladex), and triptorelin pamoate (Trelstar). Between April 2012 and April 2017, the ASPs for each of these products increased, ranging from 0.1 percent per year for Lupron to 15.1 percent per year for Zoladex. In 2015, mean annual payment per beneficiary for these three products ranged from $1,300 to $2,000.
- Viscosupplements in which hyaluronate is used to treat osteoarthritis of the knee. In 2015, Part B spending for these products totaled about $405 million. The products in this group include a high-molecular-weight form of hyaluronic acid (Orthovisc), hylan G-F-20 (Synvisc and Synvisc One), and sodium hyaluronate (which is a combined billing code for the brand-name products Hyalgan and Supartz). Between April 2012 and April 2017, the ASP for Synvisc/Synvisc One increased by 0.3 percent per year while the ASPs for Hyalgan/Supartz and Orthovisc decreased by 0.5 percent and 1.6 percent per year, respectively. In 2015, mean annual payment per beneficiary for these three products ranged from $500 to $900.
- Botulinum toxins, which are used in the treatment of various focal muscle spastic disorders and excessive muscle contractions, such as dystonias, spasms, and twitches. In 2015, Part B spending totaled $278 million. Products in this group include onabotulinumtoxinA (Botox), rimabotulinumtoxinB (Myobloc), and incobotulinumtoxinA (Xeomin). Between April 2012 and April 2017, the ASP of Botox, which accounted for most of the spending for botulinum toxins (93 percent), increased by 1.6 percent per year. In 2015, mean annual payment per beneficiary for these three products ranged from $1,600 to $2,100.

In 2015, Medicare spending for all the products in the above-listed eight therapeutic groups totaled $9.5 billion. In addition to the groups of products listed above, there are other examples of groups to consider under a broader consolidated billing code policy.

An issue to be considered regarding broader consolidated billing (beyond a reference biologic and its biosimilars) is what criteria CMS would use to determine when products should be grouped together and when they should retain their separate billing codes. For example, it could consider the potential effects on access to care, program spending, and future research on drugs in the category. CMS would also need to develop a process to identify groups of products that achieve comparable clinical outcomes. Some

(continued next page)

Creating consolidated billing codes for single-source products with similar health effects (cont.)

stakeholders have raised concerns about the feasibility of Medicare defining groups of drugs and groups of biologics with similar health effects.

To address this concern, CMS could solicit input from clinical experts 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, including the Drug Effectiveness Review Project at the Pacific Northwest Evidence-based Practice Center and the Agency for Healthcare Research and Quality's (AHRQ's) Technology Assessment Program. For example, AHRQ sponsored a 2015 technology assessment that reviewed evidence on the effectiveness of hyaluronic acid in the treatment of joint disease of the knee (Agency for Healthcare Research and Quality 2015). CMS could also seek input from pharmacy benefit managers, commercial health plans, and other such entities that have grouped therapeutically similar single-source drugs and therapeutically similar single-source biologics to develop their coverage and payment policies (Aetna 2017, CVS Health 2016). Once the Part B Drug Value Program (DVP) (a voluntary, market-based alternative to the ASP payment system for physicians and hospital outpatient departments) is in place, CMS could also seek guidance from DVP contractors. Any process for seeking clinical expertise and stakeholder input would need to be carefully designed to avoid conflicts of interest, give the public adequate notice and opportunity for comment, and allow for decisions to be reconsidered as clinical evidence evolves. ■

biosimilars associated with a reference biologic increased. As of October 2016, the FDA had reviewed at least one biosimilar application for a second biosimilar for Remicade and a second biosimilar for Neupogen (Truven Health Analytics 2016).[40]

Under separate codes, price competition between a reference biologic and its biosimilar is not maximized

Two examples of the pricing behavior exhibited by the manufacturers of currently available reference biologics and biosimilar products (biosimilars Zarxio and Inflectra and their respective reference biologics Neupogen and Remicade) suggest that putting the reference biologic and its biosimilars in the same billing code would generate even more price competition than under the current policy of assigning each product a separate billing code. The ASPs for both reference biologics have increased despite the availability of their biosimilars, and Medicare's initial payment rate for one of the biosimilars was higher than the reference biologic's rate:

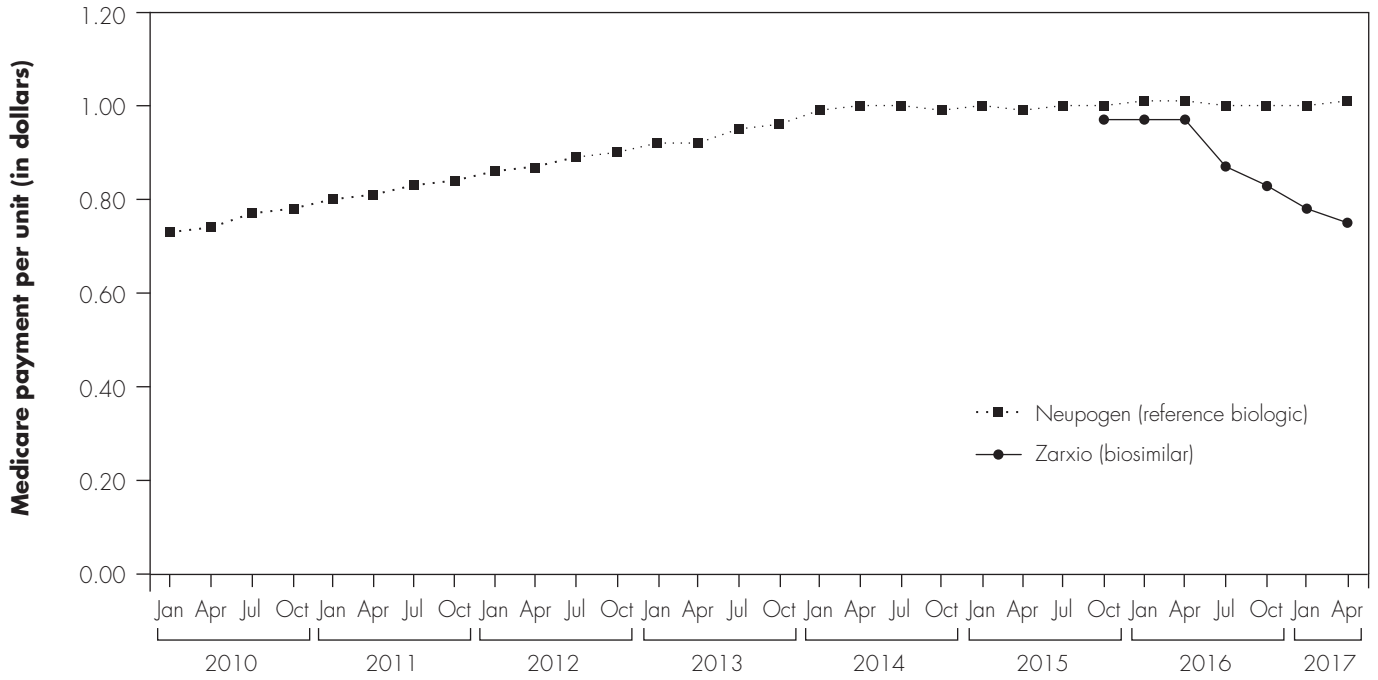
- Since the launch of its biosimilar Zarxio, the ASP for the reference biologic Neupogen has modestly increased, despite price reductions for Zarxio.
- During the two calendar quarters since its launch, the WAC-based payment rate for the biosimilar Inflectra has been higher than the payment rate for its reference biologic Remicade. During this period, the payment rate of the reference biologic increased.

Since its launch, biosimilar Zarxio's payment rate has been lower than that of its reference biologic, Neupogen. Initially, in October 2015, Zarxio's payment rate was 3 percent lower than Neupogen's rate. By April 2017 (the most recent ASP data available), Zarxio's payment rate was 25 percent lower than Neupogen's rate. During this period, Zarxio's payment rate declined by 22 percent while Neupogen's payment rate increased by 1 percent (Figure 2-3).

In contrast, biosimilar Inflectra's initial payment rates during the first two calendar quarters of 2017 were higher than the ASP rate of its reference biologic, Remicade, by 22.0 percent and 17.2 percent, respectively (Table 2-5). During this period, Remicade's ASP increased by 4.1 percent. If Inflectra and Remicade were in a consolidated billing code in the first two quarters of 2017, Medicare would have paid for both products based solely on Remicade's ASP-based rate, which would have reduced the payment rate for Inflectra by 18.0 percent and 14.7 percent, respectively. That is, under a consolidated billing code policy, Medicare's payment rate would be based

FIGURE 2–3

Medicare's payment rate for the biosimilar Zarxio has been lower than its reference biologic, Neupogen



Note: Zarxio was launched in the United States in September 2015. The first two calendar quarters of Zarxio's payment were based on wholesale acquisition cost plus 6 percent. Thereafter, Zarxio's payment is based on average sales price (ASP) plus 6 percent. During this period, Granix was launched in the United States in November 2013. Granix is, like Neupogen and Zarxio, a granulocyte-colony stimulating factor.

Source: CMS's ASP quarterly pricing files, 2010–2017.

solely on ASP data (not on WAC data). In contrast, under current policy, the initial payment rate for the biosimilar Inflectra, like other new products assigned to a new billing code, is based on its WAC because ASP data for new products are not available for nearly three calendar quarters to allow time for manufacturers to report sales data and CMS to calculate an ASP.

Although biosimilars offer potential savings from the reference product's price, the amount of savings is

TABLE 2–5

Medicare's payment rate for the biosimilar Inflectra is greater than its reference biologic, Remicade, and the payment rate for Remicade continues to grow

	Medicare's payment rate per unit				
	2010 q1	2012 q1	2015 q1	2017 q1	2017 q2
Remicade (reference biologic)	$58.66	$62.68	$74.11	$82.22	$85.59
Inflectra (biosimilar)	N/A	N/A	N/A	100.31	100.31

Note: q (quarter), N/A (not available). Inflectra was launched in the United States in November 2016. The first two calendar quarters of Inflectra's payment were based on wholesale acquisition cost plus 6 percent. Remicade's payment was based on average sales price (ASP) plus 6 percent for the period indicated.

Source: CMS's ASP quarterly pricing files, 2010–2017.

Case studies of Medicare promoting competition by assigning drugs to a single billing code

Because most products have their own billing code, the structure of the average sales price (ASP) payment system does not promote the strongest price competition among single-source products for which there are therapeutic alternatives. The following two case studies show that when Medicare assigned products to the same billing code, more price competition was generated among products than when each product was assigned to its own billing code.

Case Study 1: Competition between drugs with similar health effects when paid for under a single billing code

Between July 1, 2007, and March 31, 2008, CMS established a single—that is, a consolidated—payment code for levalbuterol, a single-source drug, and albuterol, a multiple-source drug with generic versions. Between January 2005 and January 2007, preceding the establishment of the new code, the ASP for the single-source drug (levalbuterol) increased by 4 percent per year, while the ASP for the multiple-source drug (albuterol) remained flat (Table 2-6). Under the consolidated billing code, Medicare's payment rate declined from $0.53 per unit (third quarter 2007 ASP plus 6 percent) to $0.44 per unit (first quarter 2008 ASP plus 6 percent).[41] The Medicare, Medicaid, and SCHIP Extension Act of 2007 reestablished separate codes for these products starting in the second quarter of 2008 and calculated each product's payment rate based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs or (2) the payment rate based on 106 percent of the ASP for the specific drug.

The coding changes resulted in shifts in Medicare utilization for both products. According to the Office of Inspector General, when each product was billed under its own code between January 2005 and June 30, 2007, use of albuterol (the less costly product) decreased while use of levalbuterol increased (Office of Inspector General 2009). By contrast, when both products were billed under the same code between the July 2007 and March 2008 dates, use shifted from levalbuterol (the more costly product) to albuterol (Office of Inspector General 2009).[42]

(continued next page)

TABLE 2–6 **Payment for two drugs using a consolidated billing code**

	2005	2006	2007				2008				2009
	q1	q1	q1	q2	q3	q4	q1	q2	q3	q4	q1
Combined payment code					$0.53	$0.42	$0.44				
Separate payment code											
Albuterol	$0.07	$0.06	$0.07	$0.08				$0.04	$0.04	$0.04	$0.04
Levalbuterol	$1.28	$1.34	$1.39	$1.54				$0.28	$0.17	$0.21	$0.24

Note: q (quarter). Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram. Between the first quarter of 2005 and the second quarter of 2007, Medicare payment was based on average sales price (ASP) plus 6 percent for each drug. Between the third quarter of 2007 and the first quarter of 2008, payment for the consolidated billing code that included albuterol and levalbuterol was based on the volume-weighted average 106 percent ASP for both drugs. Beginning in the second quarter of 2008, payment for each drug was based on the lower of (1) the volume-weighted average of 106 percent of the ASP for both drugs or (2) the payment rate based on ASP plus 6 percent for the specific drug.

Source: CMS's ASP quarterly pricing files, 2005–2009.

Case studies of Medicare promoting competition by assigning drugs to a single billing code (cont.)

Case Study 2: Competition between drugs with similar health effects when paid for under a prospective payment system

Price competition increased between two vitamin D drugs that were previously paid separately when they were paid for under a payment bundle (with a single payment rate assigned to the bundle). Since 2011, Medicare has paid for outpatient dialysis services under a prospective payment system (PPS) that is based on a bundle of services that includes certain dialysis drugs that were previously paid separately. Since the start of the dialysis PPS, the ASPs for the two leading vitamin D agents each declined between January 2012 and January 2017 by 13 percent per year (Figure 2-4). In contrast, between January 2005 and January 2010, the ASP for both products fluctuated, but overall changed moderately (average annual change of 2 percent to 3 percent over the period). In addition, between 2010 and 2014, per treatment use of the more costly vitamin D drug (paricalcitol) declined while per treatment use of the less costly product (doxercalciferol) increased (Medicare Payment Advisory Commission 2016b).[43] ■

FIGURE 2–4

Price competition increased for vitamin D agents after Medicare implemented dialysis PPS in 2011

Note: PPS (prospective payment system), ASP (average sales price). CMS implemented the dialysis PPS, which bundled dialysis drugs that were previously separately billable, in January 2011. The vertical line represents drug pricing at the start of the PPS after accounting for a two-quarter ASP reporting lag (i.e., ASPs for the third quarter of 2011 reflect pricing at the start of the PPS in January 2011).

Source: Commission analysis of CMS's ASP pricing files, 2005–2017.

lessened by the substantial price growth that occurs for the reference product in the years before biosimilar entry. During the five-year period before its biosimilar became available, the cumulative price growth for Neupogen (Figure 2-3, p. 53) and Remicade (Table 2-5, p. 53) was 28.4 percent and 26.1 percent, respectively. While biosimilar Zarxio's payment rate has been discounted relative to Neupogen's rate, the biosimilar's initial

payment rate was greater than the average price for its reference biologic in 2013.

Implementation issues

There are several issues to consider when implementing consolidated billing codes. One issue is how CMS would determine when products should be grouped together and when they should retain their separate billing codes. For reference biologics and their biosimilars, the FDA's determination that the products are biosimilars would serve as a basis for CMS's decision to consolidate these products.[44,45]

Another key issue is how CMS would set a single payment rate for the reference biologic and its biosimilars that are all assigned to a single payment code. The agency could base its payment according to the volume-weighted ASP of the products assigned to the code. CMS currently uses such an approach when determining the payment rate for generic drugs and their associated brand drug and all biosimilar products associated with, but not grouped with, a given reference biologic.[46]

Under a consolidated billing code policy, a third issue concerns beneficiary access to a particular product for clinical reasons. Under such a policy, the clinician would continue to have the choice to prescribe the product most appropriate for the patient, with Medicare's payment based on the volume-weighted ASP of all products assigned to the code (or some alternative). The Congress could consider allowing the Secretary to provide a very limited payment exception process under which Medicare would reimburse the provider based on the ASP of the higher priced product if the clinician provided justification that the product was medically necessary, such as instances for which there has been documented clinical failure of a particular product. A payment exception process addresses the concern that beneficiary access under a consolidated billing policy could be harmed if some providers were unwilling to supply the higher cost product to a beneficiary for whom the product was a medical necessity.[47] Providers could submit medical justification to the 12 regional Medicare administrative contractors (MACs), and the exception process could be coupled with Medicare's existing appeals process that gives beneficiaries, providers, or their representatives the right to appeal the MACs' coverage and payment decisions.

However, unless carefully designed, a payment exception process could create incentives for the use of higher priced products when the beneficiary's clinical circumstance does not support an exception. Since the add-on of a higher priced product generates more revenue for the provider than the add-on of a lower priced product, selection of the higher priced product could generate more profit, depending on the provider's acquisition costs for the two products. In addition, direct-to-consumer advertisements could affect provider prescribing (American Medical Association 2015) as well as the promotions (e.g., speaker and consulting fees) offered by some pharmaceutical manufacturers to providers (Fleischman et al. 2016). To minimize such unintended effects, the clinician's payment from Medicare when an exception is granted could be set at the higher cost product's ASP without an add-on payment (i.e., 100 percent of ASP). The Medicare program would pay the provider 80 percent of the ASP of the exception (higher cost) product that was furnished, and the beneficiary would pay the provider 20 percent of the exception (higher cost) product's ASP.

Some stakeholders see advantages to using consolidated billing codes while others see drawbacks. While some industry stakeholders acknowledge that a consolidated billing code policy would result in lower drug prices in the short term, they argue that the subsequent lower prices for the products paid under the policy would reduce the profit potential and return on investment for new products, which would result in the loss of investment capital from venture capitalists (Burich 2016). According to the industry's assumptions, the loss of investment capital would, in turn, decrease the number of manufacturers choosing to enter (or remain in) the biosimilar market, which would decrease the uptake of biosimilars. Ultimately, critics contend, there would be fewer products available, thus leading to less competition and higher prices.

Available objective, transparent data are insufficient regarding the research and development costs of new drugs, biologics, and biosimilars. Given the large market for Part B drugs, it could be argued that development of drugs and biologics is likely to continue, even in the presence of a consolidated billing code policy. With the enormous market that biologics command—in 2015, 8 of the top 10 Part B products ranked by spending were biologics (Table 2-1, p. 38)—biosimilar manufacturers have the opportunity for substantial revenue gains, even with the expected biosimilar discounts that studies estimate range from 10 percent to 50 percent of reference biologics (Mulcahy et al. 2014). In addition, some might argue that biosimilars are in the strongest competitive position with the reference biologic when they are in the same billing code and can compete directly on price. In

Europe, the biosimilar market has grown (with, in some instances, multiple biosimilars in a given therapeutic class) even with the downward pressure on prices. As of March 2017, there are 28 biosimilars available in Europe (European Medicines Agency 2017).

With fewer biosimilars, critics also contend that clinicians would be less likely to prescribe biosimilars because the marketing outreach and education efforts would focus more on the reference biologic than on the available biosimilars. However, assigning all products to the same code would give clinicians the incentive to select the lower cost product when clinically appropriate.

An additional concern is that combined billing codes could have an adverse impact on beneficiary access. Some assert that if a beneficiary needed a particular product paid under a combined billing code and that product were 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 to use the lower priced products, the clinician would continue to have the choice to select the product most appropriate for the patient. The payment rate for products paid under a combined billing code currently 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 lower priced products would be higher than if they were paid under separate codes. Thus, clinicians would earn more net revenue than they otherwise would on lower cost products, and that additional revenue could help offset the cost of a higher priced product if needed by a particular patient.[48] A payment exception process might also mitigate any risk of beneficiaries' access being adversely affected.

Some stakeholders are concerned that the use of consolidated billing codes would not permit researchers to conduct safety analyses of Medicare claims data that track a specific product given to a particular beneficiary. The Commission previously stated that if the Secretary concludes that Medicare claims data identifying specific products (i.e., the reference biologic and its biosimilars) could be helpful in supplementing safety analyses such as the FDA's Sentinel System, we believe CMS could develop a way to distinguish these products on claims, such as reporting this information using modifiers (Medicare Payment Advisory Commission 2015a).

Some researchers contend that access to care and the affordability of care should be considered when evaluating drug pricing proposals and other policy changes (e.g., patent laws) on biomedical innovation. Some have reported that high drug prices adversely affect access to care when patients forgo treatment or are less adherent to a treatment regimen because of high prices (Bach 2015, Walker 2015). Kapczynski and Kesselheim (2016) contend that policies that lower drug prices would improve patient access to care and that the net gains to population health would dwarf possible risks to pharmaceutical innovation. For example, in some European countries, there has been a large volume increase as lower prices for biosimilars (and, in some cases, lower prices for reference products) made the therapies more affordable (IMS Institute for Healthcare Informatics 2016). Nichols (2015) acknowledges the importance of striking the right balance between encouraging innovation—by granting temporary monopoly pricing power—and ensuring affordability by encouraging postmonopoly competition. This researcher goes on to contend that "the [drug] cost problem is sufficiently serious and escalating that it is impossible to believe that we are being well served by the current configuration of innovation encouraging policies and actual pricing choices that specialty drug manufacturers are making" (Nichols 2015).

Developing a market-based alternative to the ASP payment system

The Commission supports the development of a voluntary, market-based alternative to the ASP payment system, calling it the Part B Drug Value Program (DVP). The purpose of such a program would be to obtain lower prices for Part B drugs by using private vendors to negotiate with manufacturers and improve incentives for providers furnishing Part B drugs by making providers accountable for cost and quality through shared savings opportunities. Key elements of this program include its structure, a shared savings component, tools to increase vendors' negotiating leverage (e.g., a formulary and, in certain circumstances, binding arbitration), and a reduction of the add-on in the ASP system.

The DVP would be informed in part by lessons learned from Medicare's experience with the competitive acquisition program (CAP) for Part B drugs. The CAP operated 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 administered. As discussed in our June 2016 report, the CAP 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 (Medicare Payment Advisory Commission 2016a). Although the CAP program faced challenges, the concept underlying the program—to create a voluntary alternative to the ASP system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Part B drugs—still has appeal.

The DVP would be designed differently from the CAP to address several issues encountered with the latter program. CAP vendors had little leverage to negotiate discounts with manufacturers because they were required to offer all single-source drugs and biologics. By contrast, DVP vendors would be permitted to use tools (such as a formulary and, in certain circumstances, binding arbitration) to give them greater negotiating leverage with manufacturers. The CAP was also hindered by low physician enrollment; many physicians perceived the process of obtaining drugs directly from CAP vendors as burdensome. Under the DVP, vendors would negotiate prices for Part B drugs, but, unlike the CAP, DVP vendors would not ship product to providers. Providers enrolled in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would also have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

A DVP would have the following features:

- voluntary enrollment for physicians and hospital outpatient departments;
- gradual reduction of the ASP add-on in the ASP system to encourage DVP enrollment;
- a small number of DVP vendors, with providers choosing one vendor;
- prices negotiated by DVP vendors (with DVP prices not released publicly);
- drugs purchased by participating providers in the marketplace at the DVP-negotiated price;
- Medicare drug payment to providers at the DVP-negotiated price (with continued payment for drug administration services under the physician fee schedule or outpatient prospective payment system (OPPS));
- shared savings opportunities for providers;
- lower beneficiary cost sharing resulting from lower DVP-negotiated prices;
- an administrative fee paid to vendors by Medicare;
- shared savings opportunities for vendors;
- authority for vendors to use a formulary and other management tools such as step therapy and prior authorization;
- an exceptions and appeals process available to providers and beneficiaries if there is a clinical need for an off-formulary drug;
- a limit on DVP-negotiated prices to no more than 100 percent of ASP;
- binding arbitration available within the DVP as a tool to facilitate vendor and manufacturer price negotiations for high-priced drugs without close substitutes;
- exclusion of DVP prices from ASP calculations; and
- phasing-in of DVP beginning with a subset of drug classes.

Providers' enrollment in DVP would be voluntary

Each year, physicians and hospitals would have the choice of whether to enroll in the DVP or remain in the ASP system. Providers could not choose which system to enroll in on a drug-by-drug basis. Providers would either choose to participate in the DVP for all drug classes covered by the DVP or remain in the buy-and-bill system for all of those drug classes.

DVP enrollment would be encouraged by reducing ASP add-on in current ASP system

One of the challenges with the original CAP was that few physicians enrolled. The current 6 percent add-on in the ASP system could make that system more attractive to providers than the DVP. To encourage enrollment in the DVP, the percentage add-on in the ASP system would be reduced and timed to coincide with the target date for starting the DVP.

The reduction of the ASP add-on would begin on that target date, regardless of the DVP's status, to create pressure for the DVP's development and implementation.

Some stakeholders contend that a reduction of the ASP add-on would accelerate the trend toward hospitals' acquisition of physician practices in specialties like oncology. A number of reasons have been cited for physicians' interest in selling to hospitals and hospitals' interest in acquiring physician practices (including availability of 340B discounts, increasing practice costs and reimbursement pressures, site-of-service payment differences, movement toward more integrated models of care, and physician interest in employment rather than ownership). These reasons are both financial and nonfinancial, and the significance of each reason varies across physicians and hospitals. While a reduction of the ASP add-on would be expected to make the ASP system less attractive to some physicians, the DVP would offer physicians an alternative to the ASP system. The DVP removes financial pressure related to drug purchasing and offers physicians new shared savings opportunities, which may encourage physicians to remain independent.

The DVP would include only a small number of vendors, with each provider selecting one vendor

It would be desirable for there to be a small number of national DVP vendors, which would give providers some choice of which vendor to work with while consolidating volume among a small number of vendors to gain greater negotiating leverage. Requiring each participating provider to select one vendor would give the vendor certainty about the size of the population it is negotiating for and make it possible for vendors to use management tools like a formulary.

Providers enrolled in the DVP would purchase drugs in the marketplace at DVP-negotiated price

A DVP vendor's role would be to negotiate prices with manufacturers and make those prices available to providers through a network of distributors and wholesalers (as well as through direct sales from manufacturers in cases where manufacturers use that distribution model). DVP vendors would not ship product to beneficiaries. Instead, providers would order drugs from distributors or wholesalers at the vendor-negotiated price for Medicare fee-for-service (FFS) beneficiaries. Since providers would not know exactly how much of the volume they were ordering would be administered to Medicare FFS beneficiaries, providers could use electronic accounting software to track the amount of product administered to Medicare FFS beneficiaries. A retroactive reconciliation process could then occur between the provider and distributor or wholesaler after the drugs are administered to confirm the quantity supplied to Medicare FFS beneficiaries and ensure that the price charged for those units was the DVP-negotiated price. The advantage of this approach is that providers would order drugs in the marketplace largely as they do now, without needing to acquire separate inventory for Medicare FFS beneficiaries through a separate entity or to stock their inventory for Medicare FFS beneficiaries separately from product for other patients.

Medicare would pay providers for drugs at the DVP-negotiated price

Providers participating in the DVP would submit a claim to Medicare for Part B drugs administered to beneficiaries, and the Medicare payment rate would be set at the DVP-negotiated price. If the Medicare payment rate were set equal to providers' acquisition costs, this model would eliminate the price spread on drugs and would be expected to give providers less of a financial stake in their prescribing decisions.[49] Under the DVP, physicians and outpatient hospitals would continue to be paid for drug administration services under the physician fee schedule or OPPS. It would be important to review the drug administration payment rates to ensure the inputs used to set those rates were accurate and reflected the cost of administering drugs. Since one aim of the DVP would be to eliminate financial incentives for prescribing Part B drugs, it would be important that manufacturers not be permitted to pay providers rebates based on the amount of volume purchased under the DVP.

DVP prices would not be public

To give DVP vendors greater negotiating leverage, DVP prices would not be public. DVP prices would be known to the government. In addition, the DVP vendor, manufacturers, wholesalers, and distributors that offered products at the DVP's negotiated price and the DVP vendor's provider members would know the DVP-negotiated prices but would not be permitted to disclose that information to others. Beneficiary savings through lower cost sharing would be structured such that the actual DVP-negotiated price for any particular drug would not be revealed.

Shared savings opportunities for providers

Including shared savings opportunities for DVP provider members would have the dual benefit of making the DVP more attractive to providers and improving incentives for provider efficiency.[50] If the DVP led to lower aggregate

costs of Part B drugs, the savings would be shared with providers. This approach would engage providers in managing the total cost of Part B drugs (i.e., the choice of product, the duration of treatment, and the appropriateness of treatment), thereby creating more robust incentives for efficient care than exist under the ASP payment system. Provider eligibility for shared savings could also be contingent on quality performance to avoid incentives for stinting. For example, one option would be to condition providers' receipt of shared savings on their use of clinical guidelines or pathways.

The DVP would be expected to generate savings for products with similar health effects by securing discounts on these products from manufacturers and by giving providers the incentive to use lower cost products where clinically appropriate. Savings would be expected to come from the DVP vendors using tools such as a formulary to negotiate drug prices with manufacturers. For example, for a drug class that includes multiple single-source products with similar health effects, the DVP vendor could secure discounts in exchange for including a manufacturer's product on the formulary. If the price negotiated by the DVP were below what Medicare pays in the ASP system, the savings resulting from the lower price would be shared with providers. In addition, with providers accountable for the total cost of Part B drugs under the DVP, providers would have the incentive to use lower cost products where clinically appropriate, which could also lead to shared savings opportunities.

Beneficiaries share in savings

Beneficiaries receiving drugs under the DVP would save through lower cost sharing. To ensure that DVP prices are not public, beneficiary cost sharing would not be based on the actual DVP-negotiated price for a particular drug. Instead, beneficiary cost sharing would be reduced in a formulaic way that would not reveal the actual price the DVP negotiated for a particular product. Cost sharing could be calculated by estimating the aggregate price that the DVP negotiated (as a percent of ASP) across all DVP drugs and setting beneficiary cost sharing at 20 percent of that amount. For example, if the DVP in aggregate negotiated prices equivalent to 95 percent of ASP across all drugs in the DVP, beneficiary cost sharing could be set at 20 percent of 95 percent of ASP for all DVP drugs.[51]

Payment of vendor

Payment to vendors should be structured in a way that creates incentives for vendors to negotiate discounts with manufacturers and lower the total cost of Part B drugs. It would be important that the vendor not be paid a percentage of DVP drug spending since that would give vendors an unintended incentive for increased drug prices and spending. Similarly, DVP vendors would generally not be permitted to receive cash payment from manufacturers (e.g., rebates) related to the DVP.[52] Instead, the vendor would be compensated by the Medicare program through an administrative fee and an opportunity for shared savings. Options for how to structure the administrative fee paid to the vendor include a fixed dollar payment, a payment per enrolled provider (possibly varying by provider specialty), or a combination of these approaches. The vendor's shared savings could be similar to provider shared savings, conditioned on whether the DVP reduced the total cost of Part B drugs and whether the vendor engaged in efforts to promote quality or met other performance standards.

Medicare shares in savings

Medicare would share in any savings generated from the DVP, along with beneficiaries, providers, and the vendor.[53] Under the DVP model, Medicare shares in the savings because Medicare's payment rate for the drugs would be set at the DVP-negotiated rate and Medicare would retain a specified share of the resulting savings.

Approach for calculating and apportioning shared savings

In designing the shared savings feature, a crucial piece would be determining how DVP savings were measured. Ideally, a measure of savings would take into account how total Part B drug spending had changed as a result of the DVP, reflecting both changes in price and utilization. It would not be prudent to measure savings based solely on price changes because that could create incentives for choice of an expensive drug with some discount over an inexpensive drug with no discount.

Another important design issue would be how any savings are apportioned among the government, providers, and vendors. Savings would be estimated separately for each DVP vendor (and its provider members). The savings associated with an individual DVP vendor would then need to be distributed among the government, the DVP provider members, and the vendor itself. A threshold could be set for the share of savings retained by the government, such as a fixed share of the savings or an amount that varied by the magnitude of savings.[54] Several approaches could be considered for apportioning the remaining

savings (net of the government's share) to providers and the vendor. One method would be to establish a fixed share of the savings that would go to providers as a whole and to the vendor. In that case, the providers' share of the savings could be apportioned among them based on how the total cost of Part B drugs for the practice or group of practices compared with a benchmark (e.g., the total cost of Part B drugs for providers not participating in the DVP). Alternatively, the providers' share of savings could be apportioned equally across DVP providers with certain adjustments (e.g., by specialty). Another approach would be market based, under which the distribution of savings (net of the government's share) among the vendor and provider members would be determined by the DVP vendor. Because DVP vendors would be competing with one another to attract providers to their membership, vendors would have an incentive to devise a shared savings apportionment approach that was desirable to both providers and the vendor itself.

Formulary authority and other management tools

A key feature of the DVP would be its use of formularies designed by the program's private vendors. Permitting vendors to exclude drugs or biologics from the formulary when other products with similar health effects exist would give them leverage to negotiate lower prices on these products. Criteria would need to be developed to define the terms of an acceptable formulary (e.g., how drug classes are defined, number of drugs required per class, the process and type of input DVP vendors must seek).[55] CMS would oversee the formularies the vendors develop to ensure they meet established standards. Medicare would need to strike a balance between how much flexibility to give DVP vendors versus how prescriptive to be in the requirements. As long as beneficiaries could obtain the medicines they need, flexibility would be beneficial in terms of greater negotiating leverage and less administrative burden for DVP vendors.

In addition to formulary authority, vendors could be permitted to use other management tools. For example, vendors could be permitted to use step therapy and prior authorization. In addition, purchasing tools such as risk-based contracting or indication-specific pricing could be permitted for use by DVP vendors, as long as resulting savings are passed back to the Medicare program.

Formulary exceptions and appeals process

If DVP vendors were allowed to exclude drugs from the formulary, an exceptions process would be needed to give providers and beneficiaries the opportunity to request coverage of a nonformulary product because of unique aspects of a beneficiary's condition. An exceptions process that involved prior authorization might be ideal in that it would permit providers and beneficiaries to know before administering a nonformulary drug whether an exception would be granted.

If the DVP granted the provider a formulary exception, the provider would obtain the nonformulary drug at the product's DVP-negotiated price. Medicare would pay the provider that price and the usual fee for drug administration services. In this way, a DVP provider member would continue to be paid for drugs under the DVP framework, including nonformulary drugs granted an exception. If the DVP denied the provider's formulary exception request, the provider and beneficiary would have an opportunity to appeal the denial.

Limit drug prices under the DVP to no more than 100 percent of ASP

For a variety of reasons, it is possible that a DVP vendor would not be able to obtain a favorable price for a particular drug. For example, at the outset of the DVP, it may not be clear to a manufacturer how much provider enrollment and product volume a DVP vendor would have, and a manufacturer could decide it was not worth offering a discount to the DVP vendor. One way to ensure that vendors could get at least typical prices for all drugs would be to require drug manufacturers whose drugs are covered under Medicare Part B to offer drugs to DVP vendors at a price no higher than 100 percent of ASP. This requirement would ensure that the DVP vendor could obtain at least typical market prices for all drugs. In addition, requiring that DVP prices be no more than 100 percent of ASP would provide price protection in situations where a nonformulary drug was furnished through the exceptions process—a circumstance under which the DVP vendor would otherwise be unlikely to obtain a favorable price.

Arbitration

For drugs that have generic substitutes, biosimilars, or other single-source drugs that serve as competition, DVP vendors would likely have the ability to negotiate favorable prices. For drugs lacking competition, such as the first drug in a therapeutic class or drugs that offer an advantage over existing drugs, the DVP vendor would likely have little negotiating leverage. In such cases, binding arbitration could be used to encourage drug manufacturers to negotiate with DVP vendors (to avoid going to arbitration) or serve as a means to arrive at an

Structuring an arbitration process

Arbitration is used to settle disputes in a wide range of areas, including labor disputes and international tax disputes. Arbitration has also been used in health care, both domestically and in other countries, to arrive at agreed-upon prices for services and products. For example, New York State employs an arbitration process to settle disputes over prices for certain out-of-network services. In Germany, arbitration is used to set the price of some new drugs as part of the country's effort to lower costs and increase value. While the Secretary would likely go through the rule-making process to establish the arbitration process between Drug Value Program (DVP) vendors and drug manufacturers, the following set of design options are commonly considered when constructing an arbitration process:

- ***Type of arbitration***—Two common forms of arbitration are conventional and final-offer arbitration (FOA), which is often referred to as "baseball arbitration"—a moniker earned because of its use to resolve labor disputes in Major League Baseball. Under conventional arbitration, the arbitrator can select any award amount, whereas under FOA, the arbitrator picks the award amount from among the offers made. Conventional arbitration gives disputants an incentive to make extreme offers because arbitrators often "split the difference" between the two offers, whereas FOA, proponents argue, provides an incentive for parties to make reasonable offers. Further, some contend that FOA encourages negotiated settlements because the parties' more reasonable offers might be relatively close together (compared with conventional arbitration) and because both parties want to avoid the risk of the arbitrator choosing the other party's offer.

- ***Eligibility for arbitration***—Because formularies create limited pressure on manufacturers to negotiate prices for any of their drugs without competitors, one option would be to limit drugs eligible for arbitration to sole-source drugs that meet some cost threshold. Limiting arbitration to expensive, sole-source drugs could minimize the number of cases going to arbitration and still create downward pressure on the prices of a subset of drugs that can be very costly to Medicare and beneficiaries. In addition, if an arbitrator sets the price of an expensive, sole-source drug and then a competitor for that drug enters the market while the arbitrated price is still in effect, DVPs could be allowed to add the new drug to their formulary and negotiate prices below the arbitrated price for either drug. Because physicians receive shared savings, they would have an incentive to use the lower cost alternative. This flexibility could help ensure that arbitration does not hinder the ability of market forces to produce lower prices when competition exists.

- ***Who goes to arbitration***—While the arbitration process would be established by the Secretary, actual arbitration proceedings would involve DVP vendors and drug manufacturers. Allowing multiple arbitration hearings for the same drug would likely be too costly and time consuming. Therefore, DVP vendors could be allowed to pursue arbitration collectively, or individual DVP vendors could be allowed to initiate an arbitration process and other vendors could be allowed to join that effort. In either option, DVP vendors would choose to go to arbitration voluntarily, while those who choose not to go to arbitration would negotiate directly with the manufacturer. Further, such a process would ensure that manufacturers would face binding arbitration only once for a product in a given time period.

- ***Who serves as the arbitrator***—Having a neutral arbitrator with sufficient subject matter expertise is essential to designing an impartial arbitration process. An individual or a panel could serve as the arbitrator. For example, in New York State, disputes are settled by a reviewer with experience in health care billing and reimbursement, in consultation with a physician (New York State Department of Financial Services 2017). Others have suggested that a neutral third party could propose

(continued next page)

Structuring an arbitration process (cont.)

a slate of arbitrators, with each party having the ability to veto certain arbitrators (Frank and Newhouse 2008). For example, the Government Accountability Office could propose a slate of five arbitrators with specialized expertise and no financial ties to either party. To give both parties input in the process, the drug manufacturer and DVP vendor could each be allowed to strike one arbitrator, leaving a final panel of three arbitrators. A majority decision of the final three arbitrators would constitute a binding decision.

- ***Types of issues to be decided by the arbitrator***—Giving the arbitrator a limited number of decisions to make could expedite the arbitration process. For example, the arbitrator could be limited to making two decisions—whether a drug is eligible for arbitration (to the extent that only certain drugs are allowed to go to arbitration) and the net price of a drug for a given period.
- ***Arbitration criteria***—Giving an arbitrator a set of criteria on which to select an offer could help ensure consistency among arbitration decisions; expedite the process, as disputants understand what points to argue and the type of information the arbitrator needs; and allow certain priorities to be elevated over others. Criteria could include clinical benefit compared with existing treatments (which could provide an incentive for manufacturers to pursue high-value drugs), prices of comparable drugs (if any exist), whether the drug addresses specific areas of need (e.g., new antibiotics), and affordability for the Medicare program and beneficiaries.
- ***Allowing DVP vendors and providers to share in savings generated by arbitration***—Enrollment in the DVP could be encouraged by including savings generated through an arbitration process when calculating shared savings payments to providers and vendors.
- ***Other design choices***—Other design choices include whether to allow the arbitrator to contract with a neutral third party to supplement or evaluate the information contained in the disputants' final offers (e.g., an independent fact finder), what the time frame would be for adjudicating a case, whether the information from the arbitration process is made public, who can call for arbitration, and who pays for arbitration (e.g., cost could be borne by the losing party, which could provide an incentive to make reasonable offers or arrive at a negotiated price before going to arbitration). ■

agreed-upon price if negotiations fail. Arbitration is a process by which two parties agree to accept the verdict of a neutral third party in a dispute—in this case, a dispute over the price of a drug. The two parties entering into arbitration in this case would be the DVP vendor—not CMS—and the drug manufacturer. (See the text box on structuring an arbitration process.)

DVP-negotiated prices would not affect ASP

DVP vendors would be expected to have the most leverage with manufacturers if DVP prices were excluded from ASP. In that case, manufacturers could negotiate low prices with the DVP vendors without DVP discounts leading to lower prices in other lines of business like commercial plans (which often pay based on a percentage of ASP). In the original CAP program, CMS excluded CAP prices from ASP initially and indicated it would revisit the policy at a later time.

Phase in DVP starting with a subset of drug classes

The complexity of operating the DVP and developing management tools would vary across types of drugs. Phasing in the DVP over time by beginning with a subset of drug classes could address the complexity and create the opportunity to learn from experience going forward. Medicare could choose to phase in the program first with drug classes for which the savings potential seems largest (i.e., drug classes that include multiple products with similar health effects) and implementation seems most straightforward.

Beyond these design issues are additional considerations related to the DVP, including enrollment incentives and the DVP's applicability to Medicare Advantage.

Providers' incentive to enroll in the DVP

An important aspect of designing a DVP would be to give providers an incentive to enroll in the program. When considering DVP enrollment, providers would be expected to consider how their net revenues earned on drugs under the ASP system would compare with the revenues they would receive under the DVP program. Two factors would encourage provider enrollment in the DVP: a reduced add-on under the ASP system and shared savings opportunities available through the DVP.

Reducing the ASP add-on in the ASP system would encourage provider enrollment in the DVP. We would expect providers who are on the higher end of the drug pricing distribution to have the strongest incentive to enroll in the DVP. Although DVP-negotiated prices would not be included in ASP, the movement of providers with relatively high drug acquisition costs out of the ASP system (and effectively out of the data on which ASP is calculated) would be expected to reduce drugs' ASPs (all else being equal). That movement, in turn, may lower the payment rates in the ASP payment system and could encourage more providers to enroll in the DVP. In addition, the gradual reduction of the ASP add-on in the ASP system, which would be timed to coincide with DVP implementation (add-on reduced to 5 percent in year 1, 4 percent in year 2, and 3 percent in years 3 and beyond), would create broader incentives to enroll in the DVP over time.

Shared savings opportunities would also encourage provider enrollment in the DVP. By aggregating volume across providers and using management tools such as a formulary, DVP vendors would likely have leverage to negotiate significant discounts for products with similar health effects. Even for large providers that may receive volume discounts and better than average drug prices, the DVP could be attractive if the vendor were able to negotiate substantial discounts on competitor drugs that could be shared with providers. Phasing in the DVP by focusing on classes of drugs with the most overall savings potential, and thus the most shared savings potential for providers, could help draw attention to the shared savings opportunities for providers and encourage provider enrollment.

In deciding whether to enroll in the DVP, providers would also be expected to consider how the DVP would affect their administrative workload. Some stakeholders suggest that the administrative processes associated with DVP vendors' use of management tools (e.g., activities such as requesting formulary exceptions or complying with step therapy or prior authorization processes) would dissuade providers from enrolling in the DVP. However, since DVP vendors would be competing with one another for provider enrollment, it would be in vendors' interests to be mindful of providers' concerns about administrative burden and to make their DVP as efficient as possible for providers.

The DVP and Medicare Advantage

The intent of the DVP is to improve Medicare FFS payment for Part B drugs. Whether DVP-enrolled providers should be permitted to purchase drugs at DVP-negotiated rates for their Medicare Advantage (MA) patients is a question that could be explored. MA plans currently have some, but not all, of the tools that DVP vendors would possess. MA plans are permitted to use prior authorization but cannot use a formulary or step therapy for Part B drugs. Permitting providers enrolled in the DVP to purchase drugs at DVP rates for their MA population would be one way to address the limited tools MA plans have for managing Part B drug costs. Another question that could be explored is whether MA plans should be permitted to use a formulary and step therapy to manage Part B drugs—a potential subject for future Commission work.

RECOMMENDATION

The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:

(1) Modify the average sales price (ASP) system in 2018 to:

- **require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.**
- **reduce wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent.**
- **require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.**
- **require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.**

(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:

- **Medicare contracts with a small number of private vendors to negotiate prices for Part B products.**

- **Providers purchase all DVP products at the price negotiated by their selected DVP vendor.**
- **Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.**
- **Beneficiaries pay lower cost sharing.**
- **Medicare payments under the DVP cannot exceed 100 percent of ASP.**
- **Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.**

(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

RATIONALE

Improvements to the ASP payment system

The recommendation would make several immediate improvements to the ASP payment system that together would generate savings for beneficiaries and taxpayers and improve the accuracy of the data on which Medicare's ASP payment rates are established.

Currently, some manufacturers that sell Part B drugs (those that lack a Medicaid rebate agreement) are not required to submit ASP data. Requiring ASP data from all manufacturers would improve the accuracy of CMS's drug prices and help prevent CMS from relying on other, less appropriate prices, such as WACs. As part of this policy, the Secretary could be given the authority to exclude repackagers from reporting, which would reduce administrative burden and avoid issues of double counting.

For the first two to three quarters a new drug is on the market, it is generally paid 106 percent of WAC, a price that does not reflect any available discounts. Reducing the WAC add-on from 6 percent to 3 percent would reduce the current excessive payment rates for WAC-priced drugs and better align the WAC-based and ASP-based payment rates for the same drug. If the ASP add-on is reduced in the future, the add-on percentage for WAC-priced drugs should be further reduced to maintain parity between WAC-priced drugs and ASP-priced drugs.

Increases in Medicare's ASP + 6 percent payment rates are driven by manufacturer pricing decisions, with no limit on how much this payment for a particular product can increase over time. An ASP inflation rebate policy would provide Medicare and beneficiaries with protection from substantial manufacturer price increases for individual products. The rebate policy would exclude low-cost drugs to reduce administrative burden and exempt utilization already subject to an inflation discount under the Medicaid rebate program and 340B program. To implement a rebate, policymakers would need to select an inflation benchmark (such as the CPI–U, like the Medicaid rebate program, or an alternative), guided by the principle that an inflation benchmark be no greater than the typical payment updates received by providers in other sectors of the Medicare program. A different approach to limiting growth in Medicare's ASP + 6 percent payment rates would be to place a limit on provider payment rates. Although both a rebate approach and provider payment limit approach have merits, the Commission has focused on the rebate approach because it places financial risk for price increases on manufacturers instead of providers.

A consolidated billing code policy that assigned the reference biologic and its biosimilars to a single billing code would be expected to increase price competition among the products. This policy is consistent with the Commission's principle that Medicare should pay similar rates for similar care. In addition to grouping a reference biologic and its biosimilars, the Commission continues to be interested in the use of broader consolidated billing for groups of products with similar health effects. We encourage the Secretary to conduct research that examines the potential for these broader groupings of Part B products with similar health effects.

Drug Value Program

The DVP would be a voluntary, market-based alternative to the ASP payment system. The program offers the potential for lower prices by permitting private DVP vendors to use tools to negotiate prices with drug manufacturers (e.g., a formulary and, for drugs meeting selected criteria, binding arbitration). The shared savings opportunities available to providers through the DVP would engage providers in managing the total cost of Part B drugs (i.e., the choice of agent, the duration of treatment, and the appropriateness of treatment). This approach has the potential to create more robust incentives for efficient care than exist under the ASP payment system. Savings achieved through the DVP would also be shared with beneficiaries through lower cost sharing and with DVP vendors and Medicare.

Reduction in the ASP add-on

To encourage provider enrollment in the DVP, the ASP add-on would be reduced in the ASP system. The reduction to the ASP add-on would be timed to coincide with the target date for implementing the DVP (2022). The add-on reduction would begin by that target date, regardless of the status of the DVP, in order to create pressure for DVP development and implementation. The ASP add-on could be reduced gradually, by 1 percentage point per year (i.e., ASP + 5 percent in 2022, ASP + 4 percent in 2023, and ASP + 3 percent in 2024 onward).

IMPLICATIONS

Spending

- The Congressional Budget Office estimates that the Commission's recommendation would reduce Medicare program spending by $250 million to $750 million in the first year and by $1 billion to $5 billion over the first five years relative to current law.

Beneficiaries and providers

- The recommendation would be expected to generate savings for beneficiaries through lower cost sharing. The policies would not be expected to adversely affect beneficiaries' appropriate access to Part B drugs. The effect of the recommendation would vary across providers. For those providers choosing to remain in the ASP system, ASP add-on payments would be reduced, but the effect on these providers' net revenues would depend on how manufacturers responded to the policy. Providers that chose to enroll in the DVP would be paid the DVP price without a percentage add-on and would have opportunities for shared savings. For these providers, the DVP could result in an increase or decrease in their revenues, depending on the magnitude of shared savings under the DVP compared with providers' margin on drugs under the ASP system.

Conclusion

The Commission's recommendation seeks to take a balanced, multipronged approach to improving payment for Part B drugs and achieving savings for taxpayers and beneficiaries. The recommendation includes policies that would improve Part B drug payment through a regulatory approach (by making reforms to the ASP payment system) and through a market-based approach (by developing a voluntary alternative DVP). The Commission's recommendation also seeks balance by including policies that would achieve savings for taxpayers and beneficiaries not just by modifying provider payment rates but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices (e.g., through consolidated billing codes, an ASP inflation rebate, and DVP vendor tools such as a formulary and binding arbitration). ■

Endnotes

1 Medicare Part B covers 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, (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 to be less than effective.

2 By statute, certain vaccines and blood products are paid based on 95 percent of average wholesale price (AWP) instead of ASP + 6 percent. Radiopharmaceuticals billed in physician offices are contractor priced (based on invoice pricing or 95 percent of AWP). Part B–covered home infusion drugs in past years were paid 95 percent of AWP, but beginning in 2017 are paid ASP + 6 percent following the 21st Century Cures Act of 2016.

3 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 ($110 in 2017) was $95 in 2015, 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.

4 The sequester reduces payments providers receive for Part B–covered drugs by 1.6 percent, which results in a net payment equivalent to ASP plus 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.

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 June 2009 report for more detail (Medicare Payment Advisory Commission 2009)).

6 This estimate of payments for drug administration services includes therapeutic, prophylactic, diagnostic, and intravitreal injections. It also includes infusions of chemotherapy and nonchemotherapy drugs. It excludes certain types of injections such as arthrocentesis injections. In addition, it excludes payment for administration of the three Part B–covered preventive vaccines (which totaled more than $500 million in 2015).

7 Aggregate 2015 Part B drug spending was about $25.7 billion based on 100 percent claims data for physicians, suppliers, and outpatient hospitals. This amount excludes Part B drug spending for critical access hospitals (about $600 million) and Maryland hospitals (about $300 million), which are not paid under the ASP system. It also excludes spending for ESRD facilities, which are mostly paid for Part B drugs through the dialysis bundled payment rate.

8 One factor driving spending growth in 2015 was increased spending (over $900 million) on the vaccine Prevnar 13. A Centers for Disease Control and Prevention advisory committee recommended a one-time vaccination of all adults age 65 and older, which led to substantial utilization of the vaccine in 2015.

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 Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and sales that are exempt from the determination of Medicaid best price (e.g., sales or discounts to other federal programs, 340B-covered entities, state pharmaceutical assistance programs, and Medicare Part D plans). The types of discounts that must be netted from ASP include volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and charge-backs and rebates (other than rebates under the Medicaid program). Bona fide service fees—for example, fees paid by the manufacturer to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and are for services the manufacturer would otherwise perform in the absence of the service arrangement—are not considered price concessions for the purposes of ASP.

11 Additional factors can create a gap between the average price providers pay for drugs and the ASP used to set the Medicare payment amount. For example, prompt-pay discounts paid by manufacturers to wholesalers (which are anecdotally reported in the range of 1 percent to 2 percent) can create a gap between ASP and provider's acquisition costs because they are subtracted from ASP but are reportedly not fully passed on to purchasers. In addition, more technical issues, such as the treatment of lagged price concessions and bundled price concessions in the ASP calculation, can create a gap between provider acquisition costs for a drug and ASP.

12 Prices in the IMS Health Incorporated data reflect all on-invoice discounts and rebates, but not off-invoice rebates. Data for clinics include physician offices, hospital outpatient departments, dialysis clinics, nonhospital surgical centers, and

public health services clinics. The IMS data for clinics include discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we focused on data in the top half of the distribution (e.g., the 75th percentile).

13 The 11 manufacturers included in the margin analysis included AbbVie, Amgen, Baxalta, Biogen, Bristol-Myers Squibb Company, Celgene, Eli Lilly and Company, Gilead Sciences, Johnson & Johnson, Merck & Co., and Pfizer.

14 We note that, when comparing ROAs across different types of industries, the ROA for drug manufacturers is thought to be overstated due to the longer than average lag time between research and development and new product launch (Congressional Budget Office 2006). In addition, the accounting treatment of drug research and development (where research and development investments are counted as expenses instead of capitalized investments) may also distort ROA estimates either upward or downward (Reinhardt 2001).

15 Yu and colleagues (2017) compared drug prices in the United States to four countries (Canada, the United Kingdom, Ireland, and Denmark) for a group of manufacturers and estimated that the additional revenue generated by the difference in prices between the United States and other countries was greater than these manufacturers' global research and development spending by about 50 percent.

16 As discussed in our June 2016 report, providers' prescribing decisions may depend on a variety of factors (Medicare Payment Advisory Commission 2016a). A number of clinical considerations may influence a provider's choice among therapeutic alternatives (e.g., the product's efficacy for patients with a particular condition or comorbidities and its potential side effects). Financial considerations may also play a role in providers' choice of drugs. 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.

17 Similar to current law, some sales, such as those to 340B hospitals, would be excluded from the ASP calculations.

18 Requiring all Part B drug manufacturers to report ASP data is also complementary to our proposed inflation limit policy since universal ASP reporting helps to ensure that there is the requisite data on all drugs to implement the policy appropriately.

19 Excluding repackagers from the reporting requirement is not expected to create access issues because (1) many Part B drugs are not repackaged, and (2) under the current ASP reporting practices, repackagers often do not report their data, and access issues related to this lack of reporting have not been reported.

20 In cases where the WAC is unavailable, CMS uses invoice pricing or 95 percent of the average wholesale price under the outpatient prospective payment system.

21 Specifically, the drugs selected were among (1) the top 20 highest expenditure Part B drugs in 2014 and (2) those whose earliest year of ASP data was after 2005.

22 For the purposes of this section, CMS's *ASP drug pricing files* refers to either the quarterly ASP file or the "not otherwise classified" (NOC) file. If a drug had a payment rate posted on the outpatient prospective payment system's quarterly addendum files before appearing in CMS's ASP or NOC file, this earlier date served as the beginning of the one-year period.

23 As an example, OIG presented the case of the Healthcare Common Procedure Coding System code J7321. OIG noted that Part B spent $67 million on this drug in 2012 and, while the manufacturers reported ASP data, they were not required to do so. If the manufacturers had not reported the data and payments were based on WAC, OIG stated that payments would have been substantially higher because the WACs of the NDCs associated with the drug were 52 percent and 96 percent higher than ASP.

24 Because biosimilars are currently assigned a Healthcare Common Procedure Coding System code separate from their reference biologic, an ASP for the first biosimilar to a reference product may not be available for nearly three calendar quarters because of a lag in data reporting. During that period, biosimilars are paid at 106 percent of their WAC.

25 The Secretary has the authority to substitute for a product's ASP + 6 percent payment rate the lesser of the widely available market price (WAMP) or 103 percent of the average market price (AMP) if OIG finds that the product's ASP exceeds the AMP or WAMP by a certain threshold (currently 5 percent). (Note that AMP is the weighted average of retail prices for all of a manufacturer's package sizes of a drug, and WAMP is the price that a prudent physician or supplier would pay for a product.) Like ASP, AMP and WAMP are driven by manufacturers' pricing decisions and do not serve as an inflation-limit mechanism.

26 We focus on products with spending of at least $5 million in 2015 because we want to avoid the potential for drugs with substantial price increases but minimal Medicare spending (e.g., less than $500,000) to skew the analysis.

27 The inflation-adjusted ASP for the billing code for a given quarter would be calculated by applying the cumulative rate

of inflation between a specified base period and that quarter (using a specified measure of inflation like CPI–U, as in Medicaid, or an alternative inflation measure) to the billing code's ASP for the base period.

28 Because Medicare pays for Part B drugs based on billing codes, the ASP inflation rebate would be calculated at the manufacturer billing-code level. (By contrast, Medicaid pays for drugs at the NDC level, so the Medicaid inflation rebate is calculated at the NDC level). The ASP inflation rebate would compare each manufacturer's billing-code-level ASP (calculated as a weighted average across all the manufacturer's NDCs) to the inflation-adjusted ASP for the entire billing code. A benefit of this approach is that it promotes equity among manufacturers in multiple-source billing codes (because it ensures that the lower priced manufacturers would pay no rebate or a smaller unit rebate than higher priced manufacturers).

29 Medicare Part B pays for three types of vaccines based on 95 percent of the average wholesale price (instead of 106 percent of ASP), and thus the ASP inflation limit would not be applicable to these products.

30 To operationalize a rebate for multiple-source drugs, utilization data for the different manufacturers' products in the multiple-source billing code would be needed. NDCs could be required to be reported on the claims as a way to identify an individual manufacturer's utilization. If NDCs posed claims processing challenges, the utilization data reported by manufacturers when submitting ASP data could be used to calculate each manufacturer's market share for a multiple-source drug.

31 The intent of this approach—in which beneficiary cost sharing was reduced to 20 percent of 106 percent of the inflation-adjusted ASP and the government increased its upfront payment to the provider to offset a portion of the cost-sharing reduction—is to share rebates to the fullest extent possible with beneficiaries. If there are claims processing challenges with this approach, an alternative would be to set the beneficiary cost sharing at 20 percent of the following: 100 percent of the reported ASP plus 6 percent of the inflation-adjusted ASP. Under this alternative approach, the beneficiary would continue to share in the rebates but to a lesser extent, and the Medicare program would not have to increase its upfront payment to the provider.

32 If an inflation rebate policy applied only to billing codes with an average annual cost per user exceeding $100, about 36 percent of Part B drug billing codes would be exempt from the policy.

33 To provide CMS the ability to track claims payment and to develop a better understanding of the use of certain biosimilar products, claims for biosimilars are required to include a modifier that identifies the product's manufacturer effective January 1, 2016.

34 In the final rule for payment year 2016, CMS clarified that biosimilars that rely on a reference product's biologics license application will be grouped into the same payment calculation for determining a single ASP payment rate.

35 Subsequently, the FDA approved the reference biologic for one additional indication (increased survival in patients acutely exposed to myelosuppressive doses of radiation) which, as of August 2016, is not yet listed on the biosimilar's label.

36 Use of Neupogen and Zarxio is derived from an analysis by the Commission's contractor (Acumen) that used 100 percent Medicare claims data.

37 In addition, a combined billing code could be assigned to single-source drugs and multiple-source drugs with similar health effects.

38 These five products are aflibercept, rituximab, pegfilgrastim, infliximab, and ranibizumab.

39 Medicare use of Mircera in 2015 and 2016 was chiefly by beneficiaries with end-stage renal disease on dialysis. As stated in our March 2017 report to the Congress, there has been a shift in the use of ESAs (Epogen, Aranesp, and Mircera) under the outpatient dialysis prospective payment bundle. A large dialysis provider announced its intent to have 71 percent of the company's ESA patients (110,000 patients) switched to epoetin beta (from epoetin alfa) by the end of the first quarter of 2016. Our analysis shows that, in 2015 (when the biologic was launched in the United States), 90,000 dialysis patients received Mircera (Medicare Payment Advisory Commission 2017).

40 As of April 2017, the following biosimilars have been approved by the FDA but not yet launched by their manufacturers: Renflexis (infliximab-abda), the biosimilar for Remicade; Amjevita (adalimumab-atto), the biosimilar for Humira; and Erelzi (etanercept-szzs), the biosimilar for Enbrel.

41 Levalbuterol remained a single-source drug for the period shown on Table 2-6 (p. 54).

42 Based on 100 percent Part B claims data for albuterol and levalbuterol, the Commission's analysis showed that albuterol volume (as measured by the number of units furnished to beneficiaries) between the first quarter of 2005 and the second quarter of 2007 declined from 91 percent to 59 percent of total volume of these inhalation drugs.

43 Between 2014 and 2015, per treatment use of both products declined under the dialysis PPS.

44 In 2010, the Biologics Price Competition and Innovation Act established a pathway for the approval of biosimilars. Applicants must demonstrate that their product is "highly similar" to the already-licensed biologic with "no clinically meaningful differences" in terms of safety, purity, and potency (Food and Drug Administration 2016).

45 If the policy were applied more broadly to groups of single-source products with similar health effects, the Secretary would need to develop a process to identify groups of products that achieve comparable clinical outcomes.

46 There are alternative approaches that CMS could consider in determining the payment rate for products assigned to a single payment code, such as basing the payment rate on the product with the lowest ASP.

47 Because small changes to manufacturing processes can alter the structure of biologics and their pharmacologic activity, some stakeholders contend that the immunogenicity of biosimilars could vary from their reference products. However, Ebbers and colleagues (2012) found no evidence from clinical trial data or postmarketing surveillance data that switching to and from different biologics (erythropoietins and granulocyte-colony stimulating agents) leads to safety concerns. A recent analysis of the interchangeability of biosimilars authored by employees of the national regulatory agencies of Germany, Finland, the Netherlands, and Norway concluded that switching patients from the original to a biosimilar or vice versa can be considered safe (Kurki et al. 2017). Advocates point to the lack of adverse events in Europe as evidence that biosimilars can be used safely by patients (Madsen 2016). In the United States, there have been no reports in the press of adverse events when Fresenius switched about 110,000 dialysis patients from epoetin alfa to epoetin beta in 2015 and 2016.

48 The two-quarter lag in the ASP payment rates also helps to offset the financial effect on providers who might be slower than average to shift toward the lower cost options.

49 Whether the sequester should apply to the DVP would need to be considered. Since the intent of the DVP is for providers to be paid their acquisition costs (i.e., the DVP rate), an argument could be made that the sequester should not apply to DVP rates paid to providers. If the sequester applied to the DVP rates paid to providers, providers would be reimbursed 1.6 percent below their acquisition costs for drugs under the DVP.

50 CMS has implemented several initiatives, such as accountable care organizations and the Oncology Care Model, that aim to improve the quality and efficiency of Medicare services, including Part B drugs. Whether these programs will lead to changes in Part B drug utilization remains to be seen. Unlike the DVP, these initiatives are not designed to lower the current ASP + 6 percent payment for Part B drugs. Precedent rules would need to be established for allocating shared savings among the DVP and these other Medicare-sponsored initiatives.

51 In any given year, the average DVP-negotiated price as a percent of ASP across all DVP drugs in aggregate will not be known until utilization data for those drugs are available after the close of the year. To base the beneficiary's cost sharing on the aggregate DVP-negotiated price, this price will need to be estimated either using prior-year data or by projecting utilization for the current year.

52 There may be innovative purchasing approaches like risk-based contracting or indication-specific pricing in which rebates are the most effective way to operationalize the policy, and, in that case, there may be a benefit to permitting rebates specifically in such circumstances, provided these arrangements are transparent to CMS and the rebates are passed through to the Medicare program.

53 Although group purchasing organization (GPO) prices are generally included in the calculation of ASP, Medicare and beneficiaries do not share in GPO savings under the ASP system to the same extent that they could share in savings under the DVP. If GPOs are able to obtain lower than average prices, then GPO prices will lower ASP to some degree, but not fully because they are averaged in the ASP calculation with prices for other purchasers. In contrast, under the DVP, the Medicare drug payment rate would be set at the DVP-negotiated rate. Beneficiaries would pay lower cost sharing based on the lower DVP-negotiated rates. Medicare would also retain a specified share of the savings with the remainder shared with providers and vendors.

54 For example, to ensure that providers and vendors find the savings opportunities attractive and are encouraged to participate, the government share of savings could be lower for the first 5 percent of savings and higher for any savings beyond 5 percent.

55 It would be important that the formulary development process include the input of physicians, as well as pharmacists and other experts, while nevertheless avoiding conflicts of interest.

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CHAPTER 3

Using premium support in Medicare

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Chapter summary

Medicare finances Part A and Part B using a combination of government funding and beneficiary premiums. Most beneficiaries are not required to pay a premium for Part A coverage. For Part B coverage, most beneficiaries pay a standard premium regardless of whether they are enrolled in the fee-for-service (FFS) program or a Medicare Advantage (MA) plan. As a result, beneficiary premiums do not reflect any differences in the underlying cost of providing the Medicare benefit package through the FFS program or an MA plan.

Under a premium support model, the amount that the government pays for each beneficiary's Medicare coverage would be changed to a fixed dollar amount that remains the same whether the beneficiary enrolls in the FFS program or a managed care plan. Beneficiaries would pay premiums that equal the difference between the overall cost of providing the Medicare benefit package and the government contribution. As a result, premiums for FFS coverage and managed care plans would vary based on the underlying differences in their overall costs. Plans with lower overall costs would charge lower premiums, while plans with higher overall costs would charge higher premiums. A form of premium support has been used in the Part D program since its inception.

The Commission makes no recommendation on whether premium support should be used. The Commission has long believed that provider and

In this chapter

beneficiary incentives can both play a role in ensuring that care is delivered in an efficient manner and has studied premium support to understand how it could give beneficiaries a financial incentive to enroll in coverage options that can provide the Medicare benefit package more efficiently. Given the Congress's interest in premium support and the Commission's role in providing analysis and guidance on Medicare issues, this chapter examines some of the key issues that policymakers may want to resolve if they decide to use premium support in Medicare and discusses some of the potential consequences of taking particular approaches to a number of issues. Because of the complexity of this topic, this chapter does not examine all of the issues raised by premium support. The key issues discussed in this chapter are:

- ***What would be the role of the FFS program, which covers about 70 percent of all Medicare beneficiaries?*** Under many premium support proposals, the FFS program would be maintained and treated as a competing plan when calculating beneficiary premiums. Under this approach, the FFS program would operate much as it does now, but Medicare would develop a "bid" for FFS that would be used, along with bids submitted by managed care plans, to determine the Medicare contribution and beneficiary premium for each coverage option. Maintaining the FFS program's current role would have several advantages. Beneficiaries would face premiums that accurately reflect differences in the relative cost of providing the Medicare benefit package through FFS compared with managed care plans. The presence of FFS would help limit program spending and beneficiary premiums in areas of the country where FFS is less expensive than managed care and would ensure that beneficiaries in areas where no managed care plans are available have a source of coverage. FFS would also limit program spending and beneficiary premiums indirectly by making it easier for managed care plans to negotiate with providers to obtain payment rates that are similar to FFS rates and thus avoid paying the much higher rates that prevail in commercial insurance. Finally, beneficiaries would be free to select the type of coverage that best meets their preferences, with beneficiaries who choose more expensive coverage paying the full incremental cost.

- ***How much should the coverage offered by the FFS program and managed care plans be standardized under a premium support system?*** Standardizing coverage would help ensure that all beneficiaries have access to adequate coverage and would make it easier for beneficiaries to understand and compare their coverage options. Standardizing coverage would also help guard against the possibility of managed care plans selectively enrolling healthier

beneficiaries and make it easier to administer a premium support system. There may be arguments for standardizing coverage options in several ways. The FFS program and all plans could offer a standard package of benefits, although managed care plans could have the flexibility to use alternative forms of cost sharing that are actuarially equivalent, as MA plans can now. Standardizing the benefit package could require changing the FFS benefit structure to make it more comparable with the benefit structures used by managed care plans (for example, by adding an annual cap on out-of-pocket expenditures). Plans could offer additional benefits if they wished, but plan enrollees would not be required to purchase the additional benefits, and those who did would pay an additional premium that reflected their full cost. Beneficiary premiums for all coverage options would also need to be standardized to reflect costs for a beneficiary of average health, to ensure that premiums reflected differences in the underlying efficiency of each coverage option instead of differences in the health of the beneficiaries enrolled. Finally, beneficiaries would need to have access to robust decision support tools that help them understand their coverage options and select the one that best meets their needs.

- ***What method would be used to calculate the Medicare contribution and beneficiary premiums?*** One key feature of a premium support system would be a "benchmark" consisting of two components: the Medicare contribution and a base beneficiary premium. The Medicare contribution would be the same for each coverage option, while the amount that beneficiaries would pay for each option would equal the base beneficiary premium plus any difference between the plan's bid and the benchmark.

  Many premium support proposals would use competitive bidding to determine benchmarks because bids would be the best way to collect information about the relative "price" of providing the standard benefit package in FFS and managed care plans. All bids would need to be risk adjusted to reflect costs for a beneficiary of average health so they could be compared on an "apples-to-apples" basis. If the bidding process used geographic regions that reflected local health care markets, benchmarks would likely vary across areas, given the geographic variation in Medicare spending and service use that now exists.

  Competitive bidding could be used in many ways to calculate benchmarks. The exact method employed would play a key role in determining the impact of premium support on program spending and beneficiary premiums because higher benchmarks would result in higher program spending and lower beneficiary premiums, and vice versa. In this chapter, the Commission

explores two options: (1) using the lower of the FFS bid or the median bid among an area's managed care plans and (2) using the weighted average of all bids. Both methods are appealing because they would produce benchmarks in most areas that fall somewhere in the broad middle of the distribution of bids. Basing benchmarks on lower plan bids would produce larger savings for the government but have correspondingly higher beneficiary premiums. In addition, low-bidding plans (particularly if they are new) may not have the capacity to serve large numbers of enrollees, and their bids could change significantly in later years if they proved to be unrealistically low, which could lead to larger year-to-year changes in beneficiary premiums.

The Commission also explores two ways to set the base beneficiary premium: (1) using a standard amount that is determined nationally (like the current Part B premium) and (2) using a standard percentage of each area's benchmark. The first method would result in lower premiums for beneficiaries in high-cost areas, while the second method would result in lower premiums for beneficiaries in low-cost areas. Some year-to-year volatility in beneficiary premiums would be likely because plan bids would change over time, but premiums would probably be more stable if benchmarks equaled the weighted average of all plan bids rather than the lower of the FFS bid or the median plan bid.

One issue in premium support is how the Medicare contribution and the base beneficiary premium would grow over time compared with the benchmark. Some premium support proposals have sought to reduce the growth in federal Medicare spending by putting a limit on the annual growth in the Medicare contribution that is lower than historical growth in health care spending or Medicare spending. If the benchmark grew more rapidly than this limit, growth in the Medicare contribution would be capped at a lower rate, and the difference would be made up by higher beneficiary premiums. This situation would be problematic because beneficiaries would bear the risk of paying higher premiums without being able to take actions that lower their premiums in a meaningful way (since the added growth in the base beneficiary premium would be a function of broader forces like the overall growth of Medicare spending and growth in the national economy). An alternative approach would be to have the benchmark, Medicare contribution, and base beneficiary premium all grow in tandem with plan bids, as they do now in the Part D program, and see whether competition among managed care plans (driven by beneficiaries' interest in lower cost plans) can achieve sufficient savings.

The method used to calculate the Medicare contribution and beneficiary premiums would play an important role in determining who bears the cost of the regional variation that exists in Medicare spending. Two components would be especially important: the geographic regions used as bidding areas and the method used to set the base beneficiary premium. The use of bidding areas that reflect local health care markets and a standard amount as the base beneficiary premium would provide greater protection against higher premiums to beneficiaries in high-cost areas.

- ***How would high-quality care be rewarded under premium support?*** Under a premium support system, quality of care could be measured by comparing the performance of managed care plans and the FFS program on a set of population-based measures to a common, market area–level standard (i.e., the average performance for all Medicare beneficiaries). Quality could be rewarded in two ways to encourage the delivery of better care to beneficiaries. In the first, the government would require all plans to meet minimum standards that ensure they can provide quality care (such as having adequate provider networks) and publicly release quality data for beneficiaries to use when selecting a coverage option, but it would not adjust the Medicare contribution based on quality. In the second, the government would also require plans to meet minimum standards and publicly release quality data, but plans with higher quality scores would receive a higher Medicare contribution, which would allow them to charge lower beneficiary premiums.

- ***What steps could be taken to mitigate or delay the impact of potentially higher premiums and protect low-income beneficiaries?*** The impact of a premium support system on beneficiaries' premiums would depend on the method used to calculate the benchmark and base beneficiary premium and on beneficiaries' willingness to avoid premium increases by switching to lower cost forms of coverage. We find that the impact would also vary across market areas: In areas where FFS is less expensive than managed care, plan enrollees could face higher premiums; in areas where managed care is less expensive than FFS, FFS enrollees could face higher premiums. The amount of the increase in some areas could be substantial. Some steps to mitigate or delay these effects include phasing in higher premiums over time or limiting the extent to which premiums for the different coverage options could vary. New Medicare beneficiaries could be automatically enrolled in managed care plans instead of FFS in areas where plans have lower premiums, but this approach could be disruptive for beneficiaries who are assigned to plans that do not have all of their current providers in their networks. In addition, low-income beneficiaries would need

to receive premium subsidies to ensure that they could obtain coverage. Those subsidies could be based on the premiums for lower cost plans to ensure that low-income beneficiaries would still have an incentive to enroll in a lower cost coverage option, but this approach would likely require beneficiaries in many areas to pay an additional premium if they chose FFS coverage.

The use of premium support could have significant effects on beneficiaries and managed care plans. Available research on several relevant issues, such as the sensitivity of beneficiaries to changes in premiums, provides some indication of potential effects. However, given the many actors and design choices (which go well beyond the issues raised in this chapter), there is no way to predict with certainty how premium support would play out. Experience in the MA and Part D programs indicates that beneficiaries respond to higher premiums by switching plans and that larger increases in premiums result in more switching. However, most MA and Part D beneficiaries keep their existing plan when premiums increase, and many beneficiaries who would benefit from changing plans do not switch. However, the changes in premiums could be larger under premium support than they have been in MA and Part D, which makes it difficult to estimate how many beneficiaries might switch coverage. Beneficiaries also consider factors besides premiums when selecting a health plan, such as the plan's network of providers and their expected out-of-pocket costs, and many beneficiaries have difficulty choosing a plan when there are a large number available. Beneficiaries would need access to decision support tools (which would ideally be more robust than the tools now used in MA and Part D) to evaluate their coverage options and select the plan that best meets their needs. Managed care plans would likely reassess which markets they serve (entering some markets and leaving others), and the greater emphasis on price competition under premium support could also lead plans to submit lower bids than they do currently. On balance, the use of premium support would likely increase the number of beneficiaries enrolled in managed care plans and reduce the number enrolled in FFS. ■

Introduction

The importance of delivering care in an efficient manner has long been a key concern for the Commission in its work evaluating the Medicare program. Delivering care efficiently is important because it helps to ensure that the program's overall costs, which are borne by both taxpayers (in the form of payroll and income taxes) and beneficiaries (in the form of premiums and cost sharing for covered services), are kept at reasonable levels.

This concern has led the Commission to make numerous recommendations over the years that affect providers. The Commission considers the experience of efficient providers—those with below-average costs and above-average performance on various quality metrics—when developing its recommendations for updates to the payment rates in Medicare's fee-for-service (FFS) program. The Commission has also examined broader changes to the FFS program that would give providers stronger incentives to deliver care efficiently, such as a unified payment system for post-acute care services (Medicare Payment Advisory Commission 2016b), the development of accountable care organizations (Medicare Payment Advisory Commission 2009), and the wider use of gainsharing arrangements among providers such as hospitals and physicians (Medicare Payment Advisory Commission 2008b). The Commission has also made recommendations that would encourage Medicare Advantage (MA) plans to be more efficient, such as setting the benchmarks used to determine MA plan payments at 100 percent of FFS costs (Medicare Payment Advisory Commission 2005).

Beneficiary incentives can also play an important role in ensuring that services are used efficiently. In 2012, the Commission recommended making a series of changes to improve and rationalize the FFS benefit. Those changes included reforming the deductibles for Part A and Part B, replacing coinsurance with copayments that could vary by the type of service and provider, and adding a cap on out-of-pocket expenditures. The Commission also found that supplemental coverage (such as medigap and employer-sponsored retiree plans), which covers some or all of Medicare's cost sharing, leads to higher utilization of services that may be of marginal value. As a result, the Commission recommended imposing a surcharge on premiums for supplemental policies to reflect the additional Medicare costs that these plans generate, which result in higher costs for taxpayers and higher premiums for beneficiaries (Medicare Payment Advisory Commission 2012a). The Commission has also supported the adoption of copayments to moderate the use of certain services such as some home health episodes (Medicare Payment Advisory Commission 2011a).

The Commission's interest in giving beneficiaries greater incentives to use Medicare services more efficiently has also led it to examine the implications of using a premium support model for Part A and Part B.[1] The Commission began its examination of premium support in its June 2013 report to the Congress—using the term *competitively determined plan contributions*—and included a chapter on the topic in its June reports for 2014, 2015, and 2016. The term *premium support* has been used elsewhere in different contexts and is thus somewhat inexact. As the Commission has used the term, premium support refers to a system in which the federal government makes a fixed, competitively determined contribution toward the cost of Medicare coverage, and beneficiary premiums are higher or lower depending on the relative costliness of the chosen plan (either the FFS program or a managed care plan).[2] The higher premiums for more expensive plans would thus encourage beneficiaries to enroll in lower cost plans.

The use of premium support would represent a significant change for the Medicare program and raises numerous concerns about how it could affect federal spending, beneficiaries, health care providers, and managed care plans. To give a few examples:

- Premium support is often viewed as a way to reduce federal Medicare spending, but spending could increase substantially if providers negotiated Medicare payment rates with managed care plans that were comparable with commercial payment rates. There has been substantial consolidation among providers, and many providers (such as hospitals) have been able to negotiate commercial rates that now far exceed Medicare rates.
- The premium support model anticipates that beneficiaries will be able to understand their coverage options and select the one that best meets their preferences. However, beneficiaries may have trouble evaluating their options without accurate, understandable, and comparable information about their coverage options. And some beneficiaries, such as those with cognitive impairments or behavioral health conditions, may have difficulty making an informed choice.

- Beneficiaries consider factors besides premiums when they select a particular type of coverage, such as access to certain providers. These other factors could make beneficiaries less willing to switch to lower cost plans.
- Premium support is based on competition among managed care plans (and the FFS program in some proposals). There would need to be a robust system of risk adjustment to compensate plans that attract a sicker than average mix of enrollees.

This chapter examines some of the key issues that policymakers may want to resolve if they decided to use premium support in Medicare. (Given the complexity of this topic, this chapter does not examine all of the issues raised by premium support.) The Commission makes no recommendation on whether premium support should be used. However, if policymakers decide to pursue the use of premium support, we discuss some of the potential consequences of particular approaches to a number of issues.

This chapter begins by providing some background on the concept of premium support and then discusses six key issues related to its use: (1) the role of the FFS program, (2) standardizing benefit packages and beneficiary premiums, (3) determining benchmarks and beneficiary premiums, (4) incorporating quality into premium support, (5) mitigating the impact of higher premiums on beneficiaries, and (6) providing premium subsidies to low-income beneficiaries. We then assess some of the possible impacts that premium support could have on beneficiaries and managed care plans.

The concept of premium support

The term *premium support* first appeared in a 1995 article by Aaron and Reischauer, but proposals to apply the concept to Medicare in some fashion have been around since the 1980s (Aaron and Reischauer 1995, Kaiser Family Foundation 2012). These proposals differ in many respects, but all envision a program in which beneficiaries would receive their Medicare benefits by choosing among competing managed care plans or (in some proposals) the traditional FFS program. This choice between managed care plans and the FFS program exists now—any beneficiary can enroll in the FFS program, and 99 percent of beneficiaries currently have access to an MA plan, with most having access to multiple plans—but under premium support, the government would use a different method to calculate the beneficiary premiums for each option.

Under current law, beneficiaries do not pay a Part A premium if they are entitled to Medicare through receipt of Social Security or Railroad Retirement Board benefits or through Medicare's end-stage renal disease program.[3] Beneficiaries who choose to enroll in Part B usually pay a monthly base premium ($134 in 2017) that equals about 25 percent of the national average per beneficiary cost of Part B benefits.[4] The base Part B premium is set nationally and does not vary across areas.

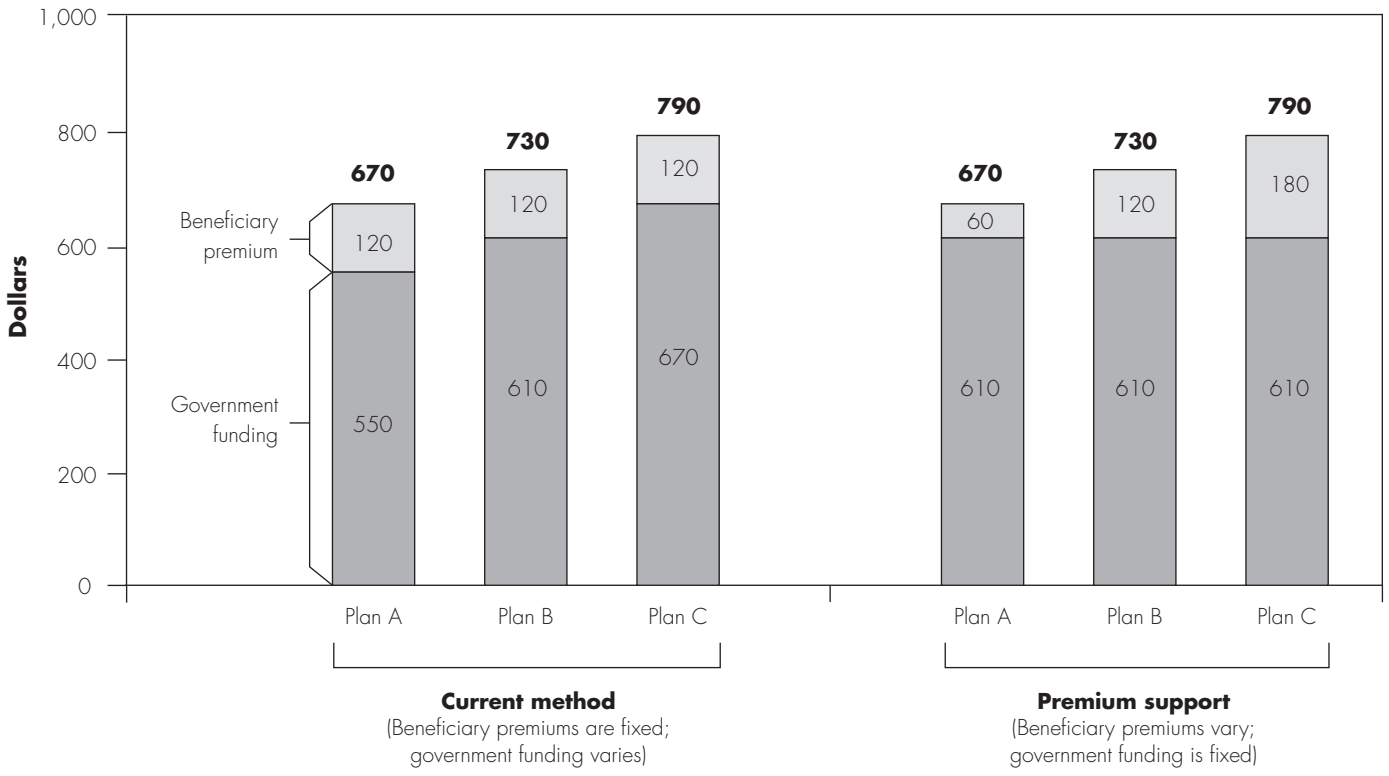
In contrast to the FFS program, premiums for MA enrollees can vary, depending on how plan bids compare with the local MA benchmark. If plan bids are higher than the benchmark (which is relatively rare), MA enrollees pay the Part B premium and the difference between the bid and the benchmark as an additional premium. If plan bids are lower than the benchmark, beneficiaries pay the Part B premium and receive part of the difference between the bid and the benchmark in the form of extra benefits and reduced premiums, including the few cases where plans have elected to offer a reduced Part B premium. However, most MA plans tend to offer extra benefits such as reduced cost sharing instead of reducing the Part B premium. As a result, most MA enrollees pay the same Part B premium as FFS enrollees.

Under premium support, Medicare would contribute a specified dollar amount toward the cost of each beneficiary's coverage in a given market area. (Throughout this chapter, *cost* refers only to expenses that the Medicare program pays for—either directly through the FFS program or indirectly through a managed care plan—and does not include beneficiary cost sharing.) The amount of this contribution would remain the same, regardless of whether the beneficiary enrolled in FFS or in a managed care plan or enrolled in one plan instead of another plan. The beneficiary premium for each coverage option would equal the difference between the total cost of that particular coverage option and Medicare's contribution. Any differences in the total cost of the available coverage options would thus be directly reflected in beneficiary premiums. Beneficiaries who qualify for both Medicare and Medicaid could conceivably be handled through a separate framework because of the challenges of coordinating the two programs.

An illustrative example helps to demonstrate the basic difference in how Medicare spending is financed under

FIGURE 3–1

Illustrative comparison of how Medicare spending is financed under current law versus a premium support system



Note: This comparison assumes that managed care plans do not charge an additional premium.

current law versus a premium support system (Figure 3-1). In this example, beneficiaries have three options for receiving their Medicare benefits—Plan A, Plan B, and Plan C. One of these "plans" is the FFS program, and the other two options are managed care plans. The total monthly cost of providing the Medicare benefit package varies across the three options: Plan A costs $670; Plan B, $730; and Plan C, $790. (For these purposes, we do not need to specify which plan is the FFS program; the key point is simply that the overall cost of the three options varies. In reality, there would likely be areas where the FFS program is the low-cost option, areas where it is the high-cost option, and areas where it falls somewhere in between. The difference in cost between the low-cost and high-cost options would also be, depending on the area, greater or lower than what is depicted here.)

Figure 3-1 shows how beneficiary premiums and government funding are currently used to finance Medicare spending. In this example, all beneficiaries pay a standard premium of $120, similar to the current Part B premium, regardless of the option they choose. (For simplicity, we assume that the two managed care plans bid below the MA benchmark and do not charge an additional premium. Note also that beneficiaries pay this premium to Medicare instead of directly to the plan.[5]) Medicare pays the remaining cost. Since the beneficiary premium does not vary, the differences in the overall cost of the three options are reflected in Medicare funding, which ranges from $550 per month for Plan A to $670 per month for Plan C.

Figure 3-1 also shows how Medicare spending would be financed under a premium support system. Under this approach, Medicare would contribute a fixed amount

toward each beneficiary's coverage—$610 in this example—regardless of which plan the beneficiary chose. Since the Medicare contribution does not vary, differences in the overall cost of the three options are reflected in the beneficiary premiums, which range from $60 for Plan A to $180 for Plan C. Plans with lower costs would thus have lower premiums than plans with higher costs, which would give beneficiaries an incentive to choose a lower cost plan.

In this example, the use of premium support reduces the premium for Plan A (from $120 under the current approach to $60 under premium support), has no impact on the premium for Plan B, and increases the premium for Plan C (from $120 to $180). However, the extent to which the premiums for the three options would change under premium support is heavily dependent on the amount of the Medicare contribution. For example, if the Medicare contribution under premium support were $550, the premium for Plan A would continue to be $120, while the premiums for Plan B and Plan C would be higher than they are today. If the Medicare contribution under premium support were $670, the premiums for Plan A and Plan B would be lower than they are today (Plan A would, in fact, not charge any premium) and the premium for Plan C would remain at $120.

Several federally funded health care programs use at least some elements of premium support to determine beneficiary or enrollee premiums:

- Under the Medicare Part D drug benefit, prescription drug plans and MA plans that offer a drug benefit submit bids that indicate the total monthly cost of providing Part D benefits. Enrollees pay a base beneficiary premium that equals 25.5 percent of the national average bid plus any difference between their plan's bid and the national average bid. Part D enrollees thus pay the full incremental cost if they decide to enroll in a plan that has above-average costs and keep the full incremental savings if they decide to enroll in a plan that has below-average costs.

- Under the Patient Protection and Affordable Care Act of 2010 (PPACA), the government pays part of the premium for eligible individuals who purchase coverage through the health insurance exchanges. The plans in the exchanges are grouped into four tiers (platinum, gold, silver, and bronze) based on their generosity. Platinum plans have the most generous coverage, while bronze plans have the least generous. The government contribution equals the difference between the premium for the silver plan with the second lowest premium in an area and an amount the individual is required to pay based on family size and income. The amount that the government contributes does not change if an individual enrolls in a different plan, so individuals who enroll in a more expensive plan—such as a platinum or gold plan or a more expensive silver plan—pay higher premiums, and individuals who enroll in a less expensive plan, such as a bronze plan, pay lower premiums.

- Under the Federal Employees Health Benefits Program (FEHBP), the federal government provides health coverage to eligible federal employees, retirees, and their dependents. The government limits its contribution for each participating health plan to either 72 percent of the weighted average premium for all FEHBP plans or 75 percent of the plan's premium, whichever is less. As a result, individuals who enroll in plans that are more expensive than the weighted average premium pay the full amount of any difference between their plan's premium and this benchmark.

- Under the MA program, local plans (plans with service areas composed of one or more counties rather than larger, CMS-specified regions) submit bids that are compared with a benchmark amount. Plans that submit bids greater than the benchmark are required to charge beneficiaries a premium that equals the difference between the plan's bid and the benchmark, so the benchmark serves as an upper bound on the government contribution. In this respect, the MA benchmark performs the same function as the weighted average premium in the FEHBP, although the MA benchmark is based on historical FFS spending while the weighted average premium in the FEHBP is determined through competition. The MA program also includes regional preferred provider organization (PPO) plans that have service areas specified by CMS and are composed of one or more states. The benchmarks for those plans are partly determined through competition because they equal a weighted average of the region's historical FFS spending and the regional PPOs' bids.

Although the basic concept of premium support is relatively straightforward, the development of a premium support system for Medicare would require policymakers to address multiple key issues, starting with the role of the FFS program.

The role of the FFS program

For its supporters, the appeal of premium support is based on the fact that managed care plans in some areas of the country submit bids to provide the Medicare benefit package at a lower cost than the FFS program.[6] However, about 70 percent of all Medicare beneficiaries are enrolled in the FFS program, the FFS program costs less than managed care plans in some areas of the country, and some beneficiaries may want the option of choosing between FFS coverage and a managed care plan. As a result, the role of the FFS program in a premium support system is a key issue to consider.

Proposals to use premium support have varied in how they treat the FFS program. For example, some proposals use premium support only to modify how Medicare pays managed care plans and leave the FFS program untouched. Other proposals continue to offer the FFS program while treating it as a competing plan when calculating beneficiary premiums. Still other proposals eliminate or phase out the FFS program and move to a system that relies entirely on managed care plans to provide Medicare benefits.

There are arguments for the FFS program to remain available under a premium support system and to be treated as a competing plan when calculating beneficiary premiums. Under this approach, the FFS program would operate much as it does now. Beneficiaries in the FFS program would essentially have no restrictions on their choice of providers and would face few constraints on their service use compared with beneficiaries enrolled in managed care plans. Providers who deliver care to FFS beneficiaries would continue to be paid under the existing FFS payment rules.

However, Medicare would also develop a "bid" for the FFS program that would be used, along with bids submitted by managed care plans, to determine the Medicare contribution and beneficiary premium for each coverage option in a given market area. The FFS bid would equal the estimated average per capita cost of providing the Medicare benefit package for a market area's FFS beneficiaries, and the bid would need to be standardized to reflect the cost for a beneficiary of average health. FFS spending data currently include some payments that are not included in MA plan bids, such as hospice, direct graduate medical education, and indirect medical education.[7] Depending on how those payments were handled under a premium support system, CMS may need to adjust FFS spending data to develop an FFS bid that could be compared with managed care plan bids.

There would be several advantages to treating the FFS program as a competing plan under a premium support system. First, it would ensure that beneficiaries face premiums that accurately reflect the difference in the cost of providing the Medicare benefit package through the FFS program compared with managed care plans. Given the number of FFS beneficiaries and the difference between the cost of the FFS program and managed care plans in many areas, switching from the FFS program to a managed care plan—or, in some areas, from a managed care plan to the FFS program—is one of the main ways that beneficiaries would be able to obtain coverage at less cost. (Some beneficiaries who are now enrolled in MA plans would also be able to obtain less expensive coverage by switching from a higher cost plan to a lower cost plan.)

Second, the presence of the FFS program would help limit program spending in areas where the FFS program is less expensive than managed care plans. Under the MA program, 18 percent of beneficiaries live in counties where the MA benchmark equals 115 percent of FFS spending, and most MA plans in those counties are more expensive than the FFS program. These areas tend to have low rates of service use, which makes it difficult for plans to offset their operating costs by reducing unnecessary service use; these areas are also more rural, so there are relatively few providers, and plans may have difficulty negotiating favorable payment rates. Under premium support, the FFS program could be the lower cost option in some counties that now have high MA benchmarks, and some plans in those counties might leave the market if they had to start charging higher premiums than the FFS program. The continued availability of the FFS program would thus serve as a safeguard in areas where managed care plans choose not to participate.

Third, the presence of the FFS program would also limit program spending indirectly because FFS payment rates would serve as a reference point for providers and managed care plans when they negotiate payment rates. Many providers have a substantial amount of market power, and there is widespread evidence that providers negotiate payment rates with commercial insurers that are substantially higher than FFS rates. For example, the rates that commercial insurers pay hospitals are often far more than 50 percent above Medicare rates. Providers that are part of an MA plan's provider network are not required to accept FFS payment rates when they deliver care to the

plan's enrollees and thus might be expected to negotiate payment rates that are closer to commercial rates. However, our discussions with plan representatives and the available research indicate that MA plans pay providers using rates that are similar to FFS rates. Providers may find it more difficult to negotiate higher payment rates with MA plans than with commercial plans because providers have to accept FFS payment rates if they cannot reach agreement with MA plans. (If a provider does not join an MA plan's provider network, the plan is allowed by law to use FFS payment rates to pay for any covered out-of-network care. And more broadly, if MA plans cannot operate profitably in a particular area and decide to leave the market, providers will be paid at FFS rates when the beneficiaries in the area enroll in the FFS program.) We anticipate that the FFS program would continue to have a dampening effect on payment rates under a premium support system if managed care plans can use FFS rates to pay for covered out-of-network care.

Finally, the continued availability of the FFS program is consistent with the Commission's long-standing view that Medicare beneficiaries should be able to receive their benefits through the FFS program or a managed care plan, with the important caveat that the government should not spend more on beneficiaries who enroll in one sector over the other (Medicare Payment Advisory Commission 2005). Enrollment in MA plans has grown substantially over the past decade, but the FFS program remains popular. Although FFS premiums could increase in many areas under a premium support system, some beneficiaries could still prefer FFS coverage for a number of reasons, such as having a free choice of providers. Under a premium support system, beneficiaries would be free to select the type of coverage that best meets their preferences, with beneficiaries who select a more expensive coverage option paying the full incremental cost in the form of higher premiums.

Standardizing benefit packages and beneficiary premiums

Under a premium support system, some level of standardization could be used in three areas—standardization of *benefits* (the items and services that would be covered by the FFS program and managed care plans), standardization of *beneficiary cost sharing*, and standardization of *risk* (adjusting beneficiary premiums and plan bids for differences in beneficiaries' health status). Standardizing these elements of a premium support system would be important for several reasons:

- to facilitate the determination of a government contribution amount that is accurate and established through competition on a level playing field,
- to aid beneficiaries in their decision making by having clear information about the price and features of each option,
- to reduce opportunities for favorable selection through benefit designs, and
- to facilitate administration of the program.

The experience with standardization in certain parts of Medicare can serve as models for a premium support system (Table 3-1). Although such a system would likely be built largely on the current MA framework, the Part D drug benefit also serves as a model, and there are lessons to be learned from the medigap experience with standardization.

If the Congress decides to use premium support and treat the FFS program as a bidding plan, then the FFS Part A and Part B benefit package could serve as the standard for determining plan bids and beneficiary premiums. In that case, beneficiary cost sharing could be standardized at FFS levels, although plans could use alternative forms of cost sharing that are actuarially equivalent. (The Commission has recommended changing the FFS benefit package to make it more like the typical MA plan's benefit package, a topic discussed more fully below.) All bids and payments to managed care plans also need to be standardized to account for differences in the health status of beneficiaries. Insurers would also be allowed to offer benefits beyond those covered by Medicare, which would allow managed care plans to innovate and give beneficiaries options that may be suited to their needs and preferences. (Some argue that enhanced benefit packages or optional supplemental benefits should also be standardized to some degree.) These elements would be similar to the current MA program. However, two features in Table 3-1 differ from current MA standards and borrow from the approach used in Part D—requiring insurers to bid on, *and offer*, a standard benefit package and requiring the cost of any induced demand in plans that offer additional benefits to be financed by beneficiary premiums instead of by the government. (In Part D, a sponsor's bid identifies the actuarial value of each of the components of the bid. In stating the value of the benefit, the bid distinguishes

TABLE 3-1

Program features that could be standardized in a premium support system and parallels in other programs

Program feature	Medicare Advantage	Medicare Part D	Medigap
1. Standardization of covered items and services	Yes (in basic benefit)	Yes (by drug classes)	Yes
2. Standardization of cost sharing	Yes (can be actuarially equivalent for basic benefits)	Yes (for standard package or through actuarial equivalence)	Yes
3. Standardization of enrollee risk for bidding or payment purposes	Yes	Yes	No (but age rating permitted)
4. All plans bid on and offer a standard package	No (offerings can consist solely of enhanced packages)	Yes	Yes (offerings standardized)
5. (a) Enhanced benefit packages are permitted	Yes (required when plans bid below benchmark and receive rebate dollars)	Yes	Not applicable (all offerings are standardized, but authority for innovative designs approved by insurance commissioners)
(b) Beneficiaries bear the full cost of induced utilization beyond the utilization level of basic coverage	No, unlike Part D	Yes	No (induced utilization of covered services is financed by Medicare)
6. Number of plans that an insurer can offer is limited	Yes (offerings must have meaningful differences)	Yes (offerings must have meaningful differences)	Yes (because of standardization)

Note: "Actuarial equivalence" is established by determining whether the dollar value of a given set of benefits and/or cost sharing is equal to the dollar value of an alternative set of benefits and/or cost sharing. A medigap plan is a product offered by a private insurance company that pays Medicare cost-sharing amounts for which a beneficiary is liable. Medigap plans can also cover the cost of care beyond Medicare's coverage limits for certain services or the cost of some additional services Medicare does not cover.

between the cost of the basic (standard) benefit defined in the statute and the separately identified cost of any supplementation of the benefit. The portion of the bid that represents supplemental benefits is financed through beneficiary premiums, not through Medicare program payments (42 CFR §423.265 and §423.286).)

Finally, the question of whether to limit the number of plans that an insurer could offer in a market area may need to be addressed. Given the array of coverage options, improved decision support tools would be needed to help beneficiaries navigate their choices, particularly for beneficiaries residing in areas with an assortment of managed care plans.

Defining standardization and reviewing its use in different programs

The experience of other parts of the Medicare program can be instructive in considering standardization in a premium support system.

Standardization in medigap

Medigap plans pay the cost sharing for Medicare-covered services that beneficiaries would otherwise pay and cover the cost of care after Medicare benefits are exhausted, in the case of inpatient hospital care. Some medigap plans also cover additional benefits such as a foreign travel benefit. The standardization imposed on medigap

policies (originally enacted in the Omnibus Budget Reconciliation Act of 1990) helps illustrate what is meant by *standardization*. With certain exceptions, all insurance companies offering medigap coverage must meet standardization requirements. In almost all states, there is a maximum of 10 standard medigap plans an insurance company can market, identified by letters A through N (E and H through J are no longer available). Each plan is distinguished by the extent of its coverage of Medicare's cost sharing and any extra benefits. One company's Plan A coverage is no different from another company's Plan A coverage. The major differences among the various plans relate to their coverage of the Part A and Part B deductibles, cost sharing for care in a skilled nursing facility, the difference between the limiting charge and the Part B payment amount for claims submitted by providers that do not accept assignment, and non-Medicare benefits.

The standardization of coverage applies to both the benefits included beyond those covered by Medicare and cost sharing for items and services. For example, Plan A and Plan F differ in terms of the non-Medicare benefits and cost-sharing coverage. Plan A does not include a foreign travel benefit, while all Plan F policies include a standard foreign travel benefit (which is a non-Medicare-covered benefit). For cost sharing, Plan A does not cover the Medicare inpatient hospital deductible; Plan F does. Thus, medigap standardizes the items and services to be covered as well as any associated cost sharing. Because insurers can offer only the standardized plans, standardization extends to the "plan offerings" that insurers can market.

The impetus for the standardization of medigap policies was the confusion that beneficiaries faced in choosing among a wide array of coverage options and the lack of transparency in the pricing of policies. After standardization, in choosing among insurance companies, a beneficiary knows that the coverage under Plan A, for example, is the same across all companies. This level of transparency in coverage would aid beneficiary decision making in a premium support system.

Despite the standardization of benefits and cost sharing in medigap, beneficiary premiums vary greatly. Policies' premiums depend on several factors: the plan's administrative costs and profit level (which are capped by a required minimum medical loss ratio); a beneficiary's age and other factors that medigap insurers can use when setting premiums; and—to a great extent—the use of health care services by a plan's beneficiary risk pool. If a given company's Plan F, for example, has an especially unhealthy pool of enrollees, its premium is likely to be higher than the Plan F premium of another company that operates in the same market area but has a healthier pool of enrollees. Because the outlays of medigap insurers are a function of the utilization of Medicare services, the geographic variation in service use seen in the FFS program also has an effect on medigap premiums. An insurer can have different premiums for the same standardized plan in different geographic rating areas. For example, New York State has 10 geographic rating areas for the pricing of medigap policies. Other factors that have been cited as contributing to the variation in medigap premiums are the limited competition in the market (where there are often dominant insurers in a state) and high "search costs" (that is, the time and effort of finding and comparing medigap options may discourage extensive comparison shopping) (Maestas et al. 2009).

Standardization in Medicare Part D

The premium support concept of using competition among plans to determine a government contribution level has a close parallel in the Medicare Part D (prescription drug) program. In terms of standardizing drug coverage, the program affords plans wide latitude once a plan meets certain minimum requirements for the number of drugs covered in each therapeutic class and coverage of most drugs in six protected therapeutic classes.

Compared with drug coverage in Part D plans, there is greater standardization of beneficiary cost sharing under the Part D drug benefit. Each year, CMS announces a set of statutorily based benefit parameters, such as the deductible and out-of-pocket maximum, that apply to all Part D plans. Part D uses standardized bids to determine the enrollment-weighted national average premium that serves as the reference point for determining the beneficiary premium for each plan. Each prescription drug plan must develop a bid for a plan using the CMS-specified standard benefit parameters or a plan with cost sharing that is actuarially equivalent. An actuarially equivalent bid has different benefit parameters (for example, a lower deductible), but the dollar value of its cost sharing is equal, on average, to the dollar value of cost sharing in a plan that uses the standard benefit parameters. Part D plans can offer enhanced packages that have less overall cost sharing, but such plans must develop a bid that breaks out the plan's standard component so that the government contribution covers only that component. Among beneficiaries who were enrolled in stand-alone plans in 2016 and did not receive Part D's low-income

subsidy, 63 percent were in enhanced plans and 37 percent were in standard, or actuarially equivalent, plans.

In Part D, plan bids are based on expected costs for a person of average health (i.e., with a risk score equal to 1.0). The weighted national average standard bid (74.5 percent of which is subsidized by Medicare) determines how much a beneficiary will pay for a given plan, with the premium in each plan also based on a person of average risk.

Standardization in Medicare Advantage

Under current bidding rules, MA plans are required to cover the full range of Medicare Part A and Part B services for their enrollees and to generally follow the same coverage guidelines used in the FFS program. The MA program's "basic" benefits are thus standardized, in the same way that a given medigap plan's set of benefits is standardized. For the evaluation of bids and determination of a plan's premium, plans are required to submit bids "with cost-sharing for those services as required under parts A and B or . . . an actuarially equivalent level cost-sharing" (Section 1852(a)(1)(B)(i) of the Social Security Act). In other words, a plan's bid may not reduce the cost sharing that, in statute, is the beneficiary's responsibility (nor may the bid include higher overall cost sharing). In MA, plans can offer supplemental benefits, but they can also require beneficiaries to purchase extra benefits as a condition of enrolling in the plan. That is, there is no requirement that a sponsor offer a plan that consists only of the standard benefit package.

In MA, premiums for basic coverage are based on the premium for a person of average health—or a 1.0 risk score—as in Part D (but not in medigap, where the premium reflects the actual relative health status of beneficiaries choosing a particular plan). The MA premium for basic coverage is determined by comparing a risk-standardized plan bid (representing a bid for a person of average health) with that plan's benchmark, which is also standardized to a 1.0 risk score. Plans with a standardized bid that exceeds the standardized benchmark are required to charge a premium equal to the difference between the two amounts. Because the premium is set for a person of average health, the premium differences among plans represent the relative efficiency of such plans as measured by their costs in relation to FFS. The premium differences do not reflect different levels of risk among the actual enrollees of the plan, as they do in medigap.[8]

Using standardization in a premium support system

Based on the experience in MA and other programs, we explore the rationale for standardizing several elements of a premium support system—the items and services that would be covered, beneficiary cost sharing, beneficiary premiums and plan payments, and the ability of managed care plans to offer additional benefits that are not covered by Medicare. There are arguments for using standardization in a particular way to address these elements.

Covered items and services

The MA and Part D programs both feature a standardized package of benefits. In MA, the plan bids that determine whether plans must charge an additional premium for Part A and Part B coverage (beyond the standard Part B premium) are based on the cost of providing the FFS benefit package. In Part D, plan bids that determine the national average premium are based on the cost of providing a basic benefit that is specified in statute. In either program—or in a premium support system—if benefits were not standardized, one plan could have a relatively lower bid than another plan simply because the lower priced plan provides less generous coverage. The standardization of benefits also guards against strategies to achieve favorable selection through benefit design.

A premium support system relies on the establishment of a reference point that can be used to compare bids for the purpose of setting the government contribution. In a premium support system where the FFS program functions as a competing plan, the FFS benefit package could serve as the reference point—that is, the standard benefit package—as is the case now for MA plans. The FFS benefit is uniform across the country and should not be modified in different market areas, particularly if the FFS program is the only coverage option available in some areas (a situation that can change, in any area, from year to year). In addition, the FFS program is used (for now) to establish the expected cost of a beneficiary with average health and thus serves as the foundation for the current risk adjustment system.

Ideally, the FFS benefit package that would exist under a premium support system would have a design different from the current package. The Commission has recommended several changes to the FFS benefit package, such as adding an annual limit on beneficiary out-of-pocket spending and using copayments rather

The Commission's recommendations to modernize the FFS benefit package

In its June 2012 report to the Congress, the Commission considered ways to reform the traditional benefit package with two main goals: (1) to give beneficiaries better protection against high out-of-pocket (OOP) spending and (2) to create incentives for them to make better decisions about their use of discretionary care (Medicare Payment Advisory Commission 2012a). The current fee-for-service (FFS) benefit design includes a relatively high deductible for inpatient stays, a relatively low deductible for physician and outpatient care, and a cost-sharing requirement of 20 percent of allowable charges for most physician care and outpatient services. Under this design, no upper limit exists on the amount of Medicare cost-sharing expenses a beneficiary can incur. Without additional coverage, the FFS benefit design exposes Medicare beneficiaries to substantial financial risk. In part because the FFS benefit design is not comprehensive, almost 90 percent of FFS beneficiaries receive supplemental coverage through medigap, employer-sponsored retiree plans, or Medicaid. This additional coverage addresses beneficiaries' concerns about the uncertainty of OOP spending under the FFS benefit. However, it also reduces incentives for beneficiaries to weigh their decisions about the use of care. As currently structured, many supplemental plans cover all or nearly all of Medicare's cost-sharing requirements, regardless of whether there is evidence that the service is ineffective or, conversely, whether it might prevent a hospitalization. Moreover, most of the costs of increased utilization are borne by the Medicare program.

In the 2012 report, the Commission included a recommendation on the redesign of the FFS benefit package. A primary goal of the recommendation is to protect beneficiaries against high OOP spending, thus enhancing the overall value of the FFS benefit and mitigating the need for beneficiaries to purchase supplemental insurance. The recommendation creates clearer incentives for beneficiaries to make better decisions about their use of care while holding the aggregate beneficiary cost-sharing liability about the same as under current law. It also allows for ongoing adjustments and refinements in cost sharing as evidence of the value of services accumulates and evolves. Finally, by adding a charge on supplemental insurance, the recommendation aims to recoup at least some of the additional costs resulting from the higher service use encouraged through supplemental insurance while allowing risk-averse beneficiaries the option to buy supplemental coverage if they wish to do so.

Recommendation 1-1 from the Commission's June 2012 report to the Congress

The Congress should direct the Secretary to develop and implement a fee-for-service benefit design that would replace the current design and would include:

- **an out-of-pocket maximum;**
- **deductible(s) for Part A and Part B services;**
- **replacing coinsurance with copayments that may vary by type of service and provider;**
- **secretarial authority to alter or eliminate cost sharing based on the evidence of the value of services, including cost sharing after the beneficiary has reached the out-of-pocket maximum;**
- **no change in beneficiaries' aggregate cost-sharing liability; and**
- **an additional charge on supplemental insurance.** ■

than coinsurance for some services, which would make the FFS benefit more like the typical MA plan's benefit package. The Commission has also recommended imposing an additional charge on supplemental coverage because it leads to higher utilization and higher program expenditures (see text box) (Medicare Payment Advisory Commission 2012a). The combination of the annual limit on out-of-pocket spending and the additional charge would likely reduce the number of beneficiaries who buy medigap coverage.

Beneficiary cost sharing

The rationale for standardizing cost sharing is similar to the argument for standardizing covered items and services. In the MA program, standardization of Medicare cost sharing—and specifying that it is equivalent to the cost sharing in the FFS program (either exactly equivalent or actuarially equivalent)—maintains comparability between MA plans and FFS and comparability in pricing among MA plans. The Part A and Part B benefit package includes specific levels of cost sharing that Medicare does not cover and for which beneficiaries are liable. A managed care plan cannot incorporate a lower level of cost sharing into its bid in order to increase the government contribution, and neither can a plan impose higher cost sharing—reducing the plan's stated costs for the Part A and Part B benefit package—so that its bid appears lower than it should be.

Although plans can use the actuarial value of FFS cost sharing to establish a standardized bid, CMS has rules that limit cost sharing for some categories of services. These limits are service specific and aim to prevent plans from using cost sharing to discourage the enrollment of sicker beneficiaries. Some limits were enacted in statute (such as those for chemotherapy administration services, renal dialysis services, and care in a skilled nursing facility) and the Secretary has the authority to identify additional services for which the cost sharing "shall not exceed the cost-sharing required for those services under parts A and B" (Section 1852(a)(1)(B)(iv) of the Social Security Act). For example, the cost sharing for Part B drugs may not exceed the 20 percent coinsurance used in the FFS program. In the advance notice of MA rates and call letter for 2018, CMS stated that it may impose additional standards for cost sharing (Centers for Medicare & Medicaid Services 2017). One area of concern is inpatient mental health, where cost-sharing levels in some MA plans appear to far exceed FFS levels. Such oversight of plans' cost-sharing structures may need to continue in a premium support system, as would the general MA rule that allows CMS to reject plan benefit designs that are discriminatory.

Permitting plans to meet the requirement through an actuarial equivalence standard gives plans great flexibility in benefit design so that cost sharing can be a tool used to promote effective care. Another cost-sharing feature that CMS is testing—value-based insurance design (VBID)—could be accommodated in a model that standardizes cost sharing based on actuarial equivalence. Under VBID, reduced cost sharing is used to promote use of certain services that improve care and increased cost sharing is used to reduce the use of low-value care. Differences in cost-sharing amounts could also target beneficiaries with specific diseases—for example, by eliminating copayments for primary care physician visits for diabetics.[9]

Beneficiary premiums and plan payments

If bids are not standardized to reflect the cost of a beneficiary of average health, the bid of an inefficient plan could be lower than the bid of a much more efficient plan only because the former could have the advantage of favorable selection—that is, it would attract healthier enrollees. Allowing premiums to vary based on differences in health status is inconsistent with the notion of using premium support to establish a "best price" determined through competition on a level playing field. If bids and premiums are not standardized, the system would have the premium variation seen in medigap.

Requiring all plans to market a basic package

In Part D, the most popular plans are those with enhanced benefits such as reduced deductibles, but all plan sponsors that wish to offer an enhanced package must also offer the standard benefit (or an actuarially equivalent design). A beneficiary can compare the price and other features of the standard and enhanced options in choosing between the two.

Unlike Part D, MA plans are not obligated to offer a benefit package that consists only of the Part A and Part B benefit package. Instead, a plan can include non-Medicare-covered benefits in its package and require enrollees to pay for the cost of such benefits through a premium. These additional benefits are known as "mandatory supplemental benefits," and they originated in the early use of private plans in Medicare, when the only organizations permitted to have Medicare contracts were HMOs and HMO-like entities that, by definition, included preventive benefits as covered benefits. Medicare did not originally cover preventive benefits, and HMOs were allowed to cover them using premium revenue from plan members. In the current MA program, plans that feature mandatory supplemental benefits must be designed in a way that does not discourage the enrollment of certain beneficiaries (for example, low-income beneficiaries who cannot afford a high premium).

There are a number of reasons for requiring plans to bid on and offer a basic benefit under premium support. This approach would help ensure that plan bids provide true estimates of the cost of providing the standard benefit and

TABLE 3–2 **Illustrative example of the impact of induced utilization on plan costs**

	Total visits	Total copays	Total allowed amount ($200 per visit)	Plan cost	Additional plan cost	Plan cost due to lower copay	Plan cost due to induced utilization
Scenario 1: $40 copayment for physician visits	1	$40	$200	$160			
Scenario 2: $20 copayment without induced utilization	1	$20	$200	$180	$20 ($180 – $160)	$20	$0
Scenario 3: $20 copayment with induced utilization	2	$40	$400	$360	$200 ($360 – $160)	$40 ($2 × $20)	$160 ($200 – $40)

would make it easier to set the government contribution and beneficiary premiums. From a beneficiary point of view, this approach would facilitate comparison among coverage options and is consistent with the concept that plans should have some flexibility in benefit design so that their offerings can meet the needs of beneficiaries looking for different benefits. There are beneficiaries who may not want any extra benefits and would be satisfied with paying a lower premium and paying for other services out of pocket.

Dowd and colleagues point out how, if plans were not required to offer a standard package, they could manipulate the bidding system to influence the determination of the government contribution through the pricing of supplemental benefits (Coulam et al. 2013, Dowd et al. 1996). The exact strategy that a company would use depends on the manner in which the government contribution is set. However, Burke and colleagues note that the manipulation of the basic bid is illegal and is something that CMS guards against when it reviews MA bids (Burke et al. 2013). We would expect a premium support system to have a bid review process that is similar to, or perhaps more intensive than, the review process for the MA program so that CMS would continue to guard against manipulation of bids. In addition, the strategy of having a product with a higher basic bid to increase the government contribution may not be feasible in a market that is highly competitive and plans are offering options that consist only of the basic plan.

In sum, then, leaving aside the issue of possible manipulation of bids, a premium support system that requires plans to offer a standardized basic package that is directly comparable with FFS would:

- help beneficiaries determine the cost of a given plan;
- help address selection bias (because supplemental benefits can be designed to attract healthier beneficiaries);
- simplify the determination of the government contribution; and
- simplify CMS oversight of the bidding process.

As a result, under premium support, each managed care plan could be required to offer an option that beneficiaries can directly compare with the FFS program.

Allowing plans to offer additional benefits

A "pure" version of premium support could require all differences among plans to be expressed in terms of their premiums, with the least expensive plans potentially offering cash rebates. Beneficiaries who wanted extra benefits not covered in Medicare's standard benefit package—such as hearing aids and routine eyeglasses—

would pay for them out of pocket. However, the practice in both MA and Part D has been to allow plans to offer multiple benefit packages that can involve the payment of an additional premium. Requiring plan sponsors to bid on, and offer, a basic package would not preclude them from offering additional benefits that beneficiaries could purchase to enhance their insurance coverage.

An important difference exists between MA and Part D in how premiums for additional benefits are determined. If policymakers decide to use premium support, the Part D approach, in which the costs of induced demand (greater service use) are included in the premium for additional benefits, could be more appropriate in a premium support system. Table 3-2 illustrates the problem with the approach used in the MA program.

In Scenario 1, a plan's benefit package has a $40 copayment for physician visits; in Scenario 2, a plan's benefit package is the same as the first plan but has a $20 copayment for physician visits. If this difference prompted a beneficiary to have two visits rather than one (Scenario 3), the second plan would need additional revenue to pay for both the difference between the $40 and $20 copayments and the cost of the additional visit. A $200 office visit with a $40 copayment would entail a $160 cost to the plan, while two $200 visits with a $20 copayment would entail a cost of $180 per visit for the plan, or $360 in total. With the lower copayment, the plan's revenue would have to increase by $200 to cover its additional costs (the difference between Scenario 3's $360 and Scenario 1's cost of $160). The induced utilization accounts for most of the additional cost ($160 of the $200). The MA program allows plans to include the entire $360 cost of the physician services in their bid for the basic Part A and Part B benefit, in effect raising program costs for taxpayers and all beneficiaries, who pay higher Part B premiums because of the higher program costs. If MA rules did not permit induced utilization to be considered part of the basic benefit (as is the case in Part D), the additional cost of $160 from induced utilization would have to be financed through beneficiary premiums.[10]

This approach would be similar to the Commission's recommendation to impose an additional charge on supplemental coverage such as medigap in recognition of the higher Medicare program costs that occur when beneficiaries who pay little or no cost sharing use more services (see text box, p. 90) (Medicare Payment Advisory Commission 2012a).[11]

Currently in MA, supplemental benefits can take the form of reduced cost sharing for Part A and Part B benefits, additional benefits that Medicare does not cover, or a combination of the two. None of these supplemental benefits are standardized. Given the experience with medigap plans, policymakers may want to consider standardizing supplemental benefits in some fashion in a premium support system (although the need for standardization would be somewhat lessened if all plans were required to offer a standard Part A and Part B benefit package). For example, the coverage of hearing aids by MA plans varies widely. A total of 2,400 MA plans covered hearing aids in 2016, but among those plans there were 123 unique variations of hearing aid coverage—by in-network or out-of-network providers; by type of hearing aid; by type of cost sharing (copayments or coinsurance); and, most commonly, by a dollar limit on the amount of coverage. However, in considering whether and how to standardize additional benefits, policymakers would need to weigh the benefits of making it easier for beneficiaries to understand their coverage options against the benefits of allowing plans to have innovative benefit designs and provide a greater range of coverage options.

Other issues related to standardization

Several issues related to standardization deserve mention: program features that would not be standardized under premium support, the importance of giving beneficiaries adequate decision support tools, the potential need for other reforms in the medigap market, and the possible need to limit the number of available managed care plans.

Under premium support, not all features would need to be standardized

We have emphasized the importance, for premium support, of standardizing the benefit package and standardizing risk for bidding purposes. It is equally important to be clear about the flexibility plans would have under this approach with respect to cost sharing and plan offerings. For cost sharing, an actuarial value standard—rather than an item-by-item set of cost-sharing parameters—gives plans latitude in designing their cost-sharing structures and facilitates their ability to develop value-based insurance designs or use different levels of cost sharing to encourage the use of preferred providers. Nevertheless, an actuarial value standard means that variation would continue to exist among plans, and beneficiaries would have to be able to understand and evaluate those differences. Requiring insurers to offer a plan that covers only the standard package of FFS benefits would help beneficiaries in their

decision making, but there could still be a wide range of varying cost-sharing structures.

Decision support tools for beneficiaries

To facilitate beneficiaries' evaluation of plans' various cost-sharing structures in a premium support system, beneficiaries would need access to decision support tools. The Health Plan Finder tool of the Medicare.gov website has a number of features to assist beneficiaries in understanding differences among plans. One such feature is the out-of-pocket cost calculator that determines how much these costs are for beneficiaries with different levels of health (poor, fair, and excellent) and/or three different diseases (diabetes, congestive heart failure, heart attack), based on a plan's premiums and cost-sharing structure. Such a tool would continue to be necessary in a premium support system that uses an actuarial value standard instead of specific, service-by-service cost-sharing parameters. In past work, we noted that the manner in which premiums are displayed through the Health Plan Finder could be more transparent so that beneficiaries can see all premiums displayed—the Part B premium and plan premiums for Part C and Part D (Medicare Payment Advisory Commission 2015b).

A plan's provider network is important to beneficiaries. Although CMS has undertaken efforts to make it easier for beneficiaries to know which providers are in a plan's network, more work is needed to convey accurate information on provider participation and whether providers are accepting new patients. In this regard, the tools available to facilitate choice in MA and Part D (such as Medicare Plan Finder) could be improved. The Commission has also recommended additional funding for the State Health Insurance Assistance Programs (SHIPs) that provide one-on-one counseling to Medicare beneficiaries (Medicare Payment Advisory Commission 2008a).

Possible reforms in the medigap market

Currently, an MA plan may change its provider network from year to year, which can result in enrollees losing the ability to see the providers they typically use. While beneficiaries can freely move among MA plans during the annual election period, MA enrollees who are interested in switching to the FFS program (and buying medigap coverage to go with it) may not be able to find an affordable medigap policy because there is a limited one-time open enrollment period for most beneficiaries to buy medigap coverage. This feature restricts beneficiaries' freedom of movement between FFS and MA and makes the playing field between the two sectors uneven. However, making it easier to obtain medigap coverage could result in greater service use and result in higher program costs, particularly if no additional charge were imposed on supplemental premiums or the additional charge did not fully offset the additional program costs. Allowing beneficiaries to move from managed care plans to the FFS program and obtain medigap coverage without allowing medigap insurers to underwrite prospective new subscribers would also likely raise medigap premiums, particularly if the beneficiaries switching to FFS were high-need, high-cost beneficiaries.

Limiting the number of plans that are offered

In both MA and Part D, CMS will not approve an insurer's plans in a given market unless there are "meaningful differences" between them. Insurers that wish to offer multiple plans in a service area "must guarantee the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs" (Centers for Medicare & Medicaid Services 2017). In MA, plans do not meet this requirement if the difference between plans in their expected out-of-pocket costs is less than $20 per member per month. Such a policy would be consistent with the design of a premium support system. For example, when the Congressional Budget Office (CBO) examined premium support, it outlined an illustrative option that had a high degree of standardization of benefits and cost sharing. CBO suggested that companies be limited to offering a maximum of four plans in a market: up to two basic plans that cover the basic Part A and Part B benefits (but which could differ based on their provider networks, for example), and one "package of enhanced benefits (with a single fixed higher actuarial value that would be the same for all insurers) to go along with each basic package offered. Enrollees would pay the full additional cost of the enhanced packages through higher premiums. Under such rules regarding packages with enhanced benefits, beneficiaries would find it easier to compare plans, and thus competition would be heightened" (Congressional Budget Office 2013).

Policymakers could also consider limiting the number of plans by disqualifying plans that submit especially high bids. This option would improve competition by giving plans an added incentive to submit the lowest possible bids. However, such an approach may not be feasible in markets where the number of companies offering Medicare plans is limited. In addition, plans could respond by submitting

TABLE 3-3 **Summary rationale for standardizing some features of a premium support system**

Program feature	Rationale for using standardization
1. Covered items and services are standardized.	Standardization of these items facilitates beneficiary decision making, with clear price signals about relative premium costs and delineation of what is covered. It ensures a level playing field among bidding plans, one of which (the fee-for-service program) is standardized in each market area. Plans can neither offer lower bids by reducing benefits or increasing cost sharing nor offer a higher bid because of reduced cost sharing or enhancement of benefits.
2. Cost sharing is standardized.	Standardized cost sharing also ensures a level playing field for bidding purposes. A standard plan can have actuarially equivalent cost sharing, as is the case under current rules for Medicare Advantage and Part D. Such a policy maintains the comparability of bids but gives plans flexibility in designing cost-sharing rules that can promote more effective care. For beneficiaries, standardized cost sharing will mean that all standard plans will have the same level of cost sharing, on an actuarial basis.
3. Enrollee risk for bidding and payment purposes is standardized.	Standardization of this feature ensures a level playing field among plans by identifying the most efficient plans. Setting premiums based on the cost for a beneficiary of average health will provide the right price signal for beneficiaries by identifying which plans are the most efficient. (Some redistribution of funds across plans may be necessary.)
4. All plans bid on, and offer, a standard package.	The use of a standard bid would make it easier to determine the government contribution and would simplify program administration. Requiring plans to offer a standard package would enhance beneficiary choice by offering a private plan that is directly comparable with the fee-for-service program.
5. (a) Enhanced benefit packages are permitted, but (b) beneficiaries bear the full cost of induced utilization beyond the utilization level of basic coverage.	The first element continues current Medicare Advantage policy, but the second element is patterned after Part D, where induced utilization is not financed by the government. The second element is also consistent with the Commission's recommendation to impose an additional charge on fee-for-service beneficiaries who have supplemental coverage.
6. Number of plans that an insurer can offer is limited.	The Medicare Advantage program limits the number of plan offerings by requiring them to have meaningful differences. Such a policy helps beneficiaries understand differences among plans, but plans should also have flexibility in designing innovative benefit packages.

bids that were too low initially with an intent to gain market share that could be retained in future years with higher bids. Moreover, if plans were disqualified for high bids in a given market, the plans could be unavailable to bid in that market in future years, which could reduce the overall level of competition in the long run.

Summary of the rationale for standardizing some features of a premium support system

Table 3-3 lists the same features of a premium support system that we used in Table 3-1 (p. 87) and summarizes the rationale for using standardization.

Determining benchmarks and beneficiary premiums

A key issue in developing a premium support system in Medicare is the method for determining the government's contribution toward each beneficiary's coverage. Under premium support, the government would first establish a benchmark that would serve as a reference point for the cost of providing the standard Medicare benefit package. This benchmark would consist of two components: the Medicare contribution and a base beneficiary premium. The Medicare contribution would remain the same,

regardless of whether beneficiaries received their Medicare benefits through the FFS program or a managed care plan.[12] In contrast, the premiums paid by beneficiaries would vary across plans and would equal the base beneficiary premium plus any difference between the benchmark and the plan's cost of providing the Medicare benefit package.

In a premium support environment, there are arguments for using competitive bidding to determine the benchmark. Under this approach, the FFS program and managed care plans would each submit bids that indicate the revenue needed to provide the Medicare benefit package, and bidding would be conducted using geographic areas that reflect local health care markets. The government could determine the benchmark in a variety of ways. We believe that two methods for determining the benchmark could have merit: (1) comparing the FFS bid with a representative measure of the bids from among the area's managed care plans and using the lower of the two as the benchmark or (2) using the enrollment-weighted average of all plan bids. Under either method, using local health care markets as bidding areas would result in benchmarks that vary across areas because of the regional variation in health care service use and spending.

Once an area's benchmark had been established, the base beneficiary premium could be a standard dollar amount that is determined nationally and is the same in every area, like the current Part B premium. Under an alternate approach, the base beneficiary premium could equal a standard percentage of the benchmark, which would result in base beneficiary premiums that vary from area to area. Under either approach, the beneficiary premium for any given plan could be higher or lower than the base beneficiary premium, depending on how the plan's bid compared with the benchmark. Regardless of how the base beneficiary premium is set, the Medicare contribution under this approach (like the benchmarks) would also vary from area to area, but would be the same for every plan within a given area.

Establishing the benchmark

Medicare could set the benchmark by using competitive bidding or some form of administered pricing. With competitive bidding, the government would collect bids from managed care plans—and prepare an FFS bid—and use those bids to determine the benchmark. Medicare follows this approach in the Part D program, where stand-alone prescription drug plans and MA plans that have drug coverage (there is no FFS program in Part D) submit bids that indicate the cost of providing drug coverage. CMS uses the bids to calculate the national average bid and uses that average to determine the base beneficiary premium and the Medicare contribution. With administered pricing, Medicare would set the benchmark using a formula that relies on certain historical data, such as FFS spending. Medicare uses this approach in the MA program, where CMS determines beneficiary premiums and plan payment rates by comparing plan bids with benchmarks that are based on historical FFS spending projected forward.

There are arguments to support using competitive bidding to establish the benchmark under a premium support system. Since the primary benefit of a premium support system would be to give beneficiaries an incentive to consider the difference in the cost of the FFS program and managed care plans, collecting accurate information about the relative "price" of the Medicare benefit package in the two sectors (i.e., FFS vs. managed care) would be essential. Under competitive bidding, the price of the benefit package would become evident through plan bids. Since we assume the bidding would be conducted annually, as in the MA program, the information provided by the bids would be updated regularly to account for changes in service use.

Policymakers would also need to decide whether the bidding process should be conducted nationally or using smaller geographic areas. The MA program uses geographic areas that are composed of individual counties or one or more states, while the Part D program conducts some bidding at the national level and some bidding using regions composed of one or more states.[13] The Commission has previously recommended that the MA program switch from its county-level system to a set of larger areas that better reflect local health care markets (Medicare Payment Advisory Commission 2005). Under this approach, urban counties would be grouped into a market area if they were located in the same state and the same core-based statistical area; rural counties would be grouped into a market area if they were located in the same state and the same health service area as defined by the National Center for Health Statistics (Medicare Payment Advisory Commission 2016b). This method would produce 1,231 market areas in the 50 states and the District of Columbia. These geographic areas could also work in a premium support system.

Once the bidding areas were defined, health care insurers would decide which areas they would serve and would submit a bid for each plan offered in a particular area.

TABLE 3–4 **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 (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 to make it comparable with MA plan bids. For comparison, FFS spending has been 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 and MA enrollees included 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 is due to enrollment in MA plans that we excluded from our analysis, such as employer group plans and special needs plans.

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

As part of the bidding process, plans would be required to serve the entire area and accept all beneficiaries who wished to enroll.[14] Each bid would indicate the monthly amount of revenue that plan required to provide the standard package of Medicare benefits and would include the plan's administrative costs and any profits. Since the FFS program would be treated as a competing plan under a premium support system, CMS would also prepare a "bid" for each area's FFS enrollees.

The experience of the MA program suggests that the number of managed care plans would vary considerably across areas (Table 3-4). We used MA plan bids for 2016 and the market areas defined above to determine how many MA plans are currently available in each area. We counted only MA plans that met three criteria: (1) the plan was available to at least half of the area's beneficiaries (making it more likely that the plan would be willing to serve the entire area under premium support); (2) the plan was open to all beneficiaries (which excluded special needs plans and employer-sponsored plans that, by definition, are available only to certain beneficiary groups); and (3) the plan had at least 100 enrollees. Under these criteria, more than 90 percent of beneficiaries had at least 3 eligible MA plans available in their areas, and more than 25 percent had more than 20 MA plans available. The areas with many plans tended to have higher FFS spending, on average, than the areas with fewer plans. These figures should be viewed only as an approximation; a premium support system would differ from the MA program in numerous respects, and an area's number of available plans could be higher or lower than it is now.

The bids from managed care plans and the FFS program could vary for two reasons—differences in the underlying efficiency of each plan (i.e., its ability to deliver the standard package of benefits at a lower cost) and differences in the health of the beneficiaries enrolled in each plan. Greater efficiency and healthier enrollees would each tend to lower a plan's bid; lower efficiency and sicker enrollees would each tend to increase a plan's bid. Consistent with the goal of giving beneficiaries an incentive to enroll in more efficient plans, any differences among an area's plans in beneficiary premiums would need to be based only on differences in the underlying efficiency of the plans. CMS would thus need to standardize all bids so that they represented the cost of serving a beneficiary of average health status, which would eliminate any variation in plans' bids that reflected differences in the health status of their respective enrollees. CMS makes similar adjustments to plan bids in MA and Part D using a combination of demographic and diagnostic information.

Once the bids were standardized, the government would establish each area's benchmark. The method used to establish the benchmark would be very important because

the benchmark is the basis for determining both the Medicare contribution and the base beneficiary premium. Relatively speaking, a method that produced higher benchmarks would result in higher Medicare contributions and higher overall Medicare spending than a method that produced lower benchmarks. Higher benchmarks would also mean lower beneficiary premiums: Because the Medicare contribution would be higher, the difference between a plan's bid and the Medicare contribution (i.e., the beneficiary premium) would be smaller than it would be using lower benchmarks.

There may be arguments for establishing the benchmark using one of two methods. The first method would compare the FFS bid with a representative measure of the bids from managed care plans and use the lower of the two as the benchmark. We used this method to develop many of this chapter's illustrative examples, with the median bid serving as the representative measure of plan bids. The second method would set the benchmark equal to the enrollment-weighted average of all bids (both FFS and managed care plans). The latter approach would be similar to the method that Part D uses to calculate its benchmark, although that program does not have an FFS component.

Both methods are appealing because they would produce benchmarks that fall somewhere in the middle of the distribution of bids. In particular, they would avoid setting the benchmark equal to one of the lower bids.[15] Although policymakers could set the benchmark equal to one of the lower bids (this method would save the government more money), such an approach could have some undesirable effects. First, the resulting benchmarks would be less generous, which means that beneficiary premiums would be correspondingly higher and more extensive measures might be needed to mitigate undesirable consequences for beneficiaries. Second, the lower bids might be unrealistically low (for example, if the plans submitting them are entering new market areas and bid low in an effort to gain enrollment), which could result in larger changes in premiums (up or down) from year to year.

Policymakers would need to consider several factors in deciding whether to use the lower-of method or the weighted-average method. First, the lower-of method would result in lower benchmarks in most market areas and thus generate more program savings. In our earlier work on premium support, we compared MA plan bids with FFS costs using the urban and rural market areas previously described, and we found that while MA plans were the lower cost option in many areas, the FFS program was the lower cost option in other areas (Medicare Payment Advisory Commission 2015a). Consistent with this finding, the lower-of method would base the benchmark on the lower cost delivery system in each area. Under this approach, benchmarks would always be equal to or lower than the FFS bid but could never be higher. In contrast, the weighted-average approach would use all bids to calculate the benchmark (not just the bids from the lower cost delivery system), resulting in higher benchmarks that could conceivably exceed the FFS bid in some areas.

Another factor to consider would be a market area's overall level of managed care penetration. Under the lower-of approach, an area's benchmark could be based on a plan's bid even if the penetration rate was very low (for example, 5 percent). This approach would result in higher premiums for FFS enrollees and give them an incentive to switch to a managed care plan, but it could also raise concerns about the plan's capacity to handle a substantial increase in enrollment. By comparison, under the weighted-average method, the benchmark for an area with 5 percent penetration would also be lower than the FFS bid, but the difference between the benchmark and the FFS bid would be relatively small because almost all of the area's beneficiaries (95 percent) would be enrolled in FFS. To address this concern, the use of competitive bidding between the FFS program and managed care plans could be limited to markets with a minimum level of managed care penetration.

Under the lower-of method, policymakers would also need to decide what to use as a "representative measure" of the bids from an area's managed care plans. Policymakers would have a number of options, such as the lowest bid, median bid, or average bid. Using the lowest bid instead of a higher figure, such as the median or average bid, would make it more likely that benchmarks would be based on managed care plan bids rather than the FFS bid. To demonstrate this point, we compared the MA plan bids that we analyzed in Table 3-4 (p. 97) with each area's FFS costs, which we used as a proxy for an FFS bid (Table 3-5). We compared FFS costs with the lowest MA bid in each area and found that FFS costs were lower in 473 of the 1,231 areas (38 percent), although the areas where FFS costs were lower had a relatively small number of Medicare beneficiaries (6.1 million, or 11 percent of the total). However, the use of the lowest bid could have some undesirable effects, as discussed earlier. Compared with either the median or average MA bid, FFS costs

TABLE 3–5

Comparison of local FFS costs and MA plan bids, 2016

	Number of areas where:		Millions of beneficiaries living in areas where:	
	FFS is lower	MA is lower	FFS is lower	MA is lower
Compare local FFS costs to ***lowest*** MA bid in area	473	758	6.1	48.4
Share of total	38%	62%	11%	89%
Compare local FFS costs to ***median*** MA bid in area	739	492	18.0	36.5
Share of total	60%	40%	33%	67%
Compare local FFS costs to ***average*** MA bid in area	722	509	18.0	36.5
Share of total	59%	41%	33%	67%

Note: FFS (fee-for-service), MA (Medicare Advantage). For this analysis, we excluded hospice, direct graduate medical education, and indirect medical education payments from FFS costs to make them comparable with MA plan bids. FFS costs and MA plan bids have both been standardized for a beneficiary of average health status. Areas consist of core-based statistical areas and health service areas in the 50 states and the District of Columbia. Number of Medicare beneficiaries are as of January 2016. Some areas did not have any eligible MA plan bids in our analysis because either (1) no MA plans were available in those areas or (2) we excluded all of the available MA plans based on the criteria we used for our analysis. The areas without any eligible MA plan bids are included in the "FFS is lower" columns.

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

were lower in about 60 percent of all areas, and those areas accounted for about 33 percent of beneficiaries.[16] Under any of these scenarios, a substantial majority of beneficiaries—two-thirds or more—would live in areas where benchmarks under a premium support system would likely be based on the bids submitted by managed care plans.

Under either method, policymakers would need to decide whether all plan bids would be used in the benchmark calculation. The MA and Part D programs do not restrict the number of entities that can sponsor plans as long as each entity meets the program's requirements to participate, but there are some limits on the number of plans that an individual sponsor can offer. Furthermore, Part D uses all plan bids to calculate its national average bid. Under premium support, CMS could follow similar policies or use a two-step process in which the agency would first disqualify some higher bidding plans from participating in a market area and then calculate benchmarks using the remaining bids. This two-step process could encourage plans to submit lower bids, given the size and importance of the Medicare market. However, it could also cause greater disruption for beneficiaries (who would need to find new coverage if they were in a plan that became ineligible to participate in Medicare) and might reduce the number of competing plans if sponsors that lose access to a market have difficulty maintaining or re-establishing their presence in the market for later rounds of bidding.

Establishing the base beneficiary premium and the Medicare contribution

Once the area benchmarks had been determined, their constituent pieces—the base beneficiary premium and the Medicare contribution—could be calculated. This calculation can be done in one of two ways: establish the base beneficiary premium first and let the remainder be the Medicare contribution or establish the Medicare contribution first and let the remainder be the base beneficiary premium.

The base beneficiary premium, if established first, could equal either a standard dollar amount or a standard percentage of the benchmark. For the standard dollar amount method, CMS would calculate a standard premium that would be the same for all areas. For example, the standard premium could equal 25 percent of the national average per beneficiary cost of Part B benefits to maintain some similarity between the base beneficiary premium and

the current Part B premium. Given the expected variation in benchmarks across areas, the use of a standard dollar amount means that the base beneficiary premium would equal a higher percentage of the benchmark in some areas compared with others. For example, if the benchmark were $900 in one area and $1,000 in another area, a standard premium of $125 per month would equal 13.9 percent of the benchmark in the first area and 12.5 percent of the benchmark in the second area.

If a standard percentage of the benchmark were used to calculate each area's base beneficiary premium, areas with low benchmarks would have lower base premiums than those with higher benchmarks. For example, the base beneficiary premium could equal 13.5 percent of the benchmark (since Part B premiums currently equal about 13.5 percent of total Part A and Part B spending). Under our contrasting hypothetical areas, this approach would produce a base beneficiary premium of $121.50 in the first area compared with $135 in the second area.

Once the base beneficiary premium had been set, each area's Medicare contribution would be the difference between the benchmark and the base beneficiary premium. Using bidding areas that reflect local health care markets would necessarily result in benchmarks that vary across areas, as would the Medicare contribution, regardless of whether the base beneficiary premium was set at a standard dollar amount or a standard percentage. In our hypothetical example, if the base beneficiary premium in both areas were set at $125, the Medicare contribution would be $775 in the first area and $875 in the second area. If the base beneficiary premium were set at 13.5 percent of the benchmark, the Medicare contribution would be $778.50 in the first area and $865 in the second area.

If the Medicare contribution is established first, the same methods—the use of either a standard dollar amount or a standard percentage of the benchmark—could be used to make the calculation. Medicare's contribution and the distributional implications for different areas would be similar to those in the examples given for the base beneficiary premium.

In the debate over premium support, one issue is how the base beneficiary premium and Medicare contribution would grow over time compared with the benchmark. Under the Part D program, the base beneficiary premium and Medicare contribution are set at 25.5 percent and 74.5 percent of the national average bid, respectively, which means that they both grow at the same rate as the national average bid. In contrast, some premium support proposals would seek to reduce the growth in federal Medicare spending by limiting the annual growth of the Medicare contribution. This limit would usually not apply until sometime after the first year of premium support, with the initial values of the benchmarks based on historical spending or determined by a bidding process. The limit itself would typically be linked to the U.S. economy's growth rate, which historically has grown more slowly than health care spending or Medicare spending. As a result, if the benchmark grew more rapidly than this limit, growth in the Medicare contribution would be capped at a lower rate. The share of the benchmark that is financed by the Medicare contribution would thus decline over time in this scenario, and the difference would be made up by higher base beneficiary premiums.

This situation would be problematic because beneficiaries would bear the risk of paying higher premiums without being able to take actions that would lower premiums in a meaningful way (since the added growth in the base beneficiary premium would be a function of broader forces like the overall growth in Medicare spending and the growth in the national economy). An alternative approach would be to have the benchmark, Medicare contribution, and base beneficiary premium all grow in tandem with plan bids, as they do now in the Part D program, and see whether competition among managed care plans (driven by beneficiaries' interest in lower cost plans) could achieve sufficient savings.

Illustrative examples of the bidding process

The bidding process under a premium support system would be fairly complex, and two illustrative examples help demonstrate how the process would work (Table 3-6). In these examples, an area has a total of six bids—the FFS bid and five managed care plan bids. Each bid shows the cost of providing a standard package of benefits to a beneficiary of average health. The bids from the managed care plans are sorted from low (Plan A, with a monthly bid of $680) to high (Plan E, with a bid of $800). In these examples, we assume that the benchmark would be set at the lower of the FFS bid or the median managed care plan bid and that the standard base beneficiary premium would be $125 in every area. (Different assumptions could be made, depending on policy choices.)

In Table 3-6, Example 1 shows how premiums would be determined in an area where the FFS bid is $700, a relatively low amount. In this instance, CMS would compare the FFS bid with the median managed care plan

TABLE 3–6

Illustrative examples of how the benchmark, base beneficiary premium, and Medicare contribution could be determined under premium support

		Managed care plans				
	FFS program	Plan A	Plan B	Plan C (median plan bid)	Plan D	Plan E
Example 1: Benchmark equals the FFS bid						
Plan bid	$700	$680	$710	$740	$770	$800
Beneficiary premium						
Base beneficiary premium	$125	$125	$125	$125	$125	$125
Difference between plan bid and benchmark	$0	–$20	$10	$40	$70	$100
Total premium	$125	$105	$135	$165	$195	$225
Medicare contribution	$575	$575	$575	$575	$575	$575
Example 2: Benchmark equals the median of the managed care plan bids (Plan C)						
Plan bid	$800	$680	$710	$740	$770	$800
Beneficiary premium						
Base beneficiary premium	$125	$125	$125	$125	$125	$125
Difference between plan bid and benchmark	$60	–$60	–$30	$0	$30	$60
Total premium	$185	$65	$95	$125	$155	$185
Medicare contribution	$615	$615	$615	$615	$615	$615

Note: FFS (fee-for-service). These examples express all plan bids as per beneficiary per month amounts for a beneficiary of average health status. In these examples, the benchmark would equal the lower of the FFS bid or the median bid from the managed care plans, and there would be a standard base beneficiary premium of $125 in all bidding areas. The exact methods used to determine the benchmark and the base beneficiary premium are both policy choices.

bid—Plan C's bid of $740. Since the FFS bid is lower than the median plan bid, the area's benchmark would be set at $700. The area's base beneficiary premium would be the standard dollar amount of $125. The premiums for each plan in the area would equal the base beneficiary premium plus the difference between the plan's bid and the benchmark. Since the FFS bid is the benchmark, the premium for FFS coverage in this area would equal the base beneficiary premium of $125. The bid for Plan A would be $20 lower than the benchmark ($680 versus $700), so the premium for Plan A would also be $20 lower than the base beneficiary premium ($105 instead of $125). The bids for Plans B through E are higher than the benchmark, resulting in premiums that are higher than the base beneficiary premium, ranging from $135 to $225 per month. The Medicare contribution for all plans would be the difference between the benchmark and the base beneficiary premium, or $575, with any payments for beneficiaries who enroll in managed care plans adjusted to account for differences in health status.

Example 2 shows how premiums would be determined in an area where the managed care plan bids are the same as in the first example, but the FFS bid is $800 per month instead of $700. Since the FFS bid is higher than the median plan bid ($740 from Plan C), the area's benchmark would be $740. The area's base beneficiary premium in the area would be the standard dollar amount of $125, and the Medicare contribution would be $615 (the difference

between the benchmark of $740 and the base beneficiary premium of $125). The bids from Plan A and Plan B are lower than the benchmark, so their premiums would be lower than the base beneficiary premium. The bid for Plan C equals the benchmark, so its premium would equal the base beneficiary premium of $125. The bids for the FFS program, Plan D, and Plan E are higher than the benchmark, so their premiums would be higher than the base beneficiary premium.

Year-to-year changes in benchmarks and premiums

If benchmarks were determined through competitive bidding, some degree of volatility in benchmarks and beneficiary premiums would be expected because plan bids would inevitably change over time. The impact that changes in individual plan bids would have on benchmarks and beneficiary premiums would depend partly on the method used to determine benchmarks.

The simplified example in Table 3-7 illustrates the interplay between changes in plan bids and the method used to determine benchmarks. The table shows plan bids, benchmarks, and beneficiary premiums over a two-year period, using one of the illustrative markets that appears in Table 3-6 (p. 101) and similarly assuming that beneficiaries would pay a base premium of $125 plus the difference between the plan's bid and the benchmark. For simplicity, we assume that all plans submit the same bid in years 1 and 2, except for Plan C, which lowers its bid by $30 (from $740 to $710). A change of that magnitude is well within the range of annual changes seen in MA plan bids.

The table shows the outcome for a benchmark that equals the lower of the FFS bid or the median plan bid. In this market, FFS spending is relatively high, and the benchmark is based on the median plan bid (Plan C in both years). The change in Plan C's bid lowers the benchmark from $740 in year 1 to $710 in year 2. Because of the lower benchmark, premiums for the market's other plans increase by $30. The premium for Plan C does not change; that plan sets the benchmark in both years, so its premium remains the base amount of $125. In this scenario, the government reaps the benefits of the lower bid, which reduces the government contribution by $30.

The table also shows the outcome for a benchmark that equals the enrollment-weighted average of all bids. We assume that half of the beneficiaries in this market are in the FFS program and the rest are divided equally among the five managed care plans. Here the change in Plan C's bid lowers the benchmark from $770 in year 1 to $767 in year 2. The $3 decrease is much smaller than the $30 decrease under the lower-of method because Plan C represents only 10 percent of total enrollment. The lower benchmark means that premiums for the market's other plans increase by $3. In contrast, the premium for Plan C decreases by $27—the net effect of the $30 decrease in the plan's bid and the $3 decrease in the benchmark. In this scenario, the government benefits less from the lower bid, and more of the gains go to Plan C's enrollees in the form of lower premiums. The table's examples show that a weighted-average method would likely produce more stable benchmarks and beneficiary premiums than a lower-of method, but at the expense of higher program spending.

Premium support and regional variation in Medicare spending

It is well known that Medicare spending varies significantly across the country. For example, in 2014, FFS spending per beneficiary on Part A and Part B benefits ranged from an average of $14,930 in Miami to $6,670 in Grand Junction, CO (Centers for Medicare & Medicaid Services 2016b).[17] This variation stems from regional differences in payment rates, beneficiaries' health status, and service use. The Commission has found that differences in service use accounts for about half of the overall variation in spending (Medicare Payment Advisory Commission 2011b). Researchers do not agree about the underlying cause of the variation in service use; some attribute the variation primarily to differences in provider practice patterns, while others find that variation is largely driven by differences in beneficiaries' health status (Cassidy 2014). MA plan bids also tend to be higher in areas with high FFS spending, even after bids have been risk adjusted to account for differences in beneficiaries' health status. However, there is less regional variation in MA plan bids than in FFS spending (Medicare Payment Advisory Commission 2013a).

As a general proposition, a premium support system would likely reduce the regional variation in spending to some degree. Figure 3-2 (p. 104) shows how plan bids and FFS spending compare across the counties in the four spending quartiles that are currently used to calculate MA benchmarks. MA plan bids tend to be relatively close to FFS costs in areas with low FFS spending (the median bid in the lowest spending quartile equals 106 percent of FFS costs, on average). However, MA plan bids are often much lower than FFS costs in areas with high FFS

TABLE 3–7

Illustrative examples of how benchmarks and beneficiary premiums could vary over time under premium support

		Managed care plans				
	FFS program	Plan A	Plan B	Plan C (median plan bid)	Plan D	Plan E
Distribution of enrollment	50%	10%	10%	10%	10%	10%
Benchmark equals lower of FFS bid or median plan bid						
Year 1:						
Plan bids (benchmark = $740)	$800	$680	$710	$740	$770	$800
Beneficiary premiums	$185	$65	$95	$125	$155	$185
Year 2:						
Plan bids (benchmark = $710)	$800	$680	$710	$710	$770	$800
Beneficiary premiums	$215	$95	$125	$125	$185	$215
Change from year 1 to year 2:						
Plan bids	$0	$0	$0	–$30	$0	$0
Beneficiary premiums	$30	$30	$30	$0	$30	$30
Benchmark equals enrollment-weighted average of all bids						
Year 1:						
Plan bids (benchmark = $770)	$800	$680	$710	$740	$770	$800
Beneficiary premiums	$155	$35	$65	$95	$125	$155
Year 2:						
Plan bids (benchmark = $767)	$800	$680	$710	$710	$770	$800
Beneficiary premiums	$158	$38	$68	$68	$128	$158
Change from year 1 to year 2:						
Plan bids	$0	$0	$0	–$30	$0	$0
Beneficiary premiums	$3	$3	$3	–$27	$3	$3

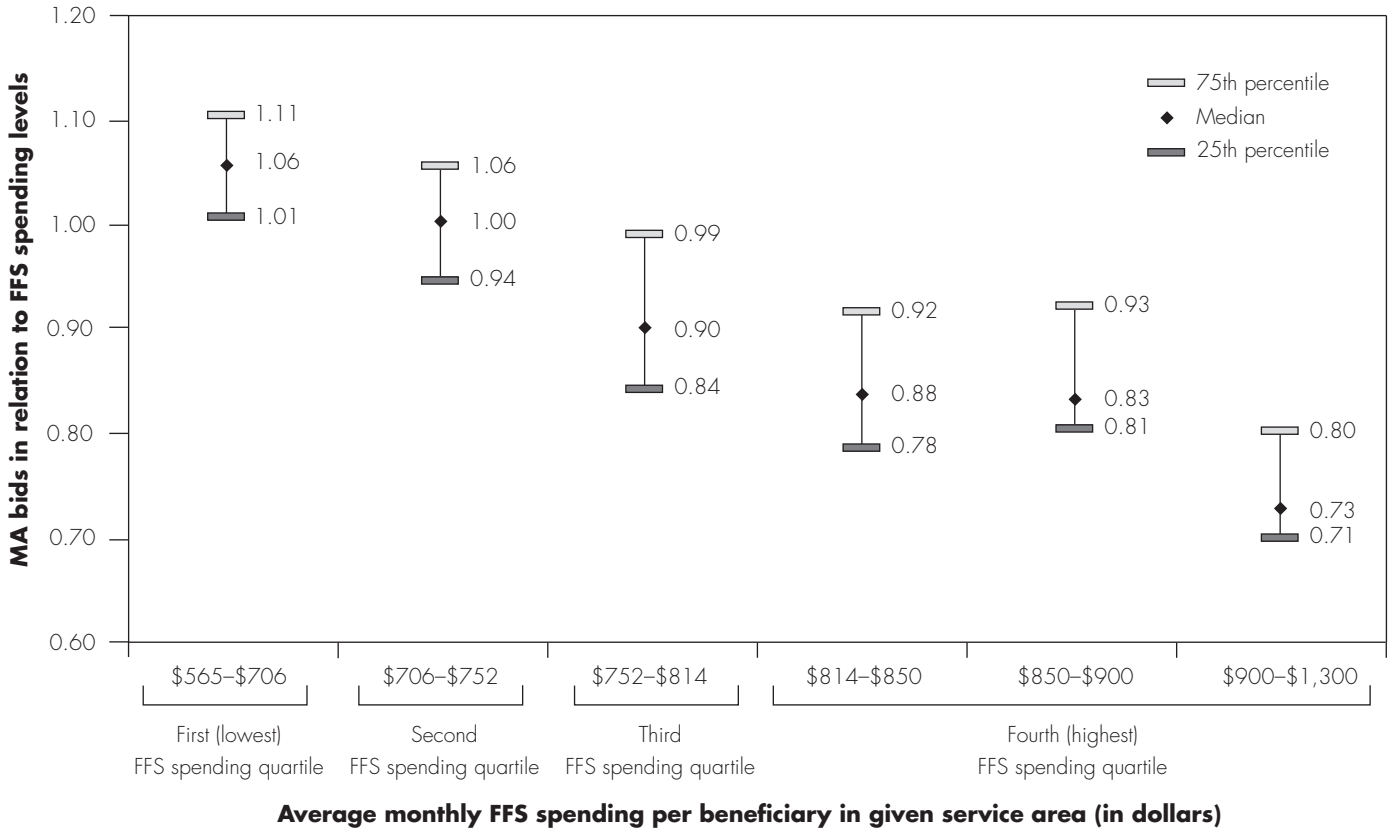
Note: FFS (fee-for-service). These examples express all plan bids as per beneficiary per month amounts for a beneficiary of average health status. In these examples, the benchmark would equal the lower of the FFS bid or the median bid from the managed care plans, and there would be a standard base beneficiary premium of $125 in all bidding areas. The exact methods used to determine the benchmark and the base beneficiary premium are both policy choices. These examples assume that the distribution of enrollment across plans would be the same in both years.

spending (the median bid in the highest spending quartile ranges from 73 percent to 88 percent of FFS costs). Under premium support, beneficiaries would face premiums that varied based on the relative cost of an area's FFS program and its managed care plans. The range in premiums would likely be smaller in areas with low FFS spending and larger in areas with high FFS spending. As a result, beneficiaries in high-spending areas would have a larger financial incentive to enroll in lower cost plans. Even so, a substantial degree of regional variation would likely remain, given the difficulty of addressing its underlying causes.

Given this regional variation in spending, in a premium support system, policymakers would need to decide how much of the additional spending in high-cost areas should be paid by the beneficiaries living in those areas and how much by the Medicare program and beneficiaries living

FIGURE 3–2

Medicare Advantage bids in relation to FFS spending levels, 2016



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

Source: Medicare Payment Advisory Commission 2016c.

in other areas. Under current law, Medicare premiums are set nationally and do not vary across areas (except for the supplemental premiums that some MA plans charge). When premiums are set nationally, the additional spending in high-cost areas is largely paid for by the government (in the form of higher Medicare payments) and by beneficiaries living in lower cost areas (who spend more on Part B premiums relative to the cost of their Medicare benefits than beneficiaries who live in high-cost areas).

Under premium support, the specific contours of the bidding process would play an important role in determining who bears the cost of the regional variation in spending. Two components of the bidding process would be especially important: the geographic regions used as bidding areas and the method used to set the base beneficiary premium. Larger bidding areas, such as the entire country or regions made up of one or more states, would be more likely to have a mix of high-cost and low-cost regions within a given area. The benchmarks in these larger areas would probably be based on some sort of overall average—much like the Part D program uses the national average bid as its benchmark—and would thus obscure the underlying variation in spending within each region. As a result, the Medicare contribution would be the same for an area's high-cost and low-cost regions. The cost of the additional spending in the high-cost regions would largely be borne by the beneficiaries who live there, in the form of higher premiums. In contrast, smaller bidding areas, such as areas that reflect local health care markets, would tend to be more uniform. Compared with larger bidding areas, spending would vary less within areas but more across areas. This distinction would result in benchmarks and Medicare contributions that would

be higher in high-cost areas and lower in low-cost areas, which means that the Medicare program would bear more of the cost of the additional spending in high-cost areas.

If the base beneficiary premium equaled a standard dollar amount, beneficiaries in high-cost areas would benefit because they would not pay a penalty (in the form of a higher base beneficiary premium) for living in a high-cost area. This benefit would be paid for by beneficiaries who live in low-cost areas, where the base beneficiary premium would equal a higher share of the benchmark than it would in high-cost areas. Conversely, if the base beneficiary premium equaled a standard share of the local benchmark, beneficiaries who lived in high-cost areas would bear more of the added costs because their base beneficiary premiums would be higher than those in low-cost areas.

One concern about using premium support is that beneficiaries would be penalized simply for living in a high-cost area. Beneficiaries in high-cost areas would, of course, have an incentive to enroll in their area's lower cost plans since the premiums for the FFS program and managed care plans would vary based on the differences in their overall cost. But even if those beneficiaries switched to lower cost plans, their overall costs would probably still be higher than in low-cost areas. Furthermore, there would be little that beneficiaries in high-cost areas could do to reduce the remaining additional costs, short of moving to a lower cost area. This concern could be addressed through a bidding process that has local bidding areas to set benchmarks and charges a standard base beneficiary premium based on a fixed dollar amount in all areas.

Incorporating quality into premium support

In a premium support system, beneficiaries should have the information they need to choose higher quality coverage options and could be rewarded for selecting higher quality coverage by paying lower premiums. Toward this end, CMS would need to measure and rate the quality of care for each area's FFS program and managed care plans.

There is currently no overall quality rating in FFS. In MA, plans receive quality bonuses (in the form of higher benchmarks) based on quality measure results that have been converted to a star rating. The star rating provides a relative ranking of overall quality for each plan, predominantly based on three types of clinical quality or patient experience measures: the Health Effectiveness Data Information Set® (HEDIS®), the Consumer Assessment of Healthcare Providers and Systems® (CAHPS®), and the Health Outcomes Survey (HOS).[18,19] The Commission has previously questioned whether HEDIS and HOS measures can provide a valid comparison across FFS and MA (Medicare Payment Advisory Commission 2010).

In previous reports to the Congress, the Commission outlined an alternative to Medicare's current system for measuring the quality of care. It contends that Medicare's current quality measurement programs, particularly in FFS Medicare, have a fundamental problem: They rely primarily on clinical measures of process (as opposed to clinical outcomes) to assess the quality of care provided by hospitals, physicians, and other providers. Tying a portion of a provider's payment to performance on specified clinical processes can exacerbate incentives in FFS to overprovide services. Such measures can also contribute to uncoordinated and fragmented care, while burdening providers and CMS with the costs of gathering, validating, analyzing, and reporting on measures that have little value to beneficiaries and policymakers (Medicare Payment Advisory Commission 2015a, Medicare Payment Advisory Commission 2014).

Under an alternative policy, Medicare would use a small set of population-based quality measures to compare the quality of care in a local area under each of Medicare's three payment models—FFS, MA, and accountable care organizations (ACOs). Population-based measures that are intuitively easy to understand and meaningful for beneficiaries could include rates of potentially preventable hospital admissions, emergency department visits, readmissions, and mortality, as well as information on patient experience and the use of low-value care. CMS would calculate measure results for FFS enrollees using claims and patient survey data and for MA enrollees using encounter data and patient survey data.[20] More population-based quality measures could be developed when additional data sources (such as lab values and electronic clinical quality data) became available.

Assuming that CMS can accurately measure a market area's FFS and plan quality (with appropriate risk adjustment), the Commission has considered two approaches to incorporate quality results in a premium support system: one approach that relies on minimum standards for managed care plans and public reporting of quality-measure information and a second approach that combines those efforts with financial rewards for high-

quality coverage. Elements of these approaches would require at least a year of information about quality and thus could not be incorporated until the second year of premium support at the earliest if policymakers want to provide quality information that reflects the care provided under premium support, not the prior Medicare program.

Minimum standards and public reporting

Under the first approach, CMS would require managed care plans to meet minimum standards to participate in Medicare and would calculate and publicly report quality measure results for the FFS program and each managed care plan in a market area. This approach resembles the way the Part D program works to ensure that beneficiaries have the information they need to choose higher quality coverage options. The MA program also has standards for participation and public reporting of quality results, but unlike Part D, it rewards plans financially for higher quality through the star bonus program.

Minimum standards for participation

CMS could require plans to meet initial and ongoing minimum standards for participation, and these standards could be based on current MA requirements. Under current MA rules, a health plan must be licensed as a risk-bearing entity in the state(s) in which it operates, and its license must be appropriate for the level of risk involved in administering an MA contract. The entity must also demonstrate to CMS that it has the capacity and readiness to function as a viable health plan. Before having a Medicare contract, an organization must have at least 5,000 enrollees (or 1,500 for a rural area) who are receiving health benefits through the organization, although this requirement is often waived. Before enrolling any beneficiaries, plans must demonstrate that they have an adequate network of contracted providers to ensure reasonable, timely access to the full range of Medicare-covered services for the plan's expected population. New MA plans are also required to have a quality assurance system and quality improvement operations that allow the plans to track and improve quality.

Once an MA plan has met CMS's standards for participation and signed a contract with CMS, the plan must continue to meet regulatory requirements for quality, including reporting encounter data and patient experience survey results, to remain in good standing. Plans must also maintain at least a three-star rating (based on clinical quality and patient performance measures). Plans that do not meet these requirements can be subject to civil monetary penalties and suspension of enrollment, payment, or both until they have corrected their deficiencies, and CMS can ultimately terminate their Medicare contracts when warranted.[21] Similar requirements would presumably continue in a premium support system.

Public reporting of quality-measure information

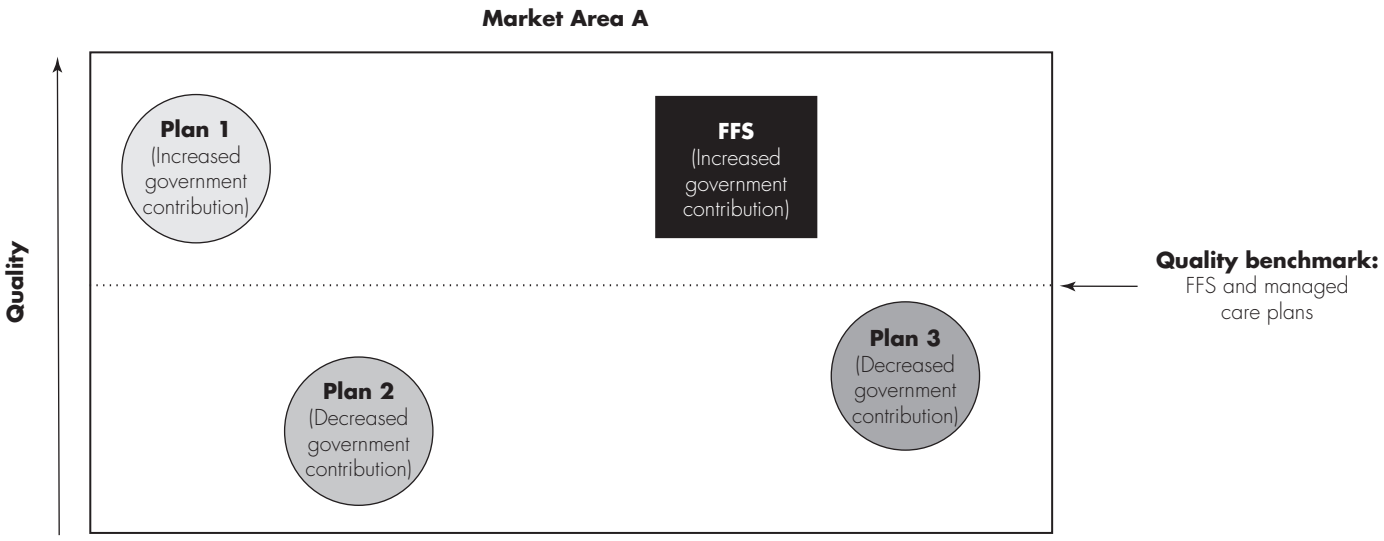
To select the best coverage option, beneficiaries would need accurate information on each option's cost, provider networks, quality, and other benefits presented through a comparison tool like the current Medicare Plan Finder website. CMS could calculate and publicly report quality results, such as the population-based outcome measures that the Commission has previously suggested (e.g., mortality, readmissions, potentially preventable emergency department visits, and patient experience) for each market area's FFS program and managed care plans. CMS could also enable more precise comparisons within a market area by reporting quality results for ACOs and the FFS program using smaller geographic units such as hospital referral areas.

CMS could also facilitate comparisons by calculating and reporting overall quality data for all of a market area's Medicare beneficiaries (both FFS and plan enrollees). The Commission's alternative quality model would use the FFS program as its benchmark, but combined market-level data might be more appropriate in a premium support system because the share of beneficiaries enrolled in FFS versus plans would probably vary significantly across markets and over time. Quality information would need to be relevant to consumers and presented in a way that is easy to understand—for example, by providing a summary overall rating (like an overall star rating) as is currently done on Medicare Plan Finder for MA and Part D plans. Detailed quality measure results would also need to be reported for beneficiaries interested in drilling down to plan and FFS measure-level results. Such detailed reporting could help plans, providers, and policymakers understand and improve the quality of care in a premium support system.

Financially rewarding higher quality

Under the second approach to incorporating quality in a premium support system, CMS would financially reward plans that provided higher quality care (in addition to meeting minimum standards for participation and publicly reporting quality-measure information). The plans in an area (which could include the FFS program) that had higher quality would receive a higher government

FIGURE 3–3 **Providing a higher government contribution to plans with higher quality**



Note: FFS (fee-for-service). Although Plan 3 has higher quality than Plan 2, both fall below the quality benchmark and receive a lower government contribution.

contribution that would be used to lower premiums and attract beneficiaries. CMS would determine which plans qualified for the higher contribution by comparing their performance with their market area's overall quality, using outcomes-based measures the Commission has recommended for the current Medicare program. This approach would be budget neutral in each market area. Once CMS reviewed the plan bids each year, it would take out a set percentage (e.g., 1 percent to 2 percent) of an area's projected FFS and MA spending and redistribute that to the higher quality coverage options in the market area. In the example in Figure 3-3, Plan 1 and the FFS program exceed the quality benchmark in Market Area A and would receive a bonus in the form of a higher government contribution, which would be used to lower the beneficiary's premium. Plans 2 and 3 have lower quality and would receive a lower government contribution and charge higher beneficiary premiums.

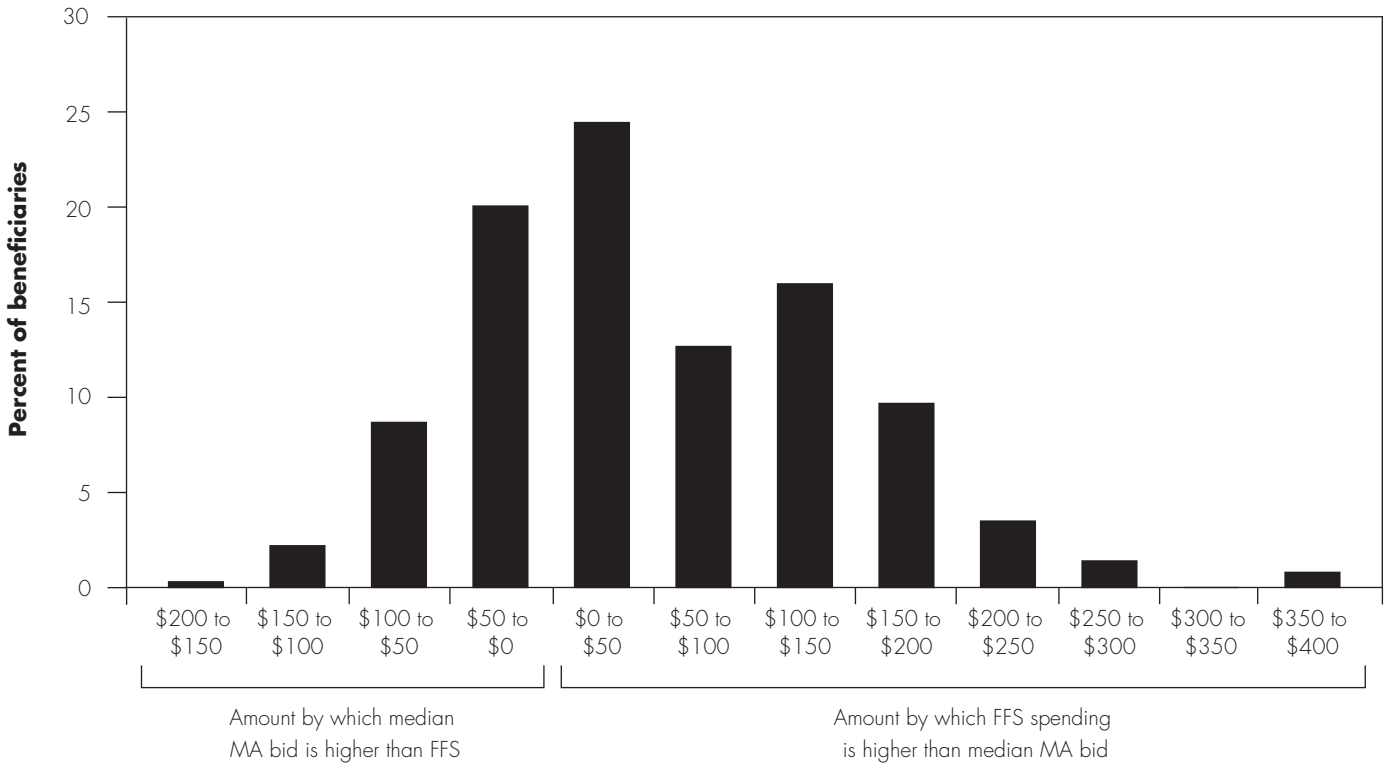
National budget neutrality for the quality reward program is assumed. However, the model would need to define a limit to the reward program that would be triggered if overall Medicare spending increased too rapidly. For example, the reward program could end if the average national managed care plan bid was above average FFS costs by a certain percentage. As with the minimum standards and public reporting of quality-measure information, the higher government contribution could not be implemented until the second year of premium support at the earliest since CMS would need quality information for the FFS program and managed care plans under the new system.

Mitigating the impact of higher beneficiary premiums

One of the biggest concerns about using premium support in Medicare is its potential impact on beneficiary premiums. Under premium support, any differences in the cost of providing the standard benefit package through the FFS program or managed care plans would be reflected in each plan's premium. Beneficiaries who are now enrolled in higher cost forms of coverage would see their premiums increase. They would either need to pay the higher premium or switch to a lower cost option. If the base beneficiary premium equaled a standard dollar amount that was determined nationally in a manner similar to the Part B premium, beneficiaries would always be able to avoid any increase in their premium by switching to a

FIGURE 3–4

Distribution of 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 month per beneficiary 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 in each area is as of January 2016. Out of 1,231 market areas in our data set, 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 Medicare enrollment data for January 2016.

plan whose bid was equal to or less than the benchmark in their area.

To illustrate how much premiums could change, we examined the impact of a premium support system in which each area's benchmark would equal the lower of the FFS bid or the median managed care plan bid (the same method shown in Table 3-6, p. 101). The base beneficiary premium would be set nationally at 25 percent of Part B spending per beneficiary, as is done currently for Medicare's Part B premium. For this analysis, we used MA plan bids and projected FFS spending for 2016 and the geographic areas that reflect local health care markets. Using these data, the base beneficiary premium would be $106 per month—that is, 25 percent of $424, the projected average Part B spending per beneficiary. This base beneficiary premium is lower than the 2016 Part B premium of $121.80 per month, but this difference is to be expected given the adjustments we made in calculating FFS spending in our data.[22] In this example, the coverage option that the base beneficiary premium pays for would vary across areas depending on how FFS spending compares with the median MA bid. In areas where FFS spending is lower than the median MA bid, the base beneficiary premium would pay for the FFS program; in areas where FFS spending is higher than the median MA bid, the base beneficiary premium would pay for the MA plan with the median bid. This analysis does not account for possible behavioral responses such as beneficiaries switching to lower cost plans or plans changing their participation or bidding behavior.

TABLE 3–8

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

	Medicare beneficiaries (in thousands)			Monthly premium under illustrative example		Change from current premium under illustrative example	
Market area	**Total**	**FFS**	**MA**	**FFS**	**MA**	**FFS**	**MA***
Rochester, NY	214	82	132	$106	$241	$0	$88
Honolulu, HI	168	87	81	106	210	0	90
Lancaster, PA	101	63	37	106	226	0	100
Erie, PA	55	30	25	106	207	0	100
Hawaii-Kauai, HI	52	33	19	106	287	0	93
Lebanon, PA	29	18	11	106	226	0	100
Braxton-Doddridge-Gilmer-Harrison-Lewis-Upshur, WV	32	22	9	106	245	0	94
Gratiot-Ionia-Mecosta, MI	27	19	9	106	211	0	46
Schuyler-Steuben, NY	26	17	8	106	219	0	91
La Crosse, WI	21	13	8	106	282	0	84

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 month per beneficiary 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. Number 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 this illustrative example account for supplemental MA premiums that beneficiaries now pay under current law.

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

This example is merely illustrative and differs from current law in several respects. MA plans now bid against benchmarks that are set administratively through statutory provisions specifying benchmark levels rather than through competitive bidding. Plans that bid below the benchmark receive a portion of the difference as a rebate that they can use to provide extra benefits. Under this example, the administratively set benchmarks would be eliminated, and the competition between FFS spending and MA plan bids would set the benchmark used to determine the Medicare contribution and beneficiary premium. The current system of rebates and extra benefits for MA plans would also be eliminated. This system 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 the Table 3-6 (p. 101) example, the difference between an area's average FFS spending and the median MA bid is a key variable in calculating beneficiary premiums. This difference is the additional monthly premium that beneficiaries would pay if they were to choose the higher cost option between FFS and the median-bid plan. Figure 3-4 summarizes the distribution of the differences between FFS and MA for all areas. About 45 percent of beneficiaries are in areas where the monthly difference is less than $50. About 3 percent of beneficiaries are in areas where the median MA bid is higher than FFS spending by $100 or more. In contrast, about 31 percent of beneficiaries are in areas where FFS spending is higher than the median MA bid by $100 or more. Even among areas where FFS is higher by a large amount, the Miami area is an outlier, with a difference of $358. In all other areas, the difference between FFS and MA is less than $300.

Markets that would see large changes in premiums

In contrast to the nationwide distribution of differences shown in Figure 3-4, Table 3-8 highlights the 10 largest

TABLE 3–9

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

	Medicare beneficiaries (in thousands)			Monthly premium under illustrative example		Change from current premium under illustrative example	
Market area	**Total**	**FFS**	**MA**	**FFS**	**MA**	**FFS**	**MA**
Chicago, IL	1,177	934	243	$253	$106	$147	$0
New York, NY	1,493	923	570	254	106	148	0
Los Angeles, CA	1,372	720	652	301	106	195	0
Northeastern New Jersey	700	581	119	247	106	141	0
Houston, TX	743	453	289	394	106	288	0
Nassau-Suffolk, NY	518	424	94	261	106	155	0
Baltimore, MD	454	410	43	243	106	137	0
Phoenix, AZ	672	392	280	265	106	159	0
Dallas, TX	535	369	166	290	106	184	0
Tampa-St. Petersburg, FL	602	307	295	322	106	216	0

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 month per beneficiary 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. Number 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 Medicare enrollment data for January 2016.

market areas (based on MA enrollment) in 2016 where the median MA plan bid exceeded average FFS spending by $100 or more under our static assumptions about beneficiary and plan bidding behavior. These are areas in which enrollees in the median-bid plan would have to pay a significantly higher premium to remain in their plan.

There are 51 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 spending under the current MA payment system. The 10 largest areas in this group, shown in Table 3-8 (p. 109), together account for about 75 percent of the group's MA enrollees. The group's largest single 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 3-8 (p. 109) also shows the estimated monthly premium that FFS and median-bid plan enrollees would pay in 2016 under our illustrative example. Since FFS spending in these areas is lower than the median MA bid, the base beneficiary premium (which is $106 in all areas in this example) would buy FFS coverage, and beneficiaries would have to pay an additional premium to enroll in the median-bid plan. For example, in the Rochester area, average FFS spending is $586 and the median MA bid is $721, or $135 higher (not shown in the table). The premium for the median-bid plan would thus be $135 higher than the base beneficiary premium of $106, for a total premium of $241. The median bid actually exceeds the current MA benchmark, so the beneficiaries enrolled in that plan now pay a supplemental premium of $47 (data not shown). As a result, the change in their premium, relative to current law, would be $135 minus $47, or $88. For the 10 largest areas, the additional premium would range from $46 to $100 per month.

At the other end of the distribution are 123 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 areas, and about 10.8 million are in the FFS program. These areas 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 3-9 shows the 10 largest areas in this group, based on FFS enrollment. These areas together account for about 50 percent of the group's FFS enrollees and include many of the nation's largest metropolitan areas. Each of the 10 areas has at least 300,000 FFS enrollees.

Table 3-9 also shows the estimated monthly premium that FFS enrollees and enrollees in the median-bid plan would pay in 2016. In these areas, the base beneficiary premium of $106 would buy coverage in the median-bid plan, and beneficiaries would have to pay an additional premium to enroll (or remain) in FFS. In the Chicago area, where the median MA bid is $720 and average FFS spending is $867, the premium for FFS coverage would thus be $147 higher than the base beneficiary premium of $106, for a total premium of $253. For the 10 largest areas, the additional premium for FFS coverage would range from $137 to $288 per month.

Options for mitigating or delaying the impact on beneficiaries

While a premium support system would give beneficiaries an incentive to choose a lower cost option and beneficiaries could switch options to mitigate the impact of large premium increases, some beneficiaries may not be immediately able to switch. Given the size of the premium increases in some areas, measures to mitigate the impact on beneficiaries could be considered. The key questions would be how much of the premium increase beneficiaries would ultimately face and how quickly premiums would reach that level. In addition, policymakers could consider automatic enrollment of beneficiaries in low-cost plans and subsidies for low-income beneficiaries.

Since the goal of premium support is to encourage beneficiaries to choose a lower cost option for receiving Medicare benefits, policymakers could decide that a smaller differential in premiums would still be sufficient encouragement and could therefore limit the allowable difference between the FFS premium and the benchmark to a specific dollar or percentage amount. (This type of limit could be used for all beneficiaries or limited to those with low incomes.) Another option would be to grandfather existing Medicare beneficiaries and use the new method of calculating premiums only for future Medicare beneficiaries, but this option would raise equity issues for beneficiaries and could be challenging for CMS to administer.

The method of calculating premiums under premium support could also be implemented over several years to minimize disruptions and give beneficiaries time to adjust. 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. Another option would be to 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 lived in areas where premiums changed significantly.

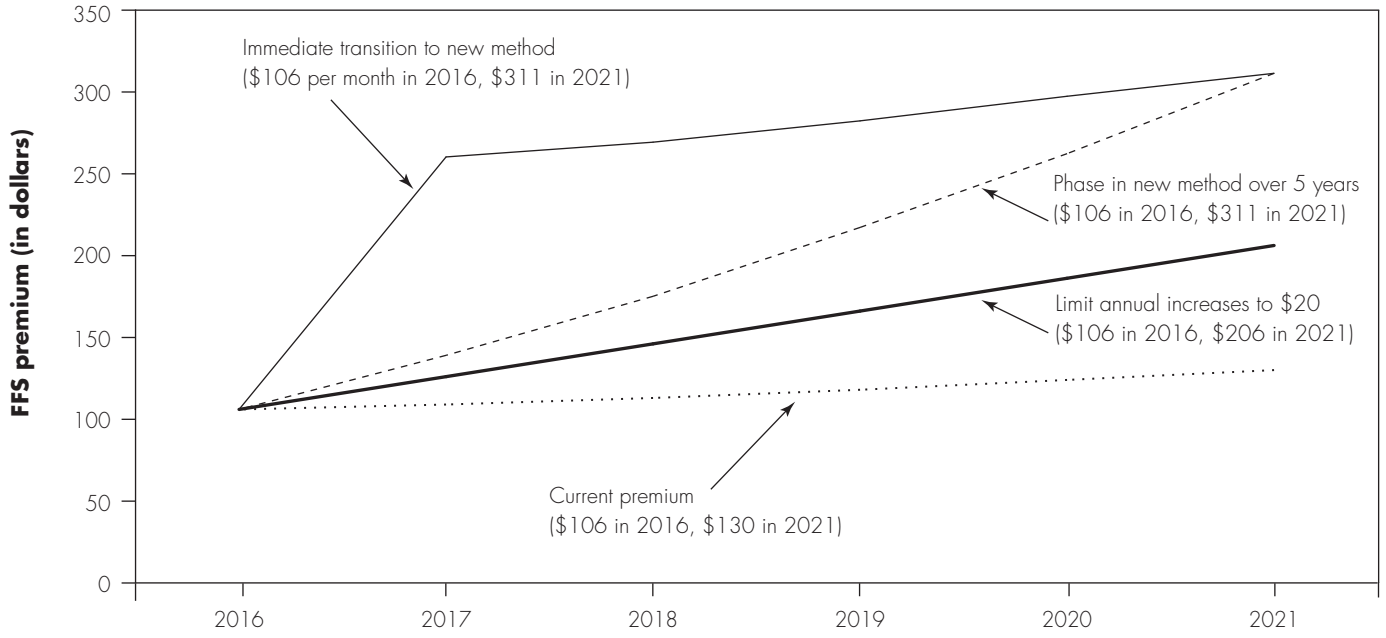
As part of the transition, beneficiaries would need to be informed of the trade-offs between FFS and a managed care plan and of differences among managed care plans themselves in such aspects as premiums and each plan's network of providers. Additional funding for SHIPs and improved decision-making tools could strengthen efforts to inform beneficiaries.

Figure 3-5 (p. 112) demonstrates how different approaches could be used to mitigate or delay premium increases. The figures here are based on the illustrative example previously used in which a nationally set base beneficiary premium pays for either FFS or the median-bid plan, whichever costs less. We use the Chicago area as an example because it is the largest market where FFS costs exceed the median bid by $100 or more. Premiums for 2016 are projected through 2021 using growth rates from the Medicare Trustees' report and assume that the transition to the new system starts in 2017.

Figure 3-5 (p. 112) shows what happens to premiums by 2021 if Medicare switched immediately in 2017 to the new system, if the higher premiums could be phased in over a five-year transition period, if FFS premium increases were limited to $20 annually, and if Medicare maintained the status quo. Given the size of the difference between this area's FFS spending and the median bid, the transition to the new system using the $20 annual limit would still be under way in 2021 and would likely take more than a decade to fully implement. These options are for illustration only, but they demonstrate how the impact of higher premiums under a premium support system could be substantially mitigated.

FIGURE 3–5

Illustrative examples of mitigating or delaying increases in FFS premiums in the Chicago area



Note: FFS (fee-for-service).

Automatically enrolling beneficiaries in lower cost plans

Under current law, new Medicare beneficiaries are automatically enrolled in the FFS program unless they select an MA plan.[23] Since premium support would lead to substantially higher FFS premiums in many areas, some of the impact in these areas could be mitigated by enrolling new beneficiaries in managed care plans with lower premiums instead of FFS.

Under this approach, individuals on the verge of eligibility for Medicare would be given a period of time to choose a coverage option on their own. Those who did not make a choice would be automatically enrolled in a lower cost plan to ensure that they had coverage in effect when they reached Medicare eligibility. For example, beneficiaries could be randomly assigned to plans with premiums equal to or lower than the base beneficiary premium. (The Part D program uses a similar approach to assign new enrollees who receive the low-income subsidy for drug plans.) Such a strategy might also encourage managed care plans to submit lower bids so that they could benefit from automatic enrollment of new beneficiaries.

As part of this process, policymakers would need to decide when automatically enrolled beneficiaries could switch to another plan. One option would be an approach used in the Medicaid program, where beneficiaries are required by many states to enroll in managed care and are automatically assigned to a Medicaid managed care plan if they do not select one on their own. In such cases, the state typically gives the beneficiary 60 to 90 days to choose a different Medicaid managed care plan. After that, beneficiaries cannot switch to another plan until the next open enrollment period.

Policymakers could also decide that existing beneficiaries should be automatically assigned to lower cost plans in certain circumstances. For example, CMS periodically reassigns beneficiaries who receive the Part D low-income subsidy to new drug plans to ensure that they remain enrolled in a plan with a zero premium. Beneficiaries who have chosen a plan on their own are not reassigned.

The potential benefits of automatically enrolling beneficiaries in lower cost plans (mitigating the financial impact of higher premiums) would need to be weighed against possible drawbacks. Some beneficiaries could have difficulty obtaining care, at least initially, if they are assigned to a plan that does not have their providers in its network. In addition, under current law, new Medicare beneficiaries who enroll immediately in MA plans may later have difficulty buying a medigap policy if they later switch to FFS coverage because there is a limited one-time open enrollment period for most beneficiaries to buy medigap coverage.

Providing premium subsidies to low-income beneficiaries

Under a premium support system, as with any financing system in Medicare, the goals of reducing program spending while ensuring adequate access to care need to be balanced. This latter concern applies in particular to low-income beneficiaries who may have difficulty paying their premiums. Medicaid currently provides subsidies that pay the Part B premium (and the Part A premium, if necessary) for low-income beneficiaries through the Medicare Savings Programs (MSPs), and Medicare provides similar subsidies for Part D premiums through that program's low-income subsidy (LIS).[24] However, in a premium support environment, the MSPs' role would need to be reassessed.

Developing a system of premium subsidies for low-income beneficiaries would involve three key issues: (1) which beneficiaries would be eligible for a subsidy, (2) what kind of subsidy they would receive, and (3) how the subsidies would be financed by the federal government and the states. We explore each issue in more detail below, drawing on the experience with the MSPs and the LIS. Since the MSPs are a Medicaid benefit, developing a system of premium subsidies would likely require changes to Medicaid as well as Medicare.

Who would be eligible for premium subsidies?

To qualify for the MSPs and the Part D LIS, beneficiaries must have both limited income and limited assets. Both programs exclude certain items when calculating an individual's income and assets and determine eligibility 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) and countable assets do not include the value of a primary residence. The eligibility limits for the LIS are slightly higher than the limits for the MSPs. For the MSPs, beneficiaries must have income below 135 percent of the federal poverty level ($16,280 for an individual) and no more than $7,390 in assets. For the LIS, beneficiaries must have income below 150 percent of the federal poverty level ($18,090 for an individual) and no more than $13,820 in assets.[25] In 2008, the Commission recommended that the Congress raise the MSP income and asset limits to LIS levels to simplify the enrollment process for beneficiaries and improve MSP participation rates (Medicare Payment Advisory Commission 2008a).

In 2015, Medicaid covered about 9.2 million people through the MSPs and spent about $11.3 billion on Part B premiums, counting both federal and state payments (Centers for Medicare & Medicaid Services 2016d, Congressional Budget Office 2017).[26] The LIS covered about 11.7 million people and spent about $3.5 billion on Part D premiums (Centers for Medicare & Medicaid Services 2016c, Medicare Payment Advisory Commission 2016c). The higher LIS enrollment is partly due to its more generous eligibility limits but also stems from differences in the enrollment processes for the two programs. Beneficiaries who qualify for one of the MSPs are automatically enrolled in the LIS, but the reverse is not true.

Under a premium support system, decisions would need to be made regarding what income and asset limits would qualify beneficiaries for premium subsidies and whether those limits should be lower than, equal to, or higher than existing MSP limits. Several factors would inform these decisions, such as the number of eligible beneficiaries, the relationship between beneficiaries' incomes and their premiums, and the process for obtaining a subsidy.

As for the number of eligible beneficiaries, Table 3-10 (p. 114) provides information on the income distribution of the Medicare population, both as a share of the federal poverty level and in dollars. The cut-offs for each income band are based on the federal poverty level for 2017; the share of beneficiaries in each income band is based on data from the Medicare Current Beneficiary Survey (MCBS) for 2012. These figures are still reasonably accurate in 2017 because the Medicare population's income distribution is relatively stable from year to year.[27]

TABLE 3–10

Income distribution of the Medicare population

Annual income as a percentage of the federal poverty level	Annual income thresholds		Share of Medicare beneficiaries
	Individual	Couple	
Less than 100 percent	<$12,060	<$16,240	17%
100 to 135 percent	12,060–16,280	16,240–21,920	13
135 to 150 percent	16,280–18,090	21,920–24,360	4
150 to 175 percent	18,090–21,110	24,360–28,420	6
175 to 200 percent	21,110–24,120	28,420–32,480	6
200 to 400 percent	24,120–48,240	32,480–64,960	31
More than 400 percent	>48,240	>64,960	24

Note: The cutoffs for each income band are based on the poverty thresholds for 2017 and have been rounded to the nearest $10. We used total beneficiary income to calculate the share of beneficiaries in each income band (i.e., we did not apply the income exclusions that the Medicare Savings Programs use to determine a beneficiary's income). The share of beneficiaries in each income band is based on 2012 data. The total does not sum to 100 percent due to rounding.

Source: Office of the Assistant Secretary for Planning and Evaluation 2017 (for annual income thresholds) and MedPAC analysis of the Medicare Current Beneficiary Survey, Cost and Use file 2012.

About 46 percent of Medicare beneficiaries have income below 200 percent of the poverty level. Within that group, 30 percent of beneficiaries have income below the MSP income limit of 135 percent of the federal poverty level. The share of beneficiaries eligible for the MSPs is lower because some beneficiaries who meet the income limit do not meet the program's asset limit, and not all beneficiaries who are eligible actually participate. The remaining 55 percent of beneficiaries have income that exceeds 200 percent of the federal poverty level (Table 3-10).

The share of beneficiaries who qualify for a subsidy would be lower than the figures in Table 3-10 if policymakers included an asset limit. The rationale for an asset limit is that it better targets premium subsidies by excluding beneficiaries who have low incomes but can afford to pay their premiums by spending some of their assets. But there are also arguments against using an asset limit. Under Medicaid, states have the flexibility to raise or eliminate the MSP asset limit. Nine states have eliminated the asset limit entirely, and three other states have adopted a higher limit (Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission 2017). Some states argue that the asset limit is not cost-effective because it is difficult to administer and screens out relatively few MSP applicants. However, an asset limit could have a larger impact if policymakers increased the income limit for premium subsidies above the current MSP limit of 135 percent of the federal poverty level.

Research suggests that beneficiaries' income and assets are highly correlated, and, as a result, a larger share of beneficiaries at higher income levels would be affected by an asset limit (Summer and Thompson 2004).

In setting the eligibility parameters for a premium subsidy, policymakers would also need to consider the relationship between beneficiaries' income and their premiums (as well as expected spending on cost sharing). This relationship would be difficult to assess with precision because of uncertainty regarding the potential impact of the new system on beneficiary premiums, but the method used to determine benchmarks and beneficiary premiums would be an important element. Because benchmarks and beneficiary premiums in a premium support system would be inversely related—higher benchmarks would mean lower beneficiary premiums and vice versa—beneficiaries would spend a larger share of their income on premiums under a system with relatively low benchmarks, which could necessitate broader eligibility for premium subsidies than under the MSPs. On the other hand, if the new system produced higher benchmarks and beneficiary premiums were more affordable, current eligibility limits could be considered sufficient.

A third factor in determining eligibility for premium subsidies would be the process for beneficiaries to obtain the subsidy. For both the MSPs and the LIS, some groups of beneficiaries qualify automatically for benefits while

others must submit an application. For example, Medicare beneficiaries who qualify for Supplemental Security Income (which provides cash benefits for disabled or elderly individuals with low incomes) are automatically eligible for Medicaid in most states and receive MSP premium subsidies as part of their package of Medicaid benefits. In contrast, some beneficiaries are eligible for MSP benefits only and must apply to receive them. For the LIS, all beneficiaries dually eligible for Medicare and Medicaid are deemed eligible for the LIS, but others must apply for benefits. A premium support system could use this kind of mixed approach.

The two programs also have different application processes. Since the MSP premium subsidy is a Medicaid benefit, beneficiaries apply through their state Medicaid office. The LIS gives beneficiaries the choice of applying through either the Social Security Administration (SSA) or their state Medicaid office, but in practice almost all LIS applicants use the SSA. Either approach could be used in a premium support system, depending in part on whether premium subsidies would be a Medicaid benefit (like the MSPs) or a federally administered program (like the LIS). Even if the premium subsidies were part of Medicaid, giving beneficiaries the option of applying through the SSA could encourage higher participation. One shortcoming of the existing system is that beneficiaries who apply for LIS benefits through the SSA are not screened for MSP eligibility, even though many applicants likely qualify for both programs. In 2008, the Commission addressed this issue by recommending that the Congress require the SSA to screen all LIS applicants for MSP eligibility and enroll them if they qualify (Medicare Payment Advisory Commission 2008a). This change could also be appropriate in a premium support system.

What kind of subsidy would be provided?

The MSPs now cover the full Part B premium for all eligible beneficiaries. However, if the premium subsidy under a premium support system fully covered beneficiary premiums no matter what coverage option beneficiaries select, then the beneficiaries receiving the subsidy would have no incentive to use a lower cost option. State spending could also increase in states where MSP enrollees are now primarily enrolled in coverage options that, under premium support, might face higher premiums (such as the FFS program in many large urban areas). However, policymakers would also need to ensure that all subsidy recipients can afford to buy coverage.

The Part D program, which uses a version of premium support, addresses this trade-off by putting an upper limit on the LIS premium subsidy, known as the low-income premium subsidy amount (LIPSA). Calculated separately for each Part D region, the LIPSA equals a weighted average of the monthly Part D premiums for the region's plans that offer basic drug coverage, with each premium weighted by the number of LIS enrollees.

LIS recipients who enroll in plans with premiums that are lower than this upper limit pay no premium. (These plans are often known as zero-premium plans.) Recipients who enroll in more expensive plans pay the difference between the plan's premium and the LIPSA. For example, if the LIPSA equals $30, an LIS beneficiary who enrolled in a plan with a $25 premium would not pay a premium, while an LIS beneficiary who enrolled in a plan with a $40 premium would pay $10. The method that CMS uses to calculate the LIPSA guarantees that there will always be at least one zero-premium plan in each area.[28] As a result, while LIS enrollees always have access to at least one zero-premium plan, they also have an incentive to avoid enrolling in higher cost plans.[29]

This approach could also be used in a premium support system for Part A and Part B. Table 3-11 (p. 116) builds on our previous illustrative examples in Table 3-6 (p. 101), showing benchmarks and beneficiary premiums in a market where the benchmark is based on the FFS bid or the median-bid plan.

The table shows the impact of two illustrative premium subsidies in these hypothetical markets. Like the Part D LIS, premium subsidies would be limited to a specified dollar amount. Beneficiaries who enrolled in less expensive plans would pay no premium; beneficiaries who enrolled in more expensive plans would pay the difference. The first premium subsidy would equal the lowest premium in the market ($105 in Example 1 and $65 in Example 2). The second premium subsidy would equal the standard base beneficiary premium of $125.

The amount of the premium subsidy (along with the distribution of plan bids) would determine the number of zero-premium plans in each market. Under the first approach, the only zero-premium plan in each market would be Plan A, the low bidder. Under the second approach, where the premium subsidy is higher, there would be two zero-premium plans in the first market (FFS and Plan A) and three zero-premium plans in the second market (Plans A, B, and C). Higher premium subsidies

TABLE 3–11

Illustrative examples showing the effects of a premium subsidy for low-income beneficiaries

		Managed care plans				
	FFS program	Plan A	Plan B	Plan C (median plan bid)	Plan D	Plan E
Example 1: Benchmark equals the FFS bid						
Plan bid	$700	$680	$710	$740	$770	$800
Beneficiary premiums; no premium subsidy	$125	$105	$135	$165	$195	$225
Beneficiary premiums; subsidy = low premium ($105)	$20	$0	$30	$60	$90	$120
Beneficiary premiums; subsidy = base premium ($125)	$0	$0	$10	$40	$70	$100
Example 2: Benchmark equals the median of the managed care plan bids (Plan C)						
Plan bid	$800	$680	$710	$740	$770	$800
Beneficiary premiums; no premium subsidy	$185	$65	$95	$125	$155	$185
Beneficiary premiums; subsidy = low premium ($65)	$120	$0	$30	$60	$90	$120
Beneficiary premiums; subsidy = base premium ($125)	$60	$0	$0	$0	$30	$60

Note: FFS (fee-for-service). These examples express all plan bids as per beneficiary per month amounts for a beneficiary of average health status. In these examples, the benchmark would equal the lower of the FFS bid or the median bid from the managed care plans, and beneficiaries would pay a premium that equals a standard amount of $125 plus the difference between the plan's bid and the benchmark. The methods used to determine the benchmark, the base beneficiary premium, and any subsidy amount are all policy choices.

would thus increase the number of zero-premium plans and vice versa. Beneficiaries who received a premium subsidy and enrolled in one of the more expensive plans would have to pay part of the premium themselves.[30] However, a higher premium subsidy would lower the amount that beneficiaries had to pay. In Example 1, the more generous subsidy would reduce the premium that eligible beneficiaries would pay to enroll in Plan C from $60 to $40.

If the new system limited the amount of the premium subsidy, the FFS program would not qualify as a zero-premium plan in all markets. In Example 1, FFS is less expensive than most managed care plans, and FFS would qualify as a zero-premium plan under the higher premium subsidy of $125. In Example 2, FFS is more expensive than most managed care plans and would not qualify as a zero-premium plan unless the premium subsidy were increased to $185. Under premium support, the FFS program would probably have one of the higher bids in many market areas, and any effort to limit the amount of the premium subsidy would result in areas where the FFS program did not qualify as a zero-premium plan. Higher premium subsidies would reduce the number of such areas, but would not eliminate them completely.

Some beneficiaries, particularly those with relatively higher incomes, could also receive a partial premium subsidy. Although the MSPs do not provide partial subsidies, the Part D LIS provides partial subsidies for beneficiaries with income between 135 percent and 150 percent of the federal poverty level. The subsidies for these beneficiaries taper off as income rises: Those with income between 135 percent and 140 percent of the federal poverty level receive a subsidy that equals 75 percent of the LIPSA, those with income between 140 percent and 145 percent receive a subsidy that equals 50 percent of the LIPSA, and those with income between 145 percent and 150 percent receive a subsidy that equals 25 percent of the LIPSA. The use of partial subsidies in this manner would allow eligibility for subsidies to be broadened while still limiting program spending.

Enrollment in zero-premium plans could be encouraged by using passive enrollment in certain situations. With passive enrollment, CMS automatically enrolls beneficiaries in a particular plan unless they take some action to change it. For beneficiaries receiving a premium subsidy, a zero-premium plan could be the default coverage option, as it is under the Part D LIS. CMS also uses passive enrollment to ensure that LIS beneficiaries remain enrolled in zero-premium plans over time. Exactly which plans qualify as zero-premium plans changes from year to year because of changes in plans' Part D bids and the LIPSA. When LIS beneficiaries are in plans that do not qualify as zero-premium plans in the following year, CMS reassigns them at the start of that year to another zero-premium plan to ensure that they do not have to start paying a premium (Centers for Medicare & Medicaid Services 2016a).[31]

The benefits of using passive enrollment (ensuring that low-income beneficiaries do not have to pay a premium) would need to be weighed against other considerations, such as respecting beneficiary choice and the potential disruption that some beneficiaries could experience if they were enrolled in a plan that did not have their providers in its network. In Part D, CMS does not use passive enrollment for LIS beneficiaries who have selected a Part D plan on their own, including those enrolled in plans with premiums that are higher than the LIPSA. One study found that 42 percent of LIS enrollees in 2010 had selected their own plan, with many choosing a zero-premium plan (Hoadley et al. 2015). Another study found that 17 percent of LIS enrollees in prescription drug plans would pay a premium in 2017 if they stayed in their current plan. These beneficiaries would pay an average of $24 per month in 2017 for their drug coverage, and 72 percent of them were in plans that also required them to pay a premium in 2016 (Hoadley et al. 2016). In 2010, CMS considered using passive enrollment to reassign some of these so-called choosers (those paying more than $10 per month in premiums) to zero-premium plans, but did not finalize its proposal (Centers for Medicare & Medicaid Services 2010).

The annual reassignment process helps keep LIS enrollees in zero-premium plans, but it is also disruptive for beneficiaries whose new plan does not cover all of the drugs they use. Something similar could happen in a premium support system if beneficiaries were reassigned to a plan that did not have all of their providers in its network. In Part D, policymakers have decided that the costs of reassigning beneficiaries outweigh the benefits when a plan's premium exceeds the LIPSA benchmark by a small amount ($2 in 2017). In these cases, CMS allows plans to retain their LIS enrollees if the plans waive payment of the remaining premium. (However, these plans cannot receive new LIS enrollees through passive enrollment.) This policy has reduced the number of LIS enrollees who are reassigned to new plans, and it could be used in a premium support system for Part A and Part B.

How would the subsidies be financed?

The MSPs and the LIS offer two examples of how premium subsidies could be financed in a premium support system. Because the MSPs are part of the Medicaid program, the federal government and the states both pay part of the cost. The federal match rate for each state is determined by a formula and ranges from 50 percent to 75 percent in 2017 (Office of the Assistant Secretary for Planning and Evaluation 2015). Across all states, the federal government pays about 61 percent of the cost of the MSP payments for Part B premiums; states pay the rest. In contrast, the Part D LIS is financed entirely by the federal government.

Under premium support, the simplest way to provide premium subsidies would likely be to build on the existing MSPs and modify them as needed, leaving the current federal–state system of financing in place. This arrangement could be revised as needed by adjusting the federal match rate. For example, if the eligibility limit for premium subsidies were raised, the federal government could pay a larger share of the costs for the newly eligible population. The Congress used this approach in 1997 when it raised the MSP eligibility limit from 120 percent to 135 percent of the federal poverty level and specified that the federal government would pay the full cost of the premium subsidies for beneficiaries in that income range.[32]

Even if MSP eligibility limits remained the same, states would be concerned that premium support might result in higher Medicaid spending, which could occur if premiums for MSP enrollees proved to be higher, on average, than the current Part B premium. Whether spending would be higher depends on numerous other factors, such as the method used to set benchmarks and beneficiary premiums and the amount of the premium subsidy. For example, a premium support system that had relatively low benchmarks and generous premium subsidies would be more likely to result in higher Medicaid costs, particularly in states where many MSP enrollees are in the FFS program.

Instead of the Medicaid-based structure of the MSPs, a new system of premium subsidies could be administered by the federal government, like the Part D LIS. Under this approach, the SSA would determine whether beneficiaries were eligible for the subsidy, and CMS would make subsidy payments for those who qualified. Since the SSA would determine eligibility for the new premium subsidies as well as the LIS, this arrangement would make it easier for policymakers to align the eligibility standards for the two programs, which would simplify the enrollment process for beneficiaries and likely improve beneficiary participation.

A major concern with creating a federally run system is the likely additional cost for the federal government. Since the MSPs are part of the Medicaid program, the states pay some of the cost of its premium subsidies. A federally run system that replaces the MSPs' premium subsidies would thus increase federal spending while reducing state spending. Some of these costs could be offset by requiring states to make maintenance-of-effort (MOE) payments to the federal government that equal what the states would have spent on MSPs under current law.[33]

Cost-sharing subsidies would be another important consideration in federalizing the MSPs and deserve mention. As noted earlier, one of the MSPs (the Qualified Medicare Beneficiary Program, for beneficiaries with income below the federal poverty level) also covers Part A and Part B cost sharing. Under a federally run system of premium subsidies, policymakers would need to decide whether these cost-sharing subsidies also would be federalized and, if so, how much of this cost sharing Medicare would pay. States can limit their spending on qualified Medicare beneficiary (QMB) cost sharing by using their Medicaid rates, which are often lower than Medicare rates, to determine their liability, and research has found that most states limit payments to some degree (Medicaid and CHIP Payment and Access Commission 2017). Prior Commission research estimated that, in aggregate, states now pay about 35 percent of cost sharing for QMBs. If Medicare paid the full amount of cost sharing under a federally run system, payments for the remaining 65 percent that states do not cover now would significantly increase federal spending because the additional federal payments would not be offset by state MOE payments. In addition, the combination of full Medicare payment of cost sharing and state MOE payments would create inequities among states because the states that now pay the smallest amount of cost sharing would benefit the most (Medicare Payment Advisory Commission 2016b).

Potential implications of a premium support system for beneficiaries and plans

Converting Medicare to a premium support model would likely have significant effects on beneficiaries and plans. Available research on several relevant issues, such as the sensitivity of beneficiaries to changes in premiums, provides some indication of potential effects. However, given the many actors and design choices (which go well beyond the issues raised in this chapter), there is no way to predict with certainty how premium support would play out.

Implications for beneficiaries

If the goal of using premium support is to encourage beneficiaries to use lower cost options for their Medicare coverage, how beneficiaries respond to premium changes and select coverage from multiple options are key considerations in designing a premium support system. The experiences of consumers in MA, the Part D program, and the PPACA exchanges (which serve a different population) can provide insight into the possible effects of premium support on beneficiaries.

Beneficiary willingness to switch plans

Available research suggests that MA enrollees and Part D prescription drug plan (PDP) enrollees switch plans at similar rates, while individuals who receive coverage through the PPACA exchanges switch plans at higher rates. Enrollee behavior in these three programs suggests certain considerations for the development of a premium support model.

Lessons from MA The share of beneficiaries who move from one Medicare sector to another (switching from FFS to MA or from MA to FFS) is roughly the same each year (Jacobson et al. 2015). However, since more beneficiaries are starting out in the FFS program, most of those who switch move from FFS into MA (Riley 2012). Between 2013 and 2014, about 17 percent of MA enrollees switched plans: 11 percent voluntarily switched to another MA plan, 2 percent voluntarily switched to the FFS program, and 5 percent were involuntarily switched (usually to another MA plan). The share of MA enrollees who voluntarily switch to another plan has been about the same every year, averaging 9 percent annually between 2007 and 2013 (Jacobson et al. 2016).

MA enrollees are more likely to switch plans as their premiums increase. Enrollees who saw their premiums increase by less than $20 switched at a rate of 11 percent compared with higher switching rates by enrollees who faced larger increases: 21 percent of those facing a $20 to $29 increase, 24 percent of those facing a $30 to $39 increase, and 29 percent of those facing an increase of $40 or more. On average, beneficiaries who switched plans saved $15.87 per month in premiums, while those who stayed in the same plan paid $4.26 more, on average. Beneficiaries who switched plans also lowered their out-of-pocket spending limit by an average of $401 (Jacobson et al. 2016).

Some observers have claimed that half of newly eligible Medicare beneficiaries join MA plans, but the Commission found that only about a quarter of the new beneficiaries in 2012 chose an MA plan. The Commission also found that new MA enrollees tended to be former FFS enrollees in their late 60s and early 70s and had thus experienced one or more MA open enrollment periods. This finding suggests that many beneficiaries may not consider enrolling in MA until they have been exposed to FFS cost sharing or MA plans' marketing efforts (Medicare Payment Advisory Commission 2015b).

Among MA enrollees, voluntary switching rates did not vary by gender, the number of plans available in the county, or the MA payment quartile for the county. However, switching rates were somewhat higher for beneficiaries ages 65 to 75 (12 percent) compared with those 85 and older (7 percent). Enrollees living in nonmetropolitan areas were more likely to be switched involuntarily than those living in metropolitan areas (8 percent vs. 4 percent) because MA plans in nonmetropolitan areas are more likely to exit the market (Jacobson et al. 2016). Among FFS enrollees, some beneficiaries with medigap coverage may be reluctant to join an MA plan because they could be subject to medical underwriting if they later switched back to the FFS program and tried to buy a new medigap policy.

The beneficiaries most likely to switch from MA to FFS are high-need, high-cost patients (McWilliams et al. 2011, Medicare Payment Advisory Commission 2012b, Newhouse et al. 2012). Their higher rate of switching could be accounted for by dual-eligible beneficiaries (who are more likely to have high costs and can switch plans at any time), unmet needs under their current plans, and provider or plan encouragement to switch. However, dual-eligible beneficiaries who are enrolled in MA special needs plans switched at lower rates (9 percent) than those enrolled in regular MA plans (13 percent) (Jacobson et al. 2016).

Focus groups have found that seniors do not find the differences between MA plans to be significant enough for them to consider shopping around (Jacobson et al. 2014). High beneficiary retention rates can send plans both positive and negative signals. On the one hand, high retention rates encourage sponsors to properly manage their enrollees' health because they will likely be enrolled in the plan for years. On the other hand, plans could conclude that the risk of losing enrollees is low unless there are large increases in premiums or significant disruptions in care.

Lessons from Part D During the first few years of the Part D program, the majority of beneficiaries remained with the plan they selected in the program's first year (Hoadley 2008). Research at the time showed that many beneficiaries were satisfied with their plan and did not intend to switch, but over one-third of enrollees stated that it was too much trouble to compare and choose a new plan (Kaiser Family Foundation 2006). The complexity of the Part D drug benefit may also have discouraged enrollees from switching plans (Hoadley 2008).

The Commission found that, between 2009 and 2010, 15 percent of enrollees in MA plans with prescription drug coverage (MA–PDs) and 13.6 percent of non-LIS enrollees in PDPs voluntarily switched plans. Among those who switched, about 90 percent of MA–PD enrollees switched to another MA–PD, and about 80 percent of PDP enrollees switched to another PDP. As with MA, gender did not affect the rate of switching; beneficiaries in nonmetropolitan areas were more likely to switch plans than enrollees in metropolitan areas

(17 percent vs. 13 percent, respectively); and older beneficiaries were less likely to switch plans. The share of Part D enrollees who switched plans was not affected by the number of PDPs available in their region. The beneficiaries who switched plans had lower out-of-pocket costs than they would have had under their old plan (Medicare Payment Advisory Commission 2013b).

Lessons from the PPACA exchanges Research indicates that individuals who receive health coverage through the PPACA exchanges switch plans at a much higher rate than those in MA or Part D in an effort to lower their premiums. In 2017, exchange enrollees could choose from an average of three participating insurers in each county, with 79 percent of enrollees having a choice of two or more and 56 percent having a choice of three or more (Office of the Assistant Secretary for Planning and Evaluation 2016b). Within the exchanges, each participating insurer can sell multiple plans across the four "metal levels" (bronze, silver, gold, and platinum) that indicate the generosity of a plan's coverage. A majority of exchange consumers select plans with low premiums (Burke et al. 2014). Exchange consumers are sensitive to premium changes and have been willing to switch plans to maintain low-cost coverage (Office of the Assistant Secretary for Planning and Evaluation 2016a). During the 2016 open enrollment period, 43 percent of the individuals who were re-enrolling switched to lower cost plans, saving $42 per month on average. However, many exchange enrollees who could switch to a lower premium plan remained in their current plan: 76 percent of the individuals who re-enrolled in the same plan for 2016 could have switched to a lower premium plan, even within the same metal level as their current plan, suggesting that beneficiaries consider other factors besides premiums in making coverage decisions (Office of the Assistant Secretary for Planning and Evaluation 2016a).

The exchanges differ from Medicare in several respects, which makes it difficult to know whether the high rates of plan switching in the exchanges would also occur in a Medicare premium support system. First, the exchanges do not have an FFS coverage option, and the competitive dynamic between the FFS program and managed care plans in a premium support system could be different (Office of the Assistant Secretary for Planning and Evaluation 2016a). Second, there was more news coverage about shopping and plan switching in the exchanges than in Medicare. Third, the premiums for exchange plans have been more volatile from year to year than MA premiums. Fourth, the exchanges serve a younger and more technologically knowledgeable population that may be more willing or better able to shop around than Medicare beneficiaries.

Evaluating coverage options and choosing a plan

Although the notion of having a wide variety of choices when deciding is appealing, research suggests that many consumers, particularly the elderly, have difficulty making decisions when faced with many choices. A premium support system will not work as well if Medicare beneficiaries struggle to understand their coverage options and have trouble selecting the coverage that best meets their needs (Hibbard et al. 1998).

Factors that beneficiaries consider when selecting coverage Interviews with focus groups conducted by the Kaiser Family Foundation and the Commission's annual beneficiary survey indicate that beneficiaries strongly consider certain factors when selecting an MA or Part D plan, such as access to particular providers (their doctors, certain hospitals and cancer treatment centers, and nearby pharmacies and physicians) and the brand name of the insurance provider (Jacobson et al. 2014, Wesolowski 2016). Beneficiaries in poorer health believed that it was more important to retain access to their current providers (Wesolowski 2016). As for specific plan features, beneficiaries in poorer health gave more consideration to out-of-pocket costs such as deductibles and copayments, while healthier beneficiaries focused more on premiums (Jacobson et al. 2014). Once beneficiaries were enrolled in a plan, they often preferred to keep that plan (even if its premiums increased) instead of searching for and changing to an unfamiliar one. They also expected annual premium increases and looked suspiciously on premium decreases and low-cost plans because they believed that lower costs indicate poorer quality or less coverage (Jacobson et al. 2014). Focus group participants were most likely to turn to friends, family, neighbors, and insurance agents for help in choosing a plan (Jacobson et al. 2014, Wesolowski 2016). Beneficiaries gave more weight to the experiences of family and friends than information they received from advertisements.

Beneficiaries often do not take full advantage of the low-cost options that are available, but may still make rational decisions given the other factors that they consider when selecting a plan. For example, a study of beneficiaries enrolled in PDPs in 2006 found that only 6 percent to 9 percent of beneficiaries had chosen the lowest cost plan (Gruber 2009). Their decision making nevertheless aligned with expected models of decision making (Abaluck and

Gruber 2011). The characteristics that determine which plan is best for a beneficiary evolve over time because of changes in the plans that are available, health status, and prescription drug needs (Heiss et al. 2016). Beneficiaries were more likely to consider switching plans when they overspent the previous year, but they remained sensitive to potential drawbacks, such as risk of losing a familiar physician and the time needed to select a new plan. (The decision to switch plans is often as complex as the initial plan selection.) With these two considerations—price and the potential drawbacks of switching—sometimes at odds with each other, tools that help beneficiaries understand their coverage options would be important elements of a premium support system because they would make it easier for beneficiaries to focus on price differences (Heiss et al. 2016). Beneficiary decisions eventually affect how plan sponsors structure their premiums and plan offerings (Ho et al. 2015, Polyakova 2016).

Helping beneficiaries evaluate their coverage options

For beneficiaries in a premium support system, the process of selecting a plan could be complex because of the number of available coverage options in some areas and the many ways that these options could differ (such as cost sharing, provider networks, and additional benefits). The selection process would be unfamiliar for many FFS enrollees in particular—although most have gone through the process of selecting a Part D plan—and could also be more challenging than the process of selecting employer-sponsored insurance, which some beneficiaries encountered during their working years. The shopping experience would be especially challenging if there is little use of standardization and few limits on the number of plans that insurers can offer.

Beneficiaries could find it particularly challenging to select a plan that best meets their needs if too many coverage options are available. Participants in consumer choice studies made better choices when confronted with 6 options as opposed to 24 or more (Iyenger and Lepper 2000). Another study found that Medicare beneficiaries were more likely to enroll in MA when they lived in an area where 15 or fewer plans were available (McWilliams et al. 2011).

The availability of tools such as the Medicare Plan Finder for Part D plans can make the selection process easier. A similar online comparison tool for managed care plans would be essential for a premium support system. The existing Medicare Compare tool would be a logical starting point, but it could be improved with better information about the providers that participate in each plan's network and better use of standardized vocabulary.

CMS would also need to engage in advertising and outreach activities to inform beneficiaries about these tools. In the MA and Part D programs, many beneficiaries are unaware of the consumer tools that can help them select a plan (Jacobson et al. 2014). In addition, some beneficiaries would not have access to online comparison tools or be comfortable using them. Additional funding for state health insurance assistance programs could provide additional decision-making support to beneficiaries.

Implications for managed care plans

Beneficiaries cannot make good plan choices unless an adequate number of plans is available. The MA program has a large number of plans and would provide a good foundation for a premium support system. Currently, 99 percent of all beneficiaries have at least one plan available (not including employer-sponsored plans and special needs plans). The average beneficiary has 18 plans available; beneficiaries in some areas have more than 40 plans available. However, the adoption of premium support would affect both the number of plans that are available and how those plans would bid.

Plan participation

The bidding process under premium support would differ from the MA bidding process in several respects and would likely prompt managed care plans to reexamine which markets they serve. In MA, each plan can define its own service area and submit a single bid for that area. That bid is compared with a benchmark that CMS calculates based on FFS spending and announces in advance. (The MA benchmarks are based on counties; when plans serve multiple counties, their bids are compared with a benchmark that equals a weighted average of the county-specific amounts.) In a premium support system, the use of competitive bidding would mean that plans do not know the benchmark in advance and that each plan's bid could affect the area's benchmark and thus the plan's premium in that area. As a result, plans would want to pay more attention to their bids for each area. Plans could decide to leave some areas if they did not expect enough enrollment to make the time and expense of the bidding process worthwhile. Plans could also decide to enter new areas based on updated competitive dynamics. Some areas that currently have few or no MA plans could appear more attractive under premium support. For example, 7 of the 10 largest counties without MA plans have benchmarks that

equal 95 percent or 100 percent of FFS costs. Depending on how they were calculated, the benchmarks in these areas could be higher under premium support than the current MA benchmarks (at least initially).

As discussed earlier, the Commission has recommended replacing the county-based payment areas now used in MA with a set of fewer, often larger, market areas. Some researchers believe that using this approach for defining market areas could lead to increased plan participation and competition (Gaynor et al. 2017).

Another element of a premium support system that could have a significant effect on plan participation would be restrictions or limitations on the number of participating plans. Because beneficiaries might have an easier time choosing plans when there are fewer and clearer plan choices, a premium support system could limit the number of plans that an insurer could offer, limit the total number of plans that can participate in a market area, or both. On the other hand, the system could have relatively few restrictions on the number of plans offered, which would be more consistent with current policies in both MA and Part D. This approach could arguably lead to greater competition. CBO's analysis of Part D bids for 2007 through 2010 found that plans in markets with more competing insurers submitted lower bids (Congressional Budget Office 2014). Another study found that an increase in the number of competing insurers between 2006 and 2009 reduced plan bids in the MA program (Song et al. 2012).

Under premium support, the potential Medicare market for managed care plans would be much larger than the current MA market and the major new markets that have opened over the past decade (Part D, Medicaid managed care, and the PPACA exchanges). Plan interest in participating in a premium support system would thus likely be widespread, even if the number of available plans was limited in some fashion.

How plans would bid

Prior Commission work and the academic literature have found that the MA market does not encourage price competition, as evidenced by plan bidding behavior. The Commission has found that MA plan bids are more strongly related to the program's administratively determined benchmarks than to local FFS spending, local FFS service use, local market prices, or insurer market power (Medicare Payment Advisory Commission 2013a). Academic studies have found that raising MA benchmarks will increase plan bids by about half of the amount of the benchmark increase (Duggan et al. 2014, Song et al. 2013, Song et al. 2012). The authors of the studies concluded that MA plans have market power and that the MA program is not perfectly competitive.

Other Commission work has shown that MA plan bids can decline when benchmarks are lowered. In 2011, the benchmarks for nonemployer MA plans equaled 113 percent of local FFS spending, on average, and the bids for those plans equaled 99 percent of FFS spending. Between 2011 and 2017, PPACA lowered the MA benchmarks to an average of 106 percent of FFS spending. Plan bids during this period fell to an average of 90 percent of FFS spending. So, while there may not be perfect competition in MA, plans have become more competitive with FFS.

In MA, beneficiaries do not see information on plan bids, and plans therefore do not compete on their bids (and resulting premiums) alone. Most MA plans do not charge an additional premium for their Part A and Part B benefits (almost all MA enrollees are required to pay the same Part B premium as FFS beneficiaries). Under a premium support system where plans bid on a standard package of Part A and Part B benefits, beneficiaries would see premiums that indicate how the bids from the FFS program and managed care plans compare. Each coverage option most likely would have a different premium, a marked change from the MA program in which many plans are displayed as "zero premium." The greater visibility of these premiums could focus the competition among plans toward premiums and away from the extra benefits that seem to dominate competition in MA.

Table 3-12 demonstrates this point with the bids from our previous illustrative examples.

In this hypothetical market, the FFS program has a bid of $800 per month and the five MA plan bids range from $680 to $800. Assume that this market's benchmark is $800 and that plans can offer extra benefits only if they bid below the benchmark and receive rebate dollars. In addition, the national Part B premium in this example equals $125, which is close to its current amount. A comparison of premiums in Medicare Compare would show that each plan's premium is $0, even though beneficiaries would be required to pay the Part B premium ($125) for each plan, and the lowest and highest bids in the market (Plans A and E, respectively) differed by $120. The five MA plans differ in terms of the extra benefits they provide, but depictions of those extra benefits are shown

TABLE 3–12

Illustrative comparison of how beneficiary premiums are displayed in the MA program and could be displayed under a premium support system

		Managed care plans				
	FFS program	Plan A	Plan B	Plan C (median plan bid)	Plan D	Plan E
Plan bid	$800	$680	$710	$740	$770	$800
Under MA:						
Part B premium	$125	$125	$125	$125	$125	$125
Additional plan premium	$0	$0	$0	$0	$0	$0
Premiums that beneficiaries see in Medicare Compare	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Under premium support:						
Base beneficiary premium	$125	$125	$125	$125	$125	$125
Difference between plan bid and $740 benchmark	$60	–$60	–$30	$0	$30	$60
Premiums that beneficiaries see in Medicare Compare	**$185**	**$65**	**$95**	**$125**	**$155**	**$185**

Note: MA (Medicare Advantage), FFS (fee-for-service). The illustrative figures for a premium support system assume that the benchmark equals $740 (the lower of the FFS bid or the median plan bid, which is Plan C) and that the base beneficiary premium equals $125. These are all policy choices.

separately on Medicare Compare, and the differences across plans can be difficult to evaluate.

Under premium support in this example, the benchmark would equal the lower of the FFS bid or the median plan bid (in this market, that means a benchmark of $740, based on the bid from Plan C). Beneficiary premiums would range from $65 for Plan A to $185 per month for the FFS program or Plan E. This information would encourage beneficiaries to enroll in lower bidding plans to save money on premiums. We believe that managed care plans would anticipate this behavior and try to lower their bids to attract enrollment.

Bids might also be lower under premium support because beneficiaries would reap the full savings from lower bids in the form of lower premiums. In MA, beneficiaries receive about two-thirds of the difference between the plan's bid and benchmark in the form of extra benefits, and the Medicare program keeps the rest of the difference. This "tax" on the difference has been cited as a factor that discourages plans from bidding lower (Stockley et al. 2014).

Key findings from CBO's analysis of premium support

Given the level of specificity needed to define what "premium support" would entail and the uncertainty about its effect on the behavior of beneficiaries, health plans, and providers, it is not surprising that few studies have tried to estimate the effects of premium support in any detail. One such study of premium support is an analysis that CBO issued in 2013 (Congressional Budget Office 2013).

In its report, CBO analyzed two possible approaches for designing a premium support system. Under one approach, the benchmark would equal the enrollment-weighted average of private plans' bids and an area's FFS per capita costs (the "average option") and the base beneficiary premium would be calculated in the same manner as the current Part B premium. Beneficiaries who chose a plan that was more expensive than the average bid would pay

the full difference, while beneficiaries who chose a plan that was less expensive than the average bid would receive the full difference back in cash rather than supplemental benefits. We focus on CBO's average option because it more closely resembles the Commission's illustrative approaches outlined in this chapter.[34]

Estimated effects on beneficiaries

Under its average option, CBO expected that beneficiaries would be more sensitive to premium differences than most research about the Medicare population shows for two reasons. First, beneficiaries would be subject to premium differences that were significantly greater than those that had been studied previously. Second, information on plan prices would be displayed to beneficiaries in a way that would encourage comparison of premiums.

Under the average option, CBO estimated that the premiums beneficiaries paid in 2020 would be 6 percent lower, on average, than what they would be under current law because federal spending would be lower and premiums (as they are under current law) would be based on a share of that lower spending. CBO also estimated that beneficiaries' total out-of-pocket spending for Medicare services would be lower because more beneficiaries would be expected to enroll in lower cost plans and use fewer services, thus incurring lower out-of-pocket spending.

However, premiums and out-of-pocket spending would vary considerably by plan choice and by geography. CBO estimated that, on average, the premium for the FFS program would be about 50 percent higher than it is under current law because plan bids in many areas would be substantially lower than FFS per capita spending. Beneficiaries in FFS would have to pay the difference when FFS exceeded the federal contribution. (CBO's analysis assumes that the FFS program would have the same features as it does under current law.) While beneficiaries would face increased price pressure to make a choice under premium support, CBO estimated that, under the average option, about 20 percent of beneficiaries would not make any choice in the first year, and it noted that policymakers would have to decide how to treat those beneficiaries who did not choose.

Estimated effects on plans

CBO reported that the average option would change the incentives that private insurers face when they develop their bids. Some changes would tend to decrease bids, while others would tend to increase bids. On net, CBO estimated that bids would be lower relative to current law by about 4 percent in 2020, but that amount could vary under different program designs. (The decline in beneficiary premiums would be larger than the decline in plan bids because, among other reasons, some beneficiaries would switch to lower premium plans.)

CBO cited several factors under a premium support system that would tend to reduce bids. First, because beneficiaries would experience different premiums based on the plan they chose, the demand for plans with lower bids would be greater. Moreover, the government would not retain a share of the difference between its contribution and the plan's bid, further adding competitive pressure because beneficiaries would retain the full difference. Second, unlike the MA program, where benchmarks are announced before plans submit bids, the government contribution would be based on the bids themselves. CBO noted that, in the MA program, benchmarks can affect bids, and if plans did not know the benchmarks in advance, they would be more likely to submit bids that were reflective of their actual costs. Third, CBO expected that private plans would experience greater favorable selection (that would not be fully corrected for by risk adjustment) than in the current MA program. In other words, people enrolling in private plans would tend to cost less than FFS enrollees with similar risk scores, allowing plans to further reduce their bids.

CBO also cited several factors that would tend to increase plan bids. First, if the FFS program became relatively smaller, private plans might have more difficulty negotiating payment rates with providers that are similar to FFS rates. This change could place upward pressure on plan costs and bids. Second, CBO expected that enrollment in private plans would be significantly higher in many areas than it is today because plan bids in those areas are significantly lower than FFS. Thus, some plans would broaden their networks to accommodate the increased enrollment, and those broader networks would tend to include providers with higher costs. However, CBO has since changed its thinking on this issue. In a recent paper, the agency found that hospital payment rates for MA plans were equal to FFS rates, on average, regardless of the share of Medicare beneficiaries enrolled in MA plans in a given market. As a result, CBO's modeling of premium support proposals now assumes that managed care plans would continue to negotiate hospital payment rates that are comparable with FFS rates, even if the share of beneficiaries enrolled in plans rises substantially. One key part of this assumption is that plans would have the statutory authority to use FFS rates to pay

TABLE 3–13 **Distribution of FFS and MA enrollment, in millions, by type of market area, 2016**

	Number of areas	Number of enrollees (in millions)		
		Total	FFS	MA
Total, all market areas	1,231	54.5	37.1	17.4
Market areas without qualifying MA plans*	208	1.3	1.2	0.1
Market areas where FFS costs ***less*** than the median MA plan:				
FFS is lower by $50 or less	295	10.7	7.3	3.4
FFS is lower by $51 to $100	185	4.7	3.3	1.3
FFS is lower by $101 or more	51	1.3	0.9	0.5
Subtotal	531	16.7	11.5	5.2
Market areas where FFS costs ***more*** than the median MA plan:				
FFS is higher by $50 or less	223	13.0	8.7	4.3
FFS is higher by $51 to $100	146	6.8	4.9	1.8
FFS is higher by $101 or more	123	16.7	10.8	6.0
Subtotal	492	36.5	24.4	12.1

Note: FFS (fee-for-service), MA (Medicare Advantage). The differences between FFS spending and the median plan bid are expressed in monthly amounts. FFS spending for 2016 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments to make it comparable with MA plan bids. FFS spending has been 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. Number of Medicare beneficiaries and MA enrollees are as of January 2016. Components may not sum to totals due to rounding.
*Market areas have no eligible plans if either (1) no MA plans are available in those areas or (2) we excluded all of the available MA plans, such as employer group plans and special needs plans, based on the criteria we used for our analysis.

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

for services provided by out-of-network providers, as they do now in MA (Maeda and Nelson 2017).

CBO emphasized that these outcomes, for both plans and beneficiaries, are highly uncertain because a premium support system would create substantial changes for beneficiaries, private plans, and providers that are all difficult to predict. The effects could vary considerably depending on the design choices that policymakers make. For example, CBO noted that the decision of whether to include the FFS program is very important and that eliminating FFS could result in program spending that is higher than under current law.

Potential shifts in FFS and plan enrollment

Our illustrative framework for setting benchmarks and beneficiary premiums can also be used to provide some impressions about the potential impact of premium support on FFS and managed care enrollment. Under this framework, the benchmark equals the lower of the FFS bid or the median plan bid. The impact of premium support would thus depend heavily on the extent to which managed care plans participated in each market area and the relationship between the FFS bid and the median plan bid.

The potential impact of premium support would vary significantly across market areas. Table 3-13 stratifies market areas based on the relationship between FFS costs and the median MA plan bid in 2016. Under our method for defining market areas, we include 1,231 market areas in our analysis. The differences between FFS costs and the median plan bid are shown as monthly amounts. The table also shows total enrollment, FFS enrollment, and MA enrollment in each type of market area.

Under premium support, managed care plans may not be available in all market areas. Based on our criteria

to measure plan availability in MA, we found that 208 market areas did not have a qualifying plan. Relatively few beneficiaries live in these areas—1.3 million, or about 2 percent of all beneficiaries—and almost all were enrolled in FFS. (The few MA enrollees in these areas were in plans that we excluded from our analysis, such as employer group plans.) For these market areas, the FFS program would likely remain the predominant source of coverage unless managed care plans became more widely available.

In another 531 market areas where MA plans were available, FFS costs were lower than the median MA plan bid. A total of 16.7 million beneficiaries (31 percent of the total) live in these areas. Although FFS costs less than the median plan in these areas, about a third of the beneficiaries living there (5.2 million) were enrolled in MA plans since MA benchmarks in many counties are higher than FFS costs under the MA payment system and most MA plans can use rebate dollars to offer additional benefits (Table 3-13, p. 125).

Under our illustrative framework for calculating benchmarks and premiums, benchmarks in these areas would be based on FFS bids, and premiums for many managed care plans would increase. However, it is unclear how much premiums might increase. On balance, plans would likely submit somewhat lower bids than they do now in MA. Such a change in bidding behavior could reduce or eliminate the increase in premiums for some plans, particularly in areas where the median bid exceeds FFS spending by less than $50. In 2016, there were 295 such market areas, with 7.3 million FFS enrollees and 3.4 million MA enrollees (Table 3-13, p. 125). In these areas, it is difficult to say which type of coverage—FFS or a managed care plan—would have lower premiums and how much enrollment would shift from one sector to the other.

The situation is somewhat clearer for the 236 market areas where, in 2016, the median bid exceeded FFS costs by more than $50 (Table 3-13, p. 125). Under premium support, most plans in these areas would probably be more expensive than FFS, even with a change in bidding behavior. Premiums for most plans in these areas could increase noticeably, and we would expect a significant portion (well above 30 percent, based on experience in the MA program) of the 1.8 million MA enrollees in these areas to switch to FFS coverage or a less expensive plan. This shift in enrollment could lead some managed care plans to stop participating in these market areas, which could either reduce the number of available plans or result in no plans being offered in some areas.

Finally, in 492 market areas, the median plan bid was lower than FFS costs (Table 3-13, p. 125). These areas have 67 percent of the Medicare population—24.4 million FFS enrollees and 12.1 million MA enrollees. Under our illustrative framework, benchmarks in these areas would be based on the median plan bid, and FFS premiums would increase by an amount equal to the difference between the FFS bid and the median plan bid. (In these areas, any effort by plans to lower their bids would only widen the difference between FFS spending and the median plan bid.) Like the areas where FFS is less expensive, in a significant number of areas (223), the difference between FFS spending and the median bid is relatively small (less than $50). The experience in the MA program suggests that somewhere between 10 percent and 30 percent of the 8.7 million FFS enrollees in these areas might switch to a managed care plan.

FFS enrollees would have stronger incentives to switch to managed care plans in areas where FFS spending exceeded the median plan bid by more than $50. (This difference means that the monthly FFS premium in these areas would increase by at least that much.) A total of 15.7 million FFS enrollees live in these areas, and 10.8 million live in areas where the FFS premium would increase by more than $100 (Table 13-3, p. 125). This latter group of market areas includes many of the country's large metropolitan areas. The MA program has not seen premium increases of this magnitude, so its experience is of somewhat limited value in assessing how many FFS beneficiaries in these areas would switch to managed care plans. Nevertheless, it seems plausible that a majority—and possibly a sizable majority—of the 15.7 million FFS beneficiaries in these areas could eventually switch to managed care plans. In market areas where FFS premiums increase by particularly large amounts ($100 or more), the share of beneficiaries who were enrolled in FFS once premium support was in effect for several years could be relatively small.

In the areas where FFS spending exceeds the median plan bid, we could also see a substantial number of MA enrollees switch plans. Since the benchmark in these areas would be based on the median plan bid, about half of the 12.1 million MA enrollees in these areas would be in plans with bids that exceeded the benchmark. As a result, these plans—most of which now provide additional benefits funded by MA rebates and do not charge a supplemental

premium—would have to begin charging premiums (for both standard coverage and any additional benefits). Some beneficiaries in this subset of plans might want to change their coverage. Since the FFS premium would be even higher than their current plan's premium, some of these MA enrollees would most likely switch to other, lower cost plans.

Across all market areas, this rough analysis suggests that about 15 million FFS enrollees would ultimately switch to a managed care plan and 2 million MA enrollees might switch to FFS coverage. If these shifts occurred, more than half of Medicare beneficiaries (roughly 55 percent) would be enrolled in managed care plans, but a significant number of beneficiaries would remain in the FFS program.

These figures are very rough estimates at best and have little predictive value. There are simply too many other elements to a premium support system that would still need to be specified, beyond the illustrative framework in this chapter. For example, the ultimate impact of premium support on FFS and plan enrollment would depend partly on whether the use of premium support was phased in over time, how much premium subsidies would be for low-income beneficiaries, and the default form of coverage for beneficiaries who do not select coverage on their own. These and other policy decisions under a premium support system would have a significant impact on the behavioral responses by beneficiaries, plans, and providers.

Conclusion

The use of premium support for Part A and Part B would fundamentally change the structure of the Medicare program. Premium support would reorient the government's role in financing Medicare and require beneficiaries to pay for the added costs of more expensive coverage in the form of higher premiums. The Commission makes no recommendation on whether premium support should be used. Rather, we discuss an array of complex issues that the Congress may want to address if it decided to develop a premium support system. ■

Endnotes

1 The Part D program already uses a form of premium support. If policymakers decided to use premium support for Part A and Part B, they would need to decide whether the two systems should be combined or the Part D system would continue to operate separately.

2 Throughout this chapter, we use *managed care plan* as a generic term that encompasses any type of Medicare health plan operated by a private health insurance company. Most MA plans are either health maintenance organizations or preferred provider organizations, but a small share of MA enrollees (about 2 percent) are in private FFS plans, which do not "manage" their enrollees' care in any meaningful way. Under a premium support system, policymakers would need to decide what types of plans health insurers could operate.

3 For 2017, individuals who are not eligible for premium-free Part A coverage pay $227 per month if they have 30–39 quarters of Medicare-covered employment and $413 per month if they have fewer than 30 quarters of Medicare-covered employment. Very few individuals are in these two categories.

4 Beneficiaries must pay a higher Part B premium if they have higher income or did not enroll in Part B when they first became eligible. For beneficiaries with higher income, the Part B premium can be as much as $428.60 a month in 2017. For beneficiaries subject to the late enrollment penalty, the Part B premium is increased by 10 percent for each 12-month period that the beneficiaries did not have Part B coverage. In 2017, many beneficiaries actually pay a lower Part B premium than the base amount of $134 because the increase in the Part B premium for 2017 was larger than the increase in their Social Security benefits, and the increase in premium was capped at the amount of the increase in their Social Security benefits.

5 There is an option in the MA program for plans to collect the Part B premium.

6 By itself, the ability of some plans to provide the Medicare benefit package at a lower cost than the FFS program does not necessarily save the government money. The extent of any savings depends on the broader question of how Medicare pays managed care plans. For example, an MA plan that submits a bid that is lower than FFS spending may still receive payments that exceed FFS costs when factors such as rebates, quality bonuses, calculation of benchmarks, and diagnosis coding for risk adjustment are taken into account.

7 Policymakers may also want to consider how payments to disproportionate share (DSH) hospitals should be treated in a premium support system. DSH payments are currently included in FFS payment rates and MA benchmarks, but they could be broken out and paid separately (Medicare Payment Advisory Commission 2016a).

8 Because the beneficiary premium is risk standardized in this manner while the Medicare payment to the plan is based on the actual risk of each enrollee, the government payment is adjusted when the average risk score of plan enrollees is above or below 1.0. A "government premium adjustment" applies to ensure that the revenue from the fixed beneficiary premium combined with the revenue from the Medicare payment that varies by the actual risk scores of enrollees equals the plan's revenue requirements. Plans with enrollees who have an average risk score of 1.1, for example, would require an additional government payment to be made whole, while plans with an average risk score below 1.0 would have reduced government payments in recognition of the excess revenue coming from enrollee premiums that are set at a 1.0 risk level. The premium adjustment mechanism does mean that beneficiaries in plans with relatively lower risk scores would be subsidizing the premiums of beneficiaries in plans with higher average risk scores. This cross-subsidization also happens with the Part B premium today, which is set at a national level and does not vary despite regional differences in demographics, service use, price levels, or the risk status of beneficiaries (for example, in 2012, county FFS risk scores in the 50 states and the District of Columbia ranged from 0.68 to 1.40). A question that may need to be considered in a premium support system is whether premium adjustments would be exclusively *intra*-area adjustments or whether there would need to be *inter*-area adjustments if the intent is to have beneficiary premiums finance 25 percent of Part B program expenditures, as is currently the case.

9 The MA program does not allow cost sharing to vary on a disease-specific basis except through the formation of special needs plans (SNPs) for beneficiaries with chronic conditions and the CMS VBID demonstration project. The Commission has recommended permitting non-SNP MA plans to use VBID cost-sharing structures as a means of eliminating most SNPs for beneficiaries with chronic conditions (Medicare Payment Advisory Commission 2013b).

10 Because the basic benefit package of an MA plan must have cost sharing that is actuarially equal to FFS cost sharing, a plan that has a $20 copayment on a $200 physician visit (whereas FFS would have a $40 coinsurance) would have to raise cost sharing in some other way (such as imposing a deductible higher than Medicare's Part B deductible) to maintain actuarial equivalence with FFS—if the reduced copayment feature was the only difference between the plan's cost sharing and that of FFS.

11 If the additional charge was not enacted, the argument that the government should not finance the induced utilization that occurs in private plans—because it is not consistent with FFS Part A and Part B coverage—would be weaker because the government would also be subsidizing the induced utilization of FFS beneficiaries who have supplemental coverage.

12 For beneficiaries who enroll in managed care plans, CMS would need to adjust Medicare's payments to the plans to account for differences in health status. CMS makes such adjustments in both the MA and Part D programs.

13 MA plans can be either regional, serving CMS-specified regions that are composed of one or more states, or local, serving one or more counties. As of November 2015, more than 90 percent of MA enrollees were in local plans (Medicare Payment Advisory Commission 2016c). The Part D program conducts competitive bidding at the national level to establish its national average bid, base beneficiary premium, and Medicare contribution. However, the program also establishes a separate benchmark in each of its 26 regions that determines which plans will have their premiums fully covered by the program's low-income subsidy.

14 Policymakers could grant exceptions to certain managed care plans, such as those that are sponsored by providers that cannot easily serve an entire market area, particularly larger areas.

15 Under our illustrative approach that would set the benchmark equal to the lower of the FFS bid or the median plan bid, benchmarks in some market areas could conceivably be based on the lowest bid (for example, in areas where only one managed care plan is available and the plan's bid is lower than the FFS bid).

16 How much the benchmark would actually change if the FFS bid were compared with the lowest bid instead of the median bid (or the average bid or some other metric) would depend on the degree of variation in the bids submitted by managed care plans. If there was relatively little variation in the bids from the managed care plans, using one bid instead of another in the comparison with the FFS bid would have relatively little impact on the benchmark. Conversely, if there was substantial variation in the bids submitted by managed care plans, using one bid instead of another in the comparison with the FFS bid could have a much larger effect on the benchmark.

17 These figures are for FFS beneficiaries who have both Part A and Part B and use the hospital referral region as the geographic unit of analysis.

18 HEDIS is a registered trademark of the National Committee for Quality Assurance.

19 CAHPS is a registered trademark of the Agency for Healthcare Research and Quality.

20 The validity of using MA encounter data to calculate population-based quality measures for plans has not been tested.

21 CMS's authority to terminate plans based on their star rating is currently suspended.

22 The difference between the estimated and actual Part B premium amounts is also due to the fact that the actual Part B premium included an additional amount that is meant to bolster the reserves of the Supplementary Medical Insurance (Medicare Part B) Trust Fund.

23 There are a few exceptions to this general rule. Sponsors of MA plans may take individuals who have been enrolled in a non-Medicare plan, such as a Medicaid managed care plan or a commercial plan, and passively enroll them in one of their MA plans when those individuals first become eligible for Medicare. In addition, some states that are participating in CMS's financial alignment demonstration passively enroll new beneficiaries who are also eligible for Medicaid in integrated Medicare-Medicaid plans.

24 *Medicare Savings Programs* is an umbrella term for four distinct Medicaid programs that pay the Part A and Part B premiums and Medicare cost sharing for certain low-income beneficiaries. These programs have distinct eligibility rules and benefit packages (for example, only one program covers Medicare cost sharing). The federal government pays the full cost for one of the MSPs, known as the Qualifying Individual Program, using funds from the Medicare Part B trust fund. This section focuses primarily on MSP coverage of the Part B premium since that element would be the one most directly affected by the use of premium support.

25 Both programs have higher income and asset limits for couples. Medicare beneficiaries who receive full Medicaid benefits qualify for the LIS regardless of their income or assets.

26 The spending figure is for federal fiscal year (FY) 2015. Medicaid also spent $3.1 billion on Part A premium subsidies in FY 2015. The vast majority of Medicare beneficiaries do not pay premiums for Part A benefits because they have a sufficient work history. Beneficiaries who do not qualify for premium-free Part A coverage typically have low incomes, and Medicaid often pays their Part A premium.

27 Many researchers believe that the MCBS underreports beneficiaries' income, but how much that income is underreported is unclear. As a result, the survey likely overstates the number of beneficiaries with income below a given threshold (such as 200 percent of the federal poverty

level). We have adjusted the income amounts reported in the MCBS to account for this shortcoming, but figures from other researchers can differ. For example, the Kaiser Family Foundation estimated that about 33 percent of beneficiaries had income below 200 percent of the federal poverty level (Jacobson et al. 2017).

28 For 2017, between 3 and 10 zero-premium prescription drug plans are available in each region (Medicare Payment Advisory Commission 2017).

29 There are usually a number of zero-premium plans available. All of them qualify as low-cost plans under the LIS, but their overall costs vary. Although beneficiaries have an incentive to enroll in a zero-premium plan under this approach, they have no incentive to enroll in one of the lower cost zero-premium plans. This feature may reduce the incentives for Part D plans to submit low bids (Congressional Budget Office 2014).

30 Policymakers would also need to decide what would happen if these beneficiaries did not pay their portion of the premium. One option would be to automatically reassign these beneficiaries to zero-premium plans.

31 If an area has more than one zero-premium plan, CMS randomly assigns LIS beneficiaries among the available plans. This feature may reduce the incentives for drug plans to submit low bids—that is, once a plan has qualified as a zero-premium plan, any effort to submit a lower bid lowers the plan's revenue without any offsetting increase in the number of passive enrollments. Part D plans thus have an incentive to bid as close to the LIPSA benchmark as possible without going over it (Congressional Budget Office 2014).

32 This segment of the MSP population is known in Medicaid parlance as "qualifying individuals" (QIs). Although the federal match rate for QIs is 100 percent, the Congress also enacted annual caps on federal payments for QI benefits, which was a departure from Medicaid's traditional structure as an open-ended entitlement program. However, these caps have had little practical effect because the Congress has periodically raised them to accommodate growth in QI enrollment and the Part B premium.

33 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.

34 The other option that CBO examined based the government contribution on the second lowest plan bid.

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CHAPTER 4

Mandated report: Relationship between physician and other health professional services and other Medicare services

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Chapter summary

Section 101(a)(3) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directs the Commission to submit a report to the Congress on the relationship between use of and expenditures for services provided by physicians and other health professionals (whom we refer to as "clinicians") and total service use and expenditures under Part A, Part B, and Part D of Medicare. This study has two parts. One evaluates the relationship between beneficiaries' use of and Medicare program spending on clinician services and all services covered under Part A and Part B of Medicare. The other part of the study assesses the relationship between beneficiaries' use of and Medicare program spending on clinician services and use of and spending on prescription drugs (as measured by gross drug spending) covered under Medicare Part D. Because the legislation directs us to evaluate Medicare Part A, Part B, and Part D but not Part C (Medicare Advantage), we report on use and spending for the Medicare fee-for-service (FFS) population only.

A positive correlation between services provided by clinicians and all other Part A, Part B, and Part D services would suggest that the services may be complements (which means that, when considering two services, greater use of one service always correlates with greater use of the other service). Alternatively, clinician services and all other services covered under Part A, Part B, and Part D of Medicare may be substitutes if there is a negative correlation.

In this chapter

We found that spending for clinician services as a share of spending for all Part A and Part B services did not change much from 2008 through 2013, indicating that spending for clinician services and for all Part A and Part B services grew at about the same rate. We caution against placing a great deal of meaning on this result, which is based on raw, unadjusted expenditures, because payment rates in the Medicare physician fee schedule were increased at a lower rate than the payment rates in other Medicare payment systems.

We assert that comparisons of service use are more meaningful than comparisons of spending when evaluating whether a given service is a complement to or a substitute for clinician services. Our assertion is based on the fact that unadjusted Medicare spending reflects various price and payment adjustments, which would distort the relationship that may exist between the use of clinician and other services.

We estimated per capita service use in 2008 and 2013 for geographic areas that are based on metropolitan statistical areas (MSAs). We estimated service use for each geographic area by adjusting Medicare program spending for regional differences in Medicare prices and for beneficiary differences in demographics and health status. Our analysis of service use found the following:

- In the aggregate, use of clinician services as a share of all Part A and Part B services increased from 24.4 percent in 2008 to 26.3 percent in 2013. We based use of clinician services on a variable that uses claims from Medicare carriers (contractors that process Medicare claims) and includes all clinician claims plus claims from other sources such as ambulatory surgical centers and ambulance providers. We estimate that claims for clinician services account for about 90 percent of the Medicare spending on all carrier claims.
- For each of the geographic areas in our analysis, we estimated the percentage change from 2008 to 2013 in per capita use of clinician services and per capita use of all Part A and Part B services. We found a moderately positive correlation between these two measures. However, when we removed clinician services from use of all Part A and Part B services, we found a weaker (almost neutral) relationship between percentage change in clinician services and percentage change in all other Part A and Part B services.
- Among geographic units in our analysis, there was a moderately positive correlation in 2013 between per capita use of clinician services and per capita use of all Part A and Part B services. However, we also found that the correlation between per capita use of clinician services and per capita use of all

Part A and Part B services with clinician services excluded was weak and not statistically significant. This finding implies that increasing clinician services had little or no effect on use of all other services.

In our assessment of use and spending from 2008 to 2013 for clinician services and Part D drugs, we found that Medicare spending on services covered under the physician fee schedule and on drugs covered under the Part D benefit grew at similar rates. However, because the two sectors use different payment methods, a similar growth in spending does not necessarily reflect comparable growth in service use.

For a subset of FFS beneficiaries who receive their drug coverage through the Part D program, we used a regression-based method to examine the relationship between the level of and growth in clinician service use and drug use (drug spending adjusted for regional variation in prices, demographic characteristics, and health status) across the MSA-based geographic areas.

Our analysis for the years 2008 and 2013 found weak to modest correlations between the clinician and Part D service use:

- In both years, clinician service use was positively correlated with drug use; that is, areas with high (or low) clinician service use tended to have high (or low) drug use.
- The change in clinician service use was negatively correlated with the area's change in drug use.

The estimated changes were generally small in magnitude and the regression models explained very little of the variation observed across geographic areas.

In summary, our findings suggest that clinician services and other services are neither clear complements nor substitutes. There are a few caveats in interpreting these findings. First, findings of correlation (or no correlation) of service use among different sectors do not prove or disprove causality. Second, our results are based on aggregate trends and do not represent any individual circumstances or specific geographic areas. An examination at a more disaggregated level may reveal different relationships from those observed at the aggregate level. ■

Section 101(a)(3) of the Medicare Access and CHIP Reauthorization Act of 2015

(3) MEDPAC REPORTS.—

(A) INITIAL REPORT.—Not later than July 1, 2017, the Medicare Payment Advisory Commission shall submit to Congress a report on the relationship between—

(i) physician and other health professional utilization and expenditures (and the rate of increase of such utilization and expenditures) of items and services for which payment is made under section 1848 of the Social Security Act (42 U.S.C. 1395w–4); and

(ii) total utilization and expenditures (and the rate of increase of such utilization and expenditures) under parts A, B, and D of title XVIII of such Act. Such report shall include a [method] to describe such relationship and the impact of changes in such physician and other health professional practice and service ordering patterns on total utilization and expenditures under parts A, B, and D of such title.

(B) FINAL REPORT.—Not later than July 1, 2021, the Medicare Payment Advisory Commission shall submit to Congress a report on the relationship described in subparagraph (A), including the results determined from applying the [method] included in the report submitted under such subparagraph. ■

Background

Section 101(a)(3) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directs the Commission to submit a report to the Congress on the relationship between beneficiary use of and Medicare spending on services provided by physicians and other health professionals and total service use and Medicare spending under Part A, Part B, and Part D of Medicare. MACRA directs the Commission to submit an initial report no later than July 1, 2017, and a final report no later than July 1, 2021 (see text box). In the interest of brevity, throughout this report, we use the term *clinicians* to mean physicians and other health professionals.

This chapter has two broad parts. The first assesses the relationship between beneficiaries' use of and Medicare spending on (1) clinician services and (2) all services covered by Part A and Part B of Medicare. The second part assesses the relationship between beneficiaries' use of and Medicare spending on (1) clinician services and (2) Part D drugs. Section 101(a)(3) of MACRA specifies that we evaluate Part A, Part B, and Part D of Medicare but not Part C (Medicare Advantage). Therefore, our analysis reports on service use and spending for the Medicare fee-for-service (FFS) population only.

Evaluating spending on and use of clinician services relative to all Part A and Part B services

Spending and service use are different measures. In this study, spending represents monetary outlays by the Medicare program. Service use reflects volume of services (how many) and the intensity of those services (long office visits have higher service use than short office visits). We derived service use by adjusting spending amounts for regional differences in the prices that Medicare sets for Part A and Part B services and for differences in demographics and health status among beneficiaries.

Data and methods

In our analysis of the relationship between Medicare spending on clinician services and on all Part A and Part B services, we used data from the Medicare Trustees' annual reports on the status of the Medicare program (Boards of Trustees 2014, Boards of Trustees 2013, Boards of Trustees 2004). We extracted data on the annual expenditures that Medicare made from 1993 through 2013 on clinician services and all services covered under Part A and Part B of Medicare for beneficiaries in FFS Medicare.

In our analysis of service use, we used beneficiary-level program spending in FFS Medicare from the Master

Beneficiary Summary Files (MBSFs) from 2008 and 2013 and claims data from the Medicare Provider and Review (MedPAR) files from 2008 and 2013. We analyzed these data at both the national level and at the level of geographic areas that are based on metropolitan statistical areas (MSAs). For beneficiaries residing in MSAs, the geographic areas we used in this study consisted of counties that are in the same state and same MSA. For beneficiaries not residing in MSAs, our geographic areas consisted of all of their state's counties not in MSAs. For example, the St. Louis, MO, MSA has 15 counties. Eight are in Illinois, and seven are in Missouri. The eight Illinois counties formed one of our geographic areas, and the seven Missouri counties formed another geographic area. The counties in Missouri that are not in an MSA formed a statewide, nonmetropolitan geographic area. In total, our study had 484 geographic areas.

We estimated service use at the national level and for each geographic area in both 2008 and 2013 by adjusting Medicare expenditures for geographic differences in wages and special payments to hospitals and clinicians. We also adjusted for differences in beneficiaries' demographics and health status.

We made these adjustments to the spending data to obtain estimated service use. Medicare pays different prices in different geographic locations to account for higher costs in one location compared with another. For example, wages for nurses are much higher in New York City than in Little Rock, AR. Also, Medicare makes special payments to hospitals and clinicians, such as payments for indirect graduate medical education, which are not evenly distributed across geographic areas. We made adjustments to remove the effects of these special payments across geographic areas. We also needed to adjust for differences in beneficiaries' demographics and health status so that service use reflected volume and intensity of services, not differences among beneficiaries themselves that can affect service use.

We transformed the Medicare expenditures into a measure of service use by removing the effects of:

- geographic differences in wages;
- additional payments to hospitals above the standard payment rates in the inpatient prospective payment system (IPPS), which include graduate medical education, indirect medical education, and disproportionate share payments;
- additional payments to clinicians above the standard rates in the physician fee schedule (PFS), which include primary care incentive payments, adjustments for having a system of electronic health records, and additional payments in health provider shortage areas; and
- additional payments to critical access hospitals that are above standard rates in the IPPS, the outpatient prospective payment system, and the skilled nursing facility payment system.

We also adjusted for demographics and health status. We conducted a beneficiary-level regression analysis using data for 100 percent of Medicare FFS beneficiaries to estimate service use for each geographic area in 2013. We used data from 2008 in the same regression-based approach to estimate service use for each geographic area in 2008. Our data from 2013 included about 37.7 million beneficiaries, and our data from 2008 included about 35.5 million beneficiaries. The regression-based method we used for this analysis is summarized in the text box about adjusting Part A and Part B spending data.

Relationship between spending on clinician services and spending on all Part A and Part B services

Data from the Medicare Trustees' annual reports indicate that the share of Medicare spending on all Part A and Part B services in FFS Medicare that was attributable to clinician services has fluctuated over the 1993 through 2013 period (Table 4-1, p. 146). Two important facts are that (1) the clinician share of total expenditures for Part A and Part B services was about 19.1 percent in both 1993 and 2013 and (2) there was only a small change in the clinicians' share of the total from 19.3 percent in 2008 to 19.1 percent 2013.

We caution against placing a great deal of meaning on the results that are based on raw, unadjusted expenditures. In particular, Medicare uses different methods for annually updating the payment rates in different health care sectors. For example, payment rates in the PFS had very small updates over the 2008 through 2013 period relative to the other sectors such as hospital outpatient services. The relatively small updates that have occurred in the PFS mitigate the share of total Medicare expenditures that is attributable to clinician services simply because prices rose more slowly for clinician services than for other services. For example, if payment rates in the PFS had been updated over the 2008 through 2013 period at the same rate as

Adjusting Part A and Part B spending data to measure Part A and Part B service use

We used the same method to estimate use of Part A and Part B services in both 2008 and 2013 for the geographic areas in our analysis. To obtain these estimates, we used data from the Master Beneficiary Summary Files (MBSFs) and, for hospital inpatient services, the Medicare Provider Analysis and Review (MedPAR) file. We developed geographic areas based on metropolitan statistical areas (MSAs) of the core-based statistical area definitions. For each state, we collected counties that are in the same MSA into a geographic area. For MSAs that cross state borders, we created geographic areas that included only the portion of the MSA in each state. For example, the Minneapolis–Saint Paul MSA consists of 16 counties in Minnesota and 4 counties in Wisconsin. We created one geographic area for the 16 Minnesota counties and a separate geographic area for the 4 Wisconsin counties. Finally, within each state, we collected all of the counties that are were not in an MSA into a single statewide, non-MSA geographic area. The result was 484 geographic areas.

We used the MBSF data to determine Medicare expenditures in six health care sectors: hospital outpatient, skilled-nursing facility, home health, durable medical equipment, hospice, and clinician services. Our computation of Medicare program spending did not include beneficiaries' payments for cost sharing. We tracked the data to each beneficiary's area of residence, not to where the services were provided.

For all services other than hospital inpatient care, we obtained beneficiary-level spending data from the MBSFs for both 2008 and 2013. We adjusted the spending data in the MBSFs for geographic differences in regional prices, including geographic practice cost indexes (GPCIs) for clinicians and hospital wage indexes (HWIs) for all other providers. We also adjusted spending for additional payments to clinicians in health professional service areas, clinicians who established electronic health record systems, and clinicians who received primary care incentive payments. Moreover, we adjusted for special outpatient and skilled nursing payments for critical access hospitals. We removed the effects that these special payments had on variation in spending by calculating the national per beneficiary amount of these special payments and adding it to each beneficiary's service use.

For a given beneficiary, we used the GPCIs and HWIs from where the beneficiary resides to adjust that spending. However, beneficiaries sometimes receive health care in geographic areas other than their area of residence. In some cases, the GPCIs and HWIs of where a beneficiary receives health care are different from the GPCIs and HWIs of where he or she resides. We did not address this issue of border crossing for services in the six sectors included in the MBSFs. This approach could result in some overestimation of service use in rural areas if patients received their ambulatory care or post-acute care in higher priced urban areas. However, we believe this issue is small for these services, relative to inpatient services, especially with regard to clinician services. For example, it is plausible that patients are less likely to travel long distances for clinician services than for inpatient care. In addition, the payment areas represented by GPCIs (89 payment areas) in the physician payment system tend to be larger than the payment areas in the inpatient payment system (about 430).

We used the MedPAR file to compute service use for hospital inpatient care. For each inpatient claim in the MedPAR file, we multiplied the relative weight for the claim's diagnosis related group by the national standardized rate to create an estimated payment for the claim that excludes the effects of adjustments for regional prices. We summed these results from the claims to the beneficiary level to create an estimate of adjusted inpatient service use for each beneficiary. Some hospitals received additional payments in the form of payments for graduate medical education, indirect medical education, and treatment for disproportionate shares of low-income patients. We removed the effects that these special payments had on variation in spending by calculating the national per beneficiary amount of these special payments and adding it to each beneficiary's adjusted inpatient service use. Finally, we adjusted the inpatient service use to include outlier payments and adjustments for transfer

(continued next page)

Adjusting Part A and Part B spending data to measure Part A and Part B service use (cont.)

cases. For outlier adjustments, we removed the effects of regional differences in input prices.

We used claims data from the MedPAR file as the source for inpatient services because beneficiaries frequently obtained care in locations where the HWI used to adjust inpatient payments for geographic differences in wages was different from the HWI of their area of residence. Use of the claims data allowed us to adjust beneficiaries' inpatient spending using the HWIs where their services were provided. If we had used spending on inpatient services from the MBSF, we would have had to adjust that spending for the border crossing that occurs more often with inpatient care than other service types. Adjusting for border crossing would have been more difficult than using our method based on the inpatient claims from the MedPAR file.

To estimate total price-adjusted spending for each beneficiary, we added the price-adjusted inpatient spending derived from the claims to the price-adjusted spending for the six health care sectors from the MBSF. One of the sectors from the MBSF, clinician services, was actually a combination of services provided by physicians and other health professionals, ambulatory surgical centers (ASCs), and ambulance providers, which are on claims from Medicare carriers (contractors that process Medicare claims). We used the services from the carrier claims (which we will call "carrier services") as a proxy for clinician services because we were not able to derive a specific category for expenditures on clinician services from the MBSFs in 2008.

We estimated that Medicare expenditures for clinician services (including Part B drugs) were about 90 percent of Medicare expenditures for physicians, other health professionals, ASCs, and ambulance providers. Most of the remaining share is heavily affected by clinicians' decisions, such as use of anesthesia and ASCs, so we viewed expenditures on carrier services as an acceptable proxy for expenditures on clinician services. We price adjusted the expenditures on physicians, other health professionals, ASCs, and ambulance services to create a price-adjusted proxy for clinician services. We created monthly price-adjusted total spending and monthly price-adjusted spending in each health care sector for each beneficiary by dividing the price-adjusted amounts

(continued next page)

payment rates in the outpatient prospective payment system had been, then clinician services as a share of all Part A and Part B services would have been more than 19.1 percent in 2013 (assuming no effect on the volume of clinician services provided).

Relationship between use of clinician services and use of all Part A and Part B services

We used several measures to evaluate the relationship between use of clinician services and use of all Part A and Part B services. These measures are described as follows:

- We determined the change from 2008 to 2013 in the share of all Part A and Part B service use that is attributable to use of clinician services.
- For each geographic area, we determined the per capita use of clinician services and per capita use of all Part A and Part B services in 2008 and 2013. We used these results to determine for each geographic area the percentage change from 2008 to 2013 in the use of clinician services and use of all Part A and Part B services.
    - We determined the correlation between the percentage change in use of clinician services and use of all Part A and Part B services among our geographic areas. A positive correlation between the percentage change in use of clinician services and percentage change in use of all Part A and Part B services would suggest that higher use of

Adjusting Part A and Part B spending data to measure Part A and Part B service use (cont.)

by the number of months the beneficiary participated in fee-for-servce (FFS) Medicare.

We then adjusted the price-adjusted spending amounts for regional differences in demographics and health status using a regression-based method. We performed a separate set of regressions for the 2008 data and the 2013 data. In both years, we performed a regression for price-adjusted total spending and regressions for price-adjusted spending in each of the health care sectors. In each regression, the dependent variable was a beneficiary's monthly FFS spending that had been adjusted for regional prices and additional payments. Explanatory variables included:

- demographic variables, such as age and sex;
- all 70 conditions in CMS's hierarchical condition category (CMS–HCC) model, which CMS used to risk adjust Medicare Advantage payments in 2008 and 2013;
- other beneficiary-level factors in the CMS–HCC model, such as disability, dual-eligible, and institutional status; and
- an indicator of the beneficiary's geographic area as defined for this study.

The regressions produced coefficients for the demographic variables, the 70 conditions, the other factors in the CMS–HCC model, and the 484 geographic areas.

We used results from the regressions to estimate both per capita total service use and per capita service use for each health care category in each geographic area as follows:

- We created national average spending amounts by multiplying each coefficient estimate—except for the indicators for the geographic areas—by the mean value of each variable and summing these products. These calculations had the effect of removing the variation in service use resulting from the population characteristics, such as demographics and health status.
- We added the coefficient for each geographic area from the regressions to the national average spending amounts. The result is our measure of service use for each geographic area.
- We used this process for total Part A and Part B services and for service use in each health care sector. ■

clinician services is associated with higher use of Part A and Part B services.

- There is a concern about "circularity" when evaluating the correlation between change in clinician services and change in all Part A and Part B services because clinician services are a large part of all Part A and Part B services. An increase in clinician services will raise the likelihood that all Part A and Part B services also increase. Therefore, we also examined the correlation between the percentage change in clinician services and the percentage change in all Part A and Part B services net of the clinician services.
- For 2013, we estimated the correlation between use of clinician services and use of all Part A and Part B services among our geographic areas. A positive correlation would suggest that greater use of all services is related to greater use of clinician services. We also estimated the correlation between use of clinician services and use of all Part A and Part B services, net of the clinician services.

A shortcoming in our data is that the 2008 MBSF does not have the data configured so that we can determine use of clinician services at the level of our geographic areas. However, we were able to approximate use of clinician services through carrier claims, which are claims for services provided by physicians, physician assistants, clinical social workers, nurse practitioners, independent

TABLE 4–1

Medicare spending on clinician services in FFS Medicare as a share of all Part A and Part B services fluctuated, 1993–2013

Year	Medicare spending (in billions of dollars)		Clinician services as a share of Part A and Part B services
	Clinician services	Part A and Part B services	
1993	$26.3	$138.0	19.1%
1994	28.8	150.3	19.2
1995	31.7	167.9	18.9
1996	31.6	175.7	18.0
1997	31.9	183.0	17.4
1998	32.4	181.6	17.8
1999	33.4	176.3	18.9
2000	37.0	182.0	20.3
2001	42.0	202.1	20.8
2002	44.8	223.8	20.0
2003	48.3	238.8	20.2
2004	54.1	262.7	20.6
2005	57.7	281.6	20.5
2006	58.1	289.8	20.0
2007	58.8	298.0	19.7
2008	60.6	313.3	19.3
2009	61.8	328.5	18.8
2010	63.9	337.6	18.9
2011	67.5	350.0	19.3
2012	69.5	362.2	19.2
2013	68.6	358.7	19.1

Note: FFS (fee-for-service). "Medicare spending" is the amount spent by the Medicare program excluding beneficiaries' cost sharing. The spending amounts are for services provided to beneficiaries in FFS Medicare and exclude services to beneficiaries in Medicare Advantage.

Source: Annual reports of the Boards of Trustees of the Medicare trust funds, 2004, 2013, and 2014.

clinical laboratories, ambulance providers, and ambulatory surgical centers. We estimated that clinician services (including Part B drugs) account for about 90 percent of the expenditures on carrier claims, and most of the remaining share is heavily influenced by clinicians' decisions such as use of anesthesia and ambulatory surgical centers. Therefore, the use of all services from carrier claims (which we will call "carrier services") is our proxy for the use of clinician services.

Variation in use of all Part A and Part B services across regions is less than the variation in use of clinician services

A comparison of service use from 2013 across our geographic areas shows that use of all Part A and Part B services varied less than use of carrier services (Table 4-2). For example, use of Part A and Part B services was 24 percent higher at the 90th percentile than at the 10th percentile. In comparison, use of carrier services was 51 percent higher at the 90th percentile than at the 10th percentile. At the extremes, use of Part A and Part B services was 1.76 times higher in the highest use area than in the lowest use area, while use of carrier services was 2.48 times higher in the highest use area than in the lowest use area.

Use of clinician services as a share of all Part A and Part B services, 2008 compared with 2013

We found that, in 2013, per capita use of carrier services was 26.3 percent of the per capita use of all Part A and Part B services. In 2008, use of carrier services was

TABLE 4–2

Use of Part A and Part B services had less regional variation than use of carrier services, 2013

Measure of variation	Part A and Part B service use	Carrier service use
Ratio of 90th to 10th percentile	1.24	1.51
Ratio of maximum to minimum	1.76	2.48
Average distance from the mean, as a percent of the mean	0.065	0.138

Note: We used services from carrier claims as a proxy for clinician services. "Part A and Part B service use" is per capita use in each geographic area of all services covered under Part A and Part B of Medicare. "Carrier service use" is per capita use of carrier services in each geographic area. We defined geographic areas as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, we divided the MSA into multiple areas based on state borders. For areas that are not in MSAs, the geographic area is all of a state's counties that are not in MSAs.

Source: MedPAC analysis of the 2013 Master Beneficiary Summary File and the 2013 Medicare Provider and Review file.

24.4 percent of the use of all Part A and Part B services. Therefore, carrier services increased as a share of all Part A and Part B services over the 2008 through 2013 period (Table 4-3).[1]

For 2008 and 2013, we also divided the total service use into 10 sectors. We found that the outpatient facilities sector had the largest service use increase from 2008 through 2013, and carrier services had the second largest increase. At the same time, the acute inpatient sector had the largest decrease in services over that period (Table 4-3). These results are consistent with the shift of services from hospital inpatient care to ambulatory settings.

Correlation between percentage change in use of clinician services and use of all Part A and Part B services

We performed a linear regression that had as the dependent variable the percentage change from 2008 to 2013 in per capita Part A and Part B service use for each geographic

TABLE 4–3

Use of carrier services as a share of all Medicare Part A and Part B services increased from 2008 to 2013

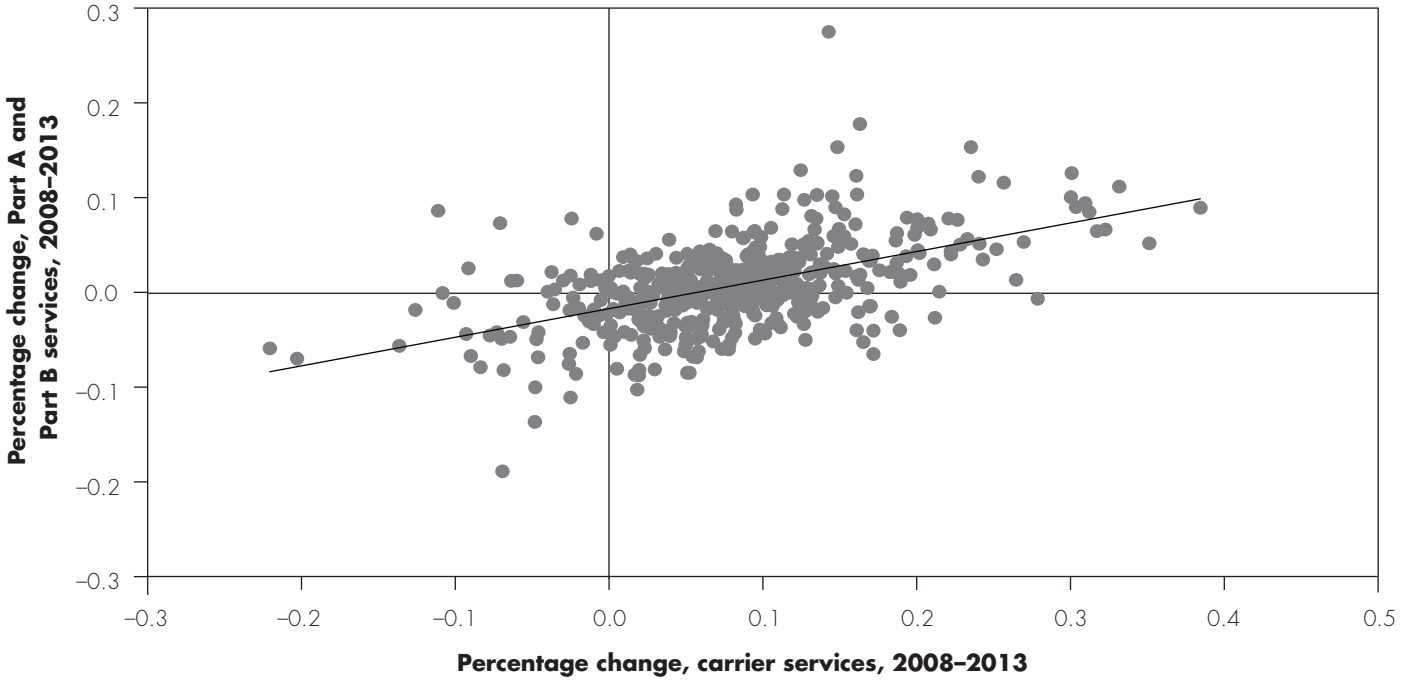
	Share of all Part A and Part B services	
Sector	2008	2013
Carrier	24.4%	26.3%
Acute inpatient	39.6	36.1
Outpatient facilities	10.4	12.5
Durable medical equipment	2.8	2.2
Hospice	4.1	4.3
Skilled nursing facility	8.4	8.1
Home health agency	5.4	5.8
Inpatient psychiatric facility	1.1	1.0
Inpatient rehabilitation facility	1.7	1.7
Long-term care hospital	2.1	2.1

Note: We used services from carrier claims as a proxy for clinician services. We deflated our 2013 service use estimates to 2008 levels to remove the effects of payment updates that occurred over the 2008 through 2013 period. Outpatient facilities consist primarily of hospital outpatient departments but also include freestanding dialysis facilities, outpatient rehabilitation facilities, and rural health clinics.

Source: MedPAC analysis of data from the 2008 and 2013 Master Beneficiary Summary Files and the 2008 and 2013 Medicare Provider and Review files.

FIGURE 4–1

Moderately positive relationship between percentage change in use of carrier services and percentage change in use of all services, 2008–2013



Note: We used services from carrier claims as a proxy for clinician services. We deflated our 2013 service use estimates to 2008 levels to remove the effects of payment updates that occurred over the 2008 through 2013 period. We defined the units of analysis as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, we divided the MSA into multiple areas based on state borders. For counties that are not in MSAs, the unit of analysis is all of a state's non-MSA counties.

Source: MedPAC analysis of data from the 2008 and 2013 Master Beneficiary Summary Files and the 2008 and 2013 Medicare Provider and Review files.

area. This regression had one explanatory variable: The percentage change from 2008 to 2013 in per capita use of carrier services for each geographic area (using all services from carrier claims as a proxy for clinician services).

Results from this regression indicate that the percentage change in carrier services explains 27 percent of the variation in the percentage change in all Part A and Part B services among geographic areas ($R^2 = 0.27$). Also, the coefficient on percentage change over time in carrier services was 0.30, which indicates a 1 percentage point increase in carrier services resulted in a 0.30 percentage point increase in the use of all Part A and Part B services, on average.

However, we are concerned about the "circularity" of this regression because carrier services are a substantial share of total Part A and Part B services. An area that has a relatively large increase in use of carrier services will tend to have a larger increase in total Part A and Part B services than an area that has a lower increase in carrier services. Therefore, we created a new variable for each geographic area—Part A and Part B service use minus carrier service use—that we will call "net Part A and Part B services."

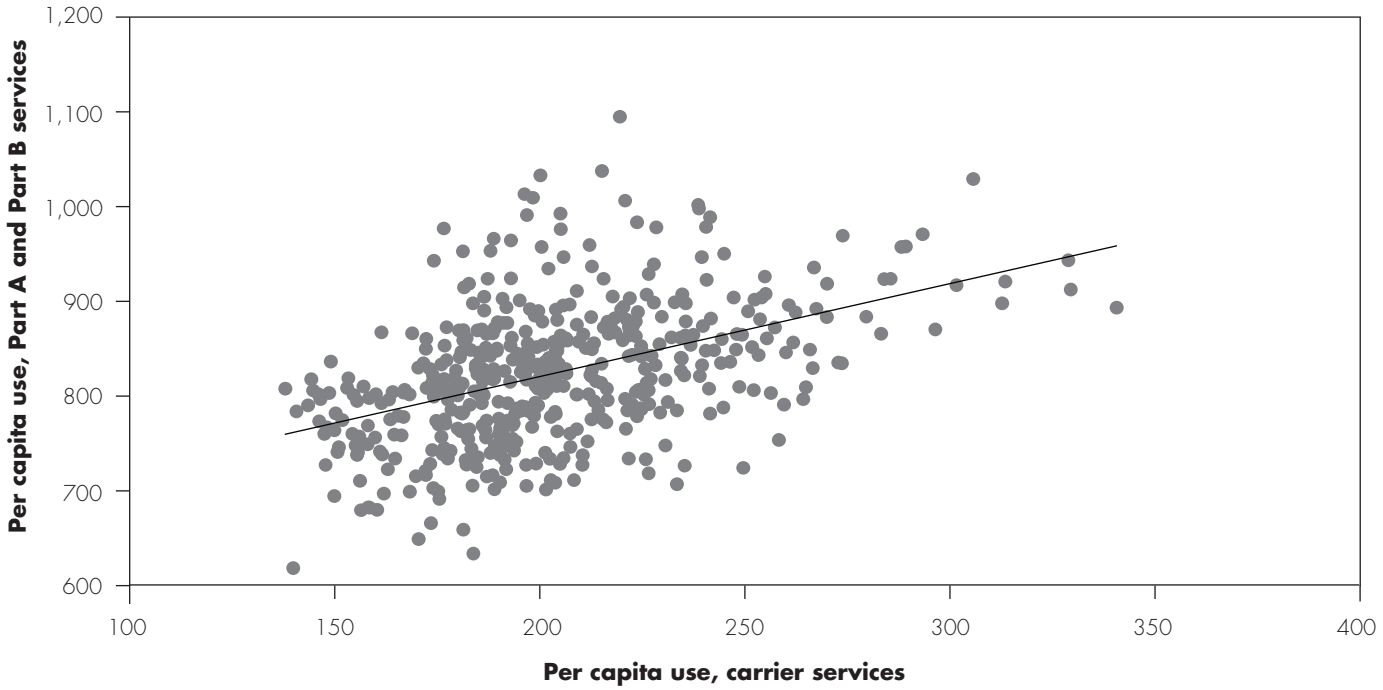
We performed a second regression that had as the dependent variable the percentage change in per capita net Part A and Part B service use over the 2008 through 2013 period. The explanatory variable was the same as in the first regression: percentage change over 2008 through 2013 in per capita use of carrier services.

Results from this second regression indicate a weak positive relationship that is nearly neutral (neither positive nor negative) between the percentage change in use of carrier services and percentage change in net Part A and Part B services. The R^2 is 0.03, and the coefficient on percentage change in use of carrier services is 0.14.

In summary, the first regression indicates that an increase in use of carrier services is associated with an increase in

FIGURE 4–2

Moderately positive relationship between use of carrier services and use of Part A and Part B services, 2013



Note: We used services from carrier claims as a proxy for clinician services. We define our units of analysis as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, the MSA is divided into multiple areas based on state borders. For counties that are not in MSAs, the unit of analysis is all of a state's non-MSA counties.

Source: MedPAC analysis of data from the 2013 Master Beneficiary Summary File and the 2013 Medicare Provider and Review file.

use of all Part A and Part B services over the 2008 through 2013 period. Figure 4-1 depicts the relationship between the percentage change in use of carrier services and the percentage change in all Part A and Part B services. Although the relationship is not strong, Figure 4-1 clearly demonstrates a positive relationship. However, the second regression shows that, after removing the carrier services from total Part A and Part B services, there is a weak (nearly neutral) relationship between change in carrier services and change in all other Part A and Part B services. A scatter plot (not shown) confirms the low correlation.

Correlation between use of clinician services and use of all Part A and Part B services

We performed two more regressions in this part of our analysis. In the first of these regressions, the dependent variable was our estimate of the per capita use of all Part A and Part B services in 2013 for each of our 484 geographic areas. The single explanatory variable was our estimate of per capita use of carrier services in 2013 for each geographic area, using services from carrier claims as a proxy for clinician services.

Results from this regression indicate that use of carrier services explains about 21 percent of the variation in use of all Part A and Part B services ($R^2 = 0.21$), and that a 1-unit increase in carrier services increases use of all Part A and Part B services by 0.88 units. These results indicate a moderately positive correlation between use of carrier services and use of all Part A and Part B services.

Figure 4-2 depicts the relationship between use of carrier services and use of all Part A and Part B services. Among our geographic areas, there was a moderately positive relationship between carrier services and all Part A and Part B services. However, much of the variation in the use of Part A and Part B services is not explained by the use of carrier services. If the relationship were stronger, the data points in Figure 4-2 would be more tightly clustered

TABLE 4–4

Part D enrollment and characteristics of beneficiaries enrolled in stand-alone PDPs, 2008 and 2013

	2008	2013
Medicare beneficiaries enrolled in Part D	27.5	37.8
Number of beneficiaries (in millions)	58%	69%
As a share of all Medicare beneficiaries		
Part D enrollees in PDPs		
Number of beneficiaries (in millions)	18.6	24.2
As a share of all Part D enrollees (remainder in MA–PDs)	68%	64%
As a share of FFS beneficiaries	50%	61%
Selected demographic characteristics of PDP enrollees		
Share:		
Female	61%	58%
Under age 65 (disabled)	27	22
Non-White	24	23
Receiving Part D's low-income subsidy	48	38
Residing in metropolitan areas	74	78

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), FFS (fee-for-service).

Source: MedPAC analysis of Medicare Part D denominator file from CMS.

around a straight line going through the center of the data points.

Once again, we were concerned about the circularity in the relationship between use of carrier services and use of all Part A and Part B services. Therefore, we performed another regression that had per capita use of Part A and Part B services net of carrier services in 2013 for each geographic area as the dependent variable. The single explanatory variable was per capita use of carrier services in 2013 for each geographic area.

Results from this regression indicated an almost neutral relationship between use of carrier services and use of net Part A and Part B services. Carrier services explain almost none of the variation in net Part A and Part B services ($R^2 = 0.005$), and the coefficient on per capita use of carrier services was not significantly different from zero at the 10 percent level. A scatter plot of the relationship between use of carrier services and use of net Part A and Part B services confirmed a very low level of correlation (not shown). This finding suggests that use of carrier services has little effect on the use of other Part A and Part B services.

Relationship between use and spending for clinician services and Part D drugs

As requested in MACRA, we examined the relationship between use and spending for clinician services relative to use and spending for prescription drugs covered under Medicare Part D.

The majority of Medicare beneficiaries receive their prescription drug coverage through Part D (Medicare Payment Advisory Commission 2016). Most other beneficiaries have prescription drug coverage from other sources, such as their former employers, that is at least as generous as the Part D benefit, but we have no drug spending data for those beneficiaries.

For this analysis, we limit our study sample to beneficiaries for whom we have both medical claims and prescription drug spending data. That is, our analysis examined a subset of beneficiaries who were enrolled in Part D's stand-alone prescription drug plans (PDPs) and received their medical services under Part A and Part B of

TABLE 4–5

Similar growth in unadjusted per capita spending on services paid under the physician fee schedule and Part D drugs from 2008 to 2013

	2008	2013	Percent change 2008–2013
Physician fee schedule payment per FFS enrollee	$1,836	$2,042	11%
Gross Part D spending per PDP enrollee	2,805	3,096	10

Note: FFS (fee-for-service), PDP (prescription drug plan). "Gross drug spending" includes payments for ingredient costs, dispensing fees, and sales taxes.

Source: MedPAC analysis based on Table IV.B2 of the annual report of the Boards of Trustees of the Medicare trust funds for 2016 and Part D prescription drug event data and denominator files from CMS.

Medicare.[2] Beneficiaries enrolled in Medicare Advantage–Prescription Drug plans (MA–PDs) were excluded from our analysis because we do not have medical claims data for them. PDP enrollees accounted for about 68 percent (18.6 million) and 64 percent (24.2 million) of Part D enrollees in 2008 and 2013, respectively (Table 4-4).

Data and methods

The method we used to estimate drug use in each geographic area parallels the method used to estimate medical service use from the MBSF. We obtained estimates of prescription drug use from Part D prescription drug event (PDE) data.[3] For our analysis, we used gross drug spending from the PDE data that reflects ingredient costs—that is, payments to pharmacies for covered drugs, excluding dispensing fees, sales tax, and any retrospective rebates and discounts from manufacturers and pharmacies. (This measure of Part D drug spending and use differs from those used to measure spending and service use covered under Part A and Part B in that it includes beneficiary cost sharing.) Because there are no special payment adjustments (such as indirect medical education) as in Part A and Part B of Medicare, we calculated drug use as the gross drug spending adjusted for regional difference in prices and in beneficiary demographic characteristics and health status; after adjustment, it reflects volume (number of prescriptions) and intensity (choice of medications such as brand name versus generic drugs).[4]

We obtained the average monthly drug use (adjusted spending) for each beneficiary by dividing total annual drug use for each beneficiary by the number of months enrolled in a Part D plan. To measure the change in drug use from 2008 to 2013, we adjusted the 2013 drug spending to account for the average increase in drug prices observed between 2008 and 2013.[5]

We used a regression-based method to obtain estimated service use by adjusting for area-specific effects, differences in demographic characteristics (e.g., age, gender, institutionalized status, low-income subsidy status), and health status as measured by the prescription drug hierarchical condition categories (see text box on regression-based method used to obtain estimated use of Part A and Part B services, pp. 143–145).

Findings on the relationship between clinician services and Part D drugs

The share of Medicare FFS beneficiaries covered under Part D has grown over time, as has the share of enrollees in MA–PDs (Table 4-4). Changes in the pattern of Part D enrollment have resulted in PDP enrollees who have somewhat different demographic characteristics in 2013 compared with 2008. For example, in 2013, a smaller share of PDP enrollees were disabled beneficiaries under age 65 (22 percent, compared with 27 percent in 2008), and a smaller share received the low-income subsidy in 2013 (38 percent, compared with 48 percent in 2008).

Similar growth in unadjusted per capita spending for both clinician services and Part D drugs from 2008 to 2013

From 2008 through 2013, unadjusted per capita spending on services covered under the physician fee schedule (clinician services) and spending for drugs covered under the Part D benefit grew at similar rates. During this period, Medicare's total annual spending per FFS enrollee for clinician services increased by 11 percent, from $1,836 to $2,042 (Table 4-5). During the same period, annual gross Part D spending per PDP enrollee increased by 10 percent, from $2,805 to $3,096.

TABLE 4–6 **Drug use had less regional variation than carrier service use, 2013**

Measure of variation	Drug use	Carrier service use
Ratio of 90th to 10th percentile	1.23	1.49
Ratio of maximum to minimum	1.89	2.30
Average distance from the mean (per member per month)	$20	$35

Note: "Drug use" is per capita drug use among stand-alone prescription drug plan enrollees in each geographic area. "Carrier service use" is per capita use of carrier services among fee-for-service (FFS) beneficiaries in each geographic area. We define geographic areas as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, we divided the MSA into multiple areas based on state borders. The measures of variation reported for carrier service use differ slightly from those reported in Table 4-2 (p. 147) because the measures are based on carrier service use by a subset of FFS beneficiaries who were enrolled in Part D (about 61 percent of all FFS beneficiaries).

Source: MedPAC analysis of the 2013 Master Beneficiary Summary File and 2013 prescription drug event data from CMS.

However, because the two sectors use different payment methods, similar growth in spending does not necessarily reflect comparable growth in service use. In particular, various adjustments applied to payments for clinician services could distort the relationship that may exist between the use of carrier services and the use of drugs under Part D.

Drug use varied less than clinician service use across regions

In our analysis of use of clinician services and use of drugs, we adjusted spending data to remove the effects of regional differences in prices and population characteristics and of special payments to providers (in the case of clinician services) to examine the relationship between carrier service use and drug use among beneficiaries enrolled in PDPs. As we did in our analysis of the relationship between use of clinician services and use of all Part A and Part B services, we used carrier services as a proxy for clinician services.

A comparison of service use across our 484 geographic areas shows that drug use (drug spending adjusted for variations in prices, demographic characteristics, and health status) varied less than use of carrier services in 2013 (Table 4-6).[6] For example, drug use in high-use areas (areas at the 90th percentile) was 23 percent higher than in low-use areas (areas at the 10th percentile). In comparison, carrier service use in high-use areas was 49 percent higher than in low-use areas. At the extremes, drug use in the highest use area was about 1.89 times that in the lowest use area compared with 2.30 times for carrier service use. Results were similar for 2008 (Medicare Payment Advisory Commission 2011).

Clinician service use is positively correlated with drug use

A cross-sectional analysis of carrier service use (with all carrier-paid services as a proxy for clinician services) and prescription drug use data, using a linear regression model, shows that the areas with high carrier service use tend to have high drug use (and likewise, those with low carrier service tend to have low drug use). Results from this regression indicate that use of carrier services explains about 7 percent of the variation in drug use ($R^2 = 0.067$) based on the 2008 data and about 24 percent of the variation in drug use ($R^2 = 0.24$) based on the 2013 data. We found a somewhat positive correlation between carrier service use and drug use in both years (estimated coefficient of 0.11 for 2008 and 0.3 for 2013). Our results suggest that the use of carrier services and the use of prescription drugs may be weak complements rather than substitutes for one another.

The positive correlation we found between carrier service use and drug use was somewhat stronger in 2013 than in 2008. It is not clear whether this finding reflects a change in the relationship between the service use in these two sectors. Although our model adjusts for population characteristics, it is possible that those adjustments do not fully capture the change in service use patterns that may have occurred as a result of the change in plan enrollment patterns among FFS beneficiaries from 2008 to 2013.

Change in drug use is negatively correlated with change in clinician service use

To examine the relationship in our geographic areas between growth in the use of carrier services and the use of drugs, we compared the level of service use in 2008

with the level of service use in 2013 to determine each area's growth rate from 2008 to 2013.

Overall, from 2008 to 2013, per capita drug use grew cumulatively by about 11.5 percent compared with nearly 13 percent for per capita carrier service use. For both carrier service use and drug use, there was a slight inverse relationship between an area's level of service use in 2008 and growth from 2008 to 2013.

We conducted a linear regression that had the change in drug use as a dependent variable. Results of the regression analysis suggest that, for the 2008 through 2013 period, change in drug use was negatively correlated with changes in an area's carrier service use (coefficient on the change in carrier service use of –0.27 ($p < 0.0001$)). The rate of growth in carrier service use explained 6 percent of the variation in the rate of growth in drug use across the 484 geographic areas.[7]

Summary

The results of our analyses indicate the following:

- Medicare spending on clinician services as a share of Medicare spending on all Part A and Part B services has been stable in recent years at about 19 percent.
- There is a moderately positive correlation between use of carrier services (which we use as a proxy for clinician services) and use of all Part A and Part B services. From 2008 to 2013:
    - use of carrier services as a share of all Part A and Part B services increased from 24.4 percent to 26.3 percent.
    - across geographic areas, there was a moderately positive relationship between the percentage change in use of carrier services and the percentage change in use of Part A and Part B services.
    - across geographic areas, there was a moderately positive relationship between use of carrier services and use of all Part A and Part B services.

We were concerned about circularity between use of carrier services and use of all Part A and Part B services because carrier services constitute a significant portion of Part A and Part B services. In response, we evaluated the relationship between use of carrier services and use of all Part A and Part B services, less the carrier services. We found the following:

- Across geographic areas, the relationship between the percentage change from 2008 to 2013 in use of carrier services and the percentage change in use of Part A and Part B services net of carrier services was positive but weak.
- Across geographic areas, there was nearly no correlation (neither positive nor negative) between use of carrier services and use of Part A and Part B services net of carrier services.
- These two correlations suggest that carrier services and all other Part A and Part B services were neither complements nor substitutes.

For a subset of FFS beneficiaries who receive their drug coverage through the Part D program, our analysis found the following:

- Carrier service use was positively correlated with drug use; that is, areas with high (or low) carrier service use tended to also have high (or low) drug use.
- The change in carrier service use was negatively correlated with the change in an area's drug use.

The positive correlation between carrier service use and drug use was weak to modest. While the regression results showed a negative relationship between the changes in carrier service use and drug use, only 6 percent of the variation in service use changes was explained by our regression model, suggesting a weak relationship between the rates of growth in carrier service use and drug use.

There are a few caveats in interpreting these findings. First, correlation in service use among different sectors does not prove causality. Second, our results are based on aggregate trends and do not represent individual circumstances or geographic areas.

While we found a moderately positive relationship between use of carrier services and use of all Part A and Part B services, that relationship was weaker and nearly neutral once carrier services were removed from the measure of Part A and Part B service use. This finding suggests that carrier services and other Part A and Part B services are neither complements nor substitutes.

Our findings on the relationship between use of carrier services and use of Part D drugs suggest a weak complementary relationship based on the level of service use, but not based on growth rates in these two sectors. While the negative relationship between the growth in use of carrier services and use of Part D drugs could be taken to mean that they are weak substitutes, the more likely interpretation may be that there is very little relationship between the service use in these two sectors measured at the MSA level, given contradictory findings (based on level of service use vs. based on growth rates), small regression coefficients, and low R^2 values. ■

Endnotes

1 Over the 2008 through 2013 period, the Medicare program increased the payment rates for clinician services by a lower percentage than for most other services. Therefore, the 2013 per capita use amounts that we used in Table 4-3 (p. 147) have been deflated to 2008 levels by removing the effects of payment updates that occurred over the 2008 through 2013 period.

2 We re-estimated the clinician service use measures for 2008 and 2013 using only FFS beneficiaries who were enrolled in stand-alone PDPs in each of these years.

3 PDE data include all payments to pharmacies for drugs covered under Part D, including payments by plans, beneficiaries, and Medicare through the low-income cost-sharing subsidy that provides cost-sharing assistance for beneficiaries with low income and assets.

4 Factors used to adjust for variation in prices across regions are based on an analysis by Acumen LLC for the Commission. Regional variation in drug prices ranged from 1 percentage point below the national average to 4 percentage points above the national average in 2008, and 2 percentage points below the national average to 6 percentage points above the national average in 2013. These prices are arrived at through negotiations between Medicare Part D plans and pharmacies and do not reflect manufacturer rebates.

5 We used the volume-weighted price index constructed by Acumen LLC for Part D–covered prescription drugs filled by PDP enrollees to adjust the 2013 drug spending to account for the increase in drug prices between 2008 and 2013. Based on price levels measured in July of 2008 and July of 2013, our adjustment reduced 2013 drug spending by 3.3 percent.

6 The geographic areas developed for our study are defined as the metropolitan statistical areas (MSAs) of the core-based statistical areas. If an MSA crosses state borders, the MSA is divided into multiple areas based on state borders.

7 The R^2 for the regression using 2008 enrollment as the weight was 0.058. Results of a regression using 2013 enrollment as the weight were similar: A coefficient on the change in carrier service use was –0.26 ($p < 0.0001$), with an R^2 of 0.057.

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CHAPTER 5

Redesigning the Merit-based Incentive Payment System and strengthening advanced alternative payment models

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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. It established two paths—one for clinicians who participate in advanced alternative payment models (A–APMs) and another for other clinicians (the Merit-based Incentive Payment System (MIPS)). Beginning in 2019 and continuing through 2024, clinicians on the A–APM path—that is, those who have sufficient participation in an A–APM—will receive a 5 percent incentive payment. From 2026 on, these clinicians, if they still meet the criteria for participation in an A–APM, will receive a higher update than other clinicians.

Clinicians who do not qualify for the A–APM incentive payment follow the MIPS path, which involves a separate incentive program based on clinicians' performance on certain measures. MIPS is organized into four categories (quality, cost, practice improvement, and electronic health record use), and performance in these categories determines whether clinicians receive a bonus or a penalty on their Medicare fee-for-service payments. Although budget neutral in aggregate, MIPS bonuses and penalties may have a large effect on payments for individual clinicians and hence on the attractiveness of being in an A–APM relative to MIPS.

In this chapter

As CMS has begun to implement these two paths, it is becoming apparent that there are some serious challenges. Clinicians are reporting data now for the first year of implementation for MIPS in 2019. Over 40 percent of clinicians are exempt from the program, and CMS created a very minimal standard that can be met by reporting information on one quality measure. Some stakeholders may view this approach as positive because the reporting requirements are minimal, and there will be very little effect on payment. Other stakeholders, who have invested in reporting infrastructure, may view this approach as negative. In the following years, if CMS proceeds to standards that are more difficult to meet, reporting will become more burdensome. It is not clear that the resulting data collected by CMS will be useful in detecting high and low performance, and minor differences in clinician scores could result in major differences in payment.

The implementation problems follow from basic issues in MACRA. Although MACRA repealed the SGR and attempted to address some of its shortcomings, it set up a complex system in which some signals to improve value may not be well aligned. It is always difficult mid-implementation to judge what sort of program will eventually result, but the Commission is concerned by the direction the program is taking. Therefore, although we have not made any recommendations, we have started to discuss ideas for improvement and present some of them in this chapter.

MIPS as presently designed is unlikely to succeed in helping beneficiaries choose clinicians, helping clinicians change practice patterns to improve value, or helping the Medicare program reward clinicians based on value. In part, this result is likely because the MIPS quality category is designed to allow clinicians to choose six measures from a large set of process measures, and if they choose measures that are "topped out" (measures on which everyone performs well), they will have high absolute scores. Other MIPS categories rely on clinician attestations that they are engaged in certain activities; clinicians will likely also score high on those measures. As a result, it will be difficult to ascertain any distinction among clinicians on their performance. This outcome will not be helpful to achieve the aims of MIPS, and it will impose a considerable reporting burden on clinicians. Fundamentally, it may be that individual clinicians cannot be judged on quality because there are too few cases per clinician for measures to be reliable.

This chapter discusses a possible alternative for MIPS. It starts with a quality withhold (i.e., payment rates are reduced by a set percentage and then returned or not under certain conditions) for all services paid under the physician fee schedule (PFS). It eliminates the current set of measures and instead relies on population outcome measures, such as:

- potentially preventable admissions and emergency department visits
- mortality and readmission rates
- patient experience
- healthy days at home
- rates of low-value care
- relative resource use

These measures would be calculated from claims or surveys and thus not require burdensome clinician reporting. Because these are population outcome measures, clinicians would need to be associated with populations and those populations would have to be of sufficient size for measures to be reliable. Under this construct, clinicians would need to be associated with a group of clinicians and there would be no individual-level assessment of clinician performance, only group-level assessment. Clinicians could choose to join an A–APM, join a group of clinicians that they define, elect to be measured in a group that CMS defines, or elect not to be measured at all. If not measured, they would lose the MIPS quality withhold. If in an A–APM, the withhold would be returned to them. If in a self-defined or a Medicare-defined group, their performance would be assessed as a part of the group's performance, which would determine how much of the withhold was returned or whether a quality bonus in excess of the withhold was given.

Another important aspect of MACRA is the imbalance in payment incentives for clinicians to join A–APMs or remain in MIPS. MACRA appears to encourage clinicians to join A–APMs, hence the 5 percent incentive payment for clinicians who have sufficient participation in A–APM entities. However, the design of this incentive is concerning because of potential payment inequities that could result. Under MACRA, a clinician must reach a threshold of revenue coming through an A–APM (e.g., 25 percent, 50 percent) to be eligible for the 5 percent incentive payment, and this payment is based on all of the clinician's PFS revenue, even that which does not come through an A–APM. Therefore, if the threshold for revenue coming through the A–APM is 25 percent, a practice with 24.9 percent of revenue generated through the A–APM would not be eligible for the 5 percent incentive payment, while a similar practice with 25.0 percent of its revenue through the A–APM would get a 5 percent incentive payment on all of its PFS revenue. This kind of payment cliff can introduce payment discontinuities, increase uncertainty, and appear inequitable. Therefore, we discuss making the payment reward proportional to the A–APM-generated revenue. That is, there would be no threshold and the reward would be proportional: Any revenue coming through an A–APM would secure the 5 percent payment incentive, but any other PFS revenue would not. This revision would eliminate the payment cliff and increase certainty for clinicians that their work through an A–APM entity would be rewarded.

Another aspect of balance between MIPS and A–APMs is the exceptional performance bonus available in MIPS. The bonus comes from a fund of $500 million per year (from 2019 to 2024) for clinicians with "exceptional performance" in MIPS. Moving this fund from MIPS to A–APMs would shift the incentives toward A–APMs and make MIPS less attractive. We discuss using the bonus to fund an asymmetric risk corridor for two-sided-risk accountable care organizations (ACOs) that qualify as A–APM entities.

Two-sided-risk ACOs and models like them are the A–APMs most in keeping with the Commission's principles for A–APMs discussed in the Commission's June 2016 report to the Congress. Those principles encourage A–APMs with a broader scope than some currently contemplated because the latter may lead to fragmentation, overlaps, and cross-incentives. We also discuss a possible design, in keeping with our principles, for an A–APM that could attract practices that are reluctant to take on a large amount of risk relative to their revenue.

These alternative constructs are a departure from the current design of MIPS and the application of the 5 percent A–APM payment incentive. However, they could (1) relieve clinicians of the MIPS quality reporting burden and make MIPS useful for beneficiaries, clinicians, and Medicare and (2) shift payment incentives toward greater clinician participation in A–APMs. Creating a better design for MIPS and A–APMs could help achieve Medicare's goals of improving quality for beneficiaries, making payments fair for clinicians, and restraining program costs for taxpayers. ■

Background

From 1999 to 2015, payment updates for clinicians who billed under Medicare's physician fee schedule (PFS) were covered by the sustainable growth rate (SGR) system, which set updates so that total spending would not increase faster than a target—a function of input costs, fee-for-service (FFS) enrollment, gross domestic product (GDP), and changes in law and regulation. Because annual spending generally exceeded these SGR parameters, payments to clinicians were scheduled to be reduced by ever-growing amounts starting in 2002, but the Congress overrode these negative cuts in all but the first year they were scheduled. Because of these overrides and because of volume growing in excess of per capita GDP, the resulting update reduction grew to a scheduled 21 percent in 2015.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the SGR system and established a new process for updating payments to clinicians. It established two paths—one for qualifying participants in advanced alternative payment models (A–APMs) and the second for all other clinicians.[1] MACRA laid out statutory updates for providers on each path.

For 2016, 2017, and 2018, updates for all clinicians under the fee schedule are 0.5 percent each year.[2] Beginning in 2019 through 2024, clinicians who meet the criteria set out in the law as qualifying APM participants receive incentive payments of 5 percent of their entire Medicare fee schedule revenue each year that they qualify.[3] From 2026 on, qualifying APM participants also receive a higher update than other clinicians: 0.75 percent versus 0.25 percent.

Under MACRA, clinicians who do not meet the A–APM criteria receive no update from 2019 through 2024 and receive lower updates than clinicians who meet the A–APM criteria in 2026 and beyond (0.25 percent). These clinicians also receive annual payment increases or decreases based on their performance in the Merit-based Incentive Payment System (MIPS), starting in 2019. Those increases and decreases in theory could be quite significant; the maximum downward adjustment increases to 9 percent of payments in 2022 and individual positive payment changes could be even greater.

The Commission commented on the proposed rule for MACRA implementation based on the discussion in its June 2016 report to the Congress (Medicare Payment Advisory Commission 2016a, Medicare Payment Advisory Commission 2016b). We noted some serious shortcomings in the MIPS program and some principles that should underlie the development of A–APMs (Medicare Payment Advisory Commission 2016b).

The final rule to implement MACRA was published on November 4, 2016 (Centers for Medicare & Medicaid Services 2016b). The final rule did not incorporate the Commission's suggestions for making MIPS a more meaningful program by focusing more on outcomes rather than process measures, and it did not follow the Commission's principles for A–APMs. Therefore, in this chapter, we present policy options for improving the design of MIPS and strengthening A–APMs. These options include redesigning MIPS to relieve reporting burden and to focus measures on outcomes of interest to beneficiaries and the program. We also address rectifying the imbalance between MIPS and A–APMs by offering a model to attract clinicians to A–APMs who are deterred from taking the risk implied in current two-sided risk models by shifting the $500 million a year (2019 to 2024) fund for clinicians with "exceptional performance" from MIPS to A–APMs, using this fund to pay for an asymmetric risk corridor for two-sided accountable care organizations that are A–APMs.

Redesigning the Merit-based Incentive Payment System

MIPS consolidates three of the existing payment adjustment programs for clinicians: the Physician Quality Reporting System (PQRS), the payment adjustment for the meaningful use of electronic health records (EHRs), and the value-based payment modifier, which includes a resource use component. The legislation allows CMS to retain the measurement process for the PQRS, EHR meaningful use, and the value-based payment modifier for use in MIPS, but merges the individual adjustments into one MIPS adjustment. MACRA continues these separate programs through 2018 and then repeals the individual programs and establishes MIPS to take effect in 2019. Under CMS's recent regulations implementing the first year of the program, clinicians must report on their quality, advancing care information, and clinical practice improvement activities during calendar year 2017 to result in a payment adjustment under MIPS that will apply in 2019.

MIPS applies to clinicians who do not qualify as A–APM participants. Annual payment increases and decreases apply based on the clinician's performance in four categories: quality, cost, clinical practice improvement

activities (CPIAs) (such as expanded practice hours), and advancing care information (ACI; formerly meaningful use of EHR). CMS has released final rulemaking for the first year of MIPS (2017 reporting year for payment adjustments in 2019) (Centers for Medicare & Medicaid Services 2016b). The first-year policies will be different from policies in later years.

MIPS assesses the first category, quality, based entirely on measures that clinicians choose to report from the MIPS measure set (based on the PQRS measure set). The roughly 275 quality measures in the MIPS measure set are largely process measures, such as whether the clinician ordered appropriate tests or followed general clinical guidelines. CMS has categorized about 170 of these measures as "high priority" because they measure outcomes (including intermediate outcome measures), patient experience, efficiency, or patient safety.

Clinicians self-attest to their performance in two other MIPS categories: CPIA and ACI. For the fourth MIPS category, cost, clinicians are assessed based on resource use (calculated from claims) relative to their peers.

Each clinician is eligible to receive a MIPS payment adjustment factor based on his or her composite performance in all four categories combined. Each clinician's composite MIPS performance score will be calculated according to weights set in law and compared against a predetermined MIPS benchmark. Clinicians above this level will receive a payment increase; clinicians below this level will receive a payment decrease.

The basic MIPS adjustments are budget neutral. MACRA set a maximum reduction for clinicians in the bottom tier of performance: 4 percent in 2019, 5 percent in 2020, 7 percent in 2021, and 9 percent in 2022 and subsequent years. The corresponding positive adjustment factors are scaled up or down to achieve budget neutrality for the basic MIPS adjustment, so the positive adjustment factors could be larger or smaller than these statutory reductions.

MACRA also appropriated an additional $500 million a year for exceptional performance in MIPS from 2019 through 2024. *Exceptional performance* is defined in the statute as performance at or above the 25th percentile above the mean (or median) of performance scores.[4]

Implementing MIPS

CMS took a "pay-for-reporting" approach for the first year of MIPS. In this approach, CMS set the MIPS benchmark at 3 points (out of 100) on the composite MIPS score, a very minimal standard. In other words, a clinician needs to score only at or above 3 points to establish eligibility for a bonus payment under MIPS in the first year. Clinicians can meet the 3-point requirement by submitting information on one quality measure, attesting to one clinical practice improvement activity, or attesting to the base advancing care information category. (CMS gave zero weight to the cost category for 2019, using its regulatory authority to override the statutory weight of 10 percent in 2019). Because of the minimal reporting requirement in the first year, CMS assumes that most MIPS-eligible clinicians (more than 90 percent) will be at or above the MIPS benchmark of 3 points. As a result, the positive payment adjustments under MIPS will be very small in the first year (Centers for Medicare & Medicaid Services 2016b).

CMS's approach for the first year of MIPS has set the administrative process in motion. As described above, in 2017, clinicians can report very little data to CMS. However, in subsequent years, clinicians may have a heavy reporting burden, and CMS will have a large amount of information to process. This information will not help CMS identify high- and low-performers, yet it could result in large differences in payment, as we discuss below.

Clinicians will be reassessed on noncomparable measures

There is wide variability in the MIPS quality measures in terms of how easy it is to achieve high performance, their relevance to the Medicare population, and their clinical relevance. Because each clinician can choose which measures to report, the amount of meaningful information received by the Medicare program varies. Under MIPS, each clinician selects six applicable measures (including an outcome measure) to report; performance on these measures determines the clinician's quality score (which is 60 percent of the MIPS score in the first year).[5] A clinician's relative performance on each measure is compared with the performance of others who reported the same measure. Many of these measures are poorly linked to outcomes of importance for beneficiaries and the program and, instead, reinforce the incentive in FFS Medicare to provide more services than are clinically necessary.

Many MIPS measures have very compressed distributions of performance. Because the measures can be reported in different ways, the result is over 600 reporting measures and method combinations for the 275 MIPS measures.[6] Of the 600, 178 are topped out (meeting CMS's criteria),

TABLE 5–1 **Potential maximum MIPS adjustments**

	2019	2020	2021	2022 and later
Base MIPS adjustments	4%	5%	7%	9%
With maximum scaling factor applied	12*	15	21	27
Plus maximum exceptional performance bonus	22*	25	31	37

Note: MIPS (Merit-based Incentive Payment System).
*Unlikely to be reached in 2019 because CMS estimates that nearly all clinicians will meet the MIPS performance standard, hence there will be very few negative adjustments to fund the positive adjustments.

Source: Medicare Access and CHIP Reauthorization Act of 2015.

and 88 have such topped-out performance that the median performance score is 100 percent.[7] For 287 measures, CMS has no performance benchmark for the first year (Centers for Medicare & Medicaid Services 2016a).

The structure of MIPS creates an inequitable system. The first inequity results from the use of self-reported quality measures, in which clinician performance is measured (and pay is adjusted) using different metrics for each clinician. The second inequity occurs because clinicians who select measures for which there is room for improvement (and that assess real, meaningful gaps in care) are much less likely to do well than clinicians who select measures on which they score highly.

Individual clinicians typically have a small number of patients qualifying for each measure

Reliably measuring performance is also a concern. For many clinicians, any individual quality measure will apply only for a subset of their patients. That number may be too small to distinguish real differences in performance on those measures from what statisticians call "noise" (unexplained variation or randomness in a sample). Combining performance on multiple measures, each with few cases, will not solve this problem.

Small differences in clinician performance may result in large differences in payment

If CMS receives compressed performance scores for quality, and two of the other three MIPS categories are attestation only, we expect that most clinicians who report to MIPS will score highly. (Those who do not report will receive the maximum negative adjustment.) In future years (when the MIPS benchmark is set at the median or mean of performance, rather than 3 points), small variations in quality measures can have an outsize effect on the MIPS composite score, even if the differences in quality performance among clinicians are clinically insignificant. Hence, payment differences may be wide (particularly if the exceptional performance bonus continues), despite the similarity of clinicians' actual performance.

The mathematical possibility for large payment adjustments in MIPS may keep some clinicians in MIPS instead of A–APMs

There is the possibility (although the likelihood is extremely small) that some clinicians could eventually receive very high payment adjustments under MIPS—up to 37 percent by 2022 (Table 5-1). This possibility arises from two factors. The first is a scaling factor to make the MIPS adjustments budget neutral: For example, if there are many more clinicians receiving penalties than bonuses, the size of the bonus would necessarily be high to maintain budget neutrality.[8] The second is the MIPS exceptional performance bonus. By statute, the MIPS exceptional performance bonus can add up to 10 percentage points to a clinician's payment adjustment.

The potential for these very high adjustments (despite the very low likelihood that they will come to pass) may provide motivation for some clinicians to remain in MIPS when they would otherwise consider joining an A–APM. CMS's MIPS APM policy, which gives participants in certain types of models high performance scores in some MIPS categories and reduces reporting burden, also works in tandem with these theoretically high MIPS payment adjustments to make MIPS relatively more attractive.

In the first year, basic MIPS adjustments will be very small for most clinicians

CMS estimates that most clinicians will receive either no adjustment or a very small positive adjustment in the first year under the basic MIPS adjustments (Centers for Medicare & Medicaid Services 2016b). CMS estimates 10 percent of clinicians will not report and will get the maximum 4 percent reduction. To preserve budget neutrality, the sum of those reductions will fund the bonuses for the other 90 percent of clinicians. Hence, the payment adjustments for the first year will be very small; CMS estimates that the maximum will be just below 1 percent (without the exceptional performance bonus). The MIPS exceptional performance bonus could add between 0 percent and 4 percent to a clinician's payment adjustment.[9]

Priorities in redesigning MIPS

MIPS, as designed, is unlikely to clearly identify high-value or low-value clinicians and hence may be of limited utility for beneficiaries (in selecting high-value clinicians), for clinicians themselves (in understanding their performance and what to do to improve), or for the Medicare program (in adjusting payments based on value).

Redesigning MIPS requires considering the current state of performance measurement and realistically setting goals for a national value-based purchasing program for clinicians. The current MIPS system is designed primarily to measure basic standards of care and processes—not outcomes. In addition, it imposes burdens on clinicians and CMS that outweigh any potential benefit because the measures used for assessing quality, the ACI category, clinical practice improvement activities, and costs are unlikely to capture true value.

Our overarching principles with respect to reforming MIPS are to measure and reward performance that is linked to outcomes and to design MIPS and A–APMs in a way that attracts a greater share of clinicians to A–APMs over time, eliminates manual clinician reporting, and develops a program that reflects the current state of performance measurement. As that state changes—for example, as data from EHRs and registries become readily available to CMS—the system should evolve to take advantage of these data.

Commission discussion: A potential redesign of MIPS

A MIPS redesign could work as follows. First, a withhold from FFS payments for all clinicians could fund a quality pool (e.g., Medicare reduces payment rates by some percentage that is sufficiently large to incentivize quality improvement). Clinicians could then:

- do nothing (and lose the withhold),
- join (or form) an A–APM (and receive the withhold back),
- join a sufficiently large group of clinicians for measurement purposes (and potentially receive a quality payment in addition to receiving the withhold back), or
- elect to be measured as part of a CMS-defined group covering a sufficiently large local population (and potentially receive a quality payment in addition to receiving the withhold back).

Under this framework, clinicians could not be worse off by choosing to be measured as a group or local area member than if they made no election at all (that is, they could not lose more than their withhold). It would also be desirable to set a maximum MIPS adjustment so that clinicians could not do better in MIPS than they could if they joined an A–APM. This redesign also contemplates moving to population-based measures rather than individual clinician-level measures. Clinicians would have the following options:

Option 1: Clinicians can choose to make no election. They would lose the withhold and would not be eligible for a quality payment. Clinicians could remain in traditional FFS and forgo any opportunity to receive a quality payment if they did not join an A–APM, join a virtual group, or elect to be measured at a local area. In other words, they would receive a reduced Medicare rate for all services (reduced by the amount of the withhold).

Option 2: Clinicians can choose to join (or form) an A–APM. Clinicians would receive their quality withhold back if they joined (or formed) an A–APM at any participation level. This option provides a modest incentive to join any A–APM and would make sure that clinicians face only one set of incentives.

Option 3: Clinicians can choose to join a "virtual" group. The virtual group, a concept introduced in MACRA (but not yet implemented through rulemaking), could mean a group of clinicians with a tax ID or legal structure in common, but could also mean a group of otherwise unrelated clinicians. For example, a virtual group could be more formally structured, such as a group practice or a group of physicians employed by a hospital,

or less formally structured, such as a physician specialty society or a geographically dispersed group of clinicians with an interest in joining together.[10]

CMS would likely have to exert some control over the size and structure of these groups to make sure the group could be measured reliably. Reliability is an issue because some clinicians are much less likely to have a sufficiently sized population of beneficiaries attributed to them. For example, a group of pathologists would be unlikely to have claims-calculated clinical outcome measures or patient experience measures, but may have relative resource use measures. CMS could set measure-specific case sizes and, in this way, implicitly require clinician groups to join with other specialties so that they would have a sufficiently large number of attributed patients for each measure.

Option 4: Clinicians can elect to be measured as part of a local or market area. CMS could define local or market areas using various characteristics. One example is to create populations of patients that use a large provider in common—for example, the hospital service area concept that groups providers together based on the hospital where their patients go most often. Under the local or market area approach, it might be possible to set a uniform case size (e.g., the local area must have at least a minimum number of beneficiaries attributed to it) so that quality measures can be robustly measured and compared against other areas or groups.

Assessing clinicians in virtual groups and local or market areas according to population-based measures (at the aggregate level)

Under a revised MIPS, CMS would use a set of CMS-calculated measures (from claims and patient experience surveys) that give insight into both the ambulatory care environment and the broader health care delivery system. Clinicians would not have to report quality data to CMS, relieving them of that burden. The Medicare program would focus on aggregate measures extracted from claims that assess care for patients across the continuum of providers, such as:

- potentially preventable admissions and emergency department visits
- mortality and readmission rates after inpatient hospital stays
- healthy days at home
- patient experience
- rates of low-value care
- relative resource use

These measures are intended to be illustrative; in general, the goal would be to use claims- and survey-calculated measures that assess performance in the categories of clinical outcomes, patient experience, and efficiency. In this redesign, MIPS would no longer include clinical practice improvement activities and EHR technology as separate categories requiring clinician attestation.[11] In addition, even clinicians who elected group- or area-level measurement would not be required to report any quality measures to CMS.

Changing the focus to assessing population-based outcomes

The alternative design described above incorporates some trade-offs, by necessity. The key one is that the Medicare program would no longer score an individual clinician's performance and no longer require clinician reporting. The concept is to adopt a broader, claims- and survey-calculated uniform measure set that assesses the overall performance of a health care delivery system and its clinicians. These population-based measures are generally not reliable at the individual clinician level. The Medicare program would assess performance (and adjust payment) based only on performance at a group or local area level. Clinicians could elect not to receive a quality payment, but if they wished to be eligible for a quality payment, they would need to join (either actively or passively) a set of clinicians to be measured (or move to an A–APM and be eligible to get back their quality withhold).

The benefits of using population-based measures are significant. First, this approach sends clinicians a signal that they should view the care they provide as part of a continuum that crosses sectors and incorporates the totality of patient care. This perspective helps to counter the silo-driven FFS system that encourages providers to focus only on the services they directly provide. Second, it aligns with other programs in Medicare (such as the Commission's vision for comparing quality across Medicare Advantage, FFS, and accountable care organizations (ACOs) (Medicare Payment Advisory Commission 2014b), sending the same set of signals to all providers involved. Third, it keeps Medicare's focus on broad, aggregate measures of performance and leaves it to provider entities (hospitals, health systems, ACOs) to determine how best to measure and assess quality in their particular environment.

Fourth, it reduces practice cost and burden on clinicians by eliminating all clinician reporting of measures.

There are drawbacks to such a redesign. CMS is already years down the path of establishing a comprehensive quality-data reporting system that uses multiple methods of data reporting and extraction. CMS has modified this system to support MIPS as well as the two additional MIPS categories that clinicians must report (advancing care information and clinical practice improvement activities). Switching gears at this point would require significant time and effort for CMS. In addition, clinicians and other providers in the broader health care delivery system have spent significant time and resources building systems and operations that feed information to CMS using this framework.

Because it would measure clinician performance at a group or regional level, the potential MIPS redesign would not help beneficiaries choose a clinician who meets their preferences—for example, a surgeon with low complication rates or a primary care clinician with good improvement in patient function. A separate issue, not discussed in this chapter, is the use of quality information for public reporting. In this chapter, we are concentrating on MACRA as it affects clinician payment—which is complex enough.

Furthermore, providers may feel that population-based outcome measures do not reflect their individual performance, and because the measurement would be group based or regional, it reflects care that is outside their control. The potential redesign would require population-based outcome measures; appropriate risk adjustment; and policy decisions about the amount of the withhold, the allocation of bonus dollars among groups, and the form and amount of the quality payment.

Despite these challenges, it is worth recalling the status quo. Presently, CMS collects a large amount of information using a variety of sources, with varying clinician burden and varying value. However, nearly half of the measures have compressed performance, and many of them measure minimal standards of care. CMS does not presently use them for public reporting through Physician Compare, in part because of the inability to compare across all providers and small sample sizes. Individual-level quality measurement is inherently challenging. Measurement at the group level can be more reliable but does not provide information on individual clinicians. This tension will not be resolved under any design. CMS has delayed full implementation of MIPS for one year, but will still face these problems in the future.

In the future, as EHRs and registries mature and become more interoperable, it might be possible to overcome some of the current limitations of quality measurement for clinicians. At that point, it might be possible for the Medicare program to assess clinician performance more readily using sources other than claims and surveys (such as EHRs or clinician data registries). However, given the current state of the art of quality measurement and the lack of interoperability (and possible data blocking) between EHRs, the design for MIPS is not now tenable.

One outcome of a redesign such as the one above is that clinicians could see signals to join an organized entity that assumes responsibility for the cost and quality of patient care. For example, if clinicians would like to receive a quality payment but do not like being measured against the performance of their local area, they could seek a group (a virtual group either more or less formal) with which to be measured. This option could prepare them to transition more easily to a structure like an ACO or other A–APM. The downside is that it could create further incentives for provider consolidation, which can increase Medicare and private-sector spending (see Chapter 10 of this report).

Rectifying the imbalance between MIPS and A–APMs

If MACRA is intended to move clinicians toward participating in A–APMs (as evidenced by the 5 percent incentive payment and higher updates in later years for clinicians participating in A–APMs), certain aspects of the law and its implementation may undermine this intent. Those aspects could make remaining in MIPS too attractive relative to A–APM participation or could make the benefits of participating in A–APMs too uncertain. Below, we discuss two policies that could help rectify this imbalance. We do not endorse policies that reward simply being in an A–APM or make it easier for an A–APM to appear to succeed; those policies undermine the concept of alternative payment models that further delivery system reform. Instead, the principles we developed last year emphasize the development of A–APMs with the potential to improve care coordination for patients over the entire course of care while protecting the Medicare program and taxpayers from excessive spending (Medicare Payment Advisory Commission 2016b). The less restrictive

definition of A–APMs that some put forward might make A–APMs more available and might make it easier for them to appear to succeed but would not necessarily result in A–APMs that further the goals of the Medicare program as the Commission understands them.

Applying the A–APM incentive payment to clinicians' revenue coming through the A–APM

Under MACRA, the 5 percent A–APM incentive payment is applied to a clinician's entire Medicare physician fee schedule (PFS) revenue from the prior year. However, to qualify for the incentive payment, a clinician (or, as defined in regulation, an A–APM entity) must meet the threshold for the share of PFS revenue coming through an A–APM. That numerical threshold is set in statute and increases over time. In 2019 and 2020, a clinician practice must have at least 25 percent of its PFS revenue through an A–APM, 50 percent in 2021 and 2022, and 75 percent in 2023 and later. Uncertainty about meeting this threshold could deter clinician participation in A–APMs.

We consider an alternative policy under which there would be no numerical threshold for participation, and instead, the 5 percent A–APM incentive payment would apply only to PFS revenue coming through the A–APM rather than to all of a clinician's PFS revenue. That is, the policy would make the incentive proportional to involvement in the A–APM. This approach would greatly simplify administration of the policy, increase the certainty of a reward for moving services into A–APMs, and make the policy fairer to clinicians. For example, it would avoid the situation of a clinician practice with 24.9 percent of PFS revenue coming through an A–APM receiving no incentive payment, and one with 25.0 percent of revenue coming through the A–APM getting a 5 percent incentive payment on all of its PFS revenue.

Under this alternative, the incentive would depend solely on the revenue of the practice that comes through the A–APM, which means that any work done through an A–APM would be rewarded with certainty. In addition, there would be no payment cliffs or discontinuities at the thresholds. (Additionally, such a revised design would help avoid uncertainty for practices that may be concerned they will lose the incentive payment as the threshold rises from 25 percent, to 50 percent, to 75 percent in later years.)

The alternative would also reduce administrative complexity. Under current policy, CMS first calculates the ratio of the entity's PFS revenue through the A–APM and its total PFS revenue. If that ratio falls short of the threshold, CMS then calculates a "patient-count ratio"—the ratio of patients attributed to the A–APM and the practice's total patients—to determine whether that ratio meets the threshold. CMS has proposed different (lower) thresholds for the patient-count method (Centers for Medicare & Medicaid Services 2016b). In addition, MACRA has an "all-payer" option in later years that requires CMS to determine what share of revenue or patients is coming through A–APM-like arrangements for other payers. That determination could require access to a practice's contracts with other payers and could be a large administrative burden on all parties. The alternative policy, which eliminates the revenue threshold, would make the patient-count and all-payer calculation methods unnecessary.

Under MACRA, clinicians are exempt from MIPS if they meet the numerical threshold (e.g., 25 percent of PFS revenue comes through an A–APM). Because the alternative policy would have no numerical threshold, determining which clinicians were exempt from MIPS would require different parameters. Under the MIPS policy option described earlier, clinicians with any A–APM participation would be exempt from MIPS, and their quality withhold would be returned to them.

Revising the model to encourage taking on two-sided risk

MACRA was designed to encourage clinicians to participate in A–APMs that place them at more than nominal financial risk. In part, this design may have been chosen because incentives to achieve savings are stronger in properly structured models with two-sided risk (i.e., there is a reward for reducing spending below a benchmark and a penalty for exceeding a benchmark) than in one-sided models, which have no penalty if spending exceeds a benchmark. In addition, a two-sided risk model provides some protection for the Medicare program from losses and could allow CMS to waive certain regulations designed to protect against overuse of services (Medicare Payment Advisory Commission 2014a). At the same time, MACRA is a clinician-focused policy that addresses payments for clinicians and creates incentives for them to join certain models. Thus, when considering a redesign of MACRA, this chapter focuses on two-sided risk models that clinicians might consider attractive.[12]

In addition, the Commission maintains that a principle for A–APMs is that the entity should be at financial risk for total Part A and Part B spending (Medicare Payment

TABLE 5–2 **Illustrative comparison of benchmark-based and revenue-based risk**

1,000	Number of beneficiaries
$10,000	Per capita Part A and Part B benchmark
$10,000,000	Total Part A and Part B benchmark
$300,000	**Benchmark-based standard: 3 percent of benchmark**
$500,000	Practice revenue through the ACO (assumed to be 5 percent of Part A and Part B)
	Revenue-based standard: 8 percent of total FFS practice revenue
$40,000	Low end: Total practice revenue is $500,000, all comes through A–APM
$160,000	High end: Total practice revenue is $2,000,000, 25 percent comes through A–APM

Note: ACO (accountable care organization), FFS (fee-for-service), A–APM (advanced alternative payment model). We assume that the only ACO participants are clinicians, and they are accountable for all Part A and Part B spending for the year.

Advisory Commission 2016b). This principle is directed at two goals: (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. However, one issue in making two-sided risk models accessible to a clinician group is that taking risk under a Part A and Part B benchmark might make the downside risk look too formidable to attempt. For example, there is usually a large difference between a clinician group's revenue through an ACO and its ACO's total Part A and Part B spending benchmark. Although clinicians influence a large share of Medicare spending, spending under the PFS itself is about 15 percent of total Medicare spending; most spending goes to other providers. In addition, a physician group would be very unlikely to capture all PFS spending as revenue for its attributed beneficiaries. A primary care group's revenue through an ACO would likely account for only about 5 percent of the Part A and Part B benchmark. Thus, benchmark spending in an ACO would be a large multiple of a clinician group's revenue through the ACO. That multiplier would be advantageous if the practice is in a one-sided risk model, but it could seem too much to venture if the practice was at two-sided risk for total spending.

One approach to resolving this dilemma is to limit the risk for the clinicians' practice. The law requires that an A–APM be at more than nominal risk, and CMS has established two options for a nominal-risk standard: either a benchmark-based standard (3 percent of the model's benchmark) or a revenue-based standard (8 percent of an entity's FFS revenue) (Centers for Medicare & Medicaid Services 2016b). In general, the benchmark-based standard represents more risk for a clinician practice than the revenue-based standard.[13]

To illustrate these differences, we consider the case of a two-sided-risk ACO and demonstrate that the revenue-based risk standard will be less than the benchmark-based standard. In this example, assume that the only participants in the ACO entity are clinicians, that they are accountable for all Part A and Part B spending for the year, and that the ACO has 1,000 beneficiaries attributed to it.[14] Also, assume the benchmark per capita Part A and Part B spending is $10,000. CMS set a 3 percent benchmark-based standard for nominal risk or an 8 percent revenue-based standard.[15]

Under these assumptions, the spending benchmark for the entity would be $10,000,000, and 3 percent of that would be $300,000 (the benchmark-based standard) (Table 5-2).

For CMS's revenue-based standard in this example, we assume that the ACO entity (which we will refer to as the practice) has Medicare FFS revenue coming through the ACO equal to 5 percent of the benchmark, or $500,000. CMS would require a minimum risk of 8 percent of the

practice's total FFS revenue. In this example, the practice's total revenue could range from $500,000 to $2,000,000. Total practice revenue must be at least $500,000—the amount coming through the ACO. The most its total revenue could be is $2,000,000—because, at a minimum, 25 percent must come through the ACO to meet the threshold, and 25 percent of $2,000,000 is $500,000.

Hence, 8 percent of total revenue must range between $40,000 (8 percent of $500,000) and $160,000 (8 percent of $2,000,000). In this example, both the minimum ($40,000) and the maximum ($160,000) amounts at risk in the revenue-based standard are less than the $300,000 at risk under the benchmark-based standard. Therefore, CMS's 8 percent of practice-revenue standard would represent less risk for the practice than the 3 percent of benchmark standard.[16]

Next, we describe a revised model in which revenue is defined as the practice's Medicare revenue coming through the A–APM (instead of CMS's definition of all Medicare practice revenue). Under this example, the 8 percent limit of the amount at risk would be $40,000 (8 percent of $500,000). This revised policy could encourage clinician groups to participate in A–APMs with more than nominal risk because it would represent a lower level of risk for the practice than the benchmark-based standard ($300,000 for the illustrative ACO model in Table 5-2) and would be the low end of CMS's revenue-based standard. This definition would be consistent with the revised 5 percent incentive payment discussed earlier. That is, the 5 percent incentive payment is proportional, applying only to the practice's revenue coming through an A–APM.

The effective risk for the practice would thus be even lower because of the 5 percent incentive payment. After accounting for the 5 percent incentive payment, the effective risk would be 3 percent of the practice's revenue coming through the A–APM (8 percent minus 5 percent). In the example in Table 5-2, that effective risk would be $15,000 (3 percent of $500,000).[17]

Thus, a revised model could:

- define revenue in the revenue-based standard as a practice's Medicare FFS revenue coming through the A–APM—consistent with the proposal to compute the 5 percent incentive on revenue through the A–APM.
- have a revenue-based instead of a benchmark-based nominal risk standard. (For consistency, the model could also define the top as well as the bottom of a risk corridor—the limit for savings and losses—in Medicare revenue terms.) (See the following section for further discussion of risk corridors.)

Consistent with the Commission's principles, shared savings and losses would be based on total Part A and Part B performance (while limited by a risk corridor), and small entities would need to aggregate to reliably detect cost and quality performance.[18] The intent is to create an incentive that is large enough to motivate improvement but limit the loss to something a practice could reasonably take on.

Retargeting the MIPS "exceptional performance" fund

MACRA appropriated an additional $500 million a year for "exceptional" performance in MIPS. This payment goes to any clinician at or above the 25th percentile above the MIPS performance standard, and the exceptional performance bonus is proportional. We have pointed out that the distribution of scores in MIPS may be very tight, with little real distinction between relatively high and low scores because almost all clinicians who report could have a very high absolute score. As a result, the MIPS exceptional performance bonus payments could be distributed to clinicians whose performance is essentially equivalent to those who do not get the bonus (e.g., those who score 99.8 versus those who score 99.6). In addition, in later years, the budget-neutral MIPS adjustments could give substantial rewards to the top scorers. Adding to this reward could theoretically create such a large reward that it would discourage clinicians from moving from MIPS to A–APMs.

One policy option would be to eliminate the $500 million MIPS exceptional performance bonus (so that MIPS becomes budget neutral) and return it to the Treasury or retarget the money. We discuss a retargeting option below that takes the revenue from the fund and uses it to help entities in A–APMs move toward two-sided risk by funding asymmetric risk corridors in two-sided-risk ACOs.[19]

A risk corridor limits the amount of savings or losses for which an entity is at risk. For example, if an entity's revenue through an ACO were $500,000, a 20 percent risk corridor would mean that the most the entity could gain or lose in shared savings or shared losses would be $100,000 (see Column 1 of Table 5-3, p. 172).[20] An asymmetric risk corridor could decrease the amount at risk, increase the maximum amount on the upside, or do both. Table 5-3 shows an example (Column 2) that increases the upside—

TABLE 5–3 **Illustration of symmetric and asymmetric risk corridors in two-sided-risk ACOs**

	Risk corridor for a clinical group with $500,000 of revenue through the ACO	
	Symmetric +20 percent / –20 percent of revenue	**Asymmetric +100 percent / –20 percent of revenue**
Limit on shared savings	$100,000	$500,000
Limit on shared losses	–$100,000	–$100,000

Note: ACO (accountable care organization).

the amount of shared savings allowed. Building on the example above, we compare illustrative symmetric and asymmetric risk corridors.

In the illustrative example in Table 5-3, the upper and lower risk corridor in the symmetric case are set at +/–$100,000, 20 percent of the clinician group's $500,000 in Medicare revenue through the ACO. In the asymmetric example, the upper limit on the risk corridor is 100 percent of revenue, or $500,000, and the lower limit is $100,000. The percentages in Table 5-3 are purely illustrative.

Effectively, the maximum reward would also include the 5 percent A–APM incentive, which would be $25,000 in this example (5 percent of the $500,000 in revenue through the A–APM). Thus, the upper limit on the practice's reward in the asymmetric case would be effectively $525,000. If the 5 percent incentive were paid on all revenue through the A–APM regardless of success in the A–APM, the loss would be at most $75,000 in both the symmetric and asymmetric cases in this example.

Additional money would be needed to fund asymmetric risk corridors because some ACOs would get shared savings and some would get shared losses from random variation. If the risk corridor were symmetric, savings and losses from random variation would balance out over the years from the Medicare program's perspective. However, if the risk corridor had higher upper than lower limits, Medicare could expect to pay out more in unwarranted shared savings than it would collect in unwarranted shared losses, overall. Because the additional spending is a potential liability for the program, one option is to retarget the $500 million in funds designated to reward exceptional performance under MIPS. The total funding needed would have to be estimated, which would require knowing the number of two-sided-risk ACOs eligible, the number of beneficiaries in each, their benchmarks, and the revenue of the clinicians coming through the ACOs. Random variation decreases as the attributed population increases, and that would also need to be factored into the calculation. The asymmetric risk corridor model would be transitional because it would terminate at the end of 2024 along with the funding for the MIPS exceptional performance bonus.

The model is designed to selectively attract clinician groups because the revenue-based standards are designed for groups whose revenue through the ACO is a small share of the total benchmark (Part A and Part B) spending. Performance would continue to be judged against total Part A and Part B spending. Hospital-based ACOs would tend toward models with a benchmark-based standard with higher benchmark-based rewards because their share of the benchmark spending would tend to be higher than a clinician group's share. Essentially, as an entity's revenue as a share of the benchmark increases, revenue-based and benchmark-based standards would converge. As an ancillary benefit, this model would likely indirectly provide support to primary care providers (PCPs). It would reward PCPs to the extent that attribution to the ACO is based on primary care evaluation and management claims, the extent that better primary care leads to savings in Medicare spending, and the extent that ACOs pass on rewards to primary care clinicians.

Conclusion

MACRA and its implementation has created a complex system that will not identify or appropriately reward high- and low-value clinicians, requires a massive reporting effort, and sends conflicting signals as to which models clinicians should move to. The Commission is concerned by the direction the program is taking in its first year and, although it is always difficult mid-implementation to judge what sort of program will eventually result, there appear to be basic aspects of the program that will make it difficult for it to succeed in later years. Therefore, although the Commission has not made any recommendations, we have introduced in this chapter three possible options to further policy discussions.

First, an alternative design could eliminate reporting burden and create incentives for clinicians to move to high-value models. MIPS as now designed will place a heavy burden on providers and CMS, but it is unlikely to identify high-value clinician performance. One potential redesign would reorient MIPS toward assessing the performance of groups of clinicians on population-based outcome measures.

Second, a modification of the 5 percent A–APM incentive payment could simplify the system and increase equity by applying the 5 percent A–APM incentive payment only to clinicians' revenue through the A–APM.

Third, to address the relative attractiveness of MIPS versus A–APMs, the MIPS exceptional performance bonus fund could be used to finance support for A–APMs. One way to do so would be to establish a two-sided-risk ACO model that contains an asymmetric risk corridor, allowing the upside to be greater than the downside risk. Further, the downside risk could be limited to a share of clinician revenue through the ACO. This approach would give clinician groups a path to two-sided risk that they might find attractive.

These options are meant to inform further policy discussions and to start to address the inherent difficulties in assessing clinician performance and the challenges of moving clinicians toward reformed payment and delivery systems. ■

Endnotes

1 For clarity, we use the terms CMS created and uses in the final rule: for example, *A–APM* instead of *eligible alternative payment model*, the term used in the statute.

2 Other policies in statute may affect the fee schedule payment update in any given year. For example, CMS did not achieve a required level of savings resulting from identifying misvalued codes, and so the effective update in 2016 was less than 0.5 percent.

3 The statute and regulation define the clinicians receiving the 5 percent incentive payment as "qualifying APM participants."

4 If the mean or median MIPS score is 50 points and performance scores are equally distributed, then all clinicians with a score at or above 67.5 points will receive a MIPS exceptional performance bonus, and the MIPS exceptional performance bonus will increase linearly from 67.5 points to the maximum performance score.

5 In the first year, the weighting is 60 percent quality, 15 percent CPIA, 25 percent ACI, and 0 percent cost. By 2021, the weighting is 30 percent quality, 15 percent CPIA, 25 percent ACI, and 30 percent cost. *Applicable* is defined as measures relevant to a particular MIPS-eligible clinician's services or care rendered. CMS has identified 26 specialty measure sets (e.g., cardiology, allergy/immunology, internal medicine) to help clinicians identify applicable measures. Clinicians can receive bonus points for reporting "high-priority" outcomes, patient experience, efficiency measures, or patient safety measures. Clinicians also have the option to report more than six measures and have CMS choose the six that give the best result.

6 The present methods of MIPS reporting are administrative claims, claims, Consumer Assessment of Healthcare Providers and Systems® for MIPS, CMS web interface, EHRs, registry, or Qualified Clinical Data Registry.

7 CMS calculates the performance of all other clinicians who reported the same measure using the same reporting mechanism (e.g., all clinicians that reported a bariatric screening measure using a registry). In its final rule for the 2019 payment year., CMS described various proposals for dealing with topped-out measures and may propose changes to the scoring for topped-out measures in the 2020 rule (that correspond to 2018 quality measure reporting).

8 This scaling effect could occur, for example, because CMS will set the benchmark prospectively. Actual performance may vary.

9 This estimate assumes that the number of clinicians (and their associated Medicare revenue) is evenly distributed above and below the MIPS exceptional performance threshold and that the MIPS exceptional performance threshold is set at 25 percent above the median of performance scores.

10 Some large group practices may have enough clinicians for reliably assessing population-based measures.

11 Assessing patient experience of care by surveying patients directly could give a truer picture of clinical practice improvement, such as greater continuity, after-hours access to needed services, and whether clinicians help facilitate transitions across providers and settings. Currently, the CPIA category in MIPS requires only that the clinician attest that they adopted these processes, even though the processes may not translate into meaningful changes for patients.

12 In theory, on the one hand, clinician practices may be well positioned to achieve savings under an A–APM model because in most cases they do not lose their own FFS revenue if they reduce services such as emergency department visits, inpatient admissions, and post-acute care use. Hence, their incentive to reduce such services may be greater than an A–APM with hospitals as participants. On the other hand, a system that includes hospitals as well as clinicians may control a broader span of services and be better able to coordinate care.

13 For entities that include hospitals as well as clinicians (i.e., the more services provided through the entity), the benchmark-based and revenue-based standards might start to converge because the revenue for the entities would include more of the benchmark.

14 We use 1,000 attributed beneficiaries for ease of illustration only. Medicare Shared Savings Program ACOs for example, must have over 5,000 attributed beneficiaries.

15 These are the minimum standards. Individual models can have higher standards.

16 For entities that have both clinicians and hospitals as participants, the revenue-based and benchmark-based standards would start to converge as the entity's revenue through the A–APM accounted for a larger share of the benchmark.

17 Policymakers would have to decide on the magnitude of the loss limit. Although 8 percent is the current standard for more than nominal risk, individual models have higher limits. CMS is considering raising the minimum in future

years. The 8 percent revenue standard is in effect for the 2017 and 2018 qualified practitioner (QP) performance periods. (The 2017 QP performance period will be used to determine which clinicians are QPs for 2019.) It is not defined for 2019 and after, but two possibilities are offered: 15 percent of revenue or 10 percent of revenue so long as risk is at least equal to 1.5 percent of benchmark.

18 Those principles are discussed in our June 2016 report to the Congress. They include making incentive payments only if the A–APM entity were successful in controlling cost, improving quality, or both; holding an A–APM entity at risk for total Part A and Part B spending; holding the entity responsible for a beneficiary population sufficiently large to detect changes in spending or quality; giving the entity the ability to share savings with beneficiaries; and having CMS give the entity regulatory relief. As discussed in our comment letter on MACRA implementation, some of the proposed A–APMs (e.g., two-sided-risk ESRD (end-stage renal disease) Seamless Care Organizations) are consistent with those principles and others (e.g., Comprehensive Primary Care Plus) are not (Medicare Payment Advisory Commission 2016a, Medicare Payment Advisory Commission 2016b).

19 We discuss two-sided-risk ACOs because they (and models like them) are the A–APMs that most closely align with the Commission's principles for A–APMs.

20 It should be noted that the practice would likely have Medicare FFS revenue outside the ACO that would not be at risk, thus the amount at risk would be a smaller share than 20 percent of the practice's total FFS revenue.

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CHAPTER 6

Payments from drug and device manufacturers to physicians and teaching hospitals in 2015

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Chapter summary

Under the Open Payments program, drug and device manufacturers and group purchasing organizations (GPOs) report information to CMS about payments to physicians and teaching hospitals. Payments to each type of provider are reported separately. This program has shed significant light on industry ties to these providers that were previously obscured.

The Open Payments database contains information on financial interactions worth about $7.3 billion in 2015. Payments for research accounted for just over half of the total; general payments (e.g., royalties and speaking fees) accounted for 35 percent; and physician ownership or investment interests accounted for 11 percent. The data include payments from 1,455 companies to about 618,000 physicians and 1,111 teaching hospitals. Physicians accounted for just over 80 percent of the payments and other transfers of value (about $6.0 billion); teaching hospitals accounted for almost 20 percent (about $1.3 billion). The category of physicians included about 502,000 medical doctors and osteopaths and almost 116,000 dentists, optometrists, podiatrists, and chiropractors.

The distribution of general payments to physicians was highly skewed. The top 5 percent of physicians accounted for 86 percent of the dollars; each of these physicians received about $56,000 in payments, on average. Likewise, the distribution of general payments to teaching hospitals was highly concentrated: 51 percent of the value of these payments ($307 million)

In this chapter

went to a single hospital (City of Hope National Medical Center), and almost all of the payments to this hospital were royalty or license payments from a single manufacturer.

Royalty or license payments to physicians (payments for the right to use patents, copyrights, and other intellectual property) totaled $527 million—the highest share of general payments to physicians in 2015 (26 percent). Royalty or license payments also had the highest average amount per physician: about $233,000 (median of $32,363). A comparatively small number of physicians—about 2,300— received one of these payments. Compensation for services other than consulting (e.g., promotional speaking fees) amounted to $509 million (25 percent of general payments to physicians) and went to about 31,000 physicians. The data reveal the prevalence of industry-provided meals to physicians (about 589,000 physicians received food and beverage), even though food and beverage accounted for only 12 percent of the total value of general payments to physicians.

The physician specialty with the highest amount of general payments was internal medicine, which accounted for $420 million (21 percent of the value of general payments received by physicians). Orthopedic surgery accounted for $410 million, or 21 percent of the value of general payments to physicians. The average payment received by orthopedic surgeons was relatively high: $19,257, with a median of $418. The large difference between the mean and median values indicates that the distribution is skewed toward physicians who received high payments. Royalty or license payments accounted for 71 percent of payments to orthopedic surgeons ($293 million), which indicates the close collaboration between orthopedic surgeons and manufacturers in product development.

We also examined the distribution of payments by the type of company that made the payment. Device manufacturers accounted for 48 percent of general payments to physicians, and drug manufacturers accounted for 46 percent. Device manufacturers accounted for the majority (84 percent) of the value of physician ownership or investment interests, while drug manufacturers accounted for only 8 percent.

Although the Open Payments program has increased the transparency of financial interactions between manufacturers and physicians and teaching hospitals, it should be expanded to include additional providers and organizations that have relationships with manufacturers, consistent with the Commission's prior recommendation. In 2009, the Commission recommended that financial ties between manufacturers and a broad range of providers and other entities (e.g., physicians and other prescribers, pharmacy benefit managers, hospitals, medical schools, organizations that sponsor continuing medical education, patient

organizations, and professional organizations) should be publicly reported. We are especially concerned that manufacturers have financial relationships with many advanced practice registered nurses, physician assistants, and patient organizations, but these relationships are not reported. In addition, the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans. Finally, CMS should require companies to report whether they are a GPO or manufacturer, what type of products they make, whether they are a physician-owned distributor, and the portion of a research payment that is related to physician compensation. ■

Introduction

Many physicians have financial relationships with drug and device manufacturers, including research contracts, consulting arrangements, investment interests, meals, and travel. Many of these financial ties have led to technological innovations and improved patient care. Physicians play an important role in the development of new drugs and devices by overseeing clinical trials, inventing new products, and providing expert advice to manufacturers (Campbell 2007). However, some of these relationships may also create conflicts between physicians' obligations to act in the best interest of their patients and the commercial interests of manufacturers.

Studies have shown that physicians' financial interactions with drug makers are associated with greater willingness to prescribe newer, more expensive drugs (Watkins et al. 2003, Wazana 2000). A recent article found that physicians in Massachusetts who received industry payments prescribed brand-name statins to Medicare beneficiaries at a higher rate than physicians who did not receive payments (Yeh et al. 2016). Another study found that physicians who received meals related to the promotion of specific brand-name medications had a higher rate of prescribing those medications to Medicare beneficiaries (DeJong et al. 2016). This study used data from the Open Payments program on industry-sponsored meals (described below).

Organizations that represent drug and device manufacturers, physicians, and academic medical centers have developed voluntary codes of conduct to manage interactions between manufacturers and physicians, but compliance is not systematically monitored or enforced by these organizations (see text box, pp. 184–187). In addition, many individual health systems and academic medical centers have adopted stringent rules for interactions with the drug and device industry.

Creating more transparency around physician–industry financial ties should help payers, researchers, and the general public better understand the scope and nature of these relationships and how they affect practice patterns and health care spending. Although disclosure alone does not eliminate conflicts of interest, public reporting can help the media, researchers, and regulatory agencies identify potential conflicts. For example, academic medical centers could check whether physicians who oversee research grants have financial interests in a manufacturer that could be affected by the research findings. Disclosure could also motivate physicians to avoid conflicts of interest (Sah and Loewenstein 2014).

In 2009, the Commission and the Institute of Medicine recommended that the Congress require drug and device manufacturers to publicly report their financial relationships with a variety of health care providers and organizations (see text box, p. 188, for Commission recommendations) (Institute of Medicine 2009, Medicare Payment Advisory Commission 2009). The Congress created a public reporting system in Section 6002 of the Patient Protection and Affordable Care Act of 2010. This system—later known as Open Payments—requires manufacturers and group purchasing organizations (GPOs) to submit information to CMS about certain payments and other financial relationships with physicians and teaching hospitals (Centers for Medicare & Medicaid Services 2016a). The database includes information on fees for promotional speeches, royalties, consulting fees, research grants, and other interactions and can be searched or downloaded from a public website. CMS has collected and released data from the last five months of 2013, all of 2014, and all of 2015. For this chapter, we analyzed data from 2015. We previously described data from 2014 in online Appendix 4-A to the March 2016 report to the Congress, available at http://www.medpac.gov (Medicare Payment Advisory Commission 2016). In addition, several journal articles have analyzed payments from the last five months of 2013 or from 2014 (Agrawal and Brown 2016, Fleischman et al. 2016, Marshall et al. 2016, Tierney et al. 2016).

Open Payments program

Under the Open Payments program, manufacturers of drugs, devices, biologics, and supplies are required to annually report to CMS information about certain payments and other transfers of value to physicians and teaching hospitals. In addition, manufacturers and GPOs are required to report ownership or investment interests that physicians or their immediate family members have in their companies. GPOs must also report payments and transfers of value to physicians who have an ownership or investment interest. GPOs are companies that purchase, arrange for, or negotiate the purchase of medical products—namely drugs, devices, biologics, and supplies—for a group of individuals or entities such as hospitals. The data reporting period for 2013 covered the last five months of the year, but the reporting period for 2014, 2015, and future years is the entire calendar year.

Industry and provider guidelines to manage financial relationships between manufacturers and providers

Organizations that represent manufacturers (e.g., the Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association) and providers (e.g., the American Medical Association, Association of American Medical Colleges, American College of Physicians, and American Academy of Orthopaedic Surgeons) have developed voluntary guidelines for interactions between manufacturers and providers. These codes of conduct set boundaries in areas such as the provision of meals and gifts to physicians, consulting arrangements, support of medical education, and sales presentations. These guidelines are described in Table 6-1 (p. 185) and Table 6-2 (pp. 186–187). The organizations that produce these codes do not systematically monitor or enforce members' compliance with them. Instead, compliance is voluntary and self-monitored by companies. For example, PhRMA refers reports of potential breaches in conduct to individual companies for investigation. Manufacturers and providers are required to comply with the federal anti-kickback statute, which prohibits companies from making payments to induce or reward the ordering or referral of items or services reimbursed by federal health programs such as Medicare. The Office of Inspector General has issued guidance to help drug manufacturers identify practices that may lead to violations of this statute (Office of Inspector General 2003).

In addition to guidelines issued by provider associations, individual hospitals, health systems, and academic medical centers (AMCs) have adopted their own rules on physician–industry relationships. The American Medical Student Association (AMSA) and the Institute on Medicine as a Profession (IMAP) rank AMCs on the stringency of their conflict of interest policies, which has spurred the development of these guidelines. AMSA grades AMCs on the rigor of their policies, with "A" being the highest grade and "C" being the lowest. According to AMSA, medical schools have been creating stricter policies in recent years, but the majority of schools still receive a rating of "B" (Carlat et al. 2016). Similarly, IMAP reported that several medical schools adopted more stringent policies regarding potential conflicts of interests between 2008 and 2011, but many remained in the middle (Chimonas et al. 2013). IMAP also found a positive correlation between the amount of funding received by the AMC from the National Institutes of Health and the stringency of the policy (i.e., more funding was associated with more stringent policies).

As an example, Harvard University's School of Medicine developed a policy that received an A rating from AMSA in 2014 (Harvard Medical School 2016). This policy prohibits faculty members from receiving gifts, meals, or travel from manufacturers. In addition, faculty members who participate in research on a specific company's technology may receive no more than $25,000 annually from that company in consulting fees or other income.

Many hospitals and health systems have also imposed restrictions on physician–industry interactions. For example, Dignity Health's policy allows employees to receive gifts or meals of only minimal value (less than $300 per year) and limits speaker's fees to less than $1,000 per year. Dignity Health also prohibits employees from investing in a privately held company with which it conducts business (Dignity Health 2016). Kaiser Permanente has also developed a detailed conflict of interest policy for its employees. As an example, individuals who have the authority to sign contracts for Kaiser Permanente are not allowed to accept anything of value from industry representatives, while employees without this authority can accept gifts or meals only if they are worth less than $25 each. Employees are also prohibited from accepting speaker's fees for presentations related to work conducted for Kaiser Permanente (Kaiser Permanente 2011). ■

(continued next pages)

Under the Open Payments program, CMS defines *physicians* as including medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. However, the statute excludes other health professionals, such as advanced practice nurses and physician assistants, and institutional organizations other than teaching hospitals. By contrast, the Commission has recommended that the program include manufacturers' financial ties to a

Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

TABLE 6-1

PhRMA and AdvaMed codes of conduct for financial relationships with physicians

	The Pharmaceutical Research and Manufacturers of America (PhRMA)	Advanced Medical Technology Association (AdvaMed)
Consulting	• May compensate physicians for "fair market value" and reimburse them for travel • Must have a contract and a legitimate need for a consultant; no trips to resorts	• Compensation must be "fair market value" • May pay for travel/lodging/food • Consulting agreements should be in writing and describe services to be provided
Speakers	• Should not use speaking engagements to reward physicians for prescribing a specific medicine/ treatment regimen • Speakers should be trained • Each company should set a cap on compensation	• Same rules as for consulting
Travel	• Permitted in some instances (consulting) but not in others (CME)	• Permitted for consulting and sales meetings, but not for guests or spouses
Gifts	• May not give items "that do not advance disease or treatment education" (no promotional mugs or pens) • No gift cards or cash permitted • Occasional educational items permitted if under $100 (e.g., anatomical models)	• Acceptable to provide educational items if less than $100 in value (no dollar limit on models or textbooks) • May not give cash or cash equivalents
Research	• Not addressed in code of conduct for interactions with physicians, but addressed in separate code related to clinical trials	• May provide grants for "independent medical research" • Research cannot be linked to medical technology sales
CME/third-party educational conferences	• Funding must go directly to program sponsor • May not pay for lodging/food	• May provide funding if money goes directly to program sponsor • Sponsor must retain control of programming • May provide refreshments
Education	• Addressed in CME section	• May provide grants/funding for fellowships for charity or medically affiliated groups
Food	• May provide food to doctors during workday meetings as a "business courtesy," as long as it is "modest as judged by local standards" and occurs in conjunction with an educational session • May provide modest meals to attendees of events with speakers	• May provide "modest meals and refreshments" to accompany educational programs or sales, promotional, and other business meetings
Entertainment	• Prohibited	• Prohibited
Monitoring/ enforcement of code	• Companies encouraged to seek external verification of their policies and procedures • Companies that comply with code are listed on PhRMA's website • Potential breaches in conduct are referred by PhRMA to the company's chief compliance officer	• Companies encouraged to create a compliance program when adopting the code and submit it to AdvaMed to receive certification • Certified companies are listed on AdvaMed's website • Companies are responsible for enforcing the code

Note: CME (continuing medical education). The PhRMA code was published in 2008 but took effect in January 2009.

Source: Advanced Medical Technology Association 2009, Pharmaceutical Research and Manufacturers of America 2008.

Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

TABLE 6-2

Codes of conduct for financial relationships with industry, developed by physician associations and Association of American Medical Colleges (cont. next page)

	American Medical Association	American College of Physicians	American Academy of Orthopaedic Surgeons	Association of American Medical Colleges
Travel	• Not addressed	• Discourages acceptance of hospitality or trips from the health care industry that might diminish the objectivity of professional judgment	• Not addressed	• Funding for travel should be prohibited except for legitimate reimbursement or contractual services
Gifts	• Prohibits acceptance of cash gifts from a group that has a direct interest in physicians' treatment recommendations or in which reciprocity is expected • Accepted gifts must be of minimal value and directly benefit patients	• Discourages acceptance of gifts from the industry that might diminish the objectivity of professional judgment	• Recommends disclosure to patient if surgeon receives anything of value	• Academic medical centers should establish their own policies, which should prohibit accepting gifts
Royalties	• Not addressed	• Not addressed	• Surgeons should disclose royalties to patients	• Not addressed
Research	• Physicians should not receive compensation for more than the value of their time • Physicians should disclose financial ties to journals	• Financial interests and funding sources should be disclosed in writing to publishers and potential research collaborators • Researchers must have contributed to research in order to have their names on it • Physicians should not participate in research if negative results will not be published	• Surgeons are allowed to receive fair market reimbursement for reasonable administrative costs related to a clinical trial • Must disclose financial interests when reporting on clinical research on a particular product or procedure • Ghostwriting is not acceptable	• Researchers should report related financial interests to the institution, including dollar amount • Ghostwriting should be prohibited
CME	• Physicians should participate in CME events but should not accept subsidies from outside groups to do so • Physicians who participate in CME events should disclose financial support from the industry	• Organizations hosting CME events may accept industry funding if they are in charge of the event; industry cannot influence programming	• Should participate in CME events	• AMCs should establish a central CME office and adhere to guidelines from the Accreditation Council for Continuing Medical Education • Physicians should not accept gifts or payments from industry for attending a CME event

Note: CME (continuing medical education), AMC (academic medical center).

Source: American Academy of Orthopaedic Surgeons 2011, American College of Physicians 2016, American Medical Association 2016b, American Medical Association 2016c, Association of American Medical Colleges 2010, Association of American Medical Colleges 2008.

Industry and provider guidelines to manage financial relationships between manufacturers and providers (cont.)

TABLE 6-2

Codes of conduct for financial relationships with industry, developed by physician associations and Association of American Medical Colleges (cont.)

	American Medical Association	American College of Physicians	American Academy of Orthopaedic Surgeons	Association of American Medical Colleges
Funding for medical education	• Institutions/fellowship programs may accept funding if: 1) funding is based on institution-specific criteria and 2) funding is not attributed to specific sponsors	• Not addressed	• Not addressed	• Scholarships/educational funds must go directly to the administration of the AMC • Funders cannot be involved in the selection of funding recipients
Food	• Not specifically addressed; gifts of "minimal value" are acceptable	• Discourages acceptance of hospitality from the industry that might diminish the objectivity of professional judgment	• Not addressed	• Institutions should prohibit food/meals at AMCs and off site
Speaking	• Not addressed	• Physicians should disclose their interests in writing when speaking	• Not addressed	• Physicians should disclose to their AMC when speaking at industry-sponsored events • Participation in speakers' bureaus should be discouraged
Drug samples	• Not addressed	• Physicians cannot sell free samples	• Not addressed	• Free samples should be handled by a central manager
Ownership of company or facility	• Physicians should not refer patients to facilities that they own/invest in if they do not also provide care there	• May invest in facilities, but should not refer patients to facilities at which they do not provide care	• Patient should be notified if surgeon has an interest in product/company	• Faculty and staff should disclose financial interests • Individuals with financial interests should not be involved in purchasing decisions related to their interests

Note: CME (continuing medical education), AMC (academic medical center).

Source: American Academy of Orthopaedic Surgeons 2011, American College of Physicians 2016, American Medical Association 2016b, American Medical Association 2016c, Association of American Medical Colleges 2010, Association of American Medical Colleges 2008.

broader set of providers and organizations, including other prescribers (e.g., advanced practice nurses and physician assistants), pharmacists, health plans, pharmacy benefit managers, hospitals, medical schools, organizations that sponsor continuing medical education, patient organizations, and professional organizations (see text box, p. 188) (Medicare Payment Advisory Commission 2009).

Manufacturers are required to report the name, state license number, national provider identifier (NPI), specialty, and address of physicians who receive payments

Prior Commission recommendations on public reporting by drug and device manufacturers of financial relationships

Recommendation 5-1 from the March 2009 report to the Congress

The Congress should require all manufacturers and distributors of drugs, biologicals, medical devices, and medical supplies (and their subsidiaries) to report to the Secretary their financial relationships with:

- physicians, physician groups, and other prescribers;
- pharmacies and pharmacists;
- health plans, pharmacy benefit managers, and their employees;
- hospitals and medical schools;
- organizations that sponsor continuing medical education;
- patient organizations; and
- professional organizations.

Recommendation 5-2 from the March 2009 report to the Congress

The Congress should direct the Secretary to post the information submitted by manufacturers on a public website in a format that is searchable by:

- manufacturer;
- recipient's name, location, and specialty (if applicable);
- type of payment;
- name of related drug or device (if applicable); and
- year.

Recommendation 5-3 from the March 2009 report to the Congress

The Congress should require manufacturers and distributors of drugs to report to the Secretary the following information about drug samples:

- each recipient's name and business address;
- the name, dosage, and number of units of each sample; and
- the date of distribution.

The Secretary should make this information available through data use agreements. ■

or other transfers of value. They must also report the name and address of teaching hospitals that receive payments. In addition, manufacturers must report the type of payment (e.g., research or consulting); the amount; the payment date; and the name of the drug or device related to the payment (if a specific drug or device is related to the payment). Manufacturers and GPOs may voluntarily report brief contextual information about payments but are not required to do so. All of these data except physician NPIs are available on a public website (the statute prohibits CMS from including NPIs on the website). The data include direct payments or transfers of value to physicians or teaching hospitals as well as indirect payments and third-party payments. Indirect payments occur when the manufacturer makes a payment to an intermediary (such as a specialty society) and requires, instructs, or directs the intermediary to provide the payment to a physician or teaching hospital. Third-party payments are payments that are designated by a physician or teaching hospital for a third-party such as a charity.

Several types of payments and transfers of value are excluded from reporting, such as samples, educational materials that are for patient use, and discounts on products purchased by physicians or teaching hospitals (such as drug rebates). In 2015, payments or transfers worth less than $10.21 are also excluded unless the aggregate amount transferred by a manufacturer to a recipient during the year exceeds $102.07.[1] Until 2016, if a manufacturer sponsored an accredited continuing medical education (CME) program, payments made

by that program to physician speakers were excluded from reporting if the manufacturer did not influence the choice of speakers. Specifically, the manufacturer was not allowed to (1) select the speaker of the program or provide a list of individuals to be selected as the speaker or (2) directly pay the speaker. Beginning in 2016, manufacturers are required to report these payments if they are indirect payments and if they know or can determine the identity of the physicians who attended or spoke at the CME event during the reporting year or by the end of the second quarter of the following reporting year (Centers for Medicare & Medicaid Services 2017c).

CMS divides the payments and transfers of value into three broad categories: research payments, ownership or investment interests, and general payments. Research payments include payments to teaching hospitals and physicians for basic research, applied research, and product development. Manufacturers must report all payments for services included in the written agreement or research protocol. Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. These payments may cover costs associated with patient care, the time spent managing the study, the drugs or devices that are studied, and other items provided by the manufacturer. The payment information does not distinguish between costs associated with the study and the physician's compensation for managing the study.

Manufacturers may request that CMS delay publication of research payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product. Publication of these payments may be delayed for four years or until the date of approval, licensure, or clearance of the product by the Food and Drug Administration, whichever date comes first. The goal of this statutory provision is to balance manufacturers' desire to protect proprietary information about new products with the goal of public transparency.

Ownership or investment interests include ownership interests by physicians in manufacturers or GPOs, including stocks, stock options, partnership shares, and limited liability company memberships. They also include loans, bonds, and other financial instruments that are secured with an entity's property or revenue. General payments include all other reported payments and transfers of value to physicians and teaching hospitals, such as promotional speaking fees, royalty and license payments, consulting fees, food and beverage, travel and lodging expenses, and education.

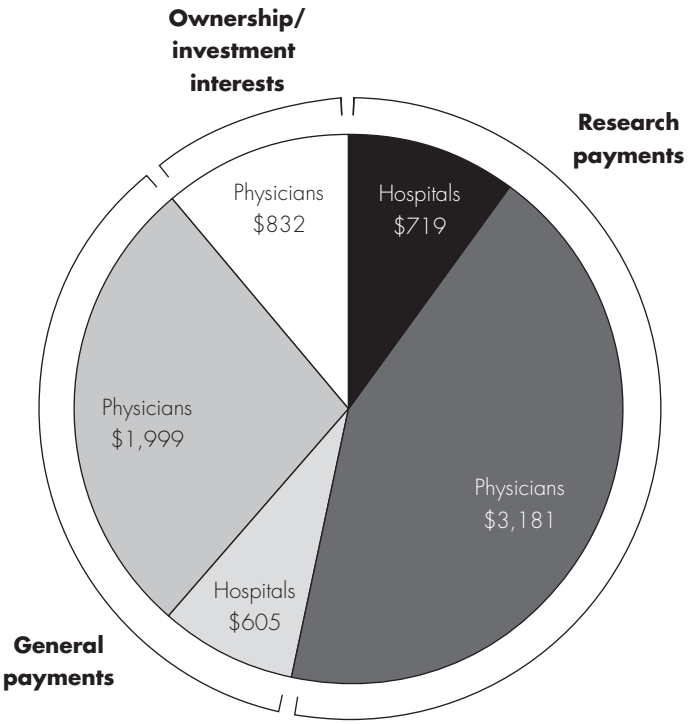
CMS encourages physicians and teaching hospitals to review data reported by manufacturers and GPOs before the records are published on the website. If these recipients register with the Open Payments system, they may dispute information reported about them that may be inaccurate. Recipients have 45 days to review and dispute records before they are posted to the website, but they may continue to dispute records after they are published. Manufacturers and GPOs are able to review disputed information and correct it if necessary.

About 28,000 physicians and 450 teaching hospitals registered in the Open Payments system to review payments made in 2013 or 2014 (Centers for Medicare & Medicaid Services 2016a). These numbers represent about 4 percent of all physicians who received a payment in either year and about 40 percent of all teaching hospitals that received a payment in either year. These recipients disputed about 25,000 payment records from 2013 or 2014 (less than 1 percent of the total). Most of these disputes (about 85 percent) were resolved by the end of the review period. About 17,000 payment records from 2015 were disputed by physicians and teaching hospitals, but CMS has not yet released the number of recipients who reviewed payments from 2015 (Centers for Medicare & Medicaid Services 2016b).

The American Medical Association (AMA) asserts that the process for physicians to register with the Open Payments system is confusing and overly burdensome, which they believe deters many physicians from reviewing and verifying payments attributed to them (American Medical Association 2016a). During 2016, CMS used e-mails, Twitter, blogs, conference calls, and presentations to educate physicians and teaching hospitals about the Open Payments program and how to register with the system to review their records (Centers for Medicare & Medicaid Services 2016c). CMS also created a free mobile app for physicians to track the payments they receive in real time, which they can use to verify the accuracy of payments reported by the industry (Centers for Medicare & Medicaid Services 2017b). In addition, the AMA has encouraged physicians to register with the system and review their payments (American Medical Association 2016d). We do not yet have information on whether the number of recipients who reviewed Open Payments data has increased over time.

FIGURE 6–1

Payments and other transfers of value by manufacturers and GPOs to physicians and teaching hospitals, by payment type, 2015 (in millions)



Note: GPOs (group purchasing organizations). "General payments" includes promotional speaking fees, royalty and license payments, consulting fees, food and beverage, and other items. "Research payments" does not include payments that are subject to delayed publication (manufacturers may request that CMS delay publication of payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product). Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors.

Source: MedPAC analysis of Open Payments data for 2015 from CMS (data released in January 2017).

Analysis of Open Payments data from 2015

To analyze Open Payments data from 2015, we used three Open Payments data files (general payments, research payments, and ownership or investment interests) for 2015 and a file that contains information on each physician who received a payment (the physician profile supplement file). We used the specialty code for each physician from the physician profile supplement file.

The Open Payments program has several limitations. First, many research payments are reported to CMS but not publicly released because of a statutory provision that allows manufacturers to delay publication of certain research payments. This provision makes it difficult to assess the full scope of industry support for research. In 2014, $1.3 billion in research payments were subject to delayed publication (CMS has not yet released the comparable number for 2015) (Centers for Medicare & Medicaid Services 2016a).

Second, the data do not indicate whether a GPO or a manufacturer made the payment or whether a manufacturer that made a payment produces drugs, biologics, devices, or supplies (the database lists the manufacturer's name but not the types of products it makes). To examine the distribution of payments by type of company, we used websites and other sources to identify whether each company was a drug manufacturer, device manufacturer, producer of both drugs and devices, a traditional GPO (not a physician-owned distributor), a physician-owned distributor (POD), or another type of company. PODs are physician-owned entities that derive revenue from selling, or arranging the sale of, implantable medical devices ordered by their physician-owners for procedures performed by the physician-owners at hospitals or other facilities (Office of Inspector General 2013a). (See Chapter 7 of this report.) According to CMS, most PODs are a type of GPO and are therefore subject to the Open Payments reporting requirements (Centers for Medicare & Medicaid Services 2013). However, PODs that purchase devices for resale to a single hospital rather than a group of hospitals do not meet CMS's definition of a GPO and are therefore excluded from reporting.[2] To identify PODs, we used the membership list of the American Association of Surgeon Distributors, a POD association. We also assumed that companies that met the following criteria were likely to be PODs:

- the company focused on spinal implants—because PODs have been most prevalent in the field of spinal surgery (U.S. Senate Committee on Finance 2016),
- the company had a small number of physician owners, and
- the ownership interest of each physician owner was worth a similar amount.

Third, in the absence of additional information, it is difficult for patients and researchers to determine from the data whether a financial relationship served a legitimate purpose or posed a potential conflict of interest. For example, the Open Payments website does not contain information on whether a consulting payment from a manufacturer to a physician was related to a written contract under which the physician performed legitimate work for the company. Fourth, there may be underreporting of information by companies. For example, the Senate Finance Committee found that many PODs do not report their physician ownership interests to CMS (U.S. Senate Committee on Finance 2016).

Results

In 2015, through the Open Payments program, manufacturers and GPOs reported about $7.3 billion in payments and other transfers of value to physicians and teaching hospitals. By comparison, the total value of payments in 2014 was $7.5 billion. The total for both years excludes research payments that were subject to delayed publication (i.e., they were reported to CMS but not published). Compared with reported payments in 2014, payments in 2015 were $40 million lower for general payments, $100 million higher for research payments, and about $230 million lower for ownership or investment interests. In 2015, research payments accounted for just over half of the total amount, general payments accounted for 35 percent, and physician ownership or investment interests accounted for 11 percent (Figure 6-1). The 2015 data include payments from 1,455 companies to about 618,000 physicians and 1,111 teaching hospitals (Centers for Medicare & Medicaid Services 2017a). The category of physicians included about 502,000 medical doctors and osteopaths and almost 116,000 dentists, optometrists, podiatrists, and chiropractors.

Among physicians who received at least one general payment, the average amount per physician was $3,242 (median of $157). To calculate the average dollar amount per physician, we aggregated all the transactions for each physician and calculated the mean dollar amount across all physicians. We did not calculate the average amount of research payments per physician because many research payments list multiple physicians as principal investigators and we could not attribute these payments to an individual physician. Teaching hospitals received $550,791, on average, in general payments (median of $16,910) and $1.04 million in research payments, on average (median of $100,409). We also examined physician ownership or investment interests in a manufacturer or GPO (companies do not report this information for teaching hospitals). Physicians had an average ownership or investment interest of $215,045 (median of $4,667).

Physicians accounted for just over 80 percent of the payments and other transfers of value in 2015 (about $6.0 billion); teaching hospitals accounted for almost 20 percent (about $1.3 billion) (Table 6-3, p. 192). About half of total physician payments were research payments, one-third were general payments, and 14 percent were ownership or investment interests. Over half of total payments to teaching hospitals were research payments and just under half were general payments.

General payments to physicians and teaching hospitals

We examined general payments in greater detail because they include a variety of payment types and most represent direct compensation to physicians.[3] By contrast, research payments may include costs associated with managing a study and patient care in addition to direct physician compensation. We analyzed general payments by type of payment, type of recipient (physician or teaching hospital), and physician specialty.

A small proportion of physicians accounted for a majority of the total dollars received by physicians in the general payments category. In 2015, the top 5 percent of physicians received 86 percent of the dollars; each of these physicians received about $56,000 in payments, on average. The top 10 percent of physicians received 91 percent of the dollars, with each physician receiving about $30,000, on average. By contrast, physicians in the bottom 90 percent received only 9 percent of the dollars, with each physician receiving $311, on average.

We examined the distribution of general payments to physicians in 2015 by type of payment (Table 6-4, p. 193). Royalty or license payments (payments for the right to use patents, copyrights, and other intellectual property) accounted for the highest share of general payments (26 percent) and had the highest average amount per physician: about $233,000 (median of $32,363). Only 2,265 physicians received a royalty or license payment. Compensation for services other than consulting accounted for 25 percent of the value of general payments to physicians. According to CMS, this category should include payments to physicians for speaking, training, and educational engagements that are not related to continuing education (e.g., a manufacturer pays a

TABLE 6–3

Payments and other transfers of value by manufacturers and GPOs to physicians and teaching hospitals, by recipient and payment type, 2015

	Physicians		Teaching hospitals		Total	
	Dollars (in millions)	Share of total physician payments	Dollars (in millions)	Share of total teaching hospital payments	Dollars (in millions)	Share of total
Research payments	$3,181	53%	$719	54%	$3,900	53%
General payments	1,999	33	605	46	2,604	35
Physician ownership or investment interests	832	14	N/A	N/A	832	11
Total	6,012	100	1,324	100	7,336	100

Note: GPO (group purchasing organization), N/A (not applicable). "General payments" includes promotional speaking fees, royalty payments, consulting fees, food and beverage, and other items. "Research payments" does not include payments that are subject to delayed publication (manufacturers may request that CMS delay publication of payments related to research or development of a new drug, device, biologic, or medical supply, or a new application of an existing product). Research payments to physicians include payments for which the physician is the primary recipient as well as payments to research institutions for which a physician is a principal investigator on a project. "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Open Payments data for 2015 from CMS (data released in January 2017).

physician to talk about a drug to other physicians at a restaurant) (Centers for Medicare & Medicaid Services 2017d). However, we also found several large payments to physicians to acquire physician-owned companies in this category, which suggests that CMS should create a separate category for such payments. About 31,000 physicians (5 percent of physicians who received at least one general payment) received compensation for services other than consulting; the average amount per physician was about $16,000 (median of $4,000) (Table 6-4). Consulting fees were received by about 36,000 physicians and accounted for 17 percent of the total value of general payments. Food and beverage accounted for 12 percent of the total but were received by about 589,000 physicians (96 percent of physicians who received at least one general payment), indicating the prevalence of industry-sponsored meals. The average value of food and beverage per physician was $400 (median of $138). A study that used Open Payments data from the last five months of 2013 and data on prescriptions from Medicare Part D found that physicians who received meals related to the promotion of specific brand-name medications had a higher rate of prescribing those medications to Medicare beneficiaries (DeJong et al. 2016). About 70,000 physicians received travel and lodging, with an average value of $2,669 per physician (median of $1,030).

The distribution of general payments to teaching hospitals in 2015 was highly concentrated: 51 percent of the value of these payments ($307 million) went to a single hospital (City of Hope National Medical Center, Duarte, CA), and almost all of the payments to this hospital were royalty or license payments from a single manufacturer. Overall, royalty or license payments accounted for 70 percent of the total value of general payments to teaching hospitals (Table 6-5, p. 194) compared with 26 percent of general payments to physicians (Table 6-4). Grants accounted for 11 percent of the value of general payments to teaching hospitals compared with only 1 percent of the physician total. The gifts category accounted for only 2 percent of the total value of general payments to teaching hospitals but was the most prevalent type of payment, received by 78 percent of hospitals.

General payments by physician specialty

Table 6-6 (p. 195) shows general payments for the top 10 physician specialties for 2015. Internal medicine accounted for $420 million, or 21 percent of the total value of general payments. The internal medicine

TABLE 6–4 **General payments by manufacturers and GPOs to physicians, by payment category, 2015**

	Payments		Physicians			
	Amount (in millions)	Share of total	Number	Share of all physicians who received a general payment*	Mean payment per physician	Median payment per physician
Royalty or license	$527	26%	2,265	<1%	$232,693	$32,363
Compensation for services other than consulting	509	25	31,369	5	16,224	4,000
Consulting fee	349	17	36,319	6	9,603	2,415
Food and beverage	235	12	589,042	96	400	138
Travel and lodging	187	9	70,046	11	2,669	1,030
Ownership or investment interest	51	3	769	<1	66,859	4,000
Honoraria	36	2	6,880	1	5,273	2,210
Education	36	2	120,341	20	297	35
Serving as faculty for medical education program	35	2	4,788	1	7,301	2,740
Grant	19	1	2,472	<1	7,802	1,873
Gift	9	0.5	22,726	4	409	90
Charitable contribution	5	0.2	257	<1	18,665	1,000
Entertainment	0.4	0.02	3,203	1	117	56
Total	1,999	100	616,567		3,242	157

Note: GPO (group purchasing organization). "Physicians" includes medical doctors, osteopaths, dentists, optometrists, podiatrists, and chiropractors. "Royalty or license payments" includes payments for the right to use patents, copyrights, and other intellectual property. "Compensation for services other than consulting" includes promotional speaking fees and payments to acquire physician-owned companies. "Ownership or investment interest" includes interests that manufacturers or GPOs give to physicians but excludes interests that are purchased by physicians. All ownership or investment interests, whether given to physicians or purchased by physicians, appear in a separate file. "Serving as faculty for medical education program" includes compensation for serving as faculty for unaccredited and accredited education programs. The number of physicians does not sum to 616,567 because a single physician could have received payments in multiple categories. Numbers for share of total payments do not sum to 100 percent due to rounding.
*This column indicates the share of physicians in the general payments file that received a payment in each category. Because a single physician could have received payments in multiple categories, this column does not sum to 100 percent.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

category includes internal medicine plus related specialties such as endocrinology, gastroenterology, medical oncology, and rheumatology. Each physician in the internal medicine category received $3,522 on average, with a median of $260. The large difference between the mean and median values indicates that a small number of physicians received high payment amounts, while most physicians received relatively small amounts. Compensation for services other than consulting (e.g., promotional speaking fees, payments to acquire physician-owned companies) accounted for the highest share of payments received by internal medicine physicians (42 percent) (data not shown).

Orthopedic surgery accounted for $410 million, or 21 percent of the total value of general payments. The average amount received by orthopedic surgeons was relatively high: $19,257, with a median of $418. Royalty or license payments accounted for 71 percent of payments to orthopedic surgeons ($293 million), which indicates the close collaboration between orthopedic surgeons and manufacturers in product development (data not shown). This specialty accounted for 56 percent of all royalty payments across all physicians.

Neurological surgeons also had relatively high average payment amounts ($21,906). Dentists and family medicine physicians had relatively low average payments ($873 and $819, respectively).

TABLE 6–5 **General payments by manufacturers to teaching hospitals, by payment category, 2015**

	Payments		Hospitals			
	Amount (in millions)	Share of total	Number	Share of all hospitals that received a general payment*	Mean payment per hospital	Median payment per hospital
Royalty or license	$423	70%	88	8%	$4,803,321	$30,690
Grant	68	11	693	63	97,704	4,463
Consulting fee	30	5	238	22	124,221	3,063
Space rental/facility fees	21	3	669	61	30,997	6,007
Charitable contribution	18	3	257	23	18,665	1,000
Compensation for services other than consulting	18	3	585	53	30,483	2,800
Education	14	2	733	67	19,761	2,221
Gift	12	2	854	78	13,768	3,578
Other categories	2	0.3	698	64	2,558	401
Total	605	100	1,098		550,791	16,910

Note: "Royalty or license payments" are payments for the right to use patents, copyrights, and other intellectual property. "Other categories" include compensation for serving as faculty for medical education programs, travel and lodging, food and beverage, honoraria, ownership or investment interest, and entertainment. Numbers in the first column ("Amount") do not sum to total due to rounding. Numbers for share of total do not sum to 100 percent due to rounding. The number of hospitals does not sum to 1,098 because a single hospital could have received payments in multiple categories.
*This column indicates the share of hospitals in the general payments file that received a payment in each category. Because a single hospital could have received payments in multiple categories, this column does not sum to 100 percent.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

Distribution of payments to physicians by type of company making the payment

We examined the distribution of payments to physicians by the type of company that made the payment: device manufacturer, drug manufacturer, manufacturer of both drugs and devices, traditional GPO (not a POD), POD, or "other" company (e.g., cryotherapy facilities and blood banks). Device manufacturers accounted for 48 percent of general payments to physicians, and drug manufacturers accounted for 46 percent (Table 6-7). Device manufacturers accounted for the majority (84 percent) of the value of physician ownership or investment interests, while drug manufacturers accounted for only 8 percent (Table 6-8, p. 196).

We identified only 8 PODs in the general payments file and 16 PODs in the physician ownership or investment interests file. A Senate Finance Committee report found evidence that many PODs do not report their physician ownership interests to Open Payments, and some PODs have changed how they compensate physicians to circumvent the reporting requirements (U.S. Senate Committee on Finance 2016) (see the section on requiring companies to report their company type, p. 198).

Expanding and improving the Open Payments program

Although the Open Payments program has shed significant light on financial interactions between manufacturers and physicians and teaching hospitals, it should be expanded to include additional providers and organizations that have relationships with manufacturers. In addition, the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans. Finally, CMS should require companies to report whether they are a GPO or manufacturer, the type of products they make, whether they are a POD, and the portion of a research payment that is related to physician compensation.

TABLE 6–6 **General payments by manufacturers and GPOs to physicians, top 10 specialties, 2015**

Specialty	Payments (in millions)	Share of total	Number of physicians	Mean payment per physician	Median payment per physician
Internal medicine	$420	21%	119,224	$3,522	$260
Orthopedic surgery	410	21	21,310	19,257	418
Cardiology	168	8	21,660	7,749	829
Psychiatry and neurology	144	7	32,282	4,455	222
Neurological surgery	98	5	4,486	21,906	461
Other surgery	76	4	23,644	3,220	249
Radiology	66	3	14,315	4,620	116
Dentist	64	3	73,310	873	63
Ophthalmology	60	3	13,725	4,346	195
Family medicine	54	3	65,549	819	178

Note: GPO (group purchasing organization). "Internal medicine" includes internal medicine, endocrinology, gastroenterology, hematology, medical oncology, pulmonary disease, rheumatology, and some other specialties. "Other surgery" includes hand surgery, pediatric surgery, plastic surgery, trauma surgery, vascular surgery, surgical oncology, and surgical critical care.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released in June 2016).

Include additional providers and organizations in the Open Payments program

The statute that created the Open Payments program requires manufacturers and GPOs to report financial interactions with physicians and teaching hospitals but not with other health professionals or organizations. Consistent with our recommendation from 2009, we urge the Congress to expand this reporting requirement so that it also applies to financial ties with other clinicians (e.g., advanced practice registered nurses (APRNs) and physician assistants (PAs)), pharmacists, health plans, pharmacy benefit managers, other hospitals, medical schools, organizations that sponsor continuing medical education, patient organizations, and professional organizations (see text box, p. 188) (Medicare Payment Advisory Commission 2009). We are especially concerned that payments and other transfers of value from

TABLE 6–7 **General payments to physicians, by type of company, 2015**

Company type	Payments		Number of unique companies	Share of total number of companies
	Amount (in millions)	Share of total		
Device manufacturer	$962	48%	816	67%
Drug manufacturer	910	46	242	20
Drug and device manufacturer	99	5	56	5
Other	15	1	69	6
GPO	10	<1	33	3
POD	3	<1	8	<1
Total	1,999	100	1,224	100

Note: GPO (group purchasing organization), POD (physician-owned distributor). "Other" includes blood banks, cryotherapy facilities, and companies whose company type could not be identified. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Open Payments data from the general payments file for 2015 from CMS (data released June 2016).

TABLE 6–8 **Value of physician ownership or investment interests, by type of company, 2015**

Company type	Ownership or investment interests: Value (in millions)	Ownership or investment interests: Share of total	Number of unique companies	Share of total number of companies
Device manufacturer	$699	84%	150	71%
Drug manufacturer	68	8	6	3
Drug and device manufacturer	33	4	4	2
Other	26	3	34	16
POD	6	1	16	8
GPO	0.1	<1	1	<1
Total	832	100	211	100

Note: POD (physician-owned distributor), GPO (group purchasing organization). "Other" includes blood banks, cryotherapy facilities, and companies whose company type could not be identified.

Source: MedPAC analysis of Open Payments data from the physician ownership file for 2015 from CMS (data released in January 2017).

manufacturers to APRNs, PAs, and patient organizations are not reported to Open Payments, even though the industry has financial relationships with many of these providers and organizations.

Growth in the number of APRNs and PAs and their interactions with drug manufacturers

The number of APRNs and PAs has increased in recent years, and they play an increasingly important role in the health care system, such as coordinating care and managing medications. From 2013 through 2015, the number of APRNs and PAs billing Medicare grew from 3.2 per 1,000 beneficiaries to 3.6 per 1,000 beneficiaries, an increase of 13.4 percent (Medicare Payment Advisory Commission 2017). According to a ProPublica analysis, these clinicians wrote about 10 percent of all Medicare Part D prescriptions in 2013 and 15 percent of prescriptions across all payers in the first five months of 2013 (Ornstein 2015). A national survey of nurse practitioners (NPs), a type of APRN, found that nearly all of them (96 percent) had regular contact with sales representatives from drug companies (Ladd et al. 2010). Almost half of the NPs reported regular attendance (one to five times during the prior six months) at industry-sponsored lunch events, and 64 percent reported regular attendance at sponsored dinner events. Almost half stated that they were more likely to prescribe a drug highlighted at an industry-sponsored event after attending the event. The exclusion of APRNs and PAs from the Open Payments system creates an incentive for manufacturers to shift payments from physicians to these clinicians to avoid the reporting requirements.

Most patient organizations receive industry funding, but many do not routinely disclose funding sources

Patient organizations engage in policy and advocacy activities, educate patients, and fund and conduct important research (Rose et al. 2017). Most of these organizations receive industry funding, which may influence their agendas and activities, but many of them do not routinely disclose all of their funding sources. A survey of these entities conducted in 2013 and 2014 found that about two-thirds received industry funding, with 12 percent receiving more than half of their funding from industry (Rose et al. 2017). The largest share of industry funding came from pharmaceutical, device, and biotechnology companies (the median share of funding from these sectors was 45 percent). A recent study of the 104 largest patient advocacy organizations found that at least 83 percent received financial support from drug, device, and biotechnology companies (McCoy et al. 2017). Although 57 percent of these organizations disclosed the donations they received, the amounts were typically disclosed as broad ranges rather than precise figures. In most cases, this practice made it impossible to calculate the precise amount of industry support for an organization.

Media coverage has also highlighted extensive financial ties between drug manufacturers and several large patient organizations (Fauber 2012, Mullins 2017, Ornstein and Weber 2011, Thomas 2016).

Industry funding can create conflicts between the missions of patient organizations and their funders' financial interests. For example, a large advocacy group for patients with pain, which received almost 90 percent of its funding from drug and device manufacturers, produced guides for patients, journalists, and policymakers that downplayed the risks associated with opioids and exaggerated their benefits (Ornstein and Weber 2011). Requiring drug and device companies to publicly report their financial support for patient organizations through Open Payments would enable the public and policymakers to assess potential conflicts of interest.

Require the Secretary to make data on drug samples available to oversight agencies, researchers, payers, and health plans

In 2012, the pharmaceutical industry provided free drug samples worth $5.7 billion to practitioners and other providers (Pew Charitable Trusts 2013). According to a national survey of physicians conducted in 2009, 64 percent of physicians received drug samples in the prior year (Campbell et al. 2010). A national survey of NPs conducted in 2007 and 2008 found that 66 percent of NPs dispensed drug samples for treatment. Although samples clearly offer benefits for many patients, they may also lead clinicians and patients to rely on more expensive drugs when cheaper products may be equally effective. Comprehensive information about the distribution of samples would enable CMS, the Office of Inspector General (OIG), congressional oversight agencies, and researchers to study their impact on prescribing patterns, overall drug spending, and patients' adherence to treatment regimens. Such data could also help payers and health plans improve their counter-detailing programs (also known as academic detailing), which provide information on drugs to physicians through educational visits by clinicians (Kaiser Family Foundation 2005). These programs are designed to reduce excessive use of expensive drugs by offering evidence-based information on the safety, efficacy, and costs of alternative medications. For example, a program may share evidence with physicians that a brand-name drug is no more effective than a cheaper, older alternative. Manufacturers and distributors of pharmaceuticals currently report information about drug samples to the Food and Drug Administration (FDA). Consistent with the Commission's recommendation from 2009 on samples, the Congress should require the Secretary to make this information available under data use agreements to oversight agencies, researchers, payers, and health plans (Medicare Payment Advisory Commission 2009).

Free samples may allow patients to start treatments sooner and help physicians evaluate a drug's effectiveness before a patient purchases the full prescription (Chew et al. 2000). Samples also help some patients without insurance or with coverage limitations obtain medication. According to a study by Cutrona and colleagues, about 10 percent of uninsured patients reported receiving at least one free drug sample in 2003 (Cutrona et al. 2008). However, the same study found that wealthy and insured patients were more likely to receive free samples than poor and uninsured individuals. In addition, other research has found that physicians who receive samples of a new drug are more likely to prescribe it (Peay and Peay 1988), patients who receive samples have higher out-of-pocket spending on drugs than patients who do not receive samples (Alexander et al. 2008), and physicians are more likely to prescribe generic medications to uninsured patients after drug samples are removed from their office (Miller et al. 2008).

Oversight agencies, researchers, payers, and plans could use data on drug samples for research and counter-detailing programs

Comprehensive data on the distribution of drug samples—combined with claims data on prescriptions—would enable further research on the effects of samples. Oversight agencies and researchers could examine questions such as:

- Does the use of samples vary by practice setting (e.g., office based vs. hospital based), physician specialty, or patient characteristics?
- Do practices that accept samples prescribe more expensive medications? Do they adopt newer drugs faster than other practices?
- Do the patients of clinicians who accept samples spend more on drugs or other health care services? Are they more likely to comply with treatment regimens?

Payers and plans could use information on practices' acceptance of drug samples to improve their counter-detailing efforts. For example, they could focus counter-detailing programs on practices that are more likely to accept samples of new drugs.

Manufacturers and distributors are required to collect and report information on drug samples to the Secretary

Under the Prescription Drug Marketing Act of 1987 (PDMA), manufacturers and distributors are required to keep internal records of the drug samples they distribute to practitioners and pharmacies of hospitals and other entities. Section 6004 of the Patient Protection and Affordable Care Act of 2010 (PPACA) requires manufacturers and distributors to annually report to the Secretary much of the information they collect under PDMA (Food and Drug Administration 2014). This information includes the identity and quantity of drug samples requested and distributed; the name, address, and professional designation of the practitioner who requested the samples; and the name and address of the practitioner (or the practitioner's designee) who received the samples.[4] The Secretary delegated the authority to collect this information to the FDA, which has released industry guidance on the reporting process (Food and Drug Administration 2014).

The Commission recommended in 2009 that the Congress require manufacturers and distributors to report detailed information about drug samples to the Secretary, which the Secretary should make available through data use agreements (see text box, p. 188). Although the Congress adopted the first part of this recommendation in PPACA, the statute does not give the Secretary authority to release information on samples to researchers or others. Therefore, we reprint our recommendation that the Congress authorize and require the Secretary to make this information available to researchers, payers, and plans that sign confidentiality and data use agreements.[5] To foster legitimate use of the data, the process for requesting and obtaining the information should not be overly restrictive.

Collect more detailed data on manufacturers, GPOs, and research payments

CMS should require companies to report whether they are GPOs or manufacturers, what type of products they make, and whether they are PODs. In addition, manufacturers should report the portion of a research payment that is related to physician compensation. CMS could likely use its existing statutory authority to require GPOs and manufacturers to report this information.

Require companies to report their company type

Although the Open Payments database lists the name of each manufacturer or GPO that made the payment or transfer of value, it does not indicate whether the company is a GPO or a manufacturer. Manufacturers do not report whether they produce drugs, biologics, devices, or supplies. Although some manufacturers are well known and users of the data may recognize whether they produce drugs, devices, or another product, some manufacturers are less well known. Moreover, some manufacturers report payments in the name of their subsidiaries.

In addition, GPOs do not report whether they are PODs (see p. 190 for the definition of PODs). According to CMS, PODs that purchase devices and other items for resale or distribution to groups of individuals or entities are considered a type of GPO and are therefore subject to the Open Payments reporting requirements (Centers for Medicare & Medicaid Services 2013). It is important to identify PODs because they have been the subject of reports and investigations by OIG and the Senate Finance Committee (Office of Inspector General 2013b, U.S. Senate Committee on Finance 2016). OIG warned that PODs are inherently suspect under the anti-kickback statute because they offer financial incentives to their physician-owners that may induce the physicians to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices sold by the PODs instead of other devices (Office of Inspector General 2013a). OIG's concerns are heightened because physicians, rather than hospitals or ambulatory surgical centers, strongly influence the choice of implantable medical devices used in procedures. OIG found that PODs supplied devices used in nearly one-fifth of spinal fusion surgeries paid for by Medicare in 2011 (Office of Inspector General 2013b). Among hospitals that purchased spinal devices from PODs, their rate of spinal surgery grew faster than the rate for hospitals overall.

The Senate Finance Committee found evidence that many PODs do not report their physician ownership interests to Open Payments, and some PODs have changed how they compensate physicians to circumvent the reporting requirements (U.S. Senate Committee on Finance 2016). The Committee reviewed Open Payments data from the last five months of 2013 and found that many PODs did not appear in the data. According to the Committee's report, an increasing number of PODs are reclassifying physicians as employees instead of owners to avoid reporting physician ownership interests. In addition, physicians who invest in PODs sometimes request that payments from the POD be made to close family members or friends instead of the physician-owners. However, the Open Payments statute requires that ownership or

investment interests by physicians *or their immediate family members* must be reported.

In our work, we engaged in a time-consuming process using websites and other sources to identify whether each company in the Open Payments database was a drug manufacturer, device manufacturer, producer of both drugs and devices, a traditional GPO (not a POD), a POD, or another type of company. In particular, it was difficult to identify PODs because they typically lack public websites, and some PODs try to obscure their financial relationships with physicians (U.S. Senate Committee on Finance 2016).

CMS should require each manufacturer or GPO that reports data under Open Payments to indicate:

- whether it is a manufacturer or GPO;
- whether, if a manufacturer, it produces drugs, biologics, devices, supplies, or a combination of products; and
- whether, if a GPO, it is a POD.

In addition, CMS should conduct outreach to PODs (or companies suspected of being PODs) to remind them of their obligation to report physician ownership information and to assess penalties on PODs that do not comply with the statute. CMS should coordinate its efforts with OIG, which identified PODs that sold spinal devices to hospitals for its report on PODs (Office of Inspector General 2013b). Including more information on the types of companies that have financial relationships with physicians and teaching hospitals would enable patients and researchers to better understand these relationships.

Require manufacturers to separately report the portion of a research payment related to physician compensation

Research payments are reported separately from general payments because research is a unique activity and payments for research do not necessarily represent a personal payment to physicians (Centers for Medicare & Medicaid Services 2013). Research payments are often very large and cover a variety of activities included in the written agreement or research protocol, such as examinations and tests for patients, the drugs or devices that are studied, other in-kind items provided by the manufacturer, and the time spent by physicians treating patients and managing the study. Because manufacturers may not know the details of how a research payment was spent, CMS does not require them to itemize the cost of specific activities (Centers for Medicare & Medicaid Services 2013).

However, it would be helpful for users of the data to be able to distinguish between the portion of the payment that included the physician's compensation for conducting the research study and the portion of the payment associated with other costs (e.g., patient care and the cost of drugs or devices). Because physician compensation for managing a study represents a direct payment to a physician, it is similar to other physician payments reported by manufacturers, such as consulting fees, royalties, and speakers' fees. Therefore, payments for these various activities could be compared and aggregated if manufacturers reported the portion of a research payment that was related to the physician's compensation. CMS should require manufacturers to separately report this information, and the agency should explore how manufacturers could obtain it.

Conclusion

The Open Payments program has shed significant light on industry ties to over 600,000 physicians and over 1,000 teaching hospitals. The database contains information on financial interactions valued at $7.3 billion in 2015, including payments for research, royalties, speaking fees, meals, and ownership interests in companies. However, the program should be expanded to include additional providers and organizations that have relationships with manufacturers. In addition, the Secretary should make information reported by manufacturers to the FDA about free drug samples available to oversight agencies, researchers, payers, and health plans. CMS should also require companies to report whether they are GPOs or manufacturers, the type of products they make, whether they are PODs, and the portion of a research payment that is related to physician compensation. These changes would make the data easier to use and increase the transparency of companies' financial relationships with providers and organizations. ■

Endnotes

1 The initial reporting thresholds for 2013 were $10 for individual payments and $100 for the aggregate amount transferred by a manufacturer to a recipient during the year. These thresholds are adjusted each year based on the change in the consumer price index.

2 CMS defines GPOs as companies that purchase, arrange for, or negotiate the purchase of medical products for a group of individuals or entities. A company that purchases a product for a single entity, rather than a group of entities, is not considered a GPO.

3 CMS released the initial files with data from 2015 in June 2016 and released updated files in January 2017. Because the total value of payments in the general payments file did not change significantly between June 2016 and January 2017, we used the June 2016 version of this file for the detailed analysis of general payments that appears in Table 6-4 (p. 193), Table 6-5 (p. 194), Table 6-6 (p. 195), and Table 6-7 (p. 195).

4 According to the regulations implementing the PDMA, drug samples may be requested only by practitioners licensed in their state to prescribe the requested drugs. The practitioner may authorize someone else to receive the drug samples and sign for them.

5 This recommendation would not apply to free drugs provided by manufacturers under prescription assistance programs to low-income, uninsured patients because drugs provided under these programs are not considered samples.

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CHAPTER 7

An overview of the medical device industry

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Chapter summary

Because Medicare does not pay directly for medical devices, the Commission has not historically studied medical devices in depth in its evaluation of Medicare payment policy. In response to recent Commissioner interest, however, this chapter provides an overview of the medical device industry and reviews how Medicare pays for medical devices.

The medical device industry makes an enormous number of products—ranging from surgical gloves to artificial joints to imaging equipment—and plays a crucial role in developing new medical technologies that can improve the ability to diagnose and treat illness. The industry has a relatively small number of large, diversified companies and a large number of smaller companies that are mainly engaged in research and development of new devices for specific therapeutic areas. The industry is distinctive both for its tendencies to make frequent, incremental changes to its products and its extensive ties with physicians.

Like prescription drugs, medical devices are regulated by the Food and Drug Administration (FDA). However, the regulatory framework that the Congress has established for medical devices is less stringent in many respects, due in part to underlying differences between medical devices and prescription drugs. Most low-risk devices can be marketed without prior FDA review, and most medium-risk devices are required to demonstrate only that they are

In this chapter

"substantially equivalent" to an existing device before being marketed. Very few devices must demonstrate that they are safe and effective before being marketed. The FDA's surveillance of devices after becoming available to the public has also been limited historically, although improvements are being made through initiatives such as requiring unique device identifiers on all devices.

The market dynamics for medical devices can vary greatly depending on the device. Markets for conventional devices such as surgical gloves and other routine surgical supplies are more competitive; companies compete heavily on price and often need high sales volumes to be profitable. In contrast, markets for advanced products like implantable medical devices involve opaque pricing, are harder to enter, and are less competitive, which allows device companies to charge higher prices and earn substantial profits. Large medical device companies are consistently profitable and typically have profit margins of 20 percent to 30 percent.

Medicare pays for medical devices indirectly by reimbursing providers when they use devices in the course of delivering care to beneficiaries. Medicare bundles the average cost of medical devices into its overall payment rate for many services, giving hospitals, for example, an incentive to use lower cost devices. However, physicians often do not have an incentive to use lower cost devices because physicians are generally not financially responsible for the cost of the device and may have financial connections to the device industry. Bundling also makes it harder to measure how much the program spends on medical devices, but Medicare cost report data for 2014 indicate that hospitals spent about $14 billion on implantable devices and $10 billion on medical supplies (e.g., handheld surgical instruments) for Medicare-covered services.

Because of the indirect manner in which Medicare pays for most medical devices, future changes designed to improve the quality of medical devices Medicare beneficiaries receive and to reduce their associated costs could focus on improving the availability of device- and provider-specific information and aligning provider incentives. Such improvements could entail adding more device-specific information to administrative claims, improving reporting by physician-owned distributors (PODs) under the Open Payments program, limiting the number of PODs, and more broadly allowing initiatives that encourage hospital-physician collaboration to reduce device costs. ■

Introduction

Medical devices play an important role in the delivery of many health care services. Defined broadly, medical devices are items that are used for the "diagnosis . . . cure, mitigation, treatment or prevention of disease" and are not absorbed or metabolized by the body.[1] The term applies to everything from common medical supplies such as latex gloves and syringes to advanced imaging equipment and implantable devices such as cardiac defibrillators. The medical device industry is thus an important component of the larger health care system and plays an essential role by developing new medical technologies that can improve the ability to diagnose and treat illness.

Most medical devices serve as inputs in the delivery of health care services and are usually not considered services by themselves. The major exceptions are medical devices that are used as durable medical equipment, prosthetics, or orthotics. As a result, Medicare has chosen to pay for many medical devices in an indirect manner, by including an amount for medical devices in its payment rates for services in which devices are used. For example, Medicare's payment to a hospital or ambulatory surgical center for cataract replacement surgery includes an amount for the cost of the artificial lens.

Since Medicare does not pay directly for medical devices, the Commission has not historically studied medical devices in depth in its evaluation of Medicare payment policy. In response to Commissioner interest, however, this chapter provides an overview of the medical device industry by reviewing its overall size and composition, the development of new medical devices, the role of the Food and Drug Administration (FDA), and some key features of the medical device market. It also examines how Medicare pays for medical devices in greater detail.

Overall size and composition of the medical device industry

Because of the wide range of items that can be considered medical devices, there is no standard way of defining the medical device industry, and estimates of its overall size vary. For example, recent studies by the Congressional Research Service (CRS), BMI Research, and the Advanced Medical Technology Association (AdvaMed, the industry's main trade association) have estimated that total U.S. spending on medical devices was $119 billion in 2011, $125 billion in 2013, and $172 billion in 2013, respectively (BMI Research 2015, Donahue and King 2015, Gravelle and Lowry 2015). All three studies are based on the same underlying data source—sales data from manufacturers that are collected by the Census Bureau—but differ by which sales are counted as medical devices and the adjustments made to convert sales data into estimates of overall U.S. spending.

These estimates indicate that medical devices account for roughly 4 percent to 6 percent of total U.S. spending on health care (BMI Research 2015, Donahue and King 2015). The AdvaMed study also found that the share of total U.S. spending on health care devoted to medical devices has changed very little over time, suggesting that spending on medical devices has grown at about the same rate as the broader health care sector (Donahue and King 2015).

Estimates of the total number of companies and employees in the medical device industry also vary somewhat. According to two studies that used data from the Census Bureau, there are roughly 5,300 to 5,600 U.S. companies in the industry, with approximately 330,000 to 365,000 employees (BMI Research 2015, International Trade Administration 2010). Medical device companies are located throughout the United States, but the industry has a larger presence in California, Massachusetts, and Minnesota.

International trade also plays a significant role in the medical device industry. Between 35 percent and 40 percent of domestic U.S. production is ultimately exported, and a similar share of domestic U.S. consumption is imported (Gravelle and Lowry 2015). Foreign sales represent 40 percent to 50 percent of overall revenues for U.S. medical device companies when sales by foreign subsidiaries are taken into account (Seligman 2013). The largest export markets for U.S. medical device companies have traditionally been the countries of the European Union and Japan (International Trade Administration 2010). The United States is the largest single market for medical devices and accounts for about 40 percent of worldwide sales (BMI Research 2015).

Most of the companies in the medical device industry are relatively small. One study that analyzed economic data from the Census Bureau found that 73 percent of medical device firms had fewer than 20 employees and that 88 percent had fewer than 100 employees (International

TABLE 7–1 The 10 largest medical device companies, 2015

Rank	Company	Country	Global medical device revenue (in billions)
1	Medtronic	United States	$27.7
2	Johnson & Johnson	United States	27.5
3	GE Healthcare	United States	18.3
4	Baxter International	United States	16.7
5	Siemens Healthcare	Germany	15.8
6	Becton Dickinson	United States	12.3
7	Philips Healthcare	Netherlands	11.2
8	Cardinal Health	United States	11.0
9	Abbott Labs	United States	10.1
10	Stryker	United States	9.7

Note: Some companies shown in this table, such as Johnson & Johnson, generate substantial revenues in industries other than medical devices; the figures for these companies are for their medical device divisions only. Figures for Medtronic and Becton Dickinson reflect their acquisitions of Covidien and CareFusion, respectively. Since its acquisition of Covidien, Medtronic has been headquartered in Ireland for tax purposes.

Source: Medical Product Outsourcing 2015.

Trade Administration 2010). These figures suggest that companies with fewer than 100 employees account for roughly 15 percent to 20 percent of total employment in the medical device industry. CRS found a similar pattern when it looked at corporate tax return data for U.S companies whose primary activity is making medical supplies and equipment: 83 percent of companies had less than $1 million in assets, and 95 percent had less than $10 million in assets (Gravelle and Lowry 2015). These smaller companies are engaged primarily in the development of new medical technologies and are often focused on relatively narrow therapeutic areas.

At the other end of the distribution, a relatively small number of large companies account for most of the medical device industry's overall employment and revenues. The same CRS study found that the top 1 percent of firms in the medical device industry accounted for 82 percent of total assets, with the top 0.2 percent of firms alone accounting for 56 percent of overall assets (Gravelle and Lowry 2015). These companies operate in many countries around the world and are highly diversified, making medical devices for several different therapeutic areas and often producing a broad range of medical devices within a therapeutic area. The 10 largest medical device companies, including those based outside the United States, are shown in Table 7-1.

The development of new medical devices

Large and small medical device companies both play a role in the development of new medical devices. Small medical device companies are engaged primarily in developing new medical technologies, and typically their work is narrowly focused on a specific therapeutic area. These companies have traditionally been funded by venture capital firms that hope to profit if the companies develop promising products. The prospects for these companies are uncertain given the challenges of securing enough start-up funding, developing the new medical device itself, figuring out how to manufacture the device in a cost-effective manner, obtaining the necessary regulatory approvals, and marketing the device to providers such as hospitals and physicians. These companies typically spend a large share of their revenues on research and development and may be unprofitable for years before developing a viable product or going out of business (Seligman 2013).

The overall amount of venture capital funding for medical device companies has declined somewhat in recent years. Between 2007 and 2009, the total amount that venture capital firms invested in medical device companies declined from $3.7 billion to $2.6 billion, and, since then,

annual investment has ranged between $2.2 billion to $2.9 billion. Similarly, the share of total venture capital funding going to medical device companies declined between 2007 and 2015, from 7.9 percent to 6.1 percent (PricewaterhouseCoopers and National Venture Capital Association 2016). Even with this recent decline, the total amount of venture capital funding going to medical device companies is still substantially higher than it was in 1992, when the industry received about $400 million in venture capital funding (Advanced Medical Technology Association 2017). The recent drop in venture capital funding has been partly offset by greater funding from large medical device companies, which also invest in start-up device companies (Walker 2013). However, the decline has raised concerns that the industry's ability to develop new medical devices could suffer (Ernst & Young 2015).

Start-up companies that develop promising new products are often acquired by one of the large medical device companies.[2] These acquisitions benefit each side in a number of ways. Small companies can find it challenging to market their products, while major device companies have established distribution networks and relationships with hospitals and other providers. Large companies can also provide additional resources to further develop and improve new medical devices. An acquisition also allows the venture capital firms that supported the start-up company to withdraw their funding and realize a profit.[3] For the large companies, acquisitions provide another way to conduct research and development and can either complement or substitute for the company's internal efforts. Large companies can also use acquisitions to branch out into new therapeutic areas or bolster existing product lines (International Trade Administration 2010, Moody's Investors Service 2015, Seligman 2013).

Although small companies play an important role in the initial discovery and development of new technologies, large medical device companies perform most of the industry's research and development. CRS found, based on corporate tax return data for U.S. companies that make medical supplies and equipment, that the 17 companies that had more than $2.5 billion in assets claimed 56 percent of the tax credits for research and experimentation. The companies with more than $500 million in assets claimed 80 percent of the credits (Gravelle and Lowry 2015).[4]

Research by financial analysts suggests that large medical device companies typically spend between 5 percent and 15 percent of their revenues on research and development, with most companies somewhere in the middle of that range (Fuhr et al. 2013, Moody's Investors Service 2015, Seligman 2013). Companies that make technologically sophisticated products such as implantable cardiovascular devices tend to spend more on research and development than companies that make less innovative products such as artificial joints (Moody's Investors Service 2015). The major medical device companies typically spend more on research and development as a share of sales revenue than other industrial firms (3 percent to 4 percent) but less than pharmaceutical manufacturers (15 percent) (Seligman 2013). However, these figures should be viewed with some caution because there is no standard way of defining which activities constitute research and development; some companies may classify activities as research and development that other companies or observers would not.

One notable difference between the medical device and pharmaceutical industries is that physicians are much more involved in the development of medical devices. Device makers often seek the input of physicians about the design and potential uses for new products and solicit feedback from physicians who use their products. In some cases, physicians bring their ideas for new or improved products to manufacturers. Research has found that physicians accounted for about 20 percent of the patents issued for medical devices between 1990 and 1996 (Seligman 2013). However, the extensive relationships between physicians and device companies have also raised concerns about the ability of device companies to influence physicians' treatment decisions (Ornstein and Weber 2011).

One particularly important feature of the medical device industry is its tendency to make "many incremental modifications of existing products, punctuated occasionally by an innovation that offers a significantly new mechanism of action, design, or risk profile" (Robinson 2015). Since medical devices are often modified, the life cycles for individual products can be relatively short compared with prescription drugs; the industry has said that most medical devices are replaced by a newer version every 18 to 24 months (Advanced Medical Technology Association 2015a). The shorter life cycle means that the payback period for research and development is also shorter, and that successful medical devices are typically not as profitable as blockbuster prescription drugs (Seligman 2013). Nevertheless, large medical device companies have been consistently profitable.

TABLE 7–2 **FDA classification and review of medical devices**

Category	Level of risk to patient	Examples	Type of review before device can be marketed
Class I	Low	• Elastic bandages • Examination gloves • Handheld surgical instruments	Most devices required only to register; a small share must submit a 510(k) notification.
Class II	Moderate	• Powered wheelchairs • Infusion pumps • Surgical drapes	Most devices must submit a 510(k) notification; a small share of devices are required only to register.
Class III	High	• Heart valves • Silicone breast implants • Implanted cerebella stimulators	Devices must submit a PMA application; in the past, a significant number of devices were able to submit a 510(k) notification.

Note: FDA (Food and Drug Administration), PMA (premarket approval).

Source: Johnson 2016.

Like the pharmaceutical industry, medical device companies frequently obtain patents to prevent other companies from copying their products for a period of time. The U.S. Patent and Trademark Office has issued more than 75,000 patents for medical devices over the past 30 years. However, patents for medical devices are usually not as specific as patents for prescription drugs, which makes patents on medical devices easier to circumvent and lawsuits for patent infringement common. The shorter life cycles for medical devices also reduce the value of patents because many devices can become obsolete before their patent expires (Seligman 2013).

The role of the Food and Drug Administration

Before medical device manufacturers can market a new product, they must comply with the requirements of the FDA, which is responsible for regulating medical devices. When the FDA was created in the 1930s, its authority over medical devices was relatively limited. The agency could prosecute individuals who misused medical devices, but medical device manufacturers did not have to obtain FDA approval before marketing their products in the same manner as pharmaceutical manufacturers. This arrangement ended in 1976, when the Congress established a new system for the FDA to regulate medical devices (Seligman 2013). However, medical devices that were already on the market were not required to comply with all aspects of the new regulatory system. This distinction between *preamendment* and *postamendment* devices—terms referring to the Medical Device Amendments of 1976—remains relevant 40 years later because many devices can enter the market by effectively demonstrating that they are similar to devices approved under the preamendment rules.

While the FDA now regulates both medical devices and prescription drugs, its regulation of medical devices is less stringent in many ways. To some extent, these regulatory differences reflect underlying differences between medical devices and prescription drugs. In particular, any regulatory scheme for medical devices must recognize that the number of medical devices on the market is much larger, that the level of risk associated with different kinds of medical devices varies more widely, and that medical devices typically evolve over time through a series of incremental improvements (Robinson 2015).

The FDA's regulation of medical devices can be divided into two broad areas: premarket requirements, which apply before devices can be marketed, and postmarket surveillance of devices after they enter the market.

Premarket requirements

The FDA's premarket requirements are based on the notion that the amount of scrutiny that should be given to a medical device before it can be marketed should reflect the

level of risk that the device poses to consumers. The FDA uses a three-tier system to categorize medical devices by risk (Table 7-2).

Medical devices that are considered low risk are categorized as Class I devices, which is the lowest tier in the FDA's system. Most medical devices in this category do not require any kind of FDA review before they can be marketed. However, the manufacturer of the device must notify the FDA beforehand by registering the device in a central database known as the FDA Unified Registration and Listing System and must follow a number of standard requirements that apply to the manufacturing of all medical devices, such as the need to use good manufacturing practices (Johnson 2016).

The 510(k) notification process

Medical devices that pose a moderate level of risk to consumers are categorized as Class II devices. Manufacturers of most Class II devices must get permission from the FDA before marketing them by submitting a premarket notification, which is more commonly known as a 510(k) notification, after the section of the Federal Food, Drug and Cosmetics Act that authorizes the process. Some Class I and Class III devices also use the 510(k) process (Johnson 2016).

Under the 510(k) process, a manufacturer must demonstrate that its device is "substantially equivalent" to another device that is already on the market, which is called the predicate device. Manufacturers decide which device to use as the predicate.[5] The 510(k) process is different from the FDA's approval process for prescription drugs because the manufacturer usually does not have to demonstrate that the medical device is safe and effective.[6] Instead, the manufacturer has to show only that the new device is substantially equivalent to an existing device. Since many predicate devices were themselves cleared through the 510(k) process through comparison with even older products, many medical devices that are cleared through the 510(k) process are ultimately being compared with devices that were first marketed before the enactment of the 1976 legislation that expanded the FDA's authority over medical devices.[7] These so-called preamendment devices were not required to demonstrate their safety or efficacy (Johnson 2016, Robinson 2015).

The FDA reviews about 4,000 510(k) submissions each year and clears most of them in 3 months to 6 months (Johnson 2016, Seligman 2013). Between 2013 and 2016, the agency cleared between 79 percent and 85 percent of 510(k) submissions within three months (Food and Drug Administration 2017a). The time needed to obtain FDA clearance has been a persistent concern for the medical device industry, and with the industry's backing, the Congress in 2002 authorized the FDA to collect user fees from medical device companies to help defray the agency's costs (Johnson 2016). However, wait times have continued to be an issue. Between 2005 and 2010, the average wait time for a 510(k) decision (mostly used for Class II devices) rose from 90 days to 154 days. The average wait time has decreased since then, reaching 128 days in 2014. The figures for wait times include time that the FDA spent reviewing the submission (typically 70 to 75 days in all) and time that medical device companies spent providing additional information (Food and Drug Administration 2017a).

The premarket approval process

The FDA's highest level of scrutiny is reserved for most Class III medical devices and is known as the premarket approval (PMA) process. Under the PMA process, manufacturers must submit clinical data that provide reasonable assurance that a device is both safe and effective.[8] As part of its review, the FDA may convene an advisory committee of outside experts to help it evaluate the PMA application. Because of the requirement to demonstrate safety and efficacy, the PMA process is the area of medical device regulation that most closely resembles the regulation of prescription drugs, but there are some important differences (Johnson 2016).

First, the clinical data supporting a PMA application are often less robust than those of prescription drugs. One study found that about two-thirds of the PMA applications for implantable cardiovascular devices relied on clinical data from a single study and that most of those studies were not randomized controlled trials (RCTs) (Dhruva et al. 2009). The FDA has traditionally required data from two RCTs when it reviews a new drug, although about half of its approvals for new drugs between 2011 and 2015—mostly those used to treat rare diseases—were based on a single trial (Gassman et al. 2017).[9]

Second, once the FDA has approved a device, manufacturers can often make minor modifications to it without submitting new clinical data by filing a "supplement" to the previously approved PMA application instead of filing an entirely new application. Supplements have lower user fees and shorter review times than traditional PMAs, which makes it easier for device manufacturers to make incremental improvements

in a device. Some devices are modified dozens of times in this manner: One study examined the PMAs for implantable cardiovascular devices and found a median of 50 supplements for each original PMA (Rome et al. 2014). Once a device has been modified many times, the relevance and value of the original clinical data become less clear (Rabin 2014).

Very few medical devices enter the market through the PMA process. One study found that 67 percent of medical devices that entered the market between 2003 and 2007 were exempt from any FDA review (these are mostly Class I devices that need to be registered only before they can be marketed), 31 percent entered through the 510(k) process, and 1 percent entered through the PMA process (Government Accountability Office 2009). The FDA reviews about 40 original PMA applications each year (Maisel 2011). The FDA is supposed to make a determination on a PMA application within 180 days, but the process can often take longer: In 2014, the average wait time for a decision on a PMA application was 270 days (Food and Drug Administration 2017a). For medical device companies, the costs of submitting a PMA application are anywhere from 4 times to 10 times higher than the cost of submitting a 510(k) notification (Seligman 2013).

Postmarket surveillance

The FDA's regulation of medical devices continues after they enter the market. The agency can never fully assess the safety and effectiveness of medical devices before market entry, so postmarket surveillance is an important element in regulating medical devices. However, devising an effective system of postmarket surveillance can be challenging because devices typically evolve over time as manufacturers make incremental changes to their designs.

The FDA uses a variety of methods to monitor the performance of medical devices after they enter the market. For example, medical device manufacturers and health care facilities such as hospitals are required to report to the FDA any adverse events that involve the use of a medical device. The agency can also require manufacturers to study a device's safety and effectiveness after it enters the market, but research has found that these studies can take a long time to complete and may be of limited value (Colvin et al. 2014, Lenzer and Brownlee 2010, Reynolds et al. 2014).

The agency is also planning to more actively monitor the safety of medical devices through an initiative known as the National Evaluation System for health Technology (NEST). Under NEST, the FDA would gain access to and analyze many different sources of electronic health data such as claims, electronic health records, and registries to generate more timely and complete information on medical device performance (Food and Drug Administration 2017d). For example, NEST could make it easier for the FDA to assess reports of safety problems with individual medical devices and reduce the need for medical device companies to conduct postmarket surveillance studies. The incorporation of unique device identifiers (see next section) into electronic health information is a key requirement for the development of NEST (Califf 2016).

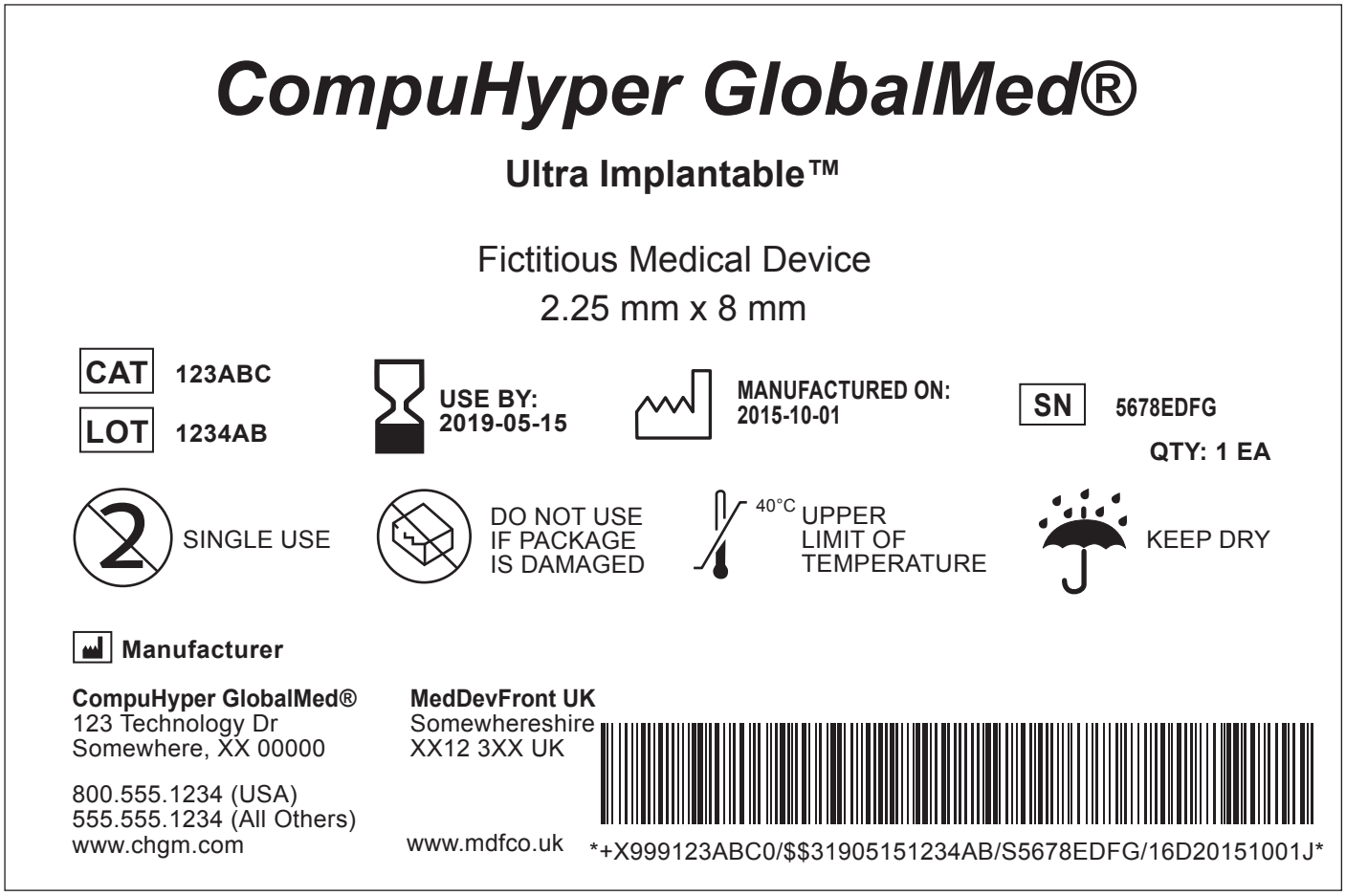
The FDA can also order product recalls for medical devices that are found to pose a health risk. For example, the FDA recalled two widely used types of leads for implantable defibrillators (leads are wires that transmit electric shocks from the defibrillator to the heart to keep it beating properly) that were found to be prone to failure, which could result in the defibrillator delivering unnecessary shocks or not functioning at all. Most recalls are carried out with the cooperation of the device manufacturer (Johnson 2016). In fiscal year 2016, the agency issued recalls for about 2,900 products. The FDA classifies its recalls based on the degree of health hazard involved; about 4 percent of the product recalls that occurred in 2016 fell into the most serious category, in which the use of a medical device poses a serious risk (Food and Drug Administration 2017c).

Unique device identifier

Another initiative designed to improve the FDA's postmarket surveillance is the requirement that all medical devices have a unique device identifier (UDI), unless an exception or alternative has been granted.[10] The Food and Drug Administration Amendments Act of 2007 directed the Secretary to establish a UDI system for medical devices (Johnson 2016).[11] The FDA issued a final rule to establish the UDI system in September 2013, with UDI adoption occurring gradually. For example, all Class III medical devices were required to have a UDI on their label and package (but not on the device itself) as of September 24, 2014, and the labels and packages of all implantable, life-supporting, and life-sustaining devices were required to bear a UDI by September 24, 2015 (Food and Drug Administration 2017b). The full transition, which includes requiring UDIs for additional lower risk devices and fully implementing UDIs as a permanent marking on the device itself (as opposed to the packaging) for certain devices, is

FIGURE 7–1

Illustrative example of a device label with a unique device identifier



Source: Health Industry Business Communications Council sample unique device identifier label (Health Industry Business Communications Council 2017).

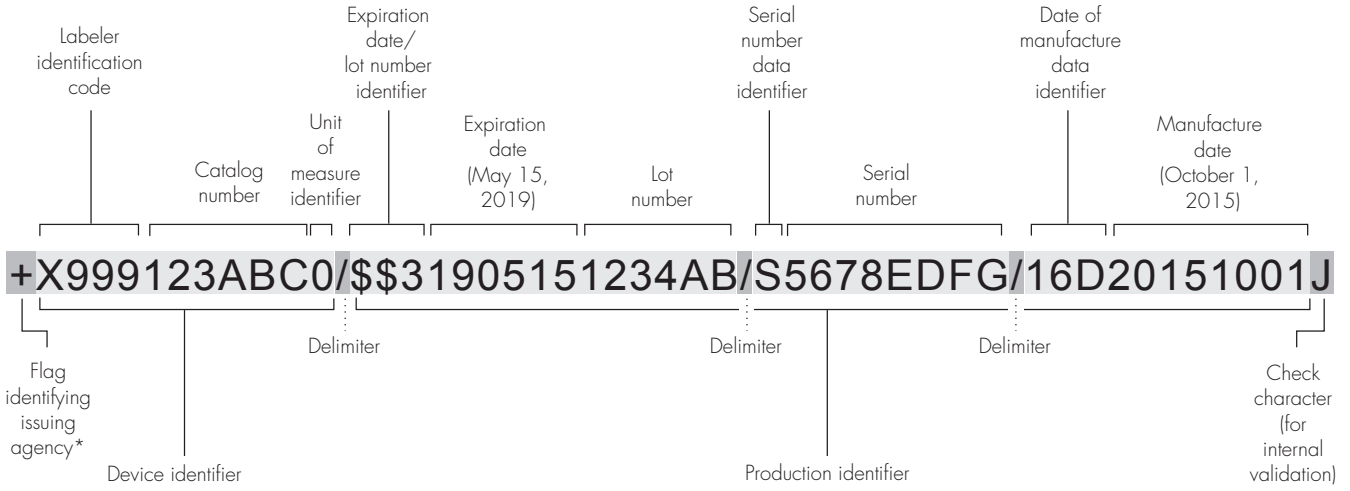
expected to be complete by September 24, 2020 (Food and Drug Administration 2017b).[12]

The UDI has two components: (1) a device identifier that indicates the manufacturer and specific model of the device and (2) a production identifier that contains additional, more specific information about the device. Currently, there are three FDA-accredited issuing agencies that assign UDIs to devices.[13] The UDIs assigned by each of the three issuing agencies have their own structure, so the device identifier and full UDI can be of varying lengths and structures depending on the agency that assigned it. Currently, across the 3 issuing agencies, the device identifier can contain up to 23 characters, and the full UDI can contain up to 75 characters. Figure 7-1 is an example of how a UDI might appear on a device label. (In this example, the UDI is located below the bar code.)

Providers are able to identify a number of device characteristics based on the UDI, which will be present in human-readable format (e.g., a string of numbers and characters) and automatic identification and data capture technology (e.g., a bar code) on device labels once UDIs are fully implemented. For instance, using the example above and the standards that each issuing agency publishes, a provider is able to tell the manufacturer,

FIGURE 7–2

Breakdown of illustrative unique device identifier



Note: *Issuing agency in this example is the Health Industry Business Communications Council.

Source: MedPAC analysis of illustrative device label and Health Industry Business Communications Council standards (Health Industry Business Communications Council 2017, Health Industry Business Communications Council 2016).

model, date of manufacture, lot number, and more by scanning the UDI. (See Figure 7-2 for a complete breakdown of the illustrative UDI.) Providers can also obtain more device attributes, such as the name of the company that produces the device and whether the device is compatible with magnetic resonance imaging procedures, by looking up the device identifier portion of the UDI in the Global Unique Device Identification Database, an FDA-maintained database that serves as a reference catalog for every device with an identifier.

UDIs should make it easier to identify medical devices that are unsafe or defective, conduct product recalls, and compare the effectiveness of different device models if UDIs are incorporated throughout the health care system (in data sources such as electronic medical records and administrative claims data). All of these activities have historically been challenging in the device market. For example, manufacturers have often experienced difficulties locating all of their recalled products. A 2011 Government Accountability Office (GAO) report found that firms were unable to correct or remove all products in roughly half of the completed or terminated recalls studied (Government Accountability Office 2011). In one particular case, GAO found that 1,732 of 23,987 pacemakers for which the device's seal may degrade (allowing excess moisture within the pacemaker) could not be recalled because no implant records were available (Government Accountability Office 2011).

There is broad agreement that UDIs can be a valuable addition to data sources like electronic health records and medical device registries, but there has been debate about including UDIs on administrative claims. The FDA and other stakeholders have supported adding UDIs to claims data, particularly for implanted devices, but others, including CMS, expressed opposition because of the cost and complexity of updating claims processing systems (Burton 2015, Centers for Medicare & Medicaid Services 2015a, Thibault 2016). For example, CMS said that UDIs on claims would be prone to errors because there are an estimated 300,000 UDIs just for high-risk implantable medical devices (IMDs), UDIs have different formats (depending on the issuing agency), and payers would not be able to validate UDIs submitted on claims against any external data source (Centers for Medicare & Medicaid Services 2015a).[14]

In response to concerns about the costs and complexity of adding UDIs to claims, a proposal was put forth to incorporate just the device identifier portion of UDIs for high-risk IMDs, which is supported by CMS, the FDA, the Office of Inspector General (OIG) of the Department of Health and Human Services, and others.

Specifically, on January 31, 2017, the American National Standards Institute's X12 Incorporated (X12) released draft revisions to the claim forms used by hospitals and physicians that included the addition of a device identifier field (X12 Incorporated 2017).[15] The proposal calls for claims to include the device identifier and a flag for whether the device was implanted or explanted in certain situations. Those situations are the implantation of a high-risk implantable device or the removal of a high-risk implantable device because of safety concerns about premature failure. In both situations, the information is to be exchanged only if the provider and payer have mutually agreed to exchange the data or are mandated by state or federal governments to do so. A list of what constitutes a high-risk implantable device has not been established.

The proposal to add device identifiers to hospital and physician claims is just one part of the larger process to update these claim forms, which involves seeking input from multiple stakeholders and can take years to complete. Stakeholders estimate, based on previous updates to the claim forms, that the change to the claim forms, including the potential addition of the device identifier field, will not be in effect until approximately 2022. For example, before being implemented, the changes must be approved by X12 after a comment period; be approved by the Designated Standard Maintenance Organizations; be reviewed by the National Committee on Vital and Health Statistics, which holds hearings, solicits input from numerous organizations, and ultimately makes a recommendation to the Secretary; and go through a formal rule-making process and implementation period. This process would be just to approve the changes to the claim forms. If CMS wanted to require providers to input actual data into the device identifier field on Medicare claims, the Secretary would likely need to issue additional regulations.

Proponents of adding device identifiers to administrative claims contend that incorporating such information would be a valuable part of the country's postmarket surveillance system. Including device identifiers in claims would not obviate the need to incorporate UDIs in many other data sources such as electronic health records and clinical registries. Rather, including device identifiers in administrative claims would leverage the scale, availability, and longitudinal nature of claims data to improve postmarket surveillance. Including device identifiers in claims could also produce other tangible benefits for the Medicare program and others. Examples of the specific benefits that proponents believe will flow from including device identifiers on claims include:

- ***Improved ability to detect potential issues at the manufacturer/model level.*** Device identifiers on claims could be used by NEST, payers, academic researchers, and others to compare quality and detect potential problems at the manufacturer/model level. For example, a longitudinal study of Medicare fee-for-service beneficiaries who received a total knee replacement could be conducted to determine whether the revision rates for certain types of knee implants increased over time or were higher for some implant models compared with others. Such studies could reveal important quality information (e.g., whether one model performs better than another) and alert researchers of a possible problem (e.g., whether revision rates spiked for the same model or manufacturer over time).

- ***Reduced Medicare expenditures by improving adherence to current device credit policy.*** Not all manufacturers offer warranties for their products. In these cases, Medicare ultimately pays for the cost of failed devices and for the replacement device. However, hospitals that do receive device credits from a manufacturer (e.g., a credit when a device fails while still under warranty) are required to report the credit to Medicare, and Medicare's payment for the revision surgery is subsequently reduced. OIG has found that hospitals often do not abide by this policy (see text box on costs of failed devices, p. 218). Including the device identifier on claims for the implanted and explanted devices could allow for easier identification of cases where device failures occur and, therefore, increase adherence to the current policy.

- ***Improved understanding of long-term device costs and aid in the development of value-based insurance designs.*** Failed and recalled devices likely cost Medicare billions of dollars (see text box on costs of failed devices, p. 218). In addition to the cost of the actual surgeries to implant or explant devices, the downstream costs for follow-up care, monitoring, post-acute care, additional surgeries, and other costs are likely substantial. Including the device identifier on claims could aid in more precisely understanding the long-term costs of certain devices. The information could also assist in any related cost-recovery efforts (Office of Inspector General 2016). Additionally, such information on costs, coupled with the quality data discussed above, could be used by payers to create value-based purchasing initiatives to help ensure patients receive the most appropriate device.

Cost of failed devices in Medicare

Medicare regulations currently require a reduced payment for certain inpatient and outpatient procedures if hospitals receive a device credit from a manufacturer for a faulty device. However, the Office of Inspector General (OIG) of the Department of Health and Human Services has found that hospitals often fail to seek and report device credits. Further, the lack of device-specific information on claims makes it difficult to quantify the total costs to Medicare and beneficiaries of device failures, including the cost of the surgeries themselves and downstream costs.

Hospitals are currently required to report the value of a device credit associated with a replacement device on outpatient claims if the hospital received a credit of 50 percent or more of the cost of the replacement device. In addition, when a device credit is received, hospitals must also indicate whether the replaced device was part of a known recall or whether the device was replaced earlier than the device's typical life cycle (Centers for Medicare & Medicaid Services 2017b). A similar policy applies to the hospital inpatient setting. In their compliance review of 145 hospitals nationwide, OIG found approximately $10 million in overpayments to hospitals for device credits that hospitals received but did not report to Medicare (about 75 percent of the $10 million) or for credits that were available under the terms of the manufacturers' warranties but not obtained by hospitals (about 25 percent of the $10 million) (Office of Inspector General 2015).

In addition to the cost of the device, Medicare spends substantial resources on the costs of the procedures related to failed devices and other downstream costs. However, quantifying these costs is difficult because of the lack of device-specific information on Medicare claims. In a letter to CMS informing the agency of preliminary results, OIG said that the lack of device-specific information in Medicare claims data impedes the ability of CMS to readily identify and track Medicare's total costs related to the replacement of recalled or defective devices (Office of Inspector General 2016). After implementing complex audit procedures (which involved subpoenaing manufacturers), OIG found $1.5 billion in Medicare payments and $140 million in beneficiary copayments and deductibles for services and procedures associated with seven recalled or failed devices. ■

- ***Other benefits.*** Proponents of adding device identifiers to claims have suggested other benefits, such as helping to implement recalls that affect an entire product (e.g., when a device's design is flawed, as was the case with metal-on-metal artificial hips), improving innovation (as more quality information becomes widely available), and enhancing the ability to monitor the effects of payment changes on the utilization of specific devices (e.g., monitoring shifts in device utilization that could occur when payments are bundled).

Opponents of including device identifiers on claims contend that doing so would have limited value for postmarket surveillance, be costly to implement and maintain, and could have other negative consequences. Some of the most prominent criticisms include:

- ***Device identifiers cannot be used to effectively identify certain issues or implement all recalls.*** Opponents contend that device identifiers are not granular enough to detect issues that affect only a portion of devices within a model. For example, a manufacturing problem could affect only certain groups of devices within a model or devices produced in a certain time period. In such cases, the full UDI (which can include the date of manufacture) may be used to precisely identify the problem and implement a recall, but the device identifier alone could be insufficient. One prominent device failure in which certain batches of a device were more prone to failure involved the Björk-Shiley convexo-concave prosthetic heart valve (Blot et al. 2005). Over 600 of these valves that were implanted were known to have fractured, often with catastrophic outcomes for the patients

(including death) (Blot et al. 2005). While multiple factors were subsequently shown to contribute to failure, valves produced within a certain time frame were shown to be more likely to fail compared with those produced at other times (Blot et al. 2005).

- ***Including device identifiers on claims could be administratively complex and costly.*** Some suggest that physicians, hospitals, payers, and others would incur substantial costs to ensure that device identifiers were accurately submitted on claims and that claims with device identifiers could be efficiently processed. Costs could involve redesigning workflows to ensure device identifiers were correctly submitted on claims and updating numerous computer systems to accept and validate the data for a large number of device identifiers. CMS has said the agency would require additional funding and resources to update legacy computer systems to accommodate device identifiers (Centers for Medicare & Medicaid Services and Food and Drug Administration 2016).
- ***Efforts to improve postmarket surveillance should focus on electronic health records and registries.*** Opponents suggest that resources should be deployed to improve and expand clinical registries and ensure UDIs are incorporated into electronic health records. As one part of a postmarket surveillance strategy, the FDA has promoted the development of device registries, although the agency said that registries might be economically feasible for only a subset of devices because of the significant costs associated with registry development and maintenance (Food and Drug Administration 2012). Certain programs, such as the Electronic Health Record Incentive Program, encourage the adoption and use of UDIs. However, some electronic health records currently cannot record UDIs, and challenges remain to make electronic health records useful repositories for UDIs, such as ensuring that records are interoperable and that providers consistently input UDIs into the records.
- ***Conclusions drawn from claims could be erroneous and could be used to restrict provider choice.*** Because administrative claims lack the clinical context often available in clinical registries or electronic health records, some contend that conclusions about a particular device's effectiveness drawn from claims alone could be erroneous. Opponents of including device identifiers on claims believe such conclusions could lead patients and physicians to make misguided device choices and could allow payers to implement overly restrictive device formularies or utilization review.

Key features of the medical device market

Once medical device manufacturers have received the FDA's permission to market their products, they are primarily engaged in selling medical devices to health care providers like hospitals, physicians, and nursing homes rather than individual consumers. The market dynamics for medical devices vary significantly depending on the device, but at a high level, devices can be divided into two groups: conventional devices and high-technology devices (Seligman 2013).

Conventional devices are products such as surgical apparel, regular wound dressings, and surgical trays. These devices are fairly easy to manufacture, with relatively few barriers to entry for new companies and relatively little product differentiation (i.e., purchasers such as hospitals can switch from one company's version to another company's version with minimal difficulty). These devices are thus treated much like commodities, and their manufacturers compete with each other based on price. Profit margins are relatively low, and manufacturers often need high sales volumes to be profitable. As a result, the ability to secure long-term supply contracts with large institutional purchasers such as hospital chains is very important (Seligman 2013).

The market dynamics for high-technology devices—such as IMDs, advanced diagnostic imaging, and some types of surgical instruments—are very different. Manufacturers typically face greater barriers to entry, such as significant research and development costs, the presence of patents, and greater regulatory scrutiny from the FDA. As a result, competition in this segment is more limited and these kinds of devices can garner higher profits than conventional devices (Seligman 2013).

Because large medical device companies are highly diversified, they sell a mix of conventional and high-technology devices. This diversification has a number of benefits. Companies can use their flagship high-technology products to boost sales of their other, more

conventional medical devices. At the same time, profits from the sale of conventional devices help provide the cash flow that companies need to conduct research and development for their high-technology products (Seligman 2013).

The remainder of this section reviews six key features of the medical device market: coverage determinations, group purchasing organizations, IMDs, the relationships between medical device companies and physicians, physician-owned distributors, and the financial performance of medical device manufacturers.

Coverage determinations

Medicare and other third-party health care payers are not required to cover every medical device that has been cleared or approved by the FDA. Health care providers are much more likely to use new forms of medical technology that are eligible for reimbursement, so ensuring coverage and payment are key considerations for device companies. Medicare's coverage decisions have particular weight because they are often followed by private health insurers (Johnson 2016).

Medical device companies can apply for Medicare coverage of new devices that do not fit into an existing service code by requesting either a national coverage determination (NCD) from CMS or a local coverage determination (LCD) from a Medicare administrative contractor (MAC) for the procedure that involves the device. NCDs apply nationwide, while an LCD applies only to the states within the jurisdiction of the MAC that issued it. CMS and the MACs make coverage decisions by determining whether the available evidence for a device supports the requested coverage. The processes for developing both NCDs and LCDs give external stakeholders the opportunity to share their views and allow the public to review and comment on draft coverage determinations. As of August 2013, there were about 300 active NCDs and 1,700 active LCDs (Office of Inspector General 2014).

There are some indications that private health insurers have tightened their standards for covering new technology in recent years. For example, some have suggested that private insurers now require device companies to provide stronger evidence of the clinical benefits of new devices and information on how their performance compares with existing products (Advanced Medical Technology Association 2015a, A. T. Kearney 2014, Rice 2014).

Group purchasing organizations

Many providers purchase medical devices with the help of entities known as group purchasing organizations (GPOs). GPOs are intermediaries that negotiate purchasing contracts with medical device companies (and other suppliers) on behalf of the providers who are members of the GPO, using their combined purchasing power to obtain lower prices. GPOs do not purchase anything themselves and play no role in distributing products from manufacturers to purchasers. GPOs play a larger role in the purchase of conventional devices than in the purchase of high-technology devices, which is often done outside of GPO contracts.

There are approximately 600 GPOs in all, but the sector has been steadily consolidating and is now highly concentrated (Government Accountability Office 2010). The top five GPOs currently account for about 90 percent of all GPO sales (Government Accountability Office 2014b). The ownership structure of GPOs varies; some are owned by their customers, while others are not. Virtually all hospitals in the United States use GPOs to purchase at least some of their supplies (many hospitals use different GPOs to buy various products), and GPO purchases represent about 75 percent of total hospital supply purchases (Government Accountability Office 2010).

As part of a GPO contract, medical device manufacturers and other suppliers pay "contract administrative fees" to the GPO. These fees typically equal a share of the sales price on items sold through the GPO contract; the fees for the five largest GPOs in 2012 were between 1 percent and 2 percent of their overall sales volume. These fees are GPOs' main funding source and can represent more than 90 percent of their overall revenues. GPOs use some of the fees to cover their operating expenses and typically distribute a significant portion of the fees to the hospitals that are their customers. In 2012, the five largest GPOs distributed about 70 percent of the $2.3 billion that they received in fees. The fees could be prohibited under the federal anti-kickback statute as an inducement to obtain business if certain conditions were met, but the Congress enacted a "safe harbor" exception in 1986 that allows GPOs to collect them (Government Accountability Office 2014b).

Although GPOs benefit from their customers' bulk purchasing power, the prices on GPO contracts may not always be the lowest possible. GPOs generally award contracts to at least two manufacturers of a particular

product, and hospitals are usually not required to make all of their purchases through the GPO contract. As a result, medical device manufacturers may not always offer a GPO the lowest prices because they cannot be certain of receiving a sufficient volume of sales in return. Individual hospitals can obtain lower prices for some products by directing their GPO to negotiate customized contracts in which the hospital agrees to purchase all of those products from a single manufacturer or supplier (Advisory Board Company 2013, Government Accountability Office 2014b).[16]

There has been some debate over whether a business model based on administrative fees is an appropriate way to structure GPOs. Critics of the current model argue that GPOs do not always have an incentive to negotiate the lowest possible price; since administrative fees are based on overall sales volume, lower prices also result in lower fees for the GPO. Supporters of the current model note that hospitals can switch GPOs if they wish and argue that competition among GPOs for hospitals' business mitigates any potential conflict of interest. Little empirical research has been done on the issue. Experts disagree on whether other business models for GPOs would be viable (for example, GPOs could be funded entirely by fees paid by member hospitals), but agree that the transition from the current model to another business model would be disruptive for both GPOs and hospitals (Government Accountability Office 2014b).

Implantable medical devices

IMDs are a segment of the medical device industry that has received significant attention from researchers, financial analysts, and others over the years. IMDs include devices such as pacemakers, coronary stents, artificial hips and knees, and artificial lenses. Although IMDs are used in many different kinds of surgery, they feature most prominently in cardiac and orthopedic procedures.

As a group, IMDs are often technologically advanced and provide innovative ways to treat conditions such as heart arrhythmia and chronic arthritis. They are also expensive; the purchase price for an IMD can equal 30 percent to 80 percent of an insurer's payment to a hospital for a procedure (Robinson 2008).

The market for IMDs has several distinctive features and is similar in many respects to the market for brand-name prescription drugs. First, companies face numerous barriers to entering the market, such as high research and development costs, the need to win regulatory approval, the presence of patents, and the difficulty in convincing hospitals to purchase their products (Seligman 2013). Most markets for particular IMDs thus have relatively few competitors. For example, three companies account for about 90 percent of pacemaker sales, and four companies account for about 95 percent of knee and hip implant sales (Collins 2016, Hollmer 2014). In economic terms, these markets are oligopolies, where the number of sellers is small and each company has some degree of control over the prices it charges for its products (Pauly and Burns 2008).

The degree of competition between companies is often limited by other factors, including differences in competing products that make switching difficult, physician preferences, and lack of pricing information. Regarding product differences, manufacturers of IMDs differentiate their devices from those made by competing firms. For example, one company's knee implant may have features or capabilities different from a competitor's knee implant, and physicians may need to use different techniques to implant each device. The short life cycles that are common in the medical device industry help manufacturers keep their products differentiated over time. Some differences among competing devices may have a clinical or therapeutic benefit, but in other cases, the benefits are unclear. However, this kind of product differentiation makes it harder for physicians to switch suppliers (because of the time required to learn how to use a new device properly) and helps limit the extent to which manufacturers have to compete on price.

Physician preferences can also dampen competition. Although hospitals are the entities that actually purchase IMDs, physicians have traditionally had significant influence on their purchasing decisions. Most physicians prefer to use a particular company's devices in their procedures, and hospitals have been willing to accommodate those preferences because of physicians' ability to control where their patients are admitted and the profitability of surgical lines such as orthopedic procedures. These devices are thus also known as *physician preference items* (Robinson 2015). Physicians have typically had little incentive to consider differences in cost when deciding which devices to use because the hospital bears the cost.

The prices that manufacturers of IMDs charge for their devices can vary considerably from hospital to hospital. Manufacturers often require that their prices be kept

TABLE 7–3

Prices paid by hospitals for common orthopedic and cardiac devices varied substantially, 2008

IMD	Minimum	25th percentile	Median	75th percentile	Maximum
Artificial knee implants	$3,380	$4,463	$4,925	$6,549	$10,944
Artificial hip implants	$3,828	$5,425	$6,238	$7,262	$10,640
Lumbar spine implants	$3,397	$5,425	$6,238	$7,262	$29,311
Cardiac pacemakers	$4,925	$5,709	$6,197	$7,024	$10,790
Cardiac defibrillators	$19,150	$22,870	$25,066	$28,599	$34,961

Note: IMD (implantable medical device). Prices are for 2008 and were taken from a study that collected data from 61 hospitals in 8 states. Figures are the actual prices paid by the hospital, as opposed to the manufacturer's list price.

Source: Robinson 2015.

confidential and have in the past filed lawsuits to prevent the disclosure of pricing data. This lack of information makes it harder for hospitals to compare their prices with those paid by other facilities. GPOs face the same challenge in trying to evaluate prices (Government Accountability Office 2012, Robinson 2008).[17] Manufacturers have list prices for their IMDs, but those prices indicate what the "least sophisticated part of the market will pay" and typically serve as a starting point for subsequent negotiation (Robinson 2015).

Some studies have examined variation in IMD prices, although they are now somewhat dated. One study that collected price information for 2008 for several common orthopedic and cardiac IMDs found that the maximum prices for IMDs were often more than twice as high as the minimum prices (Table 7-3). Some of that variation could be due to outlier hospitals that paid unusually high or low prices, but there was also substantial variation in the middle of the distribution: The prices paid by hospitals at the 75th percentile were 23 percent to 47 percent higher than the prices paid by hospitals at the 25th percentile (Robinson 2015). GAO also found significant variation in the prices for cardiac and orthopedic IMDs when it examined the prices that some hospitals paid in fiscal year 2010 (Government Accountability Office 2012). As with prescription drugs, hospitals are more likely to negotiate favorable prices when they can promise significant sales in return. Hospitals have typically tried to do this by negotiating longer contracts and limiting the number of suppliers they use for a particular device, but the latter strategy may not be feasible for hospitals where physicians have strong preferences about which IMDs they use (Robinson 2015).

The prices for a particular model of an IMD can rise or fall over time, depending on a number of factors. Manufacturers of devices that can demonstrate clinical superiority over competing products may be in a stronger position to increase prices, or at least keep them stable (Seligman 2013). In contrast, prices for a specific model can decline over time if other manufacturers enter the market or launch newer versions of existing products (where the newer versions "catch up" by incorporating features found in existing devices, introduce entirely new features, or both). Manufacturers also have an incentive to lower prices and reduce their inventory of devices that will soon be replaced by a newer model.[18] The manufacturer then typically launches the new model at a higher price. Manufacturers may also lower prices if concerns are raised about the safety of a particular procedure, and physicians become more conservative in their treatment choices (Seligman 2013). A study funded by AdvaMed found that the average prices of seven types of IMDs declined between 2007 and 2011 by 5 percent to 25 percent. The AdvaMed study looked at average prices across all IMD models, so the change in prices for specific models could have been different (Long et al. 2013). Concerns about safety and overuse could have contributed to the decline in prices for two of those IMDs—coronary stents and implantable defibrillators (iData Research 2015, Seligman 2013).

Several recent changes in the health care sector have given hospitals more ability to negotiate favorable prices for

IMDs. First, the hospital industry has had a significant number of mergers and acquisitions in recent years, which has given some hospital systems control over larger volumes of IMD purchases. Second, the number of physicians employed by hospitals or hospital systems has increased in recent years. The shift toward hospital employment has reduced the influence of physician preferences and given hospitals greater control over device purchases. Hospitals are increasingly trying to negotiate lower prices on IMDs by purchasing from only two or three manufacturers. These efforts are often overseen by "technology assessment committees" that are composed of hospital management and physicians from the relevant specialties and that consider both cost and clinical benefit in their decision making (A. T. Kearney 2014, Robinson 2015).[19]

Price transparency for IMDs

Another facet of the IMD market is the extent to which prices are opaque. Some IMD price information is commonly known, such as list prices, but the market is far from transparent. Our work on IMDs provides an overview of what IMD price information is known by various actors in the IMD market, arguments for and against increasing IMD price transparency, and other issues to consider regarding increased IMD price transparency.

Our review of what each actor in the IMD market knows about prices focuses on manufacturers, hospitals, physicians, patients, and the Medicare program.[20] First, of all these actors, patients have the least information about IMD prices. The procedure summaries patients receive from hospitals rarely identify the costs of each device (Lerner et al. 2008).[21] Further, patient cost sharing is typically based on the procedure's total payment. For example, a Medicare beneficiary who receives a stent is responsible for the same amount of cost sharing (e.g., roughly 20 percent of the payment rate in a hospital outpatient department) regardless of how much the hospital paid for the stent. While beneficiaries have limited information on device costs and their marginal costs for any given surgery are not affected by how much a hospital paid for a device, beneficiaries bear the burden of higher device costs through higher premiums and higher total cost sharing (because higher device costs ultimately get built into payment rates).

Physicians have also been shown to have a limited knowledge of device prices, despite their substantial influence over the choice of device. One study asked orthopedic surgeons to estimate the price of several commonly used devices and found that about 80 percent of the responses were incorrect, which was defined as being more than 20 percent different from the actual purchase price (Okike et al. 2014). There are several reasons why physicians might be unaware of device prices. First, many physicians are not financially responsible for the cost of devices, so there may not be an incentive for them to seek pricing information. Second, to the extent physicians do seek device prices, hospitals can be limited in the type of information they can share with physicians because IMD manufacturers often put confidentiality clauses in their contracts. For example, GAO has reported that some hospitals restricted by confidentiality clauses have resorted to using colored stickers to indicate to physicians which devices are the high-, medium-, and low-cost options (Government Accountability Office 2012).

Hospitals, which are predominantly responsible for purchasing IMDs, have more knowledge about the prices paid for IMDs but still face limitations. Hospitals know the prices they themselves paid for devices and the prices competing manufacturers submitted to their institutions. However, hospitals often do not know what other buyers (e.g., hospitals and ambulatory surgical centers) paid for the same or similar devices. This inability to discern the price at which manufacturers are willing to sell IMDs could contribute to large variations in transaction prices. Because IMD costs often constitute a large majority of the cost associated with a given procedure, opaque prices can contribute to large variations in the profitability of the same procedures across hospitals.

Hospitals have responded to opaque device prices by working with GPOs and consulting firms to gain insight into the prices paid by other hospitals (Robinson 2008). For example, one firm sells hospitals access to a database that allows them to benchmark the price they paid for devices relative to the lowest, 25th percentile, median, 75th percentile, and highest price that other hospitals paid for the same device (ECRI Institute 2017). However, while such services provide hospitals with additional information, not all hospitals share such information (so a given database might not represent the full market); also, hospitals might be limited by manufacturer nondisclosure clauses from sharing certain information, and off-invoice or other discounts might not be captured.

The Medicare program has only aggregate information on device costs. Through Medicare claims data and cost reports, the approximate total device costs for a

procedure and total hospital spending on devices are documented. However, Medicare cannot determine from this information the exact devices used in a procedure or the price that hospitals paid for a specific device.[22] Also, because ambulatory surgical centers do not submit cost reports, Medicare knows even less about how much those entities spend on devices.

Finally, manufacturers know the actual transaction prices, net of all rebates and discounts, at which their own firms sell devices to their customers. Arraying this information in certain ways could help manufacturers gain a better understanding about the device market. For example, the data could be arrayed longitudinally to understand trends in pricing and by hospital characteristics to better understand the willingness of certain types of hospitals to pay higher or lower prices. In addition, manufacturers may know the pricing behavior of the limited number of competitors in the IMD market. Some have suggested that manufacturers gain insight into their competitors' pricing behaviors by commissioning studies by third parties and by their sales representatives routinely getting information about their competitors' bids from hospital staff (Lerner et al. 2008).

Proponents of greater IMD price transparency suggest that the asymmetrical availability of pricing data has allowed IMD prices to remain high and that increasing transparency can counteract that historical imbalance. Arguments in favor of increased IMD price transparency include:

- ***Decreased prices.*** Proponents believe increasing IMD price transparency could assist hospitals in making better informed decisions about the value of devices and negotiate lower prices for them accordingly.
- ***Reduced price variation.*** Even if increased price transparency does not reduce IMD prices on average, some believe an attenuation of the variation could be beneficial. Because IMDs can represent a substantial majority of the costs associated with a procedure and the prices hospitals pay for IMDs can vary greatly, some hospitals might find device-intensive procedures extremely profitable while others may not. Narrowing the variation in IMD prices (and therefore the profitability of device-intensive procedures) could help ensure continued access to these services without a need for higher payment rates. One example of transparency leading to a narrower price distribution is what occurred in the German electricity market a year after the government mandated publication of transmission charges—the average price was little changed but the distribution of rates narrowed (Congressional Budget Office 2008).
- ***Increased value.*** Some contend increasing physicians' understanding of IMD prices could serve as a mechanism for hospitals to engage physicians in jointly negotiating with device manufacturers (Pauly and Burns 2008). Improved pricing information could also enhance the ability of technology assessment committees to properly judge the value of a device.

Opponents of IMD price transparency argue that the current system has worked well to keep the growth in device costs low and that mandatory price transparency would increase costs. In concentrated markets (as IMD markets often are), increased transparency could lead to higher prices since such markets are more likely to be conducive to firms coordinating to keep prices high (Congressional Budget Office 2008). For example, if prices were made completely transparent, IMD manufacturers might have few incentives to offer lower prices to hospitals because if their competitors could see and match their prices, their price discounts would be unlikely to win them business. In addition, in a concentrated market with transparent prices, a manufacturer can be assured that none of its competitors is undercutting their price because they can see all their competitors' prices. The Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) have said that even aggregated data that contain less than five providers would not fall in their "safety zone" for antitrust concerns (Department of Justice and the Federal Trade Commission 1996). This threshold could be an issue for price transparency in the IMD market since there are often few manufacturers for specific devices. Empirical research is limited regarding whether price transparency in concentrated health care markets increases prices, but three studies from industries outside health care are commonly cited to demonstrate the point: a study that showed mandatory price transparency increased prices in the Danish concrete industry and two studies that showed companies took advantage of a U.S. law requiring railroads to disclose some of their contract terms with grain shippers by raising their prices when they could observe what their competitors in concentrated markets were charging (Congressional Budget Office 2008).

The ramifications of any policy designed to increase IMD price transparency vary greatly depending on the details of the program. Some of the key design choices for

policymakers to consider when designing a program to increase IMD price transparency include:

- ***Transparent to whom.*** Physicians and hospitals have the largest influence over IMD purchases, so transparency efforts could be aimed at improving their understanding of prices. Allowing payers to access pricing data could allow them to improve payment accuracy and potentially advance value-based insurance designs. In contrast, increasing beneficiary awareness of IMD prices is unlikely to lower device costs, at least in part because beneficiaries pay only a fraction of the cost of the procedure and their costs often do not vary with device selection. In addition, sharing pricing data with IMD manufacturers, which is tantamount to what happens when the data are publicly reported, could result in collusive behavior and higher prices.

- ***Timing of pricing data.*** Data that are more current are likely more beneficial to providers seeking to negotiate with IMD manufacturers. However, data that are more current could be used in an anticompetitive manner. The FTC and DOJ have suggested that, to avoid antitrust scrutiny, pricing data should be more than three months old to help ensure that competitors cannot use the information for coordination of prices (Department of Justice and the Federal Trade Commission 1996).

- ***Type of pricing data reported.*** The prices collected need to represent actual transaction prices, net of any rebates or discounts. Beyond this, one question is how granular the data should be. Legislation that was introduced in the Congress in 2007 but never enacted had sought public disclosure of the average and median device prices for certain devices (U.S. Senate 2007). Others have suggested that more granular data, including information on the range of prices offered, could be more helpful (Pauly and Burns 2008). In general, the more granular the data, the more useful the data become to providers in their negotiations with manufacturers; however, more granular data could potentially allow manufacturers to "back out" their competitors' prices. Another consideration is whether pricing information should represent the price at which manufacturers sell IMDs or the price at which hospitals buy them. These prices could be different if devices are first sold through a physician-owned distributor or other intermediary, which could also have implications for who would be responsible for reporting the data—providers (hospitals and ambulatory surgical centers) or manufacturers.

- ***Administrative costs.*** Collecting sales data from manufacturers or providers would increase administrative costs for the reporting entity and CMS. Other proposals to increase transparency that do not involve data reporting (e.g., prohibiting manufacturers from limiting price disclosures between hospitals and physicians) would involve lower administrative costs.

Relationships between device manufacturers and physicians

The medical device industry is particularly notable for the substantial relationships that often exist between medical device manufacturers and physicians. These ties are often deeper and more extensive than those between physicians and drug makers (Robinson 2008). These relationships can take many different forms, such as:

- royalty payments to physicians who help develop medical devices;
- consulting fees to physicians for providing feedback about the performance and design of a company's devices;
- funding for physicians to conduct research;
- funding for medical education activities; and,
- for physicians who use IMDs, regular interactions with the manufacturer's sales representatives, who are often present at the physician's invitation in the operating room during procedures and may help the physician make a final decision about which devices to use (Robinson 2015).

In many instances, these relationships can benefit the public by fostering the development and improvement of new medical devices and educating physicians about how medical devices can be used safely and effectively (Demske 2008). However, physicians have substantial influence over the purchase and use of many medical devices, and device manufacturers have a strong incentive to cultivate close relationships with physicians and encourage the use of their products. Manufacturers can also use their relationships with physicians to implicitly reward physicians for using their products, which has led to persistent concerns that these relationships may affect physicians' judgment about the best way to treat their patients (Robinson 2015).[23]

Device companies were generally not required to disclose information about their financial relationships with physicians until 2010, when the Patient Protection and Affordable Care Act required drug manufacturers, device manufacturers, and GPOs to submit information to CMS about their payments to physicians and teaching hospitals. The Commission had previously recommended the reporting and disclosure of this information in a 2009 report to the Congress (Medicare Payment Advisory Commission 2009). CMS refers to this initiative as the Open Payments program and has released information for part of 2013 and all of 2014 and 2015.

We analyzed Open Payments data for 2015—the most recent year of data available—to identify non-research payments made by medical device manufacturers to physicians. We found that device manufacturers accounted for $1.7 billion of the $2.8 billion in non-research payments to physicians in 2015, or 59 percent of the total. By comparison, drug manufacturers made $1.0 billion in payments (35 percent of the total). The remaining $0.2 billion in payments (7 percent of the total) were made by companies that produce both devices and drugs or by other entities. The non-research payments made by device manufacturers to physicians comprised ownership or investment interests in companies (42 percent) and "general payments" (58 percent), a category that includes promotional speaking fees, royalty and license payments, consulting fees, food and beverage, travel and lodging expenses, education, and other transfers of value.

Physician-owned distributors

Physician-owned distributors (PODs) are entities that derive revenue from selling, or arranging for the sale of, IMDs ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (Office of Inspector General 2013a). While IMD manufacturers traditionally sell and distribute their products directly to hospitals, PODs can operate as intermediaries between device manufacturers and hospitals that purchase devices—that is, a device manufacturer sells a device to a POD and the POD resells the device to a hospital at a higher price. Also, some PODs purport to design or manufacture their own devices (Office of Inspector General 2013a). In such cases, a POD might seek a 510(k) clearance to market a relatively simple device, such as a surgical screw, and then outsource the production of the device to a contract manufacturer.[24] A third model PODs often use is the "GPO model." Under this type of arrangement, physicians form a POD to aggregate their purchasing power and get bulk discounts from manufacturers (U.S. Senate Committee on Finance 2011).

PODs commonly supply devices used in spinal surgery. In the most comprehensive report on the prevalence of PODs, OIG surveyed 596 hospitals in which spinal fusion was performed in 2011 and determined whether each hospital purchased spinal devices from PODs.[25] OIG found that PODs supplied at least some of the spinal devices for nearly one in five spinal fusion surgeries billed to Medicare in 2011 and that roughly a third of hospitals purchased these devices from PODs (Office of Inspector General 2013b). In addition, the use of PODs grew dramatically in the years immediately preceding the survey. For instance, 88 percent of hospitals that purchased spinal devices from a POD said that they began doing so only after 2005 (Office of Inspector General 2013b).

While the OIG report established the historical use of devices purchased from PODs in spinal surgeries, less is known about the current prevalence of such use and the extent to which PODs are involved in other clinical areas, at least partially because of their lack of reporting under the Open Payments program. PODs have historically been limited to supplying devices for spinal surgery, but some are concerned that PODs may now be appearing in other areas such as joint replacements, prosthetics, and orthotics (U.S. Senate Committee on Finance 2016). Under the Open Payments program, drug and device manufacturers and GPOs report information to CMS about payments to physicians and teaching hospitals. While PODs that fall within the definition of an applicable manufacturer or GPO must report under the Open Payments program, few PODs have actually reported under the program (Centers for Medicare & Medicaid Services 2013). (See Chapter 6 of this report.)

Critics have charged that PODs present an inherent conflict of interest because their physician-owners can determine which devices to use in their procedures and benefit financially when they use devices supplied by their POD. The conflict of interest can lead to increased Medicare expenditures, increased costs for hospitals, and potentially inappropriate care for beneficiaries. Specific concerns raised by POD critics include:

- ***Increased volume.*** Opponents of PODs contend that physicians have a financial interest in referring more patients for surgery because physicians profit from the

devices used in surgery. Referring a larger number of patients for surgery increases costs for Medicare and beneficiaries.

- ***Increased intensity.*** POD critics suggest that physicians using devices from their POD have a financial incentive to use more devices in patients referred for surgery. Physicians can use more devices during surgery or refer beneficiaries for more intense procedures that require more devices. For example, physicians can refer a patient for spinal fusion rather than decompression, a less intense procedure. For patients with a common spinal condition that has several treatment options, researchers have found that "more complex procedures were associated with greater complications, mortality, hospital charges, and other measures of health care use, even after adjustment for patient demographic and clinical characteristics" (Deyo et al. 2010).
- ***Inappropriate care.*** Opponents of PODs contend that physicians who have a financial interest in a POD may have an incentive to refer patients for surgery inappropriately. In addition, some have suggested that surgeons have an incentive to use devices of inferior quality or that are not best suited for the procedure simply because they have a financial interest in choosing the devices that their PODs sell (U.S. Senate Committee on Finance 2011).
- ***Higher device costs.*** Because the physician-owners of PODs can profit from the difference between the price at which a POD buys a device from a manufacturer and the price at which it then sells it to a hospital, critics suggest that PODs have an incentive to seek the highest price possible from their hospital clients. Some hospitals might have a limited ability to negotiate lower prices because IMDs are typically physician preference items, and hospitals could risk losing patients if they refuse to purchase devices from PODs.[26] Higher IMD prices put pressure on hospital margins and can contribute to calls for higher reimbursements from Medicare.

Proponents of PODs argue that PODs can save money if properly structured. Specifically, proponents suggest that PODs can lower device costs by aggregating the buying power of multiple physicians, eliminating the cost of sales representatives that is part of the traditional model for selling and distributing IMDs, and increasing competition.

One group that advocates on behalf of PODs—the American Association of Surgeon Distributors (AASD)—has developed standards that PODs should adhere to in order to mitigate the conflict of interest many believe is inherent in PODs. For example, AASD standards include adhering to an appropriate-use monitoring policy and keeping device price increases below a certain level (American Association of Surgeon Distributors 2017). A case study authored by individuals with financial interests in PODs found that devices acquired through five PODs that were members of AASD were, on average, 36 percent less expensive compared with similar devices not acquired through PODs (Steinmann et al. 2015). However, the results of this case study contradict the results of OIG's study that examined a broader universe of PODs.

Specifically, OIG found that none of the six types of spinal devices they examined was less costly per unit when purchased through a POD, and one—spinal plates—cost $845 more on average when supplied by a POD ($2,475 vs. $1,630) (Office of Inspector General 2013b). Further, OIG found that the rate of spinal surgery grew faster among hospitals that began purchasing devices from PODs compared with all hospitals (16 percent vs. 5 percent, respectively). The rate of spinal fusions—surgeries that are more likely to use devices—grew more than twice as fast among hospitals that acquired devices from PODs compared with all hospitals (21 percent vs. 9 percent, respectively). However, OIG found that surgeries in which the devices were acquired through PODs involved fewer devices on average (12.3 vs. 14.2 when not acquired through PODs), and the findings were mixed with regard to the complexity of surgeries at hospitals that acquired devices through PODs and those that did not.

OIG also issued a Special Fraud Alert about the use of PODs in 2013, calling them "inherently suspect under the anti-kickback statute" (Office of Inspector General 2013a). While the legality of any particular POD depends on the intent of the parties, OIG highlighted specific characteristics of concern. For example, PODs are particularly concerning when the size of the investment offered to each physician varies with the volume or value of devices used by the physician. Because a violation of the anti-kickback statute applies to both parties in an illegal kickback scheme (e.g., the hospital and the POD), some hospitals began enacting policies forbidding or strictly curtailing business with PODs after OIG issued the Special Fraud Alert (Office of Inspector General 2013b, U.S. Senate Committee on Finance 2016). For example,

The excise tax on medical devices

The Congress enacted an excise tax on medical devices in 2010 as part of the Health Care Education and Reconciliation Act, the companion piece of legislation that modified the Patient Protection and Affordable Care Act. The excise tax equals 2.3 percent of the manufacturer's price for certain medical devices, which makes it akin to a sales tax. The tax applies to all medical devices sold in the United States except those that are "generally purchased by the general public at retail for individual use" or exported. Medical device companies can deduct the excise tax as a business expense on their corporate income tax returns, which reduces the impact of the excise tax on profitable firms by about 35 percent. The tax went into effect on January 1, 2013, and was expected to generate $29 billion in additional tax revenue over 10 years (Gravelle and Lowry 2015).

The medical device industry has been strongly opposed to the excise tax. The industry has argued that the tax reduces incentives to invest in the development of new medical devices and thus harms the industry's ability to develop innovative new products. In particular, the tax is seen as a hardship for small medical device companies that are heavily engaged in research and development since they must pay the tax even if they are not profitable. (The tax is based on medical device sales, so the tax liability for a medical device company is effectively a function of its gross revenues rather than its profits.) The industry has also argued that the tax will lead to higher prices for medical devices, which would reduce the demand for them. The industry has estimated that the combination of lower investment, higher prices, and lower demand will result in significant job losses and encourage U.S. device companies to relocate abroad (Advanced Medical Technology Association 2015b, Furchtgott-Roth and Furchtgott-Roth 2011).

Supporters of the tax have argued that the health reform law will ultimately benefit the medical device industry

(continued next page)

Intermountain Healthcare implemented restrictions on contracting with PODs after the 2013 Special Fraud Alert (U.S. Senate 2015).

While the 2013 Special Fraud Alert made clear that PODs are inherently suspect, federal prosecutions have been limited. Some have suggested that government enforcement actions against PODs have been rare at least partly because the anti-kickback statute requires proof of intent. The most prominent POD prosecution involves a series of cases brought by the Department of Justice against Dr. Aria Sabit, a POD in which Sabit was an investor (Apex Medical Technologies), and others. In one case, Sabit pled guilty and was sentenced in 2017 (Department of Justice 2017). In connection with his guilty plea, Sabit admitted that:

- the financial incentives provided to him by his POD caused him to use more spinal implant devices than were medically necessary to treat his patients to generate more sales revenue for his POD, which resulted in serious bodily injury to his patients; and
- the money he made from using his POD's spinal implant devices motivated him either to refer patients for unnecessary spine surgeries or for more complex procedures that they did not need (Department of Justice 2017).

Despite these actions, PODs continue to operate throughout the country. For example, a 2016 report from the Senate Finance Committee majority staff states that PODs were believed to be operating in 43 states (U.S. Senate Committee on Finance 2016). In addition, PODs may be changing their operations to avoid hospital-level POD policies and to avoid reporting under the Open Payments program. For example, PODs may be shifting to smaller and more rural hospitals, which may have not yet developed POD-specific policies. In addition, PODs may be changing their structures—such as physicians becoming employees of PODs instead of investors—to

The excise tax on medical devices (cont.)

by increasing the number of people in the United States with health insurance, which should increase the use of health care services. They also note that the health reform law raises revenues from several other health care sectors (for example, by imposing industry-wide fees on health insurers and brand-name pharmaceutical manufacturers) and argue that the medical device industry is being treated in a similar manner. Further, they assert that the tax will not lead medical device companies to relocate abroad because medical devices that are imported for sale in the United States are also subject to the tax (Van de Water 2015).

The Congressional Research Service (CRS) found that the impact of the tax on the medical device industry will be relatively small. CRS based its conclusion on the fact that the tax rate is relatively low and that about half of domestic U.S. production will not be subject to the tax because of the exemptions for retail sales and exports. CRS also argued that the demand for health care services is not very sensitive to price changes, which will enable medical device manufacturers to pass along the impact of the tax in the form of higher prices. Overall, CRS estimated that the tax would reduce employment and output in the medical device industry by no more than 0.2 percent. CRS also noted that initial tax collections were lower than expected, suggesting that some manufacturers may not be aware that they are required to pay the tax (Gravelle and Lowry 2015).

The Congress enacted a two-year moratorium on the tax at the end of 2015, so medical device companies do not have to pay it in 2016 or 2017. However, if the Congress takes no additional action, the tax will go back into effect in 2018. ■

avoid reporting under the Open Payments program (U.S. Senate Committee on Finance 2016).

Financial performance

Most financial assessments of the medical device industry focus on the roughly 20 to 30 largest companies. These firms are publicly traded, so data on their financial performance are readily available, and the firms account for most of the industry's overall revenues. In contrast, most small medical device companies are privately held and do not release their financial information to the public.

Large medical device companies have consistently been highly profitable, with annual operating margins that are often between 20 percent and 30 percent (A. T. Kearney 2014, Seligman 2013).[27] The investment bank J. P. Morgan recently examined nine major U.S. device companies—including six of the eight U.S. companies listed in Table 7-1 (p. 210)—and found that their profit margins in 2014 ranged from 19 percent to 39 percent, with a median profit margin of 30 percent.[28] These nine companies were projected to have similar profit margins over the 2015 to 2017 period (Weinstein et al. 2016).

Annual revenue growth for large device companies slowed noticeably after the 2007 to 2009 recession, dropping between 2008 and 2013 from about 7 percent to about 2 percent or 3 percent (Weinstein et al. 2016). However, many companies reduced their costs in response, and overall profit margins remained stable (PricewaterhouseCoopers 2012). Annual revenue growth has since improved and is projected to range between 4 percent and 6 percent for most companies over the next few years (Weinstein et al. 2016). These companies have also been able to maintain their profit margins despite the enactment of a controversial excise tax on medical devices (see text box).

Large medical device companies are highly profitable for a number of reasons already discussed. These companies receive a significant portion of their revenues and profits from the sale of IMDs and other advanced medical devices, and the markets for those products typically have significant barriers to entry (high research and development costs, FDA regulatory oversight, patents) and limited competition. Similar to brand-name prescription drugs, medical devices can require significant research and

development before entering the market but, after that, the cost of producing them is relatively low (Seligman 2013). Some hospitals have difficulty negotiating lower prices for devices because of the influence of physician preferences, and the methods that some private health insurers use to pay for IMDs encourage hospitals to purchase higher cost devices.

In contrast, the profit margins for smaller, publicly traded device companies are generally much lower. GAO's analysis of net profits between 2005 and 2014 for 102 device companies of varying sizes found that the small- and medium-sized companies, in aggregate, experienced net losses each year (Government Accountability Office 2015). These companies are typically less diversified than the large device companies, and their success or failure may depend heavily on a particular device. These companies may lose money for several years because of a combination of high research and development costs and the time needed to persuade physicians and hospitals to use their products.

How Medicare pays for medical devices

Although Medicare uses a wide variety of methods to pay for health care services, its payment rules for medical devices have two common elements. First, Medicare does not pay medical device companies directly for their products. Instead, the program reimburses health care providers—such as hospitals and physicians—when they use medical devices to deliver care. Second, Medicare rarely makes payments for individual medical devices. Instead, reimbursement for a medical device is typically part of a bundled payment that covers many of the items needed to deliver the associated service or procedure. For example, Medicare's payment to a hospital for knee replacement surgery covers the cost of the operating room, routine surgical supplies, and the knee implant itself (Robinson 2015). To do otherwise—that is, pay separately for each individual medical device—would be administratively burdensome and give providers little incentive to use devices in a cost-effective manner.

Accounting for the cost of medical devices in payment rates

CMS uses several methods to account for the cost of medical devices, depending on the type of associated service. Examples of three methods for calculating cost include those associated with inpatient and outpatient hospital services, clinician services, and durable medical equipment (DME).

For inpatient and outpatient hospital services, CMS accounts for the cost of medical devices using data that hospitals submit each year in their cost reports. The cost reports have information on both costs and charges, which CMS uses to calculate cost-to-charge ratios for major categories of hospital activity known as cost centers. The cost of medical devices is reported in several different cost centers, such as one for medical supplies and another for implantable devices. CMS uses the cost-to-charge ratios to convert charges that hospitals submit on claims to an estimated cost of providing services. CMS calculates the average cost for each service across all hospitals and uses that as the basis for its payment rates under both the inpatient prospective payment system (IPPS) and the outpatient prospective payment system (OPPS). As a result, Medicare's payment rates for an inpatient or outpatient service include an amount that approximates the average amount that hospitals pay for the medical devices used in that service.[29]

For clinician services, CMS accounts for the cost of medical devices using information collected from surveys fielded by specialty societies. These surveys ask about the time and intensity involved in providing a service and the associated practice costs, such as nonphysician clinical staff and the specific medical devices used in each procedure.[30] A group of health care professionals known as the AMA/Specialty Society Relative Value Scale Update Committee then recommends clinician payment rates to CMS based on the survey information and their professional judgment. CMS converts information on the types of devices used for a given service into an overall cost estimate using price data that it collects. CMS then calculates weights that measure the relative costliness of each physician service. However, the amount included for medical devices can often be inaccurate because the information on the number and type of medical devices used in a procedure is based on a small number of surveys, and CMS has not thoroughly updated the information on prices since 2004. In some cases, the price of a device is based on only one or two invoices.

Unlike hospital and physician services, DME (as well as prosthetics and orthotics) is an area where medical devices such as wheelchairs and home oxygen equipment are considered services in their own right. CMS traditionally used a fee schedule to pay for these products, but the Congress required the agency to begin using competitive

bidding in 2009 to determine the payment rate for many DME products and has expanded its use since then. Under competitive bidding, DME suppliers submit bids to provide certain products in selected metropolitan areas and indicate how much of each product they can supply. CMS selects suppliers who offer the best price and meet applicable quality and financial standards and then uses the median bid from the winning suppliers as its payment rate. The DME competitive bidding program has substantially reduced DME payment rates, thereby saving Medicare and beneficiaries billions of dollars since its inception (Centers for Medicare & Medicaid Services 2016, Government Accountability Office 2014a). CMS has also reported that the implementation of the DME competitive bidding program has not resulted in widespread beneficiary access issues (Government Accountability Office 2016).

Ramifications of bundling medical devices with other inputs

Medicare's general strategy of bundling its payment for medical devices with its payment for all of the other "inputs" used to provide a service is beneficial because it gives providers an incentive to limit their spending on medical devices (as well as the other inputs that are bundled into the payment rate). Providers do not receive any additional payment when they use a more expensive device, and they lose money if their costs exceed the Medicare payment rate. This incentive is particularly strong for IMDs, which can make up a significant share of the overall costs of an inpatient stay or outpatient procedure. Conversely, providers that can keep their costs below the Medicare payment rate benefit financially.

The experience of private health insurers illustrates how bundling medical devices into payment rates can help control spending. In contrast to Medicare, private insurers are often forced to carve IMDs out of their payment rates and pay for them separately, instead of bundling them with other inputs. Some hospitals can also add a significant markup to their purchase price when they negotiate IMD payment rates with private insurers. This arrangement allows some hospitals to turn IMDs into a significant source of profit and (since the markups are usually calculated on a percentage basis) gives them an incentive to use more expensive devices (Robinson 2015).

Bundling medical devices with other inputs also has some drawbacks, although they are outweighed by the benefits. One drawback to bundling is that claims data cannot be used to determine how much Medicare spends on medical devices or monitor how that spending—in aggregate or for specific procedures—changes over time. This lack of information may not matter much for inputs like common medical supplies, but it may be more significant for high-cost items such as IMDs. Given the limitations of claims data, Medicare cost reports for hospitals can be used as an alternate source of information. Hospitals are the largest purchasers of medical devices, and they must submit information on the overall costs and charges for both medical supplies and implantable devices on their cost reports. However, this information is highly aggregated and better suited for analyzing major areas of hospital costs than the underlying costs of individual services.

Using cost report data, we estimate that medical supplies and implantable devices in 2014 represented about 15 percent of total hospital costs for Medicare-covered services (Table 7-4, p. 232). That year, hospitals spent about $14 billion on implantable devices and almost $10 billion on medical supplies. Between 2011 and 2014, spending on implantable devices grew at an average annual rate of 4.7 percent, compared with 2.0 percent for total hospital costs. During this period, implantable devices also grew as a share of total hospital costs, rising from 8.0 percent to 8.7 percent, while spending on medical supplies increased slightly faster than total hospital costs. The higher growth in spending on implantable devices relative to total hospital spending could be due to higher prices for IMDs, higher utilization rates for procedures that use IMDs, and sluggish growth in inpatient stays that do not involve IMDs.

Another concern about bundling medical devices with other inputs is that CMS's IPPS and OPPS rates are ultimately based on historical data from cost reports. There is a two-year delay before cost reports for a given year are available, and this lag discourages hospitals from using new devices that benefit patients but are more expensive than existing technology (Robinson 2015). CMS mitigates this incentive during the period between the introduction of a new device and the availability of suitable cost report data by increasing payment rates for devices that satisfy three criteria: (1) they have received FDA approval or clearance within the past three years; (2) they are sufficiently expensive that existing payment rates are inadequate; and (3) they have a clear clinical benefit.[31] These new-technology payments remain in effect for no more than three years; by that time, hospitals have submitted cost reports that include the costs of the new technology, and CMS can use its regular methodology to set payment rates. For inpatient services, the new-technology payment equals 50 percent of the difference

TABLE 7–4

Hospital spending on implantable devices and medical supplies for Medicare-covered services in 2011 and 2014

	Reported costs (billions of dollars)		Average annual growth 2011–2014	Share of total hospital costs	
	2011	2014		2011	2014
Implantable devices	$12.1	$13.8	4.7%	8.0%	8.7%
Medical supplies	$9.1	$9.8	2.4	6.1	6.2
Total	$21.2	$23.6	3.7	14.1	14.8
Total hospital costs	$150.2	$159.1	2.0	100.0	100.0

Note: The figures in this table are based on Medicare cost report data for 3,002 hospitals that submitted cost reports for each year between 2011 and 2014, used the same cost reporting period during those years, were paid under the inpatient prospective payment system, and did not use all-inclusive rates. Figures include costs for both inpatient and outpatient services. Actual costs for implantable devices may be somewhat higher than these figures indicate because some hospitals may report the cost of some implantable devices in other sections of the cost report (for example, by including coronary stents in the cost of a cardiac catheterization laboratory). Components may not sum to totals because of rounding.

Source: MedPAC analysis of Medicare hospital cost reports.

between the estimated cost of the inpatient stay and the regular Medicare payment rate, or 50 percent of the cost of the new device, whichever is less. For outpatient services, the new-technology payment equals the estimated cost of the device, which CMS calculates using the hospital's cost-to-charge ratio. Hospitals identify the services that qualify for new-technology payments by including specific procedure or service codes on their claims.

Relatively few devices have qualified for these new-technology payments. Between 2001 and 2015, CMS approved only 19 of 53 applications (from both device and drug manufacturers) for new-technology payments under the IPPS. Medicare spending for new-technology payments has also been relatively low; between fiscal years 2002 and 2013, the program spent about $200 million on new-technology payments under the IPPS (Hernandez et al. 2015). The medical device industry has argued that CMS should make it easier to qualify for new-technology payments and that the IPPS should pay 80 percent of the cost of a new device or drug instead of 50 percent to more strongly encourage the use of new technology (Advanced Medical Technology Association 2016). However, the existing criteria encourage hospitals to negotiate discounts on new devices, which limits the ability of device companies to introduce new devices at higher prices and helps to contain program spending (Robinson 2015).

Gainsharing in Medicare

While bundled payments give hospitals an incentive to keep their costs low, physicians significantly influence device selection, and physicians may be indifferent or antagonistic to hospitals' efforts to lower costs (Robinson 2008). One way to align hospital and physician incentives is to engage in gainsharing. Our work provides a brief overview of what constitutes gainsharing, gainsharing in Medicare, and arguments for and against allowing broader participation in gainsharing arrangements in Medicare.

While gainsharing arrangements take many forms, the term generally refers to programs that allow hospitals to share savings with physicians if costs are reduced below a historical or other benchmark. Gainsharing arrangements between hospitals and physicians can generate savings in several ways. Strategies traditionally used in gainsharing arrangements to lower costs include product standardization (which may allow hospitals to negotiate lower prices based on increased volume and to realize other efficiencies), product substitution (whereby physicians choose a lower priced device that is clinically appropriate), opening packaged items only as needed, and limiting the use of certain supplies or devices (Morris 2005). Gainsharing can also generate other savings by focusing on patient management, such as optimizing

bed management in intensive care units by transitioning patients to less intense settings in the hospital (e.g., "step-down" units) when appropriate (Hopkins et al. 2015).

Gainsharing arrangements between hospitals and physicians can violate federal law. Three laws are of particular concern—the gainsharing civil monetary penalty (CMP) law, the anti-kickback statute, and the physician self-referral law (Centers for Medicare & Medicaid Services 2015b). The gainsharing CMP law prohibits a hospital from knowingly making a payment to a physician as an inducement to reduce or limit medically necessary services to Medicare beneficiaries under the physician's care. Before the Medicare Access and CHIP Reauthorization Act of 2015, the gainsharing CMP law prohibited paying a physician to reduce or limit any care, regardless of whether the care was medically necessary (Centers for Medicare & Medicaid Services 2015b). The anti-kickback statute makes it a criminal offense to knowingly offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services payable by Medicare or other federal health care programs (Centers for Medicare & Medicaid Services 2015b). OIG has said that certain gainsharing arrangements could violate the anti-kickback statute, such as arrangements designed to attract physicians' referrals to a particular hospital or those that reward physicians over an extended period for previously achieved savings (Morris 2005). Finally, the physician self-referral law, which generally prohibits physicians from making referrals for certain services to an entity with which they have a financial relationship, may not contain exceptions sufficiently flexible to encourage beneficial gainsharing arrangements (Centers for Medicare & Medicaid Services 2015b).

Because of these legal concerns, gainsharing arrangements involving Medicare FFS beneficiaries have been limited outside of programs approved through OIG's advisory opinion process and demonstrations operating under waivers. OIG has issued a number of advisory opinions allowing specific gainsharing programs. Medicare has also tested gainsharing directly and allowed gainsharing as part of larger demonstrations. For example, the Bundled Payments for Care Improvement (BPCI) initiative, which is a demonstration testing whether giving providers larger payment bundles can lower costs and improve quality, gives participants many options for creating customized gainsharing arrangements after meeting certain requirements, such as specifying the methods for calculating and distributing gainsharing payments in their implementation protocol (Lewin Group 2016).[32] Most BPCI participants intend to engage in gainsharing; for instance, 80 percent, 83 percent, and 93 percent of BPCI participants in Models 2, 3, and 4 of the initiative, respectively, have indicated their intention to participate in gainsharing (Lewin Group 2016). While data regarding the implementation of these gainsharing programs are not yet available, interviews with BPCI participants indicate that gainsharing is a useful tool to redesign care (Lewin Group 2016). Outside of programs where fraud and abuse laws are waived by the government, industry stakeholders have suggested that providers are hesitant to enter into a gainsharing arrangement involving Medicare FFS beneficiaries because of the legal risk.

Proponents of gainsharing argue that aligning the incentives of hospitals and physicians has proved effective at reining in high device costs and producing other efficiencies. The Commission has recommended that gainsharing arrangements between physicians and hospitals be permitted, with appropriate safeguards (Medicare Payment Advisory Commission 2008, Medicare Payment Advisory Commission 2005). Much of the research on gainsharing supports the utility of such arrangements. For example, a 2008 study of 13 OIG-approved gainsharing programs for coronary stent patients found several positive results: Gainsharing reduced costs by an average of 7.4 percent (with 91 percent of the savings from lower prices and 9 percent from lower utilization), surgical volume before and after implementing gainsharing remained steady, patient characteristics remained largely unchanged, and quality metrics either remained steady or showed significant improvement at gainsharing hospitals (Ketcham and Furukawa 2008). More recent studies substantiate these findings. For example, one hospital participating in CMS demonstrations that coupled bundled payments with the ability to institute gainsharing lowered its orthopedic implant costs by 29 percent from 2008 to 2015, while the three measured quality metrics either remained stable (emergency room visits and readmissions) or improved (the proportion of episodes with a prolonged length of stay) (Navathe et al. 2017).[33] The authors noted that this finding highlights the critical role gainsharing played in encouraging physicians to provide efficient care since the hospital in the study already had an incentive to keep its costs low under Medicare's diagnosis related group payment before the demonstrations.[34]

Critics of gainsharing include the medical device industry and those who are concerned that gainsharing

arrangements can become "potential vehicles for the unscrupulous to disguise payment for referrals or compromise the quality of care for patients in the interest of maximizing revenue" (Centers for Medicare & Medicaid Services 2008). The medical device industry has expressed concern that gainsharing in CMS's bundled payment demonstrations could encourage hospitals and physicians to purchase lower cost and lower quality devices (Advanced Medical Technology Association 2015c).[35] OIG, CMS, and others have also raised concerns about gainsharing arrangements in which physicians are compensated for overall cost savings without knowing what specific actions generated those savings (Centers for Medicare & Medicaid Services 2008, Morris 2005). Such poorly structured arrangements may lack accountability (e.g., a transparent system that identifies what specific actions lead to savings), sufficient safeguards against improper referral payments, and objective quality measures (Morris 2005). In the process of trying to create an exception (that was ultimately not finalized) for gainsharing arrangements from the physician self-referral law, CMS noted that improperly structured gainsharing arrangements could lead to:

- ***Payment for referrals.*** Gainsharing payments from hospitals to physicians could be used to generate referrals to hospitals, which could lead to an increase in utilization.
- ***Stinting.*** Physicians could have a financial incentive to inappropriately reduce the amount or intensity of care received to achieve cost savings.
- ***Cherry picking.*** Physicians could have an incentive to treat only healthier patients.
- ***Steering.*** Physicians could have a financial incentive to avoid sicker patients or steer them to other facilities.
- ***"Quicker and sicker" discharges.*** Physicians could have a financial incentive to discharge beneficiaries too quickly in order to achieve cost savings (Centers for Medicare & Medicaid Services 2008).

In addition to the empirical research that supports the notion that gainsharing can lower costs and increase (or not affect) quality, several relatively recent changes to the manner in which Medicare pays for hospital care could mitigate some of these concerns. For example, the Hospital Readmissions Reduction Program, which began in fiscal year 2013, penalizes hospitals for excess readmissions for certain conditions and procedures, such as heart failure, pneumonia, and elective total hip and/or total knee replacement (Centers for Medicare & Medicaid Services 2017a). The penalties associated with this program could help moderate any incentives to discharge patients inappropriately early because the hospital would be penalized if a high share of beneficiaries were subsequently readmitted. Other programs that could protect quality under gainsharing programs include the hospital value-based purchasing program (which began in fiscal year 2013) and the Hospital-Acquired Condition Reduction Program (which began in fiscal year 2015). Together with the Hospital Readmissions Reduction Program, these initiatives can increase a hospital's inpatient payments by as much as 3.5 percent and lower payments by as much as 6.0 percent (Medicare Payment Advisory Commission 2017).

Gainsharing could also leverage increased price transparency for IMDs to lower device costs. Specifically, implementing a policy allowing all hospitals to share IMD prices with physicians who practice at their hospitals provides for the information necessary to make better judgments about value. Allowing hospitals and physicians to engage in gainsharing provides the impetus to use that data to lower device costs.

Conclusion

This chapter provides an overview of the medical device industry and how Medicare pays for devices. While the medical device industry produces valuable tools that improve the lives of beneficiaries, some challenges remain to ensure that Medicare and beneficiaries receive the best value for the substantial resources spent on devices.

Because Medicare does not pay directly for most medical devices, future changes designed to improve the quality of medical devices received by Medicare beneficiaries and reduce their associated costs could focus on improving the availability of device- and provider-specific information and aligning provider incentives. First, requiring device identifiers on administrative claims for certain devices could improve the information available to conduct postmarket surveillance, which is critical to ensure device quality. Second, information about the prevalence of PODs could be improved by requiring all PODs to report under the Open Payments program. Further, given the

adverse incentives that many believe are inherent in PODs, actions could also be taken to reduce the number of PODs; such actions could entail revisions to physician self-referral regulations. Finally, similar to the Commission's recommendations in 2005 and 2008, hospital–physician gainsharing arrangements could be more broadly allowed in the Medicare program, potentially in combination with bundled payments. As past gainsharing efforts prove, well-structured programs provide an incentive for hospitals and physicians to collaborate to lower costs while maintaining or improving the quality of care. ■

Endnotes

1 This definition of a medical device is in Section 201 of the Federal Food, Drug and Cosmetics Act. The exclusion of items that are absorbed or metabolized by the body distinguishes medical devices from prescription drugs.

2 A start-up company is often acquired when its medical device meets a key developmental milestone such as reaching the conclusion of promising clinical or preclinical tests or securing regulatory approval to market the device in the United States or the European Union.

3 Venture capital firms can also recoup their investments when start-up companies go public and sell stock to raise additional capital.

4 These figures overestimate the share of research and development conducted by large medical device companies to some degree because small device companies that engage in research and development but are not yet profitable cannot claim the credit.

5 The predicate device cannot be a device that requires premarket approval, discussed later in the chapter.

6 The FDA requires manufacturers of brand-name drugs to submit clinical data demonstrating that a drug is both safe and effective. Manufacturers of generic drugs do not have to submit data on safety and effectiveness, but they must demonstrate that the active ingredient in their product is identical to the active ingredient in the brand-name version of the drug. As long as the active ingredients are identical, the data on safety and effectiveness for the brand-name version of the drug are assumed to be equally valid for any generic versions of the drug.

7 The FDA uses distinct terminology to refer to its go-ahead for the marketing of medical devices through the 510(k) process versus the premarket approval process. In FDA parlance, the agency *clears* 510(k) notifications, and these actions are referred to as *clearances*. The terms *approves* and *approval* are reserved for devices that use the premarket approval process (Johnson 2016).

8 Before submitting a PMA application, a medical device manufacturer must first obtain an investigational device exemption (IDE) from the FDA. The IDE allows the manufacturer to use the device in the clinical trials that will support the eventual PMA application (Johnson 2016).

9 Conducting RCTs of medical devices can be difficult, especially for implantable devices. If the only individuals who undergo surgery are those in the treatment group, patients and providers can learn who is in the treatment group and who is in the control group, which can undermine the integrity of the trial. Some trials have addressed this issue by using sham surgeries on individuals in the control group, but this approach is controversial given the inherent risks of undergoing surgery. Participants in medical device trials may also be more likely to insist on being switched from the control group to the treatment group, or vice versa (Robinson 2015). However, the placebo effect may be stronger for implantable medical devices than for drugs, underscoring the potential value of using sham surgeries in RCTs (Redberg 2014).

10 Several exceptions from the UDI requirements exist. For example, Class I devices that bear a Universal Product Code on their labels and device packages are deemed to meet all UDI labeling requirements.

11 The Food and Drug Administration Safety and Innovation Act of 2012 established a deadline for the Secretary to issue UDI regulations (Johnson 2016).

12 For a full UDI implementation time line, see https://www.fda.gov/medicaldevices/deviceregulationandguidance/ uniquedeviceidentification/compliancedatesforudirequirements/default.htm.

13 The three FDA-accredited issuing agencies are GS1, the Health Industry Business Communications Council, and the International Council for Commonality in Blood Banking Automation.

14 The Global Unique Device Identification Database contains the device identifier, not the full UDI, associated with each device.

15 X12 is one of several organizations, referred to as Designated Standard Maintenance Organizations, that have been chosen by the Secretary to aid in updating and maintaining standards for health care transactions.

16 GPO contracts may include "commitment provisions" that provide additional rebates or discounts to customers that purchase a certain volume through the contract. But individual hospitals—especially large hospitals—may still be able to obtain more favorable prices for some products.

17 Many hospitals buy their IMDs directly from manufacturers because they can negotiate more favorable prices than the prices available on GPO contracts.

18 Medical device manufacturers bear most of the financial risk of maintaining inventory for IMDs. Hospitals usually do not stock IMDs and rely instead on the manufacturers' sales

representatives to bring devices with them when they visit hospitals (Robinson 2015).

19 A hospital might be able to negotiate lower prices by purchasing from only one manufacturer, but that strategy has some potential drawbacks. A hospital may have difficulty finding a manufacturer that can supply every kind of device that the hospital uses (even within a specific therapeutic area), and a hospital that uses a single vendor is more likely to have its supply of IMDs disrupted if the manufacturer has problems with production or distribution. A hospital that uses a single vendor may also have more difficulty switching to a new vendor later on because its physicians and staff have become accustomed to using the current vendor's products (Robinson 2015, Robinson 2008).

20 Other actors could be involved in the IMD market, such as physician-owned distributors or GPOs.

21 Patient summaries often include charges, which can vary substantially from costs, and itemized bills often group all devices used during surgery together, limiting patients' ability to identify the cost of any particular device.

22 Cost-to-charge ratios are averages. Therefore, applying these ratios to hospital charges does not provide an exact price. In addition, more than one device is often used in a procedure, so the total device charges reported on a revenue center does not necessarily indicate the specific charge associated with an individual device.

23 Numerous medical device companies have been the subject of lawsuits alleging that they provided illegal inducements or kickbacks to physicians to encourage them to use the company's products. Many of these lawsuits are "whistleblower" suits filed under the False Claims Act, which allows private citizens to file suit on behalf of the government against entities that have committed fraud against government programs and receive a share of any eventual settlement. In these cases, the whistleblower is usually a former employee of the company.

24 In its 2013 Special Fraud Alert, OIG noted that it "did not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent."

25 Of the 596 hospitals surveyed by OIG, 589 hospitals responded.

26 A 2016 report from the Senate Finance Committee majority staff suggested that PODs have become so engrained in some markets that they have distorted competition and pricing for medical devices, forcing doctors and hospitals who refuse to purchase from PODs into an untenable financial position.

27 Operating margins measure profits as a share of total sales revenue and include all costs except taxes, interest, and certain other expenses.

28 J. P. Morgan measured profit margins using a measure known as earnings before interest, taxes, depreciation, and amortization (EBITDA). Many financial analysts prefer to measure profitability using EBITDA because it factors out the effects of a company's financing and accounting decisions (i.e., how much money it has borrowed and how it accounts for its capital investments), which makes it easier to compare the performance of different companies.

29 This discussion does not apply to critical access hospitals and cancer hospitals that are not paid under the IPPS and OPPS. CMS pays those hospitals based on their reasonable costs, which means that each hospital is essentially reimbursed for the full cost of the medical devices that it uses. However, these facilities account for only a small share of Medicare spending for inpatient and outpatient services.

30 The term *medical devices* has the same broad meaning here that is used throughout this chapter and encompasses everything from latex gloves to surgical instruments to imaging equipment. In the context of physician services, CMS classifies medical devices as either medical supplies (items that are used only once) or medical equipment (items that are used more than once).

31 CMS also makes new-technology payments for prescription drugs. Drugs must meet the same eligibility criteria as devices under the IPPS, but are subject to somewhat different criteria under the OPPS.

32 Other programs under which gainsharing has been tested include the Medicare Participating Heart Bypass Center Demonstration, Medicare Hospital Gainsharing Demonstration, Medicare Acute Care Episode Demonstration, and Comprehensive Care for Joint Replacement Model.

33 The authors note that the proportion of episodes with a prolonged length of stay is a validated measure of complications for the studied procedures.

34 Another recent study demonstrates an additional area where gainsharing could improve efficiency. Specifically, the study found approximately $968 of surgical supplies per case was wasted for the 58 neurosurgical cases studied at one academic hospital (Zygourakis et al. 2017).

35 The use of bundled payments for knee and hip replacements has prompted some device manufacturers to look for new ways to lower their costs, such as developing lower cost joint implants and eliminating the use of sales representatives for certain hospitals (Abrams and Phillips 2016).

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CHAPTER 8

Stand-alone emergency departments

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Chapter summary

The number of health care facilities devoted primarily to emergency department (ED) services and located apart from hospitals—referred to as stand-alone EDs—has grown rapidly in recent years. The majority of stand-alone EDs have opened since 2010. This growth has been driven by payment systems that reward treating lower severity cases in the higher paying ED setting, competition for patient market share, and an exemption in law that allows stand-alone EDs to receive higher hospital outpatient payments for non-ED services. Despite being a potentially efficient way to expand access to ED services in underserved areas, very few stand-alone EDs are located in rural areas. In 2016, almost all of the 566 stand-alone EDs were located in metropolitan areas that have existing ED capacity and were often located in more affluent ZIP codes with higher household incomes and higher shares of privately insured patients.

Stand-alone EDs, which provide ED services and basic imaging and laboratory services, come in two forms: off-campus emergency departments (OCEDs), which are affiliated with a hospital and therefore reimbursed by Medicare; and independent freestanding emergency centers (IFECs), which, until recently, typically were not affiliated with a hospital and therefore not eligible for Medicare reimbursement. However, in recent years, many IFECs have chosen to affiliate with hospitals to enable them to bill Medicare.

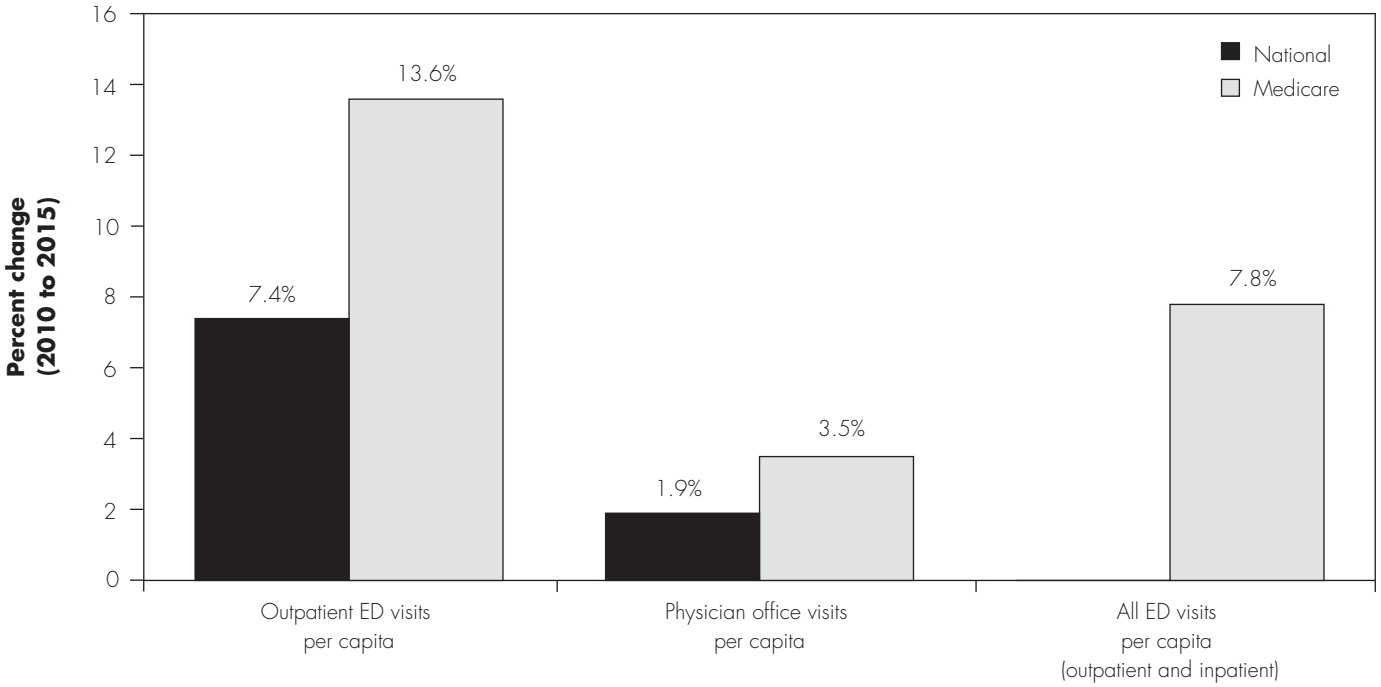
In this chapter

Concern exists about whether Medicare pays OCEDs appropriately because, while they are paid the same rates as on-campus hospital EDs, available data suggest that stand-alone EDs may serve lower acuity (severity of illness) patients, more like the mix of patients treated at urgent care centers than at on-campus hospital EDs.

Policymakers may wish to consider the suggestions, recommendations, and policy options derived from the Commission's discussions about stand-alone EDs. In our June 2016 report to the Congress, the Commission discussed stand-alone EDs in the context of rural areas and suggested that rural stand-alone EDs could have a role in the Medicare program (Medicare Payment Advisory Commission 2016). In our March 2017 report, in response to the concern about a lack of Medicare claims data specific to stand-alone EDs, the Commission recommended that the Secretary of Health and Human Services require hospitals to add a modifier on claims for all services provided at stand-alone EDs (Medicare Payment Advisory Commission 2017). Based on our findings to date, policymakers could consider realigning payment rates for OCEDs to reduce payment disparities between settings where low-acuity patients receive services; encourage the development of stand-alone EDs in areas with inadequate access to ED services; and eliminate policy exceptions to site-neutral payment for ambulatory (i.e., hospital outpatient and physician) services. ■

FIGURE 8–1

Emergency department visits increased at a faster rate than physician office visits, nationally and within Medicare, 2010–2015



Note: ED (emergency department). "Outpatient ED visits" refers to ED visits that do not result in an inpatient hospital admission. The "national" category for all ED visits per capita is not shown because the data across all payers are not currently available.

Source: American Hospital Association, National Center for Health Statistics' National Health Interview Survey, and Medicare claims data.

Background

Emergency departments (EDs) play a growing role in the U.S. health care system, and in recent years the number of facilities providing ED services that are located apart from a hospital campus has also grown. Some researchers believe the volume of ED visits has increased because patients lack access to other providers, providers have changed their practice patterns, or patients desire more immediate access to care (Gindi et al. 2016, Morganti et al. 2013, Pines et al. 2013). Others believe the growth in ED visits is linked to the profitability of ED services (Wilson and Cutler 2014). A contributing factor to the increase in ED visits may include the recent proliferation of facilities providing ED services located apart from the hospital campus, which we refer to as stand-alone EDs.[1]

Emergency department visits have increased

Between 2010 and 2015, the number of hospital outpatient ED visits nationally increased by more than 7 percent per capita compared with an increase of just under 2 percent per capita for physician office visits (Figure 8-1). Among Medicare beneficiaries over the same period, outpatient ED visits increased nearly 14 percent per beneficiary and physician office visits increased approximately 4 percent per beneficiary. In addition, the number of total Medicare ED visits, combining outpatient ED visits that did not result in an inpatient hospital admission and those that did, increased nearly 8 percent per beneficiary. In 2015, Medicare beneficiaries accounted for approximately 28 million total ED visits (data not shown).

Patient wait times in emergency departments have decreased

Between 2013 and 2016, patient wait times in hospital EDs declined, reversing a trend from prior years. CMS's Hospital Compare data for this period show that the median number of minutes patients waited in hospital EDs to be seen by a clinician declined from 28 minutes to 22 minutes. This decline represents a reversal of a trend from

a decade earlier, when several studies established long and increasing ED wait times as a concern (Government Accountability Office 2009, Horwitz and Bradley 2009, Wilper et al. 2008). The most recent of these studies concluded that, between 1997 and 2006, median ED wait times increased from 22 minutes to 33 minutes (Horwitz and Bradley 2009). The authors found that the source of the increase was growth in patient demand stemming from population growth and reduced primary care access as well as a decline in the number of ED facilities. ED wait times remain a focus of the hospital industry, and hospitals commonly advertise their current ED wait times.

Proliferation of facilities providing ED services

A growing number of ED facilities are located apart from a hospital campus. In 2016, no fewer than 566 stand-alone EDs were in operation. There are two types of these facilities: hospital-affiliated off-campus emergency departments (OCEDs) and independent freestanding emergency centers (IFECs). The regulation of EDs largely occurs at the state level. Other providers such as urgent care centers and physicians' offices compete with stand-alone EDs for low-acuity (severity of illness) patients.

Hospital-affiliated off-campus emergency departments

In 2016, 363 OCEDs operated in 35 states and were affiliated with roughly 300 hospitals. These facilities represented 64 percent of all stand-alone EDs. About 6 percent of hospitals had at least one OCED; these hospitals have tended to be urban, relatively large facilities that are affiliated with a health system. Most of these hospitals operate a single OCED, but about 30 hospitals operate multiple OCEDs. Between 2008 and 2016, the number of hospitals with an OCED increased 97 percent.

OCEDs are paid by Medicare if they are deemed off-campus provider–based departments. 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 clinicians can bill under the Medicare fee schedule for physicians and other health professionals just as in an on-campus ED. Most other payers pay OCEDs a facility fee and generally consider OCEDs in-network facilities. To be deemed a Medicare provider–based department, an OCED must be in compliance with the standard Medicare and state hospital ED requirements, be financially and clinically integrated with the hospital, be publicized as an affiliate of the hospital, and be located within 35 miles of the hospital (Centers for Medicare & Medicaid Services 2008).[2]

The majority of OCEDs offer ED services 24 hours per day; basic imaging services such as X-ray, computed tomography (CT) scans, and ultrasound; and on-site lab services for basic diagnostic analysis. They do not typically provide trauma services (e.g., for patients coming from car accidents or having gunshot wounds), and most receive ambulance transports less frequently than do hospital EDs.[3] OCEDs range in size, with larger facilities serving as many as 100 patients per day and the smallest facilities serving 20 or fewer patients per day. Larger OCEDs can also offer MRI and primary care, house physician specialists' offices, and tend to take more ambulance transports than smaller OCEDs. OCEDs have one or more physicians on-site at all times, and physicians are typically contracted. OCEDs are often marketed as open longer (24 hours per day) than urgent care centers and as serving higher acuity medical conditions, such as respiratory distress, head injuries, dehydration, infection, orthopedic injuries and fractures, and abdominal pain.

Where OCEDs choose to locate depends on several factors related to the general characteristics of the immediate health care marketplace. According to industry representatives, the purpose of stand-alone EDs can include expanding access in areas that lack ED services, relieving overcrowding in on-campus hospital EDs, and offering patients greater convenience to ED services. The industry typically uses data-driven market real estate–analysis methods to identify "voids in community healthcare delivery systems" (Adeptus Health Inc. 2016). Developers focus on variables such as the location of other EDs, population growth, household income, and insurance coverage in the target area's population. In the absence of Medicare claims data for these facilities, we cannot identify the socioeconomic characteristics of the Medicare patients served by stand-alone EDs. However, anecdotally, we know that OCEDs are typically located where there has been recent population growth and where developers estimate that patient business will be sufficient to support their enterprise. Representatives of the industry asserted that OCEDs are typically developed within 5 to 10 miles of their affiliated hospital. We also observed that sometimes these facilities are located in urban areas close to other hospital EDs or stand-alone EDs, and sometimes they are located in areas where there are few providers offering ED services. In cases where these facilities are located close to other ED providers, it appears the developers' intention is to capture market share from

competitors. In cases where OCEDs are located in areas lacking ED services, the communities appear relatively new and may not include many other providers, or the community has recently lost a provider of ED services. In many of these cases, the OCEDs are owned by hospitals affiliated with large regional health systems and located in areas where residents tend to have health insurance.

According to industry representatives, stand-alone EDs are a mechanism that hospitals and health systems can use to capture patient market share and control patient service use. Spokespeople assert that stand-alone EDs offer hospitals and health systems a way to extend their service areas into their competitors' service areas. They also assert that as hospitals and health systems consolidate in several markets, and in some cases develop their own insurance plans, providers are transitioning to a population health strategy in which they benefit from controlling a patient's overall service use. Stand-alone EDs also allow these systems to maintain more control of their patients' services use.

Independent freestanding emergency centers

In 2016, 203 IFECs operated in the United States, representing about 36 percent of all stand-alone EDs. The majority of IFECs are in Texas, where the number increased from none in June 2010 (when state licensure of IFECs began) to 191 facilities in 2016. Colorado, Minnesota, and Rhode Island also have IFECs. More than 50 unique entities own IFECs, most of which are for-profit entities. The largest is Adeptus Health Inc., which owns 52 IFECs. The business model of IFECs is similar to OCEDs in terms of the services they offer and where they choose to locate. They offer ED services, imaging services (X-rays and CT scans), and basic laboratory services. Similar to OCEDs, developers of IFECs use data-driven market real estate–analysis methods to identify gaps in community delivery systems. Therefore, developers decide to place IFECs based on the following variables: the location of other EDs, population growth, household income, and insurance coverage of the target areas' population. What we observe is that IFECs are almost always in urban and suburban communities and very often are located close to other ED providers.

Currently, IFECs are not defined in Medicare law or regulation. As a result, IFECs cannot bill Medicare, and they do not have to meet any of Medicare's provider-based requirements or conditions of participation. However, 70 percent of states with stand-alone EDs have state licensure requirements for stand-alone EDs that closely follow the intent of the federal requirements for Medicare and Medicaid providers to screen and stabilize all patients requiring care under the Emergency Medical Treatment and Labor Act of 1986 (Gutierrez et al. 2016).[4]

Representatives of IFECs assert that the patient mix at their facilities consists of higher shares of privately insured patients because IFECs cannot bill for treating Medicare patients. A smaller share of their patient mix consists of Medicare, Medicaid, or uninsured patients. Private insurers do not typically contract with IFECs, instead treating them as out-of-network providers. According to several news reports, private insurers are charged significantly higher rates when IFECs are out-of-network facilities, and patients are often left to pay the balance of these charges when claims are denied in part or in full (Rice 2016).

Regulation of stand-alone EDs

The regulation of stand-alone EDs occurs largely on the state level, but a few provisions of Medicare statute and regulation impact these facilities. A recent study of state-level regulation of stand-alone EDs concluded that states vary widely in their standards and regulation regarding these facilities' location, staffing, and clinical capabilities (Gutierrez et al. 2016). Gutierrez and colleagues found 21 states with policies regulating stand-alone EDs, 29 states without regulations for stand-alone EDs, and 1 state (California) with specific hospital regulations that prohibit these facilities. The net effect of this variation is that most states (e.g., Florida and Ohio) allow OCEDs but not IFECs, and these states view OCEDs as an extension of the hospital. A few states (Colorado, Minnesota, Rhode Island, and Texas) permit both OCEDs and IFECs.

The presence of certificate of need (CON) laws in some states may limit the growth of stand-alone EDs to a degree, but the presence or absence of stand-alone EDs does not vary consistently with state CON laws. A recent study of CON laws concluded that states with CON requirements had fewer stand-alone EDs per capita than states without CONs laws (Gutierrez et al. 2016). However, the presence of CON laws is not a predictor of stand-alone ED growth in some key states. For example, both California and Texas lack CON laws, but only Texas has stand-alone EDs (National Conference of State Legislatures 2016).

Medicare's regulation of stand-alone EDs is defined in statute and regulation related to provider-based facilities and hospital conditions of participation. Two components of the provider-based definition have a significant impact

on stand-alone EDs. First, Medicare's 35-mile limit on provider-based facilities is a significant provision because it prevents hospitals and health systems from developing OCEDs in isolated rural areas or beyond their existing service areas. Second, Section 603 of the Bipartisan Budget Act of 2015 altered the provider-based definition to exempt both emergency and nonemergency services provided in "dedicated EDs" from the law prohibiting certain off-campus provider-based departments from billing Medicare under the OPPS. Section 603 defines dedicated EDs as facilities where at least one-third of a facility's outpatient visits for the treatment of emergency medical conditions are on an urgent basis without requiring a previously scheduled appointment.[5] Under this exemption for EDs, both ED and non-ED services provided in off-campus facilities are paid the higher hospital OPPS rates (as opposed to rates paid in the physician office setting). Therefore, a new provider-based physician office that might otherwise be prohibited from billing at higher hospital OPPS rates as a stand-alone office could instead receive those higher rates by locating inside the OCED and satisfying enrollment and compliance requirements. Moreover, because Medicare claims data cannot currently distinguish OCED claims from on-campus hospital ED claims, CMS cannot automatically verify what services are being delivered in these facilities.

Facilities competing with stand-alone EDs for low-acuity patients

Stand-alone EDs generally have two types of competitors: providers offering ED services and providers serving generally lower acuity patients. More than 4,400 hospital EDs submit claims for ED services annually, by far the most common type of ED facility (American Hospital Association 2015). These facilities are located within a hospital, or on a hospital campus. A relatively new type of hospital ED is the micro-hospital. These facilities are smaller than full-service hospitals and offer a limited range of services but maintain full hospital status. They typically maintain a small number of inpatient beds (e.g., 10 beds) and their focus is primarily on ED services. Some micro-hospitals also offer limited surgical and rehabilitation services, while others house primary care practices, specialty practices, and labor and delivery rooms (Andrews 2016). Most micro-hospitals do not offer higher intensity services such as trauma care in the ED, intensive care units, cancer services, and transplant services. Representatives of micro-hospitals stated that patients requiring prolonged care are regularly transferred to larger facilities (Rudavsky 2016). There are currently very few micro-hospitals, but several are being developed by hospital systems such as SCL Health in Colorado; Dignity Health in Las Vegas; Baylor Scott & White in Texas; and Emerus, a for-profit entity that also owns stand-alone EDs.

Urgent care centers, retail clinics, and primary care physician practices serve lower acuity patients who are similar to the low-acuity patients served by hospital EDs. More than 7,000 urgent care centers, 2,800 retail clinics, and more than 200,000 practicing primary care physicians may compete for lower acuity patients.[6] Urgent care centers come in two forms: those affiliated with a hospital (i.e., "provider based") and those not affiliated with a hospital. These facilities provide a broad range of nonemergency services but generally maintain somewhat less service capacity than on-campus hospital EDs. They are typically open fewer than 24 hours per day; are staffed by physicians, nurses, and physicians' assistants; and offer relatively limited lab and imaging services. Retail clinics consist of pharmacy- or retailer-based health clinics such as CVS Minute Clinic and Target Clinic. These facilities offer brief medical visits with an advanced practice provider such as a physician assistant or nurse practitioner, are open fewer than 24 hours per day, and are designed to provide immunizations and core services for simple illnesses (Thygeson et al. 2008). They do not offer diagnostic services. Primary care physicians who deliver direct patient care generally are in group practices rather than individual physician practices. Physicians' offices are generally open during standard business hours; are staffed with physicians, registered nurses, and physicians' assistants; and may offer lab or imaging services.

Urgent care centers, retail clinics, physician offices, and EDs provide overlapping access to care for patients with lower severity health needs, but research suggests that the cost of providing care is higher when lower acuity patients are treated in emergency departments. A variety of sources confirm this overlap, and a 2010 study estimated that between 13 percent and 27 percent of cases served in hospital EDs could be served similarly at urgent care centers or retail clinics (Ashwood et al. 2016, Weinick et al. 2010). In addition, several studies have documented that the cost of treating lower acuity patients in on-campus hospital EDs exceeds the cost of treating these patients in non-ED settings (Baker and Baker 1994, Mehrotra et al. 2009, Thygeson et al. 2008). To date, cost data are not available to enable a comparison of costs at these settings with stand-alone EDs.

The Commission's recent activity related to stand-alone EDs

In our June 2016 report to the Congress, the Commission discussed stand-alone EDs in the context of rural areas and suggested there may be a role for rural stand-alone EDs in the Medicare program (Medicare Payment Advisory Commission 2016). At our November 2016 public meeting, the Commission revisited stand-alone EDs as a separate topic, discussing these facilities in the context of both rural and urban areas. As a part of this discussion, the Commission voiced concern about (1) the inability to differentiate between Medicare ED claims at on-campus hospital EDs and stand-alone EDs and (2) the inability to determine the appropriateness of payment for ED services in the two different settings. As a result, the Commission recommended in its March 2017 report to the Congress that the Secretary of the Department of Health and Human Services require hospitals to add a modifier on claims for all services provided at off-campus stand-alone ED facilities (Medicare Payment Advisory Commission 2017).

Research methods

A variety of sources were used to obtain information for this analysis. The universe of stand-alone EDs was identified using data from the American Hospital Association, various stand-alone ED companies, and online research. To understand where stand-alone EDs locate, these data were paired with population data from the U.S. Census Bureau to calculate the density of stand-alone EDs in each metropolitan statistical area (MSA). To determine whether stand-alone EDs induce demand for ED services, the Commission analyzed Medicare and private-payer ED claims data in the 7 MSAs with the highest concentration of stand-alone EDs (and at least 1 million residents) and compared this data with the change in ED claim volume in the 11 MSAs with more than 1 million residents and no stand-alone EDs. In the absence of distinguishable Medicare claims data for stand-alone EDs, we used information from Colorado's Center for Improving Value in Health Care (CIVHC) and the Maryland Health Care Commission to assess possible differences in patient mix and payment amounts between stand-alone EDs and competing facilities. The small number of stand-alone EDs in these two states may not be representative of all stand-alone EDs. However, these data are the only available information that shed light on the practices of stand-alone EDs. Our findings were also based on interviews with representatives of stand-alone EDs, hospitals, and the ambulance industry, as well as visits to stand-alone EDs in New York and Virginia.

Medicare payments promote expansion of stand-alone EDs

Medicare pays for ED services using three payment systems—an arrangement largely mirrored by private payers. Medicare beneficiaries who receive ED services generate a physician claim and a hospital outpatient ED claim. Physician claims for ED visits are paid through the Medicare physician fee schedule (PFS). Hospital claims for ED visits that do not result in an admission are paid through the hospital OPPS. ED claims that result in a hospital admission are bundled into a diagnosis related group and paid through the inpatient prospective payment system (IPPS).

The PFS and OPPS both use a five-tiered scale to pay for ED visits. The five levels of PFS and OPPS ED visits are based on the same standard set of Current Procedural Terminology codes and general descriptions of the service. Level 1 visits represent the lowest acuity, and Level 5 visits represent the highest acuity. The two systems maintain separate sets of fixed payment rates for each of the five levels (Table 8-1, p. 252). The OPPS maintains two sets of rates: Type A ED rates for hospital EDs open 24 hours per day and Type B ED rates for EDs open fewer than 24 hours per day. Type B rates are generally lower than Type A rates because Type B facilities do not need to maintain ED staff 24 hours per day. OCEDs receive the higher Type A ED rates, similar to on-campus hospital EDs. The volume of visits paid at Type B ED rates is low, accounting for approximately 1 percent of all Medicare ED claims in 2015.

Providers have the financial incentive to treat patients in the ED because Medicare's total ED payment (facility payment plus physician payment) is higher than its total payment made to other settings for a comparable case. For ED services provided in a hospital ED open 24 hours per day, the facility bills Medicare for the ED visit and other outpatient services (e.g., imaging and lab services) under the OPPS and the physician bills Medicare under the PFS. Under a hypothetical example of a non-life-threatening medical condition—that is, a Level 3 ED visit—Medicare pays the hospital EDs and OCEDs that are open 24 hours per day $196 (not including other outpatient services) and the physician $63, for a total Medicare payment of $259 (Figure 8-2, p. 252). If the same patient were treated at a hospital ED or OCED open fewer than 24 hours per day (that is, the Type B rate), Medicare would pay the facility $115 and the physician $63, for a total payment of $178.[7]

TABLE 8–1

Medicare payment rates for emergency department visits under the Medicare physician fee schedule and hospital outpatient prospective payment system, 2016

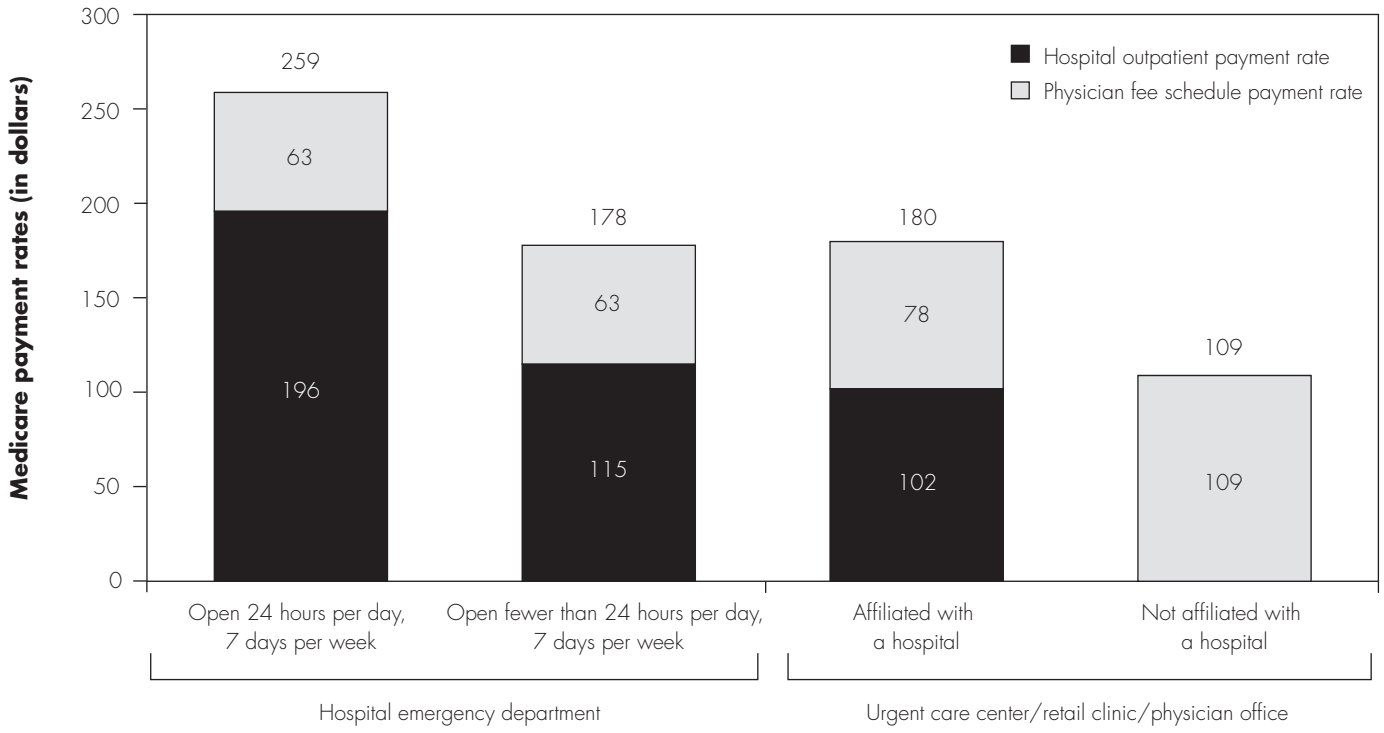
Emergency department payment level	Physician fee schedule payment for emergency department visits	OPPS payment amount: Type A emergency department visit (facility open 24 hours per day)	OPPS payment amount: Type B emergency department visit (facility open fewer than 24 hours per day)
Level 1	$21.48	$59.30	$79.22
Level 2	41.89	109.51	76.17
Level 3	62.66	195.98	115.20
Level 4	118.87	326.99	196.25
Level 5	175.44	486.04	315.88

Note: OPPS (outpatient prospective payment system). The data reflect 2016 Medicare payment rates under the physician fee schedule and OPPS and do not include patient cost sharing or payments for ancillary services that might be incurred at the time of treatment. Level 1 visits represent the lowest acuity, and Level 5 visits represent the highest acuity.

Source: Centers for Medicare & Medicaid Services, calendar year 2016 hospital OPPS final rule.

FIGURE 8–2

Hypothetical example of differences in 2016 Medicare payment rates for similar services delivered at hospital emergency departments and other providers

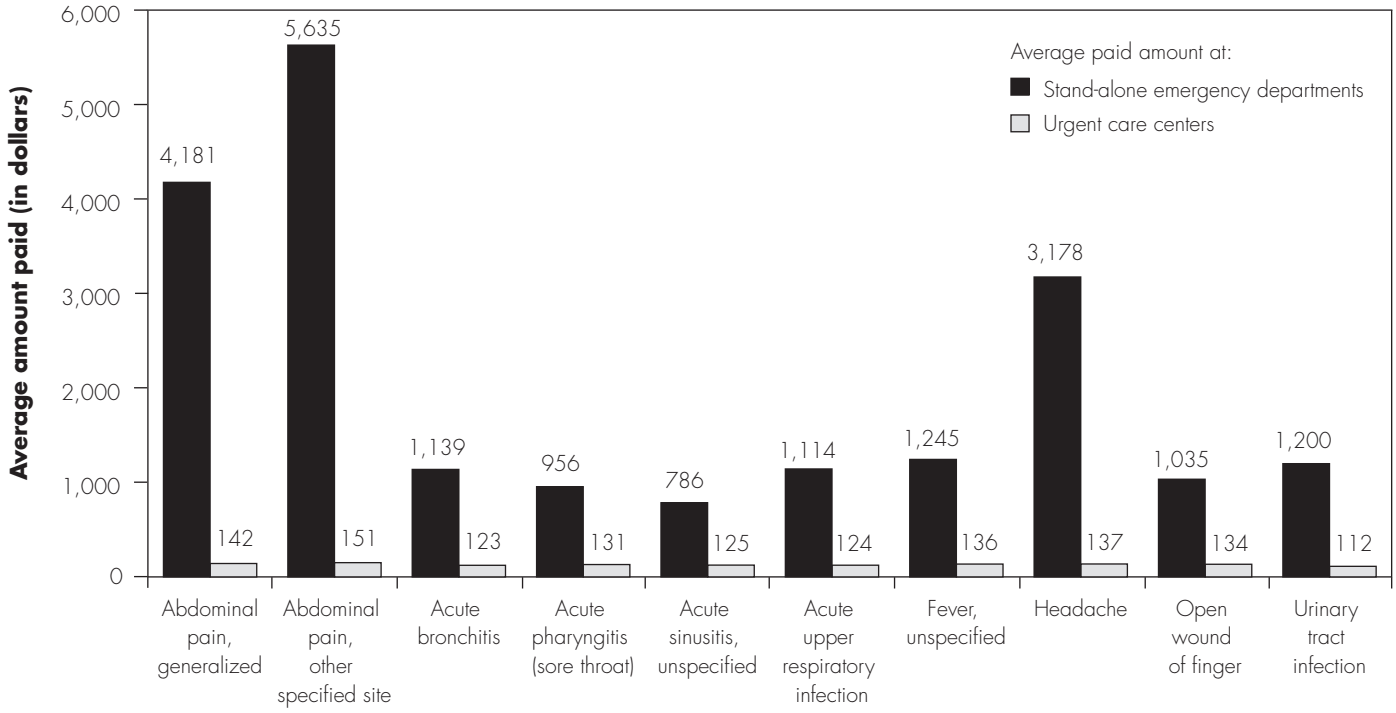


Note: The physician fee schedule payment rates for services delivered in hospital emergency departments (EDs) reflect Level 3 physician ED services; payment rates for services delivered in urgent care centers and physician offices reflect Level 3 evaluation and management codes for new patients. The hospital outpatient payment rates for services delivered in hospital EDs reflect Level 3 ED services; payment rates for services delivered in urgent care centers and physician offices reflect the hospital outpatient clinic visits code.

Source: MedPAC description of Medicare 2016 hospital outpatient prospective payment system payment rates and physician fee schedule payment rates.

FIGURE 8–3

Average amounts paid for commercial insurance claims for various health conditions were higher at stand-alone emergency departments in Colorado than at urgent care centers, 2014



Source: Colorado Center for Improving Value in Health Care 2016.

Total Medicare payments for urgent care centers, retail clinics, and physicians' offices are generally lower than rates paid to hospital EDs and OCEDs for the same types of patients. Urgent care centers, retail clinics, and physicians' offices owned by a hospital and deemed provider based are paid under the OPPS and PFS; they are not permitted to bill for ED services. Using the same hypothetical example, at one of these hospital-affiliated providers, Medicare would pay a total of $180: $102 for a hospital outpatient clinic visit plus $78 for a Level 3 facility-based evaluation and management (non-ED) visit (Figure 8-2).

Non-hospital-affiliated urgent care centers, retail clinics, and physician offices are paid only under the PFS and are not permitted to bill for ED services. Using the same hypothetical example, at one of these non-hospital-affiliated providers, Medicare would pay the physician $109 for a Level 3 nonfacility evaluation and management (non-ED) visit.

Medicare claims data do not allow us to demonstrate actual payment differences for similar patients treated at stand-alone EDs compared with urgent care centers, but we were able to construct an example using data from Colorado's CIVHC. Claims data for privately insured patients in Colorado in 2014 demonstrate that patients with similar conditions incur higher payments when served at stand-alone EDs relative to urgent care centers.[8] In an analysis isolating payments made to a small sample of stand-alone EDs in Colorado only, CIVHC found that, in 2014, privately insured patients paid higher amounts—exceeding 10 times the amount—for treatment at stand-alone EDs compared with treatment at urgent care centers. For example, in 2014, the average payment amount for an acute upper respiratory infection (a non-life-threatening condition) at stand-alone EDs was $1,114, compared with $124 at urgent care centers. Similar differences existed for other conditions (Figure 8-3).[9]

TABLE 8–2

Medicare Type B ED visits consisted of a higher share of low-acuity claims and were less common than Type A ED visits, 2015

Emergency department payment level	Type A ED visits (facility open 24 hours per day)		Type B ED visits (facility open fewer than 24 hours per day)	
	Number of visits	Share of visits	Number of visits	Share of visits
Level 1	644,482	3.6%	33,945	16.6%
Level 2	1,332,648	7.4	57,446	28.1
Level 3	5,211,454	28.9	81,315	39.8
Level 4	6,254,606	34.7	26,625	13.0
Level 5	4,559,691	25.3	4,927	2.4
Total	18,002,881	100.0	204,258	100.0

Note: ED (emergency department). Components may not sum to stated totals due to rounding. Level 1 visits represent the lowest acuity, and Level 5 visits represent the highest acuity.

Source: Centers for Medicare & Medicaid Services, calendar year 2016 hospital outpatient prospective payment system final rule.

Shifting services to higher cost settings increases patients' financial liability. In recent years, articles in the popular press have documented how patients with minor medical conditions chose an OCED instead of an urgent care center and ended up with higher than expected medical bills because the care was billed as an ED visit rather than an urgent care center visit (Schlachter 2014). The same is true under Medicare, for which beneficiaries (without supplemental insurance) must pay a 20 percent coinsurance for services received at either an urgent care center or an OCED. Using the same hypothetical example discussed earlier, this distinction could mean the beneficiary's copayment at an on-campus hospital ED or OCED would be 20 percent of $259 ($52); at an urgent care center affiliated with a hospital, 20 percent of $180 ($36); or at a non-hospital-affiliated physician office, 20 percent of $109 ($22).

Medicare Type B ED claims were lower acuity and less common than Type A ED claims in 2015

Although Medicare claims data do not allow us to demonstrate differences in the severity level of Medicare beneficiaries served at stand-alone EDs relative to on-campus hospital EDs, claims data do display differences between Type B ED visits and Type A ED visits. In 2015, about 85 percent of the Medicare Type B ED visits were for one of the three lowest ED acuity levels (Table 8-2). By contrast, approximately 40 percent of all Type A ED visits were in one of the three lowest ED acuity levels. Overall, Type B visits accounted for approximately 1.1 percent of all Medicare ED claims and 2.4 percent of Medicare ED claims in one of the three lowest ED acuity levels.

Out-of-network payment rates from private insurers are higher

Stand-alone EDs can receive higher payment rates when they bill private insurers as out-of-network providers rather than in-network providers. For example, according to representatives of stand-alone EDs, in-network ED visit rates are about $1,000 per visit compared with out-of-network ED visit rates that are about $1,800. This payment difference may lead stand-alone EDs to operate without directly contracting with private insurers to establish prices. Under a provision in the Public Health Service Act, effective 2015, plans are required to cover ED services and maintain the same cost-sharing requirements whether the services are delivered by in-network or out-of-network providers.[10] However, the patient may be required to pay the amount the out-of-network provider charges over the amount insurers are required to pay. This practice is commonly referred to as balance billing, and patients are shielded from balance billing by law in some states.

The out-of-network payment strategy may be more common at IFECs than OCEDs, but we cannot quantify how often it is used. IFECs may be more likely to use this strategy because they are not affiliated with a hospital or

system that is likely to have a contract in place with private insurers. Anecdotally, we have heard that some insurers have contracted with IFECs for lower than standard ED payment rates. OCEDs are more likely to bill in-network payment rates because they are affiliated with hospitals. However, it is also conceivable that OCEDs bill out-of-network payment rates for patients without insurance or patients with insurance through private insurers that the OCEDs choose not to contract with.

Concerns about patients being billed by providers for services they receive out of network (i.e., balance billing) apply to patients with commercial insurance but not to Medicare fee-for-service or Medicare Advantage beneficiaries. Medicare beneficiaries are protected from balance billing, and several states have acted to prohibit providers from balance billing commercially insured patients (Hoadley and Lucia 2009, Pollitz 2016).

Stand-alone EDs are concentrated in certain markets and positioned to grow rapidly

Further analysis of stand-alone EDs suggests that the payment policies of Medicare and private payers promote expansion of stand-alone EDs in a manner that does not represent good value. Stand-alone EDs are concentrated in certain markets, notably in Texas and Colorado, and they tend to locate in areas where patients have above-average incomes. At the same time, ED service use has increased in some markets where stand-alone EDs are more common. In addition, IFECs appear to be taking steps to affiliate with hospitals, which would give them provider-based status and the opportunity to bill Medicare. Our analysis of detailed data from two states shows that patients served by stand-alone EDs tend to be lower acuity compared with patients served by on-campus EDs, making the stand-alone facilities similar to urgent care centers. However, for treating similar patients—as our previous hypothetical example shows—these facilities receive higher payment rates relative to urgent care centers.

Stand-alone EDs are concentrated in certain markets

Stand-alone EDs operate in many MSAs and the majority of states, but are concentrated in a few dozen MSAs. In 2016, the 566 stand-alone EDs were located in 39 percent of MSAs.[11] About 64 percent of stand-alone EDs were OCEDs (363 facilities), and about 36 percent were IFECs (203 facilities). In 2016, the number of stand-alone EDs per resident ranged from zero facilities per million residents to more than 20 facilities per million residents. Across all markets, 37 MSAs had more than 5 stand-alone EDs per million residents. This group of MSAs included relatively small MSAs with only a couple of stand-alone EDs as well as large MSAs with numerous stand-alone EDs.[12]

In 2016, 20 large MSAs (500,000 or more residents) accounted for over 60 percent of all stand-alone EDs. Five of these MSAs (Austin, Dallas, El Paso, Houston, and San Antonio) had more than 10 stand-alone EDs per million residents, including both OCEDs and IFECs (Table 8-3, p. 256).[13] Two MSAs in Colorado were also in the top 20, Denver and Colorado Springs. These MSAs had 8.5 and 7.2 stand-alone EDs per million residents, respectively, and both contained OCEDs and IFECs. Several MSAs in Ohio were in the top 20, but these MSAs included only OCEDs. By contrast, many large MSAs did not have stand-alone EDs, including Atlanta, Las Vegas, Los Angeles, Pittsburgh, and San Francisco.

Stand-alone EDs were concentrated in several smaller MSAs (fewer than 500,000 residents) in Colorado, Connecticut, and Texas. Smaller MSAs in Texas include Tyler (22.4 stand-alone EDs per million residents), Corpus Christi (19.9), Midland (18.0), and Beaumont (14.7). Smaller MSAs in Colorado and Connecticut include Greeley, CO (14.0); Pueblo, CO (12.2); and Norwich, CT (11.0).

Nineteen stand-alone EDs were located in rural areas, defined as being outside the boundary of an MSA. Most of these facilities were OCEDs, and most were located in Colorado, Michigan, Minnesota, and Ohio. The only three rural IFECs were located in Texas.

The distribution of OCEDs and IFECs varies by MSA, and markets with more OCEDs per million residents are more likely to impact the Medicare program. MSAs with the highest overall levels of stand-alone EDs per capita had both OCEDs and IFECs. For example, Houston had about 16 stand-alone EDs per million residents, of which approximately half were OCEDs (Table 8-3, p. 256). By contrast, all of the stand-alone EDs in Cleveland were OCEDs. This distinction is relevant to our analysis of ED utilization within MSAs because Medicare beneficiaries are treated only at OCEDs. Therefore, to measure the growth of Medicare ED utilization, we focused on MSAs with high rates of OCEDs; to measure the growth of private-payer ED utilization, we focused on MSAs with high rates of both OCEDs and IFECs.

TABLE 8–3

Stand-alone emergency departments were concentrated in 20 large MSAs, and the type of facility varies by market, 2016

		Number of:				Number per million residents		
Rank	MSA Name	All stand-alone EDs	OCEDs	IFECs	2015 population	Stand-alone EDs	OCEDs	IFECs
1	Houston, TX	104	44	60	6,656,947	15.6	6.6	9.8
2	El Paso, TX	10	4	6	838,972	11.9	4.8	7.2
3	Dallas-Fort Worth, TX	79	31	48	7,102,796	11.1	4.4	6.5
4	Austin, TX	22	9	13	2,000,860	11.0	4.5	6.5
5	San Antonio, TX	26	6	20	2,384,075	10.9	2.5	8.0
6	Denver, CO	24	19	5	2,814,330	8.5	6.8	1.8
7	Akron, OH	6	6	0	704,243	8.5	8.5	0.0
8	Colorado Springs, CO	5	4	1	697,856	7.2	5.7	1.4
9	Dayton, OH	5	5	0	800,909	6.2	6.2	0.0
10	Cleveland, OH	12	12	0	2,060,810	5.8	5.8	0.0
11	Portland, ME	3	3	0	526,295	5.7	5.7	0.0
12	Youngstown, OH	3	3	0	549,885	5.5	5.5	0.0
13	Wichita, KS	3	3	0	644,610	4.7	4.7	0.0
14	Jacksonville, FL	6	6	0	1,449,481	4.1	4.1	0.0
15	Richmond, VA	5	5	0	1,271,334	3.9	3.9	0.0
16	Oklahoma City, OK	5	5	0	1,358,452	3.7	3.7	0.0
17	Charlotte, NC	8	8	0	2,426,363	3.3	3.3	0.0
18	Cincinnati, OH	7	7	0	2,157,719	3.2	3.2	0.0
19	Raleigh, NC	4	4	0	1,273,568	3.1	3.1	0.0
20	Toledo, OH	2	2	0	646,833	3.1	3.1	0.0
	Rural non-MSAs	19	16	3	46,064,445	0.4	0.4	0.1
	All MSAs	547	347	200	275,354,375	2.0	1.3	0.7
	United States	566	363	203	321,418,820	1.8	1.1	0.6

Note: MSA (metropolitan statistical area), ED (emergency department), OCED (off-campus emergency department), IFEC (independent freestanding emergency center). The Census Bureau's most recent MSA-level data are for 2015.

Source: MedPAC count of stand-alone emergency department facilities from various sources and population data from the Census Bureau.

Stand-alone EDs locate in areas where patients have higher incomes and are better insured

Recent data suggest stand-alone EDs tend to locate in ZIP codes with higher than average incomes and higher shares of patients with private insurance coverage. In a 2016 study, Schuur and colleagues concluded that, in the three states where stand-alone EDs were most common (Colorado, Ohio, and Texas), stand-alone EDs tended to locate in ZIP codes where the median household income was higher than in ZIP codes without stand-alone EDs (Schuur et al. 2016). For example, in Texas, ZIP codes with stand-alone EDs had a median household income of $73,003, compared with a median household income of $49,267 in ZIP codes without stand-alone EDs (Table 8-4). The same trend was identified in Colorado and Ohio.

This study also found that ZIP codes with stand-alone EDs tended to have patients who were better insured. In Ohio, ZIP codes with stand-alone EDs had higher shares of patients with private insurance (77 percent) than ZIP codes without stand-alone EDs (71 percent), lower shares of patients with Medicaid (12 percent) than ZIP codes without stand-alone EDs (16 percent), and lower shares of patients without any insurance (9 percent) than ZIP codes without stand-alone EDs (11 percent). Similar trends existed in Texas and, to a lesser extent, Colorado.

TABLE 8–4 **Median household incomes and patient payer mix for ZIP codes in Texas, Ohio, and Colorado with and without stand-alone emergency departments, 2015**

Characteristic	Texas ZIP codes		Ohio ZIP codes		Colorado ZIP codes	
	With stand-alone EDs	Without stand-alone EDs	With stand-alone EDs	Without stand-alone EDs	With stand-alone EDs	Without stand-alone EDs
Median household income	$73,003	$49,267	$58,482	$49,646	$70,604	$59,831
Share of patients:						
With private insurance	72%	54%	77%	71%	76%	71%
With Medicaid insurance	10	19	12	16	9	13
Without insurance	16	25	9	11	14	14

Note: ED (emergency department). The authors' list of stand-alone EDs in Texas, Ohio, and Colorado was compiled as of March 31, 2015; median income data were drawn from the Environmental Systems Research Institute Demographics files at the Center for Geographic Analysis at Harvard University; and patient payer-mix data were drawn from the 2013 American Community Survey.

Source: Schuur et al. 2016.

In addition, the authors of the study found that Ohio's stand-alone EDs located in ZIP codes where hospital EDs were absent, while Texas's stand-alone EDs located in ZIP codes where hospital EDs were present (data not shown).

Similarly, our own analysis of stand-alone-ED location in 2016 found that within MSAs, stand-alone EDs disproportionately located in ZIP codes with higher incomes. Including both types of stand-alone EDs, 64 percent in the Houston MSA were located in ZIP codes with an average household income above $90,000, but these ZIP codes made up only 31 percent of the total in the Houston MSA (Table 8-5, p. 258).[14] In the Denver MSA, 65 percent of stand-alone EDs were located in ZIP codes with an average household income above $90,000, which made up 39 percent of ZIP codes in the Denver MSA. (See online Appendix 8-A, available at http://www.medpac.gov, for further detail.)

ED services use grew faster in some MSAs where stand-alone EDs were more common

The use of ED services within Medicare and private-payer populations grew somewhat more rapidly in recent years in a few large MSAs with higher rates of stand-alone EDs per capita. However, the growth in ED service use was not consistent across all MSAs with higher rates of stand-alone EDs, suggesting that stand-alone EDs may not maintain significant enough market share to drive MSA-wide service use and that other factors contribute to service use trends.

Medicare ED service use grew faster in some MSAs where OCEDs are more common

Among the seven MSAs with the highest shares of OCEDs, Denver and Oklahoma City saw particularly high growth in ED service use. Between 2010 and 2014, the number of ED visits per 1,000 Medicare beneficiaries in Denver and Oklahoma City grew 17.7 percent and 14.4 percent, respectively (see online Appendix 8-A, available at http://www.medpac.gov). By contrast, growth in ED visits in the five other MSAs ranged from –2.8 percent to 8.2 percent. Collectively, during this period, ED service use in all 7 of the MSAs with highest rates of OCEDs increased 5.5 percent, compared with 0.4 percent among 11 comparably sized MSAs without any OCEDs.

Privately insured patients' ED service use grew faster in some MSAs where stand-alone EDs are more common

Among the seven MSAs with the highest shares of all stand-alone EDs, Denver and San Antonio saw particularly high growth in ED service use by privately insured patients. Between 2012 and 2014, the growth in the number of ED visits per 1,000 privately insured patients was 7.0 in Denver and 17.2 in San Antonio (see online Appendix 8-A, available at http://www.medpac.gov). By contrast, growth in ED visits in the other five MSAs

TABLE 8–5

Larger share of stand-alone EDs in Denver and Houston were located in ZIP codes with higher average household incomes, 2016

	Denver MSA		Houston MSA	
Average household income, by quintile	Share of ZIP codes	Share of stand-alone EDs	Share of ZIP codes	Share of stand-alone EDs
$120,000 to $285,000	12%	26%	12%	29%
$90,000 to $119,999	27	39	19	35
$65,000 to $89,999	35	22	27	24
$40,000 to $64,999	25	13	37	12
$0 to $39,999	2	0	6	0
Total	100	100	100	100

Note: ED (emergency department). One stand-alone emergency department in Denver and one in Houston were excluded from this analysis because they were located in ZIP codes without income data. ZIP codes devoted to schools, corporations, or other large entities often do not possess residents from whom to collect income data. Column totals may not sum to 100 percent due to rounding.

Source: MedPAC analysis of stand-alone ED industry and population data from the Census Bureau.

ranged from –6.1 percent to 1.8 percent. Collectively, during this period, the 7 MSAs with the highest rates of stand-alone EDs increased 1.0 percent, compared with a 1.3 percent decline across 11 comparably sized MSAs without any stand-alone EDs.

More stand-alone EDs may begin billing Medicare soon

In 2016, 363 stand-alone EDs were OCEDs and permitted to bill Medicare, but we estimate another 203 stand-alone EDs were IFECs that may become OCEDs and begin billing Medicare in the near future. The 363 OCEDs billing Medicare were defined as provider-based facilities and submitted claims to Medicare through their affiliated hospital's provider ID number. However, because CMS does not separately track claims from these off-campus facilities, we do not know exactly which ones are billing Medicare or for what services they are billing.

Many of the 203 IFECs appear to be taking steps to affiliate with hospitals to gain Medicare provider–based status and begin billing Medicare, effectively converting to new OCEDs. For example, in recent years, the largest owner of IFECs, Adeptus, modified its business model to partner with hospitals to enable its IFECs to bill Medicare and Medicaid. In Arizona and Ohio, Adeptus partnered with large health systems to build new stand-alone EDs. In Colorado, Adeptus partnered with the University of Colorado Health (UCHealth) to build new hospitals with which its existing IFECs could then affiliate. In Texas, Adeptus built its own new hospitals (without partnering with a hospital system) and partnered with the hospital system Texas Health Resources to enable 31 of their IFECs in Dallas to begin billing Medicare.

In two states, patients served at stand-alone EDs were lower acuity

Colorado

Claims data for privately insured patients in Colorado in 2014 suggest that most patients served by stand-alone EDs were treated for non-life-threatening conditions, similar to conditions treated at urgent care centers. These data also suggest that the patients served by stand-alone EDs are somewhat different from those served at hospital EDs. In July 2016, Colorado's CIVHC used claims data from nine stand-alone EDs to compare with claims from urgent care centers and hospital EDs. CIVHC concluded that among the top 10 conditions for which privately insured patients sought care at stand-alone EDs, 7 were for non-life-threatening conditions (Table 8-6). At urgent care centers, all 10 of the top 10 conditions were non–life threatening, whereas at on-campus hospital EDs, 3 of the top 10 were for non-life-threatening conditions. Between

TABLE 8–6

Ten most common conditions treated at stand-alone emergency departments, urgent care centers, and hospital emergency departments in Colorado, by facility type and condition type, 2014

Conditions	Stand-alone emergency departments	Urgent care centers	Hospital emergency departments
Number of non-life-threatening conditions	7	10	3
Number of life-threatening conditions	3	0	7
Non–life threatening			
Common cold	✓	✓	✓
Urinary tract infection	✓	✓	✓
Open wound (finger)	✓	✓	✓
Sore throat	✓	✓	
Bronchitis	✓	✓	
Ear infection	✓	✓	
Ankle sprain	✓		
Cough		✓	
Strep throat		✓	
Sinus infection		✓	
Pain in limb		✓	
Life threatening			
Fever	✓		
Viral infection	✓		
Abdominal pain	✓		✓
Loss of consciousness			✓
Head injury			✓
Headache			✓
Chest pain			✓
Chest pain, other			✓
Abdominal pain, other			✓

Note: The definitions of non-life-threatening and life-threatening conditions were determined using the National Institutes of Health's guidelines for emergency care. Data for stand-alone emergency departments (EDs) are from eight facilities in Colorado for which the Colorado Center for Improving Value in Health Care could specifically identify claims. Data for urgent care centers and hospital EDs are for all facilities in Colorado.

Source: Colorado Center for Improving Value in Health Care.

stand-alone EDs and urgent care centers, six of the most common conditions overlapped, and none of them were life threatening. Between stand-alone EDs and hospital EDs, four of the most common conditions overlapped, and three were non–life threatening.

Maryland

A 2015 report from the Maryland Health Care Commission (MHCC) about the three stand-alone EDs in the state concluded that the patients they serve were generally of lower acuity (Maryland Health Care Commission 2015). MHCC reported that between 68 percent and 80 percent of patients served by the three stand-alone EDs in 2014 were in one of the three lowest ED payment levels (out of five levels) compared with between 46 percent and 64 percent of patients served at the nearest competing hospital-based ED. Between 3 percent and 6 percent of patients served by the three stand-alone EDs in 2014 were later admitted as inpatients to a hospital compared with between 15 percent and 19 percent of patients served at the nearest competing hospital EDs. In addition, at the Maryland stand-alone EDs in Bowie and Germantown, 97 percent and 95 percent of patients, respectively, arrived as walk-ins rather than by ambulance. By contrast, the Emergency Department Benchmarking Alliance and the American College of Emergency

Physicians reported that, in 2013, 17 percent of all ED patients nationally arrived at the ED by ambulance (Augustine 2014).

MHCC also concluded that patients served by the three Maryland stand-alone EDs in 2014 were younger, more likely to have private insurance coverage, and had treatment options other than the ED available to them. Compared with all EDs in Maryland, the stand-alone EDs tended to treat a larger share of children and a smaller share of patients older than age 41, tended to serve a slightly larger share of privately insured patients, and tended to serve a lower share of Medicare and Medicaid patients. In addition, the vast majority of patient visits at the three stand-alone EDs occurred during hours when a viable alternative for treating lower acuity conditions was likely available.

Policy options for aligning payments to stand-alone EDs with the acuity of their patients

The growth in stand-alone EDs in recent years appears to signal that existing Medicare and private-insurer payment policies encourage providers to shift services from lower paying settings such as urgent care centers and physicians' office to higher paying settings such as EDs. The Commission's position on aligning payment rates across settings is that Medicare should ensure that patients have access to settings that provide the appropriate levels of care and that Medicare should strive to base payment rates on the resources needed to treat patients in the most efficient setting. For example, under Medicare payment policy, payments are higher for services delivered in the hospital outpatient department compared with payments for the same service delivered in the physician office setting. To capitalize on this contrast, some hospitals are acquiring physician practices and can bill higher hospital OPPS rates for those physician-provided services. The concern in the case of stand-alone EDs is that providers seek to gain market share for low-severity conditions that could be treated more efficiently in other settings. For example, some hospitals are building ED facilities or partnering with IFECs to enable them to bill for services for low-acuity conditions at higher ED rates.

Several policy options could be considered to ensure that payments to stand-alone EDs are aligned with the acuity of their patients and designed to address access concerns. Policymakers could consider paying OCEDs the lower Type B ED payment rates. Paying OCEDs Type B ED rates would reduce providers' incentive to serve lower acuity cases in the higher paying ED setting by more closely aligning payment rates for stand-alone EDs with both urgent care centers and physicians' offices. Moreover, Type B ED rates appear to be a good match for OCEDs because lower acuity cases account for the majority of Medicare claims receiving Type B ED rates and lower acuity cases account for the majority of cases served by the stand-alone EDs for which claims data exist. Policymakers could also consider allowing OCEDs in isolated rural areas to receive the higher Type A ED payment rates. Paying higher ED rates may enable stand-alone EDs to open in isolated areas that lack access to ED services, or it may enable an isolated rural community with a full-service hospital on the verge of closing to maintain ED services. Finally, policymakers could consider amending Section 603 of the Bipartisan Budget Act of 2015 so that services provided at physician offices connected to stand-alone EDs do not receive higher hospital outpatient department payment rates. The exemption given to "dedicated EDs" under Section 603 encourages the development of stand-alone EDs and encourages hospitals and health systems to expand medical office space inside stand-alone EDs.

Conclusion

The stand-alone ED industry has grown significantly over a short period of time, and the role these facilities play in the Medicare program is growing. Today, there are 363 OCEDs billing Medicare and potentially another 203 facilities that may begin billing Medicare in the near future. In March 2017, the Commission recommended the Secretary of Health and Human Services begin collecting claims data for these facilities because it is unclear what types of Medicare beneficiaries are served at stand-alone EDs versus on-campus hospital EDs. Using information gathered from alternative sources, we found that many more stand-alone EDs could begin billing Medicare in the near future, stand-alone EDs tend to locate in ZIP codes with higher incomes and better insurance coverage, and stand-alone EDs serve lower acuity patients. Policymakers could consider amending the existing Medicare payment rates for stand-alone EDs by aligning payments more closely with patient severity and accounting for the costs of stand-by capacity. ■

Endnotes

1 Stand-alone EDs are also commonly referred to—in the media or in research literature—as freestanding EDs. We purposely chose not to use the term *freestanding EDs* because it may cause confusion for readers when we begin to draw the important distinctions between the two different types of stand-alone EDs, those affiliated with a hospital and those not affiliated with a hospital.

2 Under the Medicare program, provider-based ED facilities are eligible for payment if they are in compliance with Medicare's provider-based department regulations, Medicare's conditions of participation, and the requirements of the Emergency Medical Treatment and Active Labor Act of 1986.

3 Representatives of ambulance suppliers in markets with OCEDs stated in interviews that they are aware of the limited set of medical services offered by OCEDs, and they exercise their own judgment in determining where to direct their transports. These suppliers stated that they generally do not transport patients to OCEDs. They specified that they typically transport patients to an OCED only when (1) the patient is not a candidate for inpatient care, (2) the OCED is the nearest provider, and (3) the patient requests the OCED for his or her own convenience.

4 The American College of Emergency Physicians summarizes the basic regulatory requirements of IFECs relative to OCEDs in a brief on their website (https://www.acep.org/Clinical---Practice-Management/Freestanding-Emergency-Departments/).

5 Section 603 of the Bipartisan Budget Act of 2015 defines dedicated EDs as any department or facility of a hospital that meets at least one of the following criteria: (1) it is licensed by the state in which it is located under applicable state law as an emergency room or emergency department; (2) it is held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

6 The number of urgent care centers was obtained from the Urgent Care Association of America's website on September 22, 2016, at http://www.ucaoa.org/?page=IndustryFAQs#Size%20of%20Industry. The number of retail clinics was obtained from a study by Accenture, as commissioned by America's Health Insurance Plans (AHIP), and downloaded from the AHIP website on September 22, 2016, at https://www.ahip.org/wp-content/uploads/2016/06/accenture-retail-health-clinics-pov.pdf. The number of primary care physicians in patient care in 2010 was obtained from the Agency for Healthcare Research and Quality website at http://www.ahrq.gov/sites/default/files/publications/files/pcwork1.pdf on September 22, 2016.

7 The OPPS is more likely than the PFS to combine the costs of primary services with ancillary services and supplies into a single payment, a concept referred to as packaging. Under the PFS, services are largely paid for separately. By contrast, the Commission has estimated in previous years that packaged items account for a small share of the total payment of evaluation and management services under the OPPS. The degree to which items and services are packaged into OPPS payments for ED services is likely to be higher than for evaluation and management services in either the OPPS or PFS setting.

8 In September 2016, CIVHC provided the Commission with an analysis it conducted in 2015 of the average paid amounts for similar cases at eight stand-alone EDs in Colorado compared with urgent care centers. In 2015, CIVHC published these data on its website under the title "Average Paid Amount for Common Health Conditions, Freestanding Emergency Rooms Versus Urgent Care Facilities" (Colorado All-Payer Claims Database, 2014 Commercial Claims, www.comedprice.org). In 2017, these data are not available on the CIVHC website. CIVHC used commercial claims data from 2014 for this analysis, and at that time, these eight stand-alone EDs were IFECs. In 2017, these eight stand-alone EDs are OCEDs because they are now affiliated with a hospital.

9 Private insurers in Colorado pay stand-alone EDs more for other services associated with non-life-threatening conditions compared with the same services at urgent care centers, including abdominal pain–other specified site ($5,635 vs. $151), acute bronchitis ($1,139 vs. $123), acute sinusitis–unspecified ($786 vs. $125), and open finger wounds ($1,035 vs. $134) (see Figure 8-3, p. 253).

10 Section 2719a of the Public Health Service Act was amended by the Patient Protection and Affordable Care Act of 2010 to require group health plans to cover emergency services without requiring any prior authorizations, regardless of whether the health care provider is a participating network provider (if the service is provided out of network); without imposing any administrative requirements or limitations on coverage that is more restrictive than the requirements that apply to in-network services (if the service is provided out of network); and without imposing any cost-sharing or coinsurance requirements that exceed the member's in-network requirements. However, the plan member may be required to pay the amount the out-of-network provider charges over the amount the plan requires them to pay. These requirements were effective for plan year 2015.

11 Stand-alone EDs are present in 35 states.

12 We defined large MSAs as those with 500,000 or more residents in 2015.

13 The two types of stand-alone EDs—OCEDs and IFECs—tend to locate in certain markets and not others. The 363 OCEDs (stand-alone EDs affiliated with hospitals) were located in 96 MSAs and 34 states. The 203 IFECs (stand-alone EDs independent of a hospital) were located in 26 markets in 4 states (Colorado, Minnesota, Rhode Island, and Texas).

14 The median household income for Houston in 2014 was $57,000. The median household income for Denver in 2015 was $58,000. Household income data are from the U.S. Census Bureau's Fact Finder tool (https://factfinder.census.gov).

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CHAPTER 9

Hospital and SNF use by Medicare beneficiaries who reside in nursing facilities

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Chapter summary

Transferring Medicare beneficiaries who are long-stay nursing facility (NF) residents to a hospital for conditions that could have been prevented or treated by the NF exposes beneficiaries to several health risks (such as falls, delirium, infections, and medication interactions) and unnecessarily raises Medicare program spending. Although Medicare does not pay for the long-term portion of care, it does pay for hospital use by long-stay NF residents. High rates of hospital use may indicate poor care coordination between the NF staff and physicians or poor quality of care provided within the NF for long-stay NF residents. In addition, transferring long-stay residents to the hospital may result in a higher paid Medicare skilled nursing facility (SNF) stay following hospital discharge. In response to Medicare's Hospital Readmission Reduction Program, some hospitals have begun to pressure NFs to adopt strategies to reduce hospital use. Through interviews with NF staff, the Commission found that these strategies include increased staff communication, staff training, medication review, and advance care planning.

As a gauge of the quality of care furnished by NFs, the Commission developed facility-level measures to track use of hospitals by long-stay NF residents, including all-cause hospital admissions, potentially avoidable hospital admissions, and a combined measure of emergency department visits and observation stays. To capture the extent to which NF residents become requalified for higher paying Medicare SNF stays, we also developed

In this chapter

a measure of long-stay beneficiaries' use of Medicare-paid SNF care following discharge from the hospital. The Commission's analyses were performed at the facility level and the measures were risk adjusted to make findings comparable across facilities.

Consistent with other studies, our analysis found that, on a risk-adjusted basis, the rates of all-cause hospital admissions were slightly less than 2 all-cause hospital admissions per 1,000 days. We also found wide variation in rates of hospital use across facilities. Differences in state Medicaid policies may explain some of the variation observed across states, but we also observed high within-state variation. Several facility-level characteristics helped to explain the variation in the measures of hospital use, including the frequency of physician visits and access to on-site X-ray capabilities. This variation indicates potential disparities in quality across facilities and suggests opportunities for reductions in hospital use, which would reduce potential harm to beneficiaries and unnecessary Medicare spending. We found more pronounced variation in the use of SNF care after a long-stay resident was discharged from the hospital.

CMS and the Congress could evaluate policies regarding hospital and SNF use by long-stay NF beneficiaries. CMS could consider developing measures of hospital and SNF use to incorporate into the NFs' public reporting requirements; if successful, the Congress could consider expanding the SNF value-based purchasing program to include additional measures such as a long-stay NF resident–hospital admission measure. CMS could also consider focusing on aberrant patterns of hospital and SNF use as part of the agency's program integrity efforts. ■

Introduction

Much of the Commission's work focuses on Medicare policies that promote care coordination and increase quality as a way to enhance the program's value to beneficiaries and taxpayers. Although beneficiaries residing in nursing facilities (NFs) are frail and at high risk for hospitalization, frequent hospital use by this population may indicate poor care coordination between the NF staff and physicians or poor quality of care in the NF. Transferring these residents to a hospital for conditions that may have been prevented or managed by the NF unnecessarily exposes beneficiaries to several health risks (including falls, delirium, nosocomial infections, pressure ulcer development, and medication interactions) and raises program spending since Medicare pays for most long-stay NF residents' hospital use (Cassel 2004, Gillick et al. 1982). Researchers contend that a lack of on-site primary care clinicians, the inability to obtain timely laboratory test results and intravenous fluids, and the inability to assess acute changes in patients' conditions have contributed to high rates of hospital admissions among NF residents (Ouslander et al. 2014). Much of the hospital use among these residents could be prevented if the NF provided high-quality care with adequate physician and ancillary resources.

NFs have a financial incentive to transfer a beneficiary to a hospital for treatment because doing so shifts the costs of more intensive nursing care and ancillary services from the NF to the hospital. In addition, some state-level policies provide incentives for NFs to hospitalize dually eligible beneficiaries (beneficiaries who are eligible for both Medicare and Medicaid). Thirty-four states require the Medicaid program to reserve a bed for the resident of the NF during an intervening hospital stay, a policy known as a "bed-hold" (Medicaid and CHIP Payment and Access Commission 2014). Further, since most facilities with long-stay NF residents also admit post-acute care patients under Medicare's skilled nursing facility (SNF) benefit, transferring residents to a hospital may requalify these residents for the higher paying Medicare SNF stay following hospital discharge.

The implementation of Medicare's Hospital Readmissions Reduction Program (HRRP) has led acute care hospitals to develop partnerships with select NFs for strategic referral purposes. Facilities with low readmission rates are able to market themselves to referring hospitals as a high-quality facility, thereby ensuring a steady referral source. The same practices that lower readmissions of post-acute care beneficiaries could also reduce hospital admissions of long-stay NF residents. Recent evaluations of an initiative funded through the Center for Medicare & Medicaid Innovation (CMMI) and administered through the Medicare–Medicaid Coordination Office found that hospital admissions of long-stay NF residents were generally declining across facilities (Ingber et al. 2016). However, the large degree of variation in the rates of hospital admissions of long-stay NF residents suggests that facilities could further reduce unnecessary hospital use.

Initiatives and strategies to reduce hospital use by long-stay NF residents

NFs may have an opportunity to participate in initiatives currently being implemented to reduce hospital use by long-stay NF residents enrolled in either fee-for-service (FFS) Medicare or certain Medicare Advantage (MA) plans. In addition, some NFs have attempted to reduce hospital use by long-stay residents without any financial arrangements with MA plans or participation in a formal initiative. In many cases, NFs report that they engage in medication review and advance care planning, expand or introduce palliative care programs, implement communication tools, work with nurse practitioners (NPs) to provide direct patient care, and increase skill training for staff both with and without additional financial or staff resources.

Reducing admissions for beneficiaries enrolled in Medicare FFS

CMMI and the CMS Medicare–Medicaid Coordination Office launched the Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents (RAH–NFR) for FFS beneficiaries. CMS's RAH–NFR initiative contracts with coordinating organizations that partner with between 15 and 30 NFs (about 140 in total) to implement evidence-based clinical and educational strategies to reduce avoidable hospitalizations.[1] These strategies can include on-site training for staff, data support, and direct patient care. Five of the seven coordinating organizations use funding from the initiative to provide advanced practice nurses, NPs, or registered nurses (RNs) to augment existing nursing staff in direct patient care. The remaining two coordinating organizations use the additional nurses to provide education and advise facilities on best practices, data trends, and staff training, but not

to engage in direct patient care (Ingber et al. 2017a). The second phase of the RAH–NFR initiative, which began in the fall of 2016, includes a three-part payment model for facilities and practitioners to assess and treat long-stay residents within the NF (see text box on Phase II of the RAH–NFR initiative) (Center for Medicare & Medicaid Innovation 2015).

Reducing admissions for beneficiaries enrolled in Medicare Advantage

Certain MA plans also attempt to avoid unnecessary hospitalizations of NF beneficiaries. MA plans have the flexibility to contract with a NF to provide payments for services beyond the traditional FFS benefits and to make payments based on the level of clinical services provided. For example, Optum's CarePlus model, formerly known as Evercare, provides care coordination to beneficiaries enrolled in the UnitedHealthcare Nursing Home Plan.[2] The CarePlus model uses "intensive service days," paying NFs to provide treatment for acute illness in the NF. In addition, Optum provides on-site nurse practitioners to participating NFs to manage the beneficiary's care and provide services including physical examinations, assessments for acute conditions, lab tests, and prescriptions. Enrollment in MA plans focused on the institutionalized population (special needs plans for the institutionalized, or I–SNPs) has been limited, however, with less than 60,000 individuals enrolled as of 2016 (representing less than 1 percent of MA enrollees) (Medicare Payment Advisory Commission 2016a). In 2015, the UnitedHealthcare Nursing Home Plan accounts for about three-quarters of this enrollment (Kaiser Family Foundation 2015, Medicare Payment Advisory Commission 2015b). One issue for insurers providing services within an institution has been enrolling a critical volume of long-stay NF residents within a given facility in the same MA plan. Without a critical volume of beneficiaries, it is financially difficult for a plan to provide on-site services and implement protocols that could reduce hospital admissions.

Strategies to reduce hospital use

To better understand the interventions and initiatives NFs use to reduce hospitalizations of long-stay residents, the Commission conducted 10 interviews with a geographically diverse set of individuals who participated in the RAH–NFR initiative; had experience with the Optum CarePlus model; or adopted tools to reduce the transfer of beneficiaries to the hospital, independent of any outside funding source for beneficiaries enrolled in FFS.[3] Interviewees cited use of additional nursing staff including NPs, increased staff communication, staff training, medication review, and advance care planning as strategies to increase the quality of care in NFs and thus reduce the likelihood of a potentially avoidable hospital admission. One interviewee also cited using telemedicine technology to extend the hours of NP availability.

Use of additional nursing staff

Additional nursing staff is a foundation of both the RAH–NFR initiative and Optum's CarePlus model, so it is not surprising that the interviewees frequently cited the value of the additional nursing staff (including RNs, advanced practice registered nurses (APRNs), and NPs). For example, interviewees reported that additional nursing staff resulted in consistent implementation of the initiative and higher quality of care provided to beneficiaries. An interviewee from a NF with the Optum CarePlus model noted the high level of expertise exhibited by the on-site NPs. It was further noted that having NPs on-site supported facility staff managing some of the residents but also assisted with education and coaching. Interviewees cited nursing staff contributions to improving staff communication, staff training, medication review, palliative care and advance care planning, and telehealth as critical to the implementation of the initiative at their facility.

Increased staff communication

Strategies to reduce hospital use by beneficiaries often include new processes designed to improve the skills of staff providing direct care to residents and to facilitate better communication between facility staff and managing clinicians.[4] Many of those interviewed used the suite of INTERACT tools to monitor changes in condition, facilitate staff communication, promote advance care planning, and support quality improvement (Ouslander et al. 2014).[5] Certain communication tools are intended to encourage providing the on-call clinician(s) with the information necessary to make informed decisions and better manage the care of NF residents with complex medical needs. A majority of interviewees cited using standardized forms to communicate with clinicians and other caregivers. One form serves as a checklist to uniformly collect information regarding the health issues, medical history, and treatment recommendations from the primary clinician. These documents are intended to better inform physicians and other health professionals before they make decisions regarding treatment and to document the decision to be carried out by NF staff.

Phase II of the Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents

The second phase of the Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents (RAH–NFR) began in the fall of 2016 and includes six of the seven coordinating organizations involved in the first phase of the initiative. Phase II provides payments directly to participating facilities and practitioners. To allow for evaluation and comparison, the payment model is being tested across two groups of nursing facilities (NFs)—facilities that participated in Phase I of the RAH–NFR initiative and facilities that did not (currently about 260 facilities in total). The payment model includes three types of payments, as described below.

One aspect of the payment model includes a new Part B code to allow NFs to bill CMS for the treatment of a qualifying condition. The qualifying conditions include pneumonia, dehydration, congestive heart failure, urinary tract infection, skin ulcers, cellulitis, chronic obstructive pulmonary disease, and asthma. The NF receives $218 per day to treat beneficiaries for a qualifying condition within the facility, which includes long-stay NF residents who are not currently receiving Medicare post-acute care skilled nursing facility (SNF) services (Center for Medicare & Medicaid Innovation 2015).

The next aspect of the payment model increases payments to physicians, nurse practitioners, and physician assistants under Medicare Part B for the treatment of a qualifying condition at the NF. This increase in payment from $137.81 to $205.64 (for physicians) for an initial visit to treat a qualifying condition equalizes the Medicare payment between services provided to a beneficiary in a hospital and services provided in a nursing facility.[6] This payment could be provided for all long-stay NF residents regardless of whether they are currently receiving Medicare post-acute care SNF services with a qualifying condition mentioned above.

The third aspect of the payment model provides a payment to physicians, nurse practitioners, and physician assistants under Medicare Part B for care coordination and caregiver engagement. Physicians receive $79.67 per visit (geographically adjusted) that involves at least 25 minutes of face-to-face time with the beneficiary or caregiver.[7] Physicians, NPs, or physician assistants can bill this code only once per year per beneficiary without a significant change in condition or once within 14 days for a significant change in condition. This payment could be provided for all long-stay NF residents regardless of whether they are currently receiving Medicare post-acute care SNF services (Center for Medicare & Medicaid Innovation 2015).

The second phase of the RAH–NFR initiative is expected to continue through 2020. The first evaluation of the second phase of this initiative is not expected for several years. ■

Staff training

Many interviewees reported that facility staff are trained to recognize changes in a patient's condition and report the changes to nursing staff or on-call clinicians in a more complete, concise, and consistent manner. For example, some facilities train nonlicensed staff to use forms to recognize and report the signs and symptoms of deteriorating health status to licensed nursing staff before a larger problem develops that could result in transfer to a hospital. Other staff training efforts include educating staff about fall prevention; improving a specific clinical skill, such as IV insertion; and teaching nurses, nurse leaders, and social workers how to effectively conduct advance care planning discussions with residents and their families.

Medication review

Medication therapy review and medication therapy management (MTM) are services pharmacists provide that focus on the patient's complete medication therapy regimen, rather than considering each medication in isolation (American Pharmacists Association and the National Association of Chain Drug Stores Foundation 2008). The goal of these pharmacy services is to ensure that the patient receives appropriate medications.

Conducting medication review is one strategy NFs reported using to reduce avoidable hospitalizations due to dosing errors, underprescribing, overprescribing, and medication interactions. In some facilities, the advanced practice nurse works with the beneficiary's clinician, pharmacist, and nursing staff to review and, as necessary, adjust each resident's drug regimen, in addition to reviews conducted independently by long-term care pharmacists and the beneficiary's drug plan.[8]

Palliative care and advance care planning

Ongoing conversations with residents about their end-of-life preferences regarding treatments, interventions, and hospital use may prevent unwanted medical care, including hospitalizations. The plan may include palliative care efforts that focus on quality of life, symptom management, and the tailoring of a patient's treatment to his or her goals and preferences. Several interviewees discussed the importance of including the resident's family in conversations about patient's preferences for care through advance care planning as well as the need for updates to advance directives following a hospital admission or change in health status.[9] State-level departments of public health maintain a variety of tools for providers to document beneficiary care goals and treatment preferences.[10] These tools include forms that capture patients' treatment preferences and are transferable across care settings (Physician Orders for Life-Sustaining Treatment Paradigm 2016).

Interviewees noted that families were generally more satisfied with the patient care provided when they were involved with medical decision making from the beginning of the resident's stay. Most of the facilities that participate in the CMS RAH–NFR initiative and the nurse practitioners in the Optum CarePlus model engage in palliative care and advance care planning with long-stay NF residents.

Telehealth

Employing telehealth is another, albeit less frequently implemented, strategy for reducing readmissions by extending the availability of health professionals and allowing examination of a resident remotely. One recent study concluded that after-hours physician-based telehealth can reduce hospitalizations by almost 10 percent; however, this particular study reflects only one NF chain's results and acknowledges that implementing this technology in NFs is complex and potentially costly (Grabowski and O'Malley 2014).

In addition to the financial barrier, workflow issues were commonly cited as reasons NFs have either not adopted a telehealth model or have had difficulty implementing telehealth broadly. For example, some facilities reported that using telehealth to care for patients requires additional in-facility staff time. Others reported that potential efficiencies gained through the use of telehealth technology are not achieved because of the low volume of beneficiaries eligible for using telehealth in a given facility. This low volume could also be attributed to a NF's inability to integrate telehealth into its regular workflow. NF staff members may need to receive approval to initiate a telehealth protocol, retrieve the telehealth cart, and complete the applicable assessments before the physician or other health professional determines the best course of action for the beneficiary. Instead, some staff prefer requesting physician orders to transfer residents to a hospital for assessment and treatment.

NFs may also be reluctant to adopt telehealth because the availability of a separate payment that covers telehealth services varies. Medicare permits rural NFs as an originating site for telehealth services, allowing physicians and other health professionals at the facility to bill for Part B payments.

One CMS RAH–NFR initiative includes a telehealth component that begins with a telephone call to an advanced practice nurse. If indicated, the NF staff then accesses the telehealth technology and the advanced practice nurse conducts the exam remotely. Based on the findings from the consultation session, the clinical staff determines whether to further assess, treat, or transfer the beneficiary to a hospital.

Evaluations of programs to reduce hospital admissions from NFs

Researchers from RTI International (RTI) released an interim evaluation of the results of the CMS RAH–NFR initiative in February 2017. Researchers found statistically significant reductions in all-cause and potentially avoidable hospital admissions across about half (three out of seven and four out of seven, respectively) of the coordinating organizations implementing evidence-based clinical and educational strategies to reduce avoidable hospitalizations. RTI found statistically significant reductions in all-cause and potentially avoidable emergency department (ED) visits between 2012 and 2015 across two coordinating organizations. RTI also found statistically significant reductions in total Medicare expenditures for all-cause hospital admissions; however, the reduction in total Medicare spending for participants

in the initiative on net was not statistically significant. Researchers found that the effects from the intervention were larger in 2015 compared with earlier years, and they concluded that models that provide direct patient care have resulted in stronger positive outcomes to date (Ingber et al. 2017a, Ingber et al. 2017b, Ingber et al. 2016).

A 2002 evaluation of the Evercare demonstration program (now known as the Optum CarePlus model) found that hospitalizations occurred less frequently for the population enrolled in the CarePlus model compared with study controls. In addition, patients enrolled in the CarePlus model used the ED approximately half as often as their peers. The CarePlus population was also seen more frequently by physicians or other health professionals (Kane et al. 2002). While the evaluation found promising reductions in hospital use across participating beneficiaries, it did not reduce spending for the Medicare program because Medicare pays for services provided to beneficiaries under the Optum CarePlus model on a capitated basis. Therefore, any savings attributed to reductions in hospital use would be retained by the health plan. (Likewise, the health plan would be at risk for any spending beyond the capitated payment.) Under current payment policy, there may be areas where plan payments are below 100 percent of what Medicare's program costs in FFS would otherwise be.

Developing measures of hospital and SNF use for beneficiaries residing in NFs

Concerns about unnecessarily exposing Medicare beneficiaries to the health risks in a hospital setting and unnecessarily raising Medicare program spending necessitate a measure of hospital use for long-stay NF residents. A 2013 Office of Inspector General (OIG) report recommended that CMS develop a quality measure of nursing home resident hospitalization rates (Office of Inspector General 2013). To address this shortcoming, the Commission contracted with Providigm to develop three hospital-use measures specific to Medicare beneficiaries who reside in NFs, including an all-cause hospital admission measure, a potentially avoidable hospital admission measure, and a combined ED use and observation visit measure. The Commission also developed a measure of SNF use by long-stay NF residents. These measures align with the Commission's long-held interests in moving to population-based outcomes measures, care coordination, and decreases in unnecessary Medicare expenditures.[11]

Defining rates of hospital use

Across the measures of all-cause hospital admission, potentially avoidable hospital admission, and combined ED visits and observation stays, we developed a rate of hospital use by calculating the applicable hospital events per 1,000 long-stay resident days for Medicare beneficiaries. We defined long-stay resident days as the total days Medicare beneficiaries resided in the NF beyond the first 100 days (see text box describing our approach to developing measures, pp. 274–275). The risk-adjusted rate of hospital admissions is calculated by dividing the number of hospital admissions by the total facility days across Medicare beneficiaries who are long-stay residents. Because these rates are calculated on a facility-level basis, using these rates for purposes of public reporting or within pay-for-performance programs should encourage quality improvement across facilities.

All-cause and potentially avoidable hospital admissions

Working with Providigm, the Commission developed definitions of all-cause and potentially avoidable hospital use by long-stay NF residents. The all-cause measure includes all hospital admissions regardless of primary diagnosis or unplanned/preplanned status (e.g., an admission for a planned surgical procedure). Researchers generally agree that certain clinical conditions in NFs can be managed in a long-term care NF and be prevented from occurring if the NF provides a sufficient level of care quality. In constructing the definition of potentially avoidable hospital admission of long-stay NF residents, we reviewed existing literature, evaluated the relevance of potentially avoidable readmissions from post-acute care providers, and relied on Providigm's clinical judgment to determine the conditions appropriate to include in our definition of potentially avoidable hospital use. We included in the definition conditions that the NF could reasonably be expected to manage or for which the NF could be held accountable for poor care management (for instance, admissions for a disease management error such as anticoagulation or diabetic complications) (Kramer et al. 2017). Unlike the all-cause measure, our potentially avoidable hospital use measure excludes admissions that are likely to be planned or not potentially avoidable (e.g., palliative surgery). In developing the measure of potentially avoidable hospital admission, we recognize that conditions considered "potentially avoidable" are not necessarily always avoidable. Thus, we do not expect the rate of potentially avoidable hospital admissions to equal zero, even at NFs that provide the highest quality of care.

Developing measures of hospital and skilled nursing facility use for NF residents

We estimated hospital use by Medicare beneficiaries residing in nursing facilities (NFs) with all-cause and potentially avoidable hospital use measures. The all-cause hospital admission measure includes all long-stay NF residents who were admitted to a hospital regardless of diagnosis. The potentially avoidable hospital admission measure counts hospitalized long-stay NF residents whose primary diagnosis for hospital admission is considered potentially avoidable—that is, the condition should have been managed or prevented in the NF setting. Because high rates of emergency department (ED) visits and observation stays may unnecessarily expose beneficiaries to health risks, we calculated a combined all-cause ED visit and observation stay rate. We also developed a rate for days the long-stay beneficiaries used the skilled nursing facility (SNF) benefit.

Measure population

To identify long-stay residents, we considered only Medicare beneficiaries who had a minimum of 100 consecutive days in the facility without a discharge to the community between June 2012 and October 2014.[12] Focusing on the population with more than 100 days of NF care excludes beneficiaries who had only a Medicare-paid post-acute SNF stay before returning to a community setting.

For the long-stay residents identified, our measures accounted for hospital and SNF use that occurred after the first 100 days of the stay. Our analysis began with about 16,000 nursing facilities; about 400 of these facilities were excluded because of missing provider data. We excluded another 435 low-volume facilities (defined as facilities with fewer than 500 days for

(continued next page)

TABLE 9–1

Variables in the risk adjustment model

Age categories
Age less than 65
Age 65 to less than 75
Age 75 to less than 85
Age 85 to less than 95
Age 95 and above
Function categories
Barthel Index, low, 0–30 (lowest function)
Barthel Index, medium, 35–55
Barthel Index, high, 60–90 (highest function)
Comorbidities
HIV/AIDS
Diabetes with chronic complications
Diabetes without complications
Protein-calorie malnutrition
Morbid obesity
End-stage liver disease
Bone, joint, muscle infections/necrosis
Rheumatoid arthritis/inflamed connective tissue
Disorders of immunity
Drug or alcohol dependence
Coma or brain compression/anoxic damage
Acute myocardial infarction
Unstable angina and other acute heart disease
Angina pectoris
Specified heart arrhythmias
Vascular disease with complications
Chronic obstructive pulmonary disease
Dialysis status
Artificial feeding/elimination openings
Amputation status, lower limb/complications
Arthritis condition
Urinary tract infection

Source: Providigm analysis of 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

The conditions included in our potentially avoidable hospital admission measure are similar to others developed for the dual-eligible populations, with some exceptions (Spector et al. 2013, Walsh et al. 2010). Our potentially avoidable hospital admission measure includes two conditions related to proper medication management—anticoagulant complications and adverse drug reactions—that can often be avoided in frail elders with careful review for drug interactions and past medication history.

Developing measures of hospital and skilled nursing facility use for NF residents (cont.)

long-stay beneficiaries or fewer than 10 qualifying beneficiaries). Excluded facilities tended to be smaller and were more likely to be hospital based than the facilities included in the analysis.

Risk adjustment

We risk adjusted each facility's rate based on its mix of resident characteristics, including demographics, function, and comorbid diseases (Table 9-1). A consistent set of variables for each of the four measures was tested, and the final risk adjustment models included only the factors that were significant (Kramer et al. 2017). We evaluated the robustness of the risk adjustment model for each measure by its ability to explain variation across facilities (using an R^2 test). The risk adjustment model helped explain about 50 percent of the variation in the all-cause hospital admission rate and about 30 percent of the variation in the potentially avoidable hospital admission rate. We were able to explain some variation across the combined measure of ED visits and observation use and the measure of SNF days, albeit at lower rates (16 percent and 10 percent, respectively). We did not include socioeconomic status in risk adjusting the rates of hospital or SNF use for the long-stay NF population. ■

We calculated risk-adjusted rates at a facility level. Risk-adjusted rates compare a facility's observed rates with its expected rates based on the mix of patients across functional outcome groups, age category, and comorbidity. The measures are intended to identify NFs with generally good or poor performance, not to identify how an individual case was handled or to determine whether hospital use by a particular beneficiary was potentially avoidable. Instead, the methodology combines two years of facility-level data and provides a single facility-level risk-adjusted rate.

ED visits and observation stays by long-stay NF residents

Another dimension of hospital use is the frequency of ED visits and observation stays. We include this outpatient visit measure because of concerns about the exposure to unnecessary health risks and the stress beneficiaries face while in an ED or observation setting.

Defining potentially avoidable ED visits is problematic for several reasons. A recent study of Medicare beneficiaries residing in NFs found substantial differences in the characteristics and health status of residents who use the ED but are not subsequently admitted to a hospital and those who use the ED and are admitted to a hospital for inpatient care. For example, a larger portion of beneficiaries not admitted to the hospital had normal vital signs and no diagnostic testing compared with the beneficiaries ultimately admitted to the hospital following ED use (Burke et al. 2015, Caffrey 2010). Further, the diagnosis assigned to an ED visit is based on more limited information than a hospital discharge diagnosis assigned at the end of a hospital stay, so it can be more difficult to identify a potentially avoidable event in an ED. Given these ambiguities, our measure of ED visits and observation stays includes all ED visits and observation stays not resulting in a hospital admission.

SNF use by long-stay NF residents

To capture the extent to which NF residents become requalified for Medicare SNF stays, we developed a measure of long-stay beneficiaries' use of Medicare-paid SNF care following discharge from the hospital. Transferring NF residents to a hospital may qualify that beneficiary for a Medicare-paid SNF stay following the hospital discharge. Since Medicare's payments for SNF care are generally higher than payment for NF care, the rate differential provides an incentive for NFs to maximize residents' time in a Medicare stay.[13] Since most facilities with long-stay NF residents also admit post-acute patients under Medicare's SNF benefit, facilities can experience increased revenues when residents are transferred back to the NF following a hospital stay. NFs can increase revenues for long-stay residents in two ways: by increasing the number of SNF days per stay (since Medicare pays on a per diem basis) and by increasing the frequency of SNF admissions. Facilities with high rates of SNF days per 1,000 long-stay resident days may be using SNF services

Illustrative rates by an average facility

Throughout this chapter, we present findings on a "per 1,000 long-stay resident day" basis. Because the average length of stay for long-stay residents varies and mortality rates are relatively high for this population, we chose to combine data across beneficiaries within a facility using the per 1,000 long-stay resident days as a denominator. To illustrate how this translates to the magnitude of hospital and SNF use, consider two 110-bed facilities with an average occupancy rate (85 percent) for which roughly half (52 percent) of days qualify as long-stay days based on the requirement that beneficiaries reside in the facility for longer than 100 days. Using these assumptions, each facility would have about 17,750 long-stay resident days per year.[14] Facility A has average hospital admission and skilled nursing facility (SNF) use rates, while Facility B has rates that place it at the 90th percentile for each rate.

Based on our analysis, Facility A would have about 29 all-cause hospital admissions per year, would have fewer than 14 potentially avoidable hospital admissions per year, and would use about 1,350 SNF days annually (Table 9-2). By comparison, Facility B would have 41 all-cause hospital admissions per year and just over 21 potentially avoidable hospital admissions per year. Long-stay residents in Facility B would use almost 3,000 SNF days annually, more than twice as many as long-stay residents in Facility A. ■

TABLE 9–2 **Illustrative annual hospitalizations and SNF use by similar facilities**

Measure	Facility A (average hospital admission and SNF use rates)	Facility B (90th percentile of hospital admission and SNF use rates)
All-cause hospital admissions	29.1	41.0
Potentially avoidable hospital admissions	13.5	21.1
All-cause ED visits and observation stays	33.0	54.8
Long-stay resident SNF days	1,353	2,998

Note: SNF (skilled nursing facility), ED (emergency department). We assumed that both Facility A and Facility B have 110 beds, an 85 percent occupancy rate, and 52 percent of days qualifying as long-stay resident days. We assumed Facility A had average rates of each measure while Facility B had rates at the 90th percentile for each measure.

Source: MedPAC analysis of facility-level rates calculated by Providigm across 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

to maximize Medicare payments rather than meet the care needs of beneficiaries.

Results

We found relatively low rates of both all-cause and potentially avoidable hospitalizations; however, we found wide variation in these rates across facilities. We noted a high degree of correlation between the two hospital admission measures (all cause and potentially avoidable). In our analysis of SNF days, we found that facilities with the highest rates of SNF use for their long-stay Medicare beneficiaries had rates 10 times higher than those with the lowest rates of SNF use. While some of this variation results from state-level policies and regional differences in medical culture, our analysis also found wide variation in rates within each state, indicating that, regardless of state-level policies, some facilities could better avoid unnecessary hospital admissions and SNF use.

Hospital admission rates

Our analysis found that, while the rate of hospital use by the long-stay population was relatively low, on average, the risk-adjusted rates of all-cause hospital admissions and potentially avoidable hospital admissions of long-stay NF

TABLE 9–3

Risk-adjusted rates of hospital use per 1,000 long-stay nursing facility resident days varied between two- and almost fourfold across facilities

Measure	Mean	Percentile					Ratio of 90th percentile to 10th percentile
		10th	25th	50th	75th	90th	
All-cause hospital admissions	1.6	1.0	1.3	1.6	1.9	2.3	2.3
Potentially avoidable hospital admissions	0.8	0.4	0.5	0.7	0.9	1.2	3.1
All-cause ED visits and observation stays	1.9	0.8	1.2	1.7	2.3	3.1	3.7

Note: ED (emergency department). The ratio of 90th percentile to 10th percentile in the last column may not necessarily equal the sixth column divided by the second column due to rounding.

Source: Providigm analysis of 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

residents equaled 1.6 and 0.8 per 1,000 long-stay resident days, respectively. However, there was wide variation in the rates across NFs (see text box on calculating illustrative rates for an average facility). For example, facilities with the highest rates of all-cause hospital admissions (those at or above the 90th percentile) had rates over two times higher than facilities with the lowest rates (those at or below the 10th percentile) (Table 9-3). This variation was greater for the potentially avoidable hospital admission measures. Facilities with the highest rates (those at or above the 90th percentile) had rates over three times higher than facilities with the lowest rates (those at or below the 10th percentile).[15]

Facilities with rates at or above the 90th percentile Given the high degree of variation across the measures, we more closely analyzed the facilities with rates at or above the 90th percentile. We found that NFs with the highest hospital admission rates (both all cause and potentially avoidable) for long-stay NF residents were more likely to be for-profit facilities (Table 9-4, p. 278). We also found a disproportionate share of rural facilities among those with the highest rates of hospital admissions. Although rural facilities made up 31 percent of facilities, they made up 37 percent of facilities with the highest rates of all-cause hospital admissions and 49 percent of facilities with the highest rates of potentially avoidable hospital admissions. Small facilities (those with 100 or fewer beds) also were more likely to have the highest rates of all-cause and potentially avoidable hospital admissions.

Facility-level characteristics Using a regression model, we found that several other facility-level characteristics aligned with the all-cause and potentially avoidable hospital admission rates.[16] For both rates, facilities with the lowest frequency of visits from physicians or other health professionals (facilities at or below the 10th percentile of provider visits) were associated with higher rates of hospital admissions. Facilities with access to on-site X-ray services had lower rates of potentially avoidable hospital admissions compared with facilities without access to these services; however, we did not find a similar association with the rate of all-cause hospital admissions (Kramer et al. 2017). We also stratified the data based on facility location (urban or rural) and found that a higher portion of urban facilities reported access to on-site X-ray services and more frequent visits from physicians and other health professionals compared with rural facilities, consistent with our regression model results.[17]

Correlation between all-cause and potentially avoidable hospital admission rates We found a positive, statistically significant correlation between the all-cause hospital admission rates and potentially avoidable hospital admission rates ($R^2 = 0.81$). However, fundamental differences between the two measures exist. A potentially avoidable measure does not hold providers or facilities accountable for every admission, so it is sometimes viewed as more fair. But it does require determinations about what types of admissions are avoidable, which can be controversial. In contrast, an all-cause measure does not attempt to litigate what providers should or should not be expected to manage. It does, however, hold them accountable for many hospitalizations that may not be avoidable.

Over the past decade, the Commission has developed potentially avoidable readmission measures for acute care hospitals, SNFs, and inpatient rehabilitation facilities.

TABLE 9–4

A disproportionate share of for-profit and rural facilities had the highest rates of hospital admissions

		Facilities at or above the 90th percentile in:	
	All facilities	All-cause hospital admissions	Potentially avoidable hospital admissions
Number of facilities	15,140	1,514	1,514
Ownership			
For profit	71%	77%	73%
Nonprofit	23	18	19
Government or other	6	5	8
Hospital based	4%	4%	5%
Freestanding	96	96	95
Urban	69%	63%	51%
Rural	31	37	49
Number of certified beds	109	102	96
50 or fewer	12%	15%	16%
51 to 100	39	43	45
101 to 200	43	38	36
201 or more	6	5	3

Note: Facilities with the highest hospital admission rates were those at or above the 90th percentile. Totals may not sum to 100 percent due to rounding.

Source: Providigm analysis of 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

The Congress enacted a readmission penalty as part of the Patient Protection and Affordable Care Act of 2010, which CMS implemented through the Hospital Readmissions Reduction Program in October 2012. In its research from 2009 through 2011, the Commission found decreases in both all-cause and potentially preventable hospital readmissions. The all-cause rate decreased by 0.3 percentage point while the potentially preventable rate decreased by 0.7 percentage point, suggesting that most of the decline in readmissions came from a reduction in potentially preventable readmissions (Medicare Payment Advisory Commission 2013).

All-cause ED and observation visit rates

On average, the risk-adjusted rate of all-cause ED visits and observation stay use was almost 2 visits per 1,000 long-stay resident days (Table 9-3, p. 277) (see text box on calculating illustrative rates by an average facility, p. 276). Analyzing facility-level characteristics using the regression models, we found that facilities with the highest level of visits from physicians or other health professionals were associated with lower rates of ED visits and observation stays. Similarly, the availability of on-site X-ray services was associated with lower rates of ED visits or observation stays for this population.

Rates of SNF days

We found that the mean risk-adjusted rate of long-stay NF residents' SNF days equaled 76 per 1,000 long-stay resident days, with a large degree of variation across facilities (see text box on calculating illustrative rates by an average facility, p. 276). Facilities at or above the 90th percentile had rates of SNF use over 10 times higher than facilities at or below the 10th percentile (Table 9-5). Two factors could contribute to the frequency and length of SNF use, including the amount of time a beneficiary spent

TABLE 9–5

Risk-adjusted rates of SNF use per 1,000 long-stay NF resident days vary more than tenfold across facilities

Measure	Mean	Percentile					Ratio of 90th percentile to 10th percentile
		10th	25th	50th	75th	90th	
Long-stay resident SNF days	76	16	32	53	95	169	10.6

Note: SNF (skilled nursing facility), NF (nursing facility).

Source: Providigm analysis of 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

in the hospital and whether the beneficiary initiated a new benefit period, enabling Medicare to cover the post-acute SNF stay with the hospitalization.

Considering facility-level characteristics, we found that long-stay NF resident in for-profit facilities used more SNF days than did their counterparts in nonprofit facilities. We also found that the residents in freestanding facilities used more days than those in hospital-based facilities. Consistent with other work showing that for-profit and freestanding facilities have longer SNF stays, our regression models confirmed that for-profit facilities are associated with a statistically significant higher rate of SNF days relative to nonprofit facilities.

State-level policy differences

Geographic variation was pronounced across the measures we explored. When we stratified our data by state, we found that the variation across states in average rates of hospital use for the all-cause hospital admission measure and the potentially avoidable hospital admission measure was almost twofold (Table 9-6). The average all-cause hospital admission rate for the 5 states with the lowest rates was 1.2 admissions per 1,000 NF resident days, while the average rate for the 5 states with the highest rates was 2.0 admissions per 1,000 NF resident days (Kramer et al. 2017). We found similar variation by state when we analyzed the measure of SNF days per 1,000 NF resident days. For this measure, states with the highest average rates of SNF days had rates that were more than twice those of states with the lowest average rates of SNF days (about 105 days per 1,000 NF resident days compared with about 47 days per 1,000 NF resident days, respectively). This degree of variation suggests that, in addition to facility characteristics, state-level policies and geographically specific practice patterns may help explain variation in hospital use rates. For example, state-level bed-hold policies and Medicaid policies could contribute

TABLE 9–6

State-level comparison of hospital and SNF use rates per 1,000 long-stay NF resident days finds about twofold variation across the measures

Measure	National average rate	Average of bottom 5 states (lowest rates)	Average of top 5 states (highest rates)	Ratio of states with highest to lowest rates
All-cause hospital admissions	1.6	1.2	2.0	1.7
Potentially avoidable hospital admissions	0.8	0.5	1.0	2.0
All-cause ED visits and observation stays	1.9	1.3	2.7	2.1
Long-stay resident SNF days	76	46.8	104.6	2.2

Note: SNF (skilled nursing facility), NF (nursing facility), ED (emergency department).

Source: MedPAC analysis of facility-level rates calculated by Providigm across 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

TABLE 9–7 **Rates of SNF use per 1,000 long-stay NF resident days vary considerably**

	Ratio of facility-level variation, 90th percentile to 10th percentile		
		State variation	
Measure	**National variation**	**Low-variation states**	**High-variation states**
All-cause hospital admissions	2.3	1.8	3.0
Potentially avoidable hospital admissions	3.1	2.2	4.3
All-cause ED visits and observation stays	3.7	2.5	5.4
Long-stay resident SNF days	10.6	4.4	27.5

Note: SNF (skilled nursing facility), NF (nursing facility), ED (emergency department). "Low-variation state" is defined as a state with variation at or below the 10th percentile. "High-variation state" is defined as a state with variation at or above the 90th percentile.

Source: MedPAC analysis of facility-level rates calculated by Providigm across 1.4 million long-stay nursing facility residents using data from fiscal years 2013 and 2014.

to facility incentives (or ability) to invest in the capital (human or technological) necessary to treat in place or better prevent hospital use. However, bed-hold policies are intended to provide a continual home for long-stay NF residents with the goal of encouraging proper hospital use. In their research, Intrator and colleagues found that facilities located in states with a bed-hold policy had higher rates of hospitalization of long-stay NF residents. States with a bed-hold policy have a greater financial incentive to transfer a beneficiary to an acute care hospital because Medicaid will continue to pay (in part or in whole) for that individual's NF bed while the beneficiary remains in the hospital (Intrator et al. 2007).[18]

We expect that different state-level policies may affect NFs' incentives to transfer a beneficiary to a hospital in conflicting ways; since we did not test each of these variables in the models, we do not know the degree to which each policy contributes to the state's average rates of unnecessary hospital use.

Intrastate variation

On a state-by-state basis, we found fairly consistent variation across facilities for the all-cause hospital admission, potentially avoidable hospital admission, and ED visit and observation stay measures compared with the degree of variation in national-level rates. For example, on a national level, the facilities with the highest rates of all-cause hospital admissions (those at or above the 90th percentile) had rates that were 2.3 times higher than that of facilities with the lowest rates (at or below the 10th percentile) (Table 9-7). We found a similar degree of variation across facilities within each state for the all-cause and potentially avoidable hospital admission measures. For these measures, states that had lower average hospital admission rates tended to have higher variation within the state. States with the highest average hospital admission rates tended to have lower variation across facilities within the state.

Based on the intrastate variation in hospital use across providers, we conclude that, while state-level policies contribute to a NF's incentive to transfer a long-stay NF resident, individual facility-specific practices also contribute to the large variation across the measures. The frequency of these visits could be influenced by the degree that the facility has a "closed" medical staff model (where the NF employs physicians to treat beneficiaries in the facility) compared with an "open" model (where beneficiaries' care is provided by physicians not employed by the NF) (Shield et al. 2014). Research suggests there are clinical benefits to having a closed medical staff on certain outcomes; however, facilities with closed systems may have more difficulty obtaining hospital referrals of post-acute care patients (Assistant Secretary for Planning and Evaluation 2006). In addition, to meet the requirements of Section 1919 of the Social Security Act, each NF resident has the right to choose a personal attending physician.

The intrastate variation in SNF use was considerable, exceeding a 25-fold difference in use between the 10th and 90th percentiles for states with the highest variation. For this measure, we did not find any correlation between the degree of variation across facilities within the state and the state average rate of SNF use for long-stay NF beneficiaries. Similar to the hospital use measures, we conclude that, while state-level policies contribute to a NF's incentive to maximize the SNF benefit for a long-stay NF resident, facility-specific practices also contribute to the large variation across the SNF use measure.

Considerations for future policy

This work suggests several options for future policy, including directing CMS to develop measures of hospital and SNF use for long-stay NF beneficiaries, public reporting of the developed measures, and consideration of incorporating the measures for long-stay NF residents into Medicare payment policy. There are also several areas the Commission could focus on in the future, including better understanding facility best practices to reduce unnecessary hospital admissions, conducting research that focuses on end-of-life and palliative care, and continuing to follow long-stay NF residents receiving care under alternative models of payment such as accountable care organizations (ACOs) and Medicare Advantage (MA).

Quality reporting

CMS could develop measures of hospital and SNF use for long-stay NF residents. The two inpatient admission measures we explored presented similar findings and were highly correlated, so the all-cause hospital admission and potentially avoidable hospital admission measures would likely have a similar effect on facilities. Once a measure or measures are developed, CMS could report the results to providers; ultimately, public reporting could be achieved through a website such as Nursing Home Compare. One option for including a long-stay NF resident hospital use measure in Medicare payment policy would involve congressional action to expand Medicare's SNF value-based purchasing program. Although Medicare does not pay for the long-term portion of care, it does pay for the hospital stays of NF residents. The threshold for a hospital or SNF use measure to affect payment should factor in the high levels of variation we found at the extreme of the rate distributions—not necessarily facilities at or slightly above the median rates.

Program integrity

Given the wide variation in rates of the measures we developed for long-stay NF residents, CMS and its auditors could consider further examining aberrant patterns of hospital and SNF use for long-stay NF beneficiaries. These patterns include high rates of hospital use, ED visits and observation stays, and SNF use. SNF use could be considered in the context of either medically unnecessary days or medically unnecessary admissions. Examining such SNF use could be an extension of OIG's 2016 work plan that focused on the documentation requirements to ensure that SNF care is reasonable and necessary, including a requirement for a physician's order at the time of admission for the resident's immediate care (Office of Inspector General 2015).

Considerations for future Commission work

The Commission could consider future work in three distinct areas: a better understanding of facilities' best practices and potential policies to allow those practices to be shared across facilities, research that focuses on end-of-life care and palliative care models, and future analysis of long-stay NF residents receiving care under alternative models of payment.

The Commission's exploration of best practices across facilities could include an analysis of the characteristics of facilities that provide high-quality care for long-stay NF beneficiaries. Once best practices are determined, the Commission could consider policies that help facilitate sharing best practices across facilities such as connecting lower quality NFs with higher quality NFs. The wide variation in rates of hospital use across NFs may suggest that some NFs currently cannot treat beneficiaries' medical conditions on-site.

The Commission could also focus research efforts on palliative and end-of-life care for the long-stay NF population and its effect on unnecessary hospital use. We could combine this effort with further exploration of palliative care models used by organizations such as ACOs. Because beneficiaries who reside in NFs typically have multiple chronic conditions, advanced diseases, and/or disabilities, palliative care may be of particular importance in this setting. Many initiatives we explored aimed at reducing hospital use by long-stay NF residents include end-of-life and palliative care efforts as one facet of a multifaceted approach; thus, evaluating the effects of these particular efforts is difficult.

As data become increasingly available, the Commission could look at trends in hospital and SNF use for long-stay NF residents receiving care under certain alternative models of payment. This analysis might include additional research on the use of ACOs with the long-stay NF population. To date, research has primarily focused on post-acute care, not necessarily the beneficiaries who are long-stay NF residents. However, CMS recently began accepting letters of intent for a new ACO model, the Medicare–Medicaid Accountable Care Organizational Model, scheduled to begin in 2018. These ACOs may be more focused on the long-stay NF population and might provide additional insights on reducing unnecessary hospital use for Medicare beneficiaries. With respect to another alternative model, the Commission issued a status report in its June 2016 report to the Congress regarding CMS's Financial Alignment Initiative between Medicare and Medicaid. We will continue to monitor its progress; in particular, we plan to focus on the development of the demonstration's care coordination models and their impact on the quality of care received by dual-eligible beneficiaries (Medicare Payment Advisory Commission 2016b). Last, as data become available and appropriately validated for analysis, the Commission could compare hospital and SNF use between the long-stay NF residents enrolled in Medicare fee-for-service compared with those in MA. ■

Endnotes

1 The coordinating organizations include the Alabama Quality Assurance Foundation, CHI/Alegent Creighton Health, HealthInsight of Nevada, Indiana University, the Curators of the University of Missouri, the Greater New York Hospital Foundation Inc., and UPMC Community Provider Services.

2 Optum CarePlus will be used to describe UnitedHealthcare's NF care coordination model even if the reference predates the change in name.

3 The Commission contracted with NORC at the University of Chicago to conduct the interviews with individuals involved in implementing these initiatives. To supplement the responses gathered through the interviews, the Commission also attended two meetings held by CMMI and further researched initiatives through a variety of phone calls, webinars, and a literature review.

4 *Clinician* refers to the resident's physician or other health professional managing the treatment of the beneficiary, including advanced practice registered nurses.

5 INTERACT is an acronym for **Inter**ventions to **R**educe **A**cute **C**are **T**ransfers. This suite includes quality improvement, communication, decision support, and advanced planning tools. The full suite can be accessed at https://interact2.net/tools_v4.html.

6 The payment is geographically adjusted. Nurse practitioners and physician assistants are paid at 85 percent of the geographically adjusted physician fee schedule amount. The original NF Current Procedural Terminology (CPT) code 99310 pays $137.81 in 2017, whereas the equivalent hospital visit CPT code 99223 pays $205.64 in 2017.

7 Nurse practitioners and physician assistants are paid at 85 percent of the geographically adjusted physician fee schedule amount.

8 Medicare Part D includes an MTM program that is intended to improve the quality of the pharmaceutical care high-risk beneficiaries receive. In the past, the Commission has questioned whether MTM programs offered through stand-alone prescription drug plans, without the cooperation and coordination of a beneficiary's care team, have the capacity to significantly improve beneficiaries' drug regimens. The Commission concluded that better medication management might be achieved through programs offered by accountable care organizations, medical homes, and other team-based delivery models. Patients might be more likely to follow the advice they receive if it comes from their physicians and pharmacists. Further, because medication errors are most likely to occur when a drug regimen is modified (e.g., when a patient transitions from one site of care to another), medication management programs that are part of a clinical setting may be more effective in identifying when patients' medications should be reviewed and reconciled (Medicare Payment Advisory Commission 2015a).

9 *Advance care planning* refers to a broad group of conversations regarding an individual's preferences for end-of-life care, formalized through written documentation. Advance care planning encompasses several types of documents. An advance directive, for example, includes a living will and a durable power of attorney for health care and goes into effect when the beneficiary is too ill to make his or her own health care decisions (National Institute on Aging 2016). The federal Patient Self-Determination Act of 1990 requires certain providers, including NFs, to maintain written policies and procedures to inform beneficiaries about advance directives. According to the Government Accountability Office, 55 percent of beneficiaries in NFs nationwide had an advance directive in 2014, with broad variation within and across states (Government Accountability Office 2015).

10 These tools include forms such as the Physician Order for Life-Sustaining Treatment, Medical Order for Life-Sustaining Treatment, Medical Order for Scope of Treatment, and Physician Order for Scope of Treatment.

11 For example, in 2013, the Commission published trends in potentially preventable hospital readmission rates and concluded that hospitals could more readily prevent certain readmissions (Medicare Payment Advisory Commission 2013). In 2014, we discussed rates of potentially preventable hospital and ED visits by all Medicare FFS beneficiaries in certain regions (Medicare Payment Advisory Commission 2014).

12 We calculated the rates using data in fiscal years 2013 and 2014. We used data from the last four months of fiscal year 2012 to determine eligibility status for beneficiaries whose NF stays began before our study period.

13 Medicare pays for up to 100 days in a SNF following an inpatient hospital stay lasting 3 days or longer per benefit period. Medicare pays in full for the first 20 days of the SNF stay, after which the beneficiary is responsible for coinsurance for days 21 through 100. In 2016, the coinsurance equaled $161 per day. A new benefit period begins with a hospital admission once the beneficiary has not used the inpatient hospital or SNF benefit for 60 days.

14 110 beds × 85 percent occupancy × 52 percent qualifying long-stay resident days × 365 days = 17,746 qualifying long-stay resident days per year

15 In prior work, the Commission found that variation in spending for post-acute care services varied twofold between the lowest 10th percentile of spending and the highest 90th percentile. The variation was less for acute inpatient services where the ratio of spending between the lowest 10th percentile and highest 90th percentile equaled 1.22 (Medicare Payment Advisory Commission 2011).

16 Given the collinearity between facility ownership and staffing levels, we conducted two separate regression analyses. One regression included ownership, the second included several staffing variables such as certified nursing assistant, licensed practical nursing, and registered nurse hours per resident day and excluded ownership. Both models produced similar explanatory power and similar results.

17 Almost 87 percent of urban facilities reported access to on-site X-ray services compared with about 63 percent of rural facilities in our analysis. We also found that 57 percent of urban facilities had rates of physician or other health professional visits exceeding 40 per 1,000 long-stay NF resident days, compared with 16 percent of rural facilities (Kramer et al. 2017).

18 Intrator and colleagues found that the states with a bed-hold policy had higher rates of hospitalization, equaling approximately 75 additional inpatient hospital stays every 5 months for every 1,000 long-stay NF residents (Intrator et al. 2007). This figure translates into 75 additional hospitalizations per 150,000 long-stay NF resident days, or 0.5 hospitalization per 1,000 days.

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CHAPTER 10

Provider consolidation: The role of Medicare policy

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Chapter summary

Consolidation in the health care industry has at least four important implications for the Medicare program. First, horizontal hospital consolidation can contribute to higher commercial prices and therefore contribute to the growing gap between the prices paid by Medicare and those paid by commercial insurers. In addition, high commercial prices can induce higher hospital costs and, in turn, pressure the Medicare program to increase its prices. Second, horizontal consolidation of physician practices can result in higher commercial prices, causing a gap between commercial and Medicare prices for physician visits, which could put pressure on Medicare to increase physician prices. Third, physician–hospital vertical consolidation can also result in higher costs for Medicare and commercial insurers. Fourth, there is a strong interest in consolidating provider services and responsibility for annual spending into one integrated entity such as a Medicare Advantage (MA) plan or an accountable care organization (ACO). Many individuals in the policy and provider communities expect these vertically integrated entities will bring down costs and improve quality by aligning incentives of providers and insurers. However, generating taxpayer savings from ACOs and MA plans has proved more difficult than expected.

This chapter is divided into two sections. The first discusses the current level of provider consolidation and how provider consolidation can affect prices. The following three types of provider consolidation are discussed:

In this chapter

- ***Horizontal hospital consolidation***—in which hospitals consolidate into larger systems
- ***Horizontal physician consolidation***—in which physicians consolidate into larger groups
- ***Vertical consolidation***—in which hospital systems acquire physician practices. Vertical consolidation can also result in greater horizontal consolidation when a collection of unaffiliated group practices is brought into one hospital-based group practice.

The second part of the chapter discusses vertical consolidation of provider functions and insurer functions by ACOs or MA plans, which can occur when insurers acquire providers, providers acquire insurers, or providers take on some cost-of-care risk through an ACO. The objective of the second part of the chapter is to discuss how the potential benefits of provider–insurer consolidation can occur without increasing costs for taxpayers and beneficiaries.

Provider consolidation

Providers have many arguments for consolidation, including economies of scale, consolidating services into centers of excellence, access to capital, improved coordination, relieving physicians of practice management duties and regulatory burdens, elimination of duplicative services through common electronic medical records, and improved quality of care. However, the literature fails to find strong evidence that financial consolidation consistently leads to lower costs or higher quality (Burns et al. 2013, Gaynor and Town 2012b, Gaynor et al. 2017). While some integrated entities report strong cost or quality performance, in other cases, systems may financially integrate for the tangible financial benefits of market power and Medicare facility fees rather than a cultural commitment to affordable integrated care.

Hospital consolidation has been occurring for the past 30 years. The resulting market power has contributed to a growing divergence between the prices Medicare pays hospitals and the prices commercial insurers pay. While commercial prices vary widely by individual hospital and individual insurer, on average, commercial prices average about 50 percent higher than hospital costs and often far more than 50 percent above Medicare prices (Cooper et al. 2015, Health Care Cost Institute 2014, Medicare Payment Advisory Commission 2014a, Selden et al. 2015). This trend is driven by two factors: Medicare has restrained prices in recent years, while commercial payers have increased their prices faster than economy-wide inflation (Health Care Cost Institute 2015). Even in recent years when hospital employees' wage growth has slowed and uncompensated care costs have declined, hospitals

have generally continued to obtain material rate increases (e.g., 3 percent to 5 percent) from commercial insurers (Health Care Cost Institute 2016, Health Care Cost Institute 2015). The result is that hospitals' all-payer profit margins reached a 30-year high in 2014, averaging 7.3 percent nationwide (Medicare Payment Advisory Commission 2016).

Physician horizontal consolidation can also lead to higher prices. Commercial prices tend to be higher in more concentrated markets and tend to increase after physicians integrate with hospitals (Capps et al. 2015, Neprash et al. 2015). In this chapter, we also show that providers with larger shares within a given market tend to receive higher prices than others in the market.

Vertical physician–hospital consolidation increases both commercial and Medicare prices paid for physician services. Commercial physician prices can increase because of the market power of the hospitals owning the practices. Medicare prices increase as the program pays a physician fee and a hospital facility fee for an office visit that would have been paid only a physician fee if the visit had been provided in a freestanding physician office. Specifically, the Commission estimated that in 2009 and 2015, the Medicare program spent $1.0 billion more and $1.6 billion more, respectively, than it would have if prices for evaluation and management (E&M) office visits in hospital outpatient departments (HOPDs) were the same as freestanding office prices (Medicare Payment Advisory Commission 2017). Similarly, in 2015, beneficiaries paid about $400 million in higher cost sharing for E&M visits because of the higher facility fees. In 2015, the Congress moved partially toward equalizing prices between new off-campus HOPDs and physician offices. However, on-campus HOPDs as well as existing off-campus HOPDs continue to receive the higher HOPD facility fees under the Bipartisan Budget Act of 2015.

Provider–insurer consolidation

The effect of insurer–provider consolidation on costs and competitiveness with traditional insurers is less clear. Some vertically integrated organizations have been profitable and have strong reputations (e.g., Scott and White, Kaiser), but in other cases, integrated entities with strong reputations (e.g., Mayo Clinic) have divested their insurance organizations. In the case of Medicare, there is a growing movement of patients into MA plans, some of which integrate care of patients in a group- or staff-model HMO and some of which contract with providers. There is a lack of evidence that integrated entities provide lower MA premiums to MA beneficiaries. On average across integrated and nonintegrated plans, Medicare has been unable to capture savings from the MA model. In 2017, risk-adjusted program spending

per MA beneficiary is expected to exceed risk-adjusted program spending per fee-for-service (FFS) beneficiary by about 4 percent on average (Medicare Payment Advisory Commission 2017).

Policy implications

Policymakers need to balance a widespread desire for more clinically integrated and coordinated care with concerns over the influence of consolidation on the cost of care. At least three responses to consolidation could be considered:

Response to horizontal consolidation—Restrain Medicare prices rather than follow increases in commercial prices

Consolidation of physician practices and hospitals can lead to market power and higher commercial prices. For many years, the Commission has recommended that the Congress restrain Medicare updates rather than follow the rise in commercial prices. This approach is possible because administered prices allow the Medicare program to be insulated (to a degree) from physicians' and hospitals' market power. The Medicare program's restraint of provider prices in turn restrains the cost of Medicare for taxpayers and beneficiaries. For example, from 2007 to 2016, the cost of Part A, Part B, and Part D benefits per FFS beneficiary increased by about 23 percent. By comparison, employer-sponsored HMO and preferred provider organization commercial premiums grew by about 50 percent over the same period (Kaiser Family Foundation and Health Research & Educational Trust 2016). If FFS Medicare had followed commercial pricing, Medicare costs would have been substantially higher.

Response to vertical provider consolidation—Site-neutral pricing

Administered prices do not insulate the Medicare program from all of the extra costs of vertical consolidation. Under current law, Medicare pays more for services when provided by on-campus hospital-owned physician practices than for services provided by independent physicians. The Commission has made recommendations in the past to set payment rates for hospital-based outpatient E&M services and selected other physician services equal to prices paid for the same services in physician offices. By establishing payments that are truly "site neutral," Medicare could be further insulated from the cost of physician–hospital consolidation. Integration that improves care and generates efficiencies would still occur, but consolidation that was driven primarily by capturing new facility fees would not. The Commission reiterated our past site-neutral recommendations in our March 2017 report, affirming the Commission's support for moving toward site-neutral pricing (Medicare Payment Advisory Commission 2017).

Response to consolidation of provider and insurance functions—Have MA plans, ACOs, and FFS compete on a level playing field

Finally, to gain the potential advantages of making providers more accountable for cost and quality without increasing costs to taxpayers, the program could move toward a level playing field across payment models. On average, Medicare currently pays more for beneficiaries in MA plans than for those in FFS. However, as we reported in June 2014, MA, traditional FFS, and ACOs all have the potential to be the low-cost option in some markets. Given that no one model is dominant, one policy option is to make program contributions financially neutral among MA, traditional FFS, and ACOs. Such a policy would create competition on a level playing field, and market forces would then illuminate the model that is most efficient given particular market conditions. Clinically integrated MA plans and ACOs that are more efficient than traditional FFS would still gain market share, but plans that can compete with FFS only when subsidized by the taxpayer would lose market share. By paying for outcomes and not corporate structure, Medicare would create incentives for organizations to continually develop more efficient delivery systems. In contrast, once Medicare pays more for a particular corporate structure, there is a disincentive to innovate into new more efficient models. ■

Introduction

The health care sector has been consolidating for decades. Consolidation includes horizontal mergers of providers—in which hospitals consolidate into larger systems or physicians consolidate into larger practices. Because consolidated hospital systems and group practices are rarely broken up, horizontal consolidation tends to ratchet up over time. There has also been a recent increase in vertical provider consolidation—in which physician practices are acquired by hospital systems. We have found that Medicare payment policy encourages vertical integration, and vertical integration in turn increases Medicare program costs. The first half of this chapter discusses horizontal and vertical provider consolidation.

The second half of the chapter discusses vertical provider–insurer consolidation—in which providers acquire an insurer (or take accountability for annual spending) or an insurer acquires a provider. Such acquisitions are premised on the idea that efficiencies can be gained by giving provider organizations greater responsibility for annual costs of care and the quality of care. However, Medicare still must be vigilant in how Medicare Advantage (MA) plans and accountable care organizations (ACOs) are compensated to avoid increasing costs for taxpayers and beneficiaries.

Hospital consolidation has increased for decades

Hospital markets are highly consolidated. In 2012, a single hospital system accounted for a majority of Medicare discharges in 146 of 391 metropolitan areas. In each of 65 small metropolitan areas (e.g., Cheyenne, WY; St. Cloud, MN), a single system accounted for 100 percent of discharges (American Hospital Association 2015, Centers for Medicare & Medicaid Services 2014). Data from 2015 suggest the merger trend is continuing, with Irving Levin reporting 265 hospitals involved in transactions in 2015 (Irving Levin Associates Inc. 2016). The Federal Trade Commission (FTC) uses the Herfindahl–Hirschman Index (HHI; the sum of the squared market shares of hospital systems in a market) as an indicator of whether there is enough consolidation in a market to generate market power. In 1990, the FTC benchmark (HHI > 2,500) suggested that 65 percent of markets were deemed "highly concentrated," with a risk of higher prices, and that figure rose to 77 percent by 2006 (Gaynor et al. 2014). By 2012, 84 percent of metropolitan areas met the FTC definition of highly concentrated (American Hospital Association 2015, Centers for Medicare & Medicaid Services 2014).

Provider consolidation has continued in part because private insurers and antitrust regulators have few tools to stop horizontal and vertical consolidation. The FTC has challenged some mergers and won a few cases in recent years. However, most examples of horizontal and vertical consolidation in recent decades were unchallenged or not successfully challenged by the FTC (Gaynor et al. 2014). In addition, some consolidation happens naturally as poorer financial performers close and better performers expand existing operations. The result is that many "markets are already highly concentrated, so there does have to be some concern about exactly how effective antitrust enforcement can be" (Gaynor 2011). We are not aware of any discussions to unwind a material number of past hospital mergers. Therefore, consolidation and the resulting market power are likely to be ongoing features of the health care market. It may be time to shift from thinking primarily about how to limit horizontal hospital consolidation and focus on how Medicare should function in markets where hospitals already have substantial market power.

Physician practices are consolidating and vertically merging with hospitals and health systems

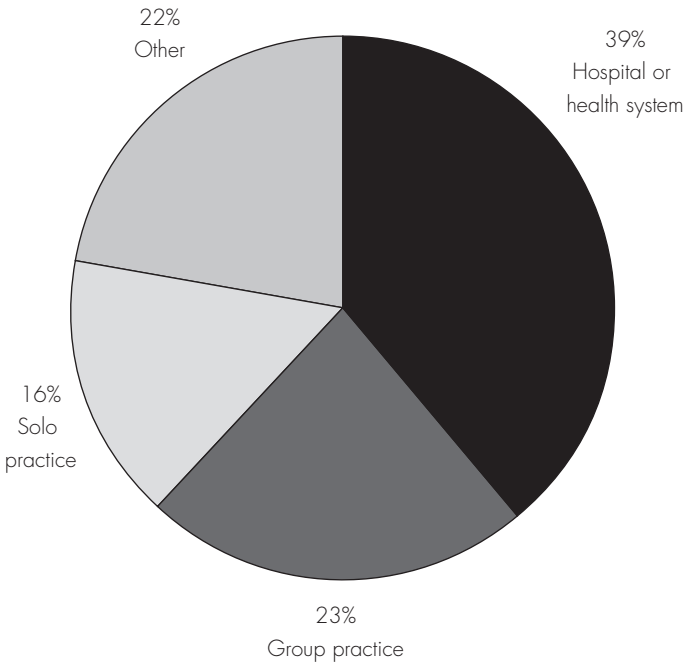
To evaluate the degree to which physician practices have consolidated and integrated with hospitals, we examined 2012 and 2014 data on the degree to which physicians are practicing in groups and joining hospital and health systems. We found the following:

- Physicians are often joining larger groups, hospitals, and health systems. However, they often do not move the location of their practice.
- While consolidation continues, small practices still provide a large share of Medicare services. Specifically, more than half of Medicare physician spending in 2014 was for physicians working in practices of five or fewer physicians.
- Financial incentives are in place for continued consolidation.

To determine what share of physicians were part of group practices, hospitals, or health systems, we used the SK&A

FIGURE 10–1

About 40 percent of physicians in SK&A database reported hospital or health system affiliation, 2014



Note: "Other" category includes independent practice associations; physicians working in group practices for which the group practice ID is missing; and physicians reporting they work with other physicians at their practice site, but who do not report a group practice identifier. Those in the group practice category do not report hospital or health system affiliation. The number of physicians in the analysis is 594,871.

Source: SK&A Office-Based Physician Database.

commercial database of physicians (see online Appendix 10-A, available at http://www.medpac.gov, for details). It contains physician names and national provider identifiers (NPIs), addresses, contact information, specialties, hospital and health system affiliations, and practice affiliations, among other variables. It is updated semi-annually through calls to practices and Internet research. The SK&A database was originally constructed for companies that made direct marketing visits to office-based physicians. Studies of its completeness have found substantive overlap with the American Medical Association Physician Masterfile and the National Plan and Provider Enumeration System file that contains records of all physicians who have an NPI (Gresenz et al. 2013). The SK&A database has been used in other health services research applications (Baker et al. 2015, Baker et al. 2014a, Capps et al. 2015, Kenney et al. 2014, Polsky et al. 2015).

Using a hierarchy of physician affiliation that assigns each physician to a discrete category (see online Appendix 10-A, available at http://www.medpac.gov), we find that 39 percent of physicians were affiliated with a health system or hospital, 23 percent were affiliated with a group practice (but not with a health system or hospital), 16 percent were solo practitioners, and 22 percent were categorized as "other" in the SK&A database in 2014 (Figure 10-1).

Physician affiliation varies by specialty, with over half of cardiologists and 35 percent of orthopedists reporting hospital or health system affiliation in 2014 (Table 10-1). The high shares of cardiologists and emergency medicine physicians reporting hospital or health system affiliation also tracks with reported merger and acquisition trends for these specialties (Barkholz 2015, Sanger-Katz 2015).

The data show trends consistent with both horizontal and vertical integration. The share of SK&A physicians reporting hospital or health system affiliation grew 7 percent per year from 2012 through 2014 (from 34 percent to 39 percent). Other data sources show a comparable trend over the same period (Kane and Emmons 2015).

Physicians are also more likely to work in larger practices in 2014 than they were five years prior. Across all locations of group practices, the share of physicians working in practices with more than 50 physicians grew between 2009 and 2014 from 16 percent to 22 percent. However, when physicians identified how many other physicians they work with in their specific practice location, the number was unchanged between 2009 and 2014 (data not shown). Physicians are part of larger organizations, but the number of physicians they work with in their immediate practice has remained constant. In other words, the data are indicative of financial consolidation (between practices or between practices and hospitals or health systems), but do not show that it resulted in physicians physically merging their practice locations.

Physician affiliation for SK&A Medicare-billing physicians

Using the NPIs, we matched the SK&A Office-Based Physician Database to the 2014 Medicare noninstitutional Part B claims at the line-item level (after excluding group billing and nonphysician claims). Seventy percent of the physician NPIs could be matched to a physician record in the SK&A database (corresponding to 84 percent of Medicare claim line items and 84 percent of Medicare spending).

TABLE 10–1

Physician affiliation varied by specialty, 2014

	Primary care	Cardiology	Emergency medicine	Orthopedic surgery	OB–GYN
Total number of physicians	190,221	23,711	19,163	23,219	26,746
Share, by type of affiliation:					
Hospital and/or health system	40%	53%	50%	35%	38%
Group practice	21	23	22	37	28
Solo practice	19	10	4	11	14
Other	20	14	24	17	20

Note: OB–GYN (obstetrician/gynecologist). "Other" category includes independent practice associations; physicians working in group practices for which the group practice ID is missing; and physicians working at a location with other physicians, but who do not report a group practice identifier. Primary care specialties include family practice, gerontology, internal medicine, general practitioner, or pediatrics.

Source: SK&A Office-Based Physician Database.

The Medicare-billing physicians without a corresponding SK&A record were disproportionately likely either to be in hospital-based specialties (radiologists, pathologists, and anesthesiologists) or to have a specialty of internal medicine but work in a hospital-based capacity (for example, as a hospitalist or intensivist).

Of the physicians who billed Medicare and could be found in the SK&A, 39 percent of physicians reported hospital or health system affiliation, 24 percent reported a group practice (and not hospital or health system affiliation) and 16 percent reported working in a solo practice. This distribution is comparable with those of the total universe of physicians in the SK&A database (Table 10-2).

A large share of Medicare spending is still delivered by physicians in unaffiliated group practices

In 2014, 24 percent of Medicare-billing physicians were in unaffiliated group practices, but they accounted for a significantly larger share of Medicare spending (31 percent) (Figure 10-2, p. 298). This difference is due in large part to the types of specialties that account for

TABLE 10–2

Distribution of Medicare-billing physicians was similar to all physicians with an SK&A record, 2014

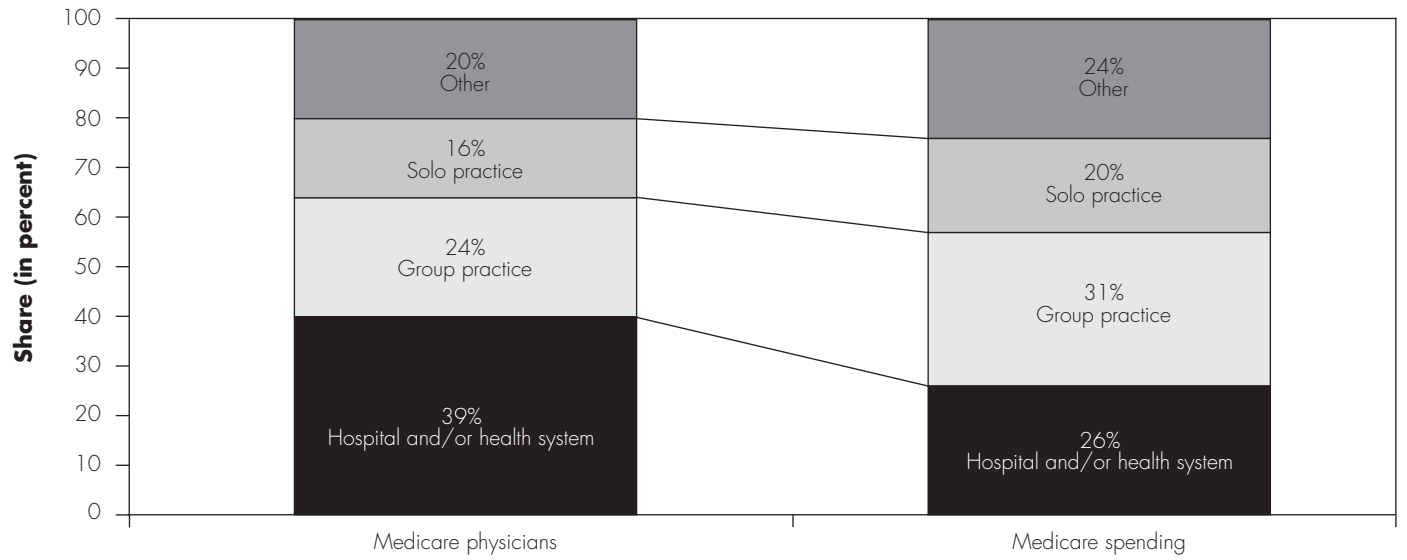
	Medicare-billing physicians	All physicians with an SK&A record
Number of Medicare-billing physicians with an SK&A record	462,195	N/A
Share, by type of affiliation:		
Hospital and/or health system	39%	39%
Group practice	24	23
Solo practice	16	16
Other	20	22
Number of physicians in Medicare claims with no SK&A record	192,373	N/A

Note: N/A (not applicable). The percentage distribution for Medicare-billing physicians is only for the 70 percent of physicians that could be matched from SK&A to Medicare claims. Percentages may not sum to 100 due to rounding.

Source: Medicare 2014 Part B Geographic Variation Database noninstitutional claim line file and the SK&A Office-Based Physician Database.

FIGURE 10–2

Physicians in unaffiliated group practices accounted for the largest share of Medicare spending, 2014



Note: Seventy percent of Medicare physicians could be matched to an SK&A record and account for 84 percent of Medicare spending. "Other" category includes independent practice associations; physicians working in group practices for which the group practice ID is missing; and physicians reporting they work with other physicians at their practice site, but who do not report a group practice identifier. Those in the group practice category do not report hospital or health system affiliation. Percentages may not sum to 100 due to rounding.

Source: Medicare 2014 Part B Geographic Variation Database noninstitutional claim line file, SK&A Office-Based Physician Database.

a significant part of Medicare spending. For example, ophthalmologists and orthopedists have a large share of their revenue that is Medicare, and both specialties are more likely to be in unaffiliated group practices (and less likely to report hospital and health system ownership). Therefore, unaffiliated group practices account for a disproportionate share of Medicare spending.

A similar phenomenon occurs with respect to practice size. Over half of Medicare spending is billed by physicians working in a practice with five or fewer physicians. While a large share of Medicare physician services is provided by small or unaffiliated practices, the financial incentives are clearly aligned for more consolidation in the future.

Motivations for horizontal and vertical consolidation

Providers have many arguments in favor of consolidation. These include economies of scale, consolidating services into centers of excellence, access to capital, improved coordination, relieving physicians of practice management duties and regulatory burdens, elimination of duplicative services through common electronic medical records, and improved quality of care. Also, some hospitals may acquire practices to secure referrals and admissions. However, the literature finds weak evidence that financial consolidation consistently leads to lower cost or higher quality (Burns et al. 2013, Gaynor and Town 2012b, Gaynor et al. 2017).

While early integration of providers before the start of the Medicare program may have been motivated by culture and philosophy, some of the more recent consolidation may be motivated by financial incentives in Medicare's payment system. For example, the culture of the group practice may have led long-standing physician groups such as the Mayo Clinic and the Billings Clinic to develop vertically integrated organizations. Given examples of these long-standing vertically and horizontally integrated entities, there may be a belief that financially integrated multispecialty groups will better coordinate care and improve outcomes. This assumption could in turn lead to calls for robust financial incentives for providers to integrate into larger systems with a common medical record. However, it may be easier to replicate the corporate structure of integrated organizations such as

the Mayo Clinic than to replicate the culture of such organizations. For example, it is not clear that incentives for financial integration lead to clinical integration. Burns and colleagues state that "many hospitals actually operate the 'groups' as dispersed collections of solo and partnership practices where the only things that really change post-acquisition are the nameplates on the door and the source of the physicians' and the office staff's W-2s" (Burns et al. 2013). Similarly, the FTC recently challenged St. Luke's Hospital's acquisition of a group practice in Idaho; it argued that the hospital already owned a physician practice and this additional acquisition would create a dominant physician practice under the hospital umbrella. In other words, the transaction would cause vertical and horizontal consolidation. The FTC presented an internal document obtained from the physicians listing "fundamental reasons" why the physician practice should integrate with the hospital. The reasons listed included "control market share," "facility fee for Medicare," and "one competition compared to two." The FTC argued that the physicians' notes did not list capital improvements or quality improvements as reasons for the merger (United States District Court for the District of Idaho 2013). In contrast, the physician group publicly stated the primary reason they wanted to be acquired was to "provide the best possible health care to the community." They further stated that consolidation was needed to "participate in the transition to value-based, integrated care." The court ruled that the "plaintiffs established a prima facie case that the merger will probably lead to anticompetitive effects in that market," and further stated that St. Luke's did "not demonstrate that efficiencies resulting from the merger would have a positive effect on competition." The court ordered St. Luke's to unwind the vertical merger (United States District Court for the District of Idaho 2015).

What incentives will create "good integration" but not "bad consolidation?"

The arguments in the St. Luke's case reflect the long-standing policy dilemma of wanting to encourage a certain culture of coordinated care but having limited levers to ensure that legal consolidation will improve care processes and not just increase prices. It is difficult to know whether financial consolidation really will lead to more coordinated care and whether the value of that care coordination outweighs the risk of higher prices. This uncertainty has traditionally led the Commission to recommend paying for outcomes (cost and quality) rather than for organizational structure (e.g., vertical consolidation or MA legal structure). By paying for good outcomes—rather than corporate structure—organizations will have an incentive to organize in ways that deliver good outcomes. If clinical integration leads to better outcomes, then paying for outcomes would be a greater incentive for true clinical integration than tying payment to financial integration.

Effects of horizontal and vertical provider consolidation

There has been a long-standing belief that physician–hospital integration into larger systems would improve quality of care, but evidence also exists that the market power achieved through financial consolidation can lead to higher costs for payers (Berenson et al. 2016, Christianson et al. 2014, Crosson and Tollen 2010, Gaynor and Town 2012b). We first review the literature below on how horizontal consolidation can lead to higher prices paid to hospitals and the uncertainty regarding whether horizontal consolidation has offsetting benefits. Second, we show that physician practices with larger market shares receive higher prices for physician office visits. Third, we review how vertical physician–hospital consolidation can lead to higher prices paid by both commercial insurers and Medicare.

Horizontal hospital consolidation increases prices paid by commercial insurers

The literature generally finds that horizontal hospital consolidation leads to higher inpatient prices. Gaynor and colleagues summarize the findings: "Mergers between rival hospitals are likely to raise the price of inpatient care and these effects are larger in concentrated markets. The estimated magnitudes are heterogeneous and differ across market settings, hospitals, and insurers" (Gaynor et al. 2014).[1] While the magnitude of the price increase associated with consolidation varies, the direction is consistently upward, which will make the costs of private insurance more expensive (Town et al. 2007). Some insurers have suggested they could counter the hospitals' market power if they consolidate. However, greater insurer concentration may not lead to lower premiums because of higher profits remaining with the insurer (Trish and Herring 2015).

Horizontal consolidation of hospitals has contributed to a growing divergence between the prices Medicare pays hospitals and the prices commercial insurers pay. While commercial prices vary widely by individual hospital

and individual insurer, on average, commercial prices average about 50 percent higher than average hospital costs and are often far more than 50 percent above Medicare prices (Cooper et al. 2015, Health Care Cost Institute 2014, Medicare Payment Advisory Commission 2014a, Selden et al. 2015). For example, Selden and colleagues found that average private prices were 75 percent higher than Medicare prices in 2012; Aetna and Blue Cross of California paid hospitals prices that were often 200 percent of Medicare's rate for inpatient care and 300 percent of Medicare's rate for outpatient services in California in 2014 (California Department of Insurance 2014a, California Department of Insurance 2014b). This trend is driven by two factors: Medicare has restrained growth in prices in recent years, while commercial payers increased their prices faster than economy-wide inflation (Health Care Cost Institute 2015). Even in recent years when hospital employees' wage growth has slowed and uncompensated care costs have declined, hospitals have generally continued to obtain material rate increases (e.g., 3 percent to 5 percent) from commercial insurers (Health Care Cost Institute 2016, Health Care Cost Institute 2015, Health Care Cost Institute 2014). The result is that hospital all-payer profit margins reached a 30-year high of 7.3 percent in 2014 and were still 7.1 percent in 2015 (Medicare Payment Advisory Commission 2017). High profits on non-Medicare patients can lead to higher hospital costs, resulting in pressure to increase Medicare prices to meet those costs (Frakt 2015a, Medicare Payment Advisory Commission 2016, White and Wu 2014).

Another indicator of a lack of price competition among hospitals is the significant heterogeneity in hospital prices. For example, if one provider is paid four or six times the price paid to another provider for the same service, it indicates that some markets are not price competitive. Truven Health Marketscan data from commercial insurers show that fees received by hospitals vary widely for identical services. In our own examination of commercial insurance prices for two common emergency room services, we found that prices for a typical emergency department emergency department (ED) visit (Current Procedural Terminology (CPT) 99284) in 2013 varied by a factor of over four, with 10 percent of hospitals receiving an average of less than $275 and 10 percent receiving an average of over $1,311 for an in-network ED visit. Head computed tomography (CT) scans (CPT 70450) varied by a factor of six, with 10 percent of hospitals receiving less than $236 and 10 percent receiving more than $1,472 for an in-network CT (Medicare Payment Advisory Commission 2016). The wide variation in prices that we and others have found suggests the market is not bringing prices down to a uniform competitive level (Cooper et al. 2015, Reinhardt 2012). In summary, hospital markets are consolidated, which can lead to high prices and prices that vary wildly from provider to provider and market to market.

Horizontal and vertical physician consolidation increases prices paid for physician services

The Commission reported that 2015 Medicare prices for physician office visits were below the average commercial rates for preferred provider organizations (PPOs) (Medicare Payment Advisory Commission 2017). While average Medicare prices have tended to be lower than commercial prices, commercial prices for physician services have varied widely (Medicare Payment Advisory Commission 2011). In 2011, we reported that average prices paid by commercial insurers were more than 50 percent above Medicare in some markets and were below Medicare in other markets. In addition to wide variation across markets, commercial prices for mid-level office visits varied by up to 100 percent in a single market (Medicare Payment Advisory Commission 2011). Our examination of data (shown below) on providers' market power and commercial prices found that prices paid to physicians without market power are often close to Medicare prices, but physicians with market power receive substantially higher prices. This variance raises the question of whether continued horizontal and vertical consolidation of physician practices (and the associated higher commercial prices) could eventually reduce physicians' interest in taking on new Medicare patients.

The literature on physician prices

The literature on private insurer prices suggests that providers' market share and hospital affiliations can affect the prices they receive. Recent studies have shown that prices tended to be higher in markets where physicians are consolidated into larger practices (Baker et al. 2014b, Clemens and Gottlieb 2017). Interviews with insurers and providers support the hypothesis that consolidation leads to higher prices (Berenson et al. 2010). Other studies have shown that vertical consolidation of physicians with hospitals has also led to higher prices. For example, Capps and colleagues examined claims from 6.4 million people from a large private insurer (Capps et al. 2015). They found that the share of physician billings from practices owned by hospital systems increased between

2007 and 2013 from 16.9 percent to 26.5 percent and that consolidation with a hospital was associated with an average 14 percent increase in commercial prices. Only about a quarter of the increase was due to hospitals charging facility fees after acquiring the practice; the rest of the increase was due to the hospital-acquired practices negotiating higher prices after being acquired by a hospital. In a similar study, Neprash and colleagues examined claims from 7.4 million privately insured individuals in the Truven private insurer database (Neprash et al. 2015). That analysis found the share of physician billings for facility fees from hospital-owned practices increased between 2008 and 2012 from 18 percent to 21.3 percent and that outpatient prices increased faster in markets where there was more physician–hospital consolidation. Neprash and colleagues did not find any reduction in inpatient volume that would offset the higher outpatient costs.

Data used to examine within-market price variation

We examined 2013 data from the Health Care Cost Institute (HCCI) to gain additional insights into the factors driving variation in prices within markets. Two hypotheses are consistent with the findings of the Baker, Clemens, Neprash, and Capps studies. First, we hypothesized that physician groups with larger market shares receive higher commercial prices for evaluation and management (E&M) services than others in their market. Second, we hypothesized that physician groups affiliated with hospitals receive higher commercial prices for E&M services than other physician practices in their market. To test these hypotheses, we created a data set that included information on the market share of entities bargaining on behalf of physicians, data on hospital affiliations, and data on prices for E&M visits in 235 core-based statistical areas (CBSAs).

We created "bargaining units" based on information collected by SK&A. We aggregated NPIs for providers that SK&A reported as being in a group practice or an independent practice association (IPA) and used 2012 and 2013 SK&A data to determine whether the physicians were affiliated with a hospital. We then examined the bargaining unit's share of all E&M visits in the market as well as market shares for selected specialties (i.e., dermatology, cardiology, and orthopedics). Market share is defined as a bargaining unit's share of all E&M visits in a specified geographic area, or CBSA, relative to all commercial E&M visits billed to insurers in our database for that CBSA. The principle being tested is that if the practice holds a large share of the insurers' business, it is able to negotiate a higher price.

Our claims data in each CBSA are from HCCI, which provides de-identified 2013 data on approximately 40 million individuals who are under 65 years of age with employer-sponsored insurance from Aetna, Humana, and UnitedHealthcare (Health Care Cost Institute 2014). We limited the data set to CBSAs in which the three insurers paid at least 2,000 E&M claims and to bargaining units that received payments for at least 200 E&M claims (to create stability in prices). The price of each E&M visit is broken down into the insurer's payment for the physician service and a facility fee that the insurer also paid to a hospital outpatient department for the visit. However, we found that these insurers rarely paid facility fees for E&M visits. To maintain data confidentiality, HCCI masked individual provider and insurer payment rates but allowed us to obtain the average payment rate per relative value unit in the CBSA and the average payment rate received by each bargaining unit in 2013. That further allowed us to determine whether bargaining units with large market shares or hospital affiliations received higher prices.

One important limitation is that we could match only 65 percent of HCCI claims to an SK&A provider number. That means that some providers could have been affiliated with a group or a hospital but showed up in our data as independent physicians. Thus, our category of small independent practices with less than 10 percent market share could actually have been a mix of independent practices and practices that were affiliated with a hospital or a group, but we did not have the linking data. Therefore, our findings could overstate the prices received by independent practices and understate the effect of market power on prices.

Consolidation and vertical consolidation associated with higher physician prices

Hospital-owned practices are paid higher prices, which is consistent with Neprash and colleagues and Capps and colleagues (Table 10-3, p. 302). In addition, practices with larger market shares are paid higher prices. For example, independent practices whose E&M visits composed over 30 percent of the visits provided by the three insurers received $148 on average for an E&M office visit, 40 percent higher than the average price received by the practices with the smallest market shares. The average price received by the smallest practices (those physicians that we could not match to a large practice, IPA, or a hospital) was about equal to Medicare's national average

TABLE 10–3 **Practices with larger market shares received higher prices for E&M visits, 2013**

Type of physician practice ownership and market share of E&M visits	Number of bargaining units	Mean number of E&M visits	Mean physician fee for a mid-level (CPT 99214) E&M visit	Physician price relative to Medicare	Total price per RVU relative to others in the CBSA
Not hospital owned					
Market share of E&M visits					
Less than 10%	4,281	620	$105	100%	93%
10% to 30%	80	2,548	128	122	104
Over 30%	9	1,469	148	141	106
Hospital owned					
Market share of E&M visits					
Less than 10%	741	1,939	123	117	104
10% to 30%	159	4,476	134	128	112
Over 30%	55	7,328	145	138	111
All bargaining units	5,325	1,020	110	105	95*

Note: E&M (evaluation and management), CBSA (core-based statistical area), CPT (Current Procedural Terminology), RVU (relative value unit). We examined prices for 5,325 bargaining units located in 235 CBSAs. The bargaining units had to have at least 200 E&M visits and the CBSA needed to have at least 2,000 E&M visits in our data set to be included in our analysis. Total prices include the physician fee and the facility fee when a facility fee was paid. We find that facility fees are rarely paid for E&M visits by the three insurers in the Health Care Cost Institute (HCCI) database so that an average facility fee per E&M visit by itself is not meaningful.
*Among all bargaining units, the unweighted mean price received for E&M visits is 95 percent of the weighted mean price in the market. The unweighted average can be less than 100 percent because the large practices tend to get higher rates than the smaller practices.

Source: MedPAC analysis of HCCI claims data and SK&A Office-Based Physician Database.

rate.[2] To focus on market power, we examined within-market variation. We found that a hospital-owned practice with a 30 percent or greater market share had prices per E&M relative value unit (RVU) equal to 111 percent of the unweighted average prices of other practices in its market. These findings suggest that market power has two effects. First, it allows dominant providers to increase the price they negotiate with insurers. Second, the high prices negotiated by a market's dominant provider could help smaller practices also negotiate somewhat higher prices. Insurers are expected to pay smaller practices prices that are lower than the dominant provider in the market but higher than prices in a perfectly competitive market. While some spillover of pricing power to smaller practices is expected, the within-market variation in prices for E&M visits indicates that no single "market price" exists in a given CBSA.

Similar to Capps and colleagues, we find that facility fees for E&M visits were rarely paid in 2013, even for hospital-owned practices. For example, for practices identified as hospital owned, 68 percent did not receive material facility fees for E&M visits. For those that received fees, they were often paid infrequently and averaged $13 per visit, suggesting that in many cases at least one of the insurers did not pay the facility fee. Taken together, this information suggests that the Medicare program is lagging behind the private sector's efforts to limit facility fees.

To disentangle the effects of hospital ownership and market share, we used two multivariate models (Table 10-4). In these models, the dependent variable is the bargaining unit's price per E&M visit RVU (including the facility fee) relative to others in the same market.[3] In the first model, we tested just the market share of overall E&M volume on price. In the second model, we added variables indicating the market shares of cardiologist E&M visits, orthopedic E&M visits, and dermatology E&M visits. Our reasoning was that a specialty practice can obtain higher rates due to its market share of the specialty rather than its share of

TABLE 10–4 **Market share and hospital ownership increase prices for E&M visits**

Practice characteristic	Regression coefficients	
	Basic model	Expanded model
Constant	0.93**	0.91**
Market share of E&M RVUs	0.44**	0.41**
Hospital affiliated	0.10**	0.08**
Cardiology practice		0.02
Cardiology practice × cardiology market share		0.22**
Orthopedic practice		0.04*
Orthopedic practice × orthopedic market share		0.22
Dermatology practice		–0.02
Dermatology practice × dermatology market share		0.24*
Other non–primary care practice		0.04**

Note: E&M (evaluation and management), RVU (relative value unit). The dependent variable in the regressions is the total average payment (by insurers and patients) per RVU to the bargaining unit relative to the average in the core-based statistical area (CBSA). Coefficients reflect the difference from a small primary care practice that is not affiliated with a hospital. Primary care practices are the omitted category in the expanded model. The regression results are ordinary least squares with the standard errors adjusted for clustering on the CBSA. The basic model (which includes only overall market share of E&M RVUs and hospital affiliation) explains 9 percent of the variance in relative prices and the expanded model explains 11 percent of the variance. The expanded model includes dichotomous variables indicating whether the bargaining unit is one of the three types of specialty practices evaluated. If the bargaining unit is a specialty practice, the expanded model also includes that practice's market share of E&M RVUs in the practice's specialty. The data set consists of prices negotiated by 5,325 bargaining units in 235 CBSAs.
*Significant at the $p < 0.05$ level.
**Significant at the $p < 0.01$ level.

Source: MedPAC analysis of Health Care Cost Institute claims data and SK&A Office-Based Physician Database.

all E&M visits. For example, in the expanded model, the constant coefficient of 0.91 suggests that a solo practitioner in the market received 91 percent of what others received on average. The regression suggests that for each 10 percent increase in market share, the prices received increased by 4.1 percent of the average price received by other practices in the market. It also suggests that hospital-affiliated practices received 8 percent more, all else equal. Finally, our analysis suggests that specialists can receive higher prices by having a large market share of their specialty rather than a large market share of all E&M RVUs. For example, for cardiologists, each 10 percent share of the cardiac market was associated with a 2.2 percent increase in commercial prices relative to others in the CBSA. This potential for higher E&M prices in specialty practices with market power likely further reduces the incentive for medical students to choose primary care practice. Finally, multispecialty and other types of practices received 4 percent higher prices for E&M services in addition to the effect of their market share.

Limitations to our examination of within-market analysis of HCCI data There are several limitations to our model. First, our model is dependent on using SK&A data to aggregate providers into groups and to indicate hospital ownership of the practice. To the extent there are errors or omissions in consolidation reported by SK&A, our results may be biased toward underestimating the effects of consolidation. In addition, our data were not able to identify hospitals and their level of market power; therefore, we cannot distinguish among differing degrees of hospital market power. CBSA-level data are used, but because each CBSA has been de-identified, we do not know insurers' market power in their respective CBSAs. Finally, we examine only E&M visits. There could be different market dynamics for other services. For example, facility fees may be more common for other services. We also have only data on payments through claims; there could be other payments such as ACO incentive payments. The model explains about 10 percent of the variation in

prices within a market, which implies that other factors such as location, reputation, bargaining ability, and individual anomalies in the negotiating process can affect commercial prices.

Hospital prices and vertical consolidation

While the effect of vertical consolidation on prices paid to physicians is clear, it is less clear how vertical consolidation affects hospital prices. A recent study by Baker and colleagues found that hospital ownership of physician practices can lead to higher hospital prices, suggesting that hospitals gain bargaining power by acquiring physician practices (Baker et al. 2015). But comparable studies found that vertical consolidation did not affect hospital prices (Ciliberto and Dranove 2006, Neprash et al. 2015). Therefore, while it appears that physician prices increase with vertical consolidation, the literature is not clear on whether vertical consolidation results in higher hospital prices.

Possible benefits of provider consolidation

In some cases, hospitals have argued for financial integration by stating it will allow for improved care coordination and better quality of care (Burns et al. 2013). For example, the reputation for high-quality care from long-standing vertically and horizontally integrated organizations such as the Mayo Clinic has led some to call for expansion of the integrated multispecialty group practice model. The complicating factor is that while the quality of the Mayo model appears high, it is the dominant integrated group in its main market and has high prices that appear to offset any financial savings from care coordination on volume, resulting in high annual costs of insurance.[4] In addition, it may be difficult to replicate the culture and outcomes of organizations such as the Mayo Clinic, which has been operating as a large multispecialty group practice for over 100 years. While a strong culture of integrated and coordinated care may foster better outcomes and result in financial consolidation, it is less clear that financial consolidation of physicians and hospitals under one corporate umbrella will foster coordinated care or result in improved efficiency.

Researchers are often skeptical that consolidation is a necessary or sufficient condition for high-quality care or low costs of care (Frakt 2015b, Gaynor and Town 2012a, Tsai and Jha 2014). For example, studies of hospital mergers have failed to show benefits from horizontal consolidation, when looking at mortality from heart attacks and stroke (Ho and Hamilton 2000, Kessler and McClellan 2000). Similarly, a recent study of physician groups found that small groups tended to have fewer preventable admissions (Casalino et al. 2014). However, others have emphasized how consolidating some complex surgeries in one location could improve outcomes (Cutler and Sahni 2013). In addition to quality effects, some studies of data from the 1980s and 1990s have argued that consolidation can reduce hospital costs (Spang et al. 2001). However, these savings appear to be limited to cases in which one hospital closes as opposed to having merged with a system (Cutler and Scott Morton 2013, Dranove and Lindrooth 2003). In general, the literature suggests that the benefits of hospital consolidation hinges on hospitals closing and concentrating services at a single high-volume location.

Another possible benefit often mentioned is the ability of larger organized groups to take on responsibility for quality and costs in either an ACO arrangement or a capitated MA-type arrangement. For example, in the 1990s, some contended that physicians and hospitals needed to consolidate to align incentives and prepare for risk-based contracting (Cuellar and Gertler 2006). The assumption was that a loose affiliation of physicians would not have an incentive to lower volume (and reduce their own income) to earn a bonus for a large group of physicians. Independent physicians in an ACO would suffer the full cost of reduced use at their practice and earn only a fraction of any shared savings. An ACO built around employed physicians or a single group practice could alleviate the "tragedy of the commons" problem (in which individuals acting independently according to their own self-interest behave contrary to the common good of all) and ease contracting with payers. However, there is little empirical evidence that consolidation is necessary for ACO formation or even correlated with ACO growth (Neprash et al. 2017). The key question is whether possible benefits of integrated organizations' care coordination and contracting abilities outweigh the risk of higher costs associated with market power.

Vertical consolidation increases prices paid by Medicare and commercial insurers

The Commission and the Government Accountability Office have documented how vertical consolidation of physicians and hospitals can lead to shifting the billing for physician services from physician offices to higher

cost outpatient sites of care (Government Accountability Office 2015, Medicare Payment Advisory Commission 2014b, Medicare Payment Advisory Commission 2013, Medicare Payment Advisory Commission 2012). Among other effects, the shift in care setting increases Medicare program spending and beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments (HOPDs) than in freestanding offices. For example, we estimate that the Medicare program spent $1.0 billion more in 2009 and $1.6 billion more in 2015 than it would have if prices for E&M office visits in HOPDs were the same as freestanding office prices. Analogously, beneficiaries' cost sharing was $260 million higher in 2009 and $400 million higher in 2015 than it would have been because of the higher prices paid in HOPD settings.[5]

To address the increased spending that results when billing for services shifts from freestanding offices to HOPDs, the Commission recommended adjusting hospital outpatient payment rates so that Medicare payment for E&M office visits is equal in freestanding physician offices and HOPDs (Medicare Payment Advisory Commission 2012). The Commission also recommended adjusting hospital outpatient payment rates for a set of other services so that payment rates are equal or more closely aligned across these two settings (Medicare Payment Advisory Commission 2014b). In 2015, the Congress moved partially toward the Commission's recommendations by equalizing rates between new off-campus HOPDs and physician offices. However, on-campus HOPDs as well as existing off-campus HOPDs will continue to receive the higher HOPD facility fees under the Bipartisan Budget Act of 2015. This policy could encourage hospitals to add practices on the main hospital campus or build new "micro-hospitals" that allow colocated physician practices to bill hospital facility fees.

Provider and insurer vertical consolidation

There is a long-standing expectation that integration of multispecialty group practices with insurers will create greater care coordination, better outcomes, and reduced costs. This belief is sometimes represented as a desire to replicate the existing HMOs that are centered on a multispecialty group practice. A description of the policy environment in 1973 stated: "Enthusiasm for HMOs is now widespread. A casual reader of the literature could be forgiven for believing that the answers to the healthcare 'crisis' were known and the problem was one of implementation" (Newhouse 1973). More than 40 years later, giving integrated groups of providers full capitation risk is still seen as a primary way to solve the Medicare program's financial difficulties. However, generating taxpayer savings from the MA plans (and ACOs) has been more difficult than it appeared at first.

In recent years, there has been rapid growth in MA plan enrollment and in assignment of patients to ACOs that, in some cases, also take downside risk for the overall cost of care. The expansion of MA plans and ACOs has increased insurer and provider group interest in being able to manage both the clinical and financial aspects of population health. This hope may have led to some of the insurer–provider consolidations in recent years. For example:

- In 2013, the Baylor Health Care System merged with Scott and White, which owns an insurance company. This is an example of horizontal consolidation across hospital systems and vertical consolidation of an insurer with an integrated provider system.
- United Healthcare acquired Monarch HealthCare, a group of 2,300 physicians in southern California in 2011.
- WellPoint, a national Blue Cross plan, acquired CareMore, an integrated insurer with physician practices, in 2011.
- DaVita (a dialysis company) acquired Healthcare Partners in 2012 and the Everett Clinic in 2015. While not a traditional insurer–provider model, the acquisitions allow DaVita to enter into models for accepting overall cost-of-care risk.

It is not clear whether the new systems will be able to bend the cost curve and be commercially successful. Earlier attempts to replicate the success of long-standing group-model HMOs have not always been successful. For example, in 2000, the Mayo Clinic Health System integrated HMO products as part of their system that included physicians, hospitals, and insurance products. But Mayo later closed its HMO business, suggesting they did not see sufficient value in the consolidation of provider and insurance functions. In 2010, Humana bought Concerta, which employs providers, but sold the firm

in 2015 (Herman 2015). More recently, both Tenet and Catholic Health Initiatives announced in 2016 that they would divest their insurance operations (Denver Post 2016, Rice 2016).

Effects of integrating provider and insurer functions

The long-standing belief that fully integrated HMOs would generate efficiencies received some support in the 1980s when a randomized trial compared costs of a group-model HMO and high-deductible plans with the costs of "free care" for those in an indemnity insurance plan that paid providers' full charges. The HMO and high-deductible plans had fewer hospital days and 25 percent to 30 percent lower overall costs than the indemnity plan (Newhouse 1993). Outcomes were not consistently better or worse for patients in the HMO model relative to the free care or high-deductible plans. Thirty years later, indemnity insurance has faded away, but the sentiment in favor of group- and staff-model HMOs is still strong among some in the health policy community. For example, a group of health policy leaders evaluating payment reform options concluded that fully integrated models have greater ability to "force transformational thinking," optimize infrastructure investment, reduce the incentive for volume, and expedite community engagement (Berenson et al. 2016).

Some may argue that the subset of HMOs that have integrated physician groups within the MA plan or are larger or older HMOs will have the best quality and cost performance (Ayanian et al. 2013).[6] Examinations of consolidated insurer and provider functions in MA plans found that the 17 percent of MA plans that owned providers had slightly higher quality metrics but also slightly higher premiums on average than nonintegrated plans (Frakt et al. 2013, Johnson et al. 2017). No differences in benefits were observed. However, another study suggested that exchange plans with integrated providers have modestly lower premiums than national insurers and Blue Cross affiliates, but have higher premiums than nonintegrated organizations that traditionally provided managed care for Medicaid enrollees, such as Molina (La Forgia et al. 2017). Burns and colleagues, in their broad 2013 review of the literature of horizontally and vertically integrated delivery models, concluded "there continues to be an extremely thin evidentiary basis for recommending any particular approach" (Burns et al. 2013).

Our own examination of Medicare program spending finds MA plans cost the Medicare program slightly more than fee-for-service (FFS) in some markets and less than FFS in markets where MA benchmarks are set low relative to FFS costs (Medicare Payment Advisory Commission 2016). On average, risk-adjusted spending per MA beneficiary is expected to be about 4 percent higher than for FFS beneficiaries in 2017, though not because MA is inherently less efficient than FFS (Medicare Payment Advisory Commission 2017). MA HMOs can reduce use of certain services and can generate program savings in certain markets (Medicare Payment Advisory Commission 2016, Newhouse and McGuire 2014). Since some MA plans may be able to generate efficiencies, the lack of program savings from MA may be due to the benchmarks (adjusted for quality bonuses) being set too high, coupled with a lack of price competition among insurers to drive down MA bids (Song et al. 2012). The Song study suggests that a marginal increase in an MA plan's benchmark will cause a marginal increase in the MA plan's bid. This relation suggests that, when benchmarks are set too high, the bidding process is not efficient enough to bring bids down to the level that would be achieved in a highly competitive market.

ACOs are another mechanism for giving provider groups accountability for overall costs and quality of care without generating large increases in administrative costs. To date, the data show that ACOs have been a roughly break-even proposition for the taxpayer. CMS data suggest savings from ACOs were more than fully offset by bonuses paid to ACOs. However, McWilliams used a different counterfactual methodology and concluded that the Medicare program savings from the ACOs slightly exceeded bonuses paid out to the ACOs (McWilliams et al. 2016). Using either analysis, we can conclude that the ACO program has operated at close to the break-even point, with the program generating savings in some markets and losing in other markets. The small savings from ACOs could reflect how elimination of unnecessary services can reduce costs in high-use markets, but reducing use through improved care coordination in a typical market is often more difficult than it first appears (Dale et al. 2016, Nelson 2012).

While no one model dominates nationally, it may be that different models can be successful in certain markets. The Commission compared the cost of MA, ACO, and traditional FFS models in a series of markets and found that each model was the low-cost method of care in at least one market (Medicare Payment Advisory Commission

TABLE 10–5 Summary of the benefits and costs of consolidation

Type of consolidation	Potential benefits	Cost concerns
Horizontal hospital consolidation	• Elimination of duplicative capacity • Centers of excellence	• Higher commercial prices • Pressure for higher Medicare prices
Horizontal physician consolidation	• Economies of scale • Peer review	• Higher commercial prices • Pressure for higher Medicare prices
Physician–hospital consolidation	• Greater coordination of care • Ability to take capitation risk	• Facility fees for Medicare • Higher commercial prices
Provider–insurer consolidation	• Lower incentive for volume • Coordinated capital costs • Greater coordination	• There is no evidence that integrated plans offer lower premiums or greater benefits than other Medicare Advantage plans. Across all types of Medicare Advantage plans, taxpayer spending has traditionally been higher than for fee-for-service Medicare.

Source: MedPAC analysis of the literature.

2015). This finding suggests there may not be one model that is universally better, but it may be better to create a system where models compete and the best model for a particular market is allowed to emerge.

Incentives for consolidations and their effects

Providers have clear financial incentives for more consolidation in physician and hospital markets. Horizontal consolidation increases prices paid for physician and hospital services. Vertical consolidation increases Medicare and commercial prices for physician services. Given these financial incentives, the strong history of consolidation should not be surprising. There are two risks for the Medicare program. First, a growing divergence of Medicare and commercial prices could eventually put pressure on beneficiaries' access to care and pressure the Medicare program to increase its rates. Second, market forces may make it less attractive for medical students to choose primary care careers. Specialists not only benefit from a fee schedule that rewards procedures but also benefit from higher commercial E&M fees to the extent that they have a dominant specialty group in their market.

The literature supports the tension between a desire for integrated care and the effect of consolidation on prices. On the one hand, some expect consolidation to improve coordination and eliminate duplicative capital spending. On the other hand, consolidation could result in higher commercial prices for hospital and physician services. Vertical consolidation can also result in higher Medicare payments for physician services. A summary of these tensions is shown in Table 10-5.

Medicare policy response

For more than 30 years, there has been a discussion about the potential benefits of consolidation (e.g., economies of scale, care coordination, elimination of unnecessary services, increased incentives to control volume) and the costs of consolidation (e.g., market power, higher prices). For most of those 30 years, consolidation was slow. However, it has accelerated in recent years, resulting in horizontally consolidated and vertically integrated markets, raising the issue of how Medicare should respond.

Because hospital markets and many physician markets are already highly consolidated, the question is not one of preventing consolidation but, rather, a question of how to work within a market that is consolidated. There are

several policy options for working within consolidated markets, which are discussed in the following sections.

Response to horizontal provider consolidation: Restrain Medicare prices rather than follow increases in commercial prices

Consolidation of hospitals and physicians can lead to market power and higher commercial prices. High revenues from commercial payers can lead to higher hospital costs and, in turn, pressure to increase Medicare prices. However, the Commission has historically recommended that the Congress restrain Medicare updates rather than follow the rise in commercial prices and costs. Such restraint is possible because administered prices allow the Medicare program to be insulated (to a degree) from hospital market power. This restraint in Medicare price increases resulted in substantial savings for taxpayers and beneficiaries. For example, from 2007 to 2016, per beneficiary Medicare Part A, Part B, and Part D costs increased by about 23 percent.[7] By comparison, employer-sponsored HMO and PPO commercial premiums grew by about 50 percent over the same period (Kaiser Family Foundation and Health Research & Educational Trust 2016). Our own analysis of national health accounts and two past studies suggest that commercial insurance costs have risen faster than Medicare for decades, but the gap in growth rates has accelerated in recent years (Boccuti and Moon 2003, Centers for Medicare & Medicaid Services 2016, Cubanski and Neuman 2016). If FFS Medicare had followed commercial pricing, Medicare costs would be substantially higher.[8]

However, as the gap between Medicare and commercial prices grows, it may become harder for Medicare to restrain growth in provider prices. In the near term, the commercial/Medicare price gap does not appear to put Medicare beneficiaries' access at risk. In 2017, hospitals' Medicare payments are still higher than hospitals' marginal costs, and most hospitals have excess capacity to serve Medicare patients. With respect to physician prices, Medicare prices for office visits are still competitive with commercial prices paid to practices without market power. This is reflected in surveys that show Medicare patients do not currently have any more trouble than private patients in obtaining a new physician (Medicare Payment Advisory Commission 2017). However, in the long term, growing provider consolidation and a growing gap in prices could be problematic. In the end, Medicare beneficiaries' access to care may depend on restraint of commercial prices to limit the divergence between those prices and Medicare's for physician and hospital services.

Response to vertical consolidation: Site-neutral pricing

Administered prices do not insulate the Medicare program from all of the extra costs of vertical consolidation. Under current law, Medicare pays more for services provided by hospital-owned physician practices that are considered part of the hospital's outpatient department. The Commission has made recommendations in the past to set payment rates for HOPD E&M services and selected other physician services equal to rates paid for visits in physician offices. By creating "site-neutral" payments, the Medicare program could be further insulated from the cost of physician–hospital consolidation. Clinical consolidation that improves care and generates efficiencies would still occur, but purely financial integration that was driven primarily by efforts to capture Medicare facility fees would not. In 2017, the Commission reiterated its past recommendations on site-neutral pricing.

Response to consolidation of provider and insurance functions: Have MA plans, ACOs, and FFS compete on a level playing field

We have found that MA, traditional FFS, and ACOs all have the potential to be the low-cost option in some markets. Because more than one model may have a role in the Medicare program, the Commission has discussed synchronizing payment rates among MA, traditional FFS, and ACOs. This equalization would create competition on a level playing field, and market forces would then illuminate which model is most efficient given particular market conditions. Integrated systems that are more efficient than FFS would still gain market share, but plans that could compete with FFS only when subsidized by the taxpayer would lose market share. Leveling the playing field will be a key component to obtaining the potential benefits of integrated delivery models without increasing costs to taxpayers.

An alternative to leveling the playing field is to try to differentiate between good integration and bad consolidation and then pay for structure and process correlated with good integration. For this differentiation to be operationalized, CMS or the Congress would have to determine what defines good integration and what characteristics are correlated with this type of integration. Then CMS could create payment incentives for consolidated entities with the characteristics deemed good.

For example, if the policy community assumed that fully integrated organizations that took on capitated risk and integrated physicians and hospitals into a single electronic medical record had better outcomes, Medicare could pay more to organizations with that integrated legal structure and that type of information technology system. However, the risk is that some organizations would just adopt a legal structure dictated in the CMS payment formula to receive the higher payment without changing clinical practice. In addition, the organizations would have a disincentive to adopt innovations that were not consistent with the CMS payments for specific types of structure or process. This risk can be avoided by paying directly for better outcomes. By paying for outcomes, organizations would have an incentive to adopt the most efficient delivery models for their markets and to continually improve their delivery systems. Innovative improvements would be rewarded.

Conclusion

In general, the policy options in this chapter would pay more for better outcomes but not pay more for having a certain corporate structure. For example, rather than paying more to a hospital system just for placing a physician practice under its corporate umbrella, the program would reward systems that truly coordinate care in ways that reduce cost and improve quality. A two-sided risk ACO model could be such a system. Similarly, Medicare could move away from paying more for an organization with an MA plan (that may just pay FFS anyway) to rewarding only MA plans that either lower program cost or improve quality. In the end, payment should depend more on the quality and efficiency of care provided by an organization's clinicians than the ability of an organization's legal staff to optimize its corporate structure in ways that increase Medicare payments. ■

Endnotes

1 The hospital industry generally disputes the relationship between market concentration and prices (see, for example, the American Hospital Association–commissioned study conducted by Charles River Associates of hospital consolidation, mergers, and acquisitions at http://www.advancinghealthinamerica.org/wp-content/uploads/2014/08/Hospital-Merger-Full-Report_1.25.17.pdf).

2 The HCCI data in Table 10-3 (p. 302) come from 235 CBSAs served by 3 large private insurers. The identity of each CBSA is masked, and we do not know whether they are representative of Medicare markets with average rates. Therefore, some of the difference between the $105 average Medicare rate for an E&M office visit and the $110 average paid by these insurers could in part be due to the geographic focus of the insurers in the HCCI database. Also, the $110 is an unweighted average, while the weighted average price for an E&M office visit is $118 (data not shown). The weighted average is higher than the unweighted average because larger practices tend to receive higher prices. To see whether the HCCI data are representative of private-payer rates, we compared the $118 average HCCI price with MarketScan data. MarketScan data, which are gathered from a different group of health plans, report a weighted average rate of $116 per E&M visit in 2013, suggesting the HCCI commercial E&M prices are reasonable. Further, certain bonus payments are not included in the Medicare or commercial rates. Omitted bonuses include primary care bonus payments paid by Medicare and quality and/or efficiency bonuses paid by private plans to physicians. Given these data limitations, we focus in Table 10-3 on relative prices, given each provider's bargaining power. These are differences in a single market for a common set of insurers. It is also possible that the $105 is an overestimate of average prices received by small independent practices if the SK&A data fail to identify associations of some physicians with larger practices.

3 Both models approximate the relationship between market share and prices using a linear model; the underlying assumption is that a 1 percent change in market share consistently results in an X percent change in relative prices, all else equal. We also examined other models with quadratic terms, dichotomous variables for distinct levels of market power, and log transformations of prices as the dependent variable. The alternative models yielded similar results. Given the similarity in results, we kept the linear model because of its simple, intuitive interpretation. However, the results are only a reasonable approximation for bargaining units with market shares similar to the population of observations in this study.

4 The Mayo Clinic has a strong reputation for quality, and its hospitals consistently score well on various types of quality metrics. However, it also appears to negotiate high prices. The potential savings from care coordination and potentially lower service use does not appear to be large enough to offset the high prices. Data on expected costs in 2016 from the Minnesota Health Insurance Exchange suggest the influence of the Mayo Clinic on health care costs in Rochester. Specifically, the exchange's 2016 Medica Applause Silver plan had expected annual costs that were 20 percent higher for a 50-year-old male in Rochester than for an identical person on the same plan in St. Paul (MNsure 2016). While the 2017 exchange plans are not exactly comparable in Rochester and St. Paul, the rate for the lowest cost silver plan in Rochester has annual expected costs that were 28 percent higher than the low-cost silver plan in St. Paul with an identical deductible. The result is a higher cost of insurance in Rochester for the insured and for taxpayers who subsidize the exchange plans.

5 To obtain these results, we used the volume of E&M visits in outpatient prospective payment system (OPPS) hospitals, OPPS prices in 2014, and physician fee schedule prices in 2014.

6 An earlier study had suggested that payment incentives for physicians within a plan can affect costs, with the lowest cost being achieved when small groups of physicians personally accept some capitation risk (Kralewski et al. 2000).

7 The 23 percent growth rate in Medicare FFS costs is the cumulative growth in the CMS actuary's estimated cost of the Part A and Part B benefits and the Commission's estimates of the cost of Part D premiums and reinsurance from 2007 to 2016. FFS cost growth would be about 2 percentage points lower (down to 21 percent) if we had accounted for the effect of the sequester. The Medicare FFS growth rate was also not adjusted for improvements in the Part D benefit that included a shrinking of the donut hole. The employer-sponsored HMO premiums grew by 53 percent and PPO premiums by 47 percent, despite rapidly increasing deductibles (Kaiser Family Foundation and Health Research & Educational Trust 2016). While deductibles grew rapidly for both employer-sponsored HMOs and PPOs, they tended to grow fastest for PPOs, possibly explaining why PPO premiums grew at a slightly slower rate than HMO premiums. Neither rate of change adjusts for changes in the demographics of individuals with Medicare FFS or employer-sponsored insurance. We note that the average age of Medicare FFS beneficiaries declined by 0.3 years over this period.

8 Several recent studies suggest that without constraint of Medicare prices, commercial prices would have risen even faster. These studies suggest that restraint of Medicare prices can slightly reduce commercial cost growth (Clemens and Gottlieb 2017, Frakt 2014, White 2013).

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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: Implementing a unified payment system for post-acute care

The Congress should direct the Secretary to:

- implement a prospective payment system for post-acute care beginning in 2021 with a three-year transition;
- lower aggregate payments by 5 percent, absent prior reductions to the level of payments;
- concurrently, begin to align setting-specific regulatory requirements; and
- periodically revise and rebase payments, as needed, to keep payments aligned with the cost of care.

Yes: *Bricker, Buto, Christianson, Coombs, Crosson, DeBusk, Ginsburg, Gradison, Hall, Hoadley, Nerenz, Pyenson, Redberg, Samitt, Thomas, Thompson, Wang*

Chapter 2: Medicare Part B drug payment policy issues

The Congress should change Medicare's payment for Part B drugs and biologicals (products) as follows:

(1) Modify the average sales price (ASP) system in 2018 to:

- require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report.
- reduce wholesale acquisition cost (WAC)-based payment to WAC plus 3 percent.
- require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP.
- require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

(2) No later than 2022, create and phase in a voluntary Drug Value Program (DVP) that must have the following elements:

- Medicare contracts with a small number of private vendors to negotiate prices for Part B products.
- Providers purchase all DVP products at the price negotiated by their selected DVP vendor.
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.
- Beneficiaries pay lower cost sharing.
- Medicare payments under the DVP cannot exceed 100 percent of ASP.
- Vendors use tools including a formulary and, for products meeting selected criteria, binding arbitration.

(3) Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

Yes: *Bricker, Buto, Christianson, Coombs, Crosson, DeBusk, Ginsburg, Gradison, Hall, Hoadley, Nerenz, Pyenson, Redberg, Samitt, Thomas, Thompson, Wang*

Chapter 3: Using premium support in Medicare

No recommendations

Chapter 4: Mandated report: Relationship between physician and other health professional services and other Medicare services

No recommendations

Chapter 5: Redesigning the Merit-based Incentive Payment System and strengthening advanced alternative payment models

No recommendations

Chapter 6: Payments from drug and device manufacturers to physicians and teaching hospitals in 2015

No recommendations

Chapter 7: An overview of the medical device industry

No recommendations

Chapter 8: Stand-alone emergency departments

No recommendations

Chapter 9: Hospital and SNF use by Medicare beneficiaries who reside in nursing facilities

No recommendations

Chapter 10: Provider consolidation: The role of Medicare policy

No recommendations

Acronyms

Acronyms

A–APM	advanced alternative payment models
AASD	American Association of Surgeon Distributors
ACI	advancing care information
ACO	accountable care organization
AdvaMed	Advanced Medical Technology Association
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
AMA	American Medical Association
AMC	academic medical center
AMP	average manufacturer price
AMSA	American Medical Student Association
anti-VEGF	anti-vascular endothelial growth factor
APM	alternative payment model
APRN	advanced practice registered nurses
ASC	ambulatory surgical center
ASHP	American Society of Health-System Pharmacists
ASP	average sales price
ASP + 6 percent	average sales price plus 6 percent
AWP	average wholesale price
B	billion
BBA	Bipartisan Budget Act of 2015
BPCI	Bundled Payments for Care Improvement
CAHPS®	Consumer Assessment of Healthcare Providers and Systems®
CAP	competitive acquisition program
CBO	Congressional Budget Office
CBSA	core-based statistical area
CEO	chief executive officer
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CIVHC	Colorado Center for Improving Value in Health Care
CME	continuing medical education
CMMI	Center for Medicare & Medicaid Innovation
CMP	civil money penalty
CMS	Centers for Medicare & Medicaid Services
CMS–HCC	CMS–hierarchical condition category
CON	certificate of need
CPIA	clinical practice improvement activities
CPI–U	consumer price index for all urban consumers
CPT	Current Procedural Terminology
CRS	Congressional Research Service
CT	computed tomography
DME	durable medical equipment
DOJ	U.S. Department of Justice
DSH	disproportionate share
DTC	direct-to-consumer [advertising]
DVP	[Part B] Drug Value Program
E&M	evaluation and management
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	emergency department
EHR	electronic health record
ESA	erythropoiesis-stimulating agent
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FEHBP	Federal Employees Health Benefits Program
FFS	fee-for-service
FOA	final-offer arbitration
FTC	Federal Trade Commission
FY	fiscal year
GAO	Government Accountability Office
G-CSF	granulocyte-colony stimulating factor
GDP	gross domestic product
GPCI	geographic practice cost index
GPO	group purchasing organization
HCCI	Health Care Cost Institute
HCPCS	Healthcare Common Procedure Coding System
	Healthcare Providers and Systems
HEDIS®	Healthcare Effectiveness Data and Information Set®
HHA	home health agency
HHI	Herfindahl–Hirschman Index
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HMO	health maintenance organization
HOPD	hospital outpatient department
HOS	Health Outcomes Survey
HRRP	Hospital Readmissions Reduction Program
HSA	hospital service area
HWI	hospital wage index
ID	identification
IDE	investigational device exemption
IFEC	independent freestanding emergency centers

IMAP	Institute on Medicine as a Profession
IMD	implantable medical device
IMPACT	Improving Medicare Post-Acute Care Transformation Act of 2014
INTERACT	Interventions to Reduce Acute Care Transfers
IPA	independent practice association
I–PAC	institutional–post acute care
IPPS	inpatient prospective payment system
IRF	inpatient rehabilitation facility
I–SNP	special needs plan for the institutionalized
LCD	local coverage determination
LGF	leukocyte growth factors
LIPSA	low-income premium subsidy amount
LIS	low-income [drug] subsidy
LLC	limited liability corporation
LTCH	long-term care hospital
MA	Medicare Advantage
MAC	Medicare administrative contractor
MACRA	The Medicare Access and CHIP Reauthorization Act of 2015
MA–PD	Medicare Advantage–Prescription Drug [plan]
MBSF	Master Beneficiary Summary File
MCBS	Medicare Current Beneficiary Survey
MedPAC	Medicare Payment Advisory Commission
MedPAR	Medicare Provider Analysis and Review [file]
MHCC	Maryland Health Care Commission
MIPS	Merit-based Incentive Payment System
MOE	maintenance of effort
MSA	metropolitan statistical area
MSP	Medicare Savings Program
MTM	medication therapy management
N/A	not applicable
N/A	not available
NCD	national coverage determination
NDC	national drug code
NEST	National Evaluation System for health Technology
NF	nursing facility
NOC	not otherwise classified
NORC	(formerly) National Opinion Research Center
NP	nurse practitioner
NPI	national provider identifier
NTA	nontherapy ancillary
OCED	off-campus emergency departments
OIG	Office of Inspector General
OOP	out-of-pocket
OPPS	outpatient prospective payment system
PA	physician assistant
PAC	post-acute care
PCP	primary care provider
PCR	payment-to-cost ratio
PDE	prescription drug event
PDMA	Prescription Drug Marketing Act of 1987
PDP	prescription drug plan
PFS	physician fee schedule
PhRMA	Pharmaceutical Research and Manufacturers of America
PMA	premarket approval
POD	physician-owned distributor
PPACA	Patient Protection and Affordable Care Act of 2010
PPO	preferred provider organization
PPS	prospective payment system
PQRS	Physician Quality Reporting System
q	quarter
QI	qualifying individual
QMB	qualified Medicare beneficiary
R&D	research and development
RA	rheumatoid arthritis
RAH–NFR	Reduce Avoidable Hospitalizations among Nursing Facility Residents
RCT	randomized controlled trial
RN	registered nurse
ROA	return on assets
RTI	RTI International
RVU	relative value unit
SGR	sustainable growth rate
SHIP	State Health Insurance Assistance Program
SNF	skilled nursing facility
SNP	special needs plan
SOI	severity of illness
SSA	Social Security Administration
UDI	unique device identifier
VBID	value-based insurance design
WAC	wholesale acquisition cost
WAMP	widely available market price
X12	X12 Incorporated

More about MedPAC

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