REPORT TO THE CONGRESS

Medicare and the Health Care Delivery System

MEDPAC

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Medicare
Payment Advisory
Commission

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

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

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

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

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June 15, 2015

The Honorable Joseph R. Biden
President of the Senate
U.S. Capitol
Washington, DC 20510

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
U.S. Capitol
Room H-232
Washington, DC 20515

Dear Mr. President and Mr. Speaker:

Having served 15 years on the Medicare Payment Advisory Commission (MedPAC), 14 years as chair, I am submitting my final report to the Congress. It has been an honor to serve with more than 50 different commissioners and our extraordinary staff, led by Executive Director Mark Miller.

During my tenure, MedPAC has made more than 300 recommendations to the Congress or the Secretary of Health and Human Services (HHS). Over 5,000 individual votes have been cast by commissioners during my tenure; more than 99 percent have been votes in favor of the recommendation at hand.

This extraordinary consensus is a credit to MedPAC's commissioners and staff. Rather than serve as advocates for their own organizations or for interest groups, commissioners have embraced their role as stewards of Medicare, putting the interests of beneficiaries and taxpayers above all else. MedPAC's staff has provided the foundation for consensus with its incisive and responsive analysis.

We, the commissioners and staff of MedPAC, are privileged to assist the Congress and HHS. I am proud that we have contributed to legislation and regulations such as:

- improving the accuracy of Medicare payments to—among others—rural hospitals, physicians and other health professionals providing primary care, and hospitals that care for severely ill patients;

- setting Medicare payment rates at a level appropriate for efficient providers: those that combine low costs and high quality, not average providers;

- stimulating improvement in care for patients discharged from hospitals by penalizing hospitals with excessive readmissions;
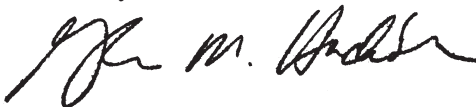
- supporting a choice for beneficiaries between traditional Medicare and private Medicare Advantage plans while creating a more level playing field for competition between those alternatives;

- disclosing financial relationships between physicians and manufacturers of health care products;

- providing financial support for research on the comparative effectiveness of alternative treatments to better guide clinician and patient decisions;

- establishing new methods of payment that encourage and support innovation in health care delivery through, for instance, accountable care organizations, medical homes, and episode-based bundling; and

- taking small but important steps toward breaking down payment "silos" so that Medicare pays the same amount for the same service regardless of the type of provider delivering that service.

Just before this report went to press, the Congress passed a major overhaul of Medicare's methods of paying physicians and other health professionals; the reform legislation includes elements long advocated by MedPAC.

More work remains to be done in other key areas, including site-neutral payment, reform of Medicare's financial support for graduate medical education, and rationalizing Medicare's benefit structure.

I leave MedPAC optimistic about the potential for ongoing improvement in Medicare. To be sure, the issues are challenging: Medicare combines size, complexity, and political sensitivity in a way that few government programs do. Debates about changes, therefore, are often heated and lengthy. Yet my 15 years on MedPAC, combined with another 5 years at HHS and 10 years in the private sector, have shown me that people of talent and goodwill in government and the private sector are committed to making Medicare work for its beneficiaries and the American people. I look forward to future opportunities to contribute to that effort.

Sincerely,

Glenn M. Hackbarth, J.D.

Enclosure

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Executive summary

Executive summary

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

- *Synchronizing Medicare policy across payment models.* In 2012, a third payment model, the accountable care organization, became available in addition to the traditional fee-for-service and Medicare Advantage payment models. Medicare's payment rules and incentives are different and inconsistent across the three payment models. We look at three issues that could help inform the process of synchronizing Medicare policy across payment models.

- *The next generation of Medicare beneficiaries.* The Medicare population is projected to increase from 54 million beneficiaries today to over 80 million beneficiaries by 2030 as the baby-boom generation ages into Medicare. We examine what this expansion means for the Medicare population.

- *Part B drug payment policy issues.* Medicare pays for most Part B drugs at payment rates set at the average sales price plus 6 percent. In 2013, Medicare and its beneficiaries paid more than $19 billion for those drugs, which are furnished by physicians, hospital outpatient departments, and suppliers. We explore two topics related to Medicare payment policy for Part B drugs: (1) a policy that converts all or part of the 6 percent add-on to a flat-fee add-on and (2) estimating the discount on Part B drugs received by hospitals under the 340B Drug Pricing Program.

- *Value-based incentives for managing Part B drug use.* Medicare's payment policies for Part B drugs do not always provide beneficiaries or taxpayers the best value because the policies do not give clinicians incentives to consider evidence of a drug's clinical effectiveness compared with its alternatives. Linking Part B payment for drugs to comparative clinical effectiveness evidence could reduce spending for beneficiaries and taxpayers. We examine several value-based incentives that could result in lower prices for Part B drugs for beneficiaries.

- *Polypharmacy and opioid use among Medicare Part D enrollees.* Studies have found a positive association between polypharmacy (the use of multiple prescription drugs) and adverse health events such as hospitalization and emergency department visits. Individuals ages 65 and older are at high risk for polypharmacy. The use of opioids as part of a multiple drug regimen can substantially affect adherence to prescribed medications and exacerbate health issues. Patterns of medication use by opioid users raise concerns about polypharmacy issues as well as potential overuse and abuse of opioids.

- *Sharing risk in Medicare Part D.* The Part D program uses private prescription drug plans to deliver prescription drug benefits. However, Medicare shares a substantial part of Part D enrollees' insurance risk with drug plans, in part because when Part D was created, one of the goals was to attract plans to enter the program. Now that the program is established, risk sharing may need to be redesigned. As an initial step, we examine the ways in which Medicare shares insurance risk with Part D plans and the patterns of spending that have resulted.

- *Hospital short-stay policy issues.* One-day inpatient stays are relatively common in the Medicare program, accounting for over 1 million inpatient admissions in 2012. Short inpatient stays have been scrutinized by Medicare's auditors because Medicare generally pays more for short inpatient stays than similar outpatient stays, and these inpatient stays are highly profitable. We make several recommendations to improve Medicare policies related to short hospital stays.

- *Next steps in measuring quality of care in Medicare.* In its June 2014 report to the Congress, the Commission put forth a concept for an alternative to Medicare's current system for measuring quality of care that would use a small set of population-based outcome measures. In this report, we examine two quality measurement concepts to determine whether they could eventually be used as such: a "healthy days at home" measure and health-related quality of life measures such as patient-reported outcomes.

In an online appendix (available at http://www.medpac. gov), as required by law, we review CMS's letter

concerning the 2016 fee schedule for physicians and other health professionals.

Synchronizing Medicare policy across payment models

Historically, Medicare has had two payment models: traditional fee-for-service (FFS) and Medicare Advantage (MA). Traditional FFS pays for individual services, such as a hospital admission, according to the payment rates established by the program. By contrast, Medicare pays private plans a per person, or capitated, rate to provide Part A and Part B services. Starting in 2012, Medicare introduced a new payment model—the accountable care organization (ACO)—under which a group of providers can share savings (or in some cases can incur losses) if the spending and quality of care for a defined beneficiary population attributed to them meets (or fails to meet) defined targets. The goal of the ACO program is to give groups of FFS providers incentives to reduce Medicare spending and improve quality, similar to the incentives for MA plans.

Medicare's payment rules and incentives are different and inconsistent across the three payment models. In Chapter 1, we look at three issues that could help inform the process of synchronizing Medicare policy across payment models:

- which model is least costly to the program in 78 markets where all 3 models have significant numbers of beneficiaries;

- how beneficiary premiums and the federal contribution might vary in each market for each model under different premium designs; and

- how "coding" (i.e., the reporting of a beneficiary's diagnoses at each encounter) affects payments, bids, and the measurement of quality.

These three aspects of synchronization raise important issues of equity and implementation that need to be resolved to reach the goal of maximizing the value of the Medicare program to its beneficiaries and taxpayers. We need to determine how to set payment rules that reward the most efficient model of care in a market, how to encourage beneficiaries to be in that model, and how to provide the information they need to make an informed decision.

We find that each of the three models is the least costly in some set of markets and that all serve a function in the current system. MA plans have the potential to reduce

excessive use in many high-service-use markets, provide greater care coordination, and provide supplemental benefits. ACOs have modestly reduced costs in markets with high service use and give beneficiaries a choice of providers. FFS continues to be the low-cost option in many low-service-use areas and gives a choice of providers. In addition, FFS hospital prices serve as a reference point for the prices MA plans pay hospitals.

Medicare should seek to encourage beneficiaries to choose the more efficient model while maintaining equity for beneficiaries across markets. (Beneficiaries in ACOs are part of FFS Medicare; thus, there are two models—FFS and MA—in the discussion of premiums.) We look at how beneficiary premiums and federal contributions might vary in each market for each model under three illustrative examples:

- a nationally set base premium that pays for FFS Medicare in every market,

- a nationally set base premium that pays for either FFS Medicare or the reference MA plan—whichever costs less—in each market, and

- locally set base premiums that pay for either FFS Medicare or the reference MA plan—whichever costs less—in each market.

We examine how coding affects bids, payments, and quality measurement. Plans bid for a beneficiary at average risk. A beneficiary's risk score (which incorporates the record of selected diagnoses and some additional factors) is multiplied by a base payment rate to determine a plan's payment. Thus, coding directly influences payment. Coding also affects how quality is measured and rewarded: directly for risk-adjusted quality outcomes and, for other quality measures, by defining the set of beneficiaries considered.

The next generation of Medicare beneficiaries

The Medicare population is projected to increase from 54 million beneficiaries today to over 80 million beneficiaries by 2030 as the baby-boom generation ages into Medicare. In Chapter 2, we examine what this expansion means for the Medicare population. The average age of the Medicare population will initially skew younger than in the recent past, but will then rapidly increase. Members of the baby-boom generation have longer life expectancies, smoke at lower rates, and have higher rates of chronic conditions

such as obesity and diabetes; however, they are more likely to have certain health conditions under control.

Baby boomers will also bring a different health insurance experience to the program. Although the oldest boomers may have had plans that paid for any provider, many baby boomers likely experienced the rise and decline of managed care, and many have had preferred provider plans with broad provider networks. Younger boomers may have begun to experience narrow-network plans, high-deductible plans, and the federal and state health insurance exchanges. In addition, it is likely that in the future, fewer Medicare beneficiaries will have generous employer-sponsored supplemental health insurance.

The recent recession has taken a toll. Median family income, median family net worth, and the median value of financial assets have not recovered to their prerecession levels. Perceptions of economic well-being are also still low. Some baby boomers may have difficulty recouping their losses before entering retirement. That could leave the next generation of Medicare beneficiaries in a more vulnerable economic state than the current Medicare population.

The aging of the baby-boom population could also stress the economic well-being of the working-age population. The number of tax-paying workers per Medicare beneficiary has declined from 4.6 during the early years of the program to 3.1 today. The Medicare Trustees project that this number will decline to 2.3 by 2030. Additionally, Medicare's reliance on general revenues is projected to increase from 41 percent of program costs today to 45 percent of program costs in about 15 years.

Part B drug payment policy issues

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments and certain drugs provided by suppliers. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). In 2013, Medicare and its beneficiaries paid more than $19 billion for Part B–covered drugs whose payment rates were set under the ASP + 6 percent policy. Chapter 3 explores two topics related to Medicare payment policy for Part B drugs.

The first topic relates to the general payment methodology for Part B drugs: ASP + 6 percent. ASP is the price realized by a manufacturer for its drug for sales to all purchasers (with certain exceptions) net of rebates,

discounts, and price concessions. Medicare pays providers ASP + 6 percent for the drug regardless of the price a provider pays to acquire the drug. This policy gives the provider a financial incentive to seek to pay the lowest available price for a given drug.

However, concern has been expressed that the 6 percent add-on to ASP may create incentives for use of higher priced drugs when lower priced alternatives are available. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selecting the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs. An alternative policy would convert part or all of the 6 percent add-on to a flat-fee add-on. A flat-fee add-on would increase payments for lower priced drugs and reduce payments for higher priced drugs compared with current policy.

Moving to a flat-fee add-on could have a number of effects. It might increase the likelihood that a provider would choose the least expensive drug in situations where differently priced therapeutic alternatives exist, potentially generating savings for Medicare beneficiaries and taxpayers. A flat-fee add-on would also reduce payment rates for very expensive drugs. As a result, some providers might find it difficult to buy those drugs, but that would depend on how the policy is structured and how drug manufacturers' pricing decisions respond to the policy.

The second topic regards estimating the discount on Part B drugs received by hospitals under the 340B Drug Pricing Program. The 340B program allows some hospitals (and certain other providers) to obtain discounted prices on covered outpatient drugs from drug manufacturers. Medicare pays the same rates (ASP + 6 percent) for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at steep discounts. Similarly, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate for outpatient drugs received at both types of hospitals.

Although 340B prices are proprietary, we estimate that the *minimum* discount that 340B hospitals receive for drugs paid under the outpatient prospective payment system (OPPS) is 22.5 percent of the drugs' ASP, on average. We also estimate that in 2013, 340B hospitals for which we have data received about $3.2 billion in Medicare revenue for drugs paid under the OPPS; by our estimate, those hospitals paid at most $2.4 billion to acquire those drugs.

Even though 340B hospitals are able to purchase outpatient drugs at a price that is, on average, at least 22.5 percent below ASP, Medicare still pays ASP + 6 percent. Given the high level of Medicare payments relative to 340B hospitals' drug acquisition costs, policymakers might consider whether Medicare should pay less than ASP + 6 percent for Part B drugs purchased by those hospitals. Alternatively, even if Medicare's program payment does not change, beneficiaries' cost sharing for 340B drugs could be reduced. Reducing payment rates or beneficiary cost sharing for Part B drugs provided by 340B hospitals would save money for Medicare beneficiaries and taxpayers, but it would also decrease the revenue those hospitals receive, which may reduce their participation in the 340B program.

Value-based incentives for managing Part B drug use

Medicare's payment policies for Part B drugs do not always provide beneficiaries or taxpayers the best value because the policies do not give clinicians incentives to consider evidence of a drug's clinical effectiveness compared with its alternatives. Linking Part B payment for drugs and biologics to comparative clinical effectiveness evidence could reduce spending for Medicare beneficiaries and taxpayers. In Chapter 4, we examine several value-based incentives that could result in a lower price for Part B drugs and biologics for beneficiaries than the current FFS price:

- *The least costly alternative (LCA) and functional equivalence policies* that Medicare used from 1995 to 2010. Under this approach, the program set the payment rate for a group of drugs with similar health effects based on the payment rate of the least costly product in the group.

- *A consolidated payment code approach* that Medicare used from 2007 to 2008. Under this approach, the program grouped drugs with similar health effects into a single payment code and set payment based on the volume-weighted average of the average sales price for each product.

- *A bundled approach*, which would cover drugs and their administration costs as well as related services (e.g., inpatient admissions, emergency department visits) across all settings and providers during a defined period under one payment (or a benchmark price across multiple providers). We examine designing oncology bundles because Medicare spending for oncology drugs

and biologics accounted for about half of 2013 Part B drug spending in physicians' offices.

These three approaches are intended to improve efficiency by creating incentives for providers to choose lower cost products within a category of products with similar health effects. The first two approaches would require the Congress to restore the Secretary's authority to establish the LCA or consolidated payment code policies. The bundling approach could be pursued by the Center for Medicare & Medicaid Innovation under its authority, or the Congress could mandate that CMS implement a bundling initiative.

For LCA and consolidated payment code approaches, Medicare would need to consider and address a number of design questions and issues including defining groups of products that treat a given condition with similar health effects, standardizing units and frequency of drug administration, and calculating and updating the payment rate. Implementing a bundled approach would include defining the bundle's scope of services, the duration of a treatment bundle, the event that triggers the use of the payment bundle, and the type of payment.

Polypharmacy and opioid use among Part D Medicare enrollees

In Chapter 5, we discuss how use of multiple drugs (polypharmacy) can affect patients' medical conditions and lead to additional service use. Adverse effects of polypharmacy can occur when a patient is prescribed more drugs than are clinically warranted or when all prescribed medications are appropriate, but the total is too many for the patient to manage.

Studies have found a positive association between polypharmacy and adverse events, such as hospitalization and emergency department visits and nonadherence to appropriate medications. Individuals ages 65 and older are at high risk for adverse events associated with polypharmacy in part because there are few clinical guidelines pertinent to prescribing and managing multiple prescription drugs among members of this population, who are more likely to suffer from multiple chronic conditions. Medication errors are most likely to occur when a drug regimen is modified (e.g., when a patient transitions from hospital to home), when a patient does not understand drug administration instructions, and when a patient does not follow clinical advice.

When opioids are included as part of a multiple drug regimen, problems related to adherence and adverse drug

events (ADEs) are more likely. Opioid use itself can lead to many ADEs, including unintentional overdoses. In addition, the side effects associated with opioids can interfere with the treatment of comorbid conditions not associated with pain.

Patterns of medication use by Part D enrollees who use opioids raise concerns about polypharmacy issues and effects on their health. In 2012, over one-third of Part D enrollees filled at least one prescription for an opioid. Opioid users filled an average of 52 prescriptions per year, including opioids, from about 10 drug classes. Enrollees with the highest use of opioids filled an average of 23 opioid prescriptions in that year. Those with very high use of opioids were more likely to be disabled beneficiaries under age 65 who received Part D's low-income subsidy. The Agency for Healthcare Research and Quality reported an 80 percent increase in the number of inpatient stays related to opioid overuse by Medicare beneficiaries between 2006 and 2012.

There has not been robust research on programs to reduce polypharmacy. In the case of opioids, some have suggested limiting the number of prescribers per patient or requiring patients to fill their prescriptions at one or two pharmacies. For more general polypharmacy issues, there has been only a limited discussion of potential policy options.

Sharing risk in Medicare Part D

The Part D program uses private stand-alone prescription drug plans (PDPs) and Medicare Advantage–Prescription Drug (MA–PD) plans to deliver prescription drug benefits. Plan sponsors must bear insurance risk for the benefit spending of their enrollees. However, as part of the initial design of Part D, Medicare shares a substantial portion of that risk with Part D plans. Chapter 6 examines the ways in which Medicare pays and shares insurance risk with Part D plans.

Part D incorporates several risk-sharing mechanisms. Medicare pays plans a per member per month amount, called the direct subsidy, which reduces premiums for all enrollees. Plan sponsors risk losing money if their enrollees' drug spending is higher than the combination of direct subsidy payments and enrollee premiums. CMS risk adjusts direct subsidy payments to counteract incentives for sponsors to avoid enrollees who use more drugs. Medicare also pays plans individual reinsurance equal to 80 percent of covered spending above the Part D benefit's catastrophic threshold. In addition, Part D has symmetric risk corridors that limit each plan's overall losses or profits

if actual spending for benefits is much higher or lower than anticipated.

Before the start of Part D, stand-alone PDPs did not exist. Individual reinsurance and risk corridors were included in the initial design of Part D to help ensure plan entry and formation of competitive markets across the country. Today, however, the Part D program has matured, and Medicare beneficiaries have many options to enroll in both PDPs and MA–PDs. Competition has kept growth in average Part D premiums fairly low over time. Similarly, Medicare spending for direct subsidy payments, on which plans bear the most insurance risk, has grown slowly. However, benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides individual reinsurance) has grown much faster. This contrast suggests that sponsors have been less successful at cost containment when they faced less risk.

Medicare makes prospective payments to Part D plans based on sponsors' bids. At the end of each benefit year, CMS reconciles prospective payments from Medicare with actual benefit costs that plans paid and then applies a statutory formula for risk corridors. Medicare's reconciliation and risk-corridor payments reveal regular patterns:

- Many plan sponsors have tended to bid too low on the amount of benefit spending they expect above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. In recent years, a majority of plan sponsors received additional money from Medicare at reconciliation because their prospective payments for individual reinsurance were too low.

- Plan sponsors have bid too high on the rest of benefit spending other than catastrophic benefits. Between 2009 and 2013, about three-fourths of parent organizations returned overpayments to Medicare through risk corridors.

Plan actuaries suggest that there are significant uncertainties affecting the amount of catastrophic drug spending their plans' enrollees will accrue that may help explain some of the observed trends in plan payments. However, it bears noting that, by underestimating catastrophic spending, plan sponsors may be able to charge lower premiums to enrollees and later get reimbursed by Medicare for 80 percent of actual catastrophic claims through additional reinsurance at reconciliation. As a practical matter, an individual sponsor is only one of many

sponsors whose bids collectively affect the amounts that Medicare pays in prospective payments. Still, Medicare's reconciliation payments show consistent patterns rather than the randomness one might expect from projection errors in the actuarial assumptions behind bids.

Policymakers may want to consider changes in Part D's risk-sharing mechanisms that better reflect today's policy goals for the program. Given what appears to be a strong market for stand-alone drug plans, it may be time to emphasize policy approaches that encourage plan sponsors to better manage drug benefits for higher cost enrollees over policies designed to encourage or sustain plan entry. While the chapter does not make specific recommendations, it does examine options such as requiring plans to include more of the costs of catastrophic spending in their covered benefits and changing the current structure of the risk corridors. By exposing plans to greater risk, plan sponsors would have stronger incentives to manage benefit spending. Several program modifications may be necessary at the same time to balance concerns about cost control and incentives for selection behavior—especially with respect to plan sponsors' willingness to enroll individuals who receive the low-income subsidy.

Hospital short-stay policy issues

One-day inpatient hospital stays are relatively common in the Medicare program, accounting for over 1 million inpatient admissions (13 percent of the total) in 2012. Short inpatient stays are a matter of concern because Medicare generally pays more for short inpatient stays than similar outpatient observation stays, and those inpatient stays are highly profitable. In Chapter 7, we make several recommendations to improve Medicare policies related to short hospital stays.

Medicare recovery audit contractors (RACs) have targeted short inpatient stays in their audit efforts, resulting in denials of these claims on the grounds that the patient's status as an inpatient was not appropriate. Partly in reaction to the heightened scrutiny of short inpatient stays, hospitals have increased their use of observation status instead of admitting patients. Greater use of outpatient observation stays has caused concern about beneficiaries' financial liability. While Medicare cost sharing for outpatient observation services is typically less than the inpatient deductible, for a subset of beneficiaries, the greater use of outpatient observation status has increased the likelihood that they will not qualify for Medicare coverage of post-acute skilled nursing facility (SNF) services (which requires a preceding three-day hospital

inpatient stay). Beneficiaries in observation status may also be liable for hospital charges related to prescription drugs received in the hospital and not covered by the Medicare outpatient prospective payment system.

In an effort to clarify admission appropriateness and alleviate concerns about increased use of observation, its impact on beneficiary liability, and hospitals' concerns about RAC audits, CMS established the "two-midnight rule" in fiscal year 2014. That rule stipulates that for stays spanning two or more midnights (including time spent in the inpatient and outpatient settings), RACs should presume these stays are appropriate for the inpatient setting and exempt them from audit. By contrast, stays of less than two midnights remain subject to audit. Hospitals have concerns about the two-midnight rule because it conflicts with existing admission criteria deferential to physician judgment and increases the burden associated with physician documentation of inpatient admissions. The two-midnight rule has been controversial, and its enforcement has been delayed by both CMS and the Congress.

Short inpatient stays have been scrutinized by RACs because Medicare generally pays more for short inpatient stays than similar outpatient observation stays and these inpatient stays are highly profitable for hospitals (conversely, their denial is profitable for the RACs). To address the payment difference between these stays, the Commission explored two approaches. Under the first approach, Medicare could create—as part of its inpatient payment system—a new set of Medicare severity–diagnosis related groups specifically designed for the one-day inpatient hospital stay. Under the second approach, Medicare could develop a site-neutral payment—that is, equalize payments across settings—for similar short inpatient and outpatient stays. We identify the advantages and disadvantages of each.

The Commission makes the following recommendations to improve hospital short-stay policy:

- **The RAC program:** The Commission makes a four-part recommendation to the Secretary to withdraw CMS's two-midnight rule, focus the RACs' review on hospitals with a high use of short stays, improve the accountability of the RACs for the claims they deny, and synchronize the timing of RAC reviews and the hospital rebilling program.

- **Hospital short-stay payment penalty:** The Commission recommends that the Secretary evaluate the development of a payment penalty for hospitals

with excess rates of short inpatient stays to substitute, in whole or in part, for RAC review of short inpatient stays.

- *Beneficiary financial liability:* The Commission makes three recommendations that would protect Medicare beneficiaries from financial vulnerabilities resulting from being placed in observation status. The Commission recommends revising the SNF eligibility requirement of three inpatient hospital days to allow for up to two outpatient observation days to count toward meeting the criterion, requiring hospitals to notify beneficiaries placed in outpatient observation status that their status may affect their financial liability for SNF care, and packaging payment for self-administered drugs provided during outpatient observation within the hospital outpatient payment system on a budget-neutral basis.

Next steps in measuring quality of care in Medicare

In its June 2014 report to the Congress, the Commission put forth a concept for an alternative to Medicare's current system for measuring the quality of care. Medicare's current quality measurement programs rely primarily on clinical process measures for assessing the quality of hospitals, physicians, and other types of providers. This approach may contribute to uncoordinated and fragmented care while burdening providers and CMS with costs of gathering, validating, analyzing, and reporting on process measures that have little value to beneficiaries and policymakers.

Under the alternative discussed in the 2014 report, Medicare would use a small set of outcome measures to evaluate quality at the population level in a local area under each of Medicare's three payment models—traditional FFS, MA, and ACOs. Examples of such measures include rates of potentially preventable hospital admissions and emergency department visits, readmissions, mortality, and patient experience measures.

Chapter 8 examines two quality measurement concepts that we are evaluating to determine whether they could fit into this small set of population-based outcome measures: "healthy days at home" and health-related quality of life measures such as patient-reported outcomes. Our initial analysis of healthy days at home as a measure using Medicare claims data suggests that such a concept may be a meaningful way to compare differences in relative health status across populations, in a way that would be relatively easy for beneficiaries, policymakers, and other stakeholders to understand. Our preliminary analysis found that the measure's ability to detect differences between populations is magnified when it is focused on beneficiaries who are diagnosed with one or more chronic conditions and that the results are sensitive to the types of service use included in the measure—broadly, post-acute care use and, in particular, the use of home health services. Patient-reported outcome measures also may have value in distinguishing quality among traditional FFS, MA, and ACO populations within a local area. More research is needed before reaching conclusions about the use of either of these measures in Medicare. ∎

Synchronizing Medicare policy across payment models

Synchronizing Medicare policy across payment models

Chapter summary

Historically, Medicare has had two payment models: traditional fee-for-service (FFS) and Medicare Advantage (MA). Traditional FFS pays per service for services covered under Part A and Part B, according to rates established by the program. In contrast, MA pays private plans a per person, or capitated, rate to provide Part A and Part B services. Starting in 2012, Medicare introduced a new payment model, the accountable care organization (ACO), under which a group of providers can share savings (or in some cases incur losses) if the spending and quality of care for a defined beneficiary population attributed to them meets (or fails to meet) defined targets. The goal of the ACO program is to give groups of FFS providers incentives to reduce Medicare spending and improve quality, similar to the incentives for MA plans.

Currently, Medicare has different rules for each payment model, creating payment inequities and inefficiencies for beneficiaries and taxpayers. Setting consistent rules across the three payment models could promote competition among MA plans, ACOs, and FFS, potentially generating several benefits. Because of that potential, the Commission studied three questions that could help inform the process of synchronization (that is, the process of setting payment rules, quality measures, and incentives that are consistent across all three models): (1) which payment model has the lowest program spending in markets where all three models have a significant number of beneficiaries, (2) how beneficiary premiums and the federal contribution could vary in each

In this chapter

- Introduction
- Comparing FFS, ACO, and MA spending within markets
- Determining beneficiary premiums
- The effect of coding on payments, bids, and quality
- Conclusion

market for each model under different premium designs, and (3) how differences in providers' strategies for "coding" claims (i.e., the reporting of a beneficiary's diagnoses at each encounter) affect payments for services, MA plans' bids, and the measurement of quality.

The Commission found that each of the three models is the least costly in some set of markets and all serve a function in the current system. MA plans have the potential to reduce excessive use in many high-service-use markets, provide greater care coordination, and provide supplemental benefits or premium reductions. ACOs have modestly reduced costs in markets with high service use and provide beneficiaries a choice of providers. FFS continues to be the low-cost option in many low-service-use areas and gives a choice of providers. In addition, FFS hospital prices serve as a reference point for the prices MA plans pay hospitals.

With respect to premium design, Medicare should seek to encourage beneficiaries to choose the most efficient option for receiving Medicare benefits while maintaining equity for beneficiaries across markets. To examine the potential effect of premium design on beneficiary choice, the Commission constructed three illustrative premium designs and studied their potential to encourage beneficiaries to choose the more efficient delivery model. (Because beneficiaries in ACOs are part of FFS Medicare, only two of Medicare's payment models—FFS and MA—were relevant to the analysis of premiums.) The designs the Commission constructed included the following:

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

Under each design, beneficiaries can choose either FFS or MA, but the premium they pay differs. In addition, the federal contribution is financially neutral across payment models—that is, equal for FFS and MA in each market. An analysis of the designs raised two important issues: how potential savings in program spending from beneficiaries choosing the lower cost model could be shared and how the financial risk of variation in Medicare spending across markets could be shared.

Medicare's coding system for reporting patients' diagnoses also plays an important role in efforts to synchronize policy because Medicare links MA payments to patients' reported diagnoses. Owing to discretion in coding, providers' coding practices differ between MA and FFS and among MA plans. The difference can result in disparate payments for patients of roughly the same health status. In the

effort to equalize payments across models, issues that center on FFS and MA providers' coding strategies need to be addressed since coding affects not only payments but also MA plans' bids and quality measurement in each model. Steps that could be taken to ensure more equitable coding across payment models could include making coding adjustments plan-specific and tightening rules for acceptable coding.

Synchronization raises important issues of equity and implementation that need to be resolved to maximize the value of the Medicare program to its beneficiaries and taxpayers. We need to determine how to set payment rules that reward the most efficient model of care in a market, how to encourage beneficiaries to be in that model, and how to provide the information they need to make informed decisions. ∎

Introduction

Under the current Medicare program, there are three payment models: traditional fee-for-service (FFS), Medicare Advantage (MA), and accountable care organizations (ACOs). Traditional FFS pays providers for individual services (or in some cases for a set of services, e.g., an inpatient hospital stay), according to the payment rates established by the program. By contrast, under MA, Medicare pays private plans a risk-adjusted per person (capitated) payment rate to provide the Part A and Part B benefit package to plan enrollees.[1] Starting in 2012, Medicare introduced a third payment model: the ACO. Under the ACO model, a group of providers is accountable for the spending and quality of care for a group of beneficiaries attributed to them. The goal of the ACO program is to give groups of FFS providers incentives to reduce Medicare spending and improve quality, similar to the incentives for MA plans. However, currently, only some ACOs bear risk; most share only savings, not losses.

In the traditional FFS Medicare and ACO models, beneficiaries essentially have no restrictions on choice of provider. In the MA model, the MA plan can restrict choice to a specified network of providers; beneficiaries receiving care from providers outside the network pay more. In this respect, MA plans are more like commercial plans commonly available to the working-age population.

Under current law, Medicare's payment rules, quality improvement measures, and incentives are different and inconsistent across the three payment models (see text boxes on the MA payment model and the ACO payment models, p. 8 and p. 9). There are various approaches to achieving consistency. In its June 2014 report, the Commission focused on setting a common spending benchmark for MA plans and ACOs based on local FFS spending. That report's focus on equal benchmarks as a key element of synchronizing Medicare policy across payment models represented a refinement of the principle of financial neutrality between FFS and MA. In this chapter, we further refine our concept of payment neutrality to be equal federal contributions across payment models in a local market. We find this redefinition necessary because, in the beneficiary-premium discussion, we look at examples in which the lower of local FFS spending or MA plan bids determines the reference point for the federal contribution and beneficiary premium.

Several benefits could arise from competition among MA plans, ACOs, and FFS if payment rules, quality measures, and incentives were synchronized. First, beneficiaries could choose a system of care delivery and providers that match their preferences. Second, competition between the models could expose inefficiencies and drive market share away from the inefficient models. For example, if the traditional FFS system has had difficulty controlling utilization in some markets, MA plans may be able to out-compete traditional FFS. Similarly, if FFS has lower costs than MA plans in some markets, they will be able to take market share from higher cost MA plans (or plans may exit the market). If ACOs can generate better care coordination than FFS and have lower overhead than MA plans, then their physicians may be able to offer a level of service that attracts patients away from MA and traditional FFS physicians. By having all models compete, beneficiaries in each market can choose which model provides them the best value.

The Commission has for many years supported giving Medicare beneficiaries a choice between traditional FFS and private plans under MA. The original goals for private plans in Medicare were to provide a mechanism for introducing innovation into the program while constraining Medicare spending. Private plans have greater flexibility to develop innovative approaches to care and can more readily use care-management tools and techniques than CMS. Those abilities could enable private plans to reduce spending and improve the quality of health care services. In turn, Medicare beneficiaries' ability to choose between traditional FFS and MA plans could lead to greater efficiency for the program if Medicare payments to plans were reduced to capture some of those gains. However, as the Medicare program adopted the goal of making MA plans available to all beneficiaries—even in markets where plans are not able to effectively compete with FFS based on cost—plan payments were increased above FFS levels, not reduced. Higher payments resulted in higher MA enrollment, but with some plans bringing higher costs and little or no innovation to the program.

As MA benchmarks are transitioning to levels that are closer to FFS as required by the Patient Protection and Affordable Care Act of 2010 (PPACA), plans have reduced their bids relative to FFS. But on average, taxpayers and beneficiaries continue to subsidize the

Under current law, Medicare Advantage (MA) plans are required to cover all Medicare Part A and Part B benefits except hospice. With some exceptions, all MA plans must also offer an option that includes the Part D drug benefit, although payments for the Part D benefit are handled separately. Plans may supplement Medicare benefits by reducing cost-sharing requirements, providing coverage of non-Medicare benefits, enhancing the Part D drug benefit, or providing a rebate for all or part of the Part B or Part D premium.

For each county, CMS sets the MA benchmark. An MA plan's payment from Medicare is based on how its bid compares with the local MA benchmark, which represents the maximum amount Medicare will pay to a plan per MA enrollee in a given area. The plan's bid reflects its costs to cover the Part A and Part B benefit package for a beneficiary of average health status and includes plan administrative costs and profit. The local MA benchmark represents a bidding target and is set using statutory formulas that start with local FFS spending and make certain adjustments that increase benchmarks in low-spending

areas and reduce them in high-spending areas. In addition, benchmarks are adjusted upward if the plan has a high quality ranking. If a plan's bid is above the benchmark, then the plan receives a payment equal to the benchmark, and enrollees in that plan have to pay a base plan premium—in addition to the Part B premium—that equals the difference between the bid and the benchmark. If a plan's bid is at the benchmark, then the payment equals the benchmark. If a plan bid is below the benchmark, then the plan receives a payment equal to its bid plus a "rebate." The rebate is a fixed percentage—50 percent, 65 percent, or 70 percent, depending on a plan's quality ranking—of the difference between the plan's risk-adjusted bid and risk-adjusted benchmark, with risk adjustment reflecting the expected spending of the plan's projected enrollment. Once the rebate dollars are determined, the plan must return the rebate to its enrollees in the form of supplemental benefits or lower premiums. A more detailed description of the MA payment system can be found at http://medpac. gov/documents/payment-basics/medicare-advantage-program-payment-system-14.pdf?sfvrsn=0. ∎

MA program through higher taxes and higher Part B premiums. In its March 2015 report to the Congress, the Commission estimated that MA plans currently cost the Medicare program, on average, 105 percent of FFS program costs. (The relative costliness of MA and FFS varies substantially across local markets.)

In this chapter, we first extend our examination, begun in previous reports, of which payment model has the lowest program spending in different markets across the country. Next, with the goal of encouraging Medicare beneficiaries to choose the model with the highest value, we look at how beneficiary premiums and federal contributions might vary in each market for each model under different approaches to calculating premiums. Third, we consider how "coding" (i.e., the reporting of a beneficiary's diagnoses at each encounter) could affect payment, bidding, and quality measurement.

Comparing FFS, ACO, and MA spending within markets

To compare Medicare-program spending across FFS, ACOs, and MA plans, we examined data for 78 markets (defined as core-based statistical areas (CBSAs) within a state) that each have more than 5,000 beneficiaries enrolled in MA plans and more than 5,000 beneficiaries attributed to ACOs. Our beneficiary sample consisted of 5.5 million beneficiaries in MA plans and 1.7 million beneficiaries in ACOs (accounting for about 70 percent of Medicare's ACO beneficiaries as of January 2013).

We compared the relative program spending on Medicare MA plans and FFS Medicare using MA benchmark data, MA bid data, and expected FFS spending data from the MA plans' 2015 bids. We aggregated these data by county in the 78 markets. We expressed the average MA program

The accountable care organization payment models

There are two models of accountable care organizations (ACOs): the Pioneer ACO and the Medicare Shared Savings Program (MSSP) ACO. (A third model, the Next Generation ACO model demonstration, is scheduled to begin January 1, 2016.)

The mechanics of how ACOs are compensated differ from MA plans. MA plans enroll beneficiaries and receive monthly capitated payments based on their benchmark and bids. The MA plans pay providers and retain the difference between payments from the Medicare program and their payments to providers (or the plans bear a loss if health care costs exceed the Medicare capitation). For ACOs, the Medicare program directly pays providers fee-for-service (FFS) rates. The ACO is paid shared savings based on the difference between what the program paid to providers and the ACO's benchmark (if actual program payments are below the ACO's benchmark and quality targets are met). In the end, the MA plans and ACOs at risk both face similar financial incentives. However, ACOs avoid the extra cost of enrolling beneficiaries and paying claims, while MA plans face these extra overhead costs. Although there is a cost to enrollment and paying claims, the MA plans can undertake utilization management activities such as requiring prior authorization for some services. MA plans also have the flexibility to pay for innovative care delivery models that do not fit Medicare FFS regulations (e.g., home health for non-homebound individuals, a skilled nursing facility stay without a prior three-day hospital stay) and can restrict beneficiaries to a limited network of providers. CMS has waived some of these rules, such as the three-day rule, for Pioneer ACOs and recently discussed waiving some for MSSP ACOs that take two-sided risk (Centers for Medicare & Medicaid Services 2014). By expanding the tools that ACOs can use to control spending and improve coordination, the hope is they can generate value for beneficiaries and taxpayers.

Unlike MA benchmarks, ACO benchmarks reflect historical FFS spending incurred by beneficiaries treated by the ACOs' physicians. In 2015, the benchmark for ACOs roughly represents the expected spending level to be incurred by the ACO's beneficiaries, above which penalties are applied (in a model with two-sided risk) and below which savings are accrued and shared among the ACO's providers. An ACO's target spending, or benchmark, is calculated as follows. First, a subset of FFS beneficiaries is attributed to the ACO, based on its three years' claims history. (Unlike in MA plans, beneficiaries do not enroll in ACOs.) Second, an ACO's baseline spending is set equal to a weighted average of FFS spending for those beneficiaries over three years. Finally, the baseline spending is trended forward based on national trends in spending growth.

At the end of each year, an ACO's actual spending is calculated as the sum of all FFS spending for the ACO's beneficiaries for the year, even if some of those beneficiaries get their care from non-ACO providers during the year. If the actual spending for the ACO's beneficiaries is below the benchmark (and in some cases exceeds a minimum difference), the difference is divided between the ACO and the Medicare program as shared savings. (The percentage of shared savings that accrues to the ACO ranges from 50 percent to 75 percent.) Most ACOs do not bear any downside risk. ∎

spending (including the cost of extra benefits) as a share of FFS program spending (i.e., MA program spending / expected FFS spending). We used MA plans' 2015 bid data to have the most recent information for MA and FFS.

The most recent ACO data we have from CMS is for 2013. We compute a measure of "savings" as the difference between expected FFS spending for the ACO beneficiaries and the sum of actual FFS spending and bonuses paid to the ACOs in the fiscal year.[2] We expressed the average ACO-program spending as a share of expected FFS program spending (i.e., ACO program spending / expected FFS spending for the ACO's beneficiaries).

For this analysis, we estimated the relative costliness of the three payment models by comparing the relative savings from ACOs with the relative savings from MA plans in those markets.[3] We considered ACOs with larger savings compared with MA plans in the same market to be that market's low-cost model. Similarly, we considered

T he 78 markets we examined have 21 million Medicare beneficiaries, representing 40 percent of all beneficiaries. After excluding individuals in employer-sponsored MA plans, MA special needs plans, and MA cost plans to allow for greater comparability between ACOs and typical MA plans, 19 million beneficiaries remained in our sample of 78 markets. The markets were distributed geographically across the United States and included areas with high and low levels of service use per beneficiary. Average service use in the 78 markets equaled the national average; service use ranged from 83 percent to 139 percent of the national average, similar to the national distribution. The 78 markets included all markets in which MA plans generated savings of more than 5

percent, with the exception of Miami-Dade, which was excluded because it had fewer than 5,000 ACO beneficiaries in 2013.

MA penetration in the 78 markets was similar to the national average. ACO penetration in the markets averaged 9 percent. ACO penetration has since increased beyond 9 percent because additional ACOs joined the program in 2013, 2014, and 2015. In general, the 78 markets in this study were representative of urban markets in the United States. However, our sample included few rural beneficiaries since rural areas were less likely to have at least 5,000 MA and 5,000 ACO beneficiaries. ∎

MA plans with larger savings compared with ACOs in a market to be that market's low-cost model. If a market's MA plans and ACOs both failed to show savings, we considered traditional FFS to be the market's low-cost model. We compared ACOs' savings from 2013 and MA plans' expected savings from 2015 because these are the most recent data for the payment models and the MA bids reflect benchmarks that are closer to FFS spending than benchmarks were in 2013. To the extent that ACO performance improves from 2013 to 2015, future relative savings from ACOs may be somewhat underestimated.

ACO and MA savings were concentrated in high-service-use markets

In comparing markets' expected FFS spending with their MA plans' and ACOs' spending, we found that savings were concentrated in high-service-use markets (Table 1-1).[4] ACOs did not generate material savings for the Medicare program in 2013 after we accounted for bonuses paid to the ACOs that generated savings. Likewise, MA plans—on average—did not generate savings for the program after we accounted for the payments to MA plans to fund supplemental benefits and the effect of quality bonuses on benchmarks. In fact, MA plans were 5 percent more costly on average than FFS.

A primary function of ACOs and MA plans is to improve coordination of care and eliminate unnecessary service use.

Our hypothesis is that those actions are easier to take in markets with high levels of FFS service use. We measured service use across all Medicare Part A and Part B services (e.g., hospital, physician, and post-acute care services and durable medical equipment) and divided the 78 markets into service-use quartiles as measured by FFS utilization (Table 1-1). In low-service-use markets, ACO and MA spending were 1 percent and 13 percent, respectively, above expected FFS spending. The higher MA spending reflects payment benchmarks in 2015 that were well above FFS, allowing bids and payments above FFS. In the 19 markets with the highest service use, ACOs and MA plans both generated savings averaging 2 percent. In the case of ACOs, savings were sufficient to pay ACOs their performance bonuses (which may be used in part to fund the ACO's care coordination costs) and save the program 2 percent. In the case of MA plans, savings were sufficient to fund some of the MA plans' supplemental benefits and yield 2 percent savings for the Medicare program.

While the MA savings for the Medicare program were modest in most markets, in 10 of the markets, MA plans generated net savings for the Medicare program of over 5 percent (the maximum was 8 percent). In many of these high-service-use markets, MA plans were able to generate program savings and provide substantial extra benefits for Medicare beneficiaries—for instance, reduced cost sharing or lower premiums for Part D drug coverage. In their bids,

TABLE
1–1

MA and ACO program savings are concentrated in the highest FFS service-use markets and remain modest

Markets, by level of FFS service use	Number of markets	ACO			MA		
		Mean level of ACO program spending relative to FFS spending	Number of ACO beneficiaries	ACO market share	Mean level of MA program spending relative to FFS spending*	Number of MA beneficiaries	MA market share**
All markets	78	100%	1.7 million	9%	105%	5.5 million	29%
Service-use quartiles							
Lowest quartile	20	101	250,000	11	113	650,000	30
Second quartile	19	100	650,000	11	105	1,530,000	25
Third quartile	20	101	450,000	8	103	1,790,000	34
Highest quartile	19	98	390,000	7	98	1,500,000	27

Note: MA (Medicare Advantage), ACO (accountable care organization), FFS (fee-for-service). "Savings" are program savings and are computed net of any funds provided to MA plans to provide extra benefits and net of any bonuses paid to ACOs, which can also be used for certain extra benefits, including care coordinators. We adjusted MA costs by 3 percent to reflect insufficient adjustments for coding made by CMS. Without the additional 3 percent MA adjustment, the relative savings from MA would have been estimated as 3 percent higher. For mean level of ACO and MA program spending relative to FFS spending, markets are weighted equally. Employer MA plans and special needs plans are excluded from the comparison because they are not in competition with ACOs or other MA plans. The number of beneficiaries in all markets is 19 million.
*"MA program spending" refers to all program spending, including spending on supplemental benefits based on 2015 benchmarks and bids.
**"MA market share" refers to the share of beneficiaries in typical MA plans, excluding employer plans and special needs plans. The total MA market share including these types of MA plans would be larger.

Source: MedPAC analysis of Medicare FFS claims data, ACO performance data from CMS, and 2015 MA bid data.

the MA plans in the 78 markets estimated the cost of the extra benefits (including profit and overhead) at about $65 per member per month, equal to 8 percent of average FFS spending. In the four quartiles of FFS service use (from lowest to highest), the value placed on the extra benefits was 8 percent, 6 percent, 9 percent, and 10 percent of FFS spending, respectively, with the extra benefits tending to be slightly higher in high-service-use markets.

ACOs serving elderly dually eligible beneficiaries tended to generate more savings

In other analyses, we have found that both MA plans and ACOs have shown some ability to bring costs below the expected traditional FFS cost for elderly Medicare–Medicaid dually eligible beneficiaries (beneficiaries with Medicare premiums and, in some cases, cost sharing paid through Medicaid or Medicare Savings Programs for individuals with low income). In our analysis of ACO shared savings, we found a statistically significant relationship between the share of elderly dual-eligible beneficiaries in an ACO and the amount of shared savings. A simple linear regression of ACO savings on service use

and share of aged dual-eligible beneficiaries indicates that for every 10 percent increase in the share of aged dual-eligible beneficiaries, shared savings increases by an average of 1 percent ($p < .01$).[5] ACOs with high shares of dual-eligible beneficiaries do not have low costs per beneficiary; the data show only that these ACOs tended to restrain costs below the relatively high expected level of spending per elderly dual-eligible beneficiary. This finding is consistent with data from MA plans, showing that dual-eligible special needs plans (SNPs) tend to have higher profit margins (Medicare Payment Advisory Commission 2015). In 2012, SNPs specializing in dual-eligible beneficiaries had an average profit margin of 8.1 percent compared with 4.5 percent for other MA plans.

No one model was uniformly the least costly

From a program-spending perspective, our analysis comparing spending across payment models in each of the 78 markets found that that no one model was lowest cost across all markets. FFS was the low-cost option in 28 markets, ACOs in 31 markets, and MA plans in 19 markets. (However, differences in many markets were small, particularly between ACOs and FFS, as would

be expected given that ACO spending was close to 100 percent of FFS in three of the service-use quartiles, as shown in Table 1-1, p. 11.) MA plans were the least likely to generate savings in low-service-use markets and the most likely to generate savings in high-service-use markets. MA plans were expected to be the high-cost model in low FFS cost areas because MA plans have benchmarks above FFS in low-service-use areas and have higher levels of overhead (which is difficult to overcome in low-service-use markets). In contrast, MA plans were expected to be the lowest cost model in high-service-use markets because they have more tools than traditional FFS and ACOs to reduce service use.

How could relative costliness change over time?

As a result of PPACA, the MA benchmarks are moving closer to FFS spending on average over time. Therefore, some improvement could occur in MA plans' relative costliness if MA plan bids are reduced to align with the lower benchmarks. However, because benchmarks in low-spending markets will continue to be 115 percent of FFS (or more with quality bonuses), we expect MA plans' program spending will still be above FFS in these markets when the new benchmarks are fully implemented in 2017.

ACO program savings could also change over time. As ACOs gain experience and less successful ACOs drop out of the program, the average savings generated for the program by the remaining ACOs could increase. In addition, for ACOs in two-sided risk models (in which providers are not only rewarded for positive performance but also penalized for poor performance), CMS discussed waiving certain restrictions such as the three-day inpatient hospital stay requirement to receive Medicare coverage for skilled nursing facility care (which it already does for Pioneer ACOs) and the homebound requirement for home health. By giving ACOs that accept two-sided risk these extra tools to manage care, we may see improved ACO performance in the future.

Effect of MA plans and ACOs on quality of care and beneficiary satisfaction

The models should not be judged based only on cost. Beneficiaries may vary in their preferences, with some preferring the care coordination and supplemental benefits provided by MA plans. Others may prefer the flexibility of FFS. For those in the FFS system, some may choose an ACO clinician with a reputation for timely coordinated care. Quality of care will also have to be compared. To facilitate quality comparisons, there should be common quality metrics across models and similar paths for rewarding quality, as we discussed in our June 2014 report (Medicare Payment Advisory Commission 2014b).

Currently, we have little information on which to base a comparison of MA and ACO quality indicators with the quality of care in FFS Medicare. The studies comparing quality and patient satisfaction between MA plans and the FFS program provide mixed results, with MA plans doing comparatively well on preventive care services but less well on patient satisfaction (Gold and Casillas 2014). In theory, the greater coordination of care within an MA plan or an ACO could improve care coordination and adherence to guidelines. However, data comparing ACOs and FFS is very limited. McWilliams and colleagues (2014) examined how patient satisfaction changed from 2010 to 2013, once physicians joined ACOs; they found that patient satisfaction with timely access to care and communication among providers improved more for the ACO patients than for other patients.[6] In addition, among patients with multiple chronic conditions, overall ratings of care improved more for the ACO group than for the FFS control group. While the McWilliams findings are positive for ACOs, more studies evaluating quality and patient satisfaction across payment models will be needed before any definitive conclusions can be made.

Interdependence of MA, FFS, and ACO payment models

The ACO program is a subset of the FFS program. It relies on the FFS system of setting prices and paying claims. Essentially, physicians in ACOs can manage the patients, but the government runs the program's administrative functions. Without FFS, there is no ACO program.

It is also true, though less clear, that the MA program is dependent on the FFS program. First, the MA benchmarks are set based on FFS spending. Without that benchmarking capability, the benchmarks would have to be set through a bidding process. The bidding process may not be an effective mechanism to constrain MA bids or prices paid to providers in markets with one dominant insurer or one dominant provider group.

The MA model is also somewhat dependent on the FFS program for setting MA prices for hospital services. The Medicare statute allows MA plans to pay hospitals the FFS rates (as opposed to hospital charges or prevailing commercial rates) for hospital care in cases where they are obligated to pay the hospital but do not have a contractually negotiated rate (e.g., if a plan's enrollee receives emergency

care at a hospital not in the plan's provider network). The net result is that, on average, MA plans pay hospitals a rate that is virtually the same as the FFS rate. This tie to Medicare FFS prices is important for the affordability of MA plans. MA bids show that hospital costs on average account for over 40 percent of all MA plan costs. Data from the American Hospital Association and other sources suggest that average commercial rates are about 50 percent above costs and more than 50 percent above Medicare FFS rates (California Department of Insurance 2014a, California Department of Insurance 2014b, Ginsburg 2011, Medicare Payment Advisory Commission 2014a, White et al. 2013). If MA plans paid hospitals at 50 percent above Medicare rates, the plans' costs would increase by over 20 percent (40 percent × 50 percent). While plans could negotiate some discounts, the magnitude of these discounts would likely be small relative to the discount they get under rates based on FFS administratively set prices. Experience from PPACA's state exchanges indicates that negotiated rates for exchange products are often not significantly below commercial rates (Mathews and Kamp 2013). Given the dramatic difference between hospital prices paid by MA plans and other commercial insurers, traditional FFS needs to continue to exist, among other reasons, to anchor the rates MA prices pay hospitals and keep MA plans affordable.

Determining beneficiary premiums

Under the current system, beneficiaries choose between FFS and MA plans to receive Medicare benefits. (Beneficiaries in ACOs are part of FFS.) The two models can look very different in terms of premiums, benefit design, and choice of providers. To encourage beneficiaries to choose the model that gives them the highest value in terms of cost and quality, the Commission believes that the Medicare program should not subsidize one choice more than another. In other words, the federal contribution toward the cost of Medicare benefits should be equal for FFS and MA in each market.

To examine how different approaches to calculating beneficiary premiums could influence a beneficiary's choice between FFS and MA, we considered different ways to set beneficiary premiums using projected FFS spending data and MA plan bids for 2015.[7] In our analysis, we defined a market area, calculated each market's projected FFS spending, and recalculated each market's MA plan bids from service-area bids. For simplicity, all FFS spending and MA plan bids in our analysis were expressed as per

beneficiary per month amounts and standardized for a beneficiary of average health status. Moreover, we assumed that quality was constant across models.[8]

Definition of market areas

For our analysis, we wanted to define market areas that best matched insurance markets served by private plans. Using market areas that are too small can result in many areas with a small number of FFS beneficiaries, and there can be instances of adjacent areas with very different levels of FFS spending. However, if a market area is too large, the cost of serving beneficiaries can vary widely within the area. Accordingly, we adopted a definition of market areas that is larger than the county definition currently used in the MA program.[9]

- In urban areas, we used collections of counties located in the same state and the same CBSA, which is a collective term for metropolitan (50,000 or more in population) and micropolitan (10,000 to 49,999 in population) areas. (Each area consists of one or more counties and includes the counties containing the core urban areas as well as any adjacent counties that have a high degree of social and economic integration with the urban core.)

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

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

Average FFS spending per beneficiary in market areas

To calculate a beneficiary premium for FFS Medicare in a given market area, we determined the equivalent of an FFS "bid" based on the area's FFS spending. To calculate FFS spending that is comparable with MA plan bids for 2015, we used the projected average monthly FFS spending per beneficiary for 2015, excluding hospice, direct graduate medical education, and indirect medical education payments.[10] The calculation was standardized for a beneficiary of average health status. Market-area average spending was calculated from county-level FFS spending weighted by the area's number of FFS beneficiaries as of January 2015.

TABLE
1–2

Distribution of market areas by average monthly FFS spending per beneficiary, 2015

Average monthly FFS spending per beneficiary	Number of market areas	Share of beneficiaries
$537–$600	32	2.3%
$600–$700	462	23.3
$700–$800	524	44.7
$800–$900	183	25.9
$900–$1,151	30	3.8
Overall average ($752)	1,231	100

Note: FFS (fee-for-service). FFS spending for 2015 is projected and excludes hospice, direct graduate medical education, and indirect medical education payments. FFS spending is 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 50 states and the District of Columbia. Number of Medicare beneficiaries is as of January 2015.

Source: MedPAC analysis of Medicare Advantage (MA) plan bids for 2015 and MA enrollment data for January 2015.

Table 1-2 shows the distribution of market areas by average monthly FFS spending per beneficiary for 2015, ranging from $537 to $1,151. About a quarter of beneficiaries lived in areas with FFS spending below $700 a month; about 45 percent in areas with spending between $700 and $800 a month; and about 30 percent of beneficiaries in areas with FFS spending above $800. Across the market areas in our analysis, the average monthly FFS spending was $752.

Adjusting MA plan bids for market areas

Under current law, MA plans are required to cover all Medicare Part A and Part B benefits except hospice (see text box on the MA payment model, p. 8).[11] For each county, CMS sets the MA benchmark. This local MA benchmark represents a bidding target and is set using statutory formulas and adjusted for the plan's quality ranking. Because under current law MA benchmarks are increased relative to local FFS spending in low-spending areas and decreased in high-spending areas, there is less variation in MA benchmarks than in FFS spending across areas. Furthermore, current MA plan bids are clustered around MA benchmarks, and as a result, there is less variation in MA plan bids than in FFS spending across areas.

Given the local MA benchmark, each MA plan selects counties that make up its service area and submits a bid for the service area.[12] The plan's bid reflects its costs to provide the Part A and Part B benefit package for a beneficiary of average health status and includes plan administrative cost and profit.[13] In our analysis, MA plan bids are monthly amounts for the Part A and Part B benefit portion only and are standardized for a beneficiary of average health status. Because the current MA plan bids are for plan-defined service areas, we made the following assumptions in our analysis in converting plans bids at the service-area level to plan bids at the market-area level.

- We assumed that plan bids were constant over the entire plan-defined service areas, where service areas can be larger or smaller than market areas.

- We assumed that if a plan was offered to at least half of the market area's Medicare beneficiaries, the plan would serve the entire market area with its current bid. If the plan was not offered to at least half of the area's beneficiaries, we assumed that it would not bid to serve that market area.

- We excluded bids for plans in market areas with little or no projected enrollment—defined in our analysis as fewer than 100 projected enrollees in the market area—because those bids would not reflect costs for those areas.

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

The number of MA plan bids varied across market areas in our analysis (Table 1-3). About 8 percent of beneficiaries had only one or two MA plans available to them. However, the vast majority of beneficiaries had at least 3 MA plans available in their market areas, and more than 20 percent had more than 20 MA plans available.

Illustrative examples for calculating beneficiary premiums

Under current law, there is no premium for Part A for beneficiaries entitled to Medicare who receive Social Security or Railroad Retirement Board benefits or are entitled to Medicare because they have end-stage renal disease.[14] All beneficiaries who elect Part B pay a base premium for that coverage, set at about 25 percent of Part B national average benefit costs per beneficiary; conversely, the government's subsidy equals 75 percent of

**TABLE
1–3**

Distribution of market areas by number of MA plan bids in market area, 2015

Number of plan bids in market area	Number of market areas	Share of beneficiaries	Average FFS spending per beneficiary	Average MA penetration rate (in percent)
1 to 2	294	8.0%	$748	15.3%
3 to 5	358	15.1	722	21.1
6 to 10	204	21.2	730	29.4
11 to 20	114	31.1	750	33.7
More than 20	30	21.8	813	43.0

Note: MA (Medicare Advantage), FFS (fee-for-service). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. "Share of beneficiaries" does not sum to 100 percent because, out of 1,231 market areas in our dataset, 231 market areas have no plan bids due to exclusions of certain MA plans.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

the Part B costs. The base Part B premium is set nationally and does not vary across areas.[15]

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

Applying the current-law method for calculating the base Part B premium to our data—25 percent of Part B spending per beneficiary—results in a base FFS premium of $101 per month. This amount represents about 13.4 percent of average combined Part A and Part B FFS spending per beneficiary—and an implied government subsidy rate of 86.6 percent of combined Part A and Part B spending.[16] Our calculated base premium of $101 per month is lower than the actual Part B premium for 2015 of $104.90 per month, but this difference is to be expected given the adjustments we made in calculating FFS spending in our data.

We examined other ways to calculate beneficiary premiums in the context of synchronizing Medicare policy. For illustrative purposes, we considered three approaches that differed in (1) the base premium charged,

and (2) which Medicare option the beneficiary can buy for the base premium. Under all three examples, beneficiaries may choose an option other than the one the base premium pays for. In that case, individual beneficiaries' total premiums equal the base premium plus the difference between the option they choose and the option the base premium pays for. Two of the following designs had a base premium set as a share of national average FFS spending and one had a base premium set as a share of local average FFS spending:

- *Example 1:* The base premium is set at 13.4 percent of the *national* average FFS spending and pays for FFS Medicare in every market. Under this approach, the premium for beneficiaries choosing an MA plan in their market area equals the base premium plus the difference between the plan bid and their market area's average FFS spending.

- *Example 2:* The base premium is also set at 13.4 percent of the *national* average FFS spending but then pays for *either* FFS Medicare or the reference MA plan—whichever costs less—in each market. Under this approach, if FFS spending is lower than the MA bid, the base premium pays for FFS Medicare. But if FFS is higher than MA, the base premium pays for MA, meaning that the Medicare option the base premium pays for would vary across market areas, depending on how FFS spending compares with MA.

- *Example 3:* The base premium is set at 13.4 percent of the *local* average FFS spending and pays for *either* FFS Medicare or the reference MA plan—whichever

TABLE
1–4

Three illustrative examples for calculating beneficiary premiums

Illustrative example	Base premium	What base premium pays for
Example 1 **National** base premium pays for FFS in every market	13.4% of national FFS	FFS Medicare in every market area
Example 2 **National** base premium pays for lower of local FFS or reference MA bid in each market	13.4% of national FFS	FFS Medicare or reference MA plan, whichever costs less
Example 3 **Local** base premium pays for lower of local FFS or reference MA bid in each market	13.4% of local FFS	FFS Medicare or reference MA plan, whichever costs less

Note: FFS (fee-for-service), MA (Medicare Advantage). In our three examples, we assume that the base premium is set to 13.4 percent of the Medicare Part A and Part B
benefit cost, which represents 25 percent of the overall Part B share of the benefit cost. The government subsidy is then 86.6 percent of the benefit cost.

costs less—in each market. Under this approach, in markets where the local FFS spending is lower than the national average FFS spending, the base premium would be lower than the nationally set base premium, whereas in markets where local FFS spending is higher than the national average FFS spending, the opposite would be true. Table 1-4 summarizes these examples.

The examples differ from current law in several aspects. For instance, MA benchmarks would no longer be set administratively. Instead, FFS spending and MA plan bids would determine the reference point for the federal contribution and beneficiary premium.

TABLE
1–5

Per beneficiary FFS spending and plan bids in selected market areas, 2015

	Market area		
	Portland, OR	**Columbus, OH**	**Miami-Dade, FL**
Number of Medicare beneficiaries (in thousands)	283	287	419
Average monthly FFS spending	**$626**	**$722**	**$1,151**
Number of MA plan bids	23	16	27
MA penetration rate	57%	46%	62%
Range of MA plan bids			
Lowest bid	$607	$614	$572
25th percentile bid	688	659	697
Median bid	**703**	**659**	**743**
75th percentile bid	736	713	816
Highest bid	783	874	956
Number of counties in area	5	10	1

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as
of January 2015.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

**FIGURE
1–1**

Example 1: Nationally set base premium pays for FFS in every market

Dollars

Portland, OR

FFS lower than MA bid
Premium for the median MA plan:
$101 + $77 = $178

Premium for FFS:
Base premium ($101)

Columbus, OH

MA bid lower than FFS
Premium for the median MA plan:
$101 − $63 = $38

Premium for FFS:
Base premium ($101)

Miami-Dade, FL

MA bid lower than FFS
Premium for the median MA plan:
$101 − $408 = −$307

Premium for FFS:
Base premium ($101)

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. In our examples, we assume the median MA plan bid as the reference MA plan bid. "Difference" is between the median MA plan bid and average FFS spending. For simplicity, a negative premium can be thought of as a reduction of the entire premium plus a cash payment.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

To illustrate what premiums would look like in dollar terms under these examples, we applied them to three market areas—Portland, OR; Columbus, OH; and Miami-Dade, FL. As shown in Table 1-5, the three areas have different levels of per beneficiary FFS spending, ranging from Portland's $626 to Miami-Dade's $1,151; Columbus's $722 is a little below the national average of $752. They all have many MA plans and high MA penetration (i.e., at least 46 percent of Medicare beneficiaries in each area are in MA plans). In all three examples, we used the median MA plan bid as the

reference MA plan bid. Defining the reference MA plan bid is also a design choice. For example, it could be the lowest bid, the second lowest bid, a weighted average bid, etc. The median plan bid in these three markets varies less than the FFS spending in those markets, in part because the MA benchmarks in 2015 for those markets also vary less than average FFS spending.

Using the data from these three markets, Figure 1-1 illustrates the first example for calculating beneficiary premiums. The base premium is $101, or 13.4 percent

FIGURE
1–2

Example 2: Nationally set base premium pays for either FFS or MA, whichever costs less, in each market

Portland, OR

FFS lower than MA bid
Premium for the median MA plan:
$101 + $77 = $178

Premium for FFS:
Base premium ($101)

Columbus, OH

MA bid lower than FFS
Premium for the median MA plan:
Base premium ($101)

Premium for FFS:
$101 + $63 = $164

Miami-Dade, FL

MA bid lower than FFS
Premium for the median MA plan:
Base premium ($101)

Premium for FFS:
$101 + $408 = $509

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. In our examples, we assume the median MA plan bid as the reference MA plan bid. "Difference" is between the median MA plan bid and average FFS spending.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

of the national average FFS spending ($752) in all three market areas. In Portland, the reference MA bid is higher than local average FFS, and the difference between MA and FFS equals $77 ($703 minus $626). Therefore, if the beneficiary chooses MA, the premium for the median plan equals the base premium ($101) plus the difference ($77), or $178. (Premiums for MA plans whose bids are lower than $703 would be less than $178.) In contrast, in Columbus and Miami-Dade, the median MA plan bid is lower than local average FFS spending—by $63 and

$408, respectively. Therefore, the premium in Columbus for the median MA plan, which equals the base premium plus the difference, is $38 ($101 minus $63) and in Miami-Dade is –$307 ($101 minus $408). For simplicity, a negative premium can be thought of as a reduction of the entire premium plus a cash payment. In this example, we assumed that the beneficiary receives the entire difference between FFS and MA. However, how to share this difference between the beneficiary and the program

**FIGURE
1–3**

**Example 3: Locally set base premium pays for either
FFS or MA, whichever costs less, in each market**

Dollars (y-axis: 0 to 1,300)

Portland, OR
- MA bid = $703
- FFS = $626
- $77 difference
- $542 federal contribution
- $84 (13.4% of FFS) base premium

Columbus, OH
- FFS = $722
- MA bid = $659
- $63 difference
- $562 federal contribution
- $97 (13.4% of FFS) base premium

Miami-Dade, FL
- FFS = $1,151
- MA bid = $743
- $408 difference
- $589 federal contribution
- $154 (13.4% of FFS) base premium

FFS lower than MA bid
Premium for the median MA plan:
$84 + $77 = $161

Premium for FFS:
Base premium ($84)

MA bid lower than FFS
Premium for the median MA plan:
Base premium ($97)

Premium for FFS:
$97 + $63 = $160

MA bid lower than FFS
Premium for the median MA plan:
Base premium ($154)
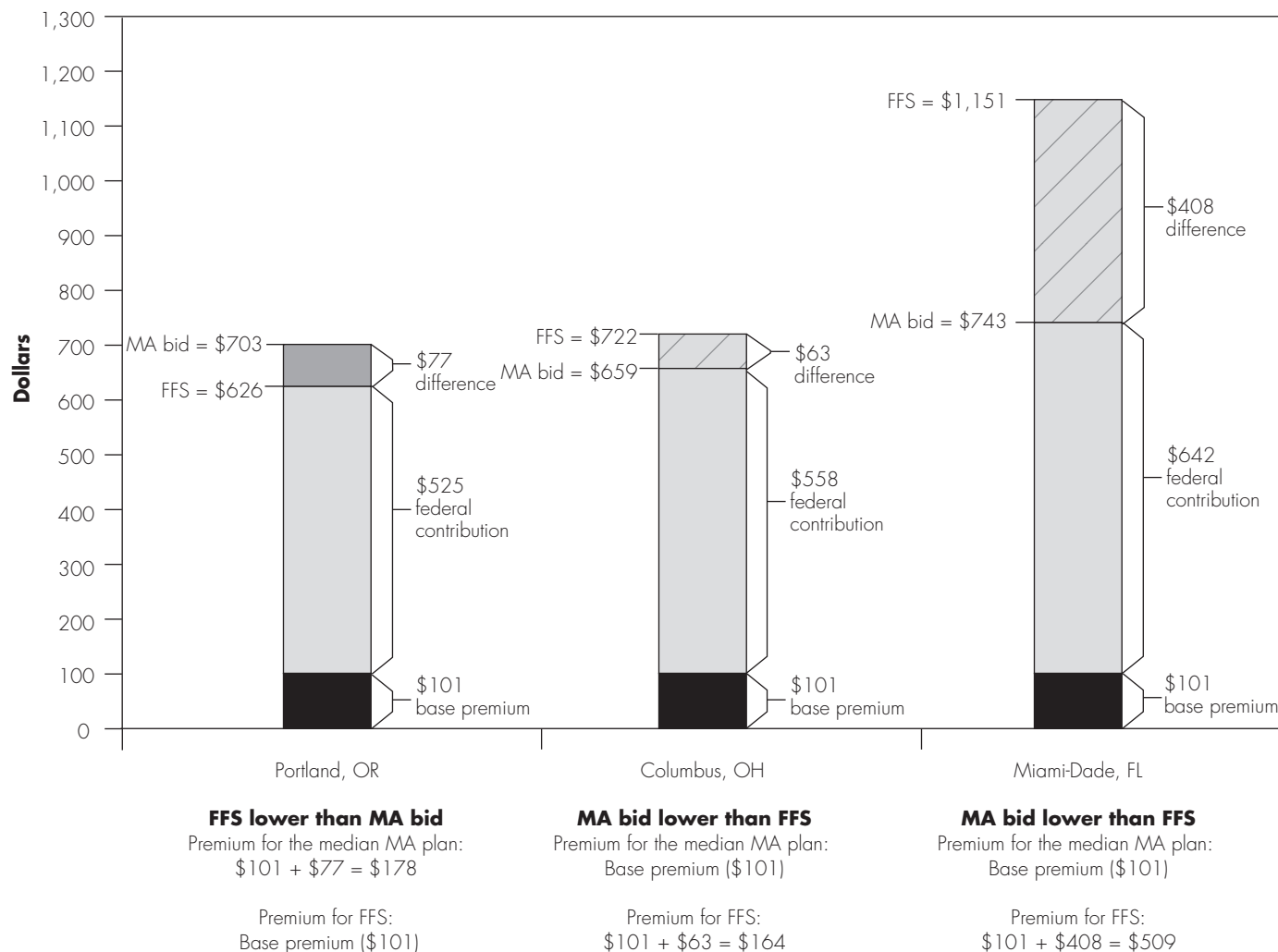
Premium for FFS:
$154 + $408 = $562

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. In our examples, we assume the median MA plan bid as the reference MA plan bid. "Difference" is between the median MA plan bid and average FFS spending.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

is a policy decision. For instance, under current rules, if MA plans bid below the benchmark, the program retains a share of the difference and the balance is commonly returned to the beneficiary in the form of extra benefits.

In the second example, the base premium of $101 no longer pays for FFS Medicare in every market (Figure 1-2). Instead, it pays for either FFS or MA—whichever costs less—in each market. Therefore, in Portland, where FFS is lower than MA, the base premium pays for FFS, whereas in Columbus and Miami-Dade, where MA is lower than FFS,

the base premium pays for MA. The difference between FFS and MA is added to the beneficiary premium of the higher cost option in each market. In other words, while the beneficiary pays the base premium of $101 for FFS in Portland and for MA in Columbus and Miami-Dade, beneficiaries pay a higher premium if they choose MA in Portland and FFS in Columbus and Miami-Dade.

Finally, under the third example, the base premium is set to 13.4 percent of the local FFS spending: $84 in Portland, $97 in Columbus, and $154 in Miami-Dade (Figure 1-3).

**TABLE
1–6**

Summary of illustrative examples for calculating beneficiary premiums

	Market area		
	Portland, OR	**Columbus, OH**	**Miami-Dade, FL**
Median MA plan bid	$703	$659	$743
Average monthly FFS spending	626	722	1,151
Difference between MA and FFS	77	–63	–408
Example 1: Nationally set base premium pays for FFS Medicare in every market			
FFS premium	101	101	101
MA premium	178	38	–307
Federal contribution	525	621	1,050
Example 2: Nationally set base premium pays for either FFS Medicare or reference MA plan, whichever costs less, in each market			
FFS premium	101	164	509
MA premium	178	101	101
Federal contribution	525	558	642
Example 3: Locally set base premium pays for either FFS Medicare or reference MA plan, whichever costs less, in each market			
FFS premium	84	160	562
MA premium	161	97	154
Federal contribution	542	562	589

Note: MA (Medicare Advantage), FFS (fee-for-service). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. In our examples, we assume the median MA plan bid as the reference MA plan bid. "Difference" is between the median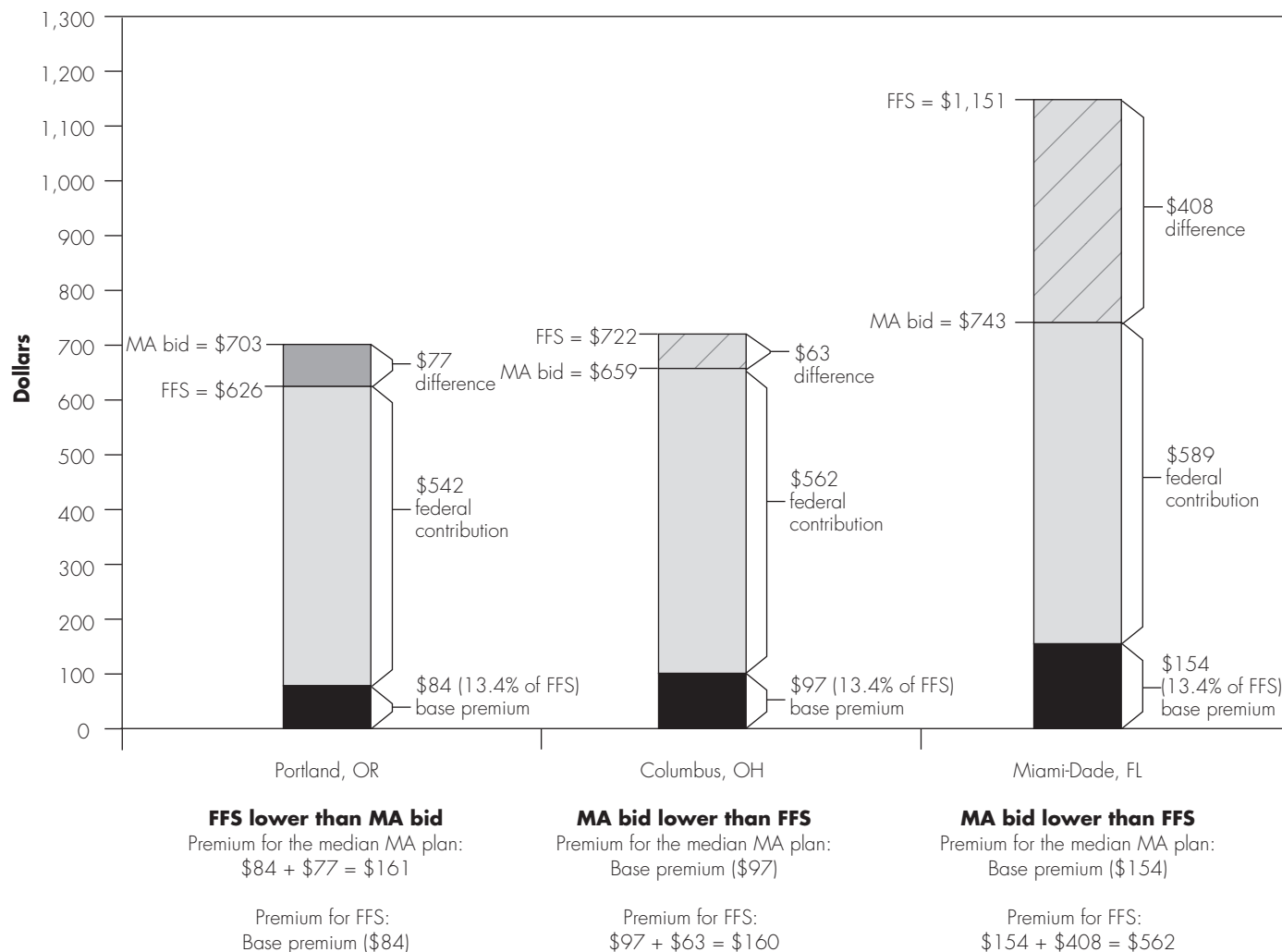 MA plan bid and average FFS spending. For simplicity, a negative premium can be thought of as a reduction of the entire premium plus a cash payment.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

These changes in the base premium, compared with those under the second example, reflect the beneficiary facing the geographic variation in FFS spending across market areas. As in the second example, the base premium pays for either FFS or MA—whichever costs less—in each area. In other words, while beneficiaries pay the base premium for FFS in Portland and for MA in Columbus and Miami-Dade, they pay a higher premium if they choose MA in Portland or FFS in Columbus and Miami.

The first and second examples for calculating beneficiary premiums highlight how the difference in the average monthly cost of the Medicare benefit under FFS and MA within each market area can be shared between the

program and the beneficiary. Differences in the reference MA bid relative to FFS in each market are summarized in Table 1-6: $77 in Portland; –$63 in Columbus; and –$408 in Miami-Dade. Under the first example, the beneficiary who chooses MA pays the entire difference only if MA is higher cost than FFS and gets the entire difference if MA is less than FFS. In contrast, in the second example, the beneficiary who chooses the higher cost option pays the entire difference regardless of which option—either FFS or MA—is higher cost, and the federal contribution is less than in Example 1 if FFS is higher cost.

The contrast between the second and third examples for calculating beneficiary premiums raises the question

Note: FFS (fee-for-service), MA (Medicare Advantage). FFS spending for 2015 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 50 states and the District of Columbia. Number of Medicare beneficiaries and MA enrollees are as of January 2015. Out of 1,231 market areas in our dataset, 231 market areas have no plan bids due to exclusions of certain MA plans.

Source: MedPAC analysis of MA plan bids for 2015 and MA enrollment data for January 2015.

of who should pay for or benefit from the geographic variation in FFS spending. Because these amounts are all risk adjusted, geographic variation arising from differences in health status or dual-eligible status are already accounted for. The remaining differences represent differences in local input prices and service use. In the second example, the base premium does not vary across areas, whereas in the third example, the base premium adjusts proportionately to local FFS spending. Is it fair for beneficiaries in high-spending areas to pay higher premiums for the same basic benefit? Alternatively, is it fair for beneficiaries in low-spending areas to cross-subsidize beneficiaries in high-spending areas? More broadly, how should the program and the beneficiary share the geographic variation in program spending?

There are potential savings in program spending in each of the examples if beneficiaries choose the lower cost

model more often. A key policy question is how those potential savings could be shared between the beneficiary and the program.

In all three illustrative examples, the difference between the average FFS spending and the reference MA bid is a key variable in calculating beneficiary premiums. Especially in the second and third examples, this difference is the additional premium beneficiaries would pay if they chose the higher cost option between FFS and the reference MA plan. Figure 1-4 summarizes the distribution of the differences between FFS and MA for all market areas. Almost half of beneficiaries are in market areas where the difference is less than $50. About 2 percent of beneficiaries are in market areas where the median MA bid is higher than FFS spending by $100 or more. In contrast, about 28 percent of beneficiaries are

Under Part D, stand-alone prescription drug plans and Medicare Advantage (MA) drug plan sponsors bid to provide an outpatient prescription drug benefit to enrollees. Each plan serves enrollees who live within 1 of 34 Part D regions, which are made up of either 1 state or multiple states. The law provides for a defined basic benefit, but, within limits, plan sponsors can offer different benefit designs that have the same actuarial value as the defined benefit. Sponsors can offer enhanced benefits if they also offer a plan with basic benefits in the same region.

For each enrollee, Medicare provides plans with a subsidy that averages 74.5 percent of basic benefits. That subsidy takes two forms: a direct subsidy (monthly capitated payment) that lowers premiums for all enrollees and individual reinsurance that pays for 80 percent of enrollee spending above Part D's catastrophic threshold.

Enrollee premiums are the direct result of Part D's bidding process. Plans submit bids that reflect their expected benefit payments plus administrative expenses after deducting expected reinsurance subsidies. CMS takes standardized bid amounts for basic benefits and calculates an average, weighted by each plan's enrollment in the previous year. The base beneficiary premium equals 25.5 percent of the national average benefit costs. Because the base premium and direct

subsidy are set nationally, those amounts do not vary across plans or by geographic region.

However, enrollees pay different premium amounts depending on the plan they select. Each plan's premium is set as the base premium plus any difference between the plan's bid and the national average bid. Enrollees choosing a plan that is costlier than the average pay a higher premium—the full difference between the plan's bid and the nationwide average. If they select a plan that has a lower than average bid, their premium is lower by that difference. If enrollees pick a plan that includes supplemental coverage, they must pay the full price for the additional benefits.

Part D ensures that beneficiaries eligible for the low-income [drug] subsidy (LIS) have premium-free plans available to them. Part D's bidding process determines a maximum amount that Medicare will pay for premiums on behalf of LIS enrollees in each of the country's 34 Part D regions. It is based on an average of premiums for plans with basic benefits, weighted by each plan's LIS enrollment in the previous year, and it ensures that at least one stand-alone prescription drug plan is available at no premium. Plans with premiums up to this regional threshold are premium free for LIS beneficiaries. As a result, LIS beneficiaries have access to at least one premium-free stand-alone drug plan, even in regions where the average bid is higher than the national average. ■

in market areas where FFS spending is higher than the median MA bid by $100 or more. Figure 1-4 (p. 21) also shows that even among market areas where FFS is higher by a large difference, Miami-Dade remains an outlier, with a difference of $408. In all other markets, the difference between FFS and MA is less than $300.

Limitations of our analysis

Our analysis has important limitations. First, in illustrating only three premium designs, our analysis does not represent a definitive or comprehensive set of design choices. For example, Part D takes a different approach to calculating beneficiary premiums (see text box). Differences in design choices can have a major impact on beneficiaries and on an area's health care marketplace.

Our June 2013 chapter on competitively determined plan contributions provides a broader discussion of key design elements (Medicare Payment Advisory Commission 2013). Furthermore, the examples used in this chapter to illustrate the relative effects of a particular design may not be realistic as actual policy choices.

Second, our analysis uses plan bids under the current MA program as a proxy for the total cost of providing the Medicare benefits through private plans because they are the best measure we have. However, these bids are the plans' responses to current rules, which are different from all three illustrative examples. Under different rules, MA plans are likely to bid differently. For example, current MA bids are highly correlated with

current MA benchmarks, which range from 95 percent to over 125 percent of FFS spending in 2015. Without those administratively set benchmarks, as in our analysis of Example 2 and Example 3, plans would likely change their bids. Additionally, plan bids would be different if the program defined a market area, as under our illustrative examples, compared with if MA plans defined their own service area, as under current law. Moreover, under different rules for calculating beneficiary premiums and the federal contribution, MA plans would likely make different decisions regarding whether to enter or exit a particular market area and how much to bid.

Finally, our analysis does not discuss how beneficiaries would respond to changes in their premiums. Our examples show that methods for calculating beneficiary premiums could have a major effect on beneficiaries' costs. But a premium is only one of many factors beneficiaries might care about. In making a choice with the highest value to them, some beneficiaries would need to trade off premiums and other aspects of the benefit package, as well as their perception of the quality of different choices.

This process can be difficult and complex. For example, under current law, choosing traditional Medicare offers no restrictions on providers but may require additional choices among Medicare supplemental plans and among Part D plans. Choosing an MA plan may simplify the process by offering all Medicare benefits—Part A, Part B, Part D, and supplemental coverage—in a single plan, but would necessitate receiving care from a limited network of providers. When choices require considering multiple dimensions simultaneously, beneficiaries' ability to compare and make trade-offs among a large set of options would likely be limited (see text box on factors affecting beneficiaries' decision making, p. 24). Moreover, if the difference in premiums among choices is too high, the choice that the beneficiary would otherwise consider most attractive might be prohibitively expensive and therefore not a realistically viable choice. These issues are additional policy considerations that must be factored into designing beneficiaries' financial incentives.

The effect of coding on payments, bids, and quality

Coding (i.e., the reporting of a beneficiary's diagnoses at each encounter) affects payment, bids, and quality

measurement. Coding can directly influence payment. In MA, for example, a beneficiary's risk score (which incorporates selected diagnoses as well as some additional factors) is multiplied by a base payment rate to determine a plan's payment. When an MA plan bids to provide the Medicare benefit in a market, that bid is for a person of average risk, which is defined as a person having a risk score of 1.0 using CMS's hierarchical condition categories (CMS–HCC) risk model. Because a beneficiary's health status, based on diagnosis codes, determines the beneficiary's risk score, coding is also crucial to bidding. Finally, for risk-adjusted quality outcomes such as readmissions, coding is important because it can affect the risk adjustment for a beneficiary and the resulting quality score. Thus, uniformity in coding is a crucial consideration when attempting to synchronize policy across the three payment models.

Coding practices and the determination of bids and payments

A key feature of MA's bidding system is that a bid is for a person of average risk (or a 1.0 risk score). Risk adjustment is designed to neutralize cost differences that are due solely to the health status of beneficiaries within each plan. Without adequate risk adjustment, a plan that had sicker enrollees would be more costly than other plans (all else being equal) and its bid would be higher. We do not want to penalize such plans, and we do not want incentives for plans or ACOs to avoid sicker beneficiaries. With adequate risk adjustment, differences in bids would reflect varying levels of resource use driven by a plan's utilization management practices, providers' practice styles, beneficiary preferences for care, and the mix of services used. Differences in cost based on such factors are the cost differences that should be reflected in plan bids.

MA plans encourage more intensive coding than is the practice among FFS providers because it increases their payments from Medicare. For example, a plan may ensure that the physician includes a diagnosis for diabetes each time a diabetic patient has an office visit to make sure that diagnosis is included in the risk-adjustment model. While the diagnosis is appropriate, a physician in FFS may not include that diagnosis if the patient is visiting for some other reason—resulting in inconsistency between the coding practices of each sector. Another source of more-intensive coding in MA plans is the inclusion of diagnoses from home assessment visits, which are initiated by MA plans but may not involve interaction with a beneficiary's primary care provider. Such visits are not a common

A policy designed to create financial incentives for beneficiaries anticipates certain behavioral responses from them (for example, reducing their use of services in response to higher cost sharing or changing their Medicare coverage in response to changes in premiums). To meet the intended goals, designing such a policy would need to take into consideration how beneficiaries make decisions and respond to incentives. In particular, it would need to take into account that beneficiaries' ability to compare and make trade-offs among a large set of options may be limited.

People's ability to understand and use health insurance—Medicare included—may be limited simply because health insurance is inherently complex. It requires the consideration of multiple dimensions simultaneously, is filled with unfamiliar terminology, and requires a high level of numeracy to make informed judgments. Moreover, people have different preferences and needs for health care, which can be uncertain and unpredictable. As a result, people often stick with the same insurance coverage year after year even when better options are available, seek advice from family or friends, and choose highly advertised plans or those from a well-known brand. (Health insurance is not unique in this way. People show similar shopping behavior in other complex financial decisions, such as mortgage shopping.)

The psychology literature suggests that the number of options people face may affect their choice (Iyengar and Kamenica 2010, Schwartz 2004). The choice overload hypothesis states that an increase in the number of options to choose from may lead to adverse consequences, such as decreased motivation to choose or less satisfaction with the option chosen. A meta-analysis of choice overload studies shows differences in the study results (Scheibehenne et al. 2010). Although the literature does not have clear answers on when and why choice overload may occur, it suggests that choice overload is more likely under certain circumstances. Choosing is more difficult when available options are similar, no clearly superior option exists among several attractive options, or decision makers have no well-defined preferences before choosing. In these situations, individuals typically use decision heuristics to simplify or limit the amount of information that must be processed to make the decision. These short cuts are not always benign. For instance, variables that are easily measured, like cost, are often subconsciously given more weight than variables that are more subjective, like quality. Ultimately, the process may arbitrarily eliminate potentially relevant details from consideration and overstate the importance of other information. Beyond the number of options available, therefore, making it easier for beneficiaries to navigate the set of available options and reducing the time and cognitive burden required to make a choice would improve the decision-making process.

Moreover, the nature of how choices are presented, described, and framed can affect people's decision making. Because people are prone to systematic biases, their decisions are sensitive to the context in which they make them (Kahneman 2011). For example, people's decisions can change depending on the order in which choices are arrayed and the words used to describe and frame them. But because these biases are predictable, they also present an opportunity to influence people's decisions in the direction policymakers desire. For example, the initial set of options influences how consumers view and interpret subsequent information and the decisions they ultimately make. Therefore, determining the default setting for sorting and displaying options has a big effect on what consumers see as their choices. ∎

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occurrence in FFS Medicare. Because the CMS–HCC model is calibrated using only FFS data, the inclusion of diagnoses from health assessments done in the home is problematic.

Recognizing the issue of more-intensive coding in MA plans, the Medicare statute currently requires a coding

adjustment to address differences in coding practices between MA plans and FFS providers so that MA payments are accurately risk adjusted. For 2015, that adjustment was a risk score reduction of 5.16 percent. However, the Commission has found that the statutory coding adjustment does not fully adjust for the differences

	Market area	
	Portland, OR	**Miami-Dade, FL**
Median bid (risk score not reduced)		
Median bid before risk adjustment to 1.0	$668	$1,025
Weighted average risk score from 2015 bids	0.95	1.38
Median bid after risk adjustment	$703	$743
Median bid (risk score reduced by 3%)		
Median bid before risk adjustment to 1.0	$668	$1,025
Weighted average risk score from 2015 bids, reduced by 3%	0.92	1.34
Median bid after risk adjustment	$725	$766
Difference in median bids after risk adjustment	$22	$23

Note: MA (Medicare Advantage). The risk scores are determined for plans other than employer group plans and special needs plans.

Source: MedPAC analysis of Medicare Advantage plan bids for 2015.

between MA and FFS and that MA risk scores should be further reduced by about 3 percent (Medicare Payment Advisory Commission 2015).

For purposes of synchronizing policies, one approach to addressing the observed coding differences is to use the current approach of an across-the-board reduction in the risk scores that MA plans report. (A similar approach could be applied to ACOs to the extent that more-intensive coding occurs among ACO providers and it has an effect on the computation of costs and savings.) The example described earlier of how to determine MA premiums and the cost to beneficiaries of FFS in the different markets already reflects the current statutory adjustment. Table 1-7 illustrates how a further adjustment of 3 percent would affect that analysis. A reduction in plan risk scores of 3 percent to adjust for more-intensive coding would raise plan bids because they would be divided by the new, lower risk score to compute a 1.0 bid. That would narrow the difference between FFS and MA in Miami-Dade, where FFS is the more costly option, and widen the difference in Portland, where MA is the more costly option.

For example, the median bid before risk adjustment in Miami-Dade was $1,025. This amount, divided by the risk score from the 2015 bids (1.38) yields a 1.0 bid of $743, which is what we used in our analysis (e.g., see Table 1-6 (p. 20) and Figure 1-1 (p. 17)). If the risk

score were reduced by 3 percent, the risk score becomes 1.34. Dividing $1,025 by that risk score yields $766 as the new 1.0 bid. As shown in Table 1-7, the median bid increases from $743 to $766 in Miami-Dade, and from $703 to $725 in the Portland, OR, metropolitan statistical area (MSA). If in Miami-Dade, beneficiaries choosing the FFS option are expected to pay the full difference between the average FFS cost and the median MA bid (as would be the case in the second and third premium design examples), the beneficiary's financial obligation is reduced by $23 per month with the coding adjustment. Table 1-7 also demonstrates that, although median MA bids in Miami-Dade and Portland are close to each other after risk adjustment ($766 and $725, respectively), there would continue to be large geographic variation in actual payments to MA plans. The MA payment rate is over 50 percent higher in Miami-Dade for the median bid ($1,025 versus $668 in Portland) because of the difference in risk scores of the beneficiaries enrolling in MA. The difference in risk scores between the two areas is also apparent in the FFS population of Miami-Dade and Portland. CMS data show that in 2012 the Miami-Dade risk score was 1.31, while in the Portland MSA it was 0.92 (Centers for Medicare & Medicaid Services 2015b).

There may be reasons to use a coding adjustment that is not an across-the-board adjustment. Currently, plans are, in effect, disadvantaged if they code less intensively

than other MA plans because the adjustment is the same for all plans. Kronick and Welch (2014) have shown that coding practices are not uniform across MA plans. An alternative to an across-the-board coding adjustment—particularly if premiums are determined at the local market level—is to have plan-specific coding adjustments (which could also apply to ACOs with more-intensive coding). This adjustment would be more difficult to determine, but it would remove some of the incentive for plans to increase coding intensity. Another approach might be to tighten the rules for acceptable coding so that MA coding more closely mirrors the coding in FFS. For example, CMS could use MA encounter data for risk-adjustment purposes, but accept only those encounters that have an analogue in FFS Medicare.[17]

A further complication is that coding also varies by geographic area in the FFS sector beyond what would be expected based solely on health status. Song and colleagues (2010) found that areas of higher utilization have more-intensive coding with "substantial differences in diagnostic practices that are unlikely to be related to patient characteristics." This finding raises questions such as whether the FFS risk scores should be reduced with a geographic-area specific coding adjustment. Should the coding adjustment for MA plans in a high-service-use area like Miami–Dade be in relation to the Miami "community standard" of coding in FFS rather than a national average? If the premiums for FFS will vary by market area in a synchronization model, should Miami–Dade FFS costs have a coding adjustment different from a low-service-use area like Portland?

Coding practices and other issues in the assessment of quality

Another aspect of synchronization across payment systems is the concept of having payment differentials based on the quality of care. The Commission has considered an approach that would give additional quality-based payments to MA plans and ACOs if their quality is better than that of FFS in their market (and lower payments if their quality is worse). This approach is predicated on the fact that MA plans and ACOs have agreed to be accountable for a population of beneficiaries and on the availability of population-based outcome measures. (See Chapter 3 of the Commission's June 2014 report for a full discussion of this approach (Medicare Payment Advisory Commission 2014b).) Currently, our ability to measure such outcomes is limited, and some of the limitations arise from differences in coding practices.

The effect of coding on quality measurement

Coding can play a part in determining a plan's performance on quality measures. A case in point is hospital inpatient readmission measures, one of which is a Healthcare Effectiveness Data and Information Set® (HEDIS®) measure used in the MA star system of quality measurement. A readmission measure also is one of the outcome measures that the Commission has suggested for population-based quality measurement.

The HEDIS readmission measure compares a plan's actual readmission rate with an expected readmission rate based on patients' demographics and diagnoses. All other things being equal, if more intensive coding results in a greater number of diagnoses in one plan compared with another, the plan with more intensive coding will show better performance on the readmission measure because its expected readmission rate will be higher.

Measures that are not risk adjusted can also be affected by coding practices. For example, many of the current HEDIS measures are for the treatment of diabetics. If MA plans are able to identify all their enrollees who have diabetes, including those in the early stages of the disease, while in FFS the diagnosis is more likely to appear in later stages (when comorbidities are more likely to be present), the MA plan's share of diabetics who control their blood sugar, cholesterol, and blood pressure may be higher than in FFS because the FFS beneficiaries diagnosed with later-stage diabetes are a more complicated set of patients.

Other issues in synchronizing quality measurement

There are many other issues in synchronizing quality measurement and assessment across the three payment models. One notable difference is that higher quality is rewarded with extra payment in the MA model, whereas in the ACO model, unless quality meets a specified threshold, shared savings payments are reduced. This difference would be resolved under our approach—rewards for both ACOs and MA plans with better quality than FFS and penalties if lower. In addition to this issue, other, more technical issues would need to be resolved. Some examples are discussed below.

The Commission's March 2010 report included a congressionally mandated study of methods to compare quality in FFS Medicare with the quality of care rendered by MA plans. The observations made in that report and its recommendations are applicable in our discussion of ensuring a level playing field in measuring quality

across the three payment models. Some of the report's recommendations have been implemented, but others have not. For example, performance of MA plans in the star rating system continues to be measured at the contract level, even though a single contract can stretch across a wide geographic area—as in the case of the first health plan listed in public use files of HEDIS data, which is "CHA HMO (Hawaii/Iowa)," with about half of the plan's enrollment in Hawaii and half in Iowa. The Commission recommended that quality reporting should be done at a smaller geographic level, using areas that correspond more closely with health care markets.

With regard to the patient experience measures collected through the Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) survey, the phrasing of the questions differs between, for example, the ACO CAHPS survey and the MA CAHPS survey. In addition, the case-mix adjustment for response bias differs. In MA, Medicare–Medicaid dual-eligibility status is a factor in assessing case mix, while in the CAHPS Clinician & Group Surveys (used for ACOs), it is not. These differences in the mechanics of quality measurement need to be addressed before we can be confident that we can judge and compare quality in the different payment models.

Conclusion

We have reviewed three aspects of synchronizing Medicare payment models in this chapter: which model has the lowest program spending in select markets, ways of designing the beneficiary premium to encourage beneficiaries to choose the lower cost model, and how coding needs to be accounted for to assure fair comparisons across models. Each of these issues can be quite complex, but there are some unifying principles for evaluating them that stem from considering the goal of synchronizing Medicare payment policy: maximizing the value of the Medicare program to beneficiaries and taxpayers. We need to determine how to set payment rules that reward the most efficient model of care in a market, how to encourage beneficiaries to be in that model, and how to provide the information they need to make informed decisions. If more beneficiaries were in the most efficient model, savings could be generated that could then be shared between the program and beneficiaries.

By the most efficient payment model in each market, we mean the model that has the lowest program spending

and provides high-quality care. In this chapter, we have focused on lower program spending and found that each of the three models has the lowest program spending in some markets and all serve a function in the current system. In our June 2014 report, we focused on quality and described a system in which MA plans and ACOs would be judged relative to the ambient level of FFS quality in each market and be rewarded (or penalized) if their quality was above (or below) that of FFS (Medicare Payment Advisory Commission 2014b). Spending and quality considerations would need to be combined to encourage providers in all markets to improve quality, control program spending, and be part of the most efficient model of care in their market.

Encouraging beneficiaries to be in the most efficient model is the next step. In this chapter, we have looked at three ways of setting beneficiaries' premiums.[18] In each illustrative example, the federal contribution is equal for FFS and MA in each market, no matter which option the beneficiary chooses. That is, in all three examples the federal contribution in a market is financially neutral between models. The examples assumed that quality was equal across models, which would be unlikely, and as discussed above, payments to each MA plan and ACO should be modified to account for quality. If MA were the lower cost model and the beneficiary premium was set to cover the cost of being in MA, the beneficiary would have to be guaranteed access to an MA plan with quality at least equal to the ambient level of FFS quality in the market. For example, only bids from plans with quality equal to or above FFS could be counted when establishing the reference bid.

Putting synchronization into practice—redesigning payments, beneficiary premiums, and benefit design—will be a complex task and will require balancing the interests of beneficiaries, taxpayers, and providers. One crucial part of the task will be defining what is equitable. There are three aspects of this definition that are of particular importance:

- *Equity for beneficiaries across the country.* As we have shown in previous work, the cost of Medicare varies widely across the country because of differences in input prices, health status, and use of Medicare services. Currently, beneficiaries' premiums for FFS reflect none of these factors, and one could argue that beneficiaries in low-cost markets are subsidizing beneficiaries in high-cost markets. Should beneficiary premiums reflect the difference between prices and service use in the local market and the

national average, or should beneficiaries be insulated from some or all of these differences? Should beneficiaries pay more or less depending on regional spending over which they have little influence?

- *Equity for beneficiaries within a market.* Beneficiaries within a market may now have the choice of many MA plans or staying in FFS Medicare. Should the government make equal contributions for all plans in a market—as we have illustrated in our examples—even if that means a beneficiary may have to pay more to remain in FFS in some markets? If there are savings, should they accrue entirely to the beneficiary, to the Medicare program, or a combination?

- *Equity across generations.* One aspect of equity we have not investigated is that of equity across generations. Under current law, taxpayers—who are increasingly in limited-network plans with high premiums, deductibles, and cost sharing—essentially guarantee Medicare beneficiaries access to any Medicare provider of their choice for a set premium across the country. At its inception in 1965, Medicare was modeled on the insurance design then prevalent in the market for those under age 65, premised on the idea that those over age 65 should have access to health insurance on similar terms. As insurance design changes, should Medicare return to that principle and

reflect current insurance design, which often does not guarantee access to all providers but only those in a defined network? If Medicare is not redesigned, should other taxpayers be asked to subsidize a benefit design that is more generous than what is becoming standard in the industry? Or should the government contribution be set to give Medicare beneficiaries an incentive similar to those with commercial insurance to pick the lower cost option?

No matter how policymakers resolve these issues of equity, other issues will need to be addressed. We have mentioned quality and risk adjustment. In addition, there will be complications in regard to how to design a synchronization policy for low-income beneficiaries, how to ensure capacity in the efficient model (that is, how would Medicare ensure that MA plans had the capacity to handle all comers if MA were the low-cost model in a market), and whether Medicare would have to change from an opt-out of FFS design to an opt-out of the more efficient model design if premiums were based on the low-cost alternative. It will be difficult to achieve consensus on these issues and others that will arise. However, the goal is one that is essential to achieve if we want the Medicare program to be affordable and maintain sufficient support from both its beneficiaries and the taxpayers who fund a large share of the program's cost. ∎

Endnotes

1   The Part A and Part B benefit package in MA excludes hospice. In our March 2014 report, the Commission recommended including the Medicare hospice benefit in the MA benefit package beginning in 2016 (Medicare Payment Advisory Commission 2014c).

2   Our set of ACOs includes Pioneer ACOs with a fiscal year that started in January 2013, MSSP ACOs with a fiscal year that started in April 2012, and MSSP ACOs with a fiscal year that started in July 2012. For simplicity, we use "2013 ACO performance" for all ACOs.

3   By comparing the savings relative to a market's FFS spending, we could use data from different years without having to account for price changes over time, which allowed us to use the most recent data available for the ACO comparisons with FFS and the MA comparisons with FFS.

4   We measured service use from 2006 to 2008 based on the data from our earlier work (Medicare Payment Advisory Commission 2011). Because the ACO benchmarks were computed using data from 2009 onward, it is advantageous to measure service use with data before 2009 to avoid random variation affecting both the ACO benchmarks and the relative service-use computations.

5   The dependent variable in the regression was ACO savings in the ACO's fiscal year (2012/2013). The independent variables were the historical service use in that CBSA (2006 to 2008), the share of ACO beneficiaries who were dual eligible and over 65, the share who were disabled, and the share who had end-stage renal disease. The objective was to see whether it was more or less difficult to generate savings when serving dual-eligible beneficiaries. The coefficient on dual-eligible status was significant ($p < 0.01$) and negative, which suggests that the ACOs have been more successful bringing dual-eligible beneficiaries' spending down than the spending on other beneficiaries. The coefficient on service use was also significant ($p < 0.001$), but the share who were disabled and the share who had end-stage renal disease did not significantly affect shared shavings. The dual-eligible finding needs to be examined further. In past research, we have found that there may be a need for separate risk adjusters for fully dual-eligible beneficiaries and partial dual-eligible beneficiaries who have slightly higher incomes. We will be testing the data in the future to see whether these findings hold true for both partial and fully dual-eligible beneficiaries.

6   ACOs have an incentive to keep patients satisfied so they do not seek care outside of the ACO. When we talked to ACO physicians, they have said that they have taken measures such as setting up new agreements with specialists to allow for more-timely appointments to improve patient satisfaction.

This one study suggests Medicare beneficiaries aligned with the ACO may be benefiting from ACO physicians' concerns about leakage.

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

8   Quality is an important aspect of synchronization. However, we could consider using quality as a payment adjustment that would take place outside of the determination of benchmarks or premiums. This approach is consistent with the Commission's approach to quality discussed in our June 2014 report (Medicare Payment Advisory Commission 2014b).

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

10 FFS spending data are from the MA rate calculation data for 2015 (Centers for Medicare & Medicaid Services 2015b).

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

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

13 We use current MA plan bids for 2015 because they represent the latest data available. As discussed, county benchmarks under the current MA program can differ significantly from county FFS spending, and plan bids tend to be correlated with benchmarks, not FFS spending. Therefore, MA plan bids would likely change if benchmarks and rules changed.

14 For individuals who are not eligible for premium-free Part A and have 30 to 39 quarters of Medicare-covered employment, the premium is $224 per month in 2015. For individuals who are not eligible for premium-free Part A and have fewer than

30 quarters of Medicare-covered employment, the premium is $407 per month. There are very few individuals in these two categories.

15 Higher income beneficiaries pay higher monthly premiums (as high as $336 a month in 2015) based on their modified adjusted gross income.

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

17 In determining FFS and MA risk scores, the current risk-adjustment system uses diagnoses from only certain sites of service and from certain providers. For example, diagnoses from skilled nursing facility or durable medical

equipment claims are not used. Diagnoses arising from a home assessment are included for risk adjustment if a health professional is billing for a Medicare-covered service. However, the claims arising from a home assessment in MA (usually billed by nurse practitioners) are very infrequent in FFS and can be thought of as not truly having an analogue in FFS. In the Final Notice of MA rates for 2016, CMS noted that "the encounter data system accepts diagnoses obtained through chart review," which also represents a difference between the diagnoses that would be present in FFS claims and diagnoses in plans' encounter data (Centers for Medicare & Medicaid Services 2015a).

18 In the chapter, we have not specified how the beneficiary premium would be collected. Currently the only mechanism is the Part B premium, which is now used to collect additional amounts for income-related premiums.

References

California Department of Insurance. 2014a. Aetna Life Insurance Company rate filing. https://interactive.web.insurance.ca.gov/apex/f?p=102:9:0::NO::P9_RATE_FILINGS_ID,P9_COMPANY_NAME,P9_REFERRING_PAGE_NUM:8347,%5CAetna%20Life%20Insurance%20Company%5C,4&cs=1EC2866C2258A4653FBF2AB75773F8514.

California Department of Insurance. 2014b. Blue Shield of California Life & Health Insurance Company rate filing. https://interactive.web.insurance.ca.gov/apex/f?p=102:9:0::NO::P9_RATE_FILINGS_ID,P9_COMPANY_NAME,P9_REFERRING_PAGE_NUM:8948,%5CBlue%20Shield%20of%20California%20Life%20%26%20Health%20Insurance%20Company%5C,4&cs=19EB00AA77FC6C786F771ED7A07590A6F.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. Memo to all Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties regarding the announcement of calendar year (CY) 2016 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. April 6. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. Ratebooks & supporting data. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data.html.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. Medicare program: Medicare Shared Savings Program—Accountable care organizations (CMS–1461–P). Proposed rule. *Federal Register* 79, no. 235 (December 8): 72759–72872.

Ginsburg, P. B. Center for Studying Health System Change. 2011. Health care industry consolidation. Testimony before the Subcommittee on Health, Ways and Means Committee, U.S. House of Representatives. 112th Cong., 1st sess. September 9.

Gold, M., and G. Casillas. 2014. *What do we know about health care access and quality in Medicare Advantage versus the traditional Medicare program?* Menlo Park, CA: Kaiser Family Foundation.

Iyengar, S., and E. Kamenica. 2010. Choice proliferation, simplicity seeking, and asset allocation. *Journal of Public Economics* 94: 530–539.

Kahneman, D. 2011. *Thinking, fast and slow.* New York: Farrar, Straus and Giroux.

Kronick, R., and W. P. Welch. 2014. Measuring coding intensity in the Medicare Advantage program. *Medicare & Medicaid Research Review* 4, no. 2.

Mathews, A. W., and J. Kamp. 2013. Another big step in reshaping health care. *Wall Street Journal*, March 1.

McWilliams, J. M., B. E. Landon, M. E. Chernew, et al. 2014. Changes in patients' experiences in Medicare accountable care organizations. *New England Journal of Medicine* 371, no. 18 (October 30): 1715–1724.

Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2014a. *A data book: Health care spending and the Medicare program.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2014b. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2014c. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

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

Medicare Payment Advisory Commission. 2011. *Report to the Congress: Regional variation in Medicare service use.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2005. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Scheibehenne, B., R. Greifeneder, and P. M. Todd. 2010. Can there ever be too many options? A meta-analytic review of choice overload. *Journal of Consumer Research* 37, no. 3 (October): 409–425.

Schwartz, B. 2004. *The paradox of choice.* New York: Ecco.

Song, Y., J. Skinner, J. Bynum, et al. 2010. Regional variations in diagnostic practices. *New England Journal of Medicine* 363, no. 1 (July 1): 45–53.

White, C., A. M. Bond, and J. D. Reschovsky. 2013. *High and varying prices for privately insured patients underscore hospital market power.* HSC research brief no. 27. Washington, DC: Center for Studying Health System Change.

2

The next generation of Medicare beneficiaries

The next generation of Medicare beneficiaries

Chapter summary

The Medicare population is projected to increase from 54 million beneficiaries today to over 80 million beneficiaries by 2030 as the baby-boom generation ages into Medicare. This expansion will bring changes to the Medicare population. First, the average age of the Medicare population will initially skew younger than in the recent past, but then grow rapidly older as the number and share of beneficiaries ages 85 and older increases. The Medicare population is, and will be for some time, less diverse racially and ethnically than the population as a whole. The health status of future Medicare beneficiaries is not clear. Compared with previous generations, the baby-boom generation has longer life expectancies and much lower rates of smoking, but also has higher rates of obesity and diabetes. Boomers appear to have higher rates of some other diseases and chronic conditions, but they are also much more likely than generations before theirs to have certain health conditions under control.

Baby boomers who have had employer-sponsored insurance likely began their working years having conventional health plans—plans in which health care can be delivered by any provider, with the insurer paying a percentage of the provider's charges. But over the course of their careers, many experienced the disappearance of conventional plans and the rise and subsequent decline of managed care. Baby boomers likely experienced preferred provider organization plans with broad provider networks. The younger boomers and

In this chapter

- Introduction
- Looming changes in the size and composition of the Medicare population
- The health of the future Medicare population
- Supplemental health insurance coverage for Medicare beneficiaries: What to expect in the future
- Income, assets, and wealth
- Challenge for Medicare financing
- Conclusion

the generation that follows them may experience narrow-network plans, high-deductible plans, and the federal and state health insurance exchanges. There are indications that the percentage of firms offering health benefits to Medicare-eligible retirees has declined over the last decade, implying that over time, fewer Medicare beneficiaries will have generous employer-sponsored supplemental health insurance.

The recent recession has taken a toll on the baby-boom generation. Median family income, median family net worth, and the median value of financial assets have not recovered to their prerecession levels. Perceptions of economic well-being are also still low. The oldest baby boomers may have difficulty recouping their losses before entering retirement, which could leave the next generation of Medicare beneficiaries in a more vulnerable economic state than the current Medicare population.

The aging of the baby-boom population could also stress the economic well-being of the working-age population. The number of taxpaying workers per Medicare beneficiary has declined from 4.6 during the early years of the program to 3.1 today; by 2030, this number is projected by the Medicare Trustees to be 2.3. Additionally, Medicare relies heavily on general revenues, and that reliance is projected to increase (from 41 percent of program costs today to 45 percent of program costs in about 15 years); as a result, fewer resources will be available to invest in growing the economic output of the future (e.g., investments in education, transportation, and research and development). Finally, while fee-for-service Medicare covers services delivered by any willing provider, health plans for the working-age population may be narrowing their provider networks and increasing deductibles in an attempt to control health care spending. ∎

Introduction

Members of the baby-boom generation (born between mid-1946 and 1964) began aging into Medicare in 2011 at a rate of about 10,000 people per day, a rate that will continue until 2030. Over the next 15 years, Medicare's enrollment is projected to increase almost 50 percent—rising from 54 million beneficiaries today to more than 80 million beneficiaries in 2030. What effect will this large cohort have on the next generation of Medicare beneficiaries and the financial health of the program? This chapter explores that question with particular focus on the following:

- How will the incoming baby boomers affect the age structure of the Medicare population?

- Will the Medicare population be more racially and ethnically diverse given the growing racial and ethnic diversity of the total U.S. population?

- Given the improvements in life expectancies, will the next generation of Medicare beneficiaries live longer and healthier lives than previous generations? Or will the longer life expectancies increase the oldest age groups in Medicare, thereby increasing the rates of disease and chronic conditions?

- What is the projected growth in the share of enrollment in private plans?

- Have baby boomers and especially the oldest of the baby boomers had time to recover from the 2007 to 2009 recession before entering retirement?

- Finally, what is the outlook for the financial health of the Medicare program as the number of taxpaying workers per beneficiary declines?

Looming changes in the size and composition of the Medicare population

Figure 2-1 (p. 38) illustrates in four graphs the aging of the population in the United States that is currently underway. The graph on the top left shows the distribution of the population by age and gender in 1970. At that time, the U.S. population was generally shaped like a pyramid: Starting at the base of the pyramid and moving up, the bars show the population declining in the older age groups. The dark gray bars depict the baby-boom population, who in 1970 were ages 6 to 24.

In 2010, the oldest boomers were a year away from Medicare eligibility, and the population pyramid was starting to look more like a population rectangle (top-right graph of Figure 2-1). By 2030, the boomers, at that point ages 66 to 84, will have all aged into Medicare and will continue to contribute to rapid population aging (bottom-left graph of Figure 2-1). The sheer numbers of older people will be much higher than in prior years, and there will be a higher proportion of older people represented in the total population. In 2050, the boomers will be ages 86 and over, resulting in a larger population in the oldest old-age groups (bottom-right graph of Figure 2-1). This age structure will be unprecedented in U.S. history. Other economically advanced countries—notably Japan, Germany, Korea, and Italy—are also facing the challenges of aging populations because of low fertility rates and increased life expectancies.

Between 2010 and 2030, the older population (persons ages 65 and over) as a share of the total population is projected to jump from 13 percent to 20 percent, doubling its share from 1970 (Figure 2-2, p. 39). (The demographics of the baby-boom population are relatively similar across the four U.S. census regions, but individual states exhibit more variation. For a description of the demographics of the baby-boom generation by region and by state, see online Appendix 2-A, available at http://www.medpac.gov.)

The Medicare population will expand, become younger, and then grow older as the baby-boom generation ages

As the baby-boom generation ages, enrollment in the Medicare program will surge (Figure 2-3a, p. 39). In 15 years, Medicare is projected to have over 80 million beneficiaries—up from 54 million beneficiaries today—almost 90 percent of whom will be of the baby-boom generation. (Medicare enrollment also includes individuals under age 65 who qualify for Medicare based on disability status. See text box, p. 42.) While Medicare enrollment is rising, the number of workers per beneficiary is rapidly declining (Figure 2-3b, p. 39). Workers pay for Medicare spending through payroll taxes and income taxes. However, the number of workers per Medicare beneficiary has declined from 4.6 during the early years of the program to 3.1 today and is projected by the Medicare Trustees to fall to 2.3 by 2030. As discussed at the end of this chapter, these demographics threaten the financial stability of the Medicare program.

FIGURE
2–1

Baby-boom generation's aging causes the U.S. age distribution to shift
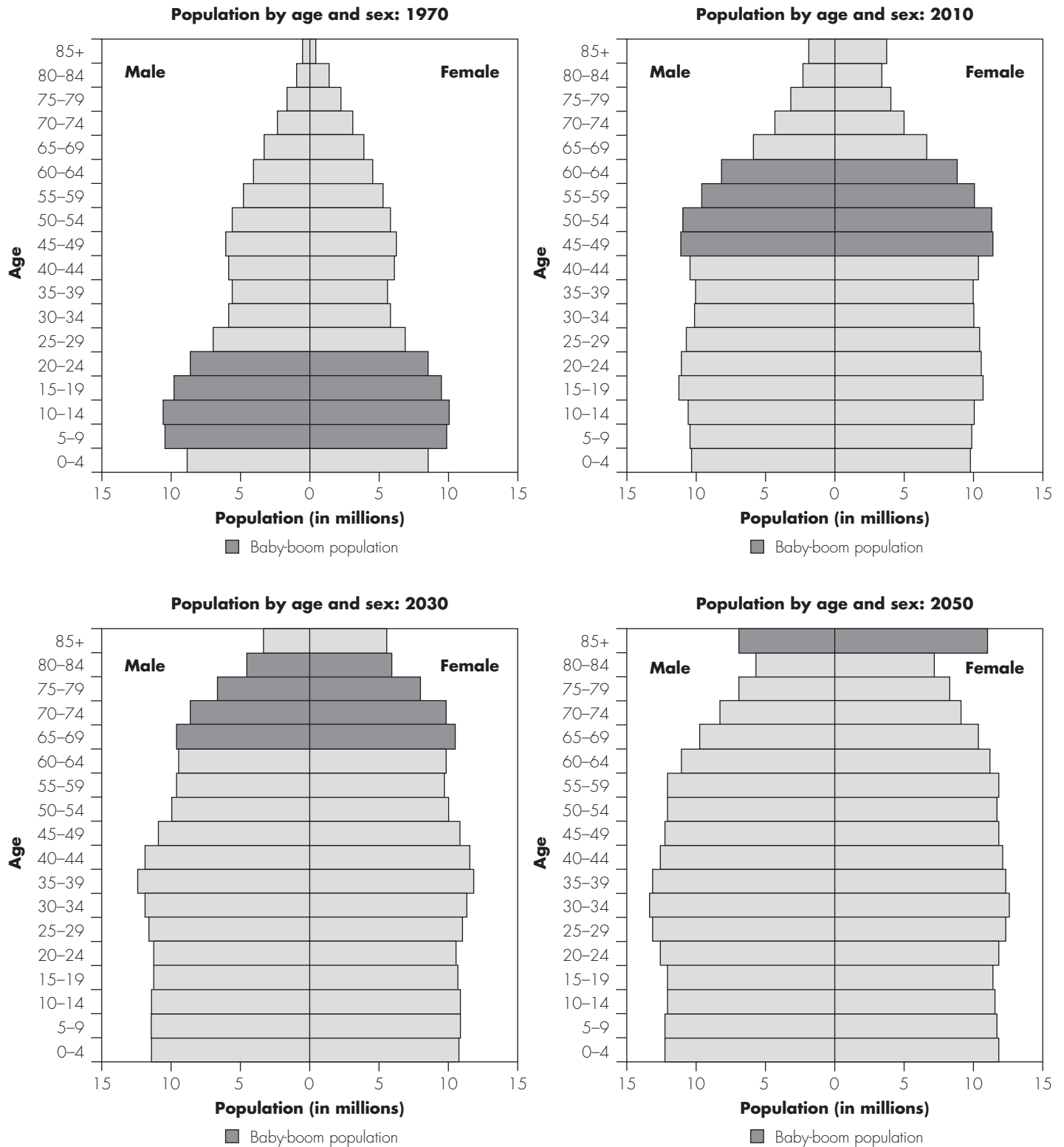
Population by age and sex: 1970

Population by age and sex: 2010

Population by age and sex: 2030

Population by age and sex: 2050

Source: Census Bureau 2015a; Census Bureau 2015b.

The sheer numbers of older people will be much higher than in prior years, as will the older population's share of the total population

Population ages 65 and older (in millions) and share of total population (in percent)

Year	1970	1980	1990	2000	2010	2020	2030	2040	2050	2060
Percent	10%	12%	11%	12%	13%	17%	20%	21%	21%	22%
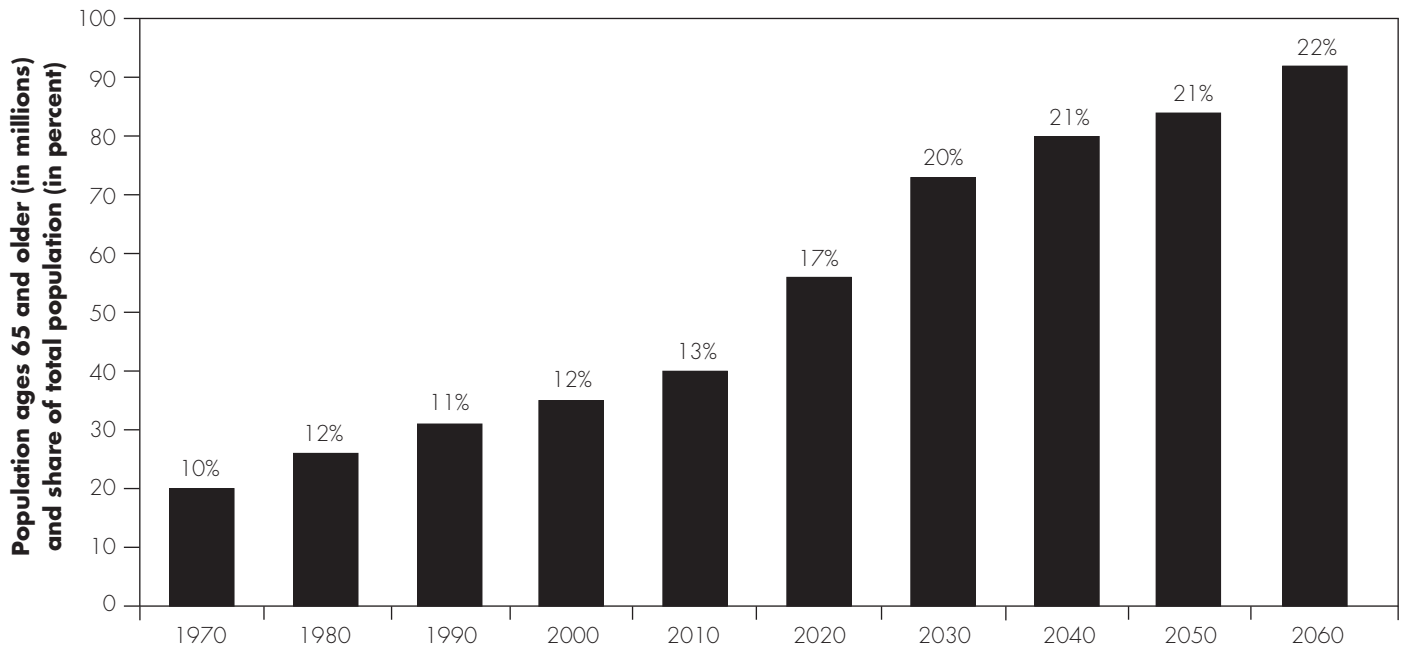
Source: Census Bureau 2015a; Census Bureau 2015b.

Medicare enrollment is rising while workers per HI beneficiary is declining

Figure 2-3a. Medicare enrollment

Medicare enrollment (in millions)
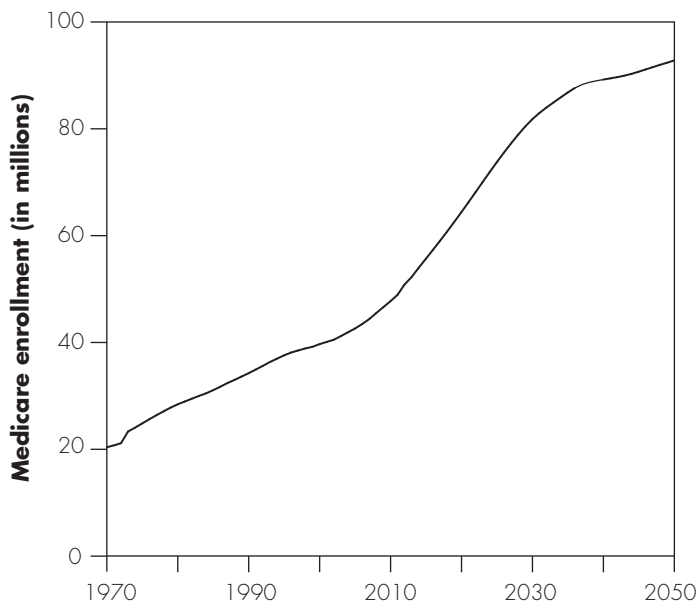
Figure 2-3b. Workers per HI beneficiary

Workers per HI beneficiary
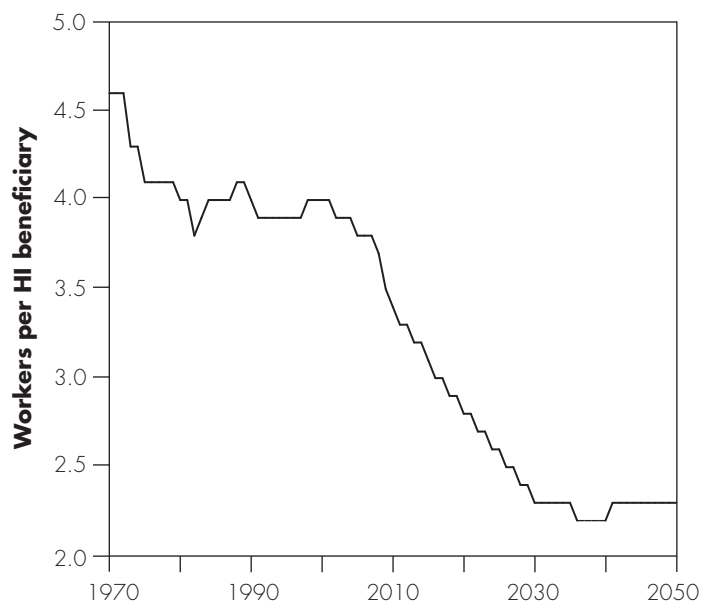
Note: HI (Hospital Insurance). Hospital Insurance is also known as Medicare Part A.

Source: Boards of Trustees 2014.

**FIGURE
2–4**

**The Medicare population will become younger and
then grow older as the baby-boom generation ages**
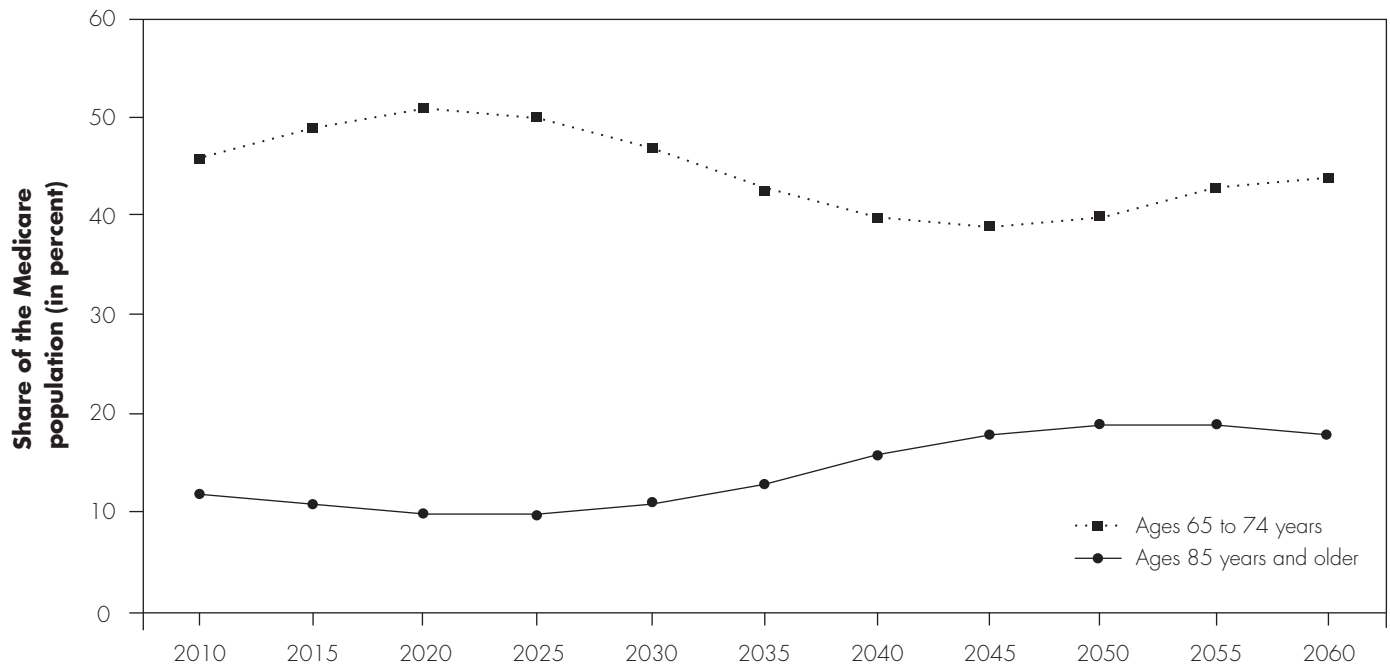
The Medicare population over the next 15 years will
be relatively younger as members of the baby-boom
generation join its ranks and swell the younger segments
(Figure 2-4). The share of the Medicare population ages
85 years and older is projected to decline slightly through
2025 and then grow as baby boomers continue to age
(Census Bureau 2012). In 2012, per beneficiary spending
for those ages 85 and older was about twice that of
those ages 65 to 74. So the changing age structure of the
Medicare population will exert somewhat less pressure
on spending in the very near term, at least on a per capita
basis, and then pressure will increase again over the longer
term.[1]

Racial and ethnic diversity of the older population will lag behind that of the total population

The older population is, and will be for some time, less
diverse racially and ethnically than the total population.
Whites will remain a majority of the older population
through 2060 (Figure 2-5a), whereas Whites will no
longer be a majority of the total population by 2043
(Figure 2-5b). The older population's racial and ethnic

diversity will lag behind that of the total population for
several reasons. First, at any given time, the racial and
ethnic composition of the Medicare population largely
reflects the U.S. population 66 to 100 years ago—when
aged Medicare beneficiaries were born. When the baby-
boom generation was born—between 1946 and 1964—
almost 90 percent of the total U.S. population was White
(Ortman et al. 2014). Second, since 1964, the nation's
population has become increasingly diverse through
increases in immigration and minority births. However,
recent immigration does not have much of an effect on
the age structure of the older population because most
immigrants are under the age of 40 when they arrive in the
United States (Ortman et al. 2014). (The racial and ethnic
diversity of the baby-boom population varies across U.S.
census regions and states. See online Appendix 2-A for a
description, available at http://www.medpac.gov.)

After 2030, the baby-boom generation's share of the
older population will begin to decline, contributing to
the increase in the racial and ethnic diversity of the older
population. The share of the older population identifying
as White is projected to decline modestly from 2012 to
2030, decreasing from 79 percent to 72 percent. By 2060,

FIGURE
2–5

The older population (ages 65 and older) is less racially
and ethnically diverse than the total population

Figure 2-5a. Percent of the older population, by race and ethnicity
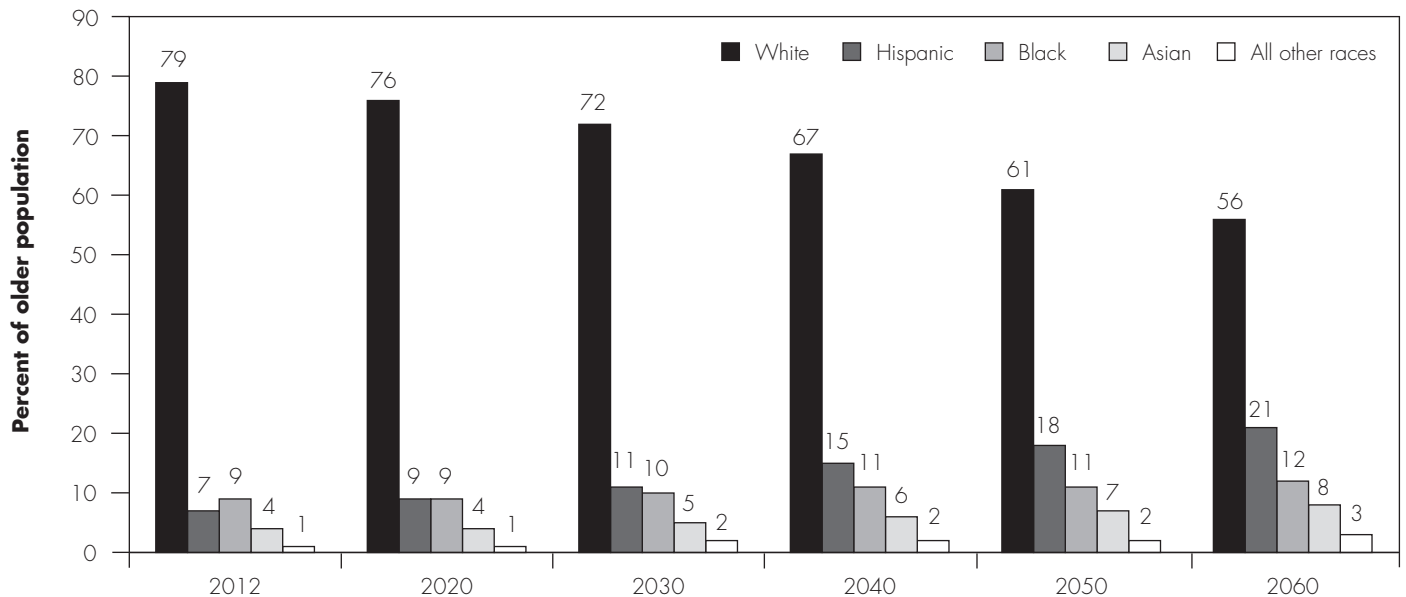
Figure 2-5b. Percent of the total population, by race and ethnicity
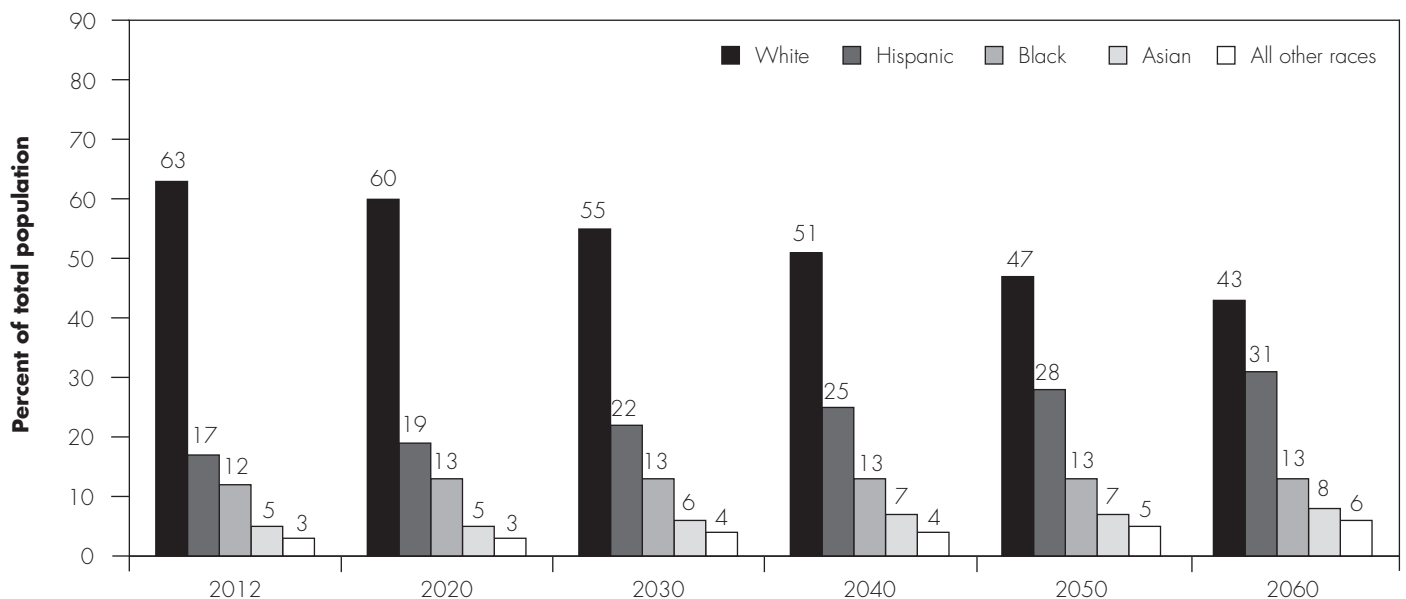
Note: "All other" includes American Indian and Alaska Native and multiracial.

Source: Census Bureau 2012.

the share of the older population identifying as White is projected to fall to 56 percent. The share identifying as Hispanic is projected to increase modestly from 2012 to 2030, increasing from 7 percent to 11 percent. By 2060, the share identifying as Hispanic is projected to increase to 21 percent, tripling its 2012 share (Figure 2-5a).

Trends in Disability Insurance enrollment

Demographic and population changes also affect the number of Medicare beneficiaries who are entitled to Medicare on the basis of disability through the Social Security Disability Insurance (SSDI) program. The SSDI program was established in 1956 for workers who are unable to engage in substantial gainful employment as a result of an impairment that would last one year or more or result in death. Currently, individuals under the age of 65 who are entitled to SSDI payments are eligible for Medicare 24 months after their disability begins.

Over the past three decades, the number of SSDI recipients has grown significantly, from 2.9 million in 1980 to 9.0 million in 2013. Part of this growth in SSDI enrollment is due to demographic changes. The rates of disability are highest for individuals ages 55 to 64. As baby boomers moved into these age categories over the past decade, the rate of SSDI enrollment has increased. Many observers expect that the rates of new SSDI recipients will slow as the baby-boom generation moves into retirement age.

Other demographic changes in the workforce have also had an effect on enrollment. Specifically, as labor force participation among women increased, the rates of women becoming entitled to SSDI based on their own work history also rose.

However, these demographic shifts do not explain all of the SSDI enrollment growth. Other changes also appear to have had a significant impact. First, administrative and statutory changes explicitly require the Social Security Administration to consider reported pain and mental impairments. As a result, the largest share of SSDI recipients report musculoskeletal impairments and mental impairments as their disabling condition. These conditions generally occur at ages younger than other disabling conditions and have relatively lower rates of mortality (Autor and Duggan 2006, Dahl and Meyerson 2010, Duggan and Imberman 2009). This demographic change means a significant group of beneficiaries are starting to receive SSDI earlier in their lives and are receiving it for longer (Schwabish 2012).

SSDI has also grown because of changes in the labor force for low-wage workers. The median wage (and particularly wages for low-income workers) has either remained flat or declined over the past decade. The SSDI benefit amount, in contrast, is indexed to the average wage and so has grown more quickly than the median wage (Autor and Duggan 2006).

SSDI applications also show a strong countercyclical pattern—as individuals lose their jobs and are unable to find new ones, applications for SSDI increase. The most recent recession has been characterized by very-long-term unemployment and high rates of job loss among older workers, and the number of SSDI applications grew by 50 percent between 2005 and 2010. But fewer than 5 percent of SSDI recipients ever return to work, which means that while SSDI enrollment increases during recessions, the number of beneficiaries does not commensurately fall when the economy recovers (Burkhauser et al. 2013).

Changes in health status and the prevalence of work-limiting disability do not appear to have played a significant role in the growing number of SSDI enrollees. The research on whether the working-age population is becoming more or less disabled over time is mixed, even when researchers use the same data sources and similar methodologies. For one thing, life expectancy has improved for individuals under the age of 65 (Duggan and Imberman 2009, Kaye 2013, King et al. 2013). For another, self-reported rates of limitations in activities of daily living (ADLs) among the total population have remained constant over time or have fallen slightly (National Center for Health Statistics 2014).

However, while the rates of individuals reporting a work-limiting disability have remained constant, reporting a serious work-limiting disability has risen slightly (Social Security Administration 2006). In addition, a few studies have shown higher rates of ADL limitations among younger workers—particularly due to rapidly growing rates of obesity and related conditions (King et al. 2013, Lakdawalla et al. 2004). Overall, however, the significant rise in the number of SSDI enrollees cannot be explained solely by changes in underlying disability among the population. ∎

FIGURE
2–6

Smoking has been on the decline ever since baby boomers began entering adulthood
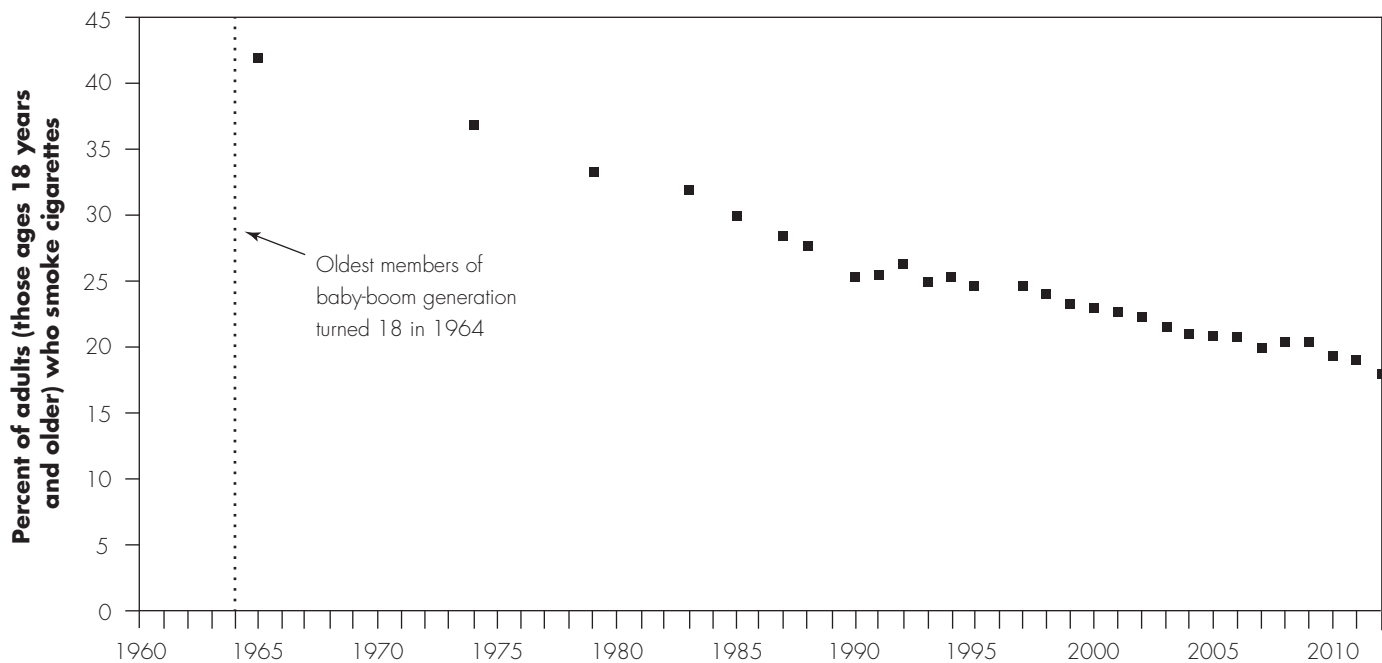
Note: Data are not available for all years because surveys were not conducted every year.

Source: National Center for Health Statistics 2014.

The health of the future Medicare population

How will the health of the Medicare population change over the next couple of decades as the baby-boom generation ages into the program? There is a lot of uncertainty surrounding that question. What is known is that members of the baby-boom generation have longer life expectancies and a much lower rate of smoking than earlier generations. However, the baby-boom generation has higher rates of obesity and diabetes than previous generations. Boomers also appear to have higher rates of other diseases and chronic conditions (like hypertension, high cholesterol, and cancer), but those higher rates could be driven by expanded testing and disease definitions. Moreover, boomers are much more likely to have some conditions under control, namely hypertension and high cholesterol.

Positive indicators: Longer life expectancies and lower rates of smoking

The baby-boom generation enjoys much longer life expectancies than earlier generations. Between 1900 and

1960, life expectancy at birth improved by more than 20 years, from 47 years to 70 years. The baby-boom generation compared with earlier generations also enjoys longer life expectancies at older ages (Census Bureau 2014). Individuals born in 1905 who reached age 65 in 1970 had a remaining life expectancy of about 15 years. Individuals born in 1945 who reached age 65 in 2010 had a remaining life expectancy of about 19 years, a 4-year increase over the 1905 birth cohort.

The baby-boom generation's rate of smoking is much lower than it was in previous generations (Cutler and Glaeser 2006). When members of the previous generation were adults in the 1950s and mid-1960s, Americans had one of the highest smoking rates in the developed world—in 1965, over 40 percent of those ages 18 years and older smoked (Census Bureau 2014). But since the mid-1960s and throughout the period that baby boomers entered adulthood, that rate has been on a dramatic decline. By 2012, only 18 percent of those ages 18 years and older smoked (Figure 2-6).

**FIGURE
2–7**

**Obesity rates are higher for the baby-boom
generation than for previous generations**

Figure 2-7a. Female obesity rate, ages 45 to 64
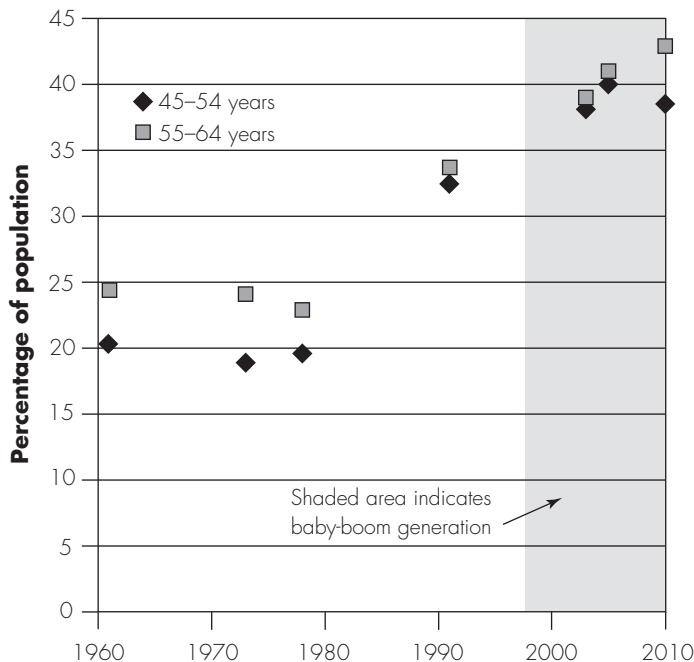
Figure 2-7b. Male obesity rate, ages 45 to 64
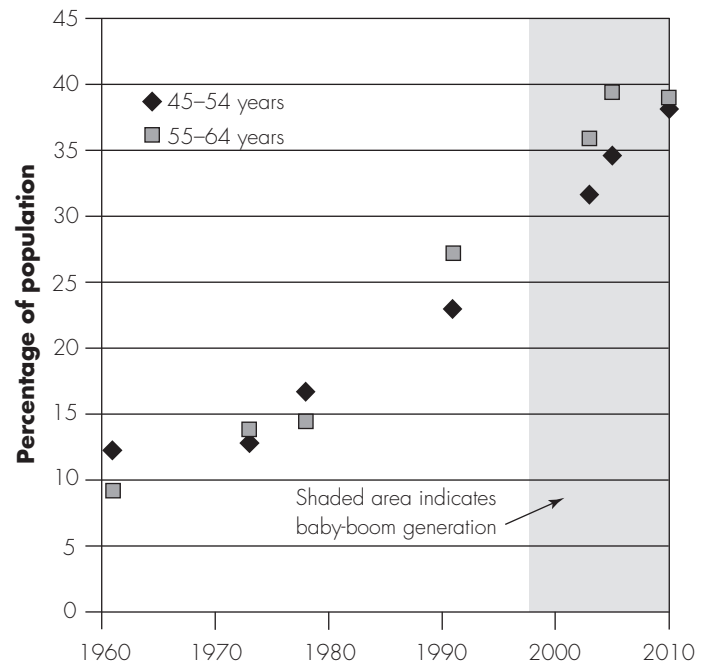
Note: Data are not available for all years because surveys were not conducted every year.

Source: National Center for Health Statistics 2014.

Negative indicators: Higher rates of obesity and diabetes

Although smoking rates have declined, the share of adults who are obese has risen dramatically over the last 40 years. In the 1970s, about 15 percent of the adult population ages 20 to 74 years was obese. By 2010, that share more than doubled—reaching 36 percent. The proportion of boomers who were obese in 2010 was even higher, at about 40 percent for both females and males (Figure 2-7). Boomers were ages 46 to 64 years in 2010. For that same age group in the 1960s, 1970s, and 1980s, obesity rates ranged from 19 percent to 24 percent for females and around 9 percent to 17 percent for males.

Related to higher rates of obesity, baby boomers have higher rates of diabetes than the previous generation (15.0 percent versus 13.9 percent, respectively). However, baby boomers diagnosed with diabetes are much more likely to have the disease under control than members of the previous generation.[2] For the U.S. adult population

overall, researchers found a doubling of the share with diabetes from 1990 to 2008 and a plateauing between 2008 and 2012 (Geiss et al. 2014). Despite the leveling off in recent years, the share of African Americans, Hispanics, and those with a high-school education or less who have diabetes appears to continue to increase.

Mortality from diabetes has declined, leading to more years spent with diabetes but fewer years lost to the disease for the average individual with diabetes (Gregg et al. 2014a, Gregg et al. 2014b). For the population as a whole, however, the number of years lost to diabetes has increased due to the increase in the numbers of people who have the disease.

Mixed indicators: Higher rates of some diseases and chronic conditions, but evidence of better management

When compared with the previous generation, the baby-boom generation has higher rates of hypertension and high cholesterol, but boomers with those conditions are much

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more likely to have them under control.[3] Perhaps because of better management of those conditions, boomers have shares of heart disease and stroke similar to the previous generation. Some research also indicates that cancer rates have increased among the baby-boom population (National Center for Health Statistics 2014).

However, higher rates of disease and chronic conditions could also be the result of increased use of diagnostic testing and more aggressive or expansive treatment practices (Welch et al. 2011). For example, an extremely slow-growing cancer may now be detectable in a person with no symptoms, but it would never progress to make the person sick, in which case, treatment might not be wise.

Also, not all diseases and chronic conditions have the same impact on per beneficiary spending. For example, high blood pressure and high cholesterol were the two most prevalent chronic conditions among Medicare beneficiaries in 2010, but stroke, chronic kidney disease, asthma, and chronic obstructive pulmonary disease were among the chronic conditions associated with the highest per beneficiary spending (Centers for Medicare & Medicaid Services 2012).

Another factor affecting per beneficiary Medicare spending is whether beneficiaries were continuously insured before age 65. Research has found that Medicare spending is significantly higher for previously uninsured adults than for previously insured adults (McWilliams et al. 2009). Therefore, the increased availability of health insurance under the Patient Protection and Affordable Care Act of 2010 (PPACA) could reduce future Medicare spending for younger baby boomers. Coverage under PPACA through Medicaid expansions (in participating states) and federal and state exchanges began in 2014, when the youngest boomers were 50 years old. So some boomers who otherwise would have been uninsured before aging into the Medicare program now may have up to 15 years of continuous coverage before becoming eligible for Medicare.

Supplemental health insurance coverage for Medicare beneficiaries: What to expect in the future

Medicare does not cover all health care expenses. According to one study, the Medicare fee-for-service (FFS) benefit covered about 80 percent of the cost of Medicare-covered services in 2011, and beneficiaries paid for some of that benefit through premiums (McArdle et al. 2012).

Beneficiaries are also responsible for paying deductibles, coinsurance, and copayments on most covered services, and all the costs of noncovered services, such as dental services. Further, there is no cap on costs for which beneficiaries are responsible. (Medicare does not have a catastrophic limit on how much beneficiaries spend out of pocket for inpatient and outpatient services in its FFS program, although there is a partial limit in Part D, in which cost sharing is significantly reduced after out-of-pocket expenditures for prescription drugs reach a catastrophic threshold.)

To cover some of those additional costs, about 90 percent of beneficiaries have coverage that supplements or replaces the Medicare benefit package. In 2013, about 28 percent of beneficiaries were enrolled in Medicare Advantage (MA) plans—private health plans that replace traditional FFS Medicare in which Medicare pays plans a fixed rate per enrollee rather than a fixed rate per service—and about 21 percent were enrolled in Medicaid—a joint federal–state program that pays for health care services for low-income people (Boards of Trustees 2014). In 2010, 31 percent of beneficiaries had employer-sponsored supplemental retiree coverage (coverage from a former employer that fills in some of Medicare's gaps in coverage such as coinsurance, copayments, and deductibles), and about 15 percent had Medicare Supplement Insurance (medigap)—coverage purchased by beneficiaries, which also fills in some of Medicare's gaps in coverage (McArdle et al. 2014). Other types of supplemental coverage include public sector coverage, such as TRICARE and Veterans Health Administration coverage. This section of the chapter examines the outlook for enrollment in MA plans and the share of Medicare beneficiaries with employer-sponsored supplemental retiree coverage.

Medicare Advantage enrollment trends

From 2005 to 2013, the share of Medicare beneficiaries enrolled in MA plans increased from 14 percent to 28 percent—a growth rate of 10 percent per year, on average (Figure 2-8, p. 46). That rapid growth was in large part due to higher per capita payments to MA plans relative to per capita FFS costs. The higher MA payment rates enabled plans to attract beneficiaries with reduced Part B and Part D premiums, lower cost sharing, and additional benefits compared with traditional FFS Medicare.

Changes specified by PPACA were intended to substantially reduce MA payment rates beginning in 2011 to bring rates more in line with FFS costs. There were expectations by some that enrollment in MA plans would

FIGURE
2–8

Enrollment in Medicare Advantage plans has increased rapidly since 2005; projections assume a slowdown
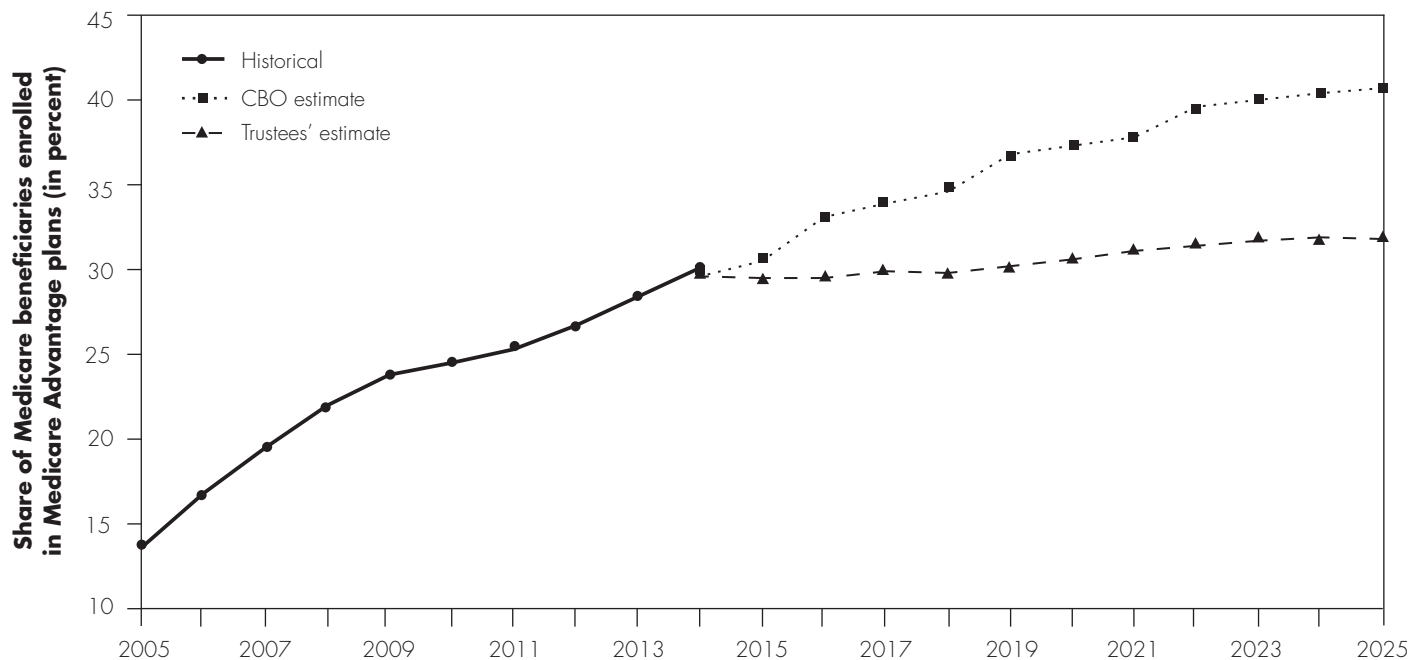
Note: CBO (Congressional Budget Office).

Source: Boards of Trustees 2014; Congressional Budget Office 2015b.

decrease. However, the PPACA-mandated payment rate cuts were offset by new quality bonus payments and plans' increased coding of beneficiaries' medical conditions (payments to MA plans are higher when beneficiaries have more medical conditions, all other things being equal); as a result, the share of Medicare beneficiaries enrolled in MA plans continued to grow through 2013.

Despite growth in the MA enrollment share of 10 percent per year over the past decade, the Trustees project growth of one-half of 1 percent per year over the next decade, resulting in an MA enrollment share of 32 percent by 2025. As shown in Figure 2-8, that projection would require a marked departure from current trends.

The Congressional Budget Office's (CBO's) projection is higher than the Trustees, but still lower than experienced historically. CBO estimates that the MA enrollment share will grow by about 3 percent per year over the next decade, resulting in a share of 41 percent by 2025.

In addition to MA payments, future enrollment in MA also depends on beneficiaries' experiences with private health

insurance coverage before Medicare enrollment. The under-65 population—accustomed to choosing coverage from a range of plans or receiving care from a limited provider network—may be more likely to consider all their options when they enroll in Medicare, including available MA plans. The baby-boom generation's experience with private health insurance coverage before they become Medicare eligible has been evolving.

In 1988, boomers were between the ages of 24 and 42, many embarking on or in the midst of their working careers. At that time, over 70 percent of workers with employer-sponsored health insurance were enrolled in conventional plans—that is, plans in which health care can be delivered by any provider, with the insurer paying a percentage of the provider's charges (Figure 2-9). Many also experienced the disappearance of conventional plans and the rise and subsequent decline of managed care in the form of HMOs—plans in which health care must be delivered by providers in a network. The share of covered workers enrolled in HMOs reached a high of about 30

FIGURE
2–9

Many boomers began their working careers in conventional plans and experienced the rise and fall of HMOs
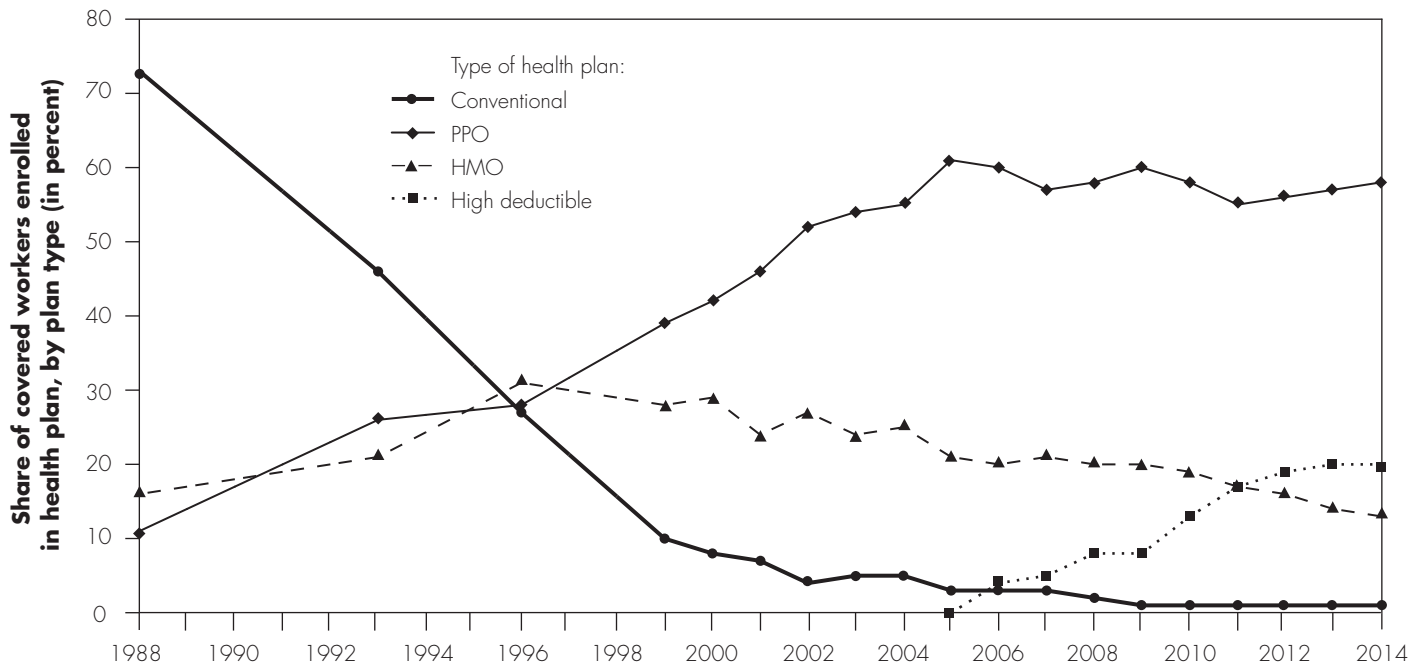
Note: HMO (health maintenance organization), PPO (preferred provider organization). Data are not available for years 1989 through 1992, 1994 through 1995, and 1997 through 1998.

Source: Kaiser Family Foundation and Health Research & Educational Trust 2014.

percent in the mid-1990s before steadily falling to its current share of 13 percent.

Throughout that time, the share of covered workers enrolled in preferred provider organizations (PPOs) has grown steadily. PPOs cover only services provided by a network of preferred providers or have lower cost sharing for services delivered by in-network providers versus out-of-network providers. A PPO's provider network is typically not as limited as an HMO's provider network. From 1988 through 2005, the share of covered workers enrolled in PPOs rose from 11 percent of the market to 61 percent and has hovered a little under 61 percent since.

What is harder to quantify is how broad or narrow the access to providers is in PPO plans and how the PPOs' provider networks may have broadened or narrowed over time. The sense from at least some industry observers is that, after the backlash against managed care in the mid-1990s to late 1990s, employees and employers favored the broadest possible access to providers and demanded very large networks, and PPO plans complied. However, since

the 2007 to 2009 recession, employees and employers have been increasingly willing to accept plans with narrower networks in return for lower premiums and cost sharing. According to one survey, 8 percent of employers with 50 or more employees reported offering a narrow-network plan in 2014 (Kaiser Family Foundation and Health Research & Educational Trust 2014). One health policy analyst estimated that, of employers with more than 500 employees, 15 percent included narrow-network plans in their plan offerings in 2013 (Carroll 2014). Narrow-network plans have also been among the offerings on the federal and state health insurance exchanges that commenced in 2014 under PPACA. One research firm estimated that narrow-network plans were available to 92 percent of consumers eligible to purchase health care through the exchanges and that broad-network plans were available to close to 90 percent of these consumers (McKinsey & Company 2014).

High-deductible plans entered the marketplace in the mid-2000s. Those plans typically have lower premiums than

**FIGURE
2–10**

**Percentage of private sector workers employed by firms offering
health insurance to Medicare-eligible retirees declined, 1997–2011**
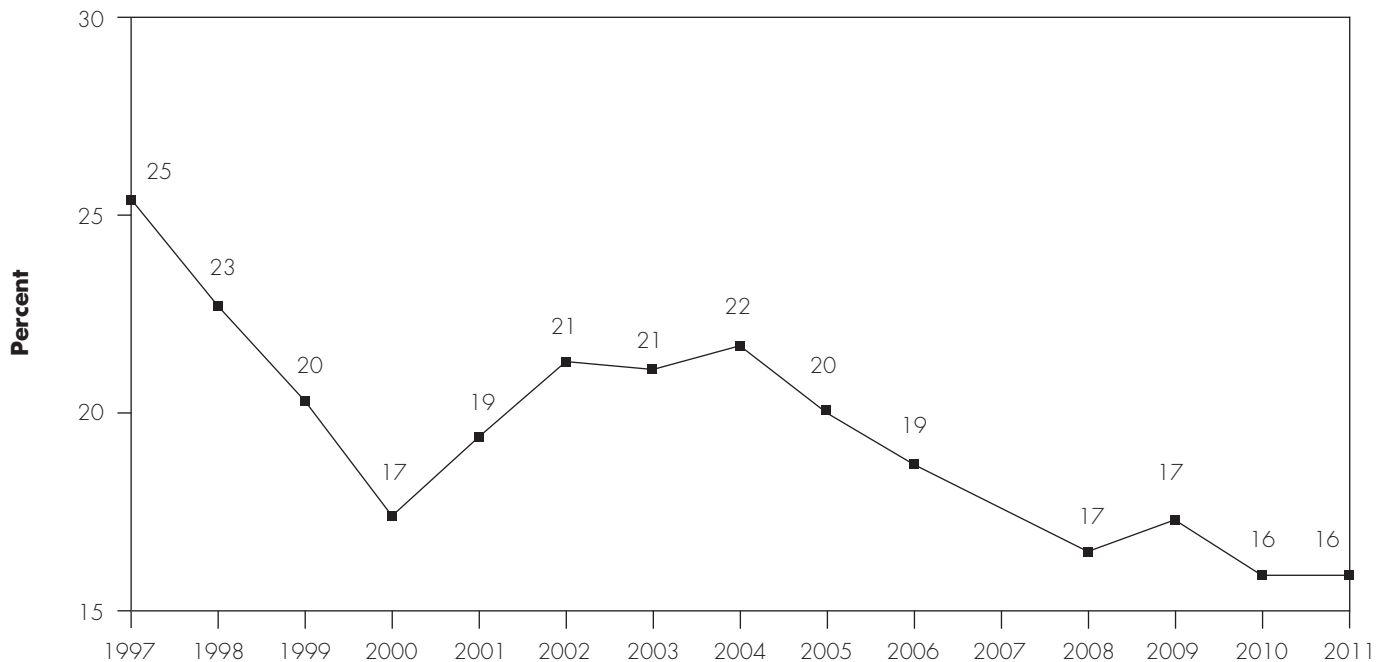
Note: Data for 2007 are unavailable.

Source: Frostin and Adams 2012 estimates from Medical Expenditure Panel Survey.

traditional plans but require the enrollee to pay a large deductible amount before receiving insurance benefits. From 2006 through 2013, high-deductible plans rose from just 4 percent of the market to 20 percent and remained at that share in 2014 (Figure 2-9, p. 47) (Kaiser Family Foundation and Health Research & Educational Trust 2014).

Boomers were 45 to 63 years old at the end of the 2007 to 2009 recession, 49 to 67 years old by the time high-deductible health plans achieved 20 percent of the market, and 50 to 68 years old when the federal and state health insurance exchanges commenced. Thus, the oldest baby boomers may not have had the experience with narrow-network plans, high-deductible plans, and the federal and state health insurance exchanges that younger boomers and the generation that follows them may have.

Employer-sponsored supplemental retiree coverage trends

Some beneficiaries receive from their former employers coverage that supplements the Medicare coverage benefit.

The plans provide benefits that fill in some of Medicare's gaps in coverage, such as coinsurance and deductibles. Plans might also provide "stop loss" coverage, which starts paying enrollees' out-of-pocket costs when they reach a specified maximum amount. Terms of the plans (e.g., benefits, premiums, and cost sharing) are determined by employers and can vary substantially across plans. In 2010, a year before baby boomers began aging into Medicare, 31 percent of Medicare beneficiaries had employer-sponsored supplemental retiree coverage (McArdle et al. 2014).

The share of Medicare beneficiaries with employer-sponsored supplemental retiree coverage will likely decline in the future because an increasing share of employers report that they are not offering retiree health benefits. From 1997 through 2011, the percentage of private sector workers employed by firms offering health insurance to Medicare-eligible retirees declined from 25 percent to 16 percent (Figure 2-10) (Fronstin and Adams 2012). While public sector employees are more likely to receive health benefits upon retirement than private

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FIGURE
2–11

Sources of family income for the population age 55 and over, 2012
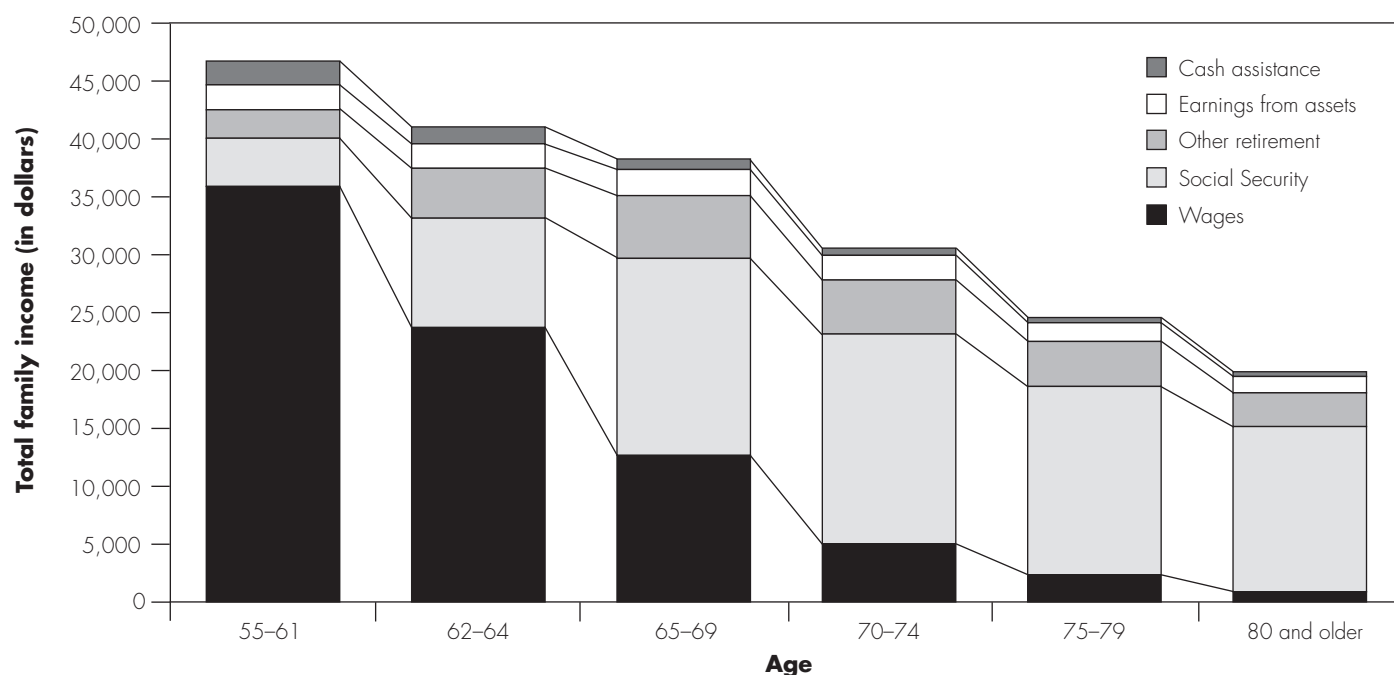
Source: Social Security Administration 2012.

sector employees, the share of state and local governments offering health insurance to Medicare-eligible retirees has also declined over the past decade. From 1997 through 2010, the share of state governments offering health insurance to Medicare-eligible retirees declined from 69 percent to 63 percent, and the share of local governments with 10,000 or more workers offering health insurance to Medicare-eligible retirees declined from 81 percent to 67 percent (data not shown in Figure 2-10) (Fronstin and Adams 2012).

The rising cost of health care coverage, especially for older populations, might have been a reason some employers dropped health benefits for Medicare-eligible retirees. Another reason may have been accounting changes issued in 1990 that required private sector companies to record retiree health-benefit liabilities on their financial statements. Also, public sector accounting changes issued in 2004 required public sector employers to accrue the cost of postretirement health benefits during the years of service as opposed to reporting the cost on a pay-as-you-go basis (Fronstin and Adams 2012).

Income, assets, and wealth

What will be the financial status of persons as they become Medicare eligible? To answer, we examine the financial resources of current beneficiaries, the resources of near-retirees in the context of the recent economic slowdown, and the effects of the recent recession on purchasing patterns and consumer sentiment.

Current picture of beneficiary income

Sources of income and total income change as individuals get older. As individuals leave the workforce, family income shifts from wages to financial assets and retirement supports such as Social Security. By age 80, the average family's income is about half the preretirement level, and the largest share is from Social Security (Social Security Administration 2012) (Figure 2-11).

Median household income is lowest for households headed by individuals ages 24 and under and ages 65 and older (DeNavas-Walt and Proctor 2013) (Table 2-1, p. 50).

TABLE
2–1

**Median household income,
by age of householder, 2013**

Age of householder	Median household income
15–24	$34,311
25–34	52,702
35–44	64,973
45–54	67,141
55–64	57,538
65 and over	35,611

Note: Measure includes cash benefits (e.g., Old Age, Survivors, and Disability Insurance) and excludes noncash benefits (e.g., Medicare).

Source: DeNavas-Walt and Proctor 2013.

Despite their relatively low income level, the share of individuals over age 65 who are below the poverty threshold is lower than it is for individuals under age 65. In 2013, the Census Bureau reported that 9.5 percent of individuals over age 65 were living in poverty, compared with 13.6 percent of individuals between the ages of 18

and 64, and 19.9 percent of children. Those differences result from the nearly universal Social Security coverage of retirees over age 65, providing a minimum level of income. The rate of individuals ages 65 and older in poverty has also fallen over time and has been roughly constant in the past two decades (Figure 2-12).

Overall median income remained relatively flat or declined for most age groups over the past decade (Figure 2-13). Income for individuals over age 65 has grown slightly, even during periods of economic contraction, because retirees' income sources (such as distributions from retirement accounts and Social Security) are less likely to be subject to fluctuations in the labor market (DeNavas-Walt et al. 2013, National Bureau of Economic Research 2014).

Effect of the recent recession

The 2007 to 2009 recession had an effect on the income, assets, and wealth of those nearing retirement as well as younger populations. The magnitude of the contraction was the largest since the Great Depression, and employment growth after the recession ended has been slow (Bureau of Labor Statistics 2012).

**FIGURE
2–12**

The poverty rate among individuals over age 65 has remained steady since the mid-1990s
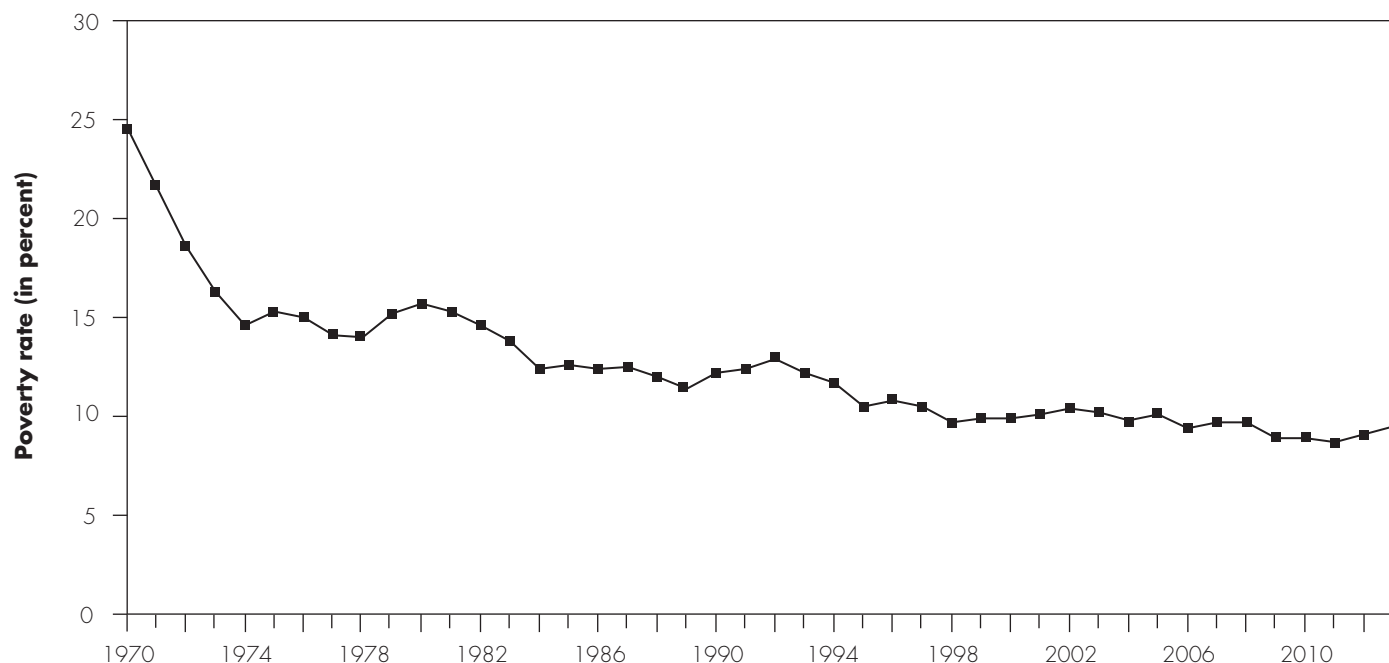
Note: The change from 2012 to 2013 is not statistically significant.

Source: DeNavas-Walt and Proctor 2013.

FIGURE
2–13

Median household income for selected ages, 1980–2013
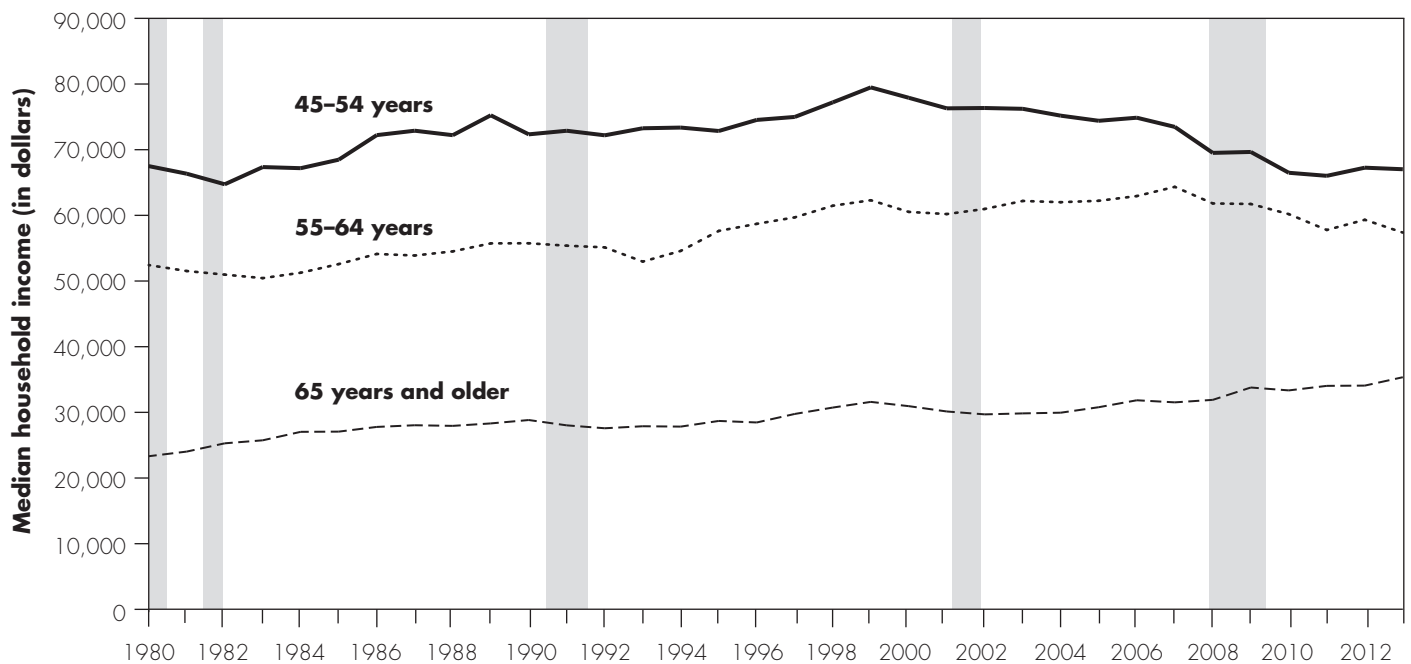
Note: Data are in 2013 dollars. Shading shows periods of National Bureau of Economic Research–defined economic contractions.

Source: DeNavas-Walt and Proctor 2013; National Bureau of Economic Research 2014.

However, the recent recession was characterized not only by labor market disruption but also by a decline in the value of housing assets and the stock market. These factors have had varying effects on individuals of different ages, complicating the question of whether individuals near retirement were worse off than younger workers during the recession.

Individuals near retirement may have been disproportionately affected by the most recent recession for three reasons. Individuals near retirement typically have the highest asset values, are less able than younger individuals to be able to modify their consumption and savings behavior to absorb economic shocks, and may be forced into early retirement because of job loss, permanently lowering their income (Hurd and Rohwedder 2010). In addition, older individuals had historically high rates of unemployment during the last recession: Rates more than doubled in a two-year period (Johnson 2012).

For other reasons, however, individuals near retirement may have been relatively shielded from the most recent recession. First, younger individuals were more likely than near-retirees to experience multiple economic shocks such as owing more on their house than the house was worth or losing their job (Gustman et al. 2012, Johnson 2012).

Second, unemployment rates for younger workers—those ages 25 to 49—were higher than for other age groups, and the overall unemployment rate for men exceeded 10 percent, a level not reported since 1940 (Hout and Cumberworth 2012, Johnson 2012).

Despite the end of the economic contraction, median household net worth has not recovered to prerecession levels; for families of varying ages, their net worth remains about a third below their peak in the middle of the last decade (Federal Reserve 2014) (Figure 2-14, p. 52).

A large share of the decline in net worth is attributable to the continued decline in the value of housing assets and a decreasing share of families who own their own home. The value of families' financial assets (for those who have them) also declined as a result of the recession. But it does appear that individuals who are either in retirement or very close to it (ages 65 to 74) have seen their financial assets recover to some extent (Figure 2-15, p. 52).

Consumer sentiment

These recent patterns in income, employment, and assets for the population as a whole support the perception that the recovery has not been robust. Perception of economic

FIGURE
2–14

Median family net worth, by age of primary householder
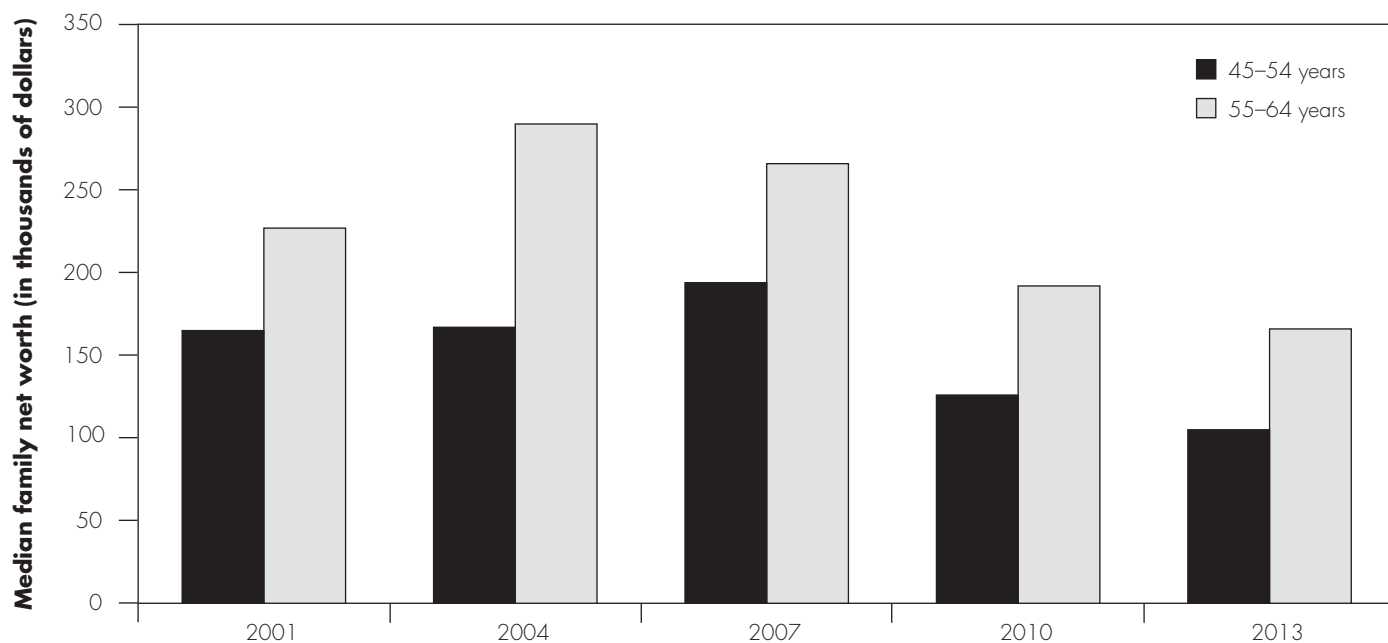
Note: Data are in 2013 dollars.

Source: Federal Reserve 2014.

FIGURE
2–15

Median value of financial assets, by age of primary householder
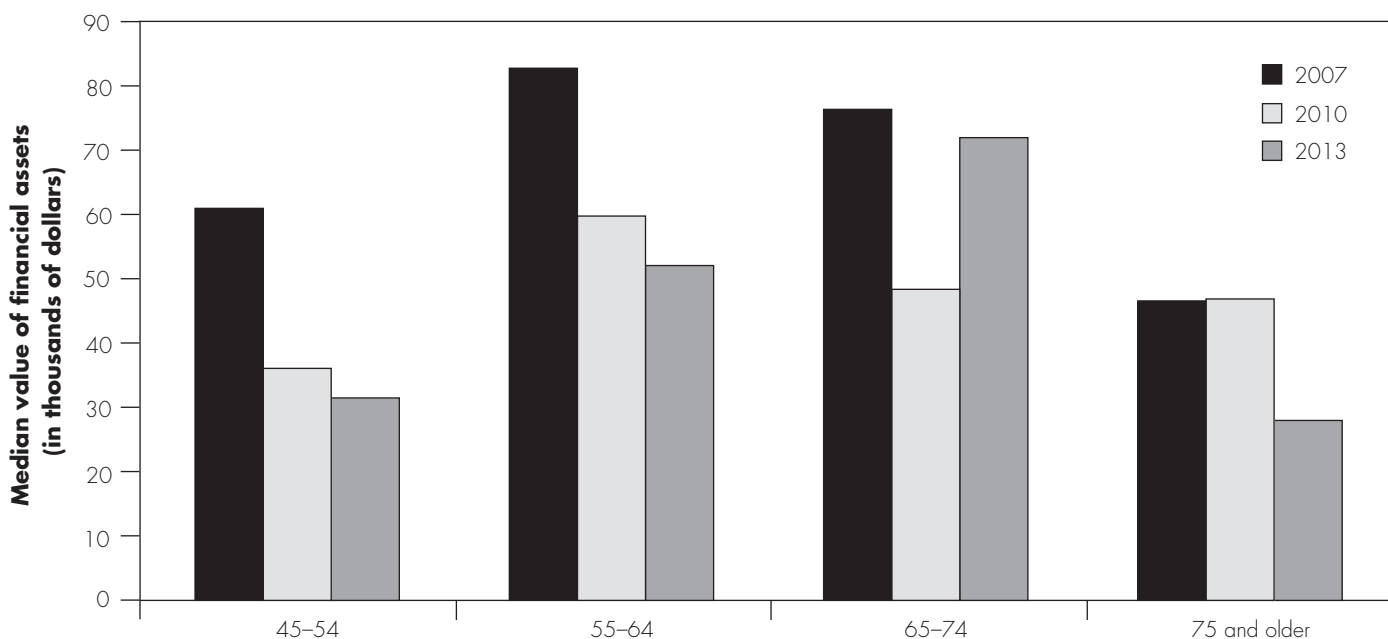
Note: Data are in 2013 dollars. Financial assets include stocks, bonds, certificates of deposit, retirement accounts, and others. Values are only for those respondents who have any financial assets.

Source: Federal Reserve 2014.

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FIGURE
2–16

Consumer sentiment remains below its prerecession level
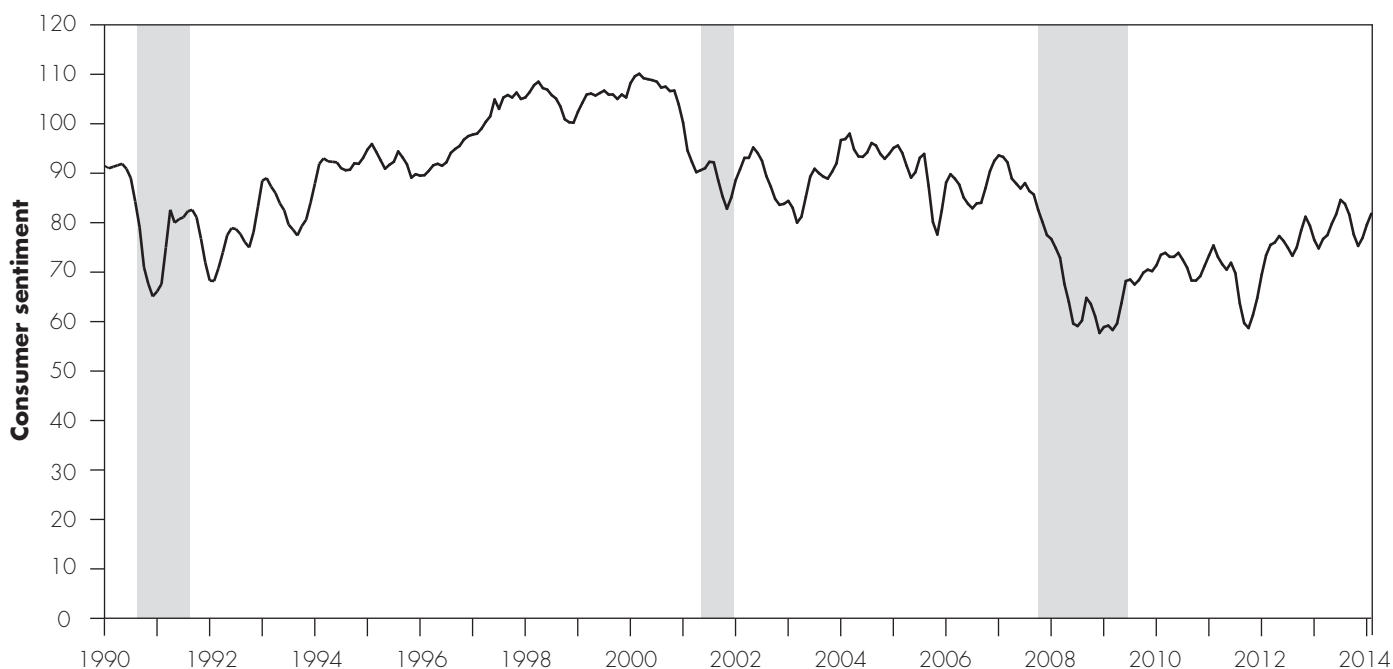
Note: Value in 1966 = 100. Shading shows periods of National Bureau of Economic Research–defined economic contractions.

Source: Regents of the University of Michigan 2014.

well-being is still low; specifically, the consumer sentiment index is well below the prerecession level, although it has improved slightly since 2012 (Regents of the University of Michigan 2014) (Figure 2-16). Longer term measures of consumer confidence, such as whether respondents expect income gains in the next five years or whether they expect to lose their job, have improved gradually since 2012, but not to prerecession levels.

It is possible that the combination of unemployment, housing, and stock market shocks characterizing this recession will have a lingering effect on the pattern of savings and consumption, akin to that of the generation who lived through the Great Depression.

Challenge for Medicare financing

The expansion of the Medicare population and its changing profile will have a profound impact on both the program and the taxpayers who support it. Medicare beneficiaries may be less financially secure than in the recent past (because of the 2007 to 2009 recession) and will be

less likely to have employer-sponsored supplemental retiree health coverage, so they may need Medicare more than ever. At the same time, the number of taxpaying workers supporting the program is projected to decline. Additionally, Medicare relies heavily on general revenues, and that reliance is projected to increase (from 41 percent of program costs today to 45 percent of program costs in about 15 years).

The Medicare Trustees project that Medicare's Hospital Insurance (HI) Trust Fund will be exhausted by 2030 (Boards of Trustees 2014). The HI Trust Fund pays for Medicare Part A services, such as inpatient hospital stays, skilled nursing facilities, and hospice, and is largely funded through a dedicated payroll tax (i.e., a tax on wage earnings). To keep the HI Trust Fund solvent through 2038, the Trustees estimate that the payroll tax would need to be increased immediately and permanently from its current rate of 2.9 percent to 3.3 percent, or Part A spending would need to be reduced immediately and permanently by 10.0 percent (Boards of Trustees 2014).

Furthermore, the HI Trust Fund accounts for only about 45 percent of Medicare spending. The Medicare

**FIGURE
2–17**

Maintaining Medicare spending at 3.0 percent of GDP through 2030 would require a 1.6 percent reduction in its average annual growth rate

Note: GDP (gross domestic product). Numbers do not sum to totals because of rounding.

Source: Congressional Budget Office 2014.

output (e.g., investments in education, transportation, and research and development).

The different financial structures of the two Medicare trust funds make it difficult to quantify the overall fiscal health of the program. One metric used is Medicare spending as a share of gross domestic product (GDP). Currently Medicare spending accounts for about 3 percent of GDP. From now through 2030 (when boomers will have all aged into Medicare), GDP is projected to grow at 4.4 percent per year on average (Congressional Budget Office 2014). Medicare spending is projected to grow at 5.9 percent per year on average, consisting of enrollment growth (2.6 percent per year) and per beneficiary spending growth (3.2 percent per year). To maintain Medicare spending at about 3 percent of GDP, its average annual growth rate would have to be reduced by 1.6 percent. Assuming no change in the projected growth rate of enrollment, this reduction would have to come from a reduction in the projected growth rate of per beneficiary spending, reducing it from an average annual growth rate of 3.2 percent to 1.7 percent (Figure 2-17).

Conclusion

Over the next 15 years, the aging baby boomers will rapidly increase the size of the Medicare population. As the Medicare population grows, the number of taxpaying workers per beneficiary will decline, straining federal and household budgets. While the nation is becoming more diverse racially and ethnically, diversity in the Medicare population will lag for some years to come. Life expectancies have increased for baby boomers; however, so have obesity rates, leaving much uncertainty about the overall health of the next generation of Medicare beneficiaries and the implications for Medicare per beneficiary spending. Under any outcome, Medicare's spending trends will be affected over the longer term by the growing share of beneficiaries in older age categories. Also, future beneficiaries will have had different experiences with their health insurance coverage because the majority of workers will have been in a PPO. For some groups of baby boomers, the 2007 to 2009 recession weakened their financial well-being, making it difficult for those closest to retirement to recover financially before entering retirement. ∎

Supplementary Medical Insurance (SMI) Trust Fund covers the rest and is made up of spending on Part B services (physician services and other ambulatory care such as services received in hospital outpatient departments) and Part D services (prescription drug coverage). The SMI Trust Fund is financed by premiums and general revenues, with beneficiaries' annual premiums accounting for about 25 percent of spending and general revenues (funded by taxpayers and federal borrowing) accounting for the rest. Premiums and general revenue transfers are reset each year to match expected SMI spending. With that construct, the SMI fund is guaranteed to remain solvent; however, as SMI spending rises, premiums and transfers from the nation's Treasury to the Medicare program also grow—increasing deficits, the debt, and the strain on the household budgets of both workers and retirees and reducing the resources available to make investments that expand future economic

Endnotes

1   For example, the Medicare Trustees estimate hospital inpatient admissions per beneficiary to decline through 2021 and begin increasing thereafter because of the aging of the baby-boom population (Boards of Trustees 2014). The Congressional Budget Office also projects comparatively slow growth in per beneficiary spending for the next decade (2015 to 2025), in part because of the influx of younger beneficiaries, who tend to use fewer health care services and therefore lower Medicare's average spending per beneficiary (Congressional Budget Office 2015a).

2   When compared with the previous generation at ages 45 to 64, the baby-boom generation had a larger share of individuals with physician-diagnosed and undiagnosed diabetes (15.0 percent versus 13.9 percent), but a smaller share of individuals with diagnosed diabetes who had poor glycemic control (14.1 percent versus 26.0 percent) (National Center for Health Statistics 2014).

3   When compared with the previous generation at ages 45 to 64, the baby-boom generation had larger shares of individuals with hypertension (42.2 percent of male and 39.5 percent of female baby boomers versus 34.2 percent and 32.8 percent of males and females, respectively, in the previous generation), but smaller shares of individuals with hypertension who had uncontrolled high blood pressure (50.2 percent of male and 36.5 percent of female boomers versus 73.1 percent and 62.1 percent of males and females, respectively, in the previous generation).

Similarly, when compared with the previous generation at ages 45 to 64, the baby-boom generation had larger shares of individuals with high cholesterol or taking cholesterol-lowering medication (39.8 percent of male and 42.4 percent of female baby boomers versus 30.1 percent and 36.4 percent of males and females, respectively, in the previous generation) but smaller shares of the population with high serum total cholesterol (16.2 percent of male and 22.4 percent of female baby boomers versus 27.2 percent and 33.4 percent of males and females, respectively, in the previous generation) (National Center for Health Statistics 2014).

References

Autor, D. H., and M. G. Duggan. 2006. The growth in the Social Security Disability rolls: A fiscal crisis unfolding. *Journal of Economic Perspectives* 20, no. 3 (Summer): 71–96.

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2014. *2014 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.* Washington, DC: Boards of Trustees.

Bureau of Labor Statistics. 2012. The recession of 2007–2009. BLS Spotlight on Statistics. http://www.bls.gov/spotlight/2012/recession/.

Burkhauser, R. V., M. C. Daly, D. McVicar, et al. 2013. *Disability benefit growth and disability reform in the U.S.: Lessons from other OECD nations.* Federal Reserve Bank of San Francisco working paper series, no. 2013–40. San Francisco, CA: Federal Reserve Bank of San Francisco.

Carroll, J. 2014. Plans use narrow networks in exchanges; public, politicians predictably perturbed. *Managed Care* 23, no. 1 (January): 5–6.

Census Bureau. 2015a. Population estimates. http://www.census.gov/popest/data/historical/index.html.

Census Bureau. 2015b. Population projections. https://www.census.gov/population/projections/data/national/index.html.

Census Bureau. 2014. *65+ in the United States: 2010.* P23–212. Washington, DC: Government Printing Office.

Census Bureau. 2012. National population projections: Downloadable files: Table 1. Projected population by single year of age, sex, race, and Hispanic origin for the United States, 2012 to 2060: Middle series. http://www.census.gov/population/projections/files/downloadables/NP2012_D1.csv.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. *Chronic conditions among Medicare beneficiaries. Chartbook: 2012 edition.* Baltimore, MD: CMS.

Congressional Budget Office. 2015a. *The budget and economic outlook: 2015 to 2025.* Washington, DC: CBO.

Congressional Budget Office. 2015b. *Updated budget projections: 2015 to 2025.* Washington, DC: CBO.

Congressional Budget Office. 2014. *The 2014 long-term budget outlook.* Washington, DC: CBO.

Cutler, D. M., and E. L. Glaeser. 2006. *Why do Europeans smoke more than Americans?* National Bureau of Economic Research working paper 12124. Cambridge, MA: NBER.

Dahl, M., and N. Meyerson. 2010. *Social Security Disability Insurance: Participation trends and their fiscal implications.* Congressional Budget Office economic and budget issue brief. Washington, DC: CBO.

DeNavas-Walt, C., and B. Proctor. 2013. *Income and poverty in the United States: 2013.* P60–249. Suitland, MD: Census Bureau.

DeNavas-Walt, C., B. Proctor, and J. Smith. 2013. *Income, poverty, and health insurance coverage in the United States: 2012.* P60–245. Washington, DC: Census Bureau.

Duggan, M., and S. A. Imberman. 2009. Why are the disability rolls skyrocketing? In *Health at Older Ages: The Causes and Consequences of Declining Disability among the Elderly.* Eds. Cutler and Wise. Chicago, IL: University of Chicago Press.

Federal Reserve. 2014. Survey of consumer finances. Historic tables and charts. http://www.federalreserve.gov/econresdata/scf/scfindex.htm.

Fronstin, P., and N. Adams. 2012. *Employment-based retiree health benefits: Trends in access and coverage, 1997–2010.* Issue brief no. 377. Washington, DC: Employee Benefit Research Institute.

Geiss, L. S., J. Wang, Y. J. Cheng, et al. 2014. Prevalence and incidence trends for diagnosed diabetes among adults aged 20 to 79 years, United States, 1980–2012. *Journal of the American Medical Association* 312, no. 12 (September 24): 1218–1226.

Gregg, E. W., Y. Li, J. Wang, et al. 2014a. Changes in diabetes-related complications in the United States, 1990–2010. *New England Journal of Medicine* 370, no. 16 (April 17): 1514–1523.

Gregg, E. W., X. Zhuo, Y. J. Cheng, et al. 2014b. Trends in lifetime risk and years of life lost due to diabetes in the USA, 1985–2011: A modelling study. *Lancet Diabetes & Endocrinology* 2, no. 11 (November): 867–874.

Gustman, A. L., T. L. Steinmeier, and N. Tabatabai. 2012. How did the recession of 2007–2009 affect the wealth and retirement of the near retirement age population in the Health and Retirement Study? *Social Security Bulletin* 72, no. 4: 47–66.

Hout, M., and E. Cumberworth. 2012. *The labor force and the Great Recession.* Great Recession issue brief. Stanford, CA: The Russell Sage Foundation and the Stanford Center on Poverty and Inequality.

Hurd, M., and S. Rohwedder. 2010. *Effect of the financial crisis and great recession on American households.* Working paper WR–810. Santa Monica, CA: RAND Corporation.

Johnson, R. W. 2012. *Older workers, retirement, and the Great Recession.* Great Recession issue brief. Stanford, CA: The Russell Sage Foundation and the Stanford Center on Poverty and Inequality.

Kaiser Family Foundation and Health Research & Educational Trust. 2014. *Employer health benefits: 2014 annual survey.* Menlo Park, CA: Kaiser Family Foundation/HRET.

Kaye, H. S. 2013. Disability rates for working-age adults and for the elderly have stabilized, but trends for each mean different results for costs. *Health Affairs* 32, no. 1 (January): 127–134.

King, D. E., E. Matheson, S. Chirina, et al. 2013. The status of baby boomers' health in the United States: The healthiest generation? *JAMA Internal Medicine* 173, no. 5 (March 11): 385–386.

Lakdawalla, D. N., J. Bhattacharya, and D. P. Goldman. 2004. Are the young becoming more disabled? *Health Affairs* 23, no. 1 (January–February): 168–176.

McArdle, D., I. Stark, Z. Levinson, et al. 2012. *How does the benefit value of Medicare compare to the benefit value of typical large employer plans? A 2012 update.* Medicare issue brief. Washington, DC: Kaiser Family Foundation.

McArdle, F., T. Neuman, and J. Huang. 2014. *Retiree health benefits at the crossroads.* Washington, DC: Kaiser Family Foundation.

McKinsey & Company. 2014. *Hospital networks: Updated national view of configurations on the exchanges.* New York: McKinsey & Company.

McWilliams, J. M., E. Meara, A. M. Zaslavsky, et al. 2009. Medicare spending for previously uninsured adults. *Annals of Internal Medicine* 151, no. 11 (December 1): 757–766.

National Bureau of Economic Research. 2014. US business cycle expansions and contractions. http://www.nber.org/cycles.html.

National Center for Health Statistics. 2014. *Health, United States, 2013: With special feature on prescription drugs.* Hyattsville, MD: NCHS.

Ortman, J. M., V. A. Velkoff, and H. Hogan. 2014. *An aging nation: The older population in the United States.* Current Population Reports P25–1140. Suitland, MD: Census Bureau.

Regents of the University of Michigan. 2014. Surveys of consumers: Index of consumer sentiment. http://www.sca.isr.umich.edu/.

Schwabish, J. 2012. *Policy options for the Social Security disability insurance program.* Washington, DC: Congressional Budget Office.

Social Security Administration. 2012. Income of the population 55 or older, 2012. Baltimore, MD: SSA. http://www.ssa.gov/policy/docs/statcomps/income_pop55/index.html.

Social Security Administration. 2006. *Trends in the Social Security and Supplemental Security Income disability programs.* Publication no. 13–11831. Washington, DC: SSA.

Welch, H. G., L. M. Schwartz, and S. Woloshin. 2011. *Overdiagnosed: Making people sick in the pursuit of health.* Boston, MA: Beacon Press.

Part B drug payment policy issues

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. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). In 2013, Medicare and its beneficiaries paid more than $19 billion dollars for Part B–covered drugs at ASP + 6 percent. This chapter explores two issues related to Medicare payment policy for Part B drugs.

The first issue relates to the general payment methodology for Part B drugs: ASP + 6 percent. ASP is the price realized by a manufacturer for its drug for sales to all purchasers (with certain exceptions), net of rebates, discounts, and price concessions. Medicare pays providers ASP + 6 percent for the drug regardless of the price a provider pays to acquire the drug. This formula gives the provider a financial incentive to seek the lowest available price for a given product.

However, concern has been expressed that the 6 percent add-on to the ASP may create incentives for use of higher priced drugs when lower priced alternatives are available. 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. Currently, it is difficult to know

In this chapter

- Background

- Average sales price payment system

- Paying for Part B drugs provided by hospitals in the 340B Drug Pricing Program

the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

Our work examines the mechanics of the ASP payment system and explores policy alternatives to the 6 percent add-on. In particular, we model two policy options that convert part or all of the 6 percent add-on to a flat-fee add-on for each day the drug is administered to a beneficiary. Our modeling demonstrates that a flat-fee add-on would increase payment rates for lower priced drugs and reduce payment rates for higher priced drugs compared with current policy.

Moving to a flat-fee add-on could have a number of effects. It might increase the likelihood that a provider would choose the least expensive drug in situations where differently priced therapeutic alternatives exist, potentially generating savings for Medicare and its beneficiaries. At the same time, a flat-fee add-on might create other incentives that could increase spending. For example, questions have been raised about whether increased payment rates for very inexpensive drugs might create incentives among some providers to overuse these drugs or spur manufacturers of low-priced drugs to raise their prices.

It would be important in structuring a flat-fee add-on to consider its effect on providers' ability to purchase drugs within the Medicare payment amount. A flat-fee add-on would reduce payment rates for very expensive drugs. With a flat-fee add-on, some providers might have difficulty purchasing very expensive drugs within the Medicare payment rate, but that would depend on how the policy is structured and how manufacturers' pricing decisions respond to the policy.

The second issue relates to the discount on Part B drugs received by certain hospitals and other providers under the 340B Drug Pricing Program. The 340B program allows certain providers ("covered entities") to obtain discounted prices on covered outpatient drugs (prescription drugs and biologics other than vaccines) from drug manufacturers. Under the outpatient prospective payment system (OPPS), Medicare pays for certain 340B drugs, such as drugs for cancer and rheumatoid arthritis, provided by hospitals in the 340B program. Medicare pays the same rates (ASP + 6 percent) for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at steep discounts. Similarly, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate for outpatient drugs, whether given at a 340B hospital or not.

The Health Resources and Services Administration (HRSA), which manages the 340B program, calculates a 340B ceiling price for each outpatient drug using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The 340B ceiling price represents the maximum price a manufacturer can

charge for a 340B drug. According to statute, HRSA is allowed to share these prices with covered entities but not with the general public.

Although 340B prices are proprietary, we estimate that the minimum discount that 340B hospitals receive for drugs paid under the OPPS is 22.5 percent of the drugs' ASP, on average. This figure represents a conservative estimate—a lower bound—of the actual discount. We also estimate that in 2013, 340B hospitals (excluding critical access hospitals, Maryland hospitals, and others for which we do not have data on Medicare revenue) received about $3.2 billion in Medicare revenue for drugs paid under the OPPS while acquiring them for at most $2.4 billion. Hospitals that qualify for 340B because they are disproportionate share hospitals accounted for nearly all of the Medicare revenue and acquisition cost for outpatient drugs among 340B hospitals.

An important policy question is whether Medicare should pay less than ASP + 6 percent for Part B drugs purchased by 340B hospitals since they are able to purchase outpatient drugs at a price that is, on average, at least 22.5 percent below ASP. It could be argued that, even if Medicare's program payment does not change, Medicare beneficiaries should pay lower cost sharing for drugs provided by 340B hospitals. Reducing Medicare's payment rates or beneficiary cost sharing for Part B drugs provided by 340B hospitals would save money for the Medicare program and beneficiaries, but it would decrease the revenue that hospitals receive through the 340B program, which may reduce their participation in 340B. ∎

Background

Medicare Part B covers infusible and injectable drugs administered in physician offices and hospital outpatient departments. 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 accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays physicians and suppliers for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).[1] CMS, through regulation, has also established a payment rate of ASP + 6 percent for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS).[2] Like other Medicare services, Part B–covered drugs are subject to the budget sequester effective April, 1, 2013, through 2024.[3]

Medicare pays ASP + 6 percent for each drug and makes an additional separate payment for administration of the drug under the physician fee schedule or OPPS. Medicare also pays an additional dispensing or supplying fee to pharmacies that dispense inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs to beneficiaries and pays a furnishing fee to providers of clotting factors. The data presented in this chapter reflect only the ASP + 6 percent payments and do not include the drug administration payments or the supplying, dispensing, or furnishing fees. In 2013, Medicare spending (program payments and beneficiary cost sharing) on Part B–covered drugs paid ASP + 6 percent amounted to over $19 billion dollars (more than $15 billion of Medicare program payments and nearly $4 billion of beneficiary cost sharing). Of that spending, physician offices accounted for over $11 billion, hospital outpatient departments accounted for nearly $7 billion, and suppliers accounted for over $1 billion. In recent years, Medicare Part B drug spending has grown more rapidly for hospital outpatient departments than for physician offices and suppliers (average annual growth of roughly 20 percent and 5 percent, respectively, for the period between 2009 and 2012). Of Medicare Part B drug spending in outpatient hospitals in 2013, roughly half was attributable to hospitals that participate in the 340B Drug Pricing Program.

Medicare Part B covers drugs and biologics for a wide range of indications, although a small number of drugs and conditions account for a large share of spending. The top 10 drugs that account for the most Part B drug spending fall into 3 areas: cancer, rheumatoid arthritis, and macular degeneration (Table 3-1, p. 66). These 10 drugs account for 48 percent of Medicare spending on Part B drugs paid ASP + 6 percent. Part B, however, covers a number of other types of drugs, some of which are used by a much larger number of beneficiaries. The top 10 Part B drugs used by the most beneficiaries in 2013 include several corticosteroids, drugs used during stress tests or imaging, an anemia drug, an antibiotic, and an inhalation drug (Table 3-1). For 9 of these 10 most frequently used drugs, total Medicare payments ranged from $2 million to $21 million per drug, while the 10th drug accounted for payments of more than $240 million. The 10 most frequently used Part B drugs as a group accounted for less total spending than any 1 of the top 10 highest expenditure Part B drugs.

Across all Part B drugs paid ASP + 6 percent, the majority of drug administrations or prescriptions involved drugs that were relatively inexpensive, while a small share of drug administrations or prescriptions accounted for the vast majority of spending (Table 3-2, p. 67).[4] For about 60 percent of drug administrations, the ASP + 6 percent payment per administration was less than $50. These drugs accounted for just 1 percent of Part B drug spending. For example, 9 of the 10 Part B drugs used by the most beneficiaries had an average ASP + 6 percent payment per administration of $13 or less (Table 3-1, p. 66). By contrast, about 5 percent of drug administrations accounted for 50 percent of Part B drug spending, with Medicare paying $2,000 or more per administration (Table 3-2). The top 10 Part B drugs that accounted for the highest total Medicare expenditures provide some examples of high-cost drugs. The ASP + 6 percent payment per drug administration for these 10 drugs ranged from more than $1,200 to over $5,200 per administration (Table 3-1). In addition, since many of these drugs are typically administered multiple times to an individual patient over the course of a year, the average total payment per beneficiary over the year is higher than the average payment per administration (Table 3-1). (For additional data on the average cost per administration and per beneficiary for high expenditure or high frequency drugs, see the online Appendix 3-A to this report, available at http://www.medpac.gov).

**TABLE
3–1**

Top 10 Part B–covered drugs by total expenditures and by number of beneficiaries who used the drug, 2013

Drug		Indication or type of drug	Total Medicare payments in 2013 based on ASP+6 percent (in millions)	Number of beneficiaries who used drug in 2013	Average ASP+6 percent payment in 2013	
					Per administration	Per beneficiary
Top 10 drugs with the highest total expenditures						
J9310	Rituximab	Cancer, rheumatoid arthritis	$1,514	69,844	$5,136	$21,262
J2778	Ranibizumab	Macular degeneration	1,368	143,464	2,013	9,240
J1745	Infliximab	Rheumatoid arthritis	1,111	59,997	3,159	18,129
J2505	Pegfilgrastim	Cancer	1,101	100,753	2,978	10,611
J0178	Aflibercept	Macular degeneration	1,090	108,423	2,106	9,774
J9035	Bevacizumab	Cancer, macular degeneration	1,037	186,617	1,240	4,533
J0897	Denosumab	Osteoporosis, cancer	635	227,511	1,237	2,615
J9305	Pemetrexed	Cancer	548	22,947	5,250	23,281
J9355	Trastuzumab	Cancer	503	17,215	2,690	28,870
J9041	Bortezomib	Cancer	453	20,285	1,462	21,889
Top 10 drugs used by the most beneficiaries						
J3301	Triamcinolone acetate	Corticosteroid	$19	1,543,805	$7	$11
J2785	Regadenoson	Stress test	242	1,152,357	208	210
J1030	Methylprednisolone 40 mg	Corticosteroid	7	1,105,159	4	6
J1040	Methylprednisolone 80 mg	Corticosteroid	9	896,093	6	10
J1100	Dexamethasone sodium phosphate	Corticosteroid	2	893,340	1	2
Q9967	LOCM 300–399mg/ml iodine	Contrast agent for imaging	14	809,484	12	17
J0702	Betamethasone acetate and sodium phosphate	Corticosteroid	14	678,672	13	19
J3420	Vitamin B12	Anemia	3	602,049	1	4
J7613	Albuterol	Bronchodilator	21	552,876	11	35
J0696	Ceftriaxone sodium	Antibiotic	3	547,504	3	4

Note: ASP (average sales price), LOCM (low osmolar contrast material), mg (milligram), ml (milliliter). Average ASP+6 percent payment per administration and per beneficiary are calculated at the drug billing code level. 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 Healthcare Common Procedure Coding System code). Because of the removal of extreme values, the average payment per beneficiary displayed in the chart will differ from the average payment per beneficiary calculated using the total payment amount and total beneficiary count displayed in the chart. Add-on payments received by the 11 cancer hospitals are not reflected in the data. "Indication or type of drug" reflects one or more common uses of the drug or the drug class. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

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

Average sales price payment system

ASP for a drug reflects the average price realized by the manufacturer. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.[5]

Manufacturers report ASP data to CMS on a quarterly basis for each of their Part B drugs. Medicare pays providers ASP + 6 percent for the drug, regardless of the price a provider pays for the drug, giving the provider a financial incentive to seek the lowest available price for the product.

The Medicare Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set the ASP + 6 percent payment rate. That means, for example, the ASP + 6 percent payment rate for the third quarter of a year is based on ASP data from the first quarter of the year.[6] The two-quarter lag in the ASP + 6 percent payment rates may provide a disincentive for manufacturers to institute large, rapid price increases because they could cause providers' acquisition costs to exceed the Medicare payment rate and potentially affect providers' willingness to purchase the product.

Payment rates for single-source drugs and biologics and multiple-source drugs are set differently. Each single-source drug (i.e., a drug without generic substitutes) and biologic is paid based on 106 percent of its own ASP. For a multiple-source drug, both the brand and generic versions of the drug receive the same ASP + 6 percent payment rate based on the weighted average of ASPs for all equivalent brand and generic products. Under the Patient Protection and Affordable Care Act of 2010 (PPACA), a different approach is used for biosimilars. A biosimilar product is paid 100 percent of its own ASP, plus 6 percent of the ASP for the reference biologic. Thus, a lower priced biosimilar receives an add-on in excess of 6 percent because its add-on will be set equal to the 6 percent add-on for the more expensive reference biologic.

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

The margin an individual provider realizes on a specific Part B drug could be more or less than 6 percent (with negative margins also possible) because the price an individual provider pays for a drug may differ from the ASP used to establish the Medicare payment rate, for several reasons. Since ASP is an average across all purchasers, net of rebates, discounts, and price concessions, some providers will pay more and some will pay less than the average (unless the manufacturer has uniform pricing). For example, if manufacturers offer discounts or rebates based on volume, small purchasers may pay higher prices than large purchasers.

Price changes can also affect the margin a provider realizes on a Part B drug. With the two-quarter lag in the ASP + 6 percent payment rate, a price increase lowers a provider's margin and a price decrease increases that margin temporarily until ASP catches up.[7] For example, when a drug first goes generic, the lag in ASP results in a large positive profit margin for providers because their payment for the generic drug is based on the brand price

| TABLE 3–2 | Low-priced drugs accounted for most Part B drug administrations, while high-priced drugs accounted for most Part B drug expenditures, 2013 |

	Percent of:	
Medicare ASP + 6 percent payment per drug administered per day	Drug administrations	Medicare Part B drug payments
Less than $10	45%	0.3%
$10–49	16	0.7
$50–199	11	3
$200–399	10	6
$400–999	6	10
$1,000–1,999	7	27
$2,000–4,999	4	32
$5,000 or more	1	21

Note: ASP (average sales price). Analysis includes Part B–covered drugs that are paid ASP + 6 percent and furnished by physicians, hospital outpatient departments, and suppliers. We excluded from the analysis drugs billed under not-otherwise-classified Healthcare Common Procedure Coding System codes. For drugs furnished by suppliers, the data reflect each prescription rather than each day the drug was administered. Medicare payment amounts include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester. Add-on payments made to the 11 cancer hospitals are excluded from the data. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

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

for at least two quarters (Office of Inspector General 2012, Office of Inspector General 2011a). For single-source drugs and biologics, there may be different pricing dynamics, depending on whether the drug or biologic faces competition from therapeutic alternatives. That is, the manufacturer of a single-source drug may increase prices with less concern about the effect it will have on providers' margins (and potentially the manufacturer's sales volume) if therapeutic alternatives do not exist for its drug. In contrast, if a single-source drug faces competition from other, therapeutically similar drugs, a manufacturer may have incentive to consider how its pricing decision affects providers' margins on its drug compared with competitor products.

Certain additional factors, such as prompt-pay discounts, wholesaler markups, and sales tax, can create a gap between manufacturers' reported ASP and the average purchase price across providers. For example, manufacturers may offer prompt-pay discounts to drug wholesalers who pay manufacturers for their purchases within a specified

time frame. These prompt-pay discounts lower ASP because they reduce the revenue the manufacturer receives for its products. Anecdotal reports from provider and pharmaceutical industry stakeholders suggest prompt-pay discounts paid by manufacturers to wholesalers may be in the range of 1 percent to 2 percent, although no data are available to verify these amounts. These discounts are reported to be an important source of revenue for wholesalers that are largely not passed on to final purchasers (e.g., physicians or hospitals). When these discounts are not passed on from wholesalers to providers, the average price paid by providers for a drug could end up higher than the manufacturer's reported ASP. Another factor that can affect providers' margin on a drug is wholesaler markup. Wholesalers may mark up the drug price they charge providers (e.g., for shipping or handling, or to generate profit). Wholesaler markup is not included in ASP because it does not affect the revenue earned by manufacturers. For some drugs, the average price paid by providers for a drug could be higher than ASP due to wholesaler markup. To the extent that wholesaler markup reflects fixed fees like shipping and handling, its effect may be most significant on provider margins for very inexpensive drugs (Medicare Payment Advisory Commission 2007). Another factor that can create a gap between ASP and providers' acquisition costs is sales tax. Many states and localities exempt providers' purchases of drugs from sales tax, but some may not. Since sales tax is not reflected in ASP, it could reduce providers' margins on drugs in areas charging sales tax.

What was the purpose of the 6 percent?

There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent is intended to cover drug storage and handling costs.[8] Others contend that the 6 percent is intended to maintain access to drugs for smaller practices and other purchasers who may pay above average prices for the drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (e.g., prompt-pay discounts). Another rationale for the percentage add-on may be to provide protection for providers when price increases occur and the payment rate has not yet caught up.

Does the percent add-on to ASP create an incentive to use high-cost drugs?

Providers' prescribing decisions may depend on a variety of factors. A number of clinical considerations may influence a provider's choice among therapeutic alternatives. For example, drugs may vary in terms of their effectiveness in treating patients with specific conditions or comorbidities, or they may have different side effects. In addition, providers may take into account whether a drug is on label or off label for a patient's condition or whether a drug is compounded. Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP may create an incentive to use higher priced drugs when cheaper therapeutic alternatives are available (Hutton et al. 2014, Sanghavi et al. 2014). At the same time, other factors may create financial incentives to use lower priced drugs in some situations. For example, when selecting a drug, a provider may take into account the cost sharing associated with each potential drug and the patient's ability to pay, which might lead to choosing a lower priced drug for some patients. Also, the capital cost associated with acquiring and keeping an inventory of a high-priced drug may be a disincentive for some providers to furnish expensive drugs.

The 6 percent add-on to ASP may create incentive to use higher priced drugs. Because 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs. However, few studies exist that examine whether the 6 percent add-on is influencing providers' choice of drugs. One study by Jacobson and colleagues (2010) of oncologists' prescribing patterns for lung cancer suggests that drug choice may to some degree be influenced by the higher add-on. Looking at five chemotherapy drugs for lung cancer, Jacobson and colleagues found a modest increase in use of the most expensive cancer drug after Medicare began paying for Part B drugs based on ASP + 6 percent in January 2005 (9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, whereas 11.0 percent of beneficiaries used that drug in the 10 months after). A study by the Office of the Inspector General reported some movement toward higher priced drugs among a group of therapeutically similar prostate cancer drugs. When the least costly alternative policy for certain prostate cancer drugs was removed in 2010 and the products began to be paid based on 106 percent of their own ASPs, OIG found a shift from the lowest priced prostate cancer drug toward higher priced competitor products (Office of Inspector General 2012).

For the 6 percent add-on to create the incentive to use a higher priced drug, there must be alternative drugs with different prices available to treat a particular patient's condition. Researchers have not quantified the amount of total Part B drug spending accounted for by drugs for which differently priced substitutes are available. This calculation would be challenging because the drugs used as substitutes may vary depending on the patient's condition, and clinical guidelines on comparable therapies change over time. Also, the existence of multiple-drug regimens makes identification of drug substitutes more complex. Thus, it is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels.

Policy analysis

We explored the idea of converting the 6 percent add-on to ASP to an unvarying—that is, flat—fee, which would help minimize financial incentives to use a more expensive product. To explore the implications of a flat-fee add-on to ASP, we developed two policy options.[9] These options are estimated to be budget neutral in aggregate relative to the current payment rate of 106 percent of ASP (i.e., ASP + 6 percent). We model budget neutrality under the assumption of no change in utilization (which is an unlikely outcome). All estimates are based on current Medicare law, meaning that the estimates are based on figures calculated before the application of the sequester. The two options modeled are:

- *Option 1:* 100 percent of ASP + $24 per drug per administration day

- *Option 2:* 102.5 percent of ASP + $14 per drug per administration day

Option 1 fully replaces the 6 percent add-on with a $24 flat fee per drug per day administered. However, as discussed subsequently, because full elimination of a percentage add-on might result in very expensive drugs being difficult to acquire at the Medicare payment amount, we also modeled a hybrid approach—a reduced percentage add-on plus fixed fee (102.5 percent of ASP + $14). In the hybrid model, the 2.5 percent add-on to ASP is intended to be illustrative. Because our model is budget neutral, the lower the percentage add-on, the higher the flat fee. Our goal was to select an add-on percentage that would not be systematically unprofitable and would generate a substantial flat fee. We chose a percentage add-on that was slightly higher than the 1 percent to 2 percent prompt-pay discounts manufacturers reportedly

pay to wholesalers, which lower ASP but are largely not passed on to providers. Models with other budget-neutral combinations of percentage and flat-fee add-ons could be explored. In addition, other structures for the add-on could be considered—for example, tiered flat-fee add-ons or percentage add-ons (or a combination) based on the ASP for the drug.

To illustrate the effect of the two policy options, Table 3-3 (p. 70) displays the payment rate under current policy (106 percent of ASP) compared with the two policy options for a variety of differently priced drugs (as measured by ASP). Both policy options increase reimbursement for lower priced drugs (ASP per administration less than $400) and decrease reimbursement for higher priced drugs (ASP per administration more than $400) compared with current policy. For example, a drug that had an ASP of $10 per administration would be paid more under Options 1 and 2 ($34 and $24.25, respectively) than under current policy ($10.60). In contrast, a drug with a $5,000 ASP per administration would be paid more under current policy ($5,300) compared with Option 1 ($5,024) and Option 2 ($5,139).

The changes in payment rates under a flat-fee add-on— the increase in payment rates for inexpensive drugs and decrease for expensive drugs—could have a number of effects. In situations where different Part B drugs exist to effectively treat a patient's condition, moving to a flat-fee add-on might increase the likelihood that a provider would choose the least expensive drug. To the extent that this type of substitution occurred and changed utilization patterns, a flat-fee add-on might have potential to generate savings for both the Medicare program and beneficiaries. However, a flat-fee add-on might also create financial incentives for the administration of drugs in smaller, more frequent doses since more administrations would generate more add-on fees. Such more frequent administration of drugs among some providers could result in higher spending.

A flat-fee add-on may help address concerns about reimbursement for very inexpensive drugs, where a 6 percent add-on may be quite small in dollar terms. In that sense, a flat-fee add-on would increase reimbursement for low-priced, generic drugs. However, for very inexpensive drugs, a flat-fee add-on would represent a relatively large payment increase (e.g., a drug with an ASP per administration of $5 would be paid $29 under Option 1 and about $19 under Option 2). There is a question of whether this increase in payment rates for very inexpensive drugs may incentivize overuse among

**TABLE
3–3**

**Drug payment rates under current policy and
two alternative policy options by ASP of the drug**

ASP per drug administered	Drug payment amount in dollars			Drug payment amount expressed as percentage of ASP		
	Current payment rate (106% ASP)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day	Current payment rate (106% ASP)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day
$5	$5.30	$29.00	$19.13	106.0%	580.0%	382.5%
$10	10.60	34.00	24.25	106.0	340.0	242.5
$50	53.00	74.00	65.25	106.0	148.0	130.5
$100	106.00	124.00	116.50	106.0	124.0	116.5
$400	424.00	424.00	424.00	106.0	106.0	106.0
$1,000	1,060.00	1,024.00	1,039.00	106.0	102.4	103.9
$2,500	2,650.00	2,524.00	2,576.50	106.0	101.0	103.1
$5,000	5,300.00	5,024.00	5,139.00	106.0	100.5	102.8
$10,000	10,600.00	10,024.00	10,264.00	106.0	100.2	102.6

Note: ASP (average sales price). "ASP per drug administered" is defined as the ASP unit price times the number of units of the drug administered to the patient on a particular day. Under the two policy options, the flat-fee add-on is paid per drug per administration day (regardless of the number of units of the drug furnished to the patient that day). For drugs furnished by suppliers, the data reflect ASP per prescription rather than ASP per administration. Medicare payment amounts include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester.

Source: MedPAC analysis.

some providers. Also, uncertainty exists about how manufacturers of low-priced drugs might respond to the higher Medicare payment rates for their products resulting from a flat-fee add-on. Would manufacturers of low-priced drugs respond by increasing their prices, or would competition among generic manufacturers serve as a check against substantial price increases?

Another important question is what the effect would be of either policy option on providers' ability to purchase drugs at a price within the Medicare payment rate. Under Option 1, expensive drugs with an ASP of $2,500 to $10,000 per day would be paid at a rate equivalent to between 100.2 percent and 101 percent of ASP (Table 3-3). In light of the prompt-pay discount potentially resulting in the average purchase price across providers being above ASP by possibly 1 percent or 2 percent, very expensive drugs could be systematically unprofitable for providers under Option 1. Option 2, which combines a reduced percentage add-on and a moderate flat fee, attempts to address this issue. Under Option 2, drugs with an ASP per administration of between $2,500 and $10,000 per day would receive payments equivalent to 102.6 percent to 103.1 percent of ASP. With these

payment rates, it would be less likely that expensive drugs would be systematically unprofitable across providers. However, variation in drug acquisition prices across providers would likely mean that some providers, especially small providers, would not be able to purchase some expensive drugs at prices within the Medicare reimbursement amount. When Medicare began paying 106 percent of ASP (instead of a share of the average wholesale price) in 2005, manufacturers responded by reducing the variation in prices across purchasers (Medicare Payment Advisory Commission 2006). It is possible that reducing the ASP add-on percentage could have a similar effect, spurring manufacturers to further reduce the variation in prices across purchasers, which could make these drugs available to more providers at a price within the Medicare payment amount. Alternatively, it is possible that price variation across purchasers would persist and that smaller oncology practices, for example, might decide to send patients to the larger oncology practices or hospital outpatient departments for certain expensive drugs. If these types of shifts in site of care occurred, the effect on beneficiaries (e.g., in terms of travel time to a provider) is unknown.

Application of the sequester to our calculations would reduce payment rates by about 1.6 percent, which may make it difficult for many purchasers to obtain the most expensive drugs within the Medicare reimbursement amount under either option. If the Congress wished to pursue a policy like Option 2 in the context of the sequester, it could consider a modified Option 2 that has a higher percentage add-on and lower flat fee. Alternatively, the Congress could choose to adopt a policy like Option 2 and override the sequester for Part B drugs, but that would increase Medicare program spending.

Changing a portion or all of the 6 percent add-on to a flat fee would redistribute revenues across providers. As expected, the revenue redistribution is larger under Option 1 (100 percent of ASP + $24) than Option 2 (102.5 percent of ASP + $14). Under both options, Medicare payments for Part B drugs would increase for physicians and suppliers and would decline for hospital outpatient departments (Table 3-4, p. 72). Although Part B drug revenues to physicians as a whole would increase, some of the physician specialties that account for a sizable portion of Part B drug spending would see Part B drug revenues decline—specifically, oncologists, ophthalmologists, and rheumatologists. In contrast, specialties that have lower Part B drug spending, such as primary care, infectious disease, and other specialties, would see Part B drug revenue increases of 5 percent or more. The percentage changes (increases and decreases) in revenues that result from these policy options are smaller when viewed in the context of providers' total Medicare revenues for all services rather than providers' Part B drug revenues only.

Paying for Part B drugs provided by hospitals in the 340B Drug Pricing Program

The 340B Drug Pricing Program allows certain hospitals and other health care providers ("covered entities") to obtain discounted prices on covered outpatient drugs (prescription drugs and biologics other than vaccines) from drug manufacturers (see text box, pp. 74–75). The program is administered by the Health Resources and Services Administration (HRSA). Covered outpatient drugs include over-the-counter drugs if they are prescribed by a physician and covered by a state Medicaid program, and they exclude inpatient drugs and drugs that are bundled with other services (such as physician and hospital

outpatient services) for payment purposes. To have their drugs covered under Medicaid, manufacturers must offer 340B discounts to covered entities. The discounts available through the 340B program for covered outpatient drugs are comparable with Medicaid drug rebates. In fiscal year 2013, covered entities saved about $3.8 billion on outpatient drugs through the program (Health Resources and Services Administration 2015).

Medicare Part B pays for certain 340B drugs that covered entities provide to beneficiaries, such as drugs used to treat cancer and rheumatoid arthritis.[10] Covered entities can purchase any Part B drug (except vaccines) at the 340B discounted price for an eligible patient. However, hospitals that were added to the program by PPACA—such as critical access hospitals (CAHs)— are excluded by statute from purchasing orphan drugs (drugs designated by the Secretary for a rare disease or condition) under 340B.[11] According to HRSA's interpretation, this provision excludes orphan drugs only when they are used for the rare disease or condition for which they received an orphan designation (Health Resources and Services Administration 2014b). The provision does not apply when orphan drugs are used for other indications.

From 2004 to 2013, Medicare spending in nominal dollars for separately payable Part B drugs at hospitals that participate in 340B grew from $0.5 billion to $3.5 billion, or 543 percent.[12] Hospitals in the 340B program accounted for 22 percent of Medicare spending for Part B drugs at all Medicare acute care hospitals in 2004, growing to 48 percent in 2013. Some of the growth in Medicare spending at 340B hospitals during this period was due to an increase in the number of participating hospitals. In 2010, PPACA allowed additional types of hospitals to participate in the 340B program (see text box, pp. 74–75). However, most of the growth in Medicare spending occurred among hospitals that were in the 340B program before the PPACA expansion. For example, 733 hospitals in the 340B program received Medicare payments for separately payable Part B drugs in both 2008 and 2013. These hospitals accounted for 73 percent of the growth in Medicare spending for separately payable Part B drugs at all 340B hospitals from 2008 to 2013.

Under the outpatient prospective payment system (OPPS), Medicare pays 340B hospitals and non-340B hospitals the same payment rates for Part B drugs, even though 340B hospitals are able to purchase outpatient drugs at steep

TABLE
3–4

Impact of flat-fee add-on options on Part B drug revenues by type of provider

| | Medicare payments for: | | Aggregate percent change in: | | | |
| | | | Part B drug payments under alternate policies | | Total Medicare payments for all types of services under alternate policies | |
	Part B drugs paid 106% ASP in 2013 (in billions)	All types of services in 2013 (in billions)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day
Physicians	$11.6	$56.0	1.3%	0.8%	0.3%	0.2%
Oncology	5.5	8.1	–1.5	–0.9	–1.0	–0.6
Ophthalmology	2.4	5.3	–3.9	–2.2	–1.7	–1.0
Rheumatology	1.1	1.6	–2.5	–1.4	–1.6	–1.0
Primary care	0.6	11.1	14.8	8.6	0.9	0.5
Urology	0.3	2.1	0.3	0.2	0.1	0.0
Infectious disease	0.1	0.3	13.4	7.8	2.5	1.5
Other specialties	1.6	27.4	16.9	9.8	0.9	0.5
Hospitals	6.7	162.6	–3.8	–2.2	–0.2	–0.1
Urban	5.9	137.0	–3.8	–2.2	–0.2	–0.1
Rural	0.8	22.7	–3.6	–2.1	–0.1	–0.1
Nonprofit	5.1	115.7	–3.8	–2.2	–0.2	–0.1
For profit	0.5	23.8	–3.2	–1.9	–0.1	0.0
Government	1.1	21.4	–3.9	–2.3	–0.2	–0.1
Major teaching	2.1	39.2	–4.1	–2.4	–0.2	–0.1
Minor teaching	2.1	55.1	–3.7	–2.2	–0.1	–0.1
Nonteaching	2.4	66.5	–3.6	–2.1	–0.1	–0.1
<100 beds	0.8	15.2	–3.6	–2.1	–0.2	–0.1
101–250 beds	1.7	46.9	–3.6	–2.1	–0.1	–0.1
251–500 beds	2.2	55.9	–3.8	–2.2	–0.1	–0.1
501+ beds	2.0	42.9	–4.0	–2.3	–0.2	–0.1
Suppliers	1.2	3.4	7.7	4.5	2.8	1.6

Note: ASP (average sales price). Policy options are modeled to apply to all Part B–covered drugs that are currently paid ASP+6 percent, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. For drugs provided by suppliers, the models assume the flat fee is per prescription. Estimates of Medicare payments for all types of services by type of provider exclude providers who did not bill for at least one Part B–covered drug. Medicare payments include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester. Add-on payments made to the 11 cancer hospitals for outpatient services (including outpatient drugs) are excluded from the data. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

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

discounts. Similarly, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate for outpatient drugs received at both types of hospitals.[13] By contrast, many state Medicaid programs pay 340B hospitals their actual cost of acquiring outpatient drugs.

In 2011, the Department of Health and Human Services Office of Inspector General found that about half of states had policies that required covered entities to bill Medicaid at their actual acquisition cost (AAC) for 340B drugs (Office of Inspector General 2011b). According to

interviews conducted by the Government Accountability Office (GAO) with 18 covered entities in 2011, most of the entities that used 340B drugs for Medicaid patients reported that Medicaid reimbursement for 340B drugs was based on the AAC plus a dispensing fee (Government Accountability Office 2011).[14] Although discounts for 340B drugs are probably substantial, the 340B prices are proprietary, and we do not have access to the data that would enable us to precisely calculate them. Instead, we developed an estimate of the minimum discount for Part B drugs paid under the OPPS.

Calculating prices for 340B drugs

HRSA calculates a 340B ceiling price for each covered outpatient drug using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The formula varies based on whether the drug is a single-source or innovator multiple-source drug (e.g., a brand-name drug); a noninnovator multiple-source drug (e.g., a generic drug); a clotting factor; or an exclusively pediatric drug.[15] According to statute, HRSA is allowed to share these prices with covered entities but not with the general public. The 340B ceiling price represents the maximum price a manufacturer can charge for a 340B drug. However, covered entities that participate in HRSA's Prime Vendor Program (PVP) may pay less than the ceiling price. The 340B statute required HRSA to establish a PVP to distribute 340B drugs to covered entities; entities have the option to participate in the PVP. By pooling the purchasing power of entities, the prime vendor (Apexus) negotiates subceiling prices on 340B drugs with manufacturers (Health Resources and Services Administration 2014a). Although there is no public information on the discounts negotiated by Apexus for specific drugs, the average savings was 10 percent below the ceiling price in fiscal year 2013 (Department of Health and Human Services 2014).

Formula for calculating 340B ceiling prices

The formula for calculating 340B ceiling prices is based on the Medicaid drug rebate formula, which is specified in the Social Security Act (SSA), Section 1927. The basic formula is as follows:

ceiling price = (average manufacturer price (AMP) – the unit rebate amount (URA)) × drug package size

AMP represents the average price paid to a manufacturer by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from a manufacturer. AMP excludes prompt-pay discounts, bona fide services fees paid by manufacturers to wholesalers or retail pharmacies, direct sales to federal purchasers, and sales to 340B-covered entities.[16] Manufacturers participating in Medicaid are required to report AMP to the Secretary, but these prices are confidential.

The URA is specified in Section 1927 of the SSA and varies by type of drug:

- For single-source and innovator multiple-source drugs, the URA is the greater of *(AMP – the best price)* or *(AMP × 23.1 percent)*. "Best price" represents the best price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, 340B-covered entities, Medicaid programs, Medicare Part D plans, and certain other entities. Manufacturers report best-price data to the Secretary of Health and Human Services, but this information is confidential. If AMP has grown faster than the rate of inflation (as measured by the consumer price index for all urban consumers (CPI–U)) since the first quarter in which the drug was marketed, an additional rebate is applied to AMP. This inflation rebate ensures that the inflation-adjusted prices paid by Medicaid programs and 340B-covered entities for drugs do not increase over time. According to the Congressional Budget Office, AMPs of brand-name oral drugs generally rise faster than the CPI–U (Congressional Budget Office 2014). We do not have information on the inflation rebate's share of the total rebates for physician-administered drugs.

- For noninnovator multiple-source drugs, the URA equals *AMP × 13 percent*.

- For clotting factors or exclusively pediatric drugs, the URA is the greater of *(AMP – the best price)* or *(AMP × 17.1 percent)*. If AMP has grown faster than the rate of inflation since the first quarter in which the drug was marketed, an additional rebate is applied to AMP.

Because data on AMP and best price are confidential, we were not able to precisely calculate the Medicaid drug rebates or 340B ceiling prices. Instead, we estimated the minimum discount received by 340B hospitals for drugs paid under the OPPS.

The 340B Drug Pricing Program

The 340B Drug Pricing Program ("340B program") was created in 1992 after the adoption of the Medicaid Drug Rebate Program. This text box contains a brief description of the program; for more information, see the report *Overview of the 340B Drug Pricing Program*, available at http://www.medpac.gov. According to the Health Resources and Services Administration (HRSA), which administers the program, the intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients (Health Resources and Services Administration 2014b).[17] The program is named for the provision in the Public Health Service Act of 1992 that authorizes it. To have their drugs covered under Medicaid, manufacturers must offer 340B discounts to the providers that participate in the 340B program ("covered entities"). Therefore, most manufacturers of outpatient drugs participate in the program (Government Accountability Office 2011).

The statute specifies which types of providers are eligible to participate in the 340B program. Several types of hospitals as well as certain clinics that receive grants from the Department of Health and Human Services (e.g., federally qualified health centers and family planning clinics) are eligible for the program. There are six types of eligible hospitals: disproportionate share (DSH) hospitals, critical access hospitals (CAHs), rural referral centers (RRCs), sole community hospitals (SCHs), children's hospitals, and freestanding cancer hospitals. Each eligible hospital must be owned by a state or local government, be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid. Each type of eligible hospital except for CAHs must have a minimum DSH adjustment percentage (which is based on the share of a hospital's inpatients who are Medicaid and low-income Medicare patients) to qualify for the program.[18]

The 340B program has grown substantially during the past decade. Covered entities and their affiliated sites spent over $7 billion to purchase 340B drugs in 2013, three times the amount spent in 2005. This figure includes both oral and physician-administered drugs and refers to the amount spent by covered entities to purchase 340B drugs, not the payments received by entities from public and private payers and patients for these drugs. By comparison, total U.S. drug spending grew by 33 percent from 2005 to 2013 (IMS Institute for Healthcare Informatics 2014, IMS Institute for Healthcare Informatics 2012). During that period, spending by covered entities on 340B drugs increased from 1.0 percent of total U.S. drug spending to 2.2 percent.

From 2005 to 2010, the number of hospital organizations in the 340B program grew from 583 to 1,365 (134 percent).[19] Most of this increase reflects growth in the number of DSH hospitals during that period, from 583 to 1,001. From 2010 to 2014, the number of 340B hospitals grew by 57 percent to 2,140. This increase was driven by growth in the number of CAHs and other types of hospitals (e.g., RRCs and SCHs) that became eligible for 340B through the Patient Protection and Affordable Care Act of 2010.[20] In 2014, about 45 percent of all Medicare acute care hospitals participated in the 340B program.

Covered entities are allowed to provide 340B drugs only to individuals who are eligible patients of the entity, but the statute does not define who should be considered "a patient of the entity." HRSA's current guidance, released in 1996, states three criteria for individuals to be considered eligible patients:

- the covered entity must have a relationship with the individual, which is defined as maintaining the individual's health care records;

- the individual receives health care services from a health care professional who is employed by the entity or who provides care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the individual's care remains with the entity;[21] and

- the individual receives a service or range of services from the covered entity that is consistent with the service or services for which grant funding

(continued next page)

or federally qualified health center look-alike status has been provided (this criterion does not apply to hospitals) (Health Resources and Services Administration 1996).

However, HRSA has not clarified the meaning of "other arrangements" or "responsibility for the individual's care." The lack of specificity in the guidelines for who is an eligible patient makes it possible for covered entities to interpret this term either too broadly or too narrowly (Government Accountability Office 2011). For example, HRSA has expressed concern that some entities might consider individuals to be eligible patients even when the entity does not have actual responsibility for their care (Government Accountability Office 2011). HRSA plans to issue proposed guidance during 2015 to clarify the definition of a 340B patient (Health Resources and Services Administration 2015).

Covered entities can use 340B drugs for all eligible patients, including patients with Medicare or private insurance, and generate revenue if the reimbursements from payers exceed the discounted prices they pay for the drugs. In 2011, the Government Accountability Office (GAO) interviewed a sample of 29 covered entities about the extent to which they generated revenue from the 340B program (Government Accountability Office 2011).The sample was selected to represent five types of covered entities in five states and is not generalizable.[22] About half the entities interviewed by GAO reported that they generated revenue that exceeded their drug costs.[23] These entities stated that they used the revenue to serve more patients and to provide additional services, such as additional locations, patient education programs, and case management.

However, the 340B statute does not restrict how covered entities can use revenue generated through the program. Therefore, entities can use these funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose.[24] HRSA does not have statutory authority to track how entities use this revenue.

In recent years, there has been a debate between 340B hospitals and drug manufacturers about the proper scope of the program. Manufacturers have questioned whether all of the hospitals in the program need discounted drugs and whether the criteria for hospitals to participate in the program—for instance, the DSH adjustment percentage—should be changed. Manufacturers seek to narrow the program's focus to helping patients who are poor and uninsured gain access to outpatient drugs. In contrast, 340B hospitals seek to preserve the current criteria for eligibility for the program and their ability to use revenue generated through the program without restrictions. They argue that the program is essential for maintaining the full range of services they provide to low-income and other patients in their communities. ∎

Estimating 340B hospitals' revenue and costs of 340B drugs and savings on 340B drugs

This section includes the following:

• Estimates of the Medicare revenue that 340B hospitals receive on 340B drugs that are separately paid under the OPPS (These are primarily physician-administered drugs).[25] We included all drugs that are separately paid except for vaccines, which are not eligible for discounted prices. We also excluded orphan drugs that are provided by CAHs, cancer hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs).[26]

• An estimate of an upper bound of the cost that 340B hospitals incur to acquire the drugs that are separately paid in the OPPS.

• Estimates of the average minimum discounts (savings) that 340B hospitals receive on separately paid OPPS-covered drugs.

We used data from 2013 for our analysis and included information from hospital outpatient claims and

information on hospitals' participation in the 340B program.

We estimated the Medicare revenue that 340B hospitals receive for OPPS-covered drugs that are paid separately by summing Medicare payments for drugs that are reported on hospital outpatient claims. This revenue includes both payments from the Medicare program and beneficiaries' cost-sharing obligations. We excluded from this analysis hospitals that are not paid on the basis of ASP + 6 percent for drugs provided in hospital outpatient departments (OPDs)—CAHs and hospitals in Maryland—and hospitals for which we did not have data on overall Medicare revenue.

As a basis for estimating the costs that 340B hospitals incur to acquire drugs covered under the OPPS, we estimated the ceiling price for each drug, *(AMP – URA) × drug package size*. Data limitations required us to modify how we estimated ceiling prices. One limitation was that we did not have access to AMP data, so we used each drug's ASP as a proxy for AMP. In most cases, ASP is slightly lower than AMP because ASP includes all discounts and rebates, while AMP does not include prompt-pay discounts. The Department of Health and Human Services Office of Inspector General found that in 2011, the difference between ASP and AMP was 3 percent at the median, with ASP generally lower than AMP (Office of Inspector General 2013). A second limitation was that we were not able to determine whether the ASPs for most drugs have risen faster than the CPI–U since the drug's market date because ASP payment was introduced in 2005 and most drugs in our analysis have a market date earlier than 2005. Consequently, we were not able to determine whether to apply inflation rebates. A third limitation was that we did not have data on the best price of the drugs.

Because of these data limitations, our estimates of ceiling prices are conservative and likely higher (possibly much higher) than what 340B hospitals actually pay. The formula we used to estimate ceiling prices for noninnovator multiple-source drugs is *ASP – ASP × 13 percent*; the formula for single-source or innovator multiple-source drugs is *ASP – ASP × 23.1 percent*. The method we used to estimate 340B hospitals' costs to acquire drugs is:

- **for noninnovator multiple-source drugs:** *(1 – 0.13) × (Medicare payment indicated on a claim) / 1.06*

- **for sole-source and innovator, multiple-source drugs:** *(1 – 0.231) × (Medicare payment indicated on a claim) / 1.06*

We divided the Medicare payment on a claim by 1.06 because the OPPS payment for all separately payable drugs is 106 percent of the drug's ASP. This adjustment resulted in our calculations of ceiling prices being based on ASP alone.[27]

This method was a simplification from the method HRSA uses to determine ceiling prices because it omitted best price and inflation rebates and used ASP as a proxy for AMP. Consequently, our method provides an upper-bound estimate of ceiling prices paid by 340B hospitals and a lower-bound estimate of the discounts they received through the 340B program, meaning that we have likely overstated costs and understated discounts.

We estimate that in 2013, 340B hospitals (excluding CAHs, Maryland hospitals, and others for which we do not have overall Medicare revenue data) received about $3.2 billion in Medicare revenue for separately payable drugs in the OPPS.[28] We estimate an upper-bound cost of acquiring these drugs of $2.4 billion (Table 3-5). Disproportionate share (DSH) hospitals accounted for nearly all of the revenue and acquisition cost for these 340B hospitals. However, the Medicare revenue and acquisition cost for the non-DSH hospitals are underrepresented because orphan drugs, which we excluded from our estimates, are a substantial share of the OPPS-covered drugs provided by non-DSH hospitals added by PPACA: CAHs, cancer hospitals, RRCs, and SCHs.

We also estimated Medicare revenue and acquisition costs for several categories of 340B hospitals: urban or rural; major teaching, other teaching, and nonteaching; nonprofit or government owned; and number of beds. The estimates varied among categories.[29] Urban hospitals accounted for about 91 percent of total revenue and acquisition costs among 340B hospitals; major teaching hospitals accounted for about 43 percent; nonprofit hospitals accounted for about 76 percent; and hospitals that have 250 or more beds accounted for about 77 percent (percentages not shown in table).

We measured the discount received by 340B hospitals for each unit of a drug as the difference between the drug's ASP and the ceiling price we estimated for the drug. The aggregate discount for all 340B hospitals is the sum of these unit discounts across all drug units furnished. We estimate that the discount on OPPS-covered drugs for 340B hospitals

**TABLE
3–5**

Medicare revenue, estimated drug acquisition cost, and differences between revenue and acquisition cost for 340B hospitals for OPPS-covered drugs

Type of hospital	OPPS drug revenue (in millions)	OPPS drug cost (in millions)	OPPS drug revenue – drug cost		
			Dollars (in millions)	Percent OPD Medicare revenue	Percent overall Medicare revenue
DSH 340B hospitals	$3,185	$2,357	$828	4.8%	1.1%
Other 340B hospitals	60	44	16	0.9	0.3
Urban	2,958	2,189	769	4.7	1.1
Rural	287	212	74	3.0	1.0
Major teaching	1,384	1,024	360	5.8	1.3
Other teaching	1,112	823	289	4.3	1.0
Nonteaching	744	551	193	3.4	0.9
Nonprofit	2,451	1,814	637	4.4	1.1
Government	794	588	207	4.8	1.2
≤ 50 beds	58	43	15	3.0	1.2
≤ 100 beds	187	138	48	3.1	1.1
101–250 beds	564	418	146	3.7	1.0
251–500 beds	1,080	799	281	3.9	0.9
> 500 beds	1,414	1,046	368	6.1	1.3

Note: OPPS (outpatient prospective payment system), OPD (hospital outpatient department), DSH (disproportionate share). DSH hospitals are eligible for the 340B program on the basis of their Medicare disproportionate share adjustment percentage and other criteria. Other 340B hospitals include cancer hospitals, pediatric hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs). This analysis excludes critical access hospitals and Maryland hospitals that participate in the 340B program and orphan drugs that are used by cancer hospitals, RRCs, and SCHs. It also excludes hospitals for which we do not have data on Medicare revenue.

Source: MedPAC analysis of 100 percent outpatient standard analytic file from 2013; file of 340B-covered entities from the Health Resources and Services Administration.

included in our analysis was 22.5 percent of the drugs' ASP. Each hospital category had similar discounts on 340B drugs (results not shown). We viewed these discount estimates as a lower bound on the actual discounts.

We also measured the difference between how much these 340B hospitals receive in Medicare revenue from OPPS-covered drugs and how much they pay to acquire them. This difference between revenue and acquisition cost is the estimated discount plus 6 percent of each drug's ASP. In aggregate, this difference is about $0.8 billion and is 1.1 percent of the overall Medicare revenue and 4.4 percent of the OPD Medicare revenue for these hospitals (Table 3-5).

For most of the hospital categories, the difference between revenue and acquisition cost as a share of overall Medicare revenue is close to the 1.1 percent for all hospitals. However, revenue minus acquisition cost as a share of

OPD Medicare revenue varies among hospital categories from 3 percent for rural hospitals and hospitals that have 50 or fewer beds to about 6 percent for major teaching hospitals and hospitals that have more than 500 beds. The reason we see wider variation among OPD revenue than overall Medicare revenue is because OPD revenue is a relatively large share of overall Medicare revenue for rural hospitals and hospitals that have 50 or fewer beds, but a relatively small share of overall Medicare revenue for major teaching hospitals and hospitals that have more than 500 beds.

Should Medicare pay lower rates for Part B drugs provided by 340B hospitals?

An important policy question is whether Medicare should pay less than ASP + 6 percent for Part B drugs purchased at 340B discounted prices by 340B hospitals.[30] Even though 340B hospitals are able to purchase outpatient

drugs at a price that is, on average, at least 22.5 percent below ASP, Medicare pays ASP + 6 percent to 340B hospitals that are paid under the OPPS. In addition, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate; their cost sharing exceeds 20 percent of 340B hospitals' estimated costs to acquire these drugs.

Reducing the payment rates for Part B drugs provided by 340B hospitals would save money for both the Medicare program and beneficiaries but would reduce the revenue from Part B drugs that 340B hospitals receive through the 340B program. Because the 340B statute does not restrict how covered entities can use this revenue, 340B hospitals can use these funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose. If 340B hospitals lose all or a significant share of the revenue

from Part B drugs that they receive through the 340B program, they may decide to reduce their participation in the program. Therefore, if policymakers decide to reduce Medicare's payment rates for Part B drugs furnished by 340B hospitals, policymakers may want to allow these hospitals to retain a share of the funds they receive through the 340B program. Under this option, 340B hospitals would retain at least some revenue from the 340B program to support their mission, giving them an incentive to continue to participate in the program.

Another consideration is whether to reduce Medicare's total payment rate (program payment plus beneficiary cost sharing) for Part B drugs provided by 340B hospitals or just beneficiaries' cost-sharing liability. It could be argued that, even if Medicare's program payment does not change, Medicare beneficiaries should pay lower cost sharing for drugs provided by 340B hospitals. ■

Endnotes

1 Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent. Our work in this report excludes these drugs and focuses only on drugs paid ASP + 6 percent.

2 Under the OPPS, Medicare pays separately for drugs that have an estimated average cost per day that exceeds a packaging threshold. That threshold is $95 in 2015 and was $80 in 2013 (the period of the 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).

3 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.

4 For drugs provided by suppliers (e.g., inhalation, oral anticancer, oral antiemetic, and immunosuppressive drugs), the data reflect the ASP + 6 percent per prescription rather than ASP + 6 percent per administration. For ease of syntax, we use the term *drug administration* to refer to a drug administration by a physician or hospital outpatient department or a full prescription provided to a beneficiary by a supplier.

5 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 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 chargebacks and rebates (other than rebates under the Medicaid program). Bona fide services fees—for example, fees for services paid by manufacturers 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 that 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.

6 For example, the manufacturer submits its first-quarter ASP data within 30 days after the close of a quarter. CMS then has 60 days to calculate the new payments rates and update the claims processing systems so that the new payments rates can be effective in the third quarter.

7 Other technical aspects of the ASP methodology (how lagged price concessions and bundled price concessions are reflected in ASP, for example) can increase or decrease the margin on a drug.

8 For drugs provided by hospital outpatient departments, some portion of the drug payment amount is intended to cover pharmacy overhead. Specifically with respect to payment for separately paid drugs under the OPPS, CMS has stated that the drug payment rate (currently ASP + 6 percent; in prior years, as low as ASP + 4 percent) includes payment for drug acquisition costs and pharmacy overhead (Centers for Medicare & Medicaid Services 2012).

9 Inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs provided by suppliers are paid ASP + 6 percent plus a flat dispensing or supplying fee. Our model does not alter these dispensing or supplying fees, but one question that could be explored is whether those fees remain necessary if ASP + 6 percent were replaced with a payment formula that included a fixed add-on.

10 Medicare Part D plans pay for 340B drugs covered under Part D that are dispensed to beneficiaries by 340B providers or community pharmacies that contract with 340B providers. Part D drugs are primarily oral drugs.

11 This provision does not apply to disproportionate share hospitals or other covered entities that were eligible for the 340B program before 2010.

12 Because some 340B hospitals do not provide 340B drugs to Medicaid beneficiaries, we excluded spending for drugs provided to patients of these hospitals who are eligible for both Medicare and Medicaid (dual-eligible beneficiaries). We also excluded spending on vaccines because they are excluded from the 340B program and spending for all orphan drugs used by hospitals that were added to the program by PPACA because claims data do not identify the indication for which an orphan drug was used.

13 In 2010, 86 percent of beneficiaries in fee-for-service Medicare had supplemental coverage, which can cover all or part of their Part B cost-sharing liabilities (Medicare Payment Advisory Commission 2014).

14 According to GAO, state Medicaid agencies may reimburse covered entities at AAC because states cannot claim Medicaid rebates for drugs when entities decide to use drugs purchased at 340B prices for Medicaid patients. GAO interviewed

entities located in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah. Therefore, these findings may not be generalizable to all states.

15 A single-source drug is typically a brand-name product with no available generic versions (SSA, Section 1927 (k)(7)(A)). An innovator multiple-source drug is typically a brand-name product that has generic versions. A noninnovator multiple-source drug is a generic version of any multiple-source product.

16 AMP also excludes payments from and rebates to pharmacy benefit managers, HMOs, mail-order pharmacies, insurers, hospitals, and clinics. However, if the drug is inhaled, infused, instilled, implanted, or injected and is not generally dispensed by a retail community pharmacy, the AMP includes payment from and rebates to these entities.

17 HRSA cites language from a House Energy and Commerce Committee report on legislation that eventually became section 340B of the Public Health Service Act (U.S. House of Representatives 1992).

18 The minimum DSH adjustment percentage varies by type of hospital. The formula for the DSH adjustment percentage is complicated, but the part that is relevant for 340B hospitals equals *5.88 percent + [0.825 × (DSH patient percentage – 20.2 percent)]*. The DSH patient percentage is the sum of the percentage of Medicare inpatient days for patients who are eligible for Supplemental Security Income and the percentage of total inpatient days for patients on Medicaid.

19 A hospital and all of its affiliated sites count as one hospital organization. Each hospital that files its own Medicare cost report must register separately with HRSA and counts as a unique organization.

20 Between 2010 and 2014, the number of CAHs in the 340B program increased from 292 to 940; the number of SCHs grew from 30 to 135; the number of RRCs increased from 10 to 50; and the number of freestanding cancer hospitals increased from 1 to 3.

21 The individual is not considered a patient if the only service he or she receives from the covered entity is the dispensing of a drug for subsequent self-administration or administration in the home.

22 GAO's sample included 5 DSH hospitals and 22 nonhospital providers (e.g., federally qualified health centers and family planning clinics) located in Illinois, Massachusetts, Tennessee, Texas, and Utah. GAO also interviewed two additional DSH hospitals located in other states. Entities were selected based on the types of services they provided and their level of participation in the 340B program.

23 GAO did not separately report its findings by type of entity.

24 Nonprofit hospitals, however, are required to conduct a community needs assessment and document their community benefits in Internal Revenue Service tax filings.

25 In the OPPS, the costs of some drugs are packaged into the cost of the service they are provided with, and others are paid separately. Separately paid drugs either have pass-through status in the OPPS or their cost per day exceeds a threshold, which was $80 in 2013 (the year of the data we are analyzing) and is $95 for 2015.

26 CAHs, cancer hospitals, RRCs, and SCHs are prohibited from using orphan drugs under 340B when the drugs are used for the rare disease or condition for which they received an orphan designation (the orphan drug exclusion). Because claims data do not identify the indication for which a drug was used, we could not determine whether an orphan drug used by one of these hospitals was eligible for 340B discounted prices. Therefore, we excluded all orphan drugs used by these types of hospitals.

27 When the sequester began in April 2013, it reduced the amount that Medicare paid for all services by 2 percent. For separately payable drugs in the OPPS, Medicare normally pays 80 percent of *1.06 × ASP*, but the sequester reduces this amount to 80 percent of *1.039 × ASP*. At the same time, Medicare patients are responsible for 20 percent of *1.06 × ASP*, and the sequester has no effect on the patient's part of the payments. The net effect of the sequester is to reduce the combined revenue from Medicare and patients for separately payable drugs in the OPPS from ASP + 6 percent to ASP + 4.3 percent. For OPPS-covered drugs provided after the start of the sequester, we divide Medicare payment by 1.043 (rather than 1.06) to estimate acquisition cost.

28 On page 71, we reported that Medicare spending on separately payable Part B drugs in 340B hospitals was $3.5 billion in 2013. This amount is greater than the $3.2 billion amount on page 76 because the amount from page 71 includes all 340B hospitals, and the amount on page 76 excludes CAHs, Maryland hospitals, and hospitals for which we do not have overall Medicare revenue data.

29 When MedPAC analyzes hospitals by ownership status, we normally use nonprofit, for-profit, and government-owned categories. However, for-profit hospitals cannot participate in the 340B program, so this analysis uses nonprofit and government owned as categories for ownership status.

30 In the final rule on the OPPS for 2009, CMS requested comments that address 10 issues related to the topic of the influence of 340B hospitals in setting payment rates for separately payable drugs. Two of these issues pertained to whether 340B hospitals should be paid for drugs under the

OPPS at different rates than non-340B hospitals (Centers for Medicare & Medicaid Services 2008). In the final rule on the OPPS for 2010, CMS said that many commenters on the issues posed in the 2009 final rule were generally opposed to differential payment rates for hospitals based on their 340B status. CMS considered these differential payment rates alongside a question of whether claims from 340B hospitals should be excluded from calculating payment rates for separately payable drugs in the OPPS. CMS decided that there should not be different payment rates based on 340B status and concluded that it was not appropriate to exclude the claims from the 340B hospitals in the context of a policy that pays all hospitals the same rate for separately payable drugs (Centers for Medicare & Medicaid Services 2009).

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare and Medicaid Programs: Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; electronic reporting pilot; inpatient rehabilitation facilities quality reporting program; revision to quality improvement organization regulations. Final rule. *Federal Register* 77, no. 221 (November 15): 68210–68565.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Medicare program; changes to the hospital outpatient prospective payment system and CY 2010 payment rates; changes to the ambulatory surgical center payment system and CY 2010 payment rates. Final rule. *Federal Register* 74, no. 223 (November 20): 60315–60983.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Medicare program: changes to the hospital outpatient prospective payment system and CY 2009 payment rates; changes to the ambulatory surgical center payment system and CY 2009 payment rates; requirements for approval and re-approval of transplant centers to perform organ transplants—clarification of provider and supplier termination policy Medicare and Medicaid programs: changes to the ambulatory surgical center conditions for coverage. Final rule. *Federal Register* 73, no. 223 (November 18): 68501–69380.

Congressional Budget Office. 2014. *Competition and the cost of Medicare's prescription drug program.* Washington, DC: CBO.

Department of Health and Human Services. 2014. *Fiscal year 2015 Health Resources and Services Administration justification of estimates for appropriations committees.* Washington, DC: HHS.

Government Accountability Office. 2011. *Drug pricing: Manufacturer discounts in the 340B Program offer benefits, but federal oversight needs improvement.* GAO–11–836. Washington, DC: GAO.

Health Resources and Services Administration. 2015. Statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration, before the Subcommittee on Health, Committee on Energy and Commerce, U. S. House of Representatives. March 5.

Health Resources and Services Administration, Department of Health and Human Services. 2014a. FAQs: 340B Drug Pricing Program. http://www.hrsa.gov/opa/faqs/index.html.

Health Resources and Services Administration, Department of Health and Human Services. 2014b. *Interpretive rule: Implementation of the exclusion of orphan drugs for certain covered entities under the 340B program.* Rockville, MD: HRSA.

Health Resources and Services Administration, Department of Health and Human Services. 1996. Notice regarding Section 602 of the Veterans Health Care Act of 1992 patient and entity eligibility. Final notice. *Federal Register* 61, no. 207 (October 24): 55156–55158.

Hutton, D., P. A. Newman-Casey, M. Tavag, et al. 2014. Switching to less expensive blindness drug could save Medicare Part B $18 billion over a ten-year period. *Health Affairs* 33, no. 6 (June): 931–939.

IMS Institute for Healthcare Informatics. 2014. IMS health study: Spending growth returns for U.S. medicines. News release. April 15.

IMS Institute for Healthcare Informatics. 2012. *The use of medicines in the United States: Review of 2011.* Parsippany, NJ: IMS Institute for Healthcare Informatics.

Jacobson, M., C. C. Earle, M. Price, et al. 2010. How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment. *Health Affairs* 29, no. 7 (July): 1391–1399.

Medicare Payment Advisory Commission. 2014. *A data book: Health care spending and the Medicare program.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Impact of changes in Medicare payments for Part B drugs.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2006. *Report to the Congress: Effects of Medicare payment changes on oncology.* Washington, DC: MedPAC.

Office of Inspector General, Department of Health and Human Services. 2013. *Comparison of average sales prices and average manufacturer prices: An overview of 2011.* OEI–03–12–00670. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2012. *Least costly alternative policies: Impact on prostate cancer drugs covered under Medicare Part B.* OEI–12–12–00210. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2011a. *Medicare payments for newly available generic drugs.* OEI–03–09–00510. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2011b. *State Medicaid policies and oversight activities related to 340B-purchased drugs.* Washington, DC: OIG.

Sanghavi, D., K. Patel, K. Samuels, et al. 2014. *Transforming cancer care and the role of payment reform: Lessons from the New Mexico Cancer Center.* Engleberg Center for Health Care Reform at Brookings. Washington, DC: The Brookings Institution.

U.S. House of Representatives. 1992. *The Medicaid drug rebate amendments of 1992.* Report 102–384, part 2. 102nd Cong., 2nd sess.

Value-based incentives for managing Part B drug use

Value-based incentives for managing Part B drug use

Chapter summary

Medicare's payment policies for Part B drugs do not always provide beneficiaries or taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. Federal agencies—the Department of Health and Human Services (HHS) Office of Inspector General and the Congressional Budget Office—have shown that linking Part B payment for drugs and biologics to comparative evidence of clinical effectiveness would reduce spending for beneficiaries and taxpayers.

Several types of value-based incentives have been implemented or proposed that seek to obtain a better price for Part B drugs and biologics for beneficiaries than under the current fee-for-service (FFS) system in traditional Medicare:

- *The least costly alternative (LCA) and functional equivalence policies* that Medicare used from 1995 to 2010. Under this approach, the program set the payment rate for a group of drugs with similar health effects (but assigned to different payment codes) based on the payment rate for the least costly product in the group.

In this chapter

- Introduction

- Applying least costly alternative and consolidated payment code policies to Part B drug payment

- Bundling oncology services

- Conclusions

- *A consolidated payment code approach* that Medicare used from 2007 to 2008. Under this approach, the program grouped drugs with similar health effects into a single payment code and set payment based on the volume-weighted average of the program's payment (average sales price) for each product.
- *A bundled approach,* which would cover drugs and their administration costs across all settings and providers as well as related services (e.g., inpatient admissions, emergency department visits) during a defined period under one payment (or a benchmark price across multiple providers). With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area that might be amenable to bundling. Design issues associated with constructing oncology bundles in FFS Medicare are complex but important since Medicare spending for oncology drugs and biologics is substantial, accounting for about half of 2013 spending on Part B drugs administered in physicians' offices.

These three approaches are intended to improve efficiency by creating incentives for providers to choose lower cost products among a category of products with similar health effects. Under LCA and consolidated payment policies, Medicare would judge the comparative clinical effectiveness of a drug relative to its alternatives. By contrast, under bundled approaches, clinicians would judge the clinical effectiveness of alternative treatment approaches. Depending on the design, bundling has the potential to encourage providers' accountability across the spectrum of care and lead to positive downstream effects such as reduced hospital admissions and emergency department visits.

The Secretary of HHS would need the Congress to restore her authority to establish LCA or consolidated payment code policies. For LCA and consolidated payment code approaches, Medicare would need to consider and address a number of design questions and issues, including defining groups of products that treat a given condition with similar health effects, standardizing units and frequency of drug administration, and calculating and updating the payment rate. By contrast, the Center for Medicare and Medicaid Innovation (CMMI) could develop and test bundling approaches that include Part B drugs, or the Congress could mandate that CMS implement an oncology bundling initiative. Issues associated with implementing a bundled oncology approach include the bundle's scope of services, the duration of the treatment bundle, the event that triggers the use of the payment bundle, and the type of payment.

Other approaches that seek to pay efficiently for oncology services while improving care quality are currently in place. They include oncology medical homes and the use of clinical pathways. The Community Oncology Medical Home (COME

HOME) is a three-year oncology medical home model that CMMI funded in 2012 with seven oncology practices. The practices offer enhanced services for Medicare and Medicaid beneficiaries and commercially insured patients who have been newly diagnosed with or relapsed in seven cancer types. Clinical pathways, which in this context are evidence-based treatment protocols that commercial payers and providers use to standardize anticancer drug regimens, seek to reduce unnecessary variation, improve quality of care, and reduce costs. ■

Introduction

Since 2005, in accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare pays physicians and suppliers the average sales price (ASP) + 6 percent for most Part B–covered drugs and biologics.[1] CMS, through regulation, has also established a payment rate of ASP + 6 percent for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS). Under the Patient Protection and Affordable Care Act of 2010 (PPACA), a biosimilar biologic product is paid 100 percent of its ASP, plus 6 percent of the ASP for the reference biologic. Chapter 3 explains in more detail how Medicare pays for Part B drugs and biologics.

Medicare spending for Part B drugs and biologics paid under ASP is substantial. In 2013, Medicare spending (program payments and beneficiary cost sharing) for Part B drugs paid under ASP amounted to over $19 billion dollars (with more than $15 billion of Medicare program payments and nearly $4 billion of beneficiary cost sharing). Of that spending, physician offices accounted for over $11 billion, hospital outpatient departments accounted for nearly $7 billion, and suppliers accounted for over $1 billion.

Medicare's payment policy for Part B drugs does not always provide beneficiaries and taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. Concerns raised by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and researchers that the 6 percent add-on to ASP may incentivize the use of higher priced drugs are summarized in a text box (p. 92). Least costly alternative (LCA), consolidated payment code, and bundling approaches have the potential to improve value by creating incentives for providers to choose lower cost products from a category of products with similar health effects. Under LCA and consolidated payment code approaches, Medicare would develop groups of drugs that are used to treat a given condition and result in similar health effects. By contrast, under bundling, providers would make decisions on the value of services included in the bundle.

Concern has also been expressed that, under fee-for-service (FFS) payment systems, providers are not accountable for the total cost of services across an episode of care, and care is often fragmented and uncoordinated. According to Bach (2007), the fragmented FFS payment system is a poor fit for cancer care because patients require different services that should be integrated seamlessly (physician services, laboratory tests, and multimodality regimens that include infusion of cancer drugs, administration of radiation oncology, and surgery) (Bach 2007).

As the Commission discussed in its June 2013 report, bundling could achieve several goals. First, bundling would encourage providers to make clinically appropriate decisions about the most efficient mix of services beneficiaries receive. It might also reduce variation in total spending. For broader bundles, care could be less fragmented because the provider(s) would be accountable for all care furnished during an episode, which might result in fewer hospitalizations and emergency department visits. Last, bundling could give providers experience managing care across a continuum that is likely to be required in broader payment initiatives (Medicare Payment Advisory Commission 2013).

Previously, the Commission has considered and made recommendations on bundled payment approaches for certain services. For example:

- In its June 2013 report, the Commission considered design aspects of a bundled payment that would begin with an initial hospital stay; span 90 days after discharge; and include any potentially avoidable readmissions, post-acute care (PAC), and physician services furnished during the hospital stay and during any institutional PAC care (Medicare Payment Advisory Commission 2013).

- In its June 2008 report, the Commission recommended that the Congress require the Secretary to create a voluntary pilot program to test the feasibility of bundled payments for services around a hospitalization for select services; PPACA included a provision that directed the Secretary to test the bundling concept (Medicare Payment Advisory Commission 2008).

- In its March 2001 report, the Commission recommended that the Congress direct the Secretary to expand the dialysis payment bundle to include dialysis drugs, laboratory tests, and other items and services related to end-stage renal disease that were previously separately billable (Medicare Payment Advisory Commission 2001); the Medicare Improvements for Patients and Providers Act of

2008 included such a provision for the Secretary to implement.

Applying least costly alternative and consolidated payment code policies to Part B drug payment

Between 1995 and 2010, Medicare implemented policies—the LCA and functional equivalence (FE) policies—that improved the value of care provided to Medicare beneficiaries by linking payment to comparative clinical effectiveness evidence. Under these policies, a group of drugs with similar health effects but assigned to different payment codes was paid based on the least costly product in the group. The LCA and FE policies are strategies in which a single payment rate is set for a group of products that result in similar health effects.

LCA and FE policies, which are types of reference pricing policies, work best for products and services that exhibit wide variation in prices but only small differences in quality or outcomes (Robinson 2013). While LCA and FE policies set the payment based on the lowest cost product, alternative ways to calculate a reference price include basing it on the mean, median, or the volume-weighted average of the prices for the individual products in a category.

Federal agencies have shown that applying LCA policies to Part B drug payment improved the value of Medicare

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spending for beneficiaries and taxpayers. OIG estimated one-year savings of nearly $7 million for beneficiaries and nearly $27 million for Medicare if an LCA policy was used for a group of drugs that treat prostate cancer (Office of Inspector General 2012). OIG also found that if Medicare had set the payment rate for drugs that treat wet age-related macular degeneration (a cause of vision loss) on the least costly one, beneficiaries would have saved $275 million and the program would have saved $1.1 billion in 2008 and 2009 (Office of Inspector General 2011). The Congressional Budget Office estimated savings of almost $500 million between 2010 and 2019 if an LCA policy was used for drugs that treat osteoarthritis of the knee (Congressional Budget Office 2008).

The Secretary would need the Congress to restore her authority to implement LCA or consolidated payment code approaches. At present, the Secretary's lack of flexibility to apply these approaches stems from the MMA, which requires that biologics (both reference products and biosimilars) and single-source drugs (without generic competition) be paid based on their own ASP and not averaged with other products. Consequently, these products receive their own payment code.

Medicare's application of least costly alternative policies

Between 1995 and 2010, the medical directors associated with the Medicare administrative contractors (MACs), which process and pay Medicare FFS claims, established LCA policies to set the payment rate for certain Part B drug classes based on guidance contained in CMS's Benefit Policy and Program Integrity Manuals.[3] The contractors' medical directors generally based LCA determinations on the premise that "if two services are clinically comparable, then Medicare does not cover the additional expense of the more costly service, when this additional expense is not attributable to that part of an item or service that is medically reasonable and necessary" (National Government Services 2009). The medical directors implemented LCA policies in local coverage decisions that applied to a defined geographic jurisdiction. LCA policies were established based on the statutory provision (1862(a)(1)(A)) that states that "no payment may be made under Part A or Part B for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Simply put, LCA policies were applied under the premise that Medicare should not

pay for the additional cost of a more expensive product if a less costly product produces a comparable clinical outcome. Although the statutory platform for making LCA determinations was based on Medicare's reasonable and necessary authority for medical services, the policy affected the payment rate of drugs. In addition, in one instance, Medicare applied an LCA-type policy—referred to as the FE policy—on the national level to set the payment rate for anti-anemia drugs paid for under the OPPS. The text box (p. 94) describes the circumstances in 2002 under which CMS implemented the FE policy under the OPPS rule-making process.

In applying LCA policies to Part B drugs, the MACs' medical directors generally followed these steps:

- determined that the product was a Medicare-covered benefit,

- determined that the product was "reasonable and necessary" for the treatment of an illness or injury,

- reviewed clinical evidence from the Food and Drug Administration and other sources and determined that the clinical effects of two or more products were comparable,

- displayed draft and final policies online and provided for a notice and comment period (Centers for Medicare & Medicaid Services 2010), and

- established the payment rate for each product covered under the LCA policy under the prevailing Medicare payment policy—based on ASP since 2005—and set the payment rate for all the products based on the product with the lowest ASP.

In some instances, the MACs' medical directors would pay the higher rate for the more costly product when the physician could document that the more costly product was medically necessary to treat a specific patient. In addition, there was an opportunity for the beneficiary to choose the more costly product. Specifically, if the physician informed the beneficiary in advance and in writing that Medicare was likely to deny payment for the more costly product and if the beneficiary signed an advance beneficiary notice for the product, then the beneficiary could pay an additional sum if the beneficiary and physician chose a more costly service. Under these circumstances, the beneficiary's liability would include the 20 percent coinsurance and the difference in the Medicare payment between the more costly and least costly product.

Applying a national least costly alternative policy: The functional equivalence standard

The functional equivalence (FE) standard is similar to the least costly alternative (LCA) policy under which payment for clinically comparable products assigned to separate payment codes is based on the least costly item. The FE policy was established in the national payment (rule-making) process and applied nationally. By contrast, LCA policies were established in the local coverage process and applied in specific geographic regions.

In 2003, in the rule-making process for the hospital outpatient prospective payment system (OPPS), CMS nationally set the payment rate for a new biologic (darbepoetin alfa) at the rate of an existing, less costly product (epoetin alfa) after concluding that both anti-anemia products were functionally equivalent because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells (Centers for Medicare & Medicaid Services 2002a).

CMS did not initially set the payment rate for the new product by using the FE standard. Rather, in the 2003 OPPS proposed rule, CMS said that it would continue the new biologic's transitional (higher) pass-through payments (Centers for Medicare & Medicaid Services 2002b). In response, a product developer argued that because both the old and the new biologic are substitutes (with the same clinical effects) for each other, they should be paid at the same rate. In the final rule, CMS reviewed the clinical evidence, concluded that both biologics were functionally equivalent, and set the payment rate of the new biologic at the same rate as the older one (Centers for Medicare & Medicaid Services 2002a). CMS contended that it would not be equitable or an efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates and used its authority under the Social Security Act (1833(t)(2)(E)) to make an adjustment it determined "necessary to ensure equitable payments."

This policy withstood a lawsuit from the product developer of the new biologic. An appeals court dismissed the case, concluding that CMS's statutory rationale for the decision was not subject to judicial review (U.S. Court of Appeals 2004).[4] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limited future use of the FE standard. The Congress prohibited use of this standard for drugs and biologics in the hospital outpatient setting unless the standard was in place before the law's enactment (the law did not prevent the use of the FE policy for erythropoiesis-stimulating agents—typically used to treat anemia—paid under the OPPS).

Medicare continued to use the FE standard in 2004 and 2005. In response to passage of the MMA, each biologic's payment rate was set under the ASP policy in 2006. ∎

In 2008, a beneficiary and the manufacturer of a particular inhalation drug challenged the proposed application of an LCA policy for that drug, arguing that the statute requires that if the drug is reasonable and necessary, Medicare must pay the statutorily defined payment rate for the drug—ASP + 6 percent.[5] The government argued that the reasonable and necessary statutory provision confers great discretion on the Secretary and that the LCA policy was permissible because the provision explicitly addresses payment and expenses.

Two federal courts agreed with the beneficiary and ruled that Medicare cannot use LCA policies to pay for that particular Part B inhalation drug, asserting that the statute's provision that sets the payment rate for Part B drugs based on its ASP precludes Medicare from applying LCA policies. These rulings apply to instances in which CMS has set a drug's payment based on the ASP of the least costly product. Effective April 2010, the MAC's medical directors rescinded the LCA policies applied to Part B drugs, and since then, Medicare's payment rate for products previously paid for under an LCA policy (including luteinizing hormone-releasing hormone agonists for prostate cancer) is 106 percent of the product's ASP.

TABLE
4–1

Grouping two inhalation products with similar health effects in a single payment code

Coding strategy	Medicare payment based on 106 percent of ASP for each drug*			Medicare payment based on volume-weighted average (106 percent of ASP) for both drugs**		
	2005: 1st quarter	2006: 1st quarter	2007: 2nd quarter	2007: 3rd quarter	2007: 4th quarter	2008: 1st quarter
Separate payment code						
Albuterol	$0.07	$0.06	$0.08			
Levalbuterol	1.28	1.34	1.54			
Combined payment code						
Albuterol				$0.53	$0.42	$0.44
Levalbuterol				0.53	0.42	0.44

Note: ASP (average sales price). 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 106 percent of ASP for each drug.
**Between the third quarter of 2007 and the first quarter of 2008, payment for the single code that included albuterol and levalbuterol was based on the volume-weighted average (106 percent of ASP) for both drugs.

Source: MedPAC analysis of CMS's Medicare Part B drug ASP data files available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.

Medicare's application of the consolidated payment code approach

Between July 1, 2007, and March 31, 2008, Medicare used a single payment code for two drugs used to treat asthma and chronic obstructive pulmonary disease—levalbuterol (which was a single-source drug until 2008) and albuterol (a multisource drug) (Food and Drug Administration 2014). Medicare covers such inhalation drugs under Part B when they are administered through a nebulizer in a patient's home. Combining both products into a single payment code essentially sets the payment amount based on the volume-weighted ASP for these products. CMS established a single payment code for the two products to comply with the MMA provisions concerning payment for drugs (Table 4-1).[6] In contrast, between January 1, 2005, and June 30, 2007, CMS used separate Level II Healthcare Common Procedure Coding System (HCPCS) codes and payment amounts for both products. The text box (p. 97) describes how Medicare establishes Level II HCPCS codes for drugs and other medical services.

Including products with divergent acquisition costs in a single payment code could initially result in Medicare's payment rate not reflecting each product's acquisition cost. After both drugs were included in the same code (in the third quarter of 2007), the payment rate for albuterol (which was multisource) increased by 563 percent, while the rate for levalbuterol (which was single source in 2007)

decreased by 66 percent. In the following two quarters (the fourth quarter of 2007 and the first quarter of 2008), the combined payment rate declined by about 17 percent.

To determine whether shifts in utilization patterns for albuterol and levalbuterol coincided with changes in Part B payment and coding policy, OIG conducted a survey of suppliers and physicians for 312 beneficiaries who had used albuterol, levalbuterol, or both products between January 2003 and December 2007. OIG found that between January 2005 and June 2007, with each drug assigned to separate payment codes, Medicare payment favored levalbuterol; one-quarter of beneficiaries who were using albuterol were changed to levalbuterol. From July 2007 through December 2007, Medicare payment favored albuterol; two-thirds of the beneficiaries in OIG's sample who had been using levalbuterol were changed to albuterol (Office of Inspector General 2009).

The Medicare, Medicaid, and SCHIP Extension Act of 2007 essentially reestablished separate codes for both albuterol and levalbuterol. Effective April 1, 2008, the law calculates each product's payment as 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 individual drug. CMS implemented this statutory provision by establishing separate payment codes for each product effective April 1, 2008 (Office of

Coding strategy	Medicare payment based on the lower of volume-weighted average of 106 percent of ASP for both drugs or 106 percent of ASP for the individual drug*			
	2008: 2nd quarter	2010: 1st quarter	2012: 1st quarter	2014: 1st quarter
Separate payment code				
Albuterol	$0.04	$0.05	$0.06	$0.05
Levalbuterol	0.28	0.20	0.26	0.09

Note: ASP (average sales price). Albuterol is unit dose, 1 milligram. Levalbuterol is unit dose, 0.5 milligram.
*Since the second quarter of 2008, Medicare payment is 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 ASP for the individual drug.

Source: MedPAC analysis of CMS's Medicare Part B drug ASP data files available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/ McrPartBDrugAvgSalesPrice/index.html.

Inspector General 2009). Between the first and second quarters of 2008, this policy resulted in payments that dropped 91 percent for albuterol and 36 percent for levalbuterol (Table 4-2). Another factor affecting the payment for levalbuterol was the Food and Drug Administration approval of this product's generic versions.

Issues in implementing LCA and consolidated payment code approaches

Key to implementing LCA and consolidated payment code approaches successfully would be to develop a transparent and predictable process that permits opportunities for public comment. CMS would need to establish processes for:

- defining groups of products that achieve comparable clinical outcomes;

- obtaining public comment from a wide range of stakeholders, including beneficiaries, providers, product developers, insurers, and researchers; and

- reconsidering comparative clinical effectiveness evidence and the payment policy over time.

Ensuring beneficiary access either for medical necessity or preference (i.e., not medical necessity) would also have to be addressed in applying these approaches to Part B drug payment.

Under these approaches, beneficiary access to the more costly product could be addressed in Medicare's appeals process.[7] As was the case under prior LCA policies, the

process could permit beneficiaries to gain access to a more costly product when not medically necessary by permitting the beneficiary to pay the difference (in the cost between the more costly and least costly service) if that is his or her preference.

Options for ensuring transparency include consulting with the public on an issue-by-issue basis or establishing an advisory group. An example of a way for CMS to gain technical expertise from the public is the Medicare Evidence Development & Coverage Advisory Committee. Established in 1998, it provides independent guidance and expert technical advice to CMS on specific clinical topics considered in the national coverage determination process.

CMS also could consult with the Evidence-Based Practice Centers (EPCs), an initiative launched by the Agency for Healthcare Research and Quality (AHRQ) in 1997 to promote evidence-based practice. The EPCs are located at universities, medical centers, and research institutions across the country and provide technology assessments for CMS, provide comparative effectiveness reviews for AHRQ's Effective Health Care Program, and support the work of the U.S. Preventive Services Task Force.

Bundling oncology services

Bundled payments set a fixed (or benchmark) price for a group of related items and services. Bundling oncology services could achieve several goals. Developing

Medicare's coding of health care services: The Healthcare Common Procedure Coding System

The Healthcare Common Procedure Coding System (HCPCS) was established in 1978 to provide a standardized coding system for the items and services provided in the delivery of health care. Initially, use of the codes was voluntary, but with the implementation of the Health Insurance Portability and Accountability Act of 1996, use of the HCPCS for transactions involving health care information became mandatory. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002.

The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. The Level I system consists of the Current Procedural Terminology–4 (CPT–4), a numeric coding system maintained by the American Medical Association to identify medical services and procedures. The Level II HCPCS is a standardized coding system that is used primarily to identify drug, biologics, supplies, and services not included in the CPT–4 codes.

Since 2003, CMS maintains the Level II HCPCS, which involves assigning new codes, modifying existing codes, or deleting codes (Centers for Medicare & Medicaid Services 2012). The CMS HCPCS Workgroup, which includes representatives from Medicaid state agencies and the Medicare administrative contractors, evaluates requests from interested parties for modifying the HCPCS Level II set (e.g., seeking a new code or a change to an existing code). In addition, coding decisions are coordinated with public and private payers. The workgroup considers factors such as whether or not an existing code adequately describes the item in a coding request. National codes are updated on an annual basis. CMS hosts annual public meetings that provide a forum for interested parties to provide additional input about requests to modify the HCPCS code set. ∎

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oncology bundles that include Part B oncology drugs and biologics—defined as anticancer drugs and supportive-care drugs given with anticancer drugs—might help address potential incentives under Medicare's current Part B payment method for providers to furnish more costly regimens when therapeutically equivalent drugs exist.

A primary rationale for bundling is to address the concern that, under FFS payment systems, providers are not accountable for the total cost of services across an episode of care, and care is often fragmented and uncoordinated. Specific to oncology care, according to the Institute of Medicine (IOM) and others, FFS payment systems can have the following effects:

- create incentives to use more costly interventions—oncology-related drugs, radiation, and surgery—that lack evidence of improved clinical effectiveness compared with other treatment options (Balogh et al. 2011, Institute of Medicine 2013, Sanghavi et al. 2014). For example, use of proton beam therapy for prostate cancer has increased among Medicare beneficiaries despite the lack of evidence showing that the intervention is better than other, less costly radiation alternatives such as three-dimensional conformal radiation therapy and intensity-modulated radiation therapy (Jarosek et al. 2012, Ollendorf et al. 2014, Yu et al. 2013).

- lead to the overuse of oncology-related interventions (Institute of Medicine 2013). For example, one study reported that many patients with metastatic non-small-cell lung cancer receive a greater number of treatments or higher doses of palliative radiation than is supported by current evidence (Chen et al. 2013). According to the IOM, use of chemotherapy near the end of life is another example of overuse.

- do not facilitate cancer care coordination, which can lead to duplication of care and result in patient complications, which is particularly problematic for patients who have comorbidities that should be managed by both the cancer care team and other specialist care teams (Sanghavi et al. 2014).

- lead to unnecessary emergency department (ED) visits and hospitalizations for potentially avoidable conditions such as nausea following chemotherapy administration (Sanghavi et al. 2014).

TABLE 4–3	Medicare spending for beneficiaries newly diagnosed with breast, colon, or lung cancer during a six-month oncology episode, 2011–2012		

Type of service	Mean total spending per beneficiary	Percent of beneficiaries receiving service type
Physician/supplier	$18,752	99.9%
Institutional outpatient	12,062	91.6
Inpatient	8,221	45.7
Home health	844	24.2
Hospice	761	14.5
All of above	$40,640	100.0

Note: This table reports Medicare spending for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Medicare spending in this table includes program payments and beneficiary payments. Inpatient spending includes services provided under the inpatient prospective payment system and by critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, and inpatient psychiatric hospitals. The number of beneficiaries included in the analysis is 61,039.

Source: MedPAC analysis of 2011–2012 100 percent claims from inpatient, institutional outpatient, physician/supplier, hospice, and home health files.

According to some researchers, medical oncology care is amenable to bundling because management of cancer care is supported by a large evidence base and regularly updated guidelines from numerous organizations, and the guidelines address the most costly components of care—anticancer drugs, supportive-care drugs, and their attendant administration fees (Bach et al. 2011, Emanuel 2014). The same researchers concluded that it is possible to assess the quality of care by measuring whether the published evidence-based guidelines are followed (Bach et al. 2011, Emanuel 2014).[8]

The implementation of oncology payment bundles in FFS would need to address multiple design issues. For instance, inherent in establishing a bundled payment amount is a judgment on what the treatment of a condition should cost. There are also trade-offs associated with deciding what is and is not included in the bundle. A bundled approach also has implications for beneficiaries, with respect to how much they pay for care. In addition, bundling could create incentives for undesirable provider behavior, such as the underprovision of care. A bundled payment may be a fixed price paid to the provider (e.g., clinicians and/ or organizations furnishing care) prospectively, and this

provider would be responsible for paying all providers furnishing care to the beneficiary during the bundle window. Alternatively, Medicare could continue to pay each provider under its FFS systems, and a benchmark would then be used to adjust net payments to providers retrospectively. Bundling could also require providers to have an infrastructure to make payments to other providers and receive payments on their behalf. Our study of these issues—an analysis of Medicare spending for certain cancer diagnoses requiring Part B oncology drugs, commercial payers' experience with bundling payment for oncology services, and other approaches to oncology care—suggests a combination of design features that could address these issues.

Medicare spending for oncology services: Findings of an exploratory analysis

As a first step in considering oncology bundles, we sought to understand spending patterns for beneficiaries with cancer. To do so, we examined Medicare spending for newly diagnosed beneficiaries with breast, colon, or lung cancer who received an oncology drug (which includes anticancer drugs and supportive-care drugs) in 2011 or 2012. We found that in an episode—defined as 180 days following an initial oncology drug paid under Part B—oncology drugs and their administration costs accounted for nearly half (46 percent) of total Part A and Part B spending. Oncology-related radiation services accounted for an additional 9 percent of total spending during the 180-day follow-up period.

Specifically, we analyzed the spending patterns for 61,039 beneficiaries with newly diagnosed (incident) breast, colon, or lung cancer who received outpatient chemotherapy in 2011 or 2012. This analysis used CMS's 2010–2012 Master Beneficiary Summary file to identify and classify the study population by cancer type and CMS's 2011–2012 100 percent claims files to determine Medicare spending (program and beneficiary payments). For each beneficiary, we constructed an episode that started the first day that the beneficiary first received a Part B–covered oncology drug and ended 180 days later or at the beneficiary's death. Each beneficiary's episode of care was divided into six 30-day periods. During the episode of care, 21 percent of beneficiaries died (12,689 beneficiaries). The study population had the following characteristics:

- Twenty-eight percent were diagnosed with breast cancer, 52 percent with lung cancer, and 23 percent with colon cancer (total does not sum to 100 percent

FIGURE
4–1

Medicare spending for beneficiaries newly diagnosed with breast, colon, or lung cancer for the six 30-day periods of an oncology episode, 2011–2012
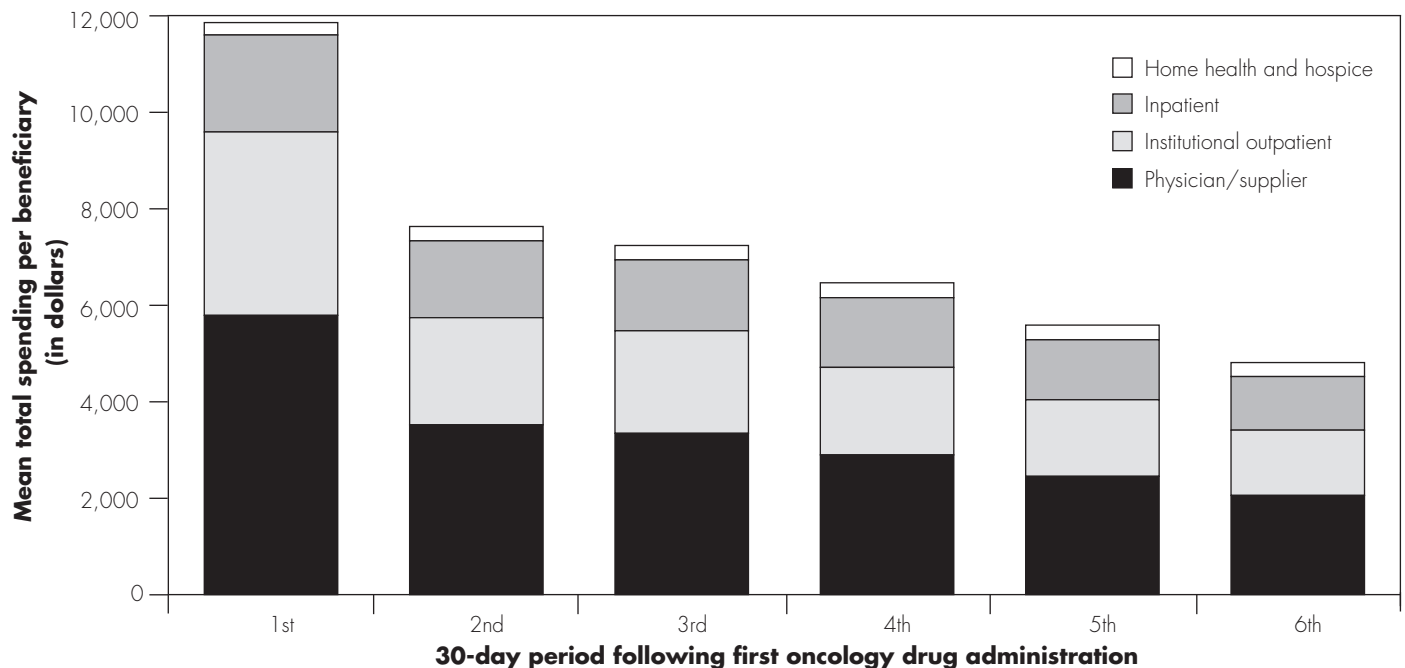
Note: "Medicare spending" in this figure is for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Beneficiaries are included in a given period if they were alive at any point during that period. Medicare spending includes program payments and beneficiary payments. Inpatient spending includes services paid under the inpatient prospective payment system and by critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, or inpatient psychiatric hospitals.

Source: MedPAC analysis of 2011–2012 100 percent claims from inpatient, institutional outpatient, physician/supplier, hospice, and home health files.

because beneficiaries may have had more than one type of cancer).

- Nine percent were under age 65, 43 percent were 65 to 74 years old, 23 percent were ages 75 to 79 years, 15 percent were ages 80 to 84 years, and 10 percent were 85 years or older.

- Forty percent were male and 60 percent were female.

- Eighty-seven percent were White, 9 percent were African American, 1 percent was Asian American, and the remainder (3 percent) were all other races or race unknown.

- Twenty-five percent resided in rural areas.

During the 180-day episode, spending for physician/supplier, institutional outpatient, inpatient, home health, and hospice services averaged $40,640. Outpatient services—physician/supplier and institutional outpatient services—accounted for 76 percent of this total (Table 4-3).[9]

During the episode, 46 percent of beneficiaries in the study population were hospitalized, 24 percent received home health services, and about 15 percent elected hospice. Part A and Part B total spending during the 180-day episode varied by cancer type, ranging from nearly $35,000 per beneficiary with breast cancer to nearly $42,000 per beneficiary with lung cancer and nearly $46,000 per beneficiary for colon cancer.

Medicare also pays for oncology drugs under Part D. Nearly 60 percent of the study population was enrolled in Part D, and roughly one-quarter of enrolled beneficiaries received an oncology drug during the 180-day episode. For enrolled beneficiaries, Part D spending for oncology drugs averaged about $700 per beneficiary during the 180-day episode.

Figure 4-1 shows mean total spending for the six 30-day periods of the episode. For this analysis, the denominator consists of all beneficiaries who were alive at any point during that period. Mean total spending per beneficiary

FIGURE
4–2

Medicare spending for physician/supplier and institutional outpatient services for the six 30-day periods of an oncology episode, 2011–2012
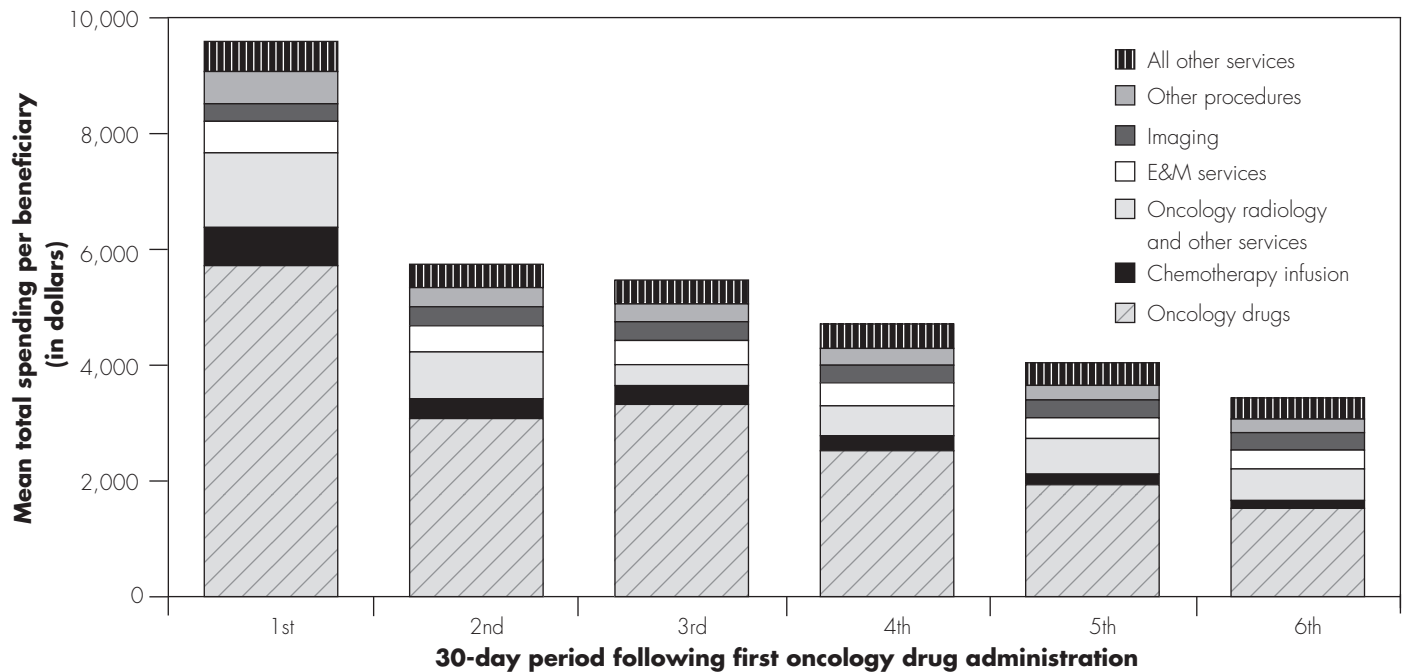
Note: E&M (evaluation and management). "Medicare spending" in this figure is for 180 days following the first administration (between January 1, 2011, and June 30, 2012) of a Part B–covered oncology drug for beneficiaries newly diagnosed with breast, colon, or lung cancer. Beneficiaries are included in a given period if they were alive at any point during that period. Medicare spending includes program payments and beneficiary payments. Inpatient spending includes services provided by inpatient prospective payment system hospitals and critical access hospitals. This analysis does not include Medicare spending for Part D drugs, durable medical equipment, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, or inpatient psychiatric hospitals.

Source: MedPAC analysis of 2011–2012 100 percent claims for institutional outpatient and physician/supplier files.

gradually decreased during the episode, from nearly $11,900 per beneficiary in the first 30-day period to about $4,800 per beneficiary in the last 30-day period.

Figure 4-2 highlights outpatient spending for physician/supplier and institutional outpatient services per 30-day period. We assigned outpatient services to mutually exclusive categories (e.g., chemotherapy and other cancer drugs, chemotherapy infusion, etc.) based on the Berenson-Eggers code and procedure code reported on the physician/supplier and institutional outpatient claims. The services in the "all other" category include non-oncology drugs, laboratory services, other tests, major procedures, and ED services. Between the first 30-day period and the last 30-day period, mean total spending per beneficiary declined from nearly $9,600 per beneficiary to $3,400. Overall, oncology drugs and their administration costs accounted for 61 percent of total oncology episode outpatient spending, and oncology-related radiation

services accounted for an additional 13 percent of spending. Across the six 30-day periods, oncology drugs and their administration costs and oncology-related radiation services ranged between 65 percent and 80 percent of total outpatient spending. The study population's 2011 spending for oncology drugs accounted for roughly 8 percent of 2011 Part B drug spending in physician offices and hospital outpatient departments (data not shown).

We also looked at spending between each beneficiary's initial cancer diagnosis in 2011–2012 and the first oncology drug furnished to the beneficiary. The number of days between the initial cancer diagnosis and first oncology treatment averaged 67 days, and total spending averaged about $14,200 per beneficiary during this period for physician/supplier, institutional outpatient, inpatient hospital, home health, and hospice services.

Payer or provider	Design summary	Status and results
Case 1: Bach et al. (2011) proposal for FFS Medicare	Prospective payment covering anticancer and support drugs and their administration. Length of episode varies for colon, breast, and lung cancer.	Proposed in *Health Affairs* article.
Case 2: UnitedHealthcare–MD Anderson pilot	One-year episode with prospective payment covering surgery, chemotherapy, and imaging. Bundles vary based on treatment for newly diagnosed head and neck cancer.	Began December 2014; expected to run for three years.
Case 3: Blue Cross and Blue Shield of Florida pilot with Mobile Surgery International	Prospective payment covers care furnished for a minimally invasive laparoscopic radical prostatectomy for localized prostate cancer, including physician, hospital, and pathology services and drugs.	Ongoing since 2011.
Case 4: UnitedHealthcare pilot (completed) with five physician practices	Practices paid FFS for nondrug services, ASP (no add-on) for anticancer drugs, and an episode payment at the initial visit. Episode payment and length varies for lung, colon, and breast cancer. Performance-based payment based on reducing total spending and meeting quality metrics.	October 2009 to December 2012. Compared with control group, participating practices had lower total spending but higher drug spending.
Case 5: CMMI proposal for physician practices	Practices paid FFS plus $160 per beneficiary per month for enhanced services. One-sided risk for first two years, optional two-sided risk for last three years. Performance-based payment based on reducing total spending and meeting quality metrics; six-month episode begins at first chemotherapy administration for all cancer types.	Seeking applications from physician practices and other payers; expected to begin spring 2016 and run five years.

Note: FFS (fee-for-service), ASP (average sales price), CMMI (Center for Medicare & Medicaid Innovation).

Source: Bach et al. 2011; Blue Cross Blue Shield of Florida 2011; Centers for Medicare & Medicaid Services 2015a; MD Anderson 2014; Newcomer et al. 2014.

Five case studies illustrating alternative bundling approaches for oncology services

Several approaches to bundling payment for oncology services have either been proposed for FFS Medicare or implemented by commercial payers. In studying five such approaches summarized in Table 4-4, we found that the bundling designs varied based on:

- the specificity of services covered by the bundle, with the narrowest bundle consisting of oncology drugs and their administration costs, and the broadest bundle consisting of all services—oncology and non-oncology—and by cancer type, with the narrowest bundle including one cancer type and the broadest bundle including all cancer types;

- the duration of the bundle, spanning from a 1-month (30-day) bundle to a 1-year bundle;

- the trigger event, including chemotherapy administration and cancer diagnosis; and

- the type of payment—for some, a fixed prospective payment, and for others, payment using an FFS mechanism with net payments adjusted retrospectively based on achieving cost and quality benchmarks.

Case 1: Proposals for FFS Medicare to bundle oncology services

In 2011, Bach and colleagues (2011) described a proposal for Medicare FFS to pilot a bundled payment for cancer care that would include chemotherapy, supportive drugs, and their administration for a predetermined period of time (Bach et al. 2011). The length of an episode would vary based on cancer type and treatment; for example, a one-month episode was proposed for metastatic non-small-cell lung cancer. The pilot would encompass the more common cancers such as metastatic lung cancer, breast cancer, and

colon cancer. Payment would be based on the average cost of caring for all patients grouped by their specific cancer diagnosis. According to Bach and colleagues, such a payment method would encourage providers to select lower priced regimens from among those deemed equally appropriate, an incentive not present in the current FFS system.[10] Program savings would be achieved by recalibrating FFS and bundled payments periodically to account for cost reductions in earlier episodes. To ensure quality, Medicare would establish standards of care, with an exceptions process, based on already existing public guidelines. The authors acknowledged the potential for backlash against the notion of Medicare's establishing care standards. Bach and colleagues pointed out that issues such as changes in treatment protocols, cost shifting, upcoding, and stinting on care would need to be addressed for this model to work. Widespread adoption of episode payments could, according to the authors, pressure drug manufacturers to lower their prices. To date, FFS has not implemented this bundled approach.

Case study 2: UnitedHealthcare–MD Anderson pilot for head and neck cancer

In December 2014, UnitedHealthcare and MD Anderson Cancer Center announced a three-year pilot that pays MD Anderson a fixed annual amount for the care of up to 150 patients (enrolled in employer-sponsored health plans) with certain types of head and neck cancer. According to MD Anderson, the prospective payment provides an incentive to focus on the essential elements of care and to avoid unnecessary steps; the program is expected to improve patient outcomes, lower costs, and improve patients' quality of life (MD Anderson 2014). The annual payments are expected to cover nearly all of a patient's cancer care for a year, including surgery, chemotherapy, and radiation services. This approach uses eight different bundles of care, which differ based on the types of oncology care (e.g., surgery, radiation, chemotherapy) that patients require. MD Anderson does not receive increased payments for patients who experience complications and need additional treatments. Because the costs of care are priced upfront, patients know the cost of care early in their treatment regimen, and MD Anderson bills patients only once for their cancer treatment.

Case study 3: Blue Cross and Blue Shield of Florida bundled payment with one provider for localized prostate cancer

In 2011, Blue Cross and Blue Shield of Florida and Mobile Surgery International implemented a bundled

payment pilot for prostate cancer patients treated with minimally invasive laparoscopic radical prostatectomy surgery (Bandell 2011, Blue Cross Blue Shield of Florida 2011). The bundle is intended to cover all care surrounding a radical prostatectomy and related procedures and includes the services of the surgeon, surgeon's assistant, and operative technical team; anesthesia and pathology services; hospital services; medications; and patient education.[11] The provider is responsible for paying the hospital and all other providers that furnish care under the bundle and will retain as profit any funds left over after the patient is treated. From the payer's perspective, the pilot provides an incentive for participating physicians to operate effectively and work cooperatively to prevent complications. It also simplifies the billing process for patients, who receive a single bill instead of separate bills from each provider, and for the payer, who no longer incurs the administrative cost of processing bills from multiple providers.

Case study 4: UnitedHealthcare episode-of-care pilot with five oncology practices

Between October 2009 and December 2012, UnitedHealthcare implemented an oncology payment pilot with 19 distinct types of clinical episodes. Five large oncology physician practices were paid ASP (instead of ASP plus the negotiated add-on amount) for chemotherapy drugs, an episode fee at the initial visit that was based on the contracted drug add-on amount to ASP, and FFS payments for most other services (e.g., office visits, drug administration, diagnostic radiology, and laboratory). The five participating practices were eligible for shared savings if, compared with physician practices in a national payer registry, quality (as measured by survival) improved or total episode costs decreased (or both). The pilot's objectives were to decrease total medical costs by aligning financial incentives supported by use and quality data and remove the link between drug selection and medical oncology income (Newcomer et al. 2014).

The pilot included 810 patients with breast, colon, and lung cancer. The 19 clinical episodes varied based on type of cancer, clinical stage (stage 0 through stage IV), and tumor histology. The duration of episodes spanned from 4 months to 12 months. At the time of the initial patient presentation, participating practices reported clinical information—such as clinical stage, histology, and intent of treatment (curative or palliative)—to the payer to determine the correct episode type.

To arrive at the episode payment for each of the 19 cancer episodes, the national drug margin for each episode was calculated by subtracting the aggregate ASP from the aggregate amount paid for chemotherapy drugs, then dividing by the total number of patients in each episode. Practices were also paid a small fee for each episode for case management that included physician hospital care services. Participating services continued to be paid FFS for physician office visits, chemotherapy administration, and diagnostic radiology. To compensate providers for furnishing palliative care services, the episode payments continued every four months for patients with metastatic disease no longer receiving chemotherapy or enrolled in hospice (Newcomer et al. 2014, UnitedHealthcare 2014).

At the beginning of the pilot, each participating practice selected a preferred drug regimen for each episode.[12] The participating practices were free to change their preferred drug regimen at any time during the three-year pilot. New studies and new drug releases resulted in changes in the preferred regimens during the pilot's implementation (Newcomer et al. 2014). Thus, providers had the flexibility to customize the regimen to individual patients, and, by paying for drugs at ASP, had less revenue-based incentive to use higher cost drugs. The episode payment was not adjusted to account for new drug selections during the course of the pilot.

The participating practices collaborated with the payer to develop quality, cost, and use measures, and the practices met annually to review their outcomes. These outcomes included total cost of care; rates of emergency room and hospitalization use; use of laboratory, diagnostic radiology, surgical services, and durable medical equipment; time to first progression for relapsed patients; hospice days for patients who died; days from last chemotherapy to death; and rate of febrile neutropenia occurrence. During the meeting, providers discussed potential solutions for variation in performance (e.g., in rates of hospital admission and use of diagnostic radiology).

UnitedHealthcare found their overall spending declined during the pilot, while drug spending increased. Specifically Newcomer and colleagues (2014) reported a 34 percent reduction in total actual spending compared with predicted total spending ($64.8 million vs. $98.1 million) and a 179 percent increase in actual drug spending compared with predicted drug spending ($21.0 million vs. $7.5 million) (Newcomer et al. 2014). The authors did not expect the increase in drug spending and

did not provide the specific components of drug spending. According to a *Washington Post* write-up of the pilot, the participating practices collectively received about one-third of the $33 million in total savings (Millman 2014).

Although the Newcomer analysis was not designed to determine the drivers of the differences in total medical spending, a subset analysis did demonstrate a statistically valid decrease in hospitalization and therapeutic radiology usage for the episode model. Most quality outcomes had insufficient numbers for statistical analysis, but the authors reported that Kaplan-Meier survival curves were monitored for all patients with metastatic disease; lung cancer survivors were the only evaluable subgroup, and there was no significant survival difference between patients in the pilot and the control groups (Newcomer et al. 2014).

Case study 5: Center for Medicare and Medicaid Innovation's Oncology Care Model

In 2015, the Center for Medicare and Medicaid Innovation (CMMI) released a request for applications for a demonstration to improve care coordination with an episode-based payment model for oncology, titled the Oncology Care Model (OCM). The model will last five years and is scheduled to begin in spring of 2016. The model's aim, through upfront payments to individual oncologists and group practices for practice transformation and care management, is that by improving the quality of care for beneficiaries with cancer, practices will lower total Medicare costs for their oncology patients and will then be eligible for performance-based payments. An episode of care lasts for six months and begins at receipt of Part B or Part D chemotherapy administration for cancer. During the episode, practices continue to receive FFS payments (including ASP + 6 percent for Part B drugs), plus a $160 per beneficiary per month (PBPM) payment to support practice transformation and coordinated care. Practices bill each month for the $160 PBPM using a HCPCS code (created for the OCM) unless a beneficiary enters hospice. The PBPM is included in the calculation of six-month episode expenditures.

Oncology practices willing to engage in practice redesign to promote care coordination and better quality outcomes are eligible to apply for the model. Practices must include at least two physicians or nonphysician providers under a single legal entity to qualify. Applicants will be screened for size, primarily to reduce random variation in the benchmarking process, and screened for past program integrity violations.

CMMI intends for this model to be a multipayer demonstration. While the practice transformation requirements must be aligned across all payers, individual payers will have discretion in designing the financial incentives to support their insured population.

Definition of episode Under the OCM model, an episode that lasts for six months and can be renewed for the demonstration's duration is triggered with an initial chemotherapy claim either in Part B or Part D. Topical formulations of chemotherapy drugs are excluded because they do not require the same intensity of management from the oncologist. The episode will not be shortened in cases when chemotherapy lasts fewer than six months; PBPM payments continue to be made for the duration of the six-month episode or until the beneficiary enters hospice.

CMMI intends for the OCM to be as broad as possible but recognizes that some cases are not amenable to being covered under the model. Beneficiaries who are not eligible for the OCM include those not enrolled in Part A and Part B, those with end-stage renal disease (ESRD), and those for whom Medicare is not the primary payer. Beneficiaries participating in other CMS models like accountable care organizations (ACOs) and those participating in clinical trials remain eligible. Beneficiaries without Part D are eligible, but their episodes are triggered only from Part B claims, and benchmarks include only Part A and Part B spending.

Beneficiary attribution In the OCM model, for payment and quality monitoring purposes, each eligible beneficiary treated at a participating practice will be aligned to the practice actively managing the beneficiary. According to CMMI, beneficiaries will be retrospectively attributed to practices after the completion of each episode (Centers for Medicare & Medicaid Services 2015b). Until the end of the demonstration in 2021, beneficiaries are eligible for new episodes of care as long as they continue to receive chemotherapy. Currently, CMMI intends to inform beneficiaries that they are in the model and they cannot opt out, but only administratively speaking. In practice, beneficiaries' can seek care from any willing provider.

Practice requirements PBPM payments in the OCM are contingent on compliance with the following practice transformation requirements: 24/7 access to a clinician with real-time access to medical records; use of a certified electronic health record system; use of data for quality improvement; available patient navigation services; development of a care plan that includes the

13 components of an IOM Care Management Plan; and adherence to national clinical guidelines for use of therapies.

Benchmarking To measure savings gained under the OCM, total Medicare expenditures in the performance period will be compared with a benchmark based on a historical baseline period, divided into six-month episodes. The benchmark includes all Medicare expenditures for eligible beneficiaries for a participating practice. The benchmark will then be adjusted for risk and geographic variation and trended forward to the performance period. Performance-year Medicare expenditures (including PBPM payments) will be compared with the baseline-year expenditures for each practice.

If a practice does not have enough eligible beneficiaries for reliable benchmarking, national and regional data will be used in conjunction with practice-level data to increase precision. Practices have the option of being pooled with other practices to further increase benchmarking precision. Other payers are free to develop a different benchmarking methodology, but it must be shared with CMMI.

A risk-adjustment methodology has not yet been finalized. Factors under consideration include beneficiary characteristics such as age, comorbidities, type of cancer, number of episodes, and types of concurrent therapies (radiation, endocrine therapy, etc.). At least for the first year, risk-adjustment data will be limited to that which can be gleaned from administrative claims. CMMI could consider collecting clinical data from practices treating oncology beneficiaries, including data on cancer stage and tumor histology.

Performance-based payment Under the OCM model, risk sharing includes a one-sided arrangement and an optional two-sided arrangement. To calculate eligibility for performance-based payment, a discount rate is applied to the baseline amount to arrive at the target spending amount (4 percent for one-sided risk sharing, 2.75 percent for two-sided risk sharing). Under one-sided risk, practices that reduce spending below the target amount are eligible for a performance-based payment. Under two-sided risk, practices are also financially responsible for Medicare spending that exceeds the target amount. The two-sided risk option will be available in the demonstration's third year, after which practices can switch between the two risk-sharing arrangements on a semi-annual basis. Performance-based payments are not made for beneficiaries with low-volume cancers for which it is not possible to calculate reliable benchmarks.

Payments will be adjusted based on performance on quality measures in the domains of care coordination, communication, patient- and caregiver-centered experience and outcomes, and clinical quality. The quality measures are intended to balance the incentives for cost reduction by ensuring that participating practices meet the OCM's goals of patient-centered, coordinated, and clinically appropriate care. CMMI limits expenditure reductions to 20 percent of the baseline expenditure amount to prevent practices from stinting. In the two-sided risk arrangement, a 20 percent maximum loss percentage also applies. Practices that have been pooled together to create a benchmark will also receive shared savings as a group; one practice is designated to receive any shared savings from CMS and distribute the savings to the other practices in the pool.

Practices participating in the OCM are not precluded from participating in other models, including shared-savings models. In cases where oncology practices are also in a Medicare ACO, oncology spending counts toward the ACO benchmark. CMS intends to recoup the OCM's discount amounts from the ACO's shared-savings amount.

Quality measurement CMMI intends to measure quality both for the purposes of performance-based payment and monitoring to prevent stinting on care. Measures include, among others, number of ED visits per beneficiary per episode, score on patient experience survey, share of beneficiaries with very short hospice stays, and share of visits that include medication reconciliation. At this time, CMMI plans to send quarterly reports to practices to aid in management of their populations.

Simulation results from RAND Under contract with CMS, RAND estimated the OCM's potential impact on spending using 2010 data inflated to 2016 dollars. It assumed that only practices with more than 50 eligible chemotherapy episodes per year would consider participating and, of those, about 10 percent of practices would do so. For these practices, RAND simulated the total spending on care management payments ($160 PBPM), baseline spending, and the spending target, assuming different levels of behavioral response (that is, changes to treatment decisions).

Spending estimates were simulated based on three scenarios: no behavioral change, 5 percent reduction in spending, and 10 percent reduction in spending. These reductions were not tied to particular actions the practices might take, but instead assumed aggregate reductions in spending at the practice level. In the scenario of no

behavioral change, total spending increased by 4 percent because all practices receive PBPM payments and some receive unearned performance-based payments.[13] The 5 percent reduction scenario resulted in spending slightly below the baseline, meaning the program would roughly break even. The 10 percent reduction scenario resulted in about 5 percent savings relative to the baseline.

Further, RAND projected the effect of the OCM payments on practice-level revenue to be significant relative to current Medicare revenue for physician services (which accounts for about 7 percent of total spending on oncology care). According to RAND, for most practices, the OCM is expected to augment existing revenue from evaluation and management services (E&M) by between 20 percent and 60 percent, and, for some practices, their E&M revenues could double, triple, or more.

Possible behavioral responses The effect that the OCM will have on Medicare spending is dependent on the degree to which practice patterns (e.g., use of inpatient hospital and ED services) change in response to the practice transformation requirements and quality measures. The OCM is not designed to specifically address the incentive under the Part B ASP payment method to use higher priced drugs. While the OCM may encourage more active management of patients, and thus fewer ED visits and hospitalizations, the model could also induce unintended behaviors.

First, if the financial incentives to change behavior and lower spending are not strong enough, practices in the one-sided risk model might not change their practice patterns. Despite the practice transformation requirements, some practices might not effectively furnish care coordination and enhanced patient care. Second, to receive the PBPM payments, some practices might offer chemotherapy to patients who would not have been offered such treatment before the OCM. Some practices could increase the number of episodes per beneficiary to generate more PBPM payments (to the extent clinically possible) (Colla et al. 2012, Elliott et al. 2010, Jacobson et al. 2010). Given the size of the PBPM payment relative to practice revenue, there seems to be a significant incentive to engage in these behaviors. Finally, to keep spending below the benchmark, some practices might select less intensely ill patients to reduce the level of management they would need to provide, or they could use less costly treatment regimens, regardless of their appropriateness for an individual patient (to the extent clinically possible).

Issues in designing oncology bundles

In its June 2013 report, the Commission discussed several approaches and design issues associated with bundling post-acute care (PAC) services. Similar challenges exist with respect to a payment bundle for oncology services. Among the design issues are decisions about the services in the bundle, the duration of the bundle, payment arrangements, and incentives to encourage more efficient provision of care. Each decision involves trade-offs between increasing the opportunities for care coordination and requiring providers to accept risk for care beyond what they furnish.

In principle, under some forms of bundled payment, providers would not have an incentive to furnish more expensive drugs to generate revenue; instead, they would deliver a mix of treatments that would enable them to improve the quality of their care while keeping Medicare spending low. However, as the Commission discussed in the June 2013 report on PAC bundling, the scope and duration of the bundle and the quality incentives linked to payment would shape the financial pressures providers experience to change their current practice patterns.

From the granularity with which the condition is defined, to the triggering event, to the length of time the bundle covers, to which services are included, a bundle could be either narrowly or broadly defined. There are advantages and disadvantages to each approach, and it may be that different conditions lend themselves to different bundling structures. In general, more narrowly defined bundles are more straightforward to implement but also have the disadvantage of fewer opportunities to gain efficiencies from the clinician's choice of services prescribed. In contrast, a broader bundle is desirable because of the flexibility it gives clinicians in choosing the appropriate treatment regimen for each patient and might result in positive downstream effects. However, the broader bundle is challenging to implement because as services are added, more providers may need to be involved, and designating the accountable provider (or providers) becomes more complex. Underlying the general concept of a narrow or broad bundle are several specific design issues that must be addressed. A discussion of these issues follows.

What triggers an episode? For oncology episodes, the triggering event could be based on the diagnosis of the patient, the initiation of chemotherapy treatment, or the initiation of some other oncology-related treatment option (e.g., surgery or radiation services).

What services are included in the bundle? Bundles that require providers to be accountable for a wide number of services create greater incentives for care management and coordination than narrowly defined bundles would. The proposal by Bach and colleagues (2011) is for a narrow bundle that consists of anticancer drugs and their administration. In contrast, CMMI's OCM proposes a broad bundle in which the episode includes both cancer and noncancer services.

How specific is the bundle? Another quality inherent in the nature of bundling is that the beneficiaries covered in the bundle must be sufficiently similar such that their costs can be estimated. Creating a bundle with a small enough scope (i.e., for beneficiaries with similar illnesses) that costs are within a predictable range is a challenge in the current environment, particularly if claims data are to be used to establish the appropriate bundle for the patient. Neither the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) nor ICD–10 coding differentiates between different stages of cancer. This lack of differentiation is important because, just as different cancer types require different mixes of services to treat, different stages of the same cancer vary in the intensity and type of treatment. For bundles to accurately reflect the services provided, the information used to assign patients to a bundle may have to be further refined.

Who gets paid, and how? Depending on the bundle's scope, one or multiple providers may be implicated. As shown by the five cases we studied, a bundled payment can be a fixed price paid to the provider prospectively or a benchmark that is used to adjust net payments to the providers retrospectively. Emanuel (2014) argued that an episode should be based on the total cost of care, with oncologists as the accountable providers, and that payments should be transitioned from a retrospective payment design to a prospective two-sided risk design.

In a narrow bundle, like Bach and colleagues' (2011) approach, the medical oncologist is the accountable provider who receives the bundled reimbursement and is responsible for patients' outcomes. By contrast, under a broader approach, determining who is designated the accountable provider may be more complex. This issue is particularly relevant for beneficiaries furnished more than one treatment regimen (e.g., oncology drugs, radiation oncology, and surgery). It would be necessary to identify the accountable provider, who could be the medical oncologist, radiation oncologist, surgeon, some other type of clinician, hospital, or type of group. In certain cases,

clinicians may be able to affect service use that is not directly under their control. And increasingly, providers act in teams to care for patients. In these situations, who is ultimately held accountable? Large provider groups and ACOs may have formalized these relationships to facilitate team-based care within bundles, but smaller providers may not have the infrastructure to do so.

What span of time does the bundle cover? The length of the bundle establishes the number of days when service utilization will be included. As the Commission noted in June 2013, longer (and broader) bundles improve the incentives for care coordination and give providers the flexibility to consider the mix and timing of services they furnish. On the other hand, compared with bundles of relatively short duration, longer bundles increase the risk that the services furnished during the episode are unrelated to the triggering event. Long (and broad) bundles require providers to assume greater financial risk. CMS's OCM and the approach proposed by Bach and colleagues (2011) addresses financial risk by setting a maximum loss threshold.

What is the best way to adjust for risk? The model should take into account differences in patient severity and other factors, particularly if they affect prognosis. How will these be accounted for in the bundle? The three commercial pilot programs and the proposal by Bach and colleagues (2011) take into account the type of cancer, cancer stage, tumor histology, and treatment. By contrast, all cancers are included in the OCM.

How to counter the incentive to stint on care? Bundled payments create an incentive to furnish fewer services than medically necessary. Options to limit such behavior include (1) requiring providers to report their use of one of the nationally recognized published clinical guidelines and provide reasons if their treatment protocol varies from national standards; (2) tying rewards to quality requirements (and keeping spending below the benchmarks); and (3) placing providers at risk for the care that is considered to result from stinting (by, for example, measuring the rate of readmissions and ED use). The OCM will use all three of these approaches to ensure quality.

How are efficiencies gained? A motivation for bundling is that, if clinicians make judicious decisions about the treatment of their patients, they may be able to reduce costs while maintaining or improving quality. The scope of the bundle determines the degree to which providers may change the mix of services to reduce costs.

In a narrower bundle, there is less flexibility in gaining efficiencies. Particularly for cancer care, for which clinical guidelines and pathways (evidence-based treatment protocols that providers use in developing a treatment plan for a patient's particular type and stage of cancer) are available, providers may have few opportunities to deviate from standard treatment. For example, in a bundle that includes only oncology drugs, the providers' effect on spending is limited to the selection of drugs. Compared with narrower bundles, larger prospective bundles may give providers more flexibility in modifying a patient's treatment plan to furnish second and third lines of chemotherapy that may be more costly than first-line regimens.

In a broad bundle, more services included mean more choices that the provider can make to deliver care most efficiently. Efficiencies could be gained not just by drug or procedure choice but also by reducing complications like unplanned hospitalizations. The UnitedHealthcare bundle illustrates this point. In its pilot program, in which financial incentives on chemotherapy drugs were reduced by omitting the drug add-on (see p. 102 for full description), overall spending decreased while drug spending increased. If the practices' performance were measured by drug spending only, it would appear that they were unsuccessful in controlling costs. However, the total cost of care shows that efficiencies were gained by reducing hospitalizations and radiology use. Broader bundles are able to capture these shifts in patterns of care.

How is the bundle updated to address changes in evidence and technology? And how does the bundle account for price growth outside the providers' influence? Clinical evidence can change rapidly. Once a bundle is established, the process of incorporating changes in recommended clinical protocols needs to be determined.

How to protect against "unbundling"? If the bundle accounts for some particular treatment regimen, it is important that it also includes its substitutes. For example, if Part B oncology drugs were included in an oncology bundle, but Part D drugs were paid outside the bundle, there might be an incentive to prescribe more (i.e., substitute) Part D drugs in place of comparable Part B drugs.

This problem was addressed in the implementation of the broader ESRD bundle in 2011. Patients on dialysis need a variety of drugs, most commonly erythropoietin-stimulating agents, vitamin D agents, iron agents, and antibiotics. Some of these drugs have both injectable and oral formulations. To prevent shifting prescribing behavior to favor drugs outside the Part B bundle, the ESRD bundle

includes both the injectable and oral formulations of these dialysis drugs. In addition, the ESRD bundle includes Part D oral ESRD-related drugs with no injectable equivalent (oral-only drugs include phosphate binders and calcimimetics).

Treatment patterns in medical oncology are similar in that they require the use of Part B and Part D drugs and procedural care, which suggests that oncology may lend itself well to a broader bundle, which can account for the broad array of services that may be required. Since a primary aim of bundling is to allow clinical decision making to reside at the level of the clinician and remove some of the revenue incentives at play in pure FFS, the bundle must be wide enough to allow clinicians to make those decisions and not leave opportunities for simultaneous reimbursement through the bundle and FFS billing.

What are the implications for beneficiaries? A bundled approach in which Medicare continues to pay individual providers under FFS (and uses a benchmark to adjust net payments to providers retrospectively) would not affect beneficiary cost sharing. By contrast, under prospective bundled approaches, beneficiary cost sharing would be tied to the bundle amount rather than FFS transactions. This arrangement might result in beneficiaries paying either more or less than they otherwise would for the same treatment under traditional FFS, which might create equity issues among beneficiaries (or at least the perception of such issues). Designing bundles specific to a given treatment and condition might help mitigate this issue. For example, the UnitedHealthcare–MD Anderson pilot uses eight different prospective bundles that vary based on the treatment regimen for head and neck cancer. Applying risk adjustment to the payment rate might also mitigate this issue.

Finally, particularly with regard to oncology care, it is appropriate to consider including end-of-life care in the bundle. The presence of the bundle should not discourage clinicians from recommending hospice or palliative care for those beneficiaries for whom it is appropriate. In fact, a well-constructed bundle may facilitate those conversations.

Other approaches to improve the efficiency of oncology care

Medicare and commercial payers have considered and implemented various approaches to address some or all of these concerns about payment for and quality of oncology care. A review of the literature and discussions with stakeholders suggest that their efforts fall under two general approaches: (1) increasing use of medical homes and (2) wide use of clinical pathways by providers and commercial payers.

Oncology medical homes

The medical home builds on the concept of patient-centered care under which a designated provider is responsible for complying with requirements for integrated or coordinated care, evidence-based medicine and performance measurement to ensure quality and safety, and enhanced access. In 2010, the first oncology practice was recognized by the National Committee for Quality Assurance as a Level III patient-centered medical home (Sprandio 2012). The adoption of an oncology medical home by providers and payers appears to be increasing over the past five years (Aetna 2013, Fox 2013).

Beginning July 2012, CMMI provided a grant for seven oncology practices to implement a three-year oncology patient-centered medical home. The Community Oncology Medical Home (COME HOME) model offers enhanced services to newly diagnosed or relapsed Medicare and Medicaid beneficiaries and commercially insured patients with one of seven cancer types (breast, lung, colon, pancreas, thyroid, melanoma, and lymphoma). These services include patient education and medication management counseling, team-based care, and enhanced practice access through triage pathways, which help manage patient symptoms on a 24/7 basis through a triage phone line, extended night and weekend office hours, and on-call providers. CMMI provided a $19.8 million grant to the participating practices to fund the enhanced services; the grant funding could not be used for services billed with an E&M service (to ensure that CMS would not be paying twice for the same service) (Centers for Medicare & Medicaid Services 2015a). According to CMS, the estimated three-year savings of this initiative is $33.5 million. The program's aim is to reduce the costs associated with ED visits by 52 percent and hospital admissions by 21 percent through enhanced symptom management, increased access to care, use of pathways, improved decision support, and improved capacity to collect and use data (McAneny 2012).[14] This demonstration is expected to conclude in 2015.

In a preliminary analysis, CMS's contractor examined whether longer patient participation in the COME HOME model in 2013 lowered Medicare FFS spending and use of hospital and ED services (NORC at the University of Chicago 2014). (This analysis did not compare cost and use data of patients who participated in the model

with a comparison group.) The contractor found that longer patient participation in the model in 2013 (i.e., more than one calendar quarter) was associated with statistically significant lower total Medicare spending per beneficiary and lower rates of all-cause hospitalizations per beneficiary. The contractor did not find a statistically significant relationship between length of patient participation and rates of ambulatory care–sensitive hospitalizations and ED visits. The contractor concluded that the reduction in cost and utilization over greater lengths of program enrollment could be a consequence of the model or a consequence of regression to the mean in the care trajectory of patients newly diagnosed with cancer.

Clinical pathways

Clinical pathways are evidence-based treatment protocols that payers and providers are adopting to standardize drug treatment, reduce unnecessary variation, and improve quality of care (DeMartino and Larsen 2012). Although pathways are generally consistent with publicly available clinical guidelines such as the National Comprehensive Cancer Network guidelines, they narrow treatment options and suggest when these options are appropriate. Most pathways began by focusing on chemotherapy, but some have broadened to include other oncology-related services (e.g., radiation oncology services) (DeMartino and Larsen 2012). Pathways typically evaluate competing regimens for a given condition based on efficacy, side effects (toxicity), strength of national guideline recommendations, and cost. One payer explicitly stated that in selecting a particular therapy as a pathway, cost is considered only after consideration of all other factors (Anthem 2014).

Clinical pathways are widely used in oncology care. One survey estimated that over half of responding practices used clinical pathways, and about 90 percent used guidelines (Barr and Towle 2011). Various companies— including eviti, New Century Health, P4 Pathways (Cardinal Health), US Oncology, Innovent Oncology (McKesson Specialty Health), Kew Group, and Via Oncology (UPMC)—have developed proprietary pathways (DeMartino and Larsen 2012). In addition, some clinician practices and large cancer centers have developed their own pathways. There are two common pathway business models (DeMartino and Larsen 2012). In the first model, a payer sponsors a company to develop pathways. The payer then provides incentives to the payer's oncologists to use the pathways. In the second model, oncologists work directly with vendors to develop pathways (Sanghavi et al. 2014). The oncologists then work with their payers to develop incentives the payers will offer for oncologists to follow the pathways. In most instances, pathways are proprietary, that is, available only to payers and clinicians.

Payers and providers have implemented various approaches that link compliance to clinical pathways to financial incentives, including providers receiving a higher reimbursement rate on drugs or other services (e.g., E&M services), an add-on per patient, and a lower risk of denied or delayed reimbursement (DeMartino and Larsen 2012). Under these approaches, providers typically have to meet a certain level of pathway compliance but can go "off pathway" to accommodate patient preferences and variation in disease development. For example, one commercial payer increases the add-on to the drug payment rate if clinicians meet a 60 percent compliance threshold (*Oncology Business Review* 2008). Another commercial payer links additional payment for each patient who receives treatment as specified by the pathways for breast, lung, and colorectal cancer. If a practice follows the pathways, it receives a $350 one-time fee at the onset of treatment and payments of $350 per patient per month while the patient is actively in therapy and treated in compliance with a pathway (Anthem 2014). The notion is that the additional payments will offset the amount of revenue the practice could gain from administering more-costly drugs (Nelson 2013).

Compared with bundled payments, payment for pathway adherence limits flexibility and (depending on the design) may not remove the incentive for some clinicians to furnish higher priced products when therapeutic equivalents exist. Compared with bundling approaches that require providers to be accountable for a wide range of care, use of pathways may not necessarily lead to more coordinated care or enhanced access for beneficiaries.[15] Because pathways are typically proprietary, it might be difficult for FFS Medicare to adopt such an approach.

Conclusions

In this chapter, we discussed the lack of value-based incentives for managing Part B drug use. Medicare's payment policy for Part B drugs does not always provide beneficiaries and taxpayers the best value because the policies do not consider evidence of a drug's clinical effectiveness compared with its alternatives. LCA, consolidated payment codes, and bundling approaches have the potential to improve value by reducing the

payment system's incentive to encourage the use of more costly drugs and biologics. These value-based approaches could be designed to reduce beneficiary and Medicare spending while maintaining quality. Alternatively, these approaches could be designed to use existing resources to improve quality of care. Bundling, in particular, has the potential to encourage providers to make clinically appropriate decisions about the most efficient mix of services beneficiaries receive and has the potential to improve care coordination and result in

positive downstream effects, such as reduced hospital admissions and ED visits. CMS could consider conducting an oncology bundling demonstration that is designed to use existing Medicare resources to improve beneficiaries' quality of care and address potential incentives under FFS that might lead to the use of more-costly drugs and other interventions, increased service volume without regard to quality or value, potentially avoidable hospital admissions and ED visits, and fragmentation of care. ■

Endnotes

1　Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent.

2　In April 2010, CMS directed its contractors to discontinue all LCA policies for Part B drugs.

3　Medicare's contractors are currently referred to as Medicare administrative contractors and previously were referred to as carriers and fiscal intermediaries.

4　To implement the functional equivalence standard, CMS used its authority (under section 1833(t)(2)(E)) to adjust the hospital outpatient prospective payment system's transitional pass-through payments that the agency determines are "necessary to ensure equitable payments." By contrast, CMS implements LCA policies under a different authority (under section 1862 (a)(1) (A)) to pay the expenses of reasonable and necessary services.

5　Ilene Hays, a beneficiary, was prescribed DuoNeb, an inhalation treatment for chronic obstructive pulmonary disease. Originally, Hays filed the motion together with the manufacturer of DuoNeb. The court held that the manufacturer had no standing because the relevant statute allows only beneficiaries to challenge contractors' local coverage determinations and dismissed the manufacturer from the case (Akin Gump 2008).

6　CMS established a single Healthcare Common Procedure Coding System (HCPCS) code for both products to comply with a provision in the MMA that the Secretary treat single-source drugs that were within the same billing code as of October 1, 2003, as if the products were multiple-source drugs. Before 2005, Medicare paid for albuterol and levalbuterol under the same Level II HCPCS code.

7　The Medicare appeals process includes five levels: (1) redetermination by a Medicare administrative contractor; (2) reconsideration by a qualified independent contractor; (3) hearing by an administrative law judge; (4) review by the Medicare Appeals Council; and (5) judicial review in district court.

8　Concerns raised about the development of clinical guidelines include the following: (1) guidelines developed by specialties often have a financial interest in having broad or permissive guidelines; (2) physicians and researchers who sit on guideline committees frequently have relationships with drug manufacturers, and organizations that sponsor guideline development also have industry relationships; (3) guidelines developed by different groups and specialties may differ in their recommendations; and (4) guidelines often focus on a single disease, and older patients usually have multiple diseases.

9　Institutional services are furnished by institutional outpatient providers such as hospital outpatient departments, rural health clinics, and dialysis facilities. Physician/supplier services are furnished by noninstitutional providers such as physicians, physician assistants, clinical social workers, nurse practitioners, and certain freestanding providers (e.g., independent clinical laboratories, ambulance providers, and freestanding ambulatory surgical centers).

10　In the initial period of the pilot, providers would be paid according to FFS policies. In Period 2 of the pilot, Medicare would use a single payment based on the average of the costs of the bundled services furnished in Period 1. In subsequent periods, payment would be recalibrated based on average utilization in the previous period.

11　According to the American Cancer Society, radical prostatectomy is the main type of surgery for prostate cancer, which involves removing the entire prostate gland plus some of the tissue around it (American Cancer Society 2015).

12　The practices committed to at least 85 percent compliance with their chosen therapies; exceptions were allowed (e.g., for medical contraindications). The groups could change the preferred regimen at any time, but they had to achieve the same level of compliance (Newcomer et al. 2014).

13　Ninety percent of this increase is due to PBPM payments, and 10 percent is due to "noise bonuses."

14　Through the COME HOME model, each practice paid $125,000 to collaborate on pathway development for seven tumor types.

15　Limited studies are available to show the clinical and financial outcomes of using pathways. One study showed that for patients with non-small-cell lung cancer over a one-year period, outpatient costs were 35 percent lower for patients on clinical pathways than for patients who received nonpathway treatment (Neubauer et al. 2010). Another study found that, for adjuvant treatment for colon cancer, the mean per patient per month treatment costs were lower for patients on pathways compared with patients not on pathways ($5,907 versus $9,121, $p \le 0.001$) (Hoverman et al. 2011). For metastatic colon cancer patients, the lower per patient per month cost for patients on pathways compared with patients not on pathways did not reach statistical significance. The authors also found that survival for patients on pathways was comparable with patients not on pathways. Wellpoint estimates the company's program will reduce treatment costs between 3 percent and 4 percent per year (Sanghavi et al. 2014). Other programs have reported more aggressive cost reductions (15 percent on cancer-related costs) (Nelson 2013).

References

Aetna. 2013. Aetna announces program with the first patient-centered medical home for oncology. Press release. November 14.

Akin Gump. 2008. Court rejects Medicare's "Least Costly Alternative" drug payment policy. http://www.akingump.com.

American Cancer Society. 2015. Surgery for prostate cancer. http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-treating-surgery.

Anthem. 2014. WellPoint Cancer Care Quality Program. http://www.anthem.com/provider/in/f4/s0/t0/pw_e213230.pdf?refer=ahpprovider.

Bach, P. B. 2007. Costs of cancer care: A view from the Centers for Medicare and Medicaid services. *Journal of Clinical Oncology* 25, no. 2 (January 10): 187–190.

Bach, P., J. Mirkin, and J. Luke. 2011. Episode-based payment for cancer care: A proposed pilot for Medicare. *Health Affairs* 30, no. 3: 500–509.

Balogh, E. P., P. B. Bach, P. D. Eisenberg, et al. 2011. Practice-changing strategies to deliver affordable, high-quality cancer care: Summary of an Institute of Medicine Workshop. *Journal of Oncology Practice* 9, no. 6 supplement: 54s–59s.

Bandell, B. 2011. Blue Cross signs first bundled payment deal with Miami firm. *South Florida Business Journal*, April 8. http://www.bizjournals.com/southflorida/print-edition/2011/04/08/blue-cross-signs-first-bundled.html?page=all.

Barr, T. R., and E. L. Towle. 2011. National Oncology Practice Benchmark, 2011 report on 2010 data. *Journal of Oncology Practice* 7, no. 6 supplement (November): 67s–82s.

Blue Cross Blue Shield of Florida. 2011. Blue Cross and Blue Shield of Florida signs bundled surgical services agreement with Mobile Surgery International. Press release. March 24.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. Health Care Innovation awards round one project profiles. http://innovation.cms.gov/files/x/hcia-project-profiles.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. Oncology care model. Request for applications. http://innovation.cms.gov/Files/x/ocmrfa.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Healthcare Common Procedure Coding System Level II coding procedures. http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/downloads/HCPCSLevelIICodingProcedures7-2011.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. *Medicare program integrity manual: Chapter 13*. Baltimore, MD: CMS. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2002a. Medicare program; changes to the hospital outpatient prospective payment system and calendar year 2003 payment rates; and changes to payment suspension for unfiled cost reports. Final rule. *Federal Register* 67, no. 212 (November 1): 66718–67046.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2002b. Medicare program; changes to the hospital outpatient prospective payment system and calendar year 2003 payment rates; and changes to payment suspension for unfiled cost reports. Proposed rule. *Federal Register* 67, no. 154 (August 9): 52092–52240.

Chen, A. B., A. Cronin, J. C. Weeks, et al. 2013. Palliative radiation therapy practice in patients with metastatic non-small-cell lung cancer: A Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) Study. *Journal of Clinical Oncology* 31, no. 5 (February 10): 558–564.

Colla, C. H., N. E. Morden, J. S. Skinner, et al. 2012. Impact of payment reform on chemotherapy at the end of life. *American Journal of Managed Care* 18, no. 5 (May): e200–208.

Congressional Budget Office. 2008. *Budget options, volume 1: Health care.* Washington, DC: CBO. December.

DeMartino, J. K., and J. K. Larsen. 2012. Equity in cancer care: Pathways, protocols, and guidelines. *Journal of the National Comprehensive Cancer Network* 10, supplement 1 (October 1): S1–9.

Elliott, S. P., S. L. Jarosek, T. J. Wilt, et al. 2010. Reduction in physician reimbursement and use of hormone therapy in prostate cancer. *Journal of the National Comprehensive Cancer Network* 102, no. 24 (December 15): 1826–1834.

Emanuel, E. 2014. A higher value U.S. cancer care system: The opportunity for bundled payments. Bundled Payments for Oncology: Creating Value-Based Episodes of Care. National Institute for Health Care Management webinar. August 22.

Food and Drug Administration. 2014. Orange Book: Approved drug products with therapeutic equivalence evaluations. http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=077756&TABLE1=OB_Rx.

Fox, J. 2013. Lessons from an oncology medical home collaborative. *AJMC*, February 25. http://www.ajmc.com/.

Hoverman, J. R., T. H. Cartwright, D. A. Patt, et al. 2011. Pathways, outcomes, and costs in colon cancer: Retrospective evaluations in two distinct databases. *Journal of Oncology Practice* 7, no. 3, supplement (May): 52s–59s.

Hutton, D., P. A. Newman-Casey, M. Tavag, et al. 2014. Switching to less expensive blindness drug could save Medicare Part B $18 billion over a ten-year period. *Health Affairs* 33, no. 6 (June): 931–939.

Institute of Medicine. 2013. *Delivering high-quality cancer care: Charting a new course for a system in crisis.* Washington, DC: The National Academies Press.

Jacobson, M., C. C. Earle, M. Price, et al. 2010. How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment. *Health Affairs* 29, no. 7 (July): 1391–1399.

Jarosek, S., S. Elliott, and B. A. Virnig, Department of Health and Human Services. 2012. *Proton beam radiotherapy in the U.S. Medicare population: Growth in use between 2006 and 2009.* Rockville, MD: Agency for Healthcare Research and Quality. February.

Malin, J. L., J. C. Weeks, A. L. Potosky, et al. 2013. Medical oncologists' perceptions of financial incentives in cancer care. *Journal of Clinical Oncology* 31, no. 5 (February 10): 530–535.

McAneny, B. 2012. Center for Medicare and Medicaid Innovation grant. Presentation at Washington State Medical Oncology Conference 2012. http://www.wsmos.org/events/view/13.

MD Anderson. 2014. MD Anderson, UnitedHealthcare launch new cancer care payment model. Press release. December 16.

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

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

Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Millman, J. 2014. One insurer's answer to the skyrocketing bills for cancer care. *Washington Post*, July 8.

National Government Services. 2009. LCD for luteinizing hormone-releasing hormone (LHRH) analogs (L26369). http://www.cms.hhs.gov/mcd/viewlcd_pdf.asp?lcd_id=26369&lcd_version=20&contractor_id=183.

Nelson, R. 2013. Clinical pathways programs can reduce costs in oncology. *Medscape*, August 7. http://www.medscape.com/viewarticle/826681.

Neubauer, M. A., J. R. Hoverman, M. Kolodziej, et al. 2010. Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. *Journal of Oncology Practice* 6, no. 1 (January): 12–18.

Newcomer, L. N., B. Gould, R. D. Page, et al. 2014. Changing physician incentives for affordable, quality cancer care: Results of an episode payment model. *Journal of Oncology Practice* 10, no. 5 (September): 322–326.

NORC at the University of Chicago. 2014. *Annual report 1: HCIA disease-specific evaluation.* Report prepared by staff from NORC at the University of Chicago for the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS. http://innovation.cms.gov/Files/reports/HCIA-DS-FirstEvalRpt.pdf.

Office of Inspector General, Department of Health and Human Services. 2012. *Least costly alternative policies: Impact on prostate cancer drugs covered under Medicare Part B.* OEI–12–12–00210. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2011. *Review of Medicare Part B avastin and lucentis treatments for age-related macular degeneration.* A–01–10–00514. Washington, DC: OIG.

Office of Inspector General. 2009. *Beneficiary utilization of albuterol and levalbuterol under Medicare Part B.* Washington, DC: OIG.

Ollendorf, D. A., J. A. Colby, and S. D. Pearson. 2014. *Proton beam therapy.* Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. http://innovation.cms.gov/Files/reports/HCIA-DS-FirstEvalRpt.pdf.

Oncology Business Review. 2008. Tearing down walls: Payers and providers align. http://oncbiz.com.

Robinson, J. C. 2013. Reference pricing: Stimulating cost-conscious purchasing and countering provider market power. http://www.nihcm.org/expert-voices-reference-pricing-stimulating-cost-conscious-purchasing-and-countering-provider-market-power.

Sanghavi, D., K. Patel, K. Samuels, et al. 2014. *Transforming cancer care and the role of payment reform: Lessons from the New Mexico Cancer Center.* Engleberg Center for Health Care Reform at Brookings. Washington, DC: The Brookings Institution.

Sprandio, J. D. 2012. Oncology patient-centered medical home. *Journal of Oncology Practice* 8, no. 3 supplement (May): 47s–49s.

UnitedHealthcare. 2014. Study: New cancer care payment model reduced health care costs, maintained outcomes. Press release. July 8.

U.S. Court of Appeals. 2004. http://pacer.cadc.uscourts.gov/docs/common/opinions/200402/03-5046a.pdf#xml=http://www.cadc.uscourts.gov/isys/Alldbs/isysquery/1b383b14-3139-45a8-abbe-432a432de2de/1/hilite/.

Yu, J. B., P. R. Soulos, J. Herrin, et al. 2013. Proton versus intensity-modulated radiotherapy for prostate cancer: Patterns of care and early toxicity. *Journal of the National Cancer Institute* 105, no. 1 (January 2): 25–32.

Polypharmacy and opioid use among Medicare Part D enrollees

Polypharmacy and opioid use among Medicare Part D enrollees

Chapter summary

Recently, the Commission examined the effects of medication adherence on health spending. We found that these effects vary with medical conditions, ranging from modest savings to increased costs. We also found it difficult to control for all the factors that can influence this relationship. One factor that we had not previously examined is how the use of multiple drugs (polypharmacy) can affect the relationship between medication adherence and health spending.

The relationship between medication adherence and health spending for individuals who are treated with multiple medications can be more complex than it is for individuals treated with a single medication or very few medications. For example, adhering to multiple drug regimens could result in drug–drug interactions that may affect a patient's medical condition and lead to additional physician visits, emergency department visits, or hospitalizations.

Adverse effects from polypharmacy can occur when a patient is prescribed more drugs than are clinically warranted or when all prescribed medications are appropriate, but the total is too many for the patient to ingest or manage safely. Studies have found that patients who are on multiple drug regimens often have difficulty managing their medications, which can lead to adverse drug events (ADEs) and nonadherence to appropriate medications. Individuals ages 65 and older, who are more likely to suffer from multiple chronic

In this chapter

- Background

- Polypharmacy and adverse drug events

- Types of problems associated with polypharmacy

- Relationship between polypharmacy, adherence, and patient confusion

- Opioid use and polypharmacy

- Examples of team-based approaches to improving pharmaceutical care

- Policy responses to polypharmacy

conditions, are at high risk for ADEs associated with polypharmacy, yet there are few clinical guidelines pertinent to prescribing and managing multiple prescription drugs among this population.

Studies find that adverse events are often associated with opioid use, in part because individuals using opioids tend to take multiple drugs and because opioid use itself can lead to many ADEs, including unintentional overdoses. In addition, the side effects associated with opioids can interfere with the treatment of comorbid conditions not associated with pain.

Patterns of medication use by Part D enrollees who use opioids raise concerns about polypharmacy issues and adverse effects on health. In 2012, over one-third of Part D enrollees filled at least one prescription for an opioid. Opioid users filled an average of 52 prescriptions per year, including opioids, from about 10 drug classes (a prescription is standardized to a 30-day supply). Beneficiaries who filled at least one prescription for opioids tended to have more comorbid conditions than those who did not fill a prescription for opioids. The enrollees with the highest use of opioids filled an average of 23 prescriptions for opioids each in 2012. Those with very high use of opioids were more likely to be beneficiaries under age 65 who received the low-income subsidy. The Agency for Healthcare Research and Quality recently reported an 80 percent increase in the number of Medicare beneficiaries' inpatient stays related to opioid overuse between 2006 and 2012.

Analysts generally agree that the most effective way to reduce adverse events associated with polypharmacy is to reduce the number of medications taken. However, research on the results of programs to reduce unnecessary drug use has been limited. In the case of opioids, some have suggested limiting the number of prescribers per patient or requiring patients to fill their prescriptions at one or two pharmacies. For more general polypharmacy issues, there has been only a limited discussion of policy options.

Medicare Part D includes a medication therapy management (MTM) program that is intended to improve the quality of pharmaceutical care received by beneficiaries who have multiple chronic conditions and are treated with multiple drug therapies. One of the goals of MTM is to prevent medication errors, which are most likely to occur when a drug regimen is modified (e.g., when a patient transitions from hospital to home), when a patient does not understand drug administration instructions, or when a patient does not follow clinical advice. However, enrollment in MTM programs remains low, and there is little evidence that the program has been effective for enrolled beneficiaries. Better medication management might be

achieved through programs offered by accountable care organizations, medical homes, and other team-based delivery models if such programs tackle the issues connected to polypharmacy, particularly when a patient is transitioning from one site of care to another. ■

Background

Recently, the Commission examined the effects of medication adherence on health spending and found that, depending on the medical condition, the effects vary widely, from modest savings to increased costs. We found it difficult to control for all the factors that can influence this relationship. One factor not previously examined is how the use of multiple drugs (polypharmacy) can affect the relationship between medication adherence and health spending.

The relationship between medication adherence and health spending for individuals who are treated with multiple medications can be more complex than it is for individuals treated with a single medication or very few medications. For example, adhering to multiple drug regimens can result in drug–drug interactions that may affect a patient's medical condition and lead to additional physician visits, emergency department (ED) visits, or hospitalizations. Studies have found that patients who are on multiple drug regimens often have difficulty managing their medications, which can lead to adverse drug events (ADEs) and/or nonadherence to appropriate medications.

What is polypharmacy?

Some Medicare beneficiaries may have medical problems caused or exacerbated by polypharmacy—that is, the use of multiple medications (Lorincz et al. 2011) (Table 5-1). Adverse effects of polypharmacy can occur when a patient is prescribed more drugs than are clinically warranted (often by multiple prescribers) or when all the prescribed medications are appropriate, but the total is too many for the patient to ingest or manage safely (Haque 2009). Individuals ages 65 and older, who are more likely to suffer from multiple chronic conditions, are at high risk for adverse events associated with polypharmacy, yet there are few clinical guidelines pertinent to prescribing and managing multiple prescription drugs among this population (Lorgunpai et al. 2014).

There is no consensus on what constitutes polypharmacy (Bushardt et al. 2008). Some researchers identify polypharmacy in terms of the number of drugs taken concurrently by a patient. Most commonly, researchers describe polypharmacy as a situation in which a patient takes five to seven drugs concurrently.

While there is a general consensus about the increased risk of adverse events associated with polypharmacy as patients take more medications, some clinicians believe

that because of the beneficial effects of medications on many chronic conditions, providers should not limit the number of drugs they prescribe, but monitor their effects (Duerden 2013, Wise 2013).

Definitions of adherence

The literature on polypharmacy and on medication adherence are different, and researchers in one area rarely cite studies from the other body of work. From some perspectives, the findings appear to be contradictory. While some studies of adherence show health benefits, often measured by reduced medical service use among adherent patients, studies of polypharmacy show that patients taking multiple drug therapies have increased ADEs, leading to more health service use. In addition, such studies find that increased drug use is associated with nonadherence to drug regimens. This finding is consistent with polypharmacy literature that finds patient confusion can result in ADEs and/or nonadherence to medications when a patient is faced with managing multiple medication regimens.

In part, these conflicting results can be ascribed to different definitions of the problem, different data, and different research designs. Both health-services

TABLE 5–1	Average number of prescriptions filled per month by Part D enrollees, 2012
	All Part D enrollees
Average number of prescriptions per enrollee per month	4
Share of enrollees, by average number of prescriptions per month	
None	6%
More than 0, less than 2	21
2 or more, less than 4	26
4 or more, less than 8	29
8 or more	19

Note: Number of prescriptions is standardized to a 30-day supply. Average number of prescriptions filled per month was estimated by dividing by 12 the annual total prescriptions filled by Part D enrollees who were enrolled in the program for the full year in 2012. Numbers may not sum to totals due to rounding.

Source: MedPAC analysis of Part D prescription drug event data.

and economic studies of adherence and patient safety studies focused on polypharmacy stress the importance of adherence, but they define it differently. Studies of medication adherence from an economic perspective often use various measures of drug possession to approximate a patient's adherence to the drug regimen. For example, in our analysis of the effects of medication adherence, our measure of adherence involved the possession of any of the study medications based on Part D prescription drug event data (Medicare Payment Advisory Commission 2014b). This type of measure allows use of administrative data and lends itself to large cross-sectional studies. Outcome measures may include hospitalizations, other types of medical service use, and medical spending.

In contrast, adherence is defined in patient-safety polypharmacy studies in terms of taking drugs as prescribed, including correct dosage; discontinuing drugs based on doctors' orders; discontinuing drugs when there are adverse events; and not taking another person's medication. These studies are more clinically based and require access to medical records and sometimes extensive interviews with patients. As a result, these studies tend to be smaller and results may not achieve statistical significance. In addition, the occurrence of adverse events, one measure of potential polypharmacy, depends on clinical judgment and may not always be reliable. Such studies are less focused on cost effects. Outcome measures are usually ADEs, ED visits, or hospitalizations.

Polypharmacy and adverse drug events

In 2005, researchers estimated that over 4.3 million health care visits and 10 percent of ED visits by Medicare beneficiaries stemmed from ADEs (Maher et al. 2014). Although adverse drug events are not necessarily linked to polypharmacy, the relationship between the number of drugs and adverse events was found consistently in multiple studies using different data, sites of care, and research designs (Field et al. 2007, Kripalani et al. 2008, Sarkar et al. 2011). A literature review of 16 studies (based on Medicare data) found polypharmacy to be a statistically significant predictor of hospitalization, nursing home placement, death, hypoglycemia, fractures, decreased mobility, pneumonia, and malnutrition (Frazier 2005). Polypharmacy among Medicare beneficiaries has also been associated with cognitive decline, falls, and urinary incontinence (Maher et al. 2014).

Some studies of potential harm associated with polypharmacy analyze data on hospitalized patients. A study by the Centers for Disease Control and Prevention (CDC), using data drawn from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project, estimated that from 2007 through 2009, about 100,000 emergency hospitalizations among the elderly for adverse drug events occurred annually. Nearly half were among adults 80 years and older. More than half of the ED visits that resulted in hospitalizations involved patients taking five or more concomitant medications. Four drug classes accounted for more than 10 percent of all cases: warfarin (33 percent), insulin (14 percent), oral antiplatelet agents (13 percent), and oral hypoglycemic agents (11 percent) (Budnitz et al. 2011).

In a study of ambulatory care visits, researchers found that the number of medications taken was the only factor significantly associated with adverse events (Gandhi et al. 2003). The study found that the number of events per patient increased by 10 percent for each additional medication. Another study of polypharmacy in ambulatory care found that almost 60 percent of older adults in the sample took at least one unnecessary drug (Maher et al. 2014). In addition, studies have found that the use of medications deemed inappropriate for the elderly by consensus panels of clinicians (e.g., Beers list drugs) increases with the number of medications taken (Mansur et al. 2009, Steinman et al. 2006).[1]

Types of problems associated with polypharmacy

Potentially harmful situations associated with polypharmacy can be classified into three broad categories: therapeutic competition, therapeutic duplication, and toxic combinations. These problems are most acute for older individuals because they tend to take more drugs than younger people and can have more difficulty absorbing them.

Therapeutic competition. This occurs when treatment for one condition worsens a coexisting condition. One study estimates that 20 percent of Medicare beneficiaries over 65 take at least one medication that can exacerbate coexisting conditions (Lorgunpai et al. 2014). For example, some medications used to treat heart failure can exacerbate urinary incontinence, a

common issue for heart failure patients, which may result in more medications if the physician prescribes a drug to treat the incontinence instead of changing heart failure medications. The consequence can be a prescribing cascade and more potential drug interactions (Tannenbaum and Johnell 2014). In a recent study of older adults with multiple chronic conditions, more than 20 percent of individuals in the sample were prescribed drugs that could worsen at least one of their other chronic conditions. Further, 13 percent had prescription drugs that could worsen multiple conditions (Lorgunpai et al. 2014).

Therapeutic duplication. Therapeutic duplication is defined as the use of multiple medications from the same therapeutic class at the same time. It can occur when a physician replaces one prescription with another but the patient does not discontinue the first drug or uses multiple pharmacies (Giusani and White 2011). One common example is therapeutic duplication of nonsteroidal anti-inflammatory drugs (NSAIDs), which can result in gastrointestinal distress, including ulcers and bloody stools. Muscle relaxants and antidepressants are also frequent sources of therapeutic duplications.

Toxic combinations. Toxic combinations occur when the interaction between two medications leads to serious complications. There are numerous examples in the literature. For example, warfarin (a blood thinner) and simvastatin (a drug to lower cholesterol in the blood) taken together increase the risk of bleeding and worsen statins' side effects. Lisinopril (a drug to treat high blood pressure and heart failure) and potassium together increase the risk of hyperkalemia, a condition in which the concentration of potassium in the blood is elevated, which can lead to heart attacks and death (Laroche et al. 2006).

Relationship between polypharmacy, adherence, and patient confusion

Studies have found that patients with complicated drug regimens often have difficulty managing their medications, leading to ADEs. Errors are most likely to occur when a drug regimen is modified, when a patient does not understand drug administration instructions, and when a patient does not follow clinical advice. Patients, particularly those discharged from hospitals, may not

understand physician instructions regarding medication use. For example, if one medication is meant to replace another, patients may not understand that they should no longer take the previously prescribed drug. They also may not tell their health care provider about any over-the-counter drugs or dietary supplements that they take (Field et al. 2007).

Additionally, some patients are unwilling to eliminate medications from their drug regimen, even when recommended by their physician. In one study, elderly patients taking five or more medications were assessed to see whether the number of drugs could be reduced. All recommendations had to be endorsed by the patient's primary care provider. Although the number of drugs was reduced by an average of 1.5 per patient, providers had recommended eliminating an average of 4.5 drugs. Patients tended to resist stopping some of their drugs. They were most reluctant to stop sleeping pills, benzodiazepines, narcotic analgesics, and all psychoactive drugs (Williams et al. 2004).

Finally, nonadherence to appropriate medications also is associated with polypharmacy (Hajjar et al. 2007, Lee et al. 2013, Salazar et al. 2007, Vik et al. 2004). Multiple drugs often result in complicated drug administration instructions that patients may find difficult to follow, a situation often referred to as "pill burden." Patients may take drugs at the wrong time of day, stop some drugs because of side effects, or find the cost of the drugs too expensive and eliminate some medications without telling their providers. One study found that about 20 percent of preventable ADEs in an ambulatory setting were caused at least in part by adherence errors by patients and their families (Field et al. 2007).

Opioid use and polypharmacy

Opioid analgesics, or opioids, are a class of drugs used to treat pain.[2] Studies find that adverse events are often associated with opioid use, in part because individuals using opioids tend to take multiple drugs (polypharmacy) and because opioid use itself can lead to many ADEs, including unintentional overdoses. In addition, the side effects associated with opioids can interfere with treatments for comorbid conditions not associated with pain. Our work examined the use of opioid analgesics by Medicare beneficiaries enrolled in Part D.

FIGURE
5–1

Wide variation in use of opioids across states, 2012

Opioid users by state
(as a percent of Part D enrollees)

- 43.1% or more
- 38.1% to 43%
- 34.1% to 38%
- 32.1% to 34%
- 22% to 32%
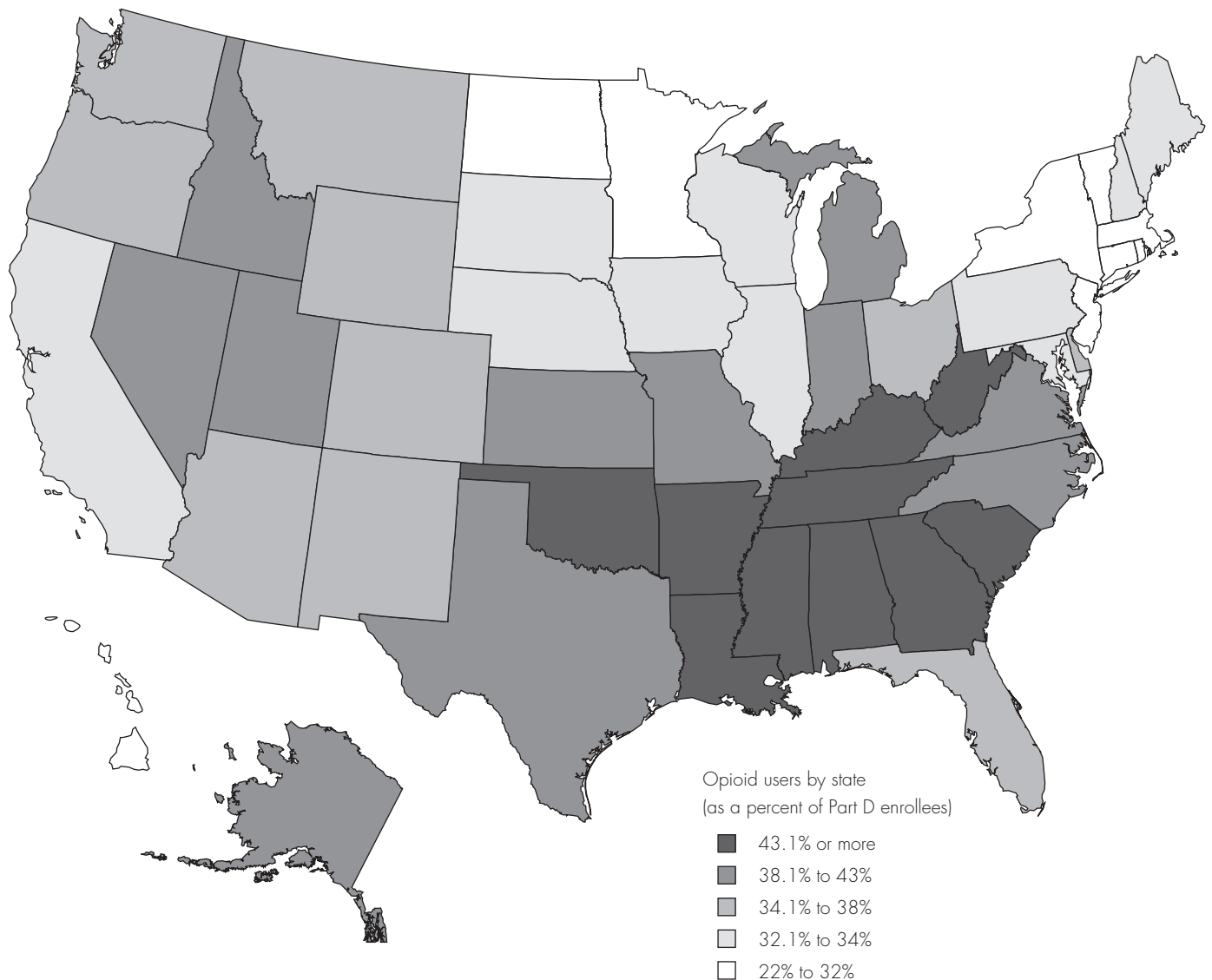
Source: MedPAC analysis of Part D denominator and prescription drug event data.

Opioid use in Part D

Opioid use is widespread among Medicare beneficiaries enrolled in Part D. Over one-third of Part D enrollees fill at least one prescription for an opioid in any given year. Opioid analgesics rank as one of the top therapeutic classes used by Part D enrollees, accounting for about 5 percent of the total volume and spending for drugs covered under the program.

Wide variation in use of opioids across states

In 2012, 12.3 million beneficiaries (about 36 percent of Part D enrollees) filled at least one prescription for an opioid. The share of Part D enrollees who used opioids in 2012 varied across states, from about 23 percent in Hawaii to about 50 percent in Alabama, with many Southern states (such as Arkansas, Georgia, Kentucky, Louisiana,

TABLE
5–2

Most opioid uses were unrelated to cancer treatment or hospice use, 2012

	All Part D opioid users	Part D opioid users by hospice use and cancer diagnosis		
		Any hospice use*	Cancer diagnosis (no hospice use)	Other
Number of beneficiaries (in millions)	12.3	0.4	1.1	10.7
As a percent of total users		3.4%	9.2%	87.4%
Total gross spending on opioids (in billions)	$3.16	$0.09	$0.26	$2.81
As a percent of total gross spending		2.9%	8.3%	88.8%
Total number of opioid prescriptions (in millions)	76.1	2.2	6.2	67.7
As a percent of total prescriptions		2.8%	8.2%	89.0%
Average annual use per beneficiary				
Gross spending on opioids	$258	$219	$232	$262
Number of opioid prescriptions	6.2	5.2	5.5	6.3

Note: "Other" refers to Part D enrollees who had opioid prescriptions but did not use hospice care or have a cancer diagnosis. Therapeutic classification and identification of generic prescriptions are based on the First DataBank Enhanced Therapeutic Classification System 1.0. Gross spending includes all payments to pharmacies for Part D–covered prescription drugs, including ingredient costs, dispensing fees, sales tax, and manufacturer discounts for brand-name drugs filled during the coverage gap by beneficiaries not receiving the low-income subsidy. Number of prescriptions is standardized to a 30-day supply. Numbers may not sum to totals due to rounding.
*For a beneficiary who used hospice at some point during the year, the opioid medications obtained through the Part D benefit may not reflect the full amount of opioid use by the beneficiary during the year because most medications, including opioids, to treat symptoms associated with the terminal condition are included in the hospice bundled payment.

Source: MedPAC analysis of Part D prescription drug event data 2012.

Oklahoma, and Tennessee) in the mid- to upper-40 percent range (Figure 5-1).

Most opioid uses are unrelated to cancer treatment or hospice use

In 2012, 12.3 million Part D enrollees filled 76.1 million opioid prescriptions at a cost of over $3 billion (Table 5-2). Of those, about 3.4 percent were in hospice at some point during the year (some with cancer diagnoses). A little over 9 percent had cancer diagnoses with no hospice use. Those with hospice use accounted for about 2.9 percent of total spending and prescriptions filled for opioids under Part D. Nonhospice beneficiaries with cancer diagnoses accounted for slightly over 8 percent of total spending and prescriptions filled for opioids. The remaining 10.7 million beneficiaries (87.4 percent) who filled at least one prescription for an opioid did not have any hospice stays during the year and were not being treated for cancer. We categorized this group of opioid users as "other" users to distinguish them from those for whom opioid uses were likely related to pain associated with cancer or terminal conditions.

Beneficiaries in the "other" category had higher average spending (6.3 prescriptions at $262 per beneficiary) than either beneficiaries with cancer (5.5 prescriptions at $232 per beneficiary) or beneficiaries in hospice (5.2 prescriptions at $219 per beneficiary).[3]

Patterns of opioid use by Part D enrollees without hospice use or cancer diagnosis

While many issues surround the use of opioids, particularly over an extended period of time, use of opioids to treat pain associated with cancer and pain at the end of life is generally well accepted and is typically closely monitored by clinicians. In contrast, while there are legitimate uses of opioids for pain not associated with cancer or terminal conditions, there are no agreed-on clinical guidelines for treating other types of pain using opioids.

In 2012, beneficiaries in the category of "other" opioid users accounted for about one-third of all Part D enrollees (Table 5-3, p. 126). Opioid users differed from Part D enrollees overall in significant ways. For example, they were more likely to be under age 65 (30 percent compared

	All Part D enrollees	"Other" opioid users
Number of beneficiaries (in millions)	33.8	10.7
Selected demographic characteristics		
Female	58%	63%
Non-White	26	26
Under age 65	21	30
Plan type		
PDP	63%	65%
MA–PD	37	35
Percent:		
LIS	36%	45%
Institutionalized	4	4

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income [drug] subsidy). "Other" refers to Part D enrollees who had opioid prescriptions but did not use hospice care or have a cancer diagnosis.

Source: MedPAC analysis of Part D denominator and prescription drug event data 2012.

with 21 percent for the overall Part D population) and more likely to receive the low-income subsidy (LIS) (45 percent compared with 36 percent for the overall Part D population). LIS enrollees made up a disproportionate share of opioid users in both stand-alone prescription drug plans (PDPs) and Medicare Advantage (MA) plans

(called MA–PDs) (data not shown). Other beneficiary characteristics, such as being non-White (26 percent) or institutionalized for at least some portion of the year (4 percent), were similar to characteristics of the overall Part D population (also 26 percent and 4 percent, respectively).

In 2012, annual gross spending per beneficiary on opioids among those in the "other" user category varied widely, ranging from about $4 for the beneficiary at the 10th percentile to over $400 at the 90th percentile. The highest spending beneficiary had over $800,000 in opioid spending. On average, opioid users enrolled in PDPs filled more prescriptions than those in MA–PDs (6.7 prescriptions compared with 5.6 prescriptions, respectively), with gross spending that was about 50 percent higher, on average ($294 compared with $202, respectively) (Table 5-4). Most of the differences between PDPs and MA–PDs reflect the fact that a higher share of opioid users enrolled in PDPs are LIS beneficiaries, who tend to fill more opioid medications than non-LIS beneficiaries, on average. LIS beneficiaries filled an average of 8.1 prescriptions at a total cost of $387, compared with an average of 4.8 prescriptions at $158 for non-LIS beneficiaries.

Beneficiaries with very high opioid use

Beneficiaries with annual opioid spending in the highest 5 percent (annual gross spending above $911) accounted for 68 percent ($1.91 billion) of total gross drug spending on opioids and about 18 percent of prescriptions (12.4 million) for opioids used by beneficiaries in the "other" opioid user category (Table 5-5). In 2012, those in the top 5 percent filled, on average, about 23 prescriptions

	All opioid users in "other" user category	Plan type		LIS status	
		PDP	MA–PD	LIS	Non-LIS
Number of beneficiaries (in millions)	10.7	7.0	3.7	4.9	5.9
As a percent of all opioid users		65%	35%	45%	55%
Average annual use per beneficiary					
Gross spending on opioids	$262	$294	$202	$387	$158
Number of opioid prescriptions	6.3	6.7	5.6	8.1	4.8

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income [drug] subsidy). "Other" refers to Part D enrollees who had opioid prescriptions but did not use hospice care or have a cancer diagnosis. Gross spending includes all payments to pharmacies for Part D–covered prescription drugs, including ingredient costs, dispensing fees, sales tax (where applicable), and manufacturer discounts for brand-name drugs filled during the coverage gap by beneficiaries not receiving the low-income subsidy. Number of prescriptions standardized to a 30-day supply.

Source: MedPAC analysis of Part D denominator and prescription drug event data.

TABLE
5–5

Opioid use and selected characteristics of the top 5 percent of opioid users in Part D compared with "other" Part D opioid users, 2012

	Opioid users by percentile of spending distribution		
	All opioid users in "other" user category	Below 95th percentile	95th percentile and above (Top 5 percent)
Number of beneficiaries (in millions)	10.7	10.2	0.5
Total gross spending on opioids (in billions)	$2.81	$0.90	$1.91
As a percent of total for "other" opioid users		32%	68%
Total number of opioid prescriptions (in millions)	67.7	55.3	12.4
As a percent of total for "other" opioid users		82%	18%
Average annual use per beneficiary			
Gross spending on opioids	$262	$88	$3,565
Number of opioid prescriptions	6.3	5.4	23.1
Share of generic opioid prescriptions	95%	98%	80%
Selected demographic characteristics			
Female	63%	63%	61%
Non-White	26	26	17
Under age 65	30	29	65
Percent:			
PDP	65%	65%	72%
LIS	45	44	65
Institutionalized	4	4	7

Note: PDP (prescription drug plan), LIS (low-income [drug] subsidy). "Other" refers to Part D enrollees who had opioid prescriptions but did not use hospice care or have a cancer diagnosis. Gross spending includes all payments to pharmacies for Part D–covered prescription drugs, including ingredient costs, dispensing fees, sales tax (where applicable), and manufacturer discounts for brand-name drugs filled during the coverage gap by beneficiaries not receiving the low-income subsidy. Number of prescriptions is standardized to a 30-day supply. Numbers may not sum to totals due to rounding.

Source: MedPAC analysis of Part D denominator and prescription drug event data.

for opioids at a cost of over $3,500, compared with an average of 5.4 prescriptions at $88 for those with spending below the 95th percentile.[4] Much of the difference in the per prescription costs for these two groups ($154 per prescription compared with $16 per prescription, respectively) is likely driven by the fact that beneficiaries in the top 5 percent were somewhat less likely to fill generic versions of opioids, compared with the other 95 percent of the opioid users (80 percent vs. 98 percent, respectively).[5]

A comparison of demographic characteristics shows that opioid users in the top 5 percent (the top users) differed from the other 95 percent in several respects. For example, the top users were more likely to be White and much more likely to be under age 65. Most of the top users (72 percent) were enrolled in PDPs, and nearly two-thirds

received the LIS. Finally, the top users were more likely to have resided in a long-term care facility at some point during the year compared with those in the other 95 percent (7 percent vs. 4 percent, respectively).

The patterns of opioid use we observed among the Part D enrollees with very high opioid use raise concerns about clinical appropriateness and, in some cases, fraud and abuse (see text box about potentially inappropriate opioid use, pp. 128–130).

Opioid use and polypharmacy concerns

Widespread use of opioids among Medicare beneficiaries is a concern. Opioid prescribing for Medicare beneficiaries by multiple prescribers is common and associated with higher rates of opioid-related hospital admissions (Jena et al. 2014). The Agency for Healthcare Research and Quality

Potentially inappropriate opioid use in Medicare Part D

The use of opioids has been growing in recent years. According to the Centers for Disease Control and Prevention (CDC), the use of prescription opioids in the United States increased by 300 percent between 1999 and 2010 (National Center for Health Statistics 2014). Because opioids have addictive properties with a high risk for abuse, they are generally classified as Schedule II drugs, the most restrictive class of medically legitimate drugs, under the Drug Enforcement Administration (DEA) classification system.[6] Thus, while opioids can play an important role in pain control and palliative care, their use must be closely monitored to prevent inappropriate use.

Inappropriate use of opioids, including overuse, can be accidental (e.g., the patient misunderstood the directions for use) or deliberate (e.g., an individual takes opioid medications prescribed for someone else), and the effects of such misuse can result in symptoms that range from pleasure to nausea, vomiting, severe allergic reactions, and overdose, in which breathing and heartbeat slow or even stop (Substance Abuse and Mental Health Services Administration 2013). The CDC reports that the death rate per 100,000 for poisoning involving opioid analgesics more than tripled between 2000 and 2010 (National Center for Health Statistics 2014).

Findings from recent government reports suggest that some of the opioid prescriptions filled under the Part D program may not be clinically indicated and may be fraudulent. For example, the Government Accountability Office found that, in 2008, about 1.8 percent of Part D enrollees may have engaged in "doctor shopping" to obtain frequently abused drugs (mostly opioids) from multiple prescribers (Government Accountability Office 2011). In addition, the Office of Inspector General's (OIG's) recent findings of questionable practices by pharmacies and prescribers suggest that the program may be vulnerable to fraud and abuse, such as diversion of opioids. For example, in examining pharmacy billing and physician prescribing behaviors, OIG found that, in 2009, over 1,000 pharmacies billed for an extremely high share of Schedule II or III drugs, and nearly 500 general-care physicians ordered an extremely high share of Schedule II or III drugs (Office of Inspector General 2013b, Office of Inspector General 2012). In a separate study, OIG found that some prescriptions ordered by individuals who did not appear to have prescribing authority were for controlled substances (Office of Inspector General 2013a).

Identifying patients who are at risk of inappropriately using opioids can be challenging in part because there is no clearly defined maximum dose in the Food and Drug Administration–approved labeling for most opioid analgesics. In addition, until recently, Part D plan sponsors and pharmacists dispensing medications to Part D enrollees often had limited ability to determine, at the point of service, whether the prescription presented was legitimate or appropriate for the clinical condition(s), or whether the individual possessed or would possess opioid medications in excess of clinically appropriate amounts.[7] Finally, because assessment of pain largely relies on self-reporting by patients, and patients who use drugs inappropriately are unlikely to be forthcoming about their addiction to opioids or their intent to divert the excess supply,

recently reported an 80 percent increase between 2006 and 2012 in the number of inpatient stays related to opioid overuse by Medicare beneficiaries (Owens et al. 2014).

Studies find that adverse events are often associated with opioid use, in part because individuals using opioids tend to take multiple drugs (polypharmacy) and because opioid use itself can lead to many ADEs, including unintentional overdoses. In addition, the side effects associated with

opioids can interfere with the treatments of comorbid conditions not associated with pain.

A study of opioid users found that over 20 percent of the users took more than 10 concurrent medications. Our analysis of Part D claims data found similar patterns among opioid users. In 2012, opioid users filled an average of 52 prescriptions per year, including opioids, from about 10 drug classes (a prescription is standardized to a 30-day

prescribers can also have difficulty identifying those individuals seeking drugs for nonclinical reasons.

Doctor shopping is often associated with individuals attempting to obtain medications for inappropriate uses. Opioid users with annual spending in the top 5 percent were more likely to obtain opioid prescriptions from four or more prescribers compared with those with spending below the 95th percentile (32 percent

vs. 9 percent, respectively) (Table 5-6). Although no definitive threshold or algorithm exists for identifying doctor shopping, obtaining prescriptions for controlled substances from four or more prescribers may indicate doctor shopping by the patient.[8] Using this threshold, among those in the top 5 percent of opioid users, the share of LIS beneficiaries who may have been doctor shopping was 36 percent compared with 23 percent for non-LIS beneficiaries.

TABLE
5–6

Opioid users in the top 5 percent were more likely to obtain opioids from multiple prescribers and pharmacies, 2012

	Below 95th percentile	95th percentile and above (Top 5 percent)		
		All	LIS	Non-LIS
Number of beneficiaries (in millions)	10.2	0.54	0.35	0.19
As a percent by LIS status			65%	35%
Share of generic opioid prescriptions	98%	80%	79%	81%
Number of unique prescribers per beneficiary*				
1 to 3	91%	68%	64%	77%
4 or more	9	32	36	23
Number of unique pharmacies per beneficiary*				
1 to 2	94%	68%	65%	74%
3 or more	6	32	35	26
Share of beneficiaries with more than one plan**	2.5%	5.2%	8.1%	1.9%

Note: LIS (low-income subsidy).
        *Unique counts of prescribers and pharmacies are based on identification (ID) information submitted on the prescription drug event (PDE) data. If a prescriber wrote prescriptions using more than one ID (e.g., National Provider Identifier and Drug Enforcement Administration ID), the claims from this prescriber under different IDs are treated as if they were written by different prescribers.
        **Reflects the number of unique plans a beneficiary obtained their prescription opioids from based on plan IDs reported on PDEs.

Source: MedPAC analysis of Part D denominator and prescription drug event data 2012.

(continued next page)

supply). Opioid users with very high opioid use may be at a greater risk of ADEs resulting from interactions with other drugs or overdose due to therapeutic duplications.

In 2012, beneficiaries who filled at least one prescription for opioids tended to have more comorbid conditions than beneficiaries who did not fill a prescription for opioids (4.8 conditions vs. 3.3 conditions, respectively). Some conditions were more prevalent among opioid users than

nonusers. For example, compared with nonusers, opioid users were more likely to have been diagnosed with:

- osteoporosis (13.0 percent vs. 9.5 percent, respectively),

- bipolar disorder (4.6 percent vs. 1.9 percent, respectively), and

- depression (21.0 percent vs. 10.0 percent, respectively).

Pharmacy shopping, like doctor shopping, is another behavior associated with inappropriate use of controlled substances. While most beneficiaries with spending below the 95th percentile (94 percent) filled their opioid prescriptions at one or two pharmacies, a much lower share (68 percent) of beneficiaries with spending in the top 5 percent did so (Table 5-6, p. 129). Among the top 5 percent of users, those who received the LIS were more likely to obtain opioid prescriptions from three or more pharmacies compared with non-LIS beneficiaries (35 percent vs. 26 percent, respectively).

In 2013, CMS responded to the widespread use of opioids and the potential for overuse among Part D enrollees by implementing a centralized data system—the Overutilization Monitoring System (OMS)—to monitor opioid use by Part D enrollees. Plans are required to take action (e.g., apply case management principles) to ensure appropriate opioid use among enrollees who are identified through OMS as being at risk for opioid or acetaminophen overuse. Plans are also required to have safety controls at point of service and conduct drug utilization reviews to proactively identify and prevent potential misuse or overuse of opioids.[9]

Other changes that are taking place in 2015 or later focus on prescribers and pharmacies that are enabling abusive or fraudulent behaviors or are part of abusive or fraudulent schemes themselves. For example, beginning in June 2015, plan sponsors must deny claims for prescriptions written by prescribers not enrolled with Medicare. CMS is also developing a tool (Predictive Learning Analytics Tracking Outcomes, or PLATO®) to assess the risk of fraud and abuse by prescribers and pharmacies based on an analysis of Part D's prescription drug event data. PLATO could help plan sponsors, CMS's Center for Program Integrity, and law enforcement agencies identify potentially fraudulent or abusive actors and take appropriate actions as needed (Abankwah 2014).

These changes may reduce the incidence of inappropriate opioid use, as well as limit the Part D program's vulnerability to fraud and abuse. Early CMS data suggest that these policy changes may have had some effect in reducing potential overuse and fraudulent cases. However, it is too early to know the full extent of their impact and effectiveness.

Additional actions could be taken to curb Medicare beneficiaries' opioid overuse and abuse. For example, Part D could limit the number of prescribers or pharmacies from which beneficiaries would be allowed to obtain some or all of their medications once they are identified as potentially at risk for overuse or abuse of controlled substances (so-called lock-in provisions). Another idea would be to limit the ability of LIS enrollees to change plans during the year if they are determined to be at high risk for abusing controlled substances. These actions, however, would be impermissible under current law because CMS does not have the authority to implement lock-in programs or limit the ability of LIS enrollees to switch plans during the year.

Balancing access to needed pain medications with the need to prevent inappropriate use of opioids is important in considering any new policy options. Monitoring the effects of efforts already under way to curb the overuse and abuse of opioids remains essential to helping policymakers better understand how CMS's current actions affect beneficiaries, plan sponsors' operations, and other actors such as pharmacies and prescribers. ∎

The prevalence of conditions related to nerve damage (e.g., neuralgia) and migraine headaches were also higher among opioid users than nonusers.

The side effects associated with opioids can worsen medical conditions that may or may not be related to pain. Opioids can cause confusion, and one characteristic of polypharmacy is that patients often have difficulty managing their medication regimen.

Opioids and therapeutic competition. As noted previously, therapeutic competition occurs when treatment for one medical condition adversely affects another condition. One of the most common side effects of opioid therapy is constipation. Research has found that about 40 percent of cancer patients taking opioids for pain relief have constipation and other gastrointestinal effects. The problem can be so acute that patients stop taking the pain therapy. The treatment for constipation can lead

to additional side effects. For example, gastrointestinal medications are often associated with other ADEs. In one study of self-reported ADEs among the elderly, researchers found that opioids were among the most common drugs associated with therapeutic competition (Chrischilles et al. 2009).

Opioids and therapeutic duplication. Opioids— including oxycodone, hydromorphone, oxymorphone, and morphine—are particularly subject to therapeutic duplication, or taking more than one drug from the same drug class concurrently. Therapeutic duplication of opioids can result in sedation, respiratory depression, constipation, dependence, and death (Giusani and White 2011). One study of self-reported adverse drug events among the elderly found that opioids were the most commonly duplicated therapeutic class (Chrischilles et al. 2009).

Toxic combinations. There are many drugs that can be toxic when taken in combination with other drugs. Some of these combinations are known, but others are not since drugs may not be tested in combinations. Opioids are only one class of drugs used to treat chronic pain. Guidelines recommend using only one class of drugs at a time to treat pain, except when transitioning from one class to another. Our data show that 33 percent of patients taking opioids also take non-narcotic analgesics, and 13 percent take sedative-hypnotics at the same time (Table 5-7).

Some common side effects of opioid use include sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance, and respiratory depression (Benyamin et al. 2008). Some common combinations of drugs with opioids increase these problems. For example, combination of opioids and other central nervous system drugs (e.g. antidepressants, barbiturates, benzodiazepines, and antipsychotics) can have additive effects on sedation. Prescription opioids are the leading cause of unintentional overdoses, in part because of the frequency with which people take multiple prescription painkillers (Benyamin et al. 2008).

Examples of team-based approaches to improving pharmaceutical care

Some organizations have developed programs to reduce opioid overuse and/or inappropriate prescribing. The programs described here use team-based care practices and involve patients and pharmacists in designing and implementing care plans. These programs were developed

TABLE 5–7	Selected drugs frequently taken by opioid users in Part D, 2012

Therapeutic classes	Share of Part D opioid users taking the drug
Antibacterial agents	68%
Antihypertensive therapy agents	54
Antihyperlipidemics	53
Peptic ulcer therapy	43
Antidepressants	41
Beta adrenergic blockers	39
Diuretics	36
Analgesic, anti-inflammatory or antipyretic—non-narcotic	33
Anticonvulsants	27
Sedative–hypnotics	13
Antipsychotics (neuroleptics)	9
Antianxiety agents	8

Note: Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0.

Source: MedPAC analysis of prescription drug event data.

by integrated health systems (Group Health of Puget Sound, Kaiser Permanente, and Fairview Health Services of Minneapolis-St. Paul).

The Group Health program focuses on safe opioid prescribing practices by the organization's clinical staff (Trescott et al. 2011). Clinical and research staff developed an online clinician education program on chronic pain management and opioid prescribing. The goal was to standardize opioid prescribing in a way that would improve safety without adding undue burdens to appropriate prescribing. Starting in 2010, a single physician is designated as responsible for management of long-term opioid therapy (90 days or more) for each patient. An individual care plan is developed with the active participation of the patient. A standardized treatment plan is agreed on, and patients are educated on the risks and potential benefits of opioid use. The prescribing physician is responsible for a minimum number of monitoring visits based on patient opioid dosage and risk factors. The program also entails drug screening for high-risk patients. Online educational support is available for physicians, and performance measures are tracked.

Under Kaiser Permanente's High Risk Medication in the Elderly initiative, clinicians, geriatricians, pharmacists, and nurse care program managers from Kaiser's regions work as a team to evaluate the safety and efficacy of drugs, including nutritional supplements, for elderly patients with multiple chronic conditions. Many of the team's recommendations are communicated directly through the patients' electronic health record (Gray and Gardner 2009).

Fairview Health Services, an integrated delivery system, has developed a team-based medication therapy management (MTM) program. The program is not limited to Medicare beneficiaries. It includes patient participation and shared savings based on total cost of care, performance measures, and patient satisfaction. The focus is on adherence to prescribed medications and avoidance of inappropriate drugs, not polypharmacy. Analysis of the results reported by participating pharmacists in the program found that of the 4,135 drug interventions, 8 percent involved unnecessary drug use while 21 percent involved the need for additional drugs. Similarly, in 30 percent of the cases, the team reported that dosages were too low compared with 8 percent of cases in which the team identified dosages that were too high (Isetts et al. 2012).

Policy responses to polypharmacy

Analysts generally agree that the most effective way to reduce the risk of harm associated with polypharmacy is to reduce the number of medications taken (Laroche et al. 2006, Milton et al. 2008). However, determining which medications can be eliminated can often be a challenge for nonclinicians (e.g., insurance plans) and even for clinicians because it requires weighing clinical benefits and costs for each medication, which are often prescribed by multiple clinicians. Other recommendations to reduce the risk of harm associated with polypharmacy include simplifying drug regimens, providing patient and provider education, limiting the number of prescribers, and avoiding treatment of ADEs with more drugs when possible (Milton et al. 2008).

However, research on results from programs to reduce unnecessary drug use has been limited. One literature review on efforts to reduce unnecessary medication among the frail elderly identified only 15 randomized controlled trials from 1966 to 2012. Most of these studies focused on individuals in nursing homes, hospices, and assisted living facilities. The effects of these efforts could not be

reliably measured (Tjia et al. 2013). Two small studies have achieved success reducing patient drug use without adverse consequences. Each study used a protocol to identify unnecessary drugs and involved pharmacists in the program (Garfinkel and Mangin 2010, Williams et al. 2004).

Because clinical guidelines are generally focused on specific conditions rather than on populations, there are no clear guidelines for treating elderly individuals who have multiple conditions. The absence of these clinical guidelines hinders clinicians' ability to prescribe appropriately for elderly patients. Although not directly related to policies that could be implemented within the Medicare program, the involvement of Medicare beneficiaries with multiple chronic conditions in clinical trials to determine, for example, the effectiveness of a given therapy could inform clinical practices for this population and could result in a greater reduction in polypharmacy.

Limits on the number of prescribers or pharmacies

The Part D program provides limited incentives and tools for plan sponsors to address polypharmacy. In the case of opioids, some have suggested limiting the number of prescribers per patient or requiring patients to fill their prescriptions at one pharmacy. While this type of policy is typically used for patients who may be at risk of opioid overuse or abuse, it may also have a broader application for more general polypharmacy issues. For example, a patient may receive better coordinated care, and therefore be at less risk for polypharmacy and ADEs, if he or she received pharmaceutical care from a limited number of clinicians. But a policy that limits the choice of providers may not always be desirable from the beneficiaries' perspective, particularly if they have chosen to be in traditional Medicare (fee-for-service) rather than a managed environment (Medicare Advantage). In addition, coordinating the pharmaceutical care with clinicians may be particularly challenging for stand-alone PDPs because they do not have contractual relationships with the prescribers.

Measuring the quality of pharmaceutical services

Medicare has tried to improve the quality of prescribing for beneficiaries. The program uses one definition of inappropriate prescribing as one of the quality measures used to rate Part D plan performance. The definition involves measuring how often plans provide inappropriate drugs to beneficiaries. The High Risk Medication measure

used in the Part D star rating system is based on the Pharmacy Quality Alliance– and National Quality Forum–endorsed list, the best known of which is the Beers list developed by a consensus panel of clinicians. However, researchers have found little association between use of Beers list drugs and ADEs (Corsonello et al. 2009, Laroche et al. 2006). The Beers list was revised in 2012, after these studies were published. CMS is considering modifying or adding measures of inappropriate drug use in the future (Centers for Medicare & Medicaid Services 2015).

Part D's medication therapy management programs

Medicare Part D includes an MTM program that is intended to improve the quality of the pharmaceutical care high-risk beneficiaries receive. To be eligible, beneficiaries must have multiple chronic diseases and take multiple drugs.

The Commission has questioned whether MTM programs offered through stand-alone PDPs, without the cooperation and coordination of a beneficiary's care team, have the capacity to significantly improve beneficiaries' drug

regimens (Medicare Payment Advisory Commission 2014a). PDPs have little incentive to offer MTM programs. Further, even within MA–PDs, which do have a financial incentive to engage in MTM-like activities (to improve the quality of pharmaceutical services and potentially reduce spending on other medical services), other care management programs or tools may have greater potential to improve outcomes for beneficiaries and address polypharmacy issues.

Better medication management might be achieved through programs offered by ACOs, medical homes, and other team-based delivery models. These programs could identify issues related to patients' medication regimens, including potentially harmful effects associated with polypharmacy. 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 reside in a clinical setting may be more effective in identifying when patients' medications should be reviewed and reconciled. ∎

Endnotes

1　The Beers list is a list of medications that are potentially inappropriate for the elderly population because they can create unfavorable risks based on expert panel reviews of clinical evidence. The list was originally developed for nursing home residents and was subsequently expanded to include all settings of geriatric care.

2　The term *opioid* generally refers to all derivatives of the opium poppy, including the naturally occurring opiate alkaloids (e.g., opium itself, morphine, and codeine) and semisynthetic agents (e.g., hydrocodone and oxycodone) (Centers for Medicare & Medicaid Services 2014).

3　For a beneficiary who used hospice at some point during the year, the opioid medications obtained through the Part D benefit likely do not reflect the full amount of opioid use by the beneficiary during the year since most medications, including opioids, to treat symptoms associated with the terminal condition are included in the hospice bundled payment.

4　Demographic characteristics and patterns of opioid use for the top 5 percent based on volume (rather than spending) may look different from those reported here.

5　Monthly costs of opioid medications can vary widely. Generic versions are available for many opioid medications, often with an average monthly cost of about $100 or less. However, branded versions can have a cost that is substantially higher than their generic counterparts, particularly in higher doses. For example, in 2011, retail prices reported on Part D claims for one branded opioid (Fentora®, typically used to treat "breakthrough" cancer pain that is not managed by other medications) ranged from several thousand dollars to over $50,000 for a one-month supply.

6　The Controlled Substances Act establishes schedules for controlled substances, ranging from Schedule I (most restrictive) to Schedule V (least restrictive). Drugs on Schedule I (e.g., heroin) currently have no accepted medical use in the United States (Kroll 2014). The DEA recently reclassified hydrocodone combination products from the more permissive Schedule III to the more restrictive Schedule II category, leaving codeine as the only opiate pain reliever in the Schedule III category.

7　Most states operate or are in the process of implementing Prescription Drug Monitoring Programs (PDMPs), electronic databases that track dispensed prescriptions for controlled substances. Although information collected by PDMPs may aid in identifying individuals who may be overusing or abusing controlled substances, access to information contained in the database varies from state to state. For example, some states allow access to the information by insurers and health insurance programs (e.g., Medicare) while others do not.

8　One study found that using a criterion of three or more prescribers and three or more pharmacies was likely to misclassify patients who were using opioids appropriately. Thus, the study used a criterion of four or more prescribers and four or more pharmacies to evaluate questionable activity in the Massachusetts prescription [drug] monitoring program data (Prescription Drug Monitoring Program Center of Excellence 2014).

9　In the final 2016 call letter, CMS reported a reduction in the number of potential opioid overusers as identified by the CMS Overutilization Monitoring System between 2011 and 2014 (Centers for Medicare & Medicaid Services 2015).

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References

Abankwah, R. 2014. Combatting Part D drug diversion. Presentation by staff from the Centers for Medicare & Medicaid Services. September 11.

Benyamin, R., A. M. Trescot, S. Datta, et al. 2008. Opioid complications and side effects. *Pain Physician* 11, no. 2 supplement (March): S105–120.

Budnitz, D. S., M. C. Lovegrove, N. Shehab, et al. 2011. Emergency hospitalizations for adverse drug events in older Americans. *New England Journal of Medicine* 365, no. 21 (November 24): 2002–2012.

Bushardt, R. L., E. B. Massey, T. W. Simpson, et al. 2008. Polypharmacy: Misleading, but manageable. *Clinical Interventions in Aging* 3, no. 2: 383–389.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Memo to all Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties regarding the announcement of calendar year (CY) 2016 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. April 6. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. *Drug diversion toolkit: Prescription opioids—An overview for prescribers and pharmacists.* Baltimore, MD: CMS. http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Provider-Education-Toolkits/Downloads/prescription-opioids-booklet0814.pdf.

Chrischilles, E. A., R. VanGilder, K. Wright, et al. 2009. Inappropriate medication use as a risk factor for self-reported adverse drug effects in older adults. *Journal of the American Geriatrics Society* 57, no. 6 (Jun): 1000–1006.

Corsonello, A., C. Pedone, F. Lattanzio, et al. 2009. Potentially inappropriate medications and functional decline in elderly hospitalized patients. *Journal of the American Geriatrics Society* 57, no. 6 (June): 1007–1014.

Duerden, M. 2013. *Polypharmacy and medicines optimization.* London: The King's Fund.

Field, T. S., K. M. Mazor, B. Briesacher, et al. 2007. Adverse drug events resulting from patient errors in older adults. *Journal of the American Geriatrics Society* 55, no. 2 (February): 271–276.

Frazier, S. C. 2005. Health outcomes and polypharmacy in elderly individuals: An integrated literature review. *Journal of Gerontological Nursing* 31, no. 9 (September): 4–11.

Gandhi, T. K., S. N. Weingart, J. Borus, et al. 2003. Adverse drug events in ambulatory care. *New England Journal of Medicine* 348, no. 16 (April 17): 1556–1564.

Garfinkel, D., and D. Mangin. 2010. Feasibility study of a systematic approach for discontinuation of multiple medications in older adults: Addressing polypharmacy. *Archives of Internal Medicine* 170, no. 18 (October 11): 1648–1654.

Giusani, M., and A. White. 2011. Therapeutic duplication. https://www.scripnet.com/therapeutic-duplication/.

Government Accountability Office. 2011. *Medicare Part D: Instances of questionable access to prescription drugs.* GAO–11–699 Washington, DC: GAO.

Gray, C. L., and C. Gardner. 2009. Adverse drug events in the elderly: An ongoing problem. *Journal of Managed Care Pharmacy* 15, no. 7 (September): 568–571.

Hajjar, E. R., A. C. Cafiero, and J. T. Hanlon. 2007. Polypharmacy in elderly patients. *American Journal of Geriatric Pharmacotherapy* 5, no. 4 (December): 345–351.

Haque, R. 2009. ARMOR: A tool to evaluate polypharmacy in elderly persons. *Annals of Long-Term Care* 17, no. 6 (June): 26–30.

Isetts, B. J., A. R. Brummel, D. R. de Oliveira, et al. 2012. Managing drug-related morbidity and mortality in the patient-centered medical home. *Medical Care* 50, no. 11 (November): 997–1001.

Jena, A. B., D. Goldman, L. Weaver, et al. 2014. Opioid prescribing by multiple providers in Medicare: Retrospective observational study of insurance claims. *British Medical Journal* 348: g1393.

Kripalani, S., M. Price, V. Vigil, et al. 2008. Frequency and predictors of prescription-related issues after hospital discharge. *Journal of Hospital Medicine* 3, no. 1 (January): 12–19.

Kroll, D. 2014. New rules for hydrocodone: What you should know. *Forbes*, August 22.

Laroche, M. L., J. P. Charmes, Y. Nouaille, et al. 2006. Impact of hospitalisation in an acute medical geriatric unit on potentially inappropriate medication use. *Drugs and Aging* 23, no. 1: 49–59.

Lee, V. W., K. K. Pang, K. C. Hui, et al. 2013. Medication adherence: Is it a hidden drug-related problem in hidden elderly? *Geriatrics & Gerontology International* 13, no. 4 (October): 978–985.

Lorgunpai, S. J., M. Grammas, D. S. Lee, et al. 2014. Potential therapeutic competition in community-living older adults in the U.S.: Use of medications that may adversely affect a coexisting condition. *PLoS One* 9, no. 2: e89447.

Lorincz, C. Y., E. Drazen, P. E. Sokol, et al. 2011. *Research in ambulatory patient safety 2000–2010: A 10-year review.* Chicago, IL: American Medical Association.

Maher, R. L., J. Hanlon, and E. R. Hajjar. 2014. Clinical consequences of polypharmacy in elderly. *Expert Opinion Drug Safety* 13, no. 1 (January): 57–65.

Mansur, N., A. Weiss, and Y. Beloosesky. 2009. Is there an association between inappropriate prescription drug use and adherence in discharged elderly patients? *Annals of Pharmacotherapy* 43, no. 2 (February): 177–184.

Medicare Payment Advisory Commission. 2014a. Letter to Ms. Marilyn Tavenner, Administrator, Centers for Medicare & Medicaid Services, regarding request for comments on the "Medicare program; contract year 2015 policy and technical changes to the Medicare Advantage and the Medicare prescription drug benefit programs, proposed rule." February 28.

Medicare Payment Advisory Commission. 2014b. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Milton, J. C., I. Hill-Smith, and S. H. Jackson. 2008. Prescribing for older people. *British Medical Journal* 336, no. 7644 (March 15): 606–609.

National Center for Health Statistics, Department of Health and Human Services. 2014. *Health, United States, 2013: Chartbook.* Figures 20–29, special feature on prescription drugs. Hyattsville, MD: NCHS. http://www.cdc.gov/nchs/hus/chartbook.htm#chartbook_special_feature.

Office of Inspector General, Department of Health and Human Services. 2013a. *Medicare inappropriately paid for drugs ordered by individuals without prescribing authority.* OEI–02–09–00608. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2013b. *Prescribers with questionable patterns in Medicare Part D.* OEI–02–09–00603. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2012. *Retail pharmacies with questionable Part D billing.* OEI–02–09–00600. Washington, DC: OIG.

Owens, P. L., M. L. Barrett, A. J. Weiss, et al. 2014. *Hospital inpatient utilization related to opioid overuse among adults, 1993–2012.* HCUP statistical brief #177 Rockville, MD: Agency for Healthcare Research and Quality. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf.

Prescription Drug Monitoring Program Center of Excellence, Brandeis University. 2014. *Study analysis 101.* Waltham, MA: PDMP Center of Excellence.

Salazar, J. A., I. Poon, and M. Nair. 2007. Clinical consequences of polypharmacy in elderly: Expect the unexpected, think the unthinkable. *Expert Opinion Drug Safety* 6, no. 6 (November): 695–704.

Sarkar, U., A. López, J. H. Maselli, et al. 2011. Adverse drug events in U.S. adult ambulatory medical care. *Health Services Research:* 10.1111/j.1475-6773.2011.01269.

Steinman, M. A., C. S. Landefeld, G. E. Rosenthal, et al. 2006. Polypharmacy and prescribing quality in older people. *Journal of the American Geriatrics Society* 54, no. 10 (October): 1516–1523.

Substance Abuse and Mental Health Services Administration, Department of Health and Human Services. 2013. *SAMHSA opioid overdose prevention toolkit.* HHS publication no. (SMA) 13-4742. Rockville, MD: SAMHSA. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf.

Tannenbaum, C., and K. Johnell. 2014. Managing therapeutic competition in patients with heart failure, lower urinary tract symptoms and incontinence. *Drugs and Aging* 31, no. 2 (February): 93–101.

Tjia, J., S. J. Velten, C. Parsons, et al. 2013. Studies to reduce unnecessary medication use in frail older adults: A systematic review. *Drugs and Aging* 30, no. 5 (May): 285–307.

Trescott, C. E., R. M. Beck, M. D. Seelig, et al. 2011. Group Health's initiative to avert opioid misuse and overdose among patients with chronic noncancer pain. *Health Affairs* 30, no. 8 (August): 1420–1424.

Vik, S. A., C. J. Maxwell, and D. B. Hogan. 2004. Measurement, correlates, and health outcomes of medication adherence among seniors. *Annals of Pharmacotherapy* 38, no. 2 (February): 303–312.

Williams, M. E., C. C. Pulliam, R. Hunter, et al. 2004. The short-term effect of interdisciplinary medication review on function and cost in ambulatory elderly people. *Journal of the American Geriatrics Society* 52, no. 1 (January): 93–98.

Wise, J. 2013. Polypharmacy: A necessary evil. *British Medical Journal* 347: f7033.

6

Sharing risk in Medicare Part D

Sharing risk in Medicare Part D

Chapter summary

In 2013, Medicare spent almost $65 billion on Part D, which uses private plans to deliver prescription drug benefits. Medicare pays for benefits whether beneficiaries use traditional Medicare and enroll in stand-alone prescription drug plans (PDPs) or they enroll in Medicare Advantage prescription drug plans. Plan sponsors bear insurance risk for the benefit spending of their enrollees. When competing plans bear risk, they have incentives to offer benefits that are attractive to beneficiaries and yet manage spending so that premiums remain affordable. Medicare shares insurance risk with Part D plans to address policy goals. This chapter examines the ways in which Medicare pays Part D plans and shares insurance risk with them.

Mechanisms for sharing risk

Part D plan sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering basic drug benefits to an enrollee of average health. After reviewing bids, CMS determines Medicare's per member per month prospective payment to plans, called the direct subsidy, which reduces premiums for all Part D enrollees. Because Medicare's direct subsidy is a fixed-dollar amount, plan sponsors risk losing money if their enrollees' drug spending is higher than the combination of direct subsidy payments and enrollee premiums.

However, plan sponsors do not bear all the risk. CMS risk adjusts direct subsidy payments to counteract incentives for sponsors to avoid enrollees

In this chapter

who use more drugs. In addition, Medicare pays plans individual reinsurance equal to 80 percent of covered spending above Part D's catastrophic threshold (in 2015, roughly $7,000 in total drug spending). Also, risk corridors limit each plan's overall losses or profits if actual spending is much higher or lower than anticipated. Corridors provide a cushion for plans in the event of large, unforeseen aggregate drug spending.

An additional feature is that Medicare pays for most premiums and cost sharing on behalf of enrollees with low incomes and assets through Part D's low-income subsidy (LIS). On average, individuals who receive the LIS tend to have poorer health and use more prescriptions. Unlike other enrollees whose cost sharing is set by plan sponsors as part of a plan's benefit design, cost sharing for LIS enrollees is set by law at nominal amounts and they face no coverage gap.

Today's role for risk sharing

Before the start of Part D, stand-alone PDPs did not exist. Initially, individual reinsurance and risk corridors were included to help ensure plan entry and formation of competitive markets. Today, Medicare beneficiaries have many enrollment options. Although there is variation across plans, competition has kept growth in average Part D premiums fairly low over time.

Now that the market for PDPs is well established, it may be time to reevaluate policy goals for risk sharing in Part D. Changes in risk sharing that provide incentive for plans to manage broader measures of cost may increase the program's efficiency. Between 2007 and 2013, spending for the competitively derived direct subsidy payments to plans—the portion of Medicare's payments on which plans bear the most insurance risk—grew by a cumulative 12 percent. In contrast, benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, where Medicare provides 80 percent reinsurance) grew much faster over the same period. Program payments for the LIS and individual reinsurance grew by a cumulative 39 percent and 143 percent, respectively. These increases suggest that sponsors have been less successful at cost containment when they faced less risk for benefit spending.

Patterns of reconciliation payments

Medicare makes prospective payments to plans based on sponsors' bids. Six months after the end of each benefit year, CMS begins reconciling prospective payments with actual benefit costs that plans paid. As a final step in reconciliation, CMS applies a statutory formula for risk corridors.

Medicare's reconciliation and risk corridor payments reveal regular patterns. First, many plan sponsors have bid too low on the amount of benefit spending they expected above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. In recent years, the majority of plan sponsors received additional money from Medicare at reconciliation because their prospective payments for individual reinsurance were too low. Second, plan sponsors have bid too high on the rest of benefit spending other than catastrophic benefits. Between 2009 and 2013, about three-fourths of parent organizations returned a portion of overpayments to Medicare through risk corridors, with Medicare collecting an aggregate of between $700 million and $1.1 billion each year. (Throughout this chapter, we use the term *overpayments* to refer to the differences by which some plans' prospective payments exceeded actual benefit costs.)

Potential reasons for the patterns of payments

Actuaries interviewed by Commission staff suggested that there is significant uncertainty behind the assumptions they make when projecting drug spending by Part D plan enrollees. At the same time, Part D's risk-sharing mechanisms may provide incentives to bid too low on catastrophic spending and too high on spending for the remainder of the Part D benefit. By underestimating catastrophic spending, plan sponsors may be able to charge lower premiums to enrollees and then later get reimbursed by Medicare for 80 percent of actual catastrophic claims through additional reinsurance at reconciliation. As a practical matter, an individual sponsor is only one of many sponsors whose bids collectively affect the amounts that Medicare pays in prospective payments. Still, Medicare's reconciliation payments show consistent patterns rather than the randomness one might expect from projection errors in the actuarial assumptions behind bids.

Potential changes to Part D risk sharing

Policymakers may want to consider changes in Part D's risk-sharing mechanisms that encourage plan sponsors to better manage drug benefits for higher cost enrollees. One option would be to require plans to include more of the costs of catastrophic spending in their covered benefits. Under this option, Medicare's overall subsidy would remain at 74.5 percent, but the makeup of Medicare's subsidy would change—plan sponsors would receive less individual reinsurance and a larger direct subsidy payment. Because a larger share of Medicare's subsidy would take the form of capitated payments, plan sponsors would be at risk for more of covered benefits, and the change would provide stronger incentive to manage drug spending. However, because they would bear more risk, plan sponsors may also need to purchase private reinsurance or build a risk premium into their bids.

A second option would be to change the structure of the risk corridors. For example, the corridors could be widened or eliminated so that sponsors would pay for more or all of plan losses and, because the corridors are symmetric, keep more or all of plan profits. By exposing plan sponsors to greater risk, they would have stronger incentives to manage benefit spending. However, because of the interaction between risk corridors and individual reinsurance, thus far the role of Part D's risk corridors has been primarily to limit the profits that plans have received above those already built into bids. The absence of corridors (with no other changes to the risk-sharing arrangement) would potentially allow sponsors to keep more profits than they do currently, if they did not change how they bid. Another option is to tighten Part D's risk corridors because plan sponsors have returned a portion of overpayments to Medicare each year.

Several program modifications may be necessary at the same time—that is, a package of changes—to balance concerns about cost control and incentives for selection behavior. One concern relates to LIS enrollees, who make up about 80 percent of individuals who reach Part D's catastrophic threshold. If, in isolation, plans were required to shoulder more of covered benefits above the catastrophic threshold, then the policy change could disproportionately affect plans with high shares of LIS enrollment. CMS could counter this effect somewhat by ensuring that Part D's risk adjusters were calibrated to take into account plans' greater degree of risk. At the same time, policymakers might also consider changes in LIS policy that give sponsors greater flexibility to contain costs. ■

Introduction

Since 2006, Medicare has used private plans to deliver prescription drug benefits to beneficiaries who choose to enroll in Part D. The program is considered an ambitious effort to use market mechanisms to deliver a large-scale entitlement benefit (Duggan et al. 2008).

In this chapter, we examine the ways in which Medicare shares insurance risk with Part D plans. When competing plans bear risk, they have an incentive to strike a balance between offering benefits that are attractive to beneficiaries and managing their enrollees' drug spending so that the plans' premiums will be affordable. Medicare shares some of this insurance risk to offset the incentive for plan sponsors to avoid higher cost enrollees and to provide a cushion for plans in the event of large, unforeseen drug spending. With the exception of new national coverage decisions, Medicare does not generally offer similar risk-sharing provisions for the Medicare Advantage program. Along with other factors, one consequence of Part D's existing risk-sharing arrangements is that pharmaceutical manufacturers are able to set high launch prices for certain new medicines.

Some forms of risk sharing were intended to help establish a market that did not exist before Part D—stand-alone prescription drug plans (PDPs). Now that Part D is in its 10th benefit year, the Commission contends that it is time to consider whether the initial design of its risk-sharing mechanisms is structured in a way that addresses current program goals.

Part D provides prescription drug benefits to most Medicare beneficiaries, whether they are in traditional fee-for-service Medicare or in Medicare Advantage (MA) plans. In 2014, 69 percent of beneficiaries were enrolled in Part D plans. Over three-fifths of those enrollees were in PDPs, with the remainder in Medicare Advantage–Prescription Drug plans (MA–PDs) (Medicare Payment Advisory Commission 2015). Under the Part D program, Medicare subsidizes 74.5 percent of the cost of basic drug benefits and enrollees pay the remaining 25.5 percent through premiums. Medicare also pays plans for some or all of enrollees' premiums and cost sharing for those who qualify for and enroll in the program's low-income subsidy (LIS), including beneficiaries dually eligible for Medicare and Medicaid.[1] In 2014, 30 percent of Part D enrollees received the LIS, and just over 70 percent of LIS enrollees were in stand-alone PDPs.

Sponsors of Part D plans must hold valid insurance licenses in the states in which they operate, and they must carry out essential industry functions such as marketing, enrollment, customer support, claims processing, making coverage determinations, and responding to appeals and grievances. Plan sponsors also carry out other specialized functions of pharmacy benefit managers (PBMs), either through firms owned by the same parent organization or through contracts with private PBMs. They develop and maintain formularies—a list of drugs the plans cover and the terms under which they will cover them—to manage the cost and use of prescription drugs. Formularies identify which drugs the plan will cover in each therapeutic class and the cost-sharing tier on which individual products fall. Formularies also list whether the drug is subject to any type of utilization management such as prior authorization, quantity limits, and step therapy. In some respects, CMS's regulations for Part D formularies prevent plan sponsors from using certain management techniques that sponsors apply in other markets.[2]

Plan sponsors and their PBMs also negotiate with drug manufacturers for rebates—payments from pharmaceutical companies to the plan sponsor for placing the manufacturer's product on a specific cost-sharing tier or for successfully encouraging enrollees to use the manufacturer's drugs. Plan sponsors manage their formularies to structure competition among drug therapies and to shift drug utilization toward certain products to obtain rebates. However, a plan sponsor's ability to negotiate rebates is limited for certain products that have no clear substitutes—for example, many high-cost specialty drugs.

Generally, health insurers seek to enroll a broad set of individuals to spread risk. Under Part D, plan sponsors face several types of risk:

- *Insurance risk*—Included in sponsors' payments for covered benefits is a portion of the cost of prescriptions filled. Sponsors are at risk because, under Medicare's capitated payment system, their plans lose money if their enrollees' drug spending is higher than the combination of capitated payments and enrollee premiums. In addition, sponsors do not have full control over spending because enrollees and prescribers (rather than the sponsor) initiate decisions about how many and what kind of prescriptions are filled.

- *Risk of adverse selection*—Sponsors face risk that their plan will attract a larger proportion of high-cost individuals than their competitors.

- *Trend risk*—Unanticipated changes can occur in the prices of drugs, the quantity of prescriptions filled, or in the mixture of prescriptions taken (e.g., brand-name drugs vs. generics). For example, if a new drug is introduced into the market and the manufacturer is able to set its launch price considerably higher than what a plan sponsor anticipated at the time it submitted its bid for Part D, the sponsor could have higher benefit spending than planned.

- *Other risks of doing business*—Sponsors face risks that their payers (including the Medicare program), other partners, and enrollees may change negotiated business deals, program rules, or behavior in unanticipated ways.

Plan sponsors seek to manage their risk in various ways, such as by influencing enrollee and physician behavior through their formularies and tiered cost sharing to encourage substitution of lower cost drugs for more expensive therapies. Drug plans employ utilization management tools such as prior authorization, quantity limits, and step therapy for drugs that are expensive or subject to misuse, or to encourage use of lower cost therapies.

From the perspective of the Medicare program, some methods that insurers use to manage their risk may not be desirable. For example, Medicare regulations aim to keep sponsors from designing benefit packages, formularies, and marketing materials that would discourage sicker beneficiaries from enrolling.

To manage trend risk, insurers collect market intelligence about the types of drugs in the development pipeline, when those drugs are likely to enter the market, the conditions they will treat, and projections of prices for new and existing drugs. This effort involves keeping abreast of the medical literature, which sometimes finds evidence for using an existing drug in new ways.

Part D's mechanisms for sharing risk

Part D plan sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering a basic drug benefit to an enrollee of average health. Part D is different from Part C (the Medicare Advantage program) in that Part D's payment-setting policy does not involve a comparison with an administratively set benchmark amount. Instead, after

reviewing the assumptions of each bid, CMS calculates a nationwide enrollment-weighted average among all bids. CMS applies a statutory formula to that nationwide average bid to determine Medicare's per member per month prospective payment to plans, which is called the *direct subsidy*. This direct subsidy reduces premiums for all Part D enrollees. Because Medicare pays a capitated amount, plan sponsors risk losing money if their enrollees' drug spending is higher than the combination of their direct subsidy payments from Medicare and enrollee premiums. Requiring plan sponsors to bear insurance risk provides incentive for them to manage benefit spending.

At the same time, Part D was designed so that plan sponsors do not bear all the risk.

- CMS risk adjusts the direct subsidy to address incentives that would otherwise exist for sponsors to seek out healthier enrollees and avoid sicker ones.

- Part D pays for 80 percent of covered spending above the basic benefit's catastrophic threshold (called *individual reinsurance*), with the plan responsible for 15 percent and the enrollee paying 5 percent.

- Part D has symmetric *risk corridors*, which enable risk to be shared between plans and the Medicare program; that is, they limit each plan's overall losses or profits if actual spending for basic benefits is much higher or lower than what was anticipated.

Special role of the LIS

A plan's number of LIS enrollees is an important factor in the context of sharing risk because LIS enrollees tend to have higher than average drug spending and plan sponsors have fewer tools to manage that spending. Unlike other Part D enrollees whose cost-sharing amounts are set by sponsors as part of their plans' benefit designs, cost-sharing amounts for LIS enrollees are set by law at nominal amounts. Similarly, under law, LIS enrollees face no coverage gap. Part D's risk-adjustment system (described in the next section) helps to mitigate the higher benefit spending of LIS enrollees. Plan sponsors also receive monthly prospective payments from Medicare for estimated LIS cost sharing that CMS later reconciles with plans based on actual prescriptions filled.

Risk adjustment of capitated payments

Spending for benefits under Part D is highly skewed. This distribution creates incentives for sponsors to avoid high-cost enrollees. In 2012, 26 percent of enrollees had

FIGURE
6–1

About one-fourth of enrollees incurred three-fourths of Part D spending, 2012
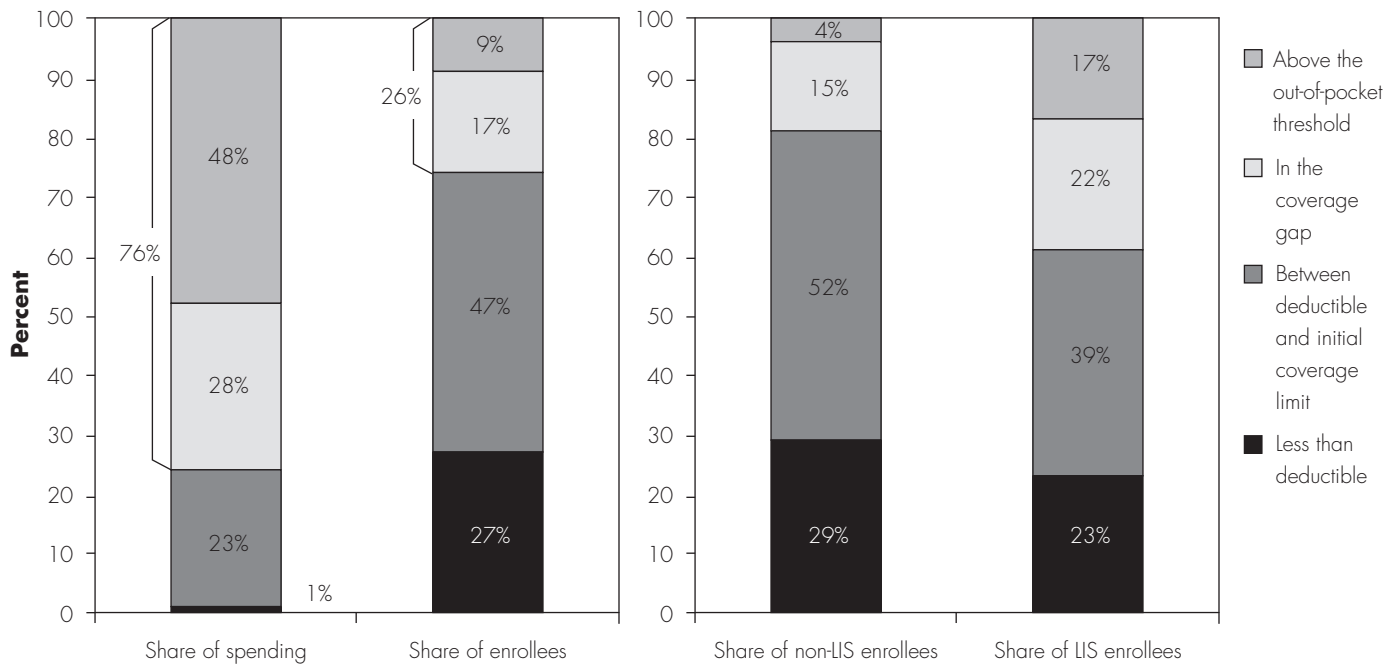
Note: The spending distributions are based on total covered drug spending. The specific amount of total covered spending at each individual's out-of-pocket threshold depends on the mix of brand and generic prescriptions filled while in the coverage gap. The dollar amounts used to show spending thresholds are for an individual not receiving Part D's low-income subsidy who has no other supplemental coverage.

Source: MedPAC analysis of 2012 Part D prescription drug event data from CMS.

gross benefit spending that could put them in the coverage gap or above the standard benefit's out-of-pocket (OOP) threshold (Figure 6-1). Their combined drug spending accounted for 76 percent of total spending for basic benefits. A much larger proportion of LIS enrollees compared with non-LIS enrollees had benefit spending high enough to reach the OOP threshold: 17 percent versus 4 percent, respectively.

To deter selection behavior, Medicare applies a risk score to sponsors' direct subsidy payments—paying more for sicker beneficiaries and less for healthier ones. CMS assigns risk scores to each Part D enrollee using estimates from the prescription drug hierarchical condition category (RxHCC) model. The RxHCC model predicts drug benefit spending based on enrollees' demographic characteristics, diagnoses from their medical claims, and other characteristics.[3]

Previously, the Commission raised questions about whether risk scores calculated under an earlier version of RxHCC were effective at overcoming incentives to avoid LIS enrollees (Hsu et al. 2010, Hsu et al. 2009, Medicare

Payment Advisory Commission 2009). However, beginning in 2011, CMS refined the RxHCC model to better capture differences in the mix of prescription drugs taken by categories of enrollees.[4] For example, among younger disabled enrollees who receive the LIS, there may be a greater prevalence of conditions such as HIV/AIDS or mental illness compared with older nondisabled enrollees, and their drug spending may be costlier on average.

Commission staff asked plan and consulting actuaries with expert knowledge about how the current RxHCC model operates. All interviewees responded that newer models are much improved for equalizing remuneration between LIS and non-LIS enrollees. However, several actuaries also said that the risk adjusters tend to undercompensate for enrollees who use high-cost specialty drugs. CMS may need to modify certain RxHCCs to recognize lags that can occur between the entrance of new high-cost drugs and the point at which claims data become available to recalibrate risk-adjustment models. At the same time, if Medicare were to base plan payments on risk-adjusted amounts that predict actual spending too closely, the result would differ

FIGURE
6–2

Medicare pays 80 percent of benefits above Part D's out-of-pocket threshold through individual reinsurance
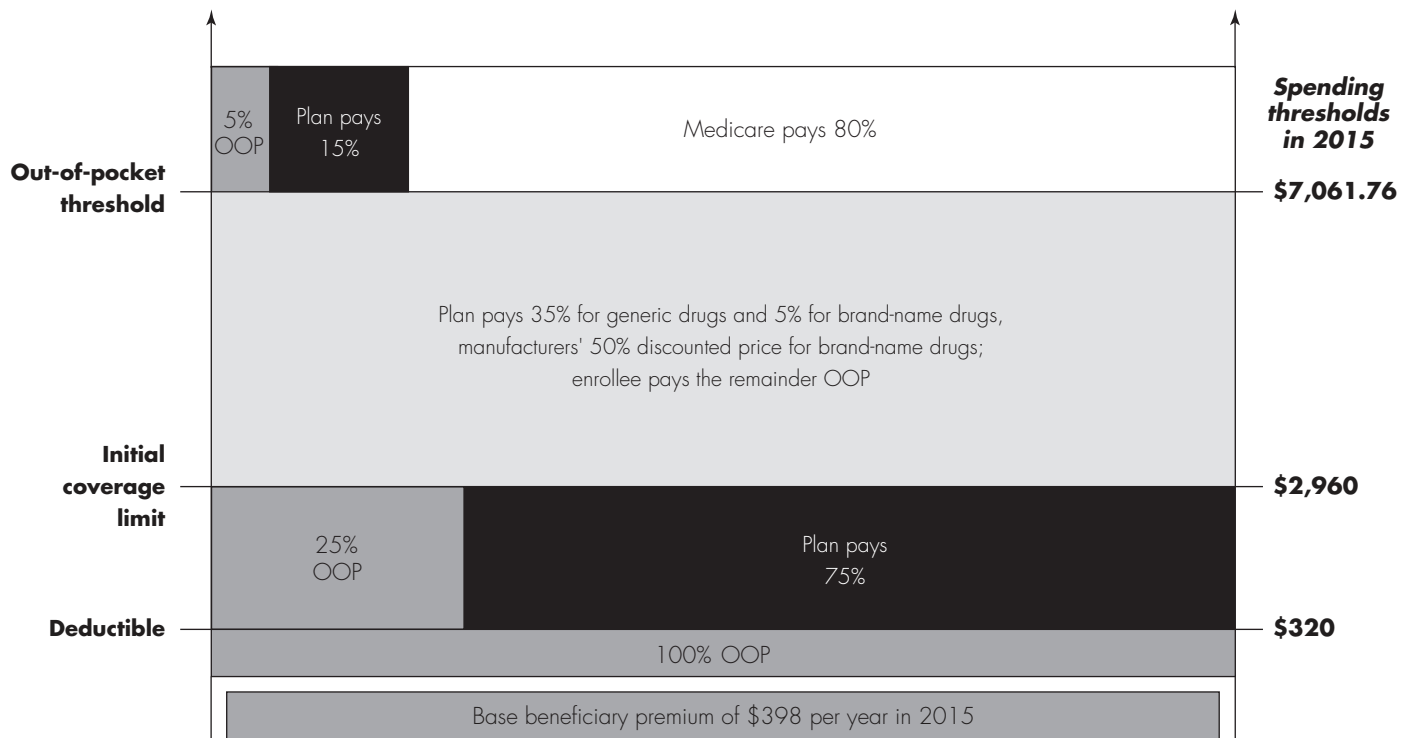
Notes: OOP (out-of-pocket). Dollar amounts and benefits between the initial coverage limit and the out-of-pocket threshold (also known as the "coverage gap") reflect Part D's defined standard benefit structure in 2015. Most plans with basic benefits modify this defined standard benefit by using different cost-sharing requirements (e.g., copayments rather than coinsurance, often no deductible), while maintaining the same average benefit value. Note that the "coverage gap" is scheduled for elimination by 2020. By that date, enrollees will pay a consistent 25 percent cost sharing up to the out-of-pocket threshold.

Source: MedPAC analysis.

little from using a system of cost-based reimbursement rather than prospective payment.

In CMS's call letter to plan sponsors for benefit year 2016, the agency stated that it is using an updated version of the RxHCC model that, in addition to basing adjusters on more recent data, adds diagnosis information and prescription drug claims from MA–PDs to estimate risk scores (Centers for Medicare & Medicaid Services 2015). That model also incorporates an actuarial adjustment to spending for treatment of hepatitis C because the 2013 claims data to which the model is calibrated do not reflect the high cost of new therapies.[5] In prior years, CMS had incomplete diagnosis information from MA–PDs and used only fee-for-service (FFS) diagnoses combined with PDP claims to build risk scores. Now that a more complete set of diagnoses is available from MA–PDs, CMS will use

updated models estimated from pooled PDP and MA–PD drug claims to better represent the Part D population (Centers for Medicare & Medicaid Services 2015)

Individual reinsurance for high-cost enrollees

Individual reinsurance is another mechanism that was intended to temper selection behavior among competing plans. For enrollees with very high drug spending, Medicare pays plan sponsors 80 percent of spending on covered benefits above Part D's OOP threshold (Figure 6-2). The remaining benefit spending is divided between the plan (15 percent) and the enrollee (5 percent).

Because LIS enrollees tend to have poorer health and higher drug spending than non-LIS enrollees, they reach Part D's OOP threshold disproportionately. Of the 2.6

FIGURE
6–3

Part D risk corridors have widened over time

Structure of risk corridors in 2006 and 2007

Structure of risk corridors since 2008
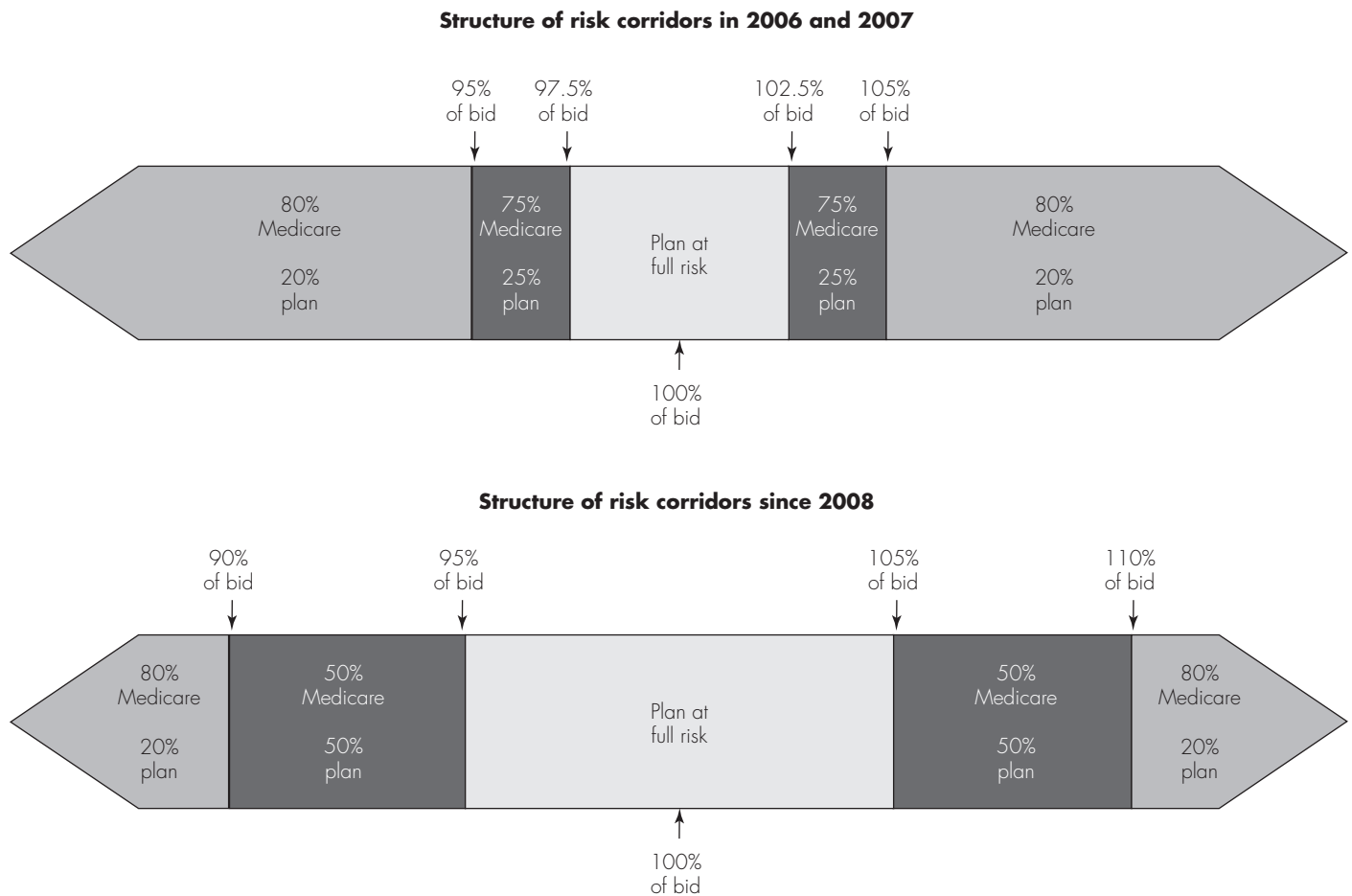
Source: MedPAC depiction of Part D risk corridors as set by law.

million enrollees in 2012 who reached the OOP drug spending threshold, about 80 percent received the LIS (Medicare Payment Advisory Commission 2015).

Risk corridors

Each of the first two methods of Medicare's risk sharing is applied separately for each enrollee. In contrast, risk corridors seek to limit a plan's overall losses across all of its enrollees when actual spending for basic benefits is higher than anticipated. Since Part D's risk corridors are symmetric, they also limit a plan's unanticipated profits when actual spending for basic benefits is lower than anticipated. Administrative costs and supplemental benefits are not part of the Part D risk corridor calculation.

Plan sponsors submit their bids seven months before the start of a Part D benefit year. If circumstances change

substantially between when a sponsor submits its bid and when it delivers benefits, risk corridors may help provide a safety net. For example, if medical literature suggests that a brand-name drug could be effective treatment for a widely prevalent condition and plan sponsors had not anticipated this news, then benefit spending could be considerably higher than expected.

The law that created Part D required plans to accept certain levels of risk during the first years of the program and then gave the Secretary of Health and Human Services authority to require additional levels of risk. Risk corridor parameters widened in 2008 (creating more plan risk) but have not changed since then (Figure 6-3). Sponsors are now at full risk for average monthly benefits within the range of 95 percent to 105 percent of the plan bid. If actual benefit spending is between 105 percent and 110

TABLE
6–1   Medicare's incurred spending for payments to Part D plans

	2007	2008	2009	2010	2011	2012	2013	Average annual rate of growth, 2007–2013	Cumulative growth, 2007–2013
In billions of dollars									
Direct subsidy	$18.1	$17.7	$18.9	$19.7	$20.1	$20.8	$20.3	1.9%	12.1%
Individual reinsurance	8.0	9.4	10.1	11.2	13.7	15.5	19.5	15.9	142.9
Low-income subsidy	16.7	18.0	19.6	21.0	22.2	22.5	23.3	5.7	39.4
Total*	$42.8	$45.2	$48.5	$51.9	$56.0	$58.8	$63.1	6.7%	47.2%
Share of total									
Direct subsidy	42%	39%	39%	38%	36%	35%	32%	N/A	N/A
Individual reinsurance	19	21	21	22	24	26	31	N/A	N/A
Low-income subsidy	39	40	40	40	40	38	37	N/A	N/A
Total	100%	100%	100%	100%	100%	100%	100%	N/A	N/A

Note: N/A (not applicable). Numbers reflect reconciliation amounts. Totals may not sum due to rounding.
*Most enrollees paid premiums directly to Part D plans or had premiums withheld from their Social Security checks, and those amounts are not included in the totals. On a cash basis, the Boards of Trustees estimate premiums of $4.1 billion in 2007, $5.0 billion in 2008, $6.1 billion in 2009, $6.7 billion in 2010, $7.3 billion in 2011, $7.8 billion in 2012, and $9.3 billion in 2013.

Source: MedPAC based on Table IV.B.9 of the 2014 annual report of the Boards of Trustees of the Medicare trust funds.

percent of the bid (or between 90 percent and 95 percent), Medicare splits the difference with the plan sponsor fifty-fifty. Beyond 110 percent (or below 90 percent), Medicare covers 80 percent of excess benefit costs (or recoups excess profits). Since 2012, the Secretary has had authority to change the structure of Part D's risk corridors as long as it keeps at least the same amount of plan risk as in 2011. Medicare recoups any amounts owed by withholding them from future monthly payments.

Evaluating today's role for risk-sharing provisions

At the start of Part D, risk corridors and individual reinsurance were included in the program to help ensure plan entry and formation of competitive markets across the country. Large numbers of plans were available initially, followed by consolidation within the industry. Yet even after these consolidations, beneficiaries have, in 2015, between 24 and 33 PDPs to choose among, depending on where they live, as well as many MA–PD plans (Medicare

Payment Advisory Commission 2015). Between 12 percent and 15 percent of enrollees have made a voluntary decision to switch plans to lower their premiums, cost sharing, or both (Hoadley et al. 2013, Suzuki 2013). That estimate excludes individuals who must change plans because of plan exits. In addition, CMS reassigns some LIS enrollees each year to plans that have premiums below regional thresholds.

How has this degree of plan rivalry affected Part D premiums? In 2014, monthly beneficiary premiums averaged about $29 across all plans (Medicare Payment Advisory Commission 2015). Although enrollee premiums vary considerably, the average premium has grown slowly at 3.3 percent per year between 2007 and 2014 and has been especially flat since 2010.

Between 2007 and 2013, per capita program spending for Part D grew at average annual rates slightly below those for combined Part A and Part B FFS spending (Medicare Payment Advisory Commission 2015). However, going forward, both the Medicare Trustees and the Congressional Budget Office project that per capita spending for Part D

will grow at about twice the rate of FFS spending (Boards of Trustees 2014, Congressional Budget Office 2015). That faster growth is due, in part, to the growing use of high-cost specialty drugs among the Medicare population.

Even in the current time frame, it is not clear that strong incentives and tools exist to control all aspects of program costs. Specifically, evidence suggests that plan sponsors have been less successful at managing benefits for high-cost enrollees, including individuals who receive the LIS. For these beneficiaries, Medicare bears the majority of insurance risk. In the case of LIS enrollees, plan sponsors have fewer tools to encourage the use of lower cost medicines.

Program spending shows plans less successful at managing spending of LIS enrollees

Evidence on program spending gives a mixed picture of the success of Part D plans at containing costs. Spending for the competitively derived direct-subsidy payments on which sponsors bear the most insurance risk has grown slowly, while benefit spending for which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides 80 percent reinsurance) has grown much faster. This evidence suggests that sponsors have been less successful at cost containment when they were at less risk for benefit spending.

In 2013, Medicare spent $63.1 billion on Part D payments to plans (Table 6-1). Program spending on behalf of the 11 million individuals who receive the LIS continued to make up the largest component. About $23 billion, or 37 percent of total Part D spending, was for premium and cost-sharing assistance for LIS enrollees. Sizable portions of direct subsidy and individual reinsurance payments to Part D plans were also on behalf of LIS enrollees. When combined, spending in 2013 for the LIS, direct subsidy, and individual reinsurance paid for LIS enrollees totaled about two-thirds of total program spending.

Between 2007 and 2013, individual reinsurance payments to plans grew from $8 billion to $19.5 billion. This increase amounts to an average annual growth rate of nearly 16 percent, or more than twice the pace of enrollment in Part D plans. By comparison, direct subsidy payments to plans—the portion of Medicare's payments on which plans bear the most insurance risk—grew by an annual average rate of less than 2 percent.

National average bid shows high growth in individual reinsurance

Changes over time in the national average bid also reflect higher growth in individual reinsurance—the portion of program spending on which plan sponsors do not bear risk. Expected total benefit spending per member per month has grown at a modest rate of 2.4 percent annually between 2007 and 2015, from $107 to $130 (Figure 6-4, p. 150). During that period, the monthly amount that plans expect to receive through Medicare's direct subsidy has declined at an average annual rate of 4.4 percent, from about $53 to about $37,while the amount per member per month that sponsors expect to receive in individual reinsurance has grown at an average annual rate of 10.5 percent, from $27 to about $60.

Sponsors have been less successful at increasing LIS enrollees' use of generics

For many therapeutic classes, plan sponsors use cost-sharing differentials along with utilization management tools to encourage generic substitution (a switch from a brand-name drug to the chemically equivalent generic drug) and therapeutic generic substitution (a switch from a brand-name drug to the generic form of a different drug in the same therapeutic class).

Both types of generic substitution have been key strategies of plan sponsors for managing overall growth in Part D spending. The Commission's set of volume-weighted indexes shows that, between January 2006 and December 2012, when generic substitution is taken into account, prices for Part D drugs decreased cumulatively by about 4 percent (Medicare Payment Advisory Commission 2015).[6] However, measured by individual national drug codes, prices rose by an average of 35 percent cumulatively over the same period. This difference suggests that generic substitution has played a key role in keeping down prices for Part D.

Both LIS enrollees and non-LIS enrollees use a greater share of generics than they did at the start of Part D. Still, plan sponsors have had more success at encouraging non-LIS enrollees to use generics than LIS enrollees. Between 2007 and 2012, LIS enrollees had a consistently lower share of prescriptions for generic drugs (generic dispensing rate, or GDR) than did non-LIS enrollees (Table 6-2, p. 150).

Encouraging LIS enrollees to use more generics has been a challenge both for MA–PDs and PDPs. Overall, a higher share of prescriptions filled by MA–PD enrollees are

FIGURE
6–4

National average plan bid for basic Part D benefits
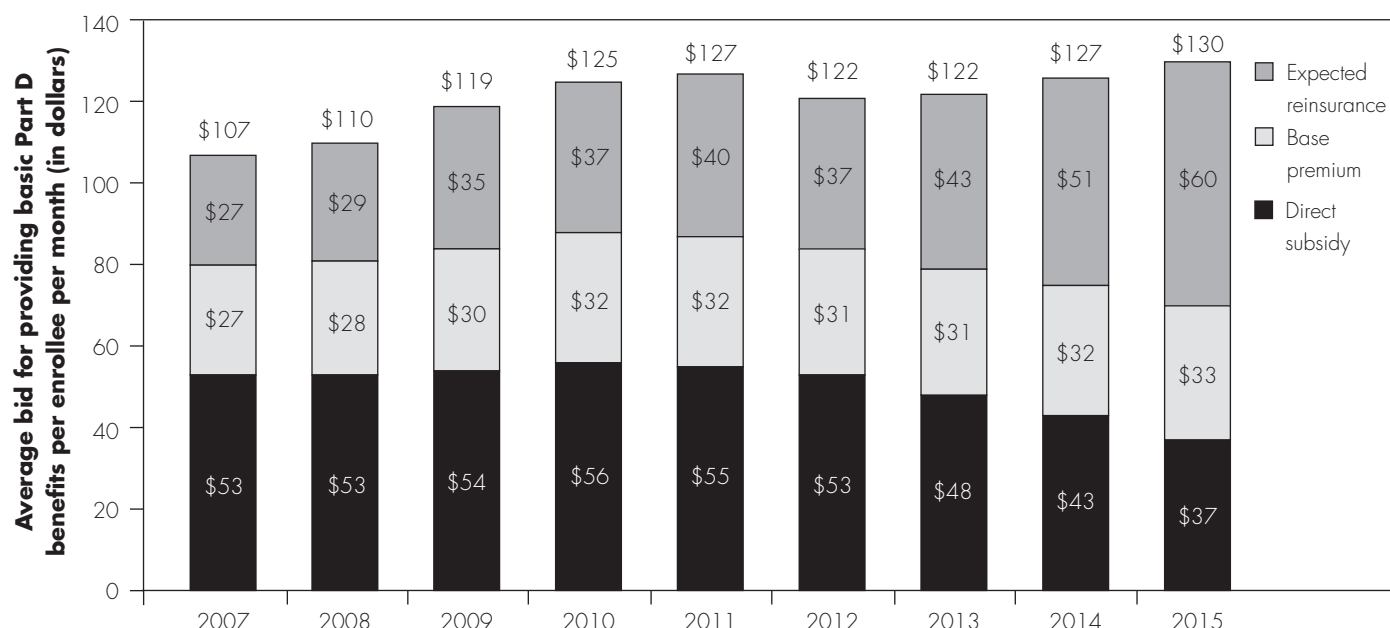
Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with Medicare.

Source: MedPAC analysis based on data from CMS.

for generics compared with prescriptions filled by PDP enrollees. Still, both plan types have been less successful at steering their LIS enrollees to use generic drugs compared with the level of generic use achieved for their non-LIS enrollees. For example, in 2012, the difference in GDRs between non-LIS and LIS enrollees was 3 percentage points and 5 percentage points among enrollees in PDPs and MA–PDs, respectively (Table 6-3).

We observed greater differences in GDRs for some of the most widely used categories of drugs. In 2012, Part D spending on antihyperlipidemics (cholesterol-lowering drugs), peptic ulcer therapies, and diabetic therapies accounted for nearly $20 billion in gross drug spending combined, or about 22 percent of total spending. Table 6-4 shows percentage point differences in GDRs for the three drug classes in 2012. In the therapeutic class of antihyperlipidemics, the GDR for non-LIS enrollees

TABLE
6–2

Generic dispensing rate by LIS status, 2007–2012

	2007	2008	2009	2010	2011	2012
All Part D	61%	67%	70%	74%	77%	81%
By LIS status						
LIS	60	65	68	71	74	78
Non-LIS	62	69	72	76	79	83

Note: LIS (low-income subsidy). Shares are calculated as a percentage of all prescriptions standardized to a 30-day supply. "Generic dispensing rate" is defined as the proportion of total prescriptions dispensed that are generic.

Source: MedPAC analysis of Medicare Part D prescription drug event data and Part D denominator file from CMS.

	Generic dispensing rate		Percentage point difference (Non-LIS vs. LIS)
	Non-LIS	**LIS**	
PDP enrollees	81%	78%	**3**
MA–PD enrollees	85	80	**5**
Percentage point difference (PDP vs. MA–PD)	**–4**	**–2**	

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Shares are calculated as a percentage of all prescriptions standardized to a 30-day supply. "Generic dispensing rate" is defined as the proportion of total prescriptions dispensed that are generic.

Source: MedPAC analysis of Medicare Part D prescription drug event data and Part D denominator file from CMS.

exceeded that of LIS enrollees by 6 percentage points and 7 percentage points among PDP and MA–PD enrollees, respectively. For peptic ulcer therapies, the differences in GDRs were 8 percentage points for PDP enrollees and 9 percentage points for MA–PD enrollees. Among prescriptions filled for diabetic therapies, the difference in GDRs between non-LIS and LIS enrollees was 13 percentage points for both PDP and MA–PD plan types.

Although generic substitution is not clinically appropriate in every circumstance, the financial implications of not using generic medications when appropriate can be substantial. Among beneficiaries enrolled in PDPs, the difference in the average cost per prescription between LIS and non-LIS enrollees ranged

from $8 for antihyperlipidemics to $27 for diabetic therapy (Table 6-4).

Multiple factors contribute to differences in GDRs among groups of beneficiaries. For example, differences in health status can limit the opportunity for clinically appropriate therapeutic substitutions. Since LIS enrollees are more likely to be disabled and tend to have a greater disease burden than non-LIS enrollees, they may have different medication needs. At the same time, because the amount and structure of copayments are set by law, plan sponsors have limited ability to use financial incentives to move LIS enrollees toward generic drugs. Some of the difference in GDRs is likely due to the cost-sharing subsidy that changes the financial incentives faced by LIS enrollees from those faced by non-LIS enrollees.

| TABLE 6–4 | Differences in average cost per prescription between LIS and non-LIS enrollees for selected therapeutic classes, 2012 |

	PDP				MA–PD			
		Average cost per prescription				Average cost per prescription		
	Percentage point difference in GDR	**LIS**	**Non-LIS**	**Dollar difference**	**Percentage point difference in GDR**	**LIS**	**Non-LIS**	**Dollar difference**
Antihyperlipidemics	6	$56	$48	$8	7	$46	$34	$12
Peptic ulcer therapy	8	57	42	15	9	45	28	16
Diabetic therapy	13	105	78	27	13	94	64	30

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), GDR (generic dispensing rate). Prescriptions are standardized to a 30-day supply. GDR is the proportion of total prescriptions dispensed that are generic.

Source: MedPAC analysis of Medicare Part D prescription drug event data and Part D denominator file from CMS.

TABLE
6–5

Amounts paid by Medicare to Part D plan sponsors resulting from payment reconciliations

Amounts in millions of dollars by benefit year

Reconciliation category	2006	2007	2008	2009	2010	2011	2012	2013
Low-income cost sharing	$90	$471	$1,250	$379	$332	$342	$633	$1,559
Individual reinsurance	–1,537	247	1,219	–64	549	1,547	3,182	4,915
Risk corridors*	–2,590	–654	–82	–783	–713	–721	–1,105	–737
Total	–$4,049	$52	$2,342	–$485	$151	$1,168	$2,710	$5,736

Note: Negative amounts reflect aggregate payments to Medicare from plan sponsors. Totals for the years 2006 through 2010 include amounts for reinsurance
demonstrations.
*Excludes amounts for Humana Limited Income Net contract.

Source: MedPAC analysis based on plan payment data from CMS.

Reconciling prospective payments with actual spending

Part D plans receive several types of prospective payments from Medicare:

- direct subsidies (modified by risk adjusters) that lower premiums for all plan enrollees,

- an average amount of individual reinsurance based on how much a plan sponsor expects the benefit spending of its enrollees to exceed the catastrophic threshold, and

- an average amount of cost sharing that the plan sponsor expects LIS enrollees will incur.[7]

Each prospective payment category is based on the bids that plan sponsors submit to CMS seven months before the start of the benefit year.

Six months after the end of each benefit year, CMS begins a reconciliation process—a comparison of prospective payments from Medicare with the actual benefit costs that plans paid. CMS and sponsors go through the following sequence of reconciliation steps:

- Review actual levels of enrollment and risk scores to reconcile the amounts of direct subsidy that plans should have received.

- Review drug claims for LIS enrollees to compare what plans should have received for low-income cost sharing through prospective payments.

- In the case of enhanced plans, estimate the amount of benefit spending associated with coverage that is more generous than basic benefits to remove that amount from the calculations.[8]

- Review drug claims to determine actual levels of drug spending net of rebates and discounts to reconcile prospective individual reinsurance with actual payments due.

- Calculate risk corridor payments as the last step of the reconciliation process.

The first steps in this sequence pertain to cash flows; in particular, they involve reconciling Medicare's prospective payments to plans with actual spending. The final step of calculating risk corridors directly affects how much of those payments sponsors may keep to offset plan losses or to augment profits beyond those already included in plan bids.

Table 6-5 shows aggregate reconciliation payments between 2006 and 2013. Positive amounts indicate that Medicare paid more to sponsors on net, while negative amounts indicate that in the aggregate, plan sponsors returned a portion of overpayments to Medicare. (Throughout this chapter, we use the term *overpayments* to

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TABLE
6–6

Flow of individual reinsurance payments, 2006–2013

Percent of parent organizations

	2006	2007	2008	2009	2010	2011	2012	2013
Sponsor paid Medicare	76%	58%	38%	50%	42%	36%	36%	32%
Medicare paid sponsor	21	40	59	49	58	64	64	68
No payments	4	2	3	1	0	0	0	0
Total	100	100	100	100	100	100	100	100

Note: Reinsurance payments are made at the plan level. Calculations for this table are based on the sum of reinsurance payments across all plans offered by the same parent organization. The shaded row shows that over time, an increasing share of parent organizations has received additional payments from Medicare Part D at reconciliation because amounts due based on actual claims experience were higher than prospective payments (that were based on plans' bids). Columns may not sum to 100 percent due to rounding.

Source: MedPAC analysis based on plan payment data from CMS.

refer to the differences by which some plans' prospective payments exceeded actual benefit costs.)

Individual reinsurance

In recent years, reconciliation payments for reinsurance show a pattern: Bids from plan sponsors have tended to underestimate spending above the catastrophic threshold. In 2008 and in 2010 through 2013, a majority of parent organizations received money from Medicare because their prospective payments for reinsurance were too low (Table 6-6). Since 2009, the share of plan sponsors receiving additional reinsurance payments from Medicare has increased.

This pattern means that plan sponsors missed out on some of the prospective payments that ultimately were due to them for reinsurance, potentially limiting their cash flow. However, underestimating catastrophic spending may provide a financial advantage to plan sponsors: They may be able to charge lower premiums to enrollees and later get reimbursed for 80 percent of actual catastrophic claims through additional reinsurance from Medicare at reconciliation.

The pattern of underestimating reinsurance was not so evident in the early years of the Part D program. Table 6-7 (p. 154) shows the sponsors of plans that are among those with the largest Part D enrollment. The gray-shaded values show payments from plan sponsors to Medicare, while the unshaded amounts reflect payments from Medicare to plan sponsors. Many of the largest sponsors had to return

reinsurance overpayments to Medicare in 2006 and 2007, but by 2011, nearly all of the large sponsors received reconciliation payments from Medicare.

Risk corridors

Once CMS completes reconciliation of individual reinsurance, it determines whether any risk corridor payments are due by comparing plans' bids for basic benefits with actual spending. In each year between 2006 and 2013, most plan sponsors returned a portion of overpayments to Medicare because of the risk corridors (Table 6-8, p. 154). In other words, plan sponsors had profits beyond the margins already included in their bids. Since 2008, the share of parent organizations returning a portion of overpayments has increased. Between 2009 and 2013, about three-fourths of parent organizations made risk corridor payments to Medicare because their reconciled benefit costs were at least 5 percent lower than their bids. Detailed data show that most parent organizations had actual costs beyond the second risk corridor threshold (data not shown).[9]

This pattern of risk corridor payments means that plan sponsors made substantially more in profits beyond the margins that were already built into their bids. If risk corridors had not been in place, profits would have been even larger. Aggregate reimbursements through the risk corridors were at their highest in 2006 ($2.6 billion), when plan sponsors had little information on which to base bids (Table 6-5). Yet sponsors were still, in the aggregate,

TABLE
6–7

**Reconciliation payments for individual reinsurance from Medicare
to Part D plan sponsors with the largest enrollment, 2006–2013**

Amounts in millions of dollars by benefit year

Parent organization	2006	2007	2008	2009	2010	2011	2012	2013
UnitedHealth Group	–$765	–$99	$84	$51	–$255	$54	$335	$912
Humana	–180	–148	325	–290	–46	293	469	541
CVS Caremark	45	–32	139	141	166	285	544	1,013
Universal American	–17	110	313	62	184	5	3	10
Health Net	75	22	19	–2	25	92	15	21
Medco	–10	–29	39	1	130	46	N/A	N/A
Express Scripts	N/A	*	1	1	3	6	456	927
Aetna	8	20	6	35	66	75	180	147
Coventry	–278	41	–39	–132	–19	111	262	163
CIGNA	64	54	60	17	10	–15	170	194
HealthSpring/NewQuest	–39	–40	14	–9	29	133	N/A	N/A
WellCare	–116	39	77	12	30	127	93	18
Munich American/Sterling	1	–3	–11	10	6	15	21	34
Windsor	–4	–2	–20	–1	5	N/A	N/A	N/A
Kaiser	–19	–23	1	10	3	21	19	88
WellPoint	28	–44	32	–90	9	28	62	74
Subtotal for the above parent organizations	–$1,207	–$134	$1,042	–$182	$346	$1,274	$2,629	$4,142
Total reconciliation payments for all parent organizations	–$1,537	$247	$1,219	–$64	$549	$1,547	$3,182	$4,915

Note: N/A (not applicable). Data may be "not applicable" typically because the organization had not yet entered the market or because it merged with or was acquired by another organization. Shaded amounts reflect years in which the plan sponsor paid Medicare. Reinsurance payments are made at the plan level. This table aggregates payments across all plans offered by the same parent organization. Columns may not sum to stated total.
*Less than $0.5 million.

Source: MedPAC analysis based on plan payment data from CMS.

TABLE
6–8

Flow of risk corridor payments, 2006–2013

Share of parent organizations

	2006	2007	2008	2009	2010	2011	2012	2013
Sponsor paid Medicare	86%	71%	60%	72%	74%	77%	78%	78%
Medicare paid sponsor	9	24	30	19	15	16	16	14
No payments	5	5	10	8	11	7	6	8
Total	100	100	100	100	100	100	100	100

Note: Risk corridor payments are made at the plan level. This table aggregates risk corridor payments across all plans offered by the same parent organization. The shaded row shows that, after 2009, about three-quarters of parent organizations returned overpayments to Medicare Part D at reconciliation because the actual benefits that plans paid were considerably lower than prospective payments. Columns may not sum to 100 percent due to rounding.

Source: MedPAC analysis based on plan payment data from CMS.

TABLE 6–9

TABLE 6–9   Risk corridor payments for plan sponsors with the largest enrollment, 2006–2013

Amounts in millions of dollars by benefit year

Parent organization	2006	2007	2008	2009	2010	2011	2012	2013
UnitedHealth Group	–$618	–$200	–$43	–$275	–$262	–$169	–$467	–$250
Humana*	–712	–107	49	–183	–177	–105	–186	–28
CVS Caremark	–67	–44	46	2	24	–126	–127	–261
Universal American	–91	–26	8	–44	–32	–5	–7	**
Health Net	–45	–14	–3	–36	–9	–3	–1	**
Medco	**	–7	4	7	6	N/A	N/A	N/A
Express Scripts	N/A	**	0	0	0	0	–2	–1
Aetna	–40	–4	–6	2	7	–14	9	–3
Coventry	–80	–70	–35	–4	–46	–8	1	56
CIGNA	–8	40	13	–2	–2	–5	–65	–75
HealthSpring/NewQuest	–34	–25	–3	–3	–7	–25	N/A	N/A
WellCare	–104	–54	14	–5	–40	–85	–63	–38
Munich American/Sterling	**	–1	5	2	**	**	–2	–5
Windsor	–1	–1	–3	–2	–4	N/A	N/A	N/A
Kaiser	–63	–11	–29	–10	–14	–14	–11	–12
WellPoint	–126	–73	–28	–70	–39	–9	–45	–16
Subtotal for the above parent organizations	–$1,988	–$598	–$9	–$620	–$594	–$568	–$966	–$633
Total reconciliation payments for risk corridors for all parent organizations	–$2,590	–$654	–$82	–$783	–$713	–$721	–$1,105	–$737

Note: N/A (not applicable). Data are typically "not applicable" because the organization had not yet entered the market or because it merged with or was acquired by another organization. Shaded amounts reflect years in which the plan sponsor paid Medicare. Risk corridor payments are made at the plan level. This table aggregates payments across all plans offered by the same parent organization. Columns may not sum to stated total.
*Excludes Humana Limited Income Net program.
**Less than plus or minus $0.5 million.

Source: MedPAC analysis based on plan payment data from CMS.

making $700 million to more than $1 billion in risk corridor payments to Medicare each year since 2009.

Plan sponsors with the largest Part D enrollment have been fairly consistent in returning a portion of overpayments to Medicare each year because of the risk corridors. In Table 6-9, gray-shaded areas show payments from plan sponsors to Medicare, while unshaded amounts reflect payments from Medicare to plan sponsors. Many of the largest plan sponsors made risk corridor payments to Medicare in most of the years between 2006 and 2013.

Feedback from plan actuaries

One might expect the flow of reconciliation payments to vary from year to year—with plan sponsors returning overpayments to Medicare in some years and receiving underpayments from Medicare in other years. Instead, payments have shown fairly regular patterns:

- Many plan sponsors have bid too low on the amount of benefit spending above Part D's catastrophic threshold relative to actual spending, resulting at reconciliation in additional reinsurance payments from Medicare to plans; and

- Plan sponsors have bid too high on the rest of (noncatastrophic) benefit spending relative to actual spending, resulting in risk corridor payments from plans to Medicare.

Does drug spending vary more than medical spending?

Some actuaries interviewed for this analysis suggested that per capita Part D drug spending is inherently more variable than medical spending because of uncertainties about the drugs that will enter the market and their prices. If true, such a factor might lend support to continuing risk-sharing arrangements in Part D.

As a simple test of that hypothesis, we compared the variation over time in combined Part A and Part B fee-for-service (FFS) spending across individual beneficiaries in the United States with the variation in individuals' Part D spending. (We measured variation as the coefficient of variation (CV), or the standard deviation of individuals' spending divided by mean spending) (Table 6-10). (For comparability to the FFS population, we used only enrollees in stand-alone drugs plans.) Mean FFS spending has grown modestly between 2008 and 2012 by an annual average of 1.1 percent. The distribution of FFS spending has remained relatively stable as measured by its CV, growing slightly from 212 percent in 2008 to 217 percent in 2012.

In 2012, Part D spending had nearly the same CV as FFS spending—211 percent compared with 217 percent. However, the distribution of Part D spending has changed dramatically over time. Mean spending grew by 1.9 percent between 2008 and 2012, and median spending fell as enrollees began using more generic drugs. As measured by its CV, Part D's spending distribution widened significantly between 2008 and 2012—from 155 percent to 211 percent. Spending levels at the top end of the distribution (the 99th percentile) grew at a faster pace than spending for FFS Part A and Part B services. ∎

TABLE 6-10

Coefficient of variation for Part D spending per beneficiary has grown while that for FFS Part A and Part B spending has remained the same

	FFS Part A and Part B			Part D (PDPs)		
	2008	**2012**	**Annual average change**	**2008**	**2012**	**Annual average change**
Population size (in millions)	32.3	34.0	1.3%	15.9	18.3	3.5%
Mean spending	$10,584	$11,057	1.1	$3,013	$3,248	1.9
Median spending	2,695	2,765	0.6	1,814	1,531	–4.1
Standard deviation	22,474	24,029	1.7	4,664	6,840	10.0
Coefficient of variation (in percent)	212%	217%	0.6	155%	211%	8.0
Spending at the 99th percentile	105,336	113,762	1.9	20,801	27,758	7.5

Note: FFS (fee-for-service), PDP (prescription drug plan). Coefficient of variation is the standard deviation divided by the mean. The values include beneficiary cost sharing as well as covered benefit spending. Values include enrollees who had no claims. The shaded row shows that while the coefficient of variation of the sum of each FFS beneficiary's Part A and Part B spending has remained stable over time, the coefficient of variation of enrollees in stand-alone Part D plans has grown.

Source: MedPAC analysis based on Master Beneficiary Summary File data and prescription drug event claims.

These patterns have persisted over several years even though CMS reviews each bid submission closely for inaccuracies.[10] To better understand these patterns, Commission staff conducted interviews with actuaries from nine organizations who have detailed knowledge about developing Part D bids.

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Timing of bid development and key uncertainties

Plan sponsors submit their bids each June—seven months before the start of the benefit year for which the bid is prepared. As part of their bids, sponsors provide information to CMS about their expected number of enrollees, how many will receive the LIS, the average cost of benefits net of rebates and discounts from drug manufacturers and pharmacies, and how much the plan expects to receive in individual reinsurance from Medicare. CMS uses this information to set prospective payments to plans.

The actuaries we spoke with all described difficulty in making key assumptions that affect drug benefit spending so far in advance. Many of the interviewees believed that drug spending is more difficult to predict than medical spending (see text box). They attributed this difficulty to unknown timing in the entry of new drugs into the market (including new specialty drugs, but also new generics whose entries are sometimes delayed) and to uncertainty about price inflation for brand-name drugs and changes in utilization. According to our interviewees, sponsors tend to "lock down" many assumptions in May before bids are due in June. Those assumptions include which drugs will enter the market and at what price; the amount of rebates and discounts that pharmaceutical manufacturers and pharmacies will provide; and trends in the price growth, utilization levels, and mix of drugs used by enrollees.

Homogeneous assumptions about spending growth

The key uncertainties and timing of the bid process reflect how difficult actuaries believe it is to bid accurately. Still, those factors do not by themselves explain the systematic patterns of payments we observed. Several interviewees' remarks regarding how plans develop their spending projections may help explain the patterns. In the process of developing bids, some sponsors use "smooth," homogeneous assumptions about trend. *Trend* refers to growth in monthly spending per enrollee associated with price inflation, changes in numbers of prescriptions filled, and changes in the mix of medications used. Sponsor actuaries must submit historical data on their plan's Part D spending, along with assumptions about future spending trends, to support their bids. Plan sponsors that project a smooth trend across all spending assume that expenditures by members who are at the lower end of their plan's spending distribution will grow at the same rate as individuals at the upper end.

However, a homogeneous trend assumption—the same projected spending growth for those at the lower and upper ends of the spending distribution—may not be appropriate. Several interviewees noted that low-spending enrollees tend to use more generic medications with relatively lower price inflation, while high-spending enrollees tend to use more brand-name and specialty drugs with higher price growth. This pattern corresponds with a previous Commission analysis of enrollees who reached the catastrophic phase of Part D, which showed that most of their spending was driven by the volume of traditional prescriptions filled and by a tendency to use brand-name medications (Medicare Payment Advisory Commission 2013). For this reason, it might be better to use different sets of trend assumptions for different therapeutic classes or for different categories of enrollees; several of the actuaries we interviewed confirmed that they take this approach. For plan sponsors who use smooth assumptions about trend, that approach might tend to overestimate spending at the lower phases of Part D's benefit structure and underestimate spending above the catastrophic threshold—where Medicare pays for individual reinsurance.

Entrance into the market of high-priced specialty drugs

Most of the actuaries we interviewed said that the entrance in December 2013 of Sovaldi, a new treatment for hepatitis C, was one explanation for underestimating individual reinsurance in Part D bids. However, the pattern of reconciliation payments that we observed predates the market entrance of Sovaldi. At an average wholesale price of $1,000 per pill, or $84,000 per treatment regimen, Sovaldi (and, more recently, other new hepatitis C therapies) appears to be an effective treatment that could be used by a potentially large population of patients. Manufacturers are introducing therapies for other conditions at similar launch prices. Insofar as plan sponsors are unable to predict the timing of FDA approval for marketing those therapies, launch prices, or the extent of use among plan enrollees, the introduction of new high-priced drugs could be one explanation for underestimating individual reinsurance, particularly after 2014.

Manufacturers' rebates

The actuaries with whom we spoke identified manufacturer rebates as another factor that may contribute to underestimation of individual reinsurance in plan bids. Manufacturers provide rebates to plan

sponsors for including their drugs on the plan's formulary or for successfully encouraging plan enrollees to use the manufacturers' medications. According to the CMS Office of the Actuary, rebates from manufacturers reduce spending for brand-name drugs in Part D by 20 percent to 30 percent (Boards of Trustees 2014).

Manufacturers provide price concessions after enrollees have filled prescriptions rather than at the time that the sponsor is developing its bid. CMS calls these types of price concessions *direct and indirect remuneration* (DIR). Another source of DIR is price discounts offered by pharmacies for having "preferred" status in a sponsor's pharmacy network. When a plan sponsor submits its bid, actuaries must net out DIR from gross benefit spending, including spending above Part D's catastrophic threshold.

The magnitude of DIR can be difficult for plan sponsors to predict. For example, one interviewee noted that his firm (a plan sponsor) had an especially contentious relationship with a major pharmaceutical manufacturer over rebates. At the time that bid submissions were due, the actuary believed there was only a fifty-fifty chance that the two sides could reach any agreement. In this situation, he used actuarial standards of practice—a conservative assumption about the magnitude of DIR in the sponsor's bid.

For purposes of netting out rebates from plans' benefit spending during reconciliation, CMS requires plans to allocate DIR proportionately to the total distribution of claims. However, for some brand-name and specialty drugs that do not have therapeutic substitutes, manufacturers are much less likely to give rebates. Thus, plan sponsors are required to apportion DIR evenly across spending, even if this allocation does not reflect how rebates are generated. This approach may contribute to underestimates of spending above Part D's catastrophic threshold. The extent to which sponsors underestimate the magnitude of total rebates in bids may lead them to overstate benefit spending on the noncatastrophic portion of the Part D benefit.

For the future, it would be useful to understand more about the organizational level at which plan sponsors negotiate and allocate rebates—for example, whether by individual Part D plans, by contracts, or for a company's entire book of business. The ways in which plan sponsors allocate rebate dollars across lines of business may provide large plan sponsors with flexibility as they develop bids and determine actual plan costs.

Uncertainty about numbers of LIS enrollees

Several interviewees noted that it can be difficult to estimate the share of their plan's enrollees who receive the LIS. This difficulty occurs because CMS sets benchmarks for the maximum amount that Medicare will pay in monthly premiums on behalf of LIS enrollees, based on the LIS enrollment–weighted average of plan bids. If a plan sponsor misses that benchmark (i.e., comes out of the bidding process with a plan premium higher than the benchmark), the sponsor stands to have its LIS enrollees reassigned by CMS to other benchmark plans.

Because LIS enrollees are much more likely to reach the catastrophic threshold, misestimating a plan's share of members who receive the LIS can also lead to misestimates of catastrophic spending and the amount of individual reinsurance that the plan will receive.

Hypothetical, simplified examples of bids, payments, and reconciliation

Our interviews with actuaries suggest there may be consistent issues in how sponsors prepare bids that lead to the patterns of plan payments we observed. However, the observed patterns may also suggest that Part D's risk-sharing mechanisms provide incentives to bid in certain consistent ways. By tending to underestimate catastrophic spending, plan sponsors may be able to charge lower premiums to enrollees and later get reimbursed for 80 percent of actual catastrophic claims through additional reinsurance from Medicare at reconciliation.

We have constructed hypothetical examples to help explain possible incentives driving sponsors' behavior in developing Part D bids, in view of their effect on payments and reconciliation. For simplicity, we show a single plan rather than multiple competing plans, which Part D uses. Although the example lacks the dynamic market-wide effects that may result from having multiple plans, it may still be useful for understanding the relationship between a plan's bid, payments from Medicare, and the financial implications of reconciliation on the plan's revenue. It can also be viewed as representing the average financial implications for plan sponsors participating in the Part D program as a whole, with the extreme assumption that all plan bids follow the same pattern. As a practical matter, an individual sponsor is only one of many sponsors whose bids collectively affect the amounts that Medicare pays in prospective payments. Still, Medicare's reconciliation

FIGURE
6–5

Hypothetical example of a simplified Part D bid

Total spending per member per month = $120

| 5% enrollee cost sharing ($2.50) | 15% plan-covered benefit ($7.50) | 80% Medicare reinsurance ($40) | **$50 above catastrophic limit** |

Catastrophic limit

| 25% enrollee cost sharing ($17.50) | 75% plan-covered benefit ($52.50) | **$70 below catastrophic limit** |

Note: This figure depicts a simplified, hypothetical benefit structure. Part D's actual defined standard benefit structure is shown in Figure 6-2, p. 146.

payments show consistent patterns rather than the randomness one might expect from projection errors in the actuarial assumptions behind bids.

For these examples, we simplified the Part D benefit structure so that there are only two phases of coverage: below and above the catastrophic threshold (Figure 6-5). For spending below the catastrophic threshold, the enrollee pays 25 percent in cost sharing, while the Medicare program covers the remaining 75 percent. The enrollee's plan is fully at risk in this part of the benefit. For spending above the threshold, the enrollee must pay 5 percent cost sharing, while Medicare and the plan cover the remaining 95 percent. Individual reinsurance, paid for by Medicare, covers 80 percent of the cost above the catastrophic threshold, while the plan is at risk for 15 percent of the cost.

A hypothetical plan bid

The bid reflects the plan sponsor's estimate of per member per month (PMPM) costs of providing benefits to an enrollee of average health. When developing the bid, plan sponsors must determine how much of that total PMPM spending will be above the catastrophic threshold (where Medicare picks up 80 percent of the cost) versus below the catastrophic threshold (where plans bear more of the insurance risk).

In this hypothetical example, the plan sponsor bids $52.50 as the cost of providing benefits below the catastrophic limit, $7.50 for benefits above the catastrophic limit, and $40 as its prospective payment for individual reinsurance (Figure 6-5). To estimate these costs, the plan first estimates the benefit's total cost ($120 PMPM) and, of that total, estimates that $50 would be above and $70 below the catastrophic limit.

Medicare program's spending for this example consists of three parts (Figure 6-6, p. 160): 15 percent of plan-covered benefit above the catastrophic limit ($7.50); 75 percent of plan-covered benefit below the catastrophic limit ($52.50); and 80 percent individual reinsurance ($40). The total cost of providing the benefit is $100 ($7.50 + $52.50 + $40.00). (The beneficiary pays $20 of the $120 in total benefit spending through cost sharing: $2.50 + $17.50.) Assuming this bid is from an average plan, Medicare's subsidy covers 74.5 percent of benefit costs and enrollees pay the remaining 25.5 percent in monthly premiums. In this example, the beneficiary premium is $25.50, while Medicare's premium subsidy covers $40.00 in expected reinsurance and $34.50 of the plan's covered benefits as the direct subsidy.

Risk corridors

For this example, we use a simplified risk corridor with just one threshold of payments set at plus or minus 10

FIGURE
6–6

Covered benefits in our hypothetical example

Covered benefit financed by enrollee premium (25.5%) and Medicare's subsidy (74.5%)

| 15% plan-covered benefit ($7.50) | + | 75% plan-covered benefit ($52.50) | + | 80% Medicare reinsurance ($40) | = $100 |
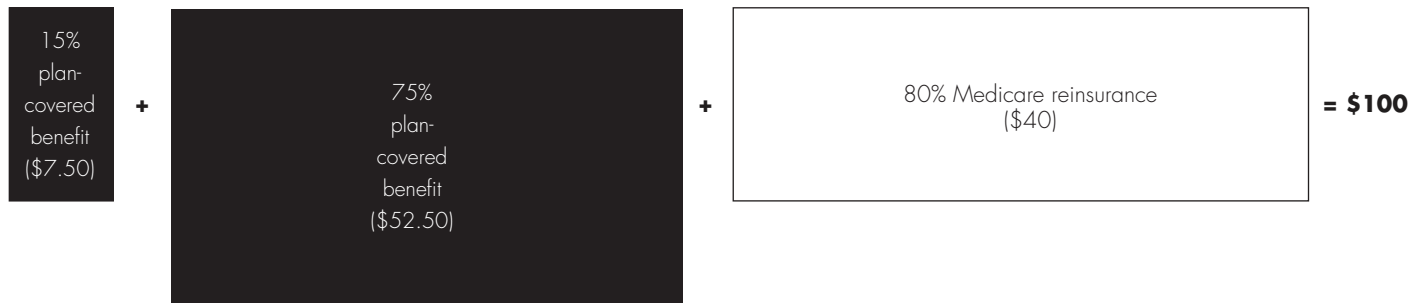
Beneficiary premium = 25.5% x $100 = $25.50 per month
Medicare subsidy = 74.5% x $100 = $74.50 per month ($40.00 in prospective reinsurance and $34.50 direct subsidy)
(**Beneficiary cost sharing =** $17.50 + $2.50 = $20.00 per month)

Note: This figure depicts covered benefits in a simplified, hypothetical benefit structure. Part D's actual defined standard benefit structure is shown in Figure 6-2, p. 146.

percent of the plan's bid. If actual costs for benefits (net of rebates and discounts) are beyond these limits (90 percent or less of the plan's bid or 110 percent or more of the plan's bid), then the sponsor and Medicare split the plan's profits or losses fifty-fifty. That is, the plan is fully at risk for up to 10 percent above (profit) or below (loss) its bid. These hypothetical risk corridors operate more simply than Part D's actual risk corridors, in which Medicare shares profits or losses beginning at 95 percent and 105 percent of the plan's bid (Figure 6-3, p. 147).

Reinsurance

Although the plan receives a monthly prospective payment for individual reinsurance based on what it assumed in its bid about the amount of spending above the catastrophic threshold ($40), CMS later reconciles prospective payments with actual spending. If the sponsor overestimates its plan's prospective payments for individual reinsurance in its bid, then the sponsor has to repay Medicare, and if it underestimates individual reinsurance, then Medicare pays back the sponsor.

Interaction between reinsurance and risk corridors

When bids are submitted to CMS, one of the key pieces of information that plan sponsors provide is how much of the total benefit spending will be above the catastrophic threshold (where Medicare pays for 80 percent of costs) versus below the catastrophic threshold (where the plan

bears more of the insurance risk). If a sponsor were to underestimate spending above the catastrophic threshold, it would have offsetting effects:

- The plan's cash flow would be lower, since Medicare's prospective payments for reinsurance would be less than actual reinsurance costs.

- There would be a loss of 15 percent of the underestimated amount for which the plan is liable above the catastrophic threshold.

- However, Medicare would pay the plan fully for 80 percent of actual costs above the catastrophic threshold at reconciliation.

- Enrollee premiums would be lower than otherwise.

Given these pros and cons, it is not immediately apparent how Part D's risk-sharing mechanisms provide incentives to underestimate catastrophic spending. However, this bidding approach makes more sense when the risk corridors are taken into account.

The risk corridors provide plans with protection from costs that are higher than expected. At the same time, they provide incentives for plan sponsors to keep benefit costs as low as possible relative to bids because sponsors keep some or all of the difference as additional profits (beyond those already included in their bids). Sponsors can achieve

this result by managing their enrollees' drug spending, by bidding conservatively (high) on expected benefit spending, or some combination of both.

A disadvantage of bidding conservatively on benefit costs is that it can lead to higher enrollee premiums. However, higher premium amounts could be offset somewhat by underestimating benefit spending above the catastrophic threshold. As long as the financial advantages of overestimating benefit costs exceed the financial disadvantages of underestimating catastrophic benefits, this approach to bidding makes sense. Further, if other plans are using this bidding approach, a plan that does not bid in this way may be put at competitive disadvantage.

Three cases of reconciled spending

We provide three scenarios for the point at which a plan reconciles payments with CMS to show the ramifications of the bid's development:

- **Case 1:** The plan's estimate of individual reinsurance is lower than actual spending, and Medicare pays the difference to the plan after reconciliation.

- **Case 2:** The plan's estimate of individual reinsurance is higher than actual spending, and the plan pays the difference to Medicare after reconciliation.

- **Case 3:** The plan's estimate of the individual reinsurance is lower than actual spending, and its estimate of the total benefit for which it is at risk is low enough to trigger a risk corridor payment. Medicare pays the difference between expected and actual reinsurance to the plan at the point of reconciliation, and the plan pays Medicare 50 percent of the profit above the 10 percent risk corridor threshold.

Case 1 and Case 3 are similar to actual patterns of Part D payments that we observed because, in both scenarios, the plan has underestimated individual reinsurance in its bid compared with actual spending. We offer Case 2 to illustrate why it is financially advantageous to plan sponsors to follow the approach in Case 1.

Table 6-11 (p. 163) shows the bid for the hypothetical plan described in Figure 6-5 (p. 159) and Figure 6-6. Of the $120 PMPM in total drug spending, the plan expects the Part D benefit will cover $100, with the plan at full risk for $60 of that $100 and the remaining $40 to be paid for by Medicare in individual reinsurance. The monthly premium for the beneficiary is $25.50, and Medicare's

premium subsidy (the combination of the direct subsidy and individual reinsurance) pays for the remaining $74.50.

In Case 1, the plan's estimate of the total cost was correct in its bid ($120), but actual spending below the catastrophic limit was lower than the amount assumed in the bid ($60 instead of $70), and spending above the catastrophic limit was higher than the amount assumed in the bid ($60 instead of $50). As a result, actual costs for the portion of the benefit on which the plan was at risk were lower ($54) than the $60 assumed in the bid. Still, the plan's actual costs were within 10 percent of the $60 bid, so risk corridor payments were not triggered and the plan keeps the $6 difference as profit. Higher than expected spending above the catastrophic limit increases the amount of individual reinsurance from $40 to $48. Therefore, Medicare retroactively pays the plan for the difference ($8). In Case 1, if the plan sponsor had known ahead of time what actual spending would be, had bid accordingly, and reflected the average costs of all competing plans, the beneficiary's share of the premiums would have been higher: $26.01 instead of $25.50.

In Case 2, the plan's estimate of the total cost was correct in its bid, but actual spending below the catastrophic limit was higher than what the plan assumed ($80 instead of $70), and spending above the catastrophic limit was lower than the amount in its bid ($40 instead of $50). That is, the actual cost of providing the benefit was lower than the amount assumed in the bid ($98 instead of $100).

As a result, the actual costs for the portion of the benefit on which the plan was at risk were higher ($66) than the $60 assumed in the bid, but within 10 percent of the $60 so that risk corridor payment was not triggered and the plan loses the difference ($6). Lower than expected spending above the catastrophic limit reduces the amount from $40 to $32 for the individual reinsurance that the plan is eligible to receive, and the plan pays back Medicare $8 at reconciliation. The plan revenue after reconciliation totals $92 PMPM, $6 lower than the actual cost of providing the benefit ($98).

In Case 3, the plan's estimate of total cost was too high: it bid $120 PMPM, but actual costs were $110 PMPM. Of the $110, actual spending below the catastrophic limit was $50 (far lower than the $70 the plan assumed in its bid), and actual spending above the catastrophic limit was $60 (higher than the $50 in its bid). As a result, actual costs for the portion of the benefit on which the plan was at risk were much lower than what it assumed in its bid: $46.50

instead of $60. Total costs of covered benefits were $94.50 rather than $100.

Because the plan underestimated individual reinsurance in its bids relative to actual catastrophic spending, Medicare pays the plan an additional $8. However, the actual costs of benefits for which the plan was at risk were more than 10 percent lower than its bid, and under the risk corridor policy, it must return 50 percent of its profits above the 10 percent threshold ($3.75 = 0.5 × ((0.9 × $60) – $46.50)). On net, the plan keeps $9.75 in profits because its revenues after reconciliation were $104.25 compared with benefit costs of $94.50.

Case 3 lends particular insight into the real-world patterns of payments we observed. In the example, the plan underestimates spending above the catastrophic limit in its bid: $50 PMPM instead of $60. This leads to an underestimate of the amount of individual reinsurance the plan will receive. As in recent real-world payment patterns, Medicare would pay the plan additional amounts ($8 PMPM) for reinsurance at reconciliation. In addition, in Case 3, the plan's bid overestimates plan-covered benefit spending ($60 PMPM compared with $46.50 PMPM in actual claims experience). This overestimate is large enough to trigger a risk corridor payment to Medicare (–$3.75 PMPM) and is similar to what has happened consistently in the Part D program. This could reflect a situation with conservative assumptions about the degree to which the plan could encourage its enrollees to use generic rather than brand-name drugs or fill their prescriptions at preferred pharmacies. Whether due to difficulty in actuarial estimation or other reasons, by underestimating individual reinsurance in its bid, plan sponsors have been able to keep part of catastrophic benefit spending out of enrollee premiums and receive the full reinsurance amounts due to them at reconciliation. Even though the plan must return some of its profit to Medicare through risk corridors, it still nets a portion of profits.

Potential policy changes to risk sharing

Options exist for refining the design of Part D's risk-sharing mechanisms that might better address today's policy goals for the program. For example, given that Medicare appears to have developed a robust market for stand-alone drug plans, it may be time for the program to emphasize policy approaches that encourage closer management of benefits for high-cost enrollees rather

than policies designed to encourage or sustain plan entry. Optimally, a package of changes would be considered to balance concerns about ensuring beneficiaries' access to appropriate therapies, program cost control, and offsetting sponsors' incentives to engage in selection behavior.

LIS enrollees are not distributed evenly among plans

In the aggregate, about one-third of Part D enrollees receive the LIS and two-thirds do not, but few plans have enrollment that tracks these averages. Plans follow a bimodal distribution: They tend to have either a smaller than average share or a larger than average share of LIS enrollment. Average risk scores of plans correlate very closely with the share of their enrollment that receives the LIS.

This distribution of plans has been consistent over time and can be explained by both program design and sponsor behavior. By design, some plans offer enhanced benefits (higher average benefit value than the basic benefit), but LIS enrollees can be assigned only to plans with basic benefits. Unless an LIS enrollee selects a plan herself, CMS follows a policy of random, automatic assignment among the Part D region's qualifying plans (Medicare Payment Advisory Commission 2015). In some regions, relatively few plans qualify, resulting in sizable numbers of assignees and likely leading to these plans' enrollment of a high proportion of LIS enrollees.

Potential changes to Part D's risk-sharing provisions need to be considered in the context of this market segmentation. For example, changes to risk sharing could adjust the parameters that determine the level of benefit spending at which Medicare begins to pay individual reinsurance or ask private plans to shoulder more of covered benefits above Part D's out-of-pocket threshold. However, policymakers would also want to consider how such measures would affect incentives to attract LIS enrollees and other high-cost enrollees. Today, individuals who receive the LIS tend to be concentrated among plans (primarily PDPs) that have a high overall proportion of LIS enrollment. Without other measures, changes to Part D's individual reinsurance could increase incentives for plan sponsors to avoid high-cost enrollees. It would be important to counter those incentives somewhat by ensuring that Part D's risk adjusters were calibrated to take plans' greater degree of risk into account.

At the same time, if policymakers required Part D plans to shoulder more risk, they would also need to give sponsors greater flexibility to contain costs. Because LIS enrollees

**TABLE
6–11**

Potential effects of risk sharing under three hypothetical scenarios

	Plan bid	Actual claims experience		
		Case 1	Case 2	Case 3
Total cost PMPM (cost sharing and covered benefit)				
Below catastrophic limit	$70	$60	$80	$50
Above catastrophic limit	$50	$60	$40	$60
Total	$120	$120	$120	$110
Part D–covered benefit				
Plan-covered benefit				
Below catastrophic limit (75%)	$52.50	$45.00	$60.00	$37.50
Above catastrophic limit (15%)	$7.50	$9.00	$6.00	$9.00
Subtotal, plan-covered benefit	$60.00	$54.00	$66.00	$46.50
Medicare reinsurance				
Above catastrophic limit (80%)	$40.00	$48.00	$32.00	$48.00
Total expected/actual benefit costs	**$100.00**	**$102.00**	**$98.00**	**$94.50**

	Premium based on bids	What premiums would have been, using actual spending		
Plan premium				
Beneficiary share (25.5%)	$25.50	$26.01	$24.99	$24.10
Medicare premium subsidy (74.5%)				
Direct subsidy	$34.50	$27.99	$41.01	$22.40
Individual reinsurance	$40.00	$48.00	$32.00	$48.00
Subtotal	$74.50	$75.99	$73.01	$70.40
Total plan revenue PMPM before reconciliation	$100.00			
Reconciliation				
Risk corridor payment		$0	$0	–$3.75
Individual reinsurance		$8.00	–$8.00	$8.00
Plan revenue after reconciliation				
Beneficiary premium		$25.50	$25.50	$25.50
Medicare premium subsidy				
Direct subsidy		$34.50	$34.50	$30.75
Individual reinsurance		$48.00	$32.00	$48.00
Total		**$108.00**	**$92.00**	**$104.25**
Plan revenue minus benefit costs		**$6.00**	**–$6.00**	**$9.75**

Note: PMPM (per member per month).

incur a disproportionate share of catastrophic benefits, it would be especially important to consider changes in LIS policy. Copayment amounts for LIS enrollees are set by law, and plans cannot use differential copayments for preferred medicines and pharmacies as they do for non-LIS enrollees. For this reason, the Commission has recommended that the Congress give the Secretary authority to provide stronger financial incentives to use lower cost generics when they are available (Medicare Payment Advisory Commission 2012).

Reduce Medicare's individual reinsurance payments to plans

By law, Medicare subsidizes 74.5 percent of the expected cost of basic drug benefits, with enrollees paying the remainder through premiums.[11] Medicare's 74.5 percent subsidy is made up of two components: monthly direct subsidy payments and expected individual reinsurance payments to plans, with Medicare paying the latter mechanism by covering 80 percent of catastrophic spending. One option to reduce these payments would be to keep Medicare's overall subsidy at 74.5 percent of expected costs, but change the structure of individual reinsurance so that plans include more of the costs of catastrophic spending in their covered benefits.

Discussions with plan executives and academic economists confirmed that Medicare's 80 percent reinsurance subsidy likely takes away the urgency for sponsors to manage prescription use among high-cost enrollees. One commenter pointed out that the rebates sponsors receive from manufacturers for all brand-name drugs dispensed to enrollees who reach Part D's catastrophic threshold (including rebates in the coverage gap phase) can more than offset plans' 15 percent share of payments for spending that exceeds the Part D catastrophic threshold. Thus, requiring plans to pay a share larger than 15 percent could provide greater incentive for sponsors to negotiate larger rebates with manufacturers or design formularies in ways that encourage greater use of lower cost drugs.

Policymakers could increase the amount of risk that plans are subject to above the catastrophic threshold to equal that for the benefit during the initial coverage phase. For example, instead of the current 80 percent individual reinsurance provided by Medicare, plans could be at risk for 75 percent of the spending above the catastrophic threshold, and Medicare's individual reinsurance would be reduced to 20 percent. Enrollee cost sharing would continue to be 5 percent of spending above the catastrophic threshold.

Table 6-12 shows that, in our hypothetical example, plans under this option would receive $10 per month in individual reinsurance instead of $40 per month, increasing plan-covered benefits from $60 to $90 per month. Medicare's overall subsidy would remain at 74.5 percent, keeping average enrollee premiums at $25.50 per month (assuming no behavioral changes that would affect the costs of providing the benefit). However, the makeup of Medicare's subsidy would change: Plan sponsors would receive the lower amount of individual reinsurance

and a larger monthly direct subsidy payment ($64.50 per month rather than $34.50 per month). Because more of Medicare's subsidy would take the form of a capitated payment rather than an open-ended individual reinsurance reconciliation payment made at the end of the year, plan sponsors would be at risk for more of covered benefits than they are today, providing a stronger incentive to manage drug spending.

Such an approach would temper but not eliminate incentives to bid in a financially advantageous way. The same incentives apply here as in Cases 1 and 3 (Table 6-11, p. 163): If a sponsor underestimates catastrophic spending, the plan could still receive a higher direct subsidy and have a somewhat lower premium than it would otherwise. Medicare would still make the plan whole for the actual costs of individual reinsurance (20 percent of the spending above the catastrophic threshold) at reconciliation. However, since the plan would be at risk for significantly more covered-benefit spending, the financial advantage of bidding in this way would be smaller.

Other approaches could be used to lower Medicare's individual reinsurance. Policymakers could raise the catastrophic threshold at which Medicare pays individual reinsurance.[12] Medicare could pay plans individual reinsurance that is below today's 80 percent rate but higher than the 20 percent used in the example above. Or policymakers could eliminate Medicare's individual reinsurance altogether; plan sponsors could choose to purchase private reinsurance if needed. All of these options would increase the risk that sponsors bear, which, in turn, would give greater incentive to manage enrollees' drug spending.

Although we assumed no behavioral change in our hypothetical example, assuming greater risk for high-spending enrollees would likely require plans to reevaluate their overall strategy. For example, plan sponsors could expend greater effort to manage drug use and spending, which could lower the costs of providing the benefit. Other behavioral changes could result in higher costs of providing the benefit. For example, because they would be bearing more risk, plan sponsors might build in a risk premium or decide to purchase private reinsurance to protect themselves from large losses (and the cost of the private reinsurance would be reflected in a higher bid). Thus, the net effect on benefit costs and the premiums enrollees pay would depend on how sponsors responded and on the specific parameters and combinations of policy changes.

TABLE
6–12

Alternative approach to Medicare's individual reinsurance

Part D–covered benefit	Current structure: Medicare individual reinsurance at 80 percent	Option: Medicare individual reinsurance at 20 percent
Medicare reinsurance above catastrophic limit	$40.00	$10.00
Benefits covered by the plan		
Below catastrophic limit	$52.50	$52.50
Above catastrophic limit	$7.50	$37.50
Subtotal, plan-covered benefits	$60.00	$90.00
Total benefit costs	$100.00	$100.00
Enrollee share (25.5%)	$25.50	$25.50
Medicare subsidy (74.5%)		
Direct subsidy	$34.50	$64.50
Individual reinsurance	$40.00	$10.00
Subtotal, Medicare subsidy	$74.50	$74.50
Plan total revenue	$100.00	$100.00

Note: The option example presented assumes no behavioral changes that would affect benefit costs. The "current structure" column is consistent with the "plan bid" column shown in Table 6-11 on p. 163.

Change Part D's risk corridors

A different approach to Part D risk sharing would involve making changes to the current risk corridor structure so that sponsors bear more of the aggregate risk for the benefit spending of all plan enrollees. For example, the corridors could be widened: Unlike today's corridors in which sponsors cover all costs (or keep all extra profits) until actual plan benefits reach 105 percent (95 percent) of plan bids, sponsors could cover all costs (or keep all profits) up to 110 percent (90 percent) of their bids. Alternatively, Medicare could eliminate the corridors altogether, making Part D plans operate similarly to Medicare Advantage plans.[13] These options are based on the notion that by exposing plan sponsors to greater risk, they would have stronger incentives to manage benefit spending.

In discussions with Commission staff, plan executives and academic economists thought that removing the risk corridors would not substantially affect sponsors' decisions about whether to stay in the market. The consensus was weaker regarding the effects of removing the risk corridors on sponsors' incentives to contain costs. In theory, risk corridors reduce the insurance risk sponsors face by limiting potential profits or losses. However, because of the interaction between spending subject to

risk corridors and spending that is paid for by Medicare through individual reinsurance, in reality, the role of risk corridors has been to limit profits that are above those profits that are already built into bids. The absence of corridors (with no other changes to the risk-sharing arrangement) would potentially allow sponsors to keep more profits than they do currently, if they did not change how they bid. However, we do not know how sponsors would bid if the corridors were not in place.

In interviews with plan actuaries knowledgeable about Part D, we asked them whether plan sponsors would bid differently if Medicare no longer provided risk corridors. Most of the actuaries made arguments in favor of retaining corridors. One interviewee contended that without risk corridors, plan sponsors would bid more conservatively than they do today, which would tend to raise premiums. Another interviewee said that although some plan sponsors are large enough to insure themselves against unforeseen risks, smaller sponsors would have to buy private reinsurance, the cost of which could deter entry of new plans. Two interviewees suggested that the presence of Medicare's risk corridors gives plan sponsors room to bid more aggressively (lower) or to try innovations (e.g., provide supplemental benefits during the gap phase) that they would not pursue otherwise. One actuary foresaw competing incentives if risk corridors were removed. On

the one hand, sponsors might bid conservatively (higher); on the other hand, the degree of competition in the Part D marketplace would mean that sponsors would still have strong incentives to bid low.

Given that Medicare has consistently collected a portion of overpayments to plans through Part D's risk corridors, some might argue in favor of narrowing the corridors. For example, Medicare could return to the corridors it used at the start of Part D, sharing profits (or losses) when actual benefits paid are less than 97.5 percent (or 102.5 percent) of bids, followed by another risk-sharing threshold at 95 percent (or 105 percent) of bids (Figure 6-3, p. 147). This option would ensure that plans returned a greater portion of overpayments to Medicare. However, the potential to earn higher profits through the structure of today's corridors may provide general incentives for plans to manage enrollees' drug spending. Narrower corridors could reduce incentives for cost control.

The role of medical loss ratio requirements

Under provisions of the Patient Protection and Affordable Care Act of 2010, Part C and Part D contracts (which often cover a number of specific plans) are subject to minimum medical loss ratio requirements (MLRs). As of 2014, if CMS determines that a Medicare contract's medical claims and quality-improving activities are less than 85 percent of revenues, the sponsor must return to Medicare the amount above 85 percent. A Medicare contract with an MLR lower than 85 percent for three or more consecutive years is subject to enrollment sanctions. If a contract's MLR is lower than 85 percent for five consecutive years, CMS will terminate the contract (Centers for Medicare & Medicaid Services 2013). Because CMS will evaluate MLRs using reconciled payments, it is unclear when MLR information will be made public.

MLR regulations serve a role similar to a one-sided risk corridor in that they limit a plan sponsor's profits. They do not, however, help pay for a drug plan's unforeseen losses. Unlike with risk corridors, in which plan profits are potentially unlimited, the MLR approach aims to set an upper bound on profits. However, costs that count as quality improving are open to interpretation and difficult to monitor. Another issue that could keep MLRs from constraining profits as much as intended is that the rules for calculating MLRs include Medicare's individual reinsurance payments. Thus, a portion of the allowable 15 percent for administrative expense and profits is based on benefit costs on which Medicare bears the risk. Some analysts might argue that, if MLR requirements are

effective at limiting Medicare contract profits, the approach could also reduce plan sponsors' incentives to control costs.

Issues of concern

Overall, options to reduce individual reinsurance and widen or eliminate risk corridors are designed to require Part D plan sponsors to shoulder more risk. Greater risk may provide plan sponsors with stronger incentives to manage benefit spending, but it also raises the question of whether plans could or would be more effective at managing their enrollees' spending than they are today.

Incentive to avoid high-cost enrollees

Another open question is how adjustments to Part D risk sharing would affect the willingness of plan sponsors to enroll high-cost beneficiaries. Policymakers could have particular concerns about coverage for LIS enrollees because such a high proportion of enrollees who reach Part D's catastrophic threshold receive the LIS.

One mechanism to counter the incentive to avoid high-cost enrollees is the RxHCC risk-adjustment system. CMS updates Part D's risk adjusters each year using newer claims information. Less frequently, the agency recalibrates the combinations of diagnoses that RxHCC uses to predict drug benefit spending. If policymakers were to make changes to Part D's risk sharing such that plan sponsors bore more risk (e.g., if Medicare paid less individual reinsurance), CMS might need to recalibrate the RxHCC model or make some actuarial adjustments to it. Over the longer term, claims data would reflect new patterns of benefit spending on which plans bear risk, and CMS would use those claims to update the risk-adjustment model.

Would more risk deter entry of new plan sponsors?

An initial justification for Part D's risk corridors was that it encouraged the creation of a market for stand-alone prescription drug benefits. One might argue that some form of risk protection is still needed to help new sponsors enter a market that is dominated by large insurers. However, a counterargument is that with so many plans available in the Part D marketplace, deterring new entry may be less of a policy priority.

Sponsors' capacity to bear risk and the availability of private reinsurance

If Medicare reduced its risk-sharing subsidies in Part D, could plan sponsors purchase private reinsurance

if needed? To answer this question, Commission staff spoke with actuaries and consultants within the private reinsurance industry.

The respondents noted that, while they have held exploratory talks with a small number of employers and insurers that offer Medicare drug benefits, private reinsurers currently do not have contracts in place. However, it is common for smaller sponsors of Medicare Advantage plans to purchase private reinsurance that covers all medical benefits, sometimes with and sometimes without prescription drug spending. One consulting actuary noted that large insurance companies have sufficient capital and cash flow on hand to set up systems of cross-subsidies among their business lines to reinsure themselves. The interviewee believed that since most of Part D's enrollment is concentrated among large insurers, those companies could incorporate their Part D plans into these self-insurance systems.

The actuaries we spoke with noted that health insurance makes up a smaller proportion of their business today than life and casualty insurance.[14] For that reason, private reinsurers may be less familiar with Part D and the claims experience of its enrollees. However, interviewees thought private reinsurance could be made available to Part D sponsors because the reinsurers would expect no more variation in drug benefit spending than in medical benefits.

When we described the current structure of Medicare's risk-sharing mechanisms, our interviewees told us that they sell similar types of products: specific stop-loss coverage that operates like Medicare's individual reinsurance and aggregate stop-loss coverage that acts as a one-sided risk corridor (insuring against losses). However, the actuaries thought that if private reinsurers were to provide coverage to Part D plan sponsors, their contracts would take forms different from Medicare's subsidies: a higher catastrophic cap and wider risk corridors. Plan sponsors would be unable to offload as much benefit risk through private reinsurance as Medicare now provides. For example, a private contract for specific stop loss might cover only the top 1 percent or 2 percent of enrollees as ranked by spending. (By comparison, in 2012, 8 percent of Part D enrollees reached the catastrophic threshold.) As another example, a private contract for aggregate stop-loss coverage could be effective if a plan's actual benefit costs averaged 110 percent or 115 percent of the plan's bid rather than 105 percent, as in Medicare's corridors. Interviewees said that the premium for such coverage would incorporate administrative costs and profits on

the order of about 20 percent to 25 percent of covered benefits. However, such spending covered by private reinsurance would be considerably smaller than the amount of risk sharing Medicare provides currently.

Could Part D sponsors negotiate better prices?

Medicare introduced the Part D program in 2006—a time when large numbers of brand-name drugs used widely by the beneficiary population had patent protection. More recently, a record number of blockbuster drugs went off patent and generic versions entered the market. As a result, Part D enrollees and other consumers have made dramatic shifts toward generics in the mix of drugs they use. However, fewer patent expirations are on the horizon, and the pipeline of new drugs under development is much more heavily dominated by biologics and specialty drugs. Many stakeholders expect these drugs to have high prices, perhaps in a range similar to new treatments for hepatitis C. Among PBMs, growth in price and use of specialty drugs is now beginning to drive the overall trend in benefit spending and, for the future, poses a big challenge to the Part D program (Medicare Payment Advisory Commission 2015).

One question to consider relates to the growing influence of higher priced specialty drugs. Even if Medicare required plan sponsors to bear more risk in Part D, would sponsors have sufficient market power to negotiate larger price discounts with pharmaceutical manufacturers? For some drug therapies with limited therapeutic substitutes, the answer is likely no. However, for others, even the prospect of potential competing drugs or biosimilars in the development pipeline has given PBMs bargaining leverage. For example, actuaries told us that a few plan sponsors were able to negotiate rebates from pharmaceutical manufacturers for new hepatitis C therapies because competing therapies were reaching the stage of obtaining FDA approval.

A further question is whether the structure of Medicare's risk-sharing subsidies—especially for individual reinsurance—facilitates a climate in which manufacturers are able to charge very high launch prices for certain drugs. Medicare's 80 percent reinsurance subsidy takes away the urgency for sponsors to manage prescription use among high-cost enrollees and might also be a factor influencing the level at which manufacturers set launch prices for new drugs. ∎

Endnotes

1   Part D enrollees may qualify for the low-income subsidy (LIS) if they have low income and assets. Of the 11 million beneficiaries with the LIS in 2014, 7 million were dually eligible for Medicare and Medicaid. Another 4 million qualified for the LIS either because they received benefits through the Medicare Savings Programs or the Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration.

2   For example, Part D sponsors may not make midyear formulary changes (other than formulary additions) without prior approval from CMS.

3   CMS's RxHCC model uses age, sex, disability status, and diagnosis codes to predict the Part D drug benefit spending. The model uses about 5,000 diagnoses and groups them into disease categories based on drugs used to treat those diseases. The version of RxHCC that has been used since 2011 was calibrated using Part D claims data from the early years of the program. Beginning in 2016, CMS will use models that are calibrated from 2012 diagnoses data and 2013 claims data.

4   Beginning in 2011, CMS replaced its single RxHCC model with five sets of model coefficients for long-term institutional enrollees, aged low-income enrollees, aged non-low-income enrollees, disabled low-income enrollees, and disabled non-low-income enrollees (Centers for Medicare & Medicaid Services 2010).

5   The claims data from 2013 that were used for recalibration do not show spending for drugs introduced in later years. CMS actuaries used more recent years of claims as a proxy to estimate what spending for the new drugs would have been if those medicines had been available in 2013.

6   Based on analysis conducted by Acumen LLC for the Commission, the indexes reflect the prices plan sponsors and beneficiaries paid to pharmacies at the point of sale and do not reflect retrospective rebates from manufacturers (Medicare Payment Advisory Commission 2015).

7   Beginning in 2011, Medicare also began providing a prospective payment to sponsors for the 50 percent discount that drug manufacturers provide on brand-name drugs for enrollees who reach the coverage gap. Medicare is later reimbursed for providing this up-front cash flow once sponsors and manufacturers know the actual numbers of enrollees who were eligible to receive the discount.

8   This estimate includes an assumption about how much basic benefit spending is induced by supplemental coverage.

9   In 2006 and 2007, this finding means that costs were 95 percent or less of their bids. In 2008 through 2010, costs for the majority of parent organizations were 90 percent or less of their bids.

10 In the agency's call letter to plan sponsors, CMS notes that sponsors submitting clearly inaccurate bids that fail to meet requirements will receive compliance notices, may receive a corrective action plan, and might not be permitted to revise their bids (Centers for Medicare & Medicaid Services 2015).

11 Medicare's 74.5 percent subsidy is based on expected benefit costs. When compared with actual benefit costs, Medicare's subsidy may be different from (and likely higher than) 74.5 percent.

12 This action could be achieved by extending the "partial" coverage gap phase (scheduled to close by 2020) or by reintroducing a gap in covered benefits.

13 Medicare Advantage plans are not subject to risk corridors. However, if CMS makes a national coverage decision that would permit payment for a new therapy or procedure in traditional Medicare, MA plans may receive additional Medicare payment if they provide those services.

14 They noted there has been an uptick in reinsurance contracts for stop-loss coverage of medical benefits because of the elimination of maximum lifetime benefits after implementation of the Patient Protection and Affordable Care Act of 2010.

References

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2014. *2014 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.* Washington, DC: Boards of Trustees.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Memo to all Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties regarding the announcement of calendar year (CY) 2016 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. April 6. http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. Medicare program; Medical loss ratio requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit programs. Final rule. *Federal Register* 78, no. 100 (May 23): 31284–31313.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. Announcement of calendar year 2011 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter. http://www.cms.gov/MedicareAdvtgSpecRateStat/downloads/announcement2011.pdf.

Congressional Budget Office. 2015. Congressional Budget Office's March 2015 Medicare baseline. https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf.

Duggan, M., P. Healy, and F. S. Morton. 2008. Providing prescription drug coverage to the elderly: America's experiment with Medicare Part D. *Journal of Economic Perspectives* 22, no. 4 (Fall): 69–92.

Hoadley, J., L. Summer, E. Hargrave, et al. 2013. Plan switching by Medicare Part D enrollees. Presentation by staff from Georgetown Health Policy Institute and NORC at the University of Chicago.

Hsu, J., V. Fung, J. Huang, et al. 2010. Fixing flaws in Medicare drug coverage that prompt insurers to avoid low-income patients. *Health Affairs* 29, no. 12 (December): 2335–2343.

Hsu, J., J. Huang, V. Fung, et al. 2009. Distributing $800 billion: An early assessment of Medicare Part D risk adjustment. *Health Affairs* 28, no. 1 (January–February): 215–225.

Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Suzuki, S. 2013. "Do Part D enrollees switch plans?: Prevalence and potential factors affecting their decisions." Unpublished manuscript submitted to *Medical Care Research and Review* on August 28, 2013. Manuscript ID number MCRR–2013–0120–DT.

Hospital short-stay policy issues

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

7-1   The Secretary should:
- direct recovery audit contractors (RACs) to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay,
- modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate,
- ensure that the RAC look-back period is shorter than the Medicare rebilling period for short inpatient stays, and
- withdraw the "two-midnight" rule.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

. . . .

7-2   The Secretary should evaluate establishing a penalty for hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for recovery audit contractor review of short inpatient stays.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

. . . .

7-3   The Congress should revise the skilled nursing facility three-inpatient-day hospital eligibility requirement to allow for up to two outpatient observation days to count toward meeting the criterion.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

. . . .

7-4   The Congress should require acute-care hospitals to notify beneficiaries placed in outpatient observation status that their observation status may affect their financial liability for skilled nursing facility care. The notice should be provided to patients in observation status for more than 24 hours and who are expected to need skilled nursing services. The notice should be timely, allowing patients to consult with their physicians and other health care professionals before discharge planning is complete.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

. . . .

7-5   The Congress should package payment for self-administered drugs provided during outpatient observation on a budget-neutral basis within the hospital outpatient prospective payment system.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Hospital short-stay policy issues

Chapter summary

Since the implementation of the acute hospital inpatient prospective payment system (IPPS), changes in technology and medical practice patterns have substantially shortened hospitals' average inpatient lengths of stay and have allowed many inpatient services to successfully migrate to the outpatient setting. As a result, the issue of whether a patient requires inpatient care or can be treated safely as an outpatient has received increasing attention. Medicare's requirements for medically necessary inpatient admissions give deference to clinicians and providers and thus are open to interpretation. One-day inpatient stays are relatively common in the Medicare program, accounting for over 1 million inpatient admissions (13 percent of the total) in 2012. Because hospitals generally receive higher payments for clinically similar patients served in an inpatient setting compared with an outpatient setting and the services provided are similar, hospitals may have a financial incentive to admit patients.

Medicare recovery audit contractors (RACs) have targeted short inpatient stays in their audit efforts, resulting in denials of these claims on the grounds that the patient's status as an inpatient was not appropriate. Hospitals have appealed many claims denied by RACs, but have expressed concern about the cost of pursuing appeals, large backlogs in the appeals process, and limited options for rebilling denied inpatient claims as outpatient claims. Partly in reaction to the heightened scrutiny of short inpatient stays, hospitals have

In this chapter

- Introduction

- Differences between inpatient admissions and outpatient observation stays

- Medicare's Recovery Audit Contractor Program and claim rebilling policy

- Use of observation services

- Characteristics of hospitals with high rates of one-day inpatient and observation use

- Beneficiary liability tied to observation status

- Hospital short-stay policy options

increased their use of observation status instead of admitting patients. Greater use of outpatient observation stays has caused concern about beneficiaries' financial liability. While Medicare cost sharing for outpatient observation services is typically less than the inpatient deductible, for a subset of beneficiaries, the greater use of outpatient observation status has increased the likelihood that they will not qualify for Medicare coverage of post-acute skilled nursing facility (SNF) services (which requires a preceding three-day hospital inpatient stay). Beneficiaries in observation status may also be liable for hospital charges related to prescription drugs received in the hospital and not covered by the Medicare outpatient prospective payment system (OPPS).

CMS established the "two-midnight rule" in fiscal year 2014 in an effort to clarify admission appropriateness and alleviate concerns about increased use of observation, its impact on beneficiary liability, and hospitals' concerns about RAC audits. This rule provides Medicare auditors with guidance pertaining to how they should review inpatient admissions for patient status determinations. It stipulates that, for stays spanning two or more midnights (including time spent in the inpatient and outpatient settings), RACs should presume these stays are appropriate for the inpatient setting and exempt them from audit. However, RACs can audit these two-midnight stays if a hospital demonstrates aberrant patterns of use. By contrast, stays of less than two midnights remain subject to audit. Hospitals have noted concerns about the two-midnight rule because it conflicts with existing admission criteria deferential to physician judgment, increases the burden associated with physician documentation of inpatient admissions, eliminates many one-day stays, and causes a shift in a large volume of stays between the inpatient and outpatient settings. The two-midnight rule has been controversial, and its enforcement has been delayed by both CMS and the Congress.

The Commission has examined issues related to short stays and, on the basis of this examination, makes recommendations related to the RAC program, a short-stay payment penalty, and beneficiary financial liability.

- **_Reduce payment differences:_** Short inpatient stays have been scrutinized by RACs because Medicare generally pays more for short inpatient stays than for similar outpatient stays, and these inpatient stays are highly profitable. To address the payment difference between these stays, the Commission has explored two of the various payment policy approaches policymakers could consider. Under one approach, Medicare could create—as part of its IPPS—a new set of Medicare severity–diagnosis related groups specifically designed for the one-day hospital stay. Under another approach, Medicare could develop a

site-neutral payment—that is, equalize payments across settings—for similar short inpatient and outpatient stays. These options, each with mixed effects on financial incentives, would involve trade-offs. The Commission has not recommended a specific payment approach but, rather, identifies the advantages and disadvantages of each.

- *The RAC program:* The Commission makes a four-part recommendation to the Secretary to focus the RAC's review on hospitals with the highest rates of short inpatient stays to reduce hospitals' administrative burden, improve the accountability of the RACs for the claims they deny, synchronize the timing of RAC reviews and the hospital rebilling program, and withdraw the entirety of CMS's two-midnight rule.

- *Hospital short-stay payment penalty:* The Commission recommends that the Secretary evaluate a payment penalty on hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for RAC review of short inpatient stays.

- *Beneficiary financial liability:* The Commission makes three recommendations that would protect Medicare beneficiaries from financial vulnerabilities resulting from being placed in observation status.

  - The Commission recommends that the Congress revise the three-inpatient-hospital-day eligibility requirement for SNF admission to allow for up to two outpatient observation days to count toward meeting the criterion.

  - The Commission recommends that the Congress require hospitals to notify beneficiaries placed in outpatient observation status that their observation status may affect their financial liability for SNF care. The notice should be provided to patients in observation status for more than 24 hours and who are expected to need SNF services. The notice should be timely, allowing patients to consult with their physicians and other health care professionals before discharge planning is complete.

  - The Commission recommends that the Congress package payment for self-administered drugs provided during outpatient observation within the hospital OPPS on a budget-neutral basis. ∎

Introduction

As inpatient stays have shortened and some inpatient services have migrated to the outpatient setting, the issue of whether a patient requires inpatient care or could be treated successfully as an outpatient has received increasing attention. The high profitability of one-day stays under the inpatient prospective payment system (IPPS) and the generally lower payment rates for similar care under the outpatient prospective payment system (OPPS) have heightened concern about the appropriateness of inpatient one-day stays. This concern led Medicare's recovery audit contractors (RACs) to focus their audits on inpatient one-day stays, leading to a large number of claims denied on the grounds of inappropriate admission (see text box concerning RACs, p. 182). Hospitals responded by increasing their use of outpatient observation status. The RAC audits and resulting increased use of observation created concerns from both hospitals and beneficiaries. For hospitals, the RAC program increased administrative burden by requiring hospitals to respond to RAC medical records requests and track appeals of claim denials. For beneficiaries, being served in observation status increased their financial responsibility if they were discharged to a skilled nursing facility (SNF) or if they required daily oral medications while they were in the hospital. In response to these concerns, CMS adopted a two-midnight policy in fiscal year 2014. This policy instructed auditors to presume that hospital stays—counting time spent in outpatient and inpatient status—spanning two or more midnights (or stays a physician expected to span two or more midnights) are appropriate for inpatient status and that stays less than two midnights are appropriate for outpatient status (with certain exceptions). The two-midnight policy has been controversial, and its enforcement has been delayed by both CMS and the Congress.

In the fiscal year 2015 IPPS proposed rule, CMS requested comments about a payment policy for short inpatient stays that might replace or supplement the existing two-midnight rule. In particular, CMS solicited comments on how short stays might be defined under such a policy and how the payment rates could be set. In its June 2014 comment letter, the Commission expressed concerns about the potential for the two-midnight rule to address the issues it set out to resolve and stated that the Commission would explore options for a short-stay payment policy and other related policies.

This chapter summarizes the Commission's perspective on issues that brought about the increase in outpatient observation utilization and its general concerns about how Medicare reimburses for and audits short hospital stays. The chapter also makes recommendations related to these issues.

Differences between inpatient admissions and outpatient observation stays

Medicare's criteria for inpatient admissions are deferential to physician judgment, but the difference between these criteria and the criteria for outpatient observation status are often unclear to providers. One-day inpatient stays—those which either cross one midnight or no midnights—are relatively common in the Medicare program.[1] Because Medicare generally pays more for patients who receive similar services in the inpatient setting compared with the outpatient setting, hospitals have a financial incentive to admit patients.

CMS criteria for inpatient admission and outpatient observation status are unclear

CMS's long-standing guidance to physicians, hospitals, and Medicare auditors concerning when Medicare beneficiaries should be admitted to the inpatient setting gives deference to the clinical judgment of the physician. This guidance has historically consisted of a general definition of admission coupled with a loose, time-based definition of how long that care should last. CMS's Medicare Benefit Policy Manual states that admission is a complex medical judgment that can be made only after the physician considers the medical predictability of something adverse happening to the patient, the severity of the patient's condition, the need for and availability of diagnostics, the types of facilities available, hospital by-laws and admissions policies, and the relative appropriateness of treatment in each setting. It also states that physicians responsible for a patient's hospital care "should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis" (Centers for Medicare & Medicaid Services 2014a).

If physicians are not sure whether patients require inpatient care, they can treat beneficiaries as outpatients under observation status. CMS's Policy Manual defines

**TABLE
7–1**

**Average payment-to-cost ratios higher for inpatient
stays with shorter lengths of stay, 2012**

Length of inpatient stay (in days)	Number of discharges	Share of discharges	Payment-to-cost ratio
1	1,189,664	13%	1.55
2	1,527,903	16	1.30
3	1,785,826	19	1.10
4	1,247,603	13	1.03
5	891,372	9	0.96
6	655,007	7	0.89
7	496,658	5	0.84
8 or more	1,640,378	17	0.72

Note: Number of inpatient days reflects the number of midnights the inpatient stay crossed. One-day stays include stays that crossed zero or one midnight. Table includes fee-for-service inpatient prospective payment system hospitals and inpatient cases discharged as deceased but excludes Maryland and critical access hospitals.

Source: Medicare claims data from the 2012 inpatient standard analytic file.

coverable outpatient observation care as short-term treatment furnished while a decision is being made about inpatient admission and states that the decision to move patients out of observation "is usually made in less than 48 hours, often in less than 24 hours, and in exceptional cases in more than 48 hours" (Centers for Medicare & Medicaid Services 2014b).[2] Medicare pays for observation under the OPPS. If certain criteria are met, observation services are packaged with other outpatient services into a payment group in the composite ambulatory payment classification (APC) system used with Medicare's OPPS. Emergency department services are among the most common outpatient services packaged with observation services in APCs. In 2012, qualifying observation stays were paid through one of two different composite APCs, depending on the severity of the case. In addition to payment for the composite observation APC, the hospital also receives payment for other nonpackaged ancillary services included on the claim— for example, higher priced drugs and diagnostic tests such as echocardiograms and imaging.

Medicare pays for observation as a part of the IPPS when a beneficiary's stay includes an inpatient admission. For example, for beneficiaries who enter the hospital through the emergency department, then spend time in outpatient observation status, and then are admitted to the hospital as an inpatient, the hospital will receive a single IPPS payment based on the beneficiary's diagnosis related group. In general, payment for the observation services

and other related outpatient services furnished by the hospital in the three days preceding the day of admission is included in the IPPS payment rate. Beneficiaries who spend time in both observation and inpatient status during a hospital stay may not be able to differentiate the two, and in particular this can lead to confusion for beneficiaries being discharged to a SNF. These beneficiaries are at times surprised to learn that they do not qualify for Medicare SNF coverage because the time they spent in outpatient status—emergency department and observation—does not count toward the SNF eligibility requirement of a three-day inpatient hospital stay (Feng et al. 2012).

Many commercial insurers manage inpatient stays differently from the Medicare fee-for-service program by using a variety of methods such as prior authorization policies or admission notification policies to validate the necessity of inpatient admissions. Under prior authorization, the hospital must contact the insurer for permission to admit the patient. Under notification policies, hospitals must notify the insurer as soon as the patient has been admitted. To make approval decisions, some insurers use automated computer systems or their own case managers inside the hospital. Insurers typically make these decisions within 24 hours.[3]

One-day inpatient stays are relatively common and profitable

Among Medicare beneficiaries, short inpatient stays are common and profitable for hospitals, relative to longer

inpatient stays. More than 1 million inpatient discharges in 2012 were for one-day stays, accounting for about 13 percent of all IPPS discharges (Table 7-1).[4]

The structure of the IPPS makes one-day inpatient stays profitable. Designed to be a system of averages, the IPPS generally pays a fixed amount per case for all patients who fall within a specific Medicare severity–diagnosis related group (MS–DRG), regardless of the length of stay; the payment rate is based on the average cost of all the cases in the group. The fixed MS–DRG payment gives hospitals the incentive to deliver care efficiently and control costs in a variety of ways, including shortening stay length. The payment rate for each MS–DRG is based on a relative weight that reflects the relative cost of the cases in one MS–DRG compared with other MS–DRGs. Each year, the weights are recalibrated using claims data from all hospitals in aggregate and from two years prior (the most current complete year available to CMS), to reflect the change in relative costs across the MS–DRGs. Over time, payment rates decline for MS–DRGs that have an above-average decrease in average cost per case. To the extent that an MS–DRG has an increasing prevalence of short inpatient stays and decreasing average cost as a result, the Medicare payment for the MS–DRG also would likely decline. But because recalibration is based on data from all hospitals and generates new MS–DRG weights based on overall average lengths of stay, individual hospitals with higher than average use of one-day stays may still benefit financially.

As would be expected under fixed MS–DRG payments, short inpatient stays are more profitable than longer stays. In 2012, across all MS–DRGs, payments exceeded costs by 55 percent (a payment-to-cost ratio of 1.55) for one-day inpatient stays (Table 7-1). By contrast, inpatient stays lasting eight or more days had the lowest mean payment-to-cost ratio (0.72), where costs exceeded payments by 28 percent.[5] The pattern of high payment-to-cost ratios for the shortest stays is observed across different types of stays. On average, medical one-day stays, which account for nearly three-quarters of all one-day stays, received payments that were double their costs (104 percent above costs, or a payment-to-cost ratio of 2.04). Surgical one-day stays received payments that were 17 percent above their costs (1.17). Stays in which the patient died during the hospital stay received payments that were 154 percent above their costs (2.54). One-day stays subject to the hospital-to-hospital and post-acute transfer policies received payments that were 30 percent (1.30) and 14 percent (1.14) above costs, respectively.[6]

In 2012, almost every one of over 700 MS–DRGs included some one-day stays, but these stays tended to be concentrated in certain MS–DRGs. The 15 MS–DRGs with the most one-day stays accounted for 30 percent of all one-day stays. Many of these 15 were also common to outpatient observation (e.g., chest pain, cardiac arrhythmia and conduction disorders, esophagitis, and syncope).[7]

Medical MS–DRGs tend to have higher payment-to-cost ratios than surgical DRGs for one-day stays. Among the 15 most common MS–DRGs for one-day inpatient stays in 2012, 12 were for medical stays and 3 were for surgical stays (Table 7-2, p. 180). Among the 12 medical MS–DRGs, payments exceeded costs by an average of between 32 and 199 percent (payment-to-cost ratios between 1.32 and 2.99). Among the three surgical MS–DRGs, payment exceeded costs on average by between 4 percent and 12 percent (payment-to-cost ratios between 1.04 and 1.12). The lower payment-to-cost ratio for surgical MS–DRGs compared with medical MS–DRGs likely reflects the fact that the costs associated with surgery are typically concentrated on the first day of the stay. In addition, higher payment-to-cost ratios for one-day stays are generally associated with MS–DRGs that have longer average lengths of stay.

Medicare pays more for inpatient short stays than for outpatient observation stays

Medicare pays for inpatient and outpatient hospital care under two different payment systems—the IPPS, paid through the Medicare Part A benefit, and the OPPS, paid through the Medicare Part B benefit.[8] In general, the amount Medicare pays for one-day inpatient stays is higher than for similar outpatient observation stays. Certain hospitals receive add-on payments for inpatient hospital stays that increase this payment differential. These add-on payments are for hospitals providing indirect medical education and those qualifying as disproportionate share hospitals. Because the services provided in these inpatient and outpatient stays are similar, the payment differential gives hospitals a financial incentive to admit beneficiaries to inpatient status. Table 7-3 (p. 181) shows the average Medicare payment for an inpatient one-day stay and an outpatient observation stay for six MS–DRGs that are among the most common to both inpatient and outpatient stays.[9] In 2012, for these six MS–DRGs, Medicare paid roughly two to three times more for a one-day inpatient stay than for a comparable outpatient observation stay.[10,11]

TABLE
7–2

Fifteen most common one-day inpatient stays by MS–DRG, 2012

MS–DRG	Type of MS–DRG	MS–DRG description	Geometric mean LOS for MS–DRG	Number of one-day stays	Payment-to-cost ratio for one-day stays
313	Medical	Chest pain	1.7	39,738	1.32
310	Medical	Cardiac arrhythmia & conduction disorders without CC/MCC	2.0	35,628	1.41
392	Medical	Esophagitis digestive disorders without MCC	2.7	29,952	1.82
871	Medical	Septicemia or severe sepsis without MV 96+ hours with MCC	5.3	28,590	2.99
247	Surgical	Percutaneous cardiovascular procedure with drug-eluting stent without MCC	1.9	27,762	1.12
312	Medical	Syncope & collapse	2.3	25,196	1.79
287	Medical	Circulatory disorders except AMI, with cardiac catheterization without MCC	2.4	24,620	1.40
39	Surgical	Extracranial procedures without CC/MCC	1.4	22,049	1.04
641	Medical	Disorders of nutrition, metabolism, fluids without MCC	2.8	21,559	1.84
69	Medical	Transient ischemia	2.2	20,087	1.65
812	Medical	Red blood cell disorders without MCC	2.7	19,438	2.03
309	Medical	Cardiac arrhythmia & conduction disorders with CC	2.9	19,019	1.86
690	Medical	Kidney & urinary tract infections without MCC	3.3	16,811	1.90
473	Surgical	Cervical spinal fusion without CC/MCC	1.5	16,245	1.04
292	Medical	Heart failure & shock with CC	3.9	13,850	2.13
		All top 15 MS–DRGs		360,544	

Note: MS–DRG (Medicare severity–diagnosis related group), LOS (length of stay), CC (complication or comorbidity), MCC (major complication or comorbidity), MV (mechanical ventilation), AMI (acute myocardial infarction). Data include inpatient prospective payment system (IPPS) hospitals reporting Medicare cost report data but exclude critical access and Maryland hospitals and Medicare Advantage claims. "One-day stay" refers to a stay for which the beneficiary has one Medicare utilization day.

Source: MedPAC analysis of Medicare standard analytic file of inpatient hospital claims and Medicare cost report data. Geometric mean length of stay data are from the CMS 2012 IPPS final rule impact file.

Medicare's Recovery Audit Contractor Program and claim rebilling policy

The Tax Relief and Health Care Act of 2006 mandated the nationwide implementation of the Medicare Recovery Audit Contractor (RAC) Program in 2010 (see text box about the RAC program, p. 182).[12] As discussed below, the Commission is concerned about the administrative burden the RAC program places on hospitals, the lack of accountability RACs face with regard to the accuracy of their audits, and the lack of coordination between the timing of the of RAC claim denials and the timing of the Medicare rebilling policy.

Administrative burden on hospitals

Hospitals report that the RAC program has increased their Medicare-related administrative burden. They assert that

RAC audits cause hospitals to expand their administrative staff and staff hours to handle RACs' requests for medical records and to track claims through the appeals process, adding to hospitals' overall costs. An American Hospital Association survey of its membership reported that, in the third quarter of 2012, costs associated with managing the RAC program totaled over $100,000 for 9 percent of hospitals and approximately $25,000 for 39 percent of hospitals (American Hospital Association 2014b). The process of filing an appeal and tracking it through the appeal process comes at a cost to hospitals. This cost may influence a hospital administrators' decision whether or not to appeal a given claim denial. Nevertheless, in general, hospitals' administrative costs of appealing claims are lower than the value of the payments tied to the denied inpatient claims.

MS–DRG	MS–DRG description	Average Medicare inpatient payment (one-day stay)	Average Medicare outpatient observation payment
313	Chest pain	$3,716	$1,655
310	Cardiac arrhythmia & conductive disorders	3,677	1,420
392	Esophagitis, gastroenteritis & miscellaneous digestive disorders	4,953	1,526
312	Syncope & collapse	4,972	1,689
287	Circulatory disorders except AMI, with cardiac catheterization without MCC	7,064	3,998
641	Disorders of nutrition, metabolism, fluid/electrolytes without MCC	4,467	1,341

Note: MS–DRG (Medicare severity–diagnosis related group), AMI (acute myocardial infarction), MCC (major complication or comorbidity). Payments reflect actual program payments (including indirect medical education and disproportionate share hospital add-ons) and beneficiary cost sharing. Data exclude Maryland and critical access hospitals. The observation data are for beneficiaries whose observation care meets the criteria for composite ambulatory payment classification payment for extended evaluation and management. Claims for outpatients are compared with inpatient claims for MS–DRGs that include patients with similar diagnoses and procedures. The bundle of services covered by the inpatient payments and outpatient payments are not entirely comparable in part because of the inpatient 72-hour rule and outpatient payments not covering self-administered drugs.

Source: MedPAC analysis of Medicare standard analytic file of inpatient and outpatient hospital claims.

In recent years, the volume of appeals has increased dramatically. The Office of Medicare Hearings and Appeals (OMHA) reported that, from fiscal years 2011 to 2013, the number of appeals occurring at the third of five levels of appeal increased over 500 percent.[13] The third level of appeal is the point at which adjudication involves an administrative law judge (ALJ) manually reviewing each claim, as opposed to the more general reviews that occur at levels one and two. The third level is also the point at which the majority of appeal overturns occur, the last level before the appeal is sent to a reviewing council or a court, and the level at which the current backlog exists. In fiscal year 2013, there were over 380,000 RAC-related appeals at the ALJ level; another 500,000 new appeals were added through the first 10 months of fiscal year 2014 (Office of Medicare Hearings and Appeals 2014). As of July 1, 2014, the ALJ backlog in OHMA exceeded 800,000 appeals. In addition, OMHA reports that the average appeal processing time is over 547 days in fiscal year 2015, up from 120 days per appeal in fiscal year 2011 (Office of Medicare Hearings and Appeals 2015).

To address the growing ALJ appeals backlog, in August 2014, CMS announced a one-time option for hospitals to settle appeals. CMS offered to pay hospitals 68 percent of the net payable amount of the denied inpatient claim in exchange for the hospital dropping the appeal. Hospitals that accepted the settlement agreed to settle all their appeals in one bundle, as opposed to settling appeals individually (Centers for Medicare & Medicaid Services 2015a).

RACs audits are industry-wide rather than focused on specific hospitals with use patterns that call for additional scrutiny. The American Hospital Association reported in 2013 that 90 percent of hospitals were affected by a RAC audit or request for information. Current rules limit the number of overall claims a RAC can audit from a given hospital, and RACs strategically select short inpatient claims for review based on the potential contingency fee value of the claim and the likelihood of being able to make a recovery. Because they are limited to reviewing a certain number of claims from each hospital, RACs have responded by auditing short inpatient stays from many hospitals rather than focus on hospitals with aberrant patterns of use. The result is that hospitals misusing a large number of short inpatient stays are being insufficiently audited, and hospitals that do not misuse short inpatient stays incur potentially unnecessary administrative burdens.

Accountability of RACs

RACs focus on short inpatient stays, and with the exception of losing payment when their claim denials are overturned, RACs are largely not held accountable for their audit accuracy. To date, RACs have focused their auditing on the differences in payment between clinically similar inpatient and outpatient stays. As a result, the majority of the overpayments identified by RACs are from Medicare Part A one-day inpatient stays. CMS estimates that, in 2013, over 94 percent of the overpayments were for inpatient hospital claims, adding that many of the individual claim denials with the highest overpayment

Medicare Recovery Audit Contractor Program

The Congress mandated the Medicare Recovery Audit Contractor (RAC) Program to be implemented in 2010 to identify and correct overpayments and underpayments made to providers on behalf of the Medicare program. Currently, four RACs contract with CMS to audit hospital claims. The RACs are permitted by law to review claims dating back four years, but to date, CMS has limited the RACs' claim look-back period to three years. The RACs are paid based on a percentage of the dollars they recover from their claims auditing activities rather than through CMS's administrative budget. These contingency fees, negotiated between CMS and the RACs, range between 9.0 and 12.5 percent. Providers can appeal a RAC's overpayment determinations. In fiscal year 2013, the RACs identified overpayments totaling $3.75 billion.

In addition to the RACs, four other types of Medicare contractors are responsible for conducting postpayment reviews of Medicare claims: Medicare administrative contractors, zone program integrity contractors, comprehensive error-rate testing contractors, and supplemental medical review contractors. The five

types of contractors have overlapping roles, but RACs handle the largest volume of these reviews. According to a Government Accountability Office analysis, RACs accounted for the vast majority (83 percent) of postpayment reviews in 2012 (Government Accountability Office 2014).

In December 2014, CMS released a list of 18 changes it intends to make to the RAC program. These changes are intended to be effective with each new RAC contract awarded on or after December 30, 2014. Among these changes is the limit on the RAC look-back period for patient status, reduced from three years to six months from the date the hospital provided the service to the patient (date of service). This change should allow hospitals to rebill more RAC-denied claims. RACs would also be required to maintain low claim overturn rates and high claim review accuracy rates to maintain full access to claims for review. CMS intends to use hospitals' past claim denial rates to determine what share of their claims will be eligible for RAC claim review. In addition, CMS intends to begin paying RACs their contingency fees later in the appeal process. ∎

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amounts were denials of short inpatient stays (Centers for Medicare & Medicaid Services 2014d). While the RACs' focus is not completely on inpatient stays, or short inpatient stays, denials of these stays appear to be the source of much of the program's revenues.

Determining the accuracy of RAC audits is obscured by the number of claims appealed in recent years. CMS reports that in 2013, the audit accuracy rates of RACs varied from 92.8 percent to 99.1 percent.[14] This high level suggests RACs are relatively accurate, but it is unclear how the recent appeals are factored into CMS's accuracy rates (Centers for Medicare & Medicaid Services 2014d). In terms of the outcome of appeals, CMS reports that, across all levels of appeal in 2013, about 8 percent of Part A overpayment determinations were completely overturned on appeal (Centers for Medicare & Medicaid Services 2014d). The audit accuracy rates and the appeal overturn rate generally correspond with one another and suggest reasonable accuracy. However, CMS also reports

that, among all Part A claim overpayment determinations made by RACs in 2013, providers appealed about 48 percent of denials. This appeals rate raises questions across the audit process continuum regarding the frequency of hospital appeals, the accuracy of RAC audits, and the processes of ALJs.

Research by the Department of Health and Human Services Office of Inspector General (OIG) demonstrates that a large share of hospital appeals of RAC denials that reach the ALJ level (a relatively small share of total RAC denials) are overturned by ALJs and that variation exists in ALJ rulings. In a 2012 report, OIG reported that, among all the appeals that reached ALJs, more than half were overturned in favor of the provider (Office of Inspector General 2012). To this point, OIG reported that, despite the random assignment of cases to the 66 ALJs they reviewed, the share of appeal rulings decided in favor of the appealing provider ranged from 18 percent to 85 percent. Variation to this degree suggests either that the

guidelines for ruling on inpatient cases are not clear or that ALJs may not uniformly possess the experience required for making clinical decisions on this subject. OIG found that ALJs often interpret Medicare policy less strictly than do qualified independent contractors and often favor the provider and beneficiary (Office of Inspector General 2012). OIG has cited problems with ALJs litigating Medicare disputes in the past.

The contingency fee structure of the RAC program differs from that of other Medicare auditors, and it does not directly hold RACs accountable for their audit accuracy. Contingency fees were adopted because they permit expansion of reviews without additional congressional appropriations for CMS's administrative budget. This structure also provides incentives for RACs to identify as many inappropriate claims and as much Medicare payment as possible. RACs must return the contingency fee to CMS if a hospital successfully appeals the denial of the claim. However, RACs face no penalties when denials are overturned on appeal and are not required to pay interest on the returned fee.

Timing of RAC reviews

Stakeholders have also cited difficulties with regard to the disparate timing between the RACs claim review period and the Medicare hospital rebilling period. Currently, RACs are permitted to review claims that are up to three years from the date of service on the claim. Medicare's rebilling policy allows hospitals one year after a denied claim's date of service to resubmit a claim for the outpatient services included on that original claim (Centers for Medicare & Medicaid Services 2013a). However, hospitals may not replace denied inpatient care with what it asserts is equivalent outpatient care.[15]

The misalignment between the one-year rebilling window and the three-year RAC look-back period largely prevents hospitals from being able to rebill denied claims. CMS estimated in its 2012 OPPS proposed rule that 75 percent of inpatient admissions denied by RACs are not eligible to be rebilled as outpatient services because they fell outside the one-year rebilling period (Centers for Medicare & Medicaid Services 2013c). The lengthy appeals process may further diminish the chances of a hospital being able to appeal a denied claim beyond the first or second level of appeal and then have the opportunity to rebill for that denied claim because the appeal process is likely to take longer than the one-year rebilling time frame permits.

Two-midnight rule leaves problems unresolved

CMS established the "two-midnight rule" in fiscal year 2014 to clarify criteria for admission appropriateness and alleviate concerns about increased use of observation, its impact on beneficiary liability, and hospitals' concerns about RAC audits. CMS's two-midnight rule provides additional guidance to its audit contractors, instructing them to use two midnights as the benchmark for assessing the appropriateness of inpatient admission rather than the Medicare Benefit Policy Manual's 24-hour guidance. The rule directs auditors to presume that inpatient admissions are reasonable and necessary when beneficiaries have more than one Medicare utilization day (stays that include two midnights) (Centers for Medicare & Medicaid Services 2013b). Under the rule, inpatient and outpatient stays spanning two midnights (or stays a physician expects to span two midnights) will be deemed appropriate for the inpatient setting, and auditors will not review or deny these claims. For inpatient and outpatient stays of less than two midnights, auditors are to presume the stay is appropriate for the outpatient setting, except under certain circumstances.[16] For claims they select for review, auditors are instructed to consider the claim appropriate for inpatient care if it meets any of the following three criteria:

- the stay crossed two midnights when both inpatient and outpatient time are counted,

- the patient received an inpatient-only procedure, or

- the physician had a reasonable expectation that the stay would cross two midnights and this assumption is supported by information documented in the medical record.[17]

The two-midnight rule may address some of the problems it was implemented to resolve. It largely alleviates hospitals of the risk of RAC audit for stays lasting more than two midnights, which should reduce their RAC-related administrative burden. In addition, some contend that a time-based criterion for inpatient status provides hospitals with a clearer definition to judge the appropriateness of their admissions.

The two-midnight rule may also change provider utilization patterns, even though it does not alter Medicare's admission criteria. Overall, the two-midnight rule will result in the movement of stays from outpatient to inpatient status and vice versa. (When the rule was

**TABLE
7–4**

Inpatient discharges by length of stay

Length of inpatient stay (in days)	Share of inpatient discharges, 2012	Percent change in number of inpatient claims per Part A beneficiary		
		2006–2012	2006–2009	2010–2012
1	13%	–23%	–10%	–13%
2	16	–6	–1	–5
3	19	–1	1	–3
4	13	–12	–4	–6
5 or more	39	–17	–8	–7
All	100	–13	–5	–7

Note: Hospitals receiving inpatient prospective payment system payments and critical access hospitals are included in this analysis.

Source: MedPAC analysis of standard analytic file of inpatient hospital claims.

originally implemented, CMS estimated a net increase in inpatient stays.[18]) However, it is not clear that the changes in patterns of use will always be beneficial for the beneficiary or the Medicare program. The two-midnight rule will likely reduce the number of long observation stays (48 hours or longer) because, absent the RAC audit risk, hospitals can more easily serve these patients in inpatient status. At the same time, it could increase the use of short observation stays because hospitals might opt to place patients in observation status until their stays exceed two midnights. Such an increase before admission would exacerbate concerns about beneficiaries not qualifying for SNF coverage because observation status does not count toward the three-day hospital stay threshold for SNF eligibility. The two-midnight rule could also influence lengths of inpatient stays. Under the new rule, hospitals might lengthen stays beyond the two-midnight threshold to gain greater certainty that they will avoid a denial and the loss of reimbursement. Unnecessarily lengthening stays could have negative consequences for beneficiaries and represent overutilization of the program.

The two-midnight rule has been controversial within the hospital industry. Some hospitals have expressed concern that the rule has increased the burden associated with physician documentation of inpatient admissions. Others are concerned that the rule complicates the admissions process by adding auditing standards that do not coincide with the inpatient criteria deferring to physician judgment. Further, others believe that the rule will eliminate many

one-day stays and that the shift of cases between the outpatient and inpatient settings will result in financial loss to some providers.

Since CMS finalized the two-midnight rule in August 2013, both CMS and the Congress have taken actions to delay the enforcement of the policy. RACs are prohibited from enforcing the new policy or auditing any inpatient admissions until September 30, 2015, unless there is evidence of systematic gaming, fraud, abuse, or delays. During this enforcement delay, CMS will assess the extent to which hospitals understand and are complying with the new policy through the Medicare Probe and Educate program.

Under the Probe and Educate program, Medicare administrative contractors (MACs) conduct limited prepayment reviews of a sample of hospital inpatient claims spanning less than two midnights. MACs may select 2 samples of 10 claims from any hospital (25 claims from larger hospitals) to verify compliance with the two-midnight rule. Hospitals with high rates of denials receive further scrutiny. MACs are permitted to deny claims if they are not reasonable and necessary inpatient claims. MACs send letters to hospitals informing them which claims were denied and for what reasons, and they call hospitals with high rates of denials to communicate this information.

The Probe and Educate program may represent some value for hospitals, but its application to the review of all inpatient claims is problematic. On the one hand,

providers generally prefer prepayment review, such as Probe and Educate, to postpayment review, such as the RAC program, because it is less disruptive to the flow of revenues and involves less administrative cost. On the other hand, applying the Probe and Educate program to all inpatient claims would require a significant administrative commitment (and financial resources) from CMS and would likely slow the payment of claims. Therefore, the Probe and Educate program may not be a realistic replacement of the RAC program. Further, some stakeholders have expressed concern that MACs have inconsistently implemented the Probe and Educate program with regard to claim denial decisions and education efforts.

Use of observation services

In response to greater scrutiny of short inpatient stays, hospitals have increased their use of outpatient observation status and opted for the lower payment associated with observation rather than risk denial of the higher paid inpatient services. As a result, the volume of one-day inpatient stays has declined, and the volume of outpatient observation stays has increased.

Use of short inpatient stays declined

Discharges for short inpatient stays have declined rapidly in recent years. Between 2006 and 2012, the number of one-day inpatient stays declined 23 percent per Medicare Part A beneficiary, a more rapid rate of decline than for longer stays (Table 7-4).[19] Stays of other lengths declined between 1 percent and 17 percent over the same period, or a 5 percent decline overall (data not shown).[20] One-day inpatient stays declined at a faster rate in more recent years, after the implementation of the RAC program in 2010. From 2006 to 2009, the volume of one-day inpatient stays decreased 10 percent compared with the 13 percent decline from 2010 to 2012. Inpatient stays of other lengths also demonstrated an increased rate of decline between these two periods. These rates of decline suggest that providers felt pressure to reduce inpatient utilization during the two periods, particularly in the years after the implementation of the RAC program.

Use of outpatient observation stays increased

Hospitals rapidly increased their use of outpatient observation status in recent years, both in number and length of stays. Many of the most common diagnoses for outpatient observations overlap with the most common diagnoses for one-day inpatient stays and with the diagnoses that account for most of the Medicare RACs' payment denials. These overlaps suggest that the increased use of outpatient observations is hospitals' response to the RACs' greater scrutiny of short inpatient stays.

Volume

In 2012, CMS processed claims for 1.7 million outpatient observation stays and another 700,000 inpatient stays preceded by observation. Between 2006 and 2012, the number of outpatient observation stays increased by 88 percent (from 28 to 53 visits per 1,000 beneficiaries), and the number of inpatient stays preceded by observation increased 96 percent (from 10 to 19 stays per 1,000 beneficiaries) (Figure 7-1, p. 186). The growth in observation was most rapid between 2011 and 2012, when outpatient observation volume rose 14 percent (from 47 to 53 visits per 1,000 beneficiaries).[21]

Length of stay

The average length of outpatient observation stays increased in recent years. From 2006 through 2012, the average length of outpatient observation stays increased from 25.6 hours per stay to 29.3 hours per stay. This increase was driven by a 228 percent increase in the number of stays of 48 or more hours. In 2012, there were over 250,000 outpatient observation stays that lasted 48 or more hours.[22]

Common diagnoses

In 2012, outpatient observation stays were concentrated among relatively few diagnoses, many of the same diagnoses that were also common among short inpatient stays. To ensure that the diagnosis codes, which are in different coding systems for inpatient and outpatient admissions, were comparable, we used a cross-walk method to convert the principle diagnoses and procedure codes of outpatient claims into inpatient MS–DRGs. The outpatient observation stays translated broadly into 90 percent of all MS–DRGs, but most of these MS–DRGs contained very few cases. Instead, six MS–DRGs accounted for about 40 percent of outpatient observation stays and were common to one-day inpatient stays.[23] Specifically, they constituted 6 of the 10 most common one-day-inpatient-stay MS–DRGs and accounted for about 50 percent of one-day inpatient stays. These six MS–DRGs also generated the most RAC overpayment revenue.

FIGURE
7–1

Outpatient observation stays and inpatient stays preceded by observation per beneficiary increased between 2006 and 2012
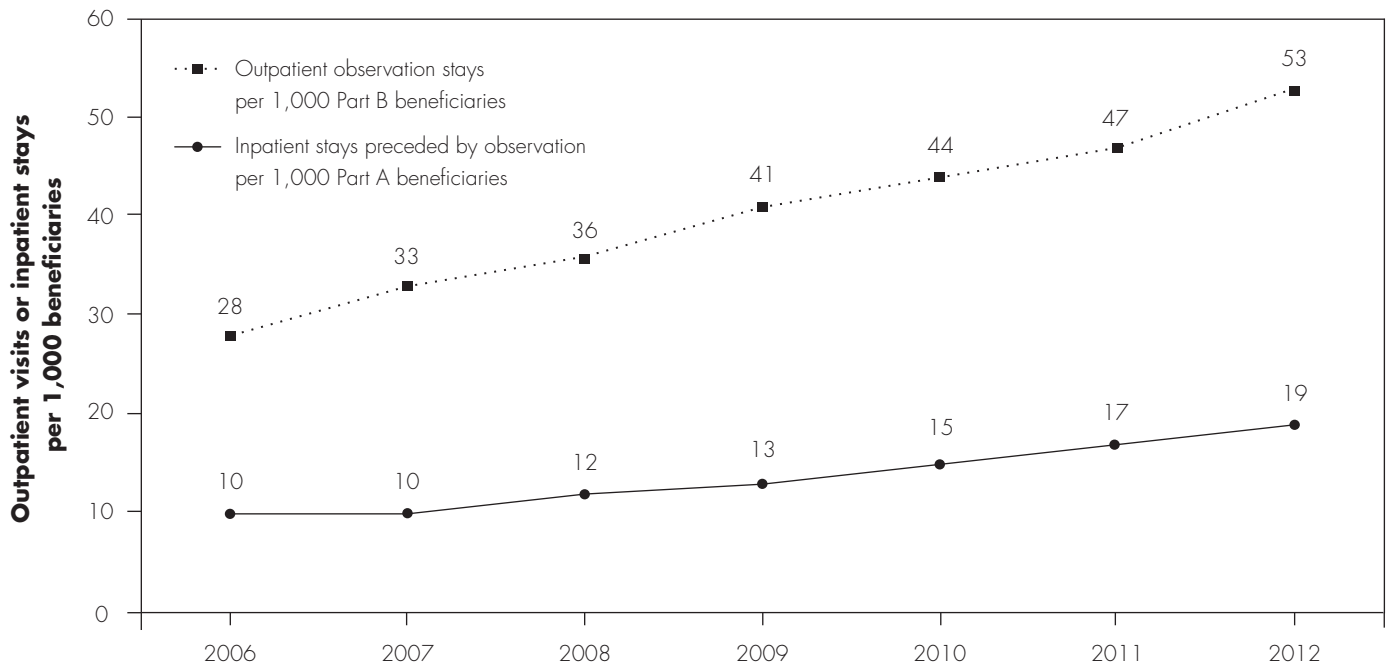
Source: Medicare inpatient and outpatient 2012 standard analytic file claims.

Characteristics of hospitals with high rates of one-day inpatient and observation use

In examining the distribution of one-day inpatient and outpatient observation stays across hospitals, the Commission found that certain hospitals use a disproportionate share of the stays. At the same time, a smaller group of hospitals is more likely to have long observation stays, defined as lasting 48 or more hours.

We calculated three ratios to better understand the variation in hospitals' use of one-day inpatient and outpatient observation stays: a one-day inpatient stay ratio, an outpatient observation stay ratio, and a long outpatient observation stay ratio.[24] Using these ratios, we examined variation in use by facility characteristics such as size, teaching status, Medicare volume, and location. The ratios were constructed using 2012 inpatient and outpatient Medicare claims data for hospitals paid under the IPPS, excluding Maryland hospitals.

To ensure adequate volume for legitimate comparison, we limited the calculation of the hospital-level ratios to only

those inpatient and outpatient stays that we grouped into one of 55 MS–DRGs. These MS–DRGs were selected because they either (1) ranked among the top MS–DRGs for both number of inpatient one-day stays and outpatient observation stays or (2) ranked among the top surgical MS–DRGs for both the number of one-day inpatient stays and the amount of dollars denied by the RACs for short inpatient stays that the RAC determined should have been provided in an outpatient setting. Using a cross-walk method, we grouped the outpatient claims' diagnosis and procedure codes into inpatient MS–DRGs.[25] (See text box, p. 188, for more information on the characteristics of beneficiaries served with one-day inpatient stays versus outpatient observation stays.)

One-day inpatient stay use

One-day inpatient stays were common across hospitals. On average, 6 percent of stays (ratio of 0.06) that came into the hospital either as an inpatient or outpatient case ended up as a one-day inpatient stay (Table 7-5). While one-day inpatient stays composed 9 percent or fewer discharges at most hospitals, a small group of hospitals utilized one-day inpatient stays at a higher rate. For example, the 90th percentile of hospitals, defined as

Utilization ratio and hospital group	Number of hospitals	Mean	Percentile				
			10th	25th	50th	75th	90th
One-day inpatient stay	3,248	0.06	0.02	0.03	0.05	0.07	0.09
Outpatient observation stay	3,248	0.09	0.02	0.05	0.08	0.12	0.16
Long outpatient observation stay	2,753	0.09	0.02	0.04	0.08	0.12	0.17

Note: Analysis is limited to 55 Medicare severity–diagnosis related groups with inpatient one-day stay and outpatient observation overlap. One-day inpatient stay ratio is defined as the number of one-day inpatient stays divided by the sum of all inpatient stays, outpatient observations stays, outpatient emergency department visits, and outpatient surgical stays. The outpatient observation stay ratio is defined as the number of outpatient observation stays over the sum of all inpatient stays, outpatient observations stays, outpatient emergency department visits, and outpatient surgical stays. The long outpatient observation stay ratio is defined the number of outpatient observation stays lasting 48 or more hours divided by all outpatient observation stays.

Source: MedPAC analysis of the standard analytic files of inpatient and outpatient hospital claims, 2012.

having a one-day inpatient stay ratio equal to or exceeding 0.09 (9 percent), had an average one-day stay ratio equal to 0.12 (12 percent) and accounted for 26 percent of the payments associated with one-day inpatient stays (data not shown). In general, this group of hospitals consisted of urban, teaching, and for-profit hospitals.

Outpatient observation stay use

On average, 9 percent of stays (ratio of 0.09) that came into the hospital either as an inpatient or outpatient case used outpatient observation status. The 90th percentile of hospitals, defined as those that had an outpatient observation ratio equal to or exceeding 0.16 (16 percent), had an average outpatient observation-stay ratio equal to 0.20 (20 percent) and accounted for 19 percent of the payments associated with outpatient observation stays (data not shown). These hospitals were disproportionately small, rural, government, and nonteaching hospitals.

Long outpatient observation stay use

Overall, 85 percent of hospitals had outpatient observation stays that lasted longer than 48 hours. Among these hospitals, an average of 9 percent of their observation stays lasted 48 hours or longer (ratio of 0.09). The 90th percentile of hospitals providing this type of stay, defined as those that had a long observation stay ratio equal to or exceeding 0.17 (17 percent), had an average long observation stay ratio of 0.24 (24 percent) and accounted for 1 percent of payments for long observation stays (data not shown). These hospitals were

disproportionately small and rural and accounted for a relatively small share of observation payments.

Beneficiary liability tied to observation status

Medicare beneficiaries' financial liability for short stays depends on whether they are admitted to the hospital for an inpatient stay or remain in outpatient observation status. Beneficiaries in an inpatient setting are responsible for paying the Part A deductible, while beneficiaries in an outpatient setting are responsible for paying a coinsurance amount based on a share of allowed charges.[26] Overall beneficiary financial liability is higher for clinically similar cases when served in the inpatient setting compared with those served in outpatient observation status. However, the time that beneficiaries were treated in outpatient observation does not count toward the SNF coverage eligibility requirement of three inpatient days, making those who require SNF care financially liable for services provided by SNFs. In addition, beneficiaries are financially responsible for self-administered drugs (SADs) provided by the hospital while in an outpatient observation stay.

Beneficiary out-of-pocket hospital liability by type of stay

In 2012, for most beneficiaries, cost sharing was less for outpatient stays compared with inpatient stays. In that year,

Characteristics of beneficiaries served with one-day inpatient stays versus outpatient observation stays

The Commission compared the characteristics of beneficiaries who received observation services with those who were admitted to a one-day inpatient prospective payment system hospital stay. We determined that these beneficiaries were largely similar in race, in the share living in an institutional setting, and in Medicaid eligibility. Beneficiaries with an observation stay lasting fewer than 24 hours had lower risk scores and were less likely to have 5 or more chronic conditions than those who were admitted to one-day inpatient stays.

Further, beneficiaries with longer observation stays (exceeding 24 hours) had more chronic conditions, higher risk scores, and were slightly older on average compared with beneficiaries with one-day inpatient stays. Beneficiaries with longer observation stays were also more likely to have a history of Alzheimer's disease and depression (Table 7-6). ∎

TABLE 7–6   Characteristics of beneficiaries served in one-day inpatient stays similar to outpatient observation stays, but differences exist between outpatient observation stays, 2012

	Share with inpatient one-day stay	Share with outpatient observation stay		
Beneficiary characteristics		All	Less than 24 hours	24 hours or more
Beneficiary with:				
Five or more chronic conditions	57%	57%	54%	60%
Alzheimer's or senile dementia	11	14	12	16
Depression	24	27	26	28
Median risk score	1.28	1.25	1.19	1.31
Average age	71	72	71	73

Source: MedPAC analysis of the 2012 Medicare standard analytic files of inpatient and outpatient hospital claims, the 2012 Master Beneficiary Summary file, and the 2012 Medicare risk score file.

the overall median beneficiary liability for an inpatient case was $1,156 (the same dollar level as the inpatient deductible); this amount was the same for stays that included one midnight (Table 7-7). The median liability for outpatient observation stays that included one midnight was substantially lower at $282. Outpatient surgical stays that included one midnight had median liability of $1,116, slightly less than the inpatient deductible. At the 90th percentile, liability for outpatient surgical stays was about $500 more than the inpatient deductible. Outpatient emergency department (ED) stays that included one midnight had a comparatively low median liability of $107. In 2012, less than 4 percent of beneficiaries served in outpatient observation status had liabilities that exceeded the level of the inpatient deductible; many of

these beneficiaries did not themselves pay these amounts because they had supplemental insurance.[27]

Beneficiaries discharged to a SNF without SNF coverage

Beneficiaries discharged to a SNF without qualifying for Medicare SNF coverage are among those most at risk of having higher financial liability if they are served in outpatient observation status. By statute, to qualify for Medicare SNF coverage, a beneficiary must have been an inpatient at a hospital for at least three consecutive calendar days preceding the SNF admission. The calculation of the three inpatient days applies only to the time between the inpatient admission date and the inpatient discharge date of a hospital stay. It does not include time spent in

TABLE
7–7

Median beneficiary out-of-pocket costs were higher for beneficiaries served in inpatient status, 2012

| | Beneficiary out-of-pocket costs | | |
Type of stay	10th percentile	Median	90th percentile
All inpatient	$0	$1,156	$1,156
Stays that crossed one midnight:			
Inpatient one-day	0	1,156	1,156
Outpatient observation	150	282	723
Outpatient surgical	443	1,116	1,651
Outpatient emergency department	47	107	278

Note: Beneficiary out-of-pocket costs for inpatient stays that are equal to $0 or less than the inpatient deductible are the result of beneficiaries having paid the inpatient deductible in the benefit period as part of a previous inpatient stay.

Source: MedPAC analysis of the 2012 Medicare standard analytic files of inpatient and outpatient hospital claims.

outpatient care, observation status, or in the ED before an inpatient admission to the hospital (Centers for Medicare & Medicaid Services 2014c). The rationale behind this policy is to ensure that Medicare SNF coverage is a post-acute care benefit, not a long-term care benefit.

SNF eligibility and coverage is of particular concern to policymakers and beneficiary advocates alike because when Medicare does not cover SNF care, the beneficiary is liable for the entire cost of the stay out of pocket. According to a recent study from OIG, about 4 percent of beneficiaries with outpatient observation stays were discharged to a SNF in 2012.[28] These beneficiaries could be liable for an average of $10,500 out of pocket for a noncovered SNF stay (Office of Inspector General 2013).

Beneficiaries served in outpatient observation status may not realize that they have not been officially admitted to the hospital as an inpatient. The Medicare program does not require hospitals to notify beneficiaries of their outpatient observation status or inform beneficiaries that time spent in observation status does not count toward the SNF three-day threshold. Several states have passed laws requiring hospitals to inform patients about their status in observation, and several others have considered action.[29]

In general, few beneficiaries find themselves in a situation in which they spend three days in the hospital and subsequently receive SNF care without having been eligible for SNF coverage. In 2012, 102,000 hospital stays involved beneficiaries who were in the hospital for longer than three days, including time in outpatient observation

status and inpatient status, but did not meet the three-day inpatient requirement for SNF coverage.[30] Among this group of hospital stays, 12,000 were discharged to a SNF despite not meeting the SNF three-day eligibility rule. From 2009 to 2012, the number of hospital stays that were discharged to a SNF without SNF coverage increased more than 70 percent. Nonetheless, CMS may have inappropriately paid SNFs for more than 90 percent of these 12,000 stays in 2012, despite beneficiaries' lack of SNF coverage (Office of Inspector General 2013). Therefore, it is difficult to quantify the degree to which beneficiaries have been responsible for the full liability associated with a noncovered SNF stay.

The Commission's evaluation of SNF-related liability for beneficiaries served in observation has led to consideration of how many cases could be helped by a policy that modifies the existing SNF three-day prior hospitalization policy. Among the group of 102,000 stays (in which beneficiaries spent three days in the hospital but did not qualify for SNF coverage) were two distinct groups of cases. First, half (about 52,000) of these stays were in the hospital for three days, of which at least one was an inpatient day. The other half (about 49,000) of these stays were in the hospital for three days but never had an inpatient admission. To estimate how many cases from these two groups might be discharged to a SNF after their hospital stay, we considered that observation cases have lower risk scores than inpatient cases and that, in 2012, about 25 percent of inpatient cases were discharged to a SNF. If we assume that 20 percent of these 102,000 cases were discharged to a SNF, then that assumption

**TABLE
7–8**

Self-administered drug charges and costs per claim among hospitals that reported charges for self-administered drugs, 2012

Type of hospital outpatient claim	Percent of claims that included self-administered drug charges	Per claim with self-administered drug charges	
		Average charges for self-administered drugs	Average estimated cost for self-administered drugs
Observation	75%	$209	$43
Emergency department	27	40	8
Surgery	32	115	24

Note   Data are limited to the two-thirds of hospitals that reported self-administered drug charges on at least one claim. Data include claims for hospital outpatients and exclude critical access hospitals, hospitals without reliable cost report data, and beneficiaries enrolled in health maintenance organizations during the year. Self-administered drugs are identified by revenue center 637. Claims that contain more than one of type of service are categorized based on the following hierarchy: observation, emergency department, and surgery.

Source: MedPAC analysis of the standard analytic files of outpatient hospital claims and cost report data from CMS, 2012.

would generate approximately 20,000 reimbursable SNF stays. Alternatively, if the 52,000 stays with at least one inpatient day were to become eligible for SNF coverage, this situation would generate about 10,000 additional reimbursable SNF stays.[31]

Self-administered drugs not covered for beneficiaries in outpatient observation

Beneficiaries who receive care in a hospital outpatient department may face an additional liability for SADs. Drugs that are usually considered self-administered (such as oral medications) are covered by Medicare Part A for hospital inpatients but are generally not covered by Medicare Part B for hospital outpatients. If a hospital provides a SAD to a hospital outpatient, the drug is considered noncovered and the hospital bills the beneficiary for the drug at full charge. Beneficiaries who have Medicare Part D coverage may be able to submit a claim to their Part D plan to get some reimbursement for the drug. However, the hospital pharmacy may not be in the Part D plan's network, or the amount the beneficiary is reimbursed by the Part D plan may be less than the amount the beneficiary owes the hospital for the drug.

To assess the scope of this concern, the Commission analyzed Medicare claims and cost report data on SAD charges and costs for hospital outpatients.[32] In 2012, about two-thirds of hospitals that submitted claims to Medicare for outpatient observation stays reported charges for noncovered SADs for at least some of their observation patients, while one-third of hospitals did not report SAD charges for any patients.[33] Among the two-thirds of hospitals reporting SAD charges, about 75 percent of

observation claims included charges for SADs (Table 7-8). These claims had average drug charges of $209 per claim and an estimated average cost of $43 per claim.

SADs were also charged on ED and outpatient surgical claims, but with a lower frequency and lower average cost. Among hospitals that reported charges for SADs in 2012, roughly 30 percent of these two types of claims included SAD charges. Average charges and costs for these drugs per ED claim were $40 and $8, respectively, and per outpatient surgical claim were $115 and $25, respectively.

Hospital short-stay policy options

The Commission's discussion of hospital short-stay issues has covered four general areas: payment for short hospital stays, the RAC program, a hospital short-stay penalty, and beneficiary financial liability. The Commission has noted several concerns related to hospital short stays that touch each of these areas.

- The Commission has concluded that one of the sources of the short-stay issue is the payment difference between short inpatient stays and similar outpatient stays. This cliff provides hospitals with the incentive to admit beneficiaries to inpatient care.

- The Commission has considered the necessity of the "two-midnight" rule.

- The Commission has identified several possible improvements to the RAC program that reduce the administrative burden on hospitals and CMS, improve

FIGURE
7–2

Effect of simulated one-day stay DRG policy for selected medical DRGs
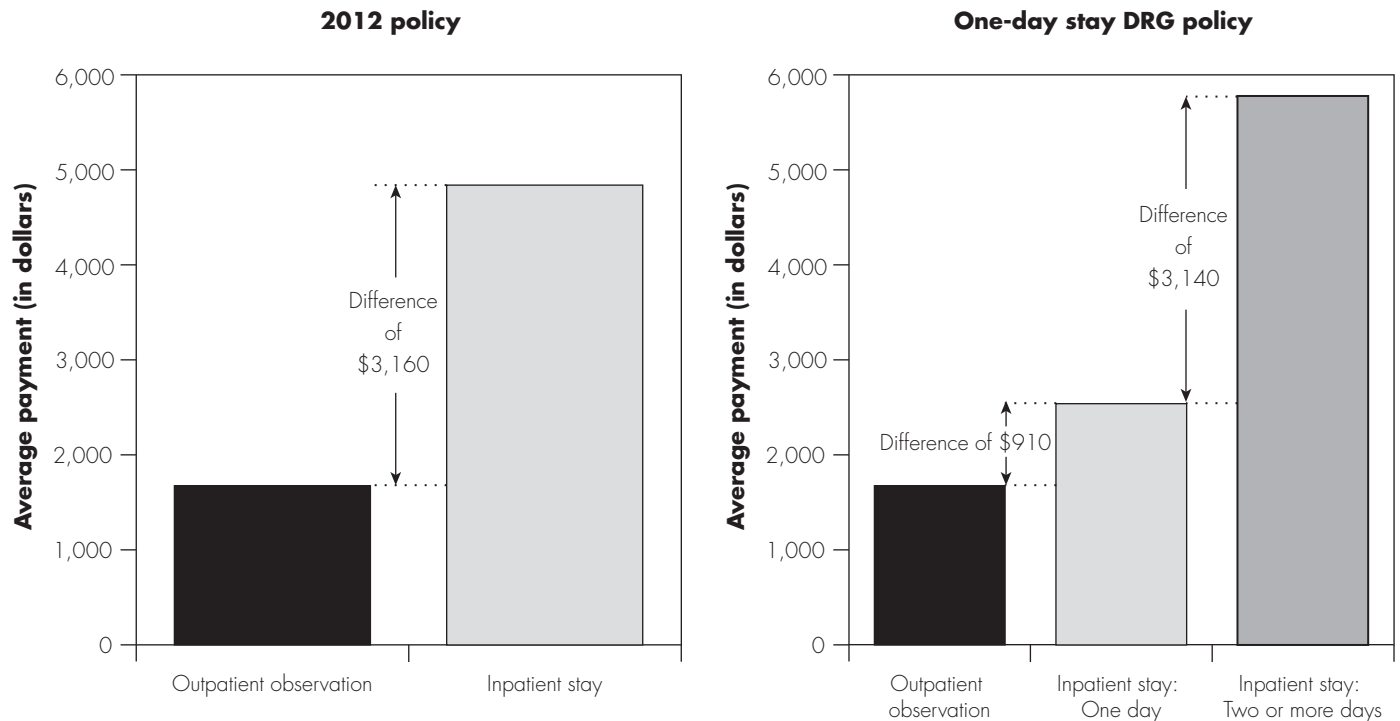
Note: DRG (diagnosis related group). Chart includes results from a simulation of a one-day stay DRG policy. Displayed in the chart is the weighted average payment rate for the 10 medical DRGs with the most one-day inpatient stays that are also common to outpatient observation. Similar outpatient observation claims are identified by using a cross-walk process to link outpatient claims to Medicare severity–diagnosis related groups. Average payment includes add-on payments such as indirect medical education and disproportionate share hospital payments.

Source: MedPAC analysis of Medicare claims and cost report data.

RAC accountability when its claim denials are overturned, and align the RAC review window with the Medicare hospital rebilling program.

- The Commission has expressed concern about how the increased use of observation stays exposes beneficiaries to excessive financial liability when they are discharged to a SNF without having met the SNF coverage eligibility threshold and when they receive self-administered drugs during an outpatient stay.

Payment policy approaches to hospital short stays

If policymakers want to address the financial incentives associated with payment differentials between short inpatient stays and similar outpatient stays, payment changes could be considered. For example, payment changes could be made to reduce or eliminate the payment difference between short inpatient stays and similar outpatient stays through one-day-stay diagnosis

related groups (DRGs) or through a site-neutral payment approach. However, there are trade-offs to these types of payment changes because they may create vulnerabilities elsewhere within the payment systems. The Commission has not recommended a specific payment approach but instead discusses the advantages and disadvantages of each of these options.

To lessen the payment difference between short inpatient stays and similar outpatient stays, policymakers could consider creating one-day-stay DRGs under the IPPS. With one-day-stay DRGs, Medicare would pay less for one-day inpatient stays and more for longer inpatient stays than the existing DRGs into which these stays are currently grouped. A one-day-stay DRG would not change the payment rate for a similar outpatient stay, but reducing the payment rate for an inpatient one-day stay would bring the two rates closer together.

Figure 7-2 illustrates the effect of creating special one-day-stay DRGs under the IPPS based on our simulation

Inpatient one-day-stay diagnosis related group simulation

To illustrate the effect of creating one-day-stay diagnosis related groups (DRGs) on hospital financial incentives, we simulated a hypothetical one-day-stay DRG policy.

Methodology for creating a hypothetical one-day-stay DRG policy

In the interest of maintaining the averaging principle underlying the DRGs as much as possible, we limited the number of DRGs that were affected by the one-day-stay policy. We selected 55 DRGs with substantial inpatient and outpatient overlap. In addition, we included any DRGs that were in the same DRG family (i.e., same base DRG) as the 55 DRGs to make the policy consistent across DRGs within the same family. This selection yielded a total of 93 DRGs, which accounted for about 61 percent of inpatient one-day stays and 73 percent of outpatient observation stays.

To construct one-day-stay DRGs, we split each of the 93 selected DRGs into 2 DRGs: a DRG for one-day

stays only and a DRG for stays of two days or more. We then collapsed the 93 one-day-stay DRGs into 44 one-day-stay DRGs by grouping one-day stays for the same base DRGs together. Payment rates were simulated for these new or modified DRGs under the assumption that the policy would be budget neutral within the inpatient setting (meaning that aggregate inpatient payments would be unchanged).

Results of the simulation

Overall, a one-day-stay DRG policy reduces the payment difference between an inpatient one-day stay and similar outpatient stay, while creating a new payment cliff within the inpatient system between a one-day inpatient stay and longer inpatient stays. To illustrate this effect, our analysis compared the average payment rate across the top 10 medical DRGs and top 10 surgical DRGs (in numbers of inpatient one-day stays) under current policy and the illustrative one-day-stay DRG policy. Under current policy, for the 10 medical DRGs, Medicare paid roughly $3,160 more,

(continued next page)

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of an illustrative one-day-stay DRG policy. (See text box for more details on the simulation methodology.) Under the 2012 policy, for 10 selected medical DRGs, inpatient stays were paid $3,160 more on average than similar outpatient observation stays. A one-day-stay DRG policy would reduce this payment difference to $910 on average, but would create a new payment differential within the IPPS between one-day and two-day (or longer) stays. Our simulation estimates that inpatient stays of two or more days would be paid $3,140 more on average than one-day inpatient stays for the selected DRGs. Thus, a one-day-stay DRG policy would reduce the financial incentive to admit a patient for one-day inpatient stays, but would create a financial incentive to extend an inpatient stay from one to two days.

Alternatively, a site-neutral approach—one that pays comparable rates for similar inpatient and outpatient stays—is another option. The effect of a site-neutral approach may be different for medical and surgical hospital stays. For medical stays, an example of a site-

neutral approach would be to pay observation stays that exceed a certain hour threshold (e.g., 24 hours) a rate comparable with a short inpatient medical stay (e.g., a one-day inpatient stay).[34] However, similar to a one-day-stay DRG policy, this approach would give hospitals the financial incentive to extend inpatient stays to reach the two-day threshold. Similarly, hospitals would have a financial incentive to keep a patient in observation until she or he met the 24-hour threshold. For medical stays, it would be difficult to eliminate the inpatient and outpatient payment differential because identifying similar stays would likely necessitate establishing length-of-stay criteria, which would create new payment differentials.[35]

Because surgery is a more clearly defined service, it might be possible to develop site-neutral payment for similar inpatient and outpatient surgeries without creating payment differentials based on length of stay. For example, criteria could be developed to identify surgical cases that occur in both the hospital outpatient and inpatient

on average, for an inpatient stay than an outpatient observation stay. For the 10 surgical DRGs, Medicare paid roughly $4,240 more, on average, for an inpatient stay than for a comparable outpatient surgery. Under the simulated one-day-stay DRG policy, the payment difference, on average, between a one-day inpatient stay and a similar outpatient visit would be reduced to about $910 for the 10 medical DRGs and $2,300 for the 10 surgical DRGs. However, the one-day-stay DRG policy creates a payment differential between a one-day inpatient stay and longer inpatient stays. The average payment for an inpatient stay lasting 2 days or more would exceed the average payment for a one-day inpatient stay by roughly $3,140 for the 10 medical DRGs and $3,330 for the 10 surgical DRGs. Thus, the one-day-stay DRG policy reduces the financial incentive to admit a patient for a one-day stay who could otherwise be treated as an outpatient, but creates a financial incentive for a hospital to keep the patient as an inpatient for a second day.

The illustrative one-day-stay DRG policy would very modestly redistribute inpatient payments to hospitals. Hospitals that have an above average number of one-day inpatient stays as a share of all inpatient stays (in the DRGs affected by the policy) would experience a revenue decrease while other hospitals would

TABLE 7–9

Effect of illustrative one-day DRG policy on hospital revenues by percentile of change to hospital

Hospital by percentile of revenue change	Percent change in revenues
Percentile	
5th	–2.2%
10th	–1.5
25th	–0.7
50th	0.0
75th	0.7
90th	1.4
95th	2.0

Note: DRG (diagnosis related group).

Source: MedPAC analysis of Medicare claims and cost report data.

experience an increase or no change in revenues (Table 7-9). Eighty percent of hospitals (between the 10th and 90th percentiles) would have a positive or negative revenue change of 1.5 percent or less. Ten percent of hospitals (below the 5th percentile and above the 95th percentiles) would have a positive or negative revenue change of roughly 2 percent or more. ■

settings and that are also very common to the outpatient setting (e.g., more than half of cases are performed in the outpatient setting). Additional criteria could be developed for identifying surgeries appropriate for site-neutral payment, such as similarity in care delivered or resources used across inpatients and outpatients. For surgeries meeting these criteria, Medicare could pay hospitals a comparable rate regardless of whether the patient was admitted. A site-neutral approach for surgeries could take a number of different forms. For example, site-neutral payment for surgeries could be carved out of the IPPS and OPPS and moved into a separate payment system. Alternatively, surgeries qualifying for site-neutral payment could be subsumed under one of the existing payment systems (i.e., require all such surgeries be billed to and paid under either the IPPS or OPPS).

Payment changes such as one-day-stay DRGs or site-neutral payment for medical stays would raise additional questions. For example, would a budget-neutrality adjustment be warranted to account for the potential increase in payments that could occur if providers lengthened inpatient stays in response to new payment differences between one-day and two-day inpatient stays? Another issue that would need to be considered is what type of audit oversight would accompany a revised payment policy. The approach used by the two-midnight rule of auditing one-day stays and generally exempting stays of two or more days from auditing would not be consistent with a one-day-stay DRG policy or a site-neutral policy. Instead, an approach to auditing focused on incentives driven by the new payment differentials under a revised payment system would be required.

Payment policy changes such as one-day-stay DRGs and site-neutral payment for medical stays would involve trade-offs. An open question is which set of incentives—those under the current payment systems or those under a revised payment system—are preferable. Several arguments can be made in favor of a revised payment system. Some stakeholders assert that short inpatient stays and observation stays represent similar care and that the distinction between an inpatient stay and an observation stay is not clear cut and essentially is artificial. From that perspective, reducing or eliminating the payment differences between short inpatient stays and similar outpatient observation stays would be a step toward rationalizing payments by paying similar rates for similar care. Revising the payment system may reduce the need to audit one-day inpatient stays for admission appropriateness because the financial consequences related to the admission decision would be reduced.

By contrast, several arguments can be made against revising the payment system and for retaining the current payment system. Because a revised payment system would create new payment cliffs and associated vulnerabilities, it may broaden the need for audit oversight. Moving away from the fixed inpatient DRG payments to one-day-stay DRGs or site-neutral payment also raises concerns about creating financial incentives for longer stays, which is counter to the original structure and intent of the DRG system. Additionally, policymakers may need to better understand how these potential policies might interact with the existing IPPS recalibration process. It is notable that the existing IPPS recalibration process may, over time, modestly lessen—although not eliminate—the payment cliff between short inpatient stays and similar outpatient stays.[36,37] Given the competing arguments for and against payment policy changes, the Commission has chosen not to recommend payment changes at this time. However, the Commission has noted interest in continuing to explore these and other potential hospital short-stay payment policy concepts in the future.

RAC program changes

The Commission has identified several concerns with RAC program audits of short stays, including the administrative burden on individual hospitals and CMS, the greater need for holding auditors accountable for their performance, and the lack of synchronization of the RAC program's look-back period and the allowable Medicare hospital rebilling window. The two-midnight rule addresses some of the problems it was intended to

resolve, but it also generates additional concerns among some stakeholders.

The Commission recommends changes to the RAC program that could alleviate some of the problems that led CMS to implement the two-midnight rule. In particular, reforming the RAC program in these three areas could make RACs more judicious in auditing claims and could mitigate the need for the two-midnight rule's safe harbor from RAC audits. Therefore, the Commission asserts that the four components of this recommendation must be treated as a package rather than as separable elements.

RECOMMENDATION 7-1

The Secretary should:

- **direct recovery audit contractors (RACs) to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay,**

- **modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate,**

- **ensure that the RAC look-back period is shorter than the Medicare rebilling period for short inpatient stays, and**

- **withdraw the "two-midnight" rule.**

RATIONALE 7-1

Administrative burden

A RAC audit focus on hospitals with excessive use of short inpatient stays would create efficiencies for compliant hospitals. In other words, the share of hospitals demonstrating high use of short inpatient stays would be subject to greater RAC review, while the share of hospitals with low use of these stays would be subject to fewer or no RAC reviews of short hospital stays.

The hospital industry contends that the RAC program has increased hospitals' administrative burden, thereby increasing their cost of providing care. The current RAC program reviews inpatient claims from a broad number of hospitals, which may amount to as much as 90 percent of all hospitals (American Hospital Association 2014a). Nearly all hospitals admit patients for short inpatient stays, but only a subset of hospitals accounts for a preponderance of these stays. However, the Commission notes that a policy designed to identify high-use hospitals would need to incorporate a risk-adjustment methodology because variation likely exists in the mix of hospitals' short-stay cases. For example, hospitals that have higher than average shares of short stays—urban, teaching, and for-profit

hospitals—may conduct a high volume of certain types of surgeries. In addition, this recommendation focuses on short inpatient stays because RACs have placed greater emphasis on these stays. The Secretary should have the discretion to define short stays because this policy may create the incentive to lengthen stays and may change hospital behavior over time.

Accountability of RAC auditors

The purpose of adjusting RACs' contingency fees based on their performance is to hold RACs more accountable for their decisions to deny hospitals' claims for short stays. If a denial overturn rate is used, the Secretary should have latitude to define the rate in a way that most accurately reflects RAC performance.

The contingency fee structure provides incentives for RACs to identify as many inappropriate payments and as many claims with the largest associated payments as possible. Currently, RACs must return the contingency fee to CMS if a hospital appeals the denial of the claim and wins its appeal, but RACs currently face no penalties when claim denials are overturned on appeal.

Rebilling claims following denial by RACs

Currently, the timing of the RAC program claim denial process and the timing of the Medicare rebilling policy are out of sync, making hospitals' rebilling of denied claims administratively infeasible. Under current policy, RACs have a three-year look-back period to review claims, but hospitals have only a one-year window to rebill denied inpatient claims. An alignment of these two processes would enable hospitals to rebill more RAC-denied inpatient claims as outpatient claims. CMS's analysis of 2011 data concluded that 25 percent of RAC-denied inpatient claims were denied within one year of the claim's date of service. Therefore, we expect that 25 percent of the RAC-denied claims would have been eligible for rebilling had that program been in place.

The Commission believes the Medicare program should increase hospitals' opportunities to rebill RAC-denied claims. In these cases, a hospital service was provided to a Medicare beneficiary and the hospital should receive reimbursement for it. However, the Medicare rebilling program should maintain a time limit from the date service was provided because hospitals should have the incentive to submit claims accurately. The Commission believes hospitals should also be permitted to appeal RAC claim denials, but at a certain point, hospitals should need to choose between continuing an appeal and rebilling

for that claim. If the rebilling program were to have no time limit, we would be concerned that hospitals would have the incentive to initially submit more claims with inpatient status, knowing that they can always rebill for the denied claim after fully exhausting all levels of appeal. Such a scenario would not be beneficial for the program, beneficiaries, or providers because it could further congest the appeals process. To balance these concerns, the RAC look-back period should be shorter than the one-year rebilling window. The period should be short enough to provide hospitals with enough time between the look-back period and the rebilling window to enable them to rebill RAC-denied claims but long enough that hospitals do not have idle time between the look-back period and the rebilling window to fully exhaust the appeals process for every RAC-denied claim. For example, in the context of a one-year rebilling window, the RAC look-back period could be shortened to between 4 and 8 months. However, the Secretary also could adjust the rebilling window consistent with the principles above: hospitals should not be able to fully exhaust the appeals process before initiating rebilling, and there should be a clear window for hospitals to rebill denied claims. The rules regarding rebilling should be structured to ensure that hospitals cannot circumvent RAC review by delaying claims submission until after the RAC look-back period has elapsed. For example, the shortened RAC look-back period could apply only to claims that the hospital submitted within a specified time frame after the date of beneficiary discharge; otherwise, the standard RAC look-back period could apply.

Two-midnight rule

Implemented in response to various stakeholders' desire to clarify the appropriateness of inpatient hospital admissions through a time-based admission standard and to provide hospitals with relief from RAC audits, the two-midnight rule addresses some of its stated goals but also generates some unintended consequences. The two-midnight rule likely reduces long observation stays, and it relieves administrative burden by exempting all stays longer than two midnights from RAC oversight (unless there is evidence of abusive practices). The scope of this exemption, or safe harbor, from RAC audits may be problematic because it provides hospitals with the incentive to lengthen stays to avoid RAC scrutiny and largely eliminates oversight for a large share of hospital claims. To avoid RAC scrutiny, hospitals might lengthen stays by increasing their use of short observation stays or inpatient stays in general to get beyond the two-

midnight threshold. Withdrawing the two-midnight rule, in conjunction with implementing the Commission's other audit-related recommendations, would be a better way to address the concerns associated with hospital short stays.

Spending

- We expect this recommendation will increase Medicare program spending. Targeted audits are unlikely to recover overpayments equal to those recovered under the existing RAC program. RAC-identified overpayments will decrease because imposing greater accountability will cause RACs to become more cautious in denying claims. The number of RAC-denied inpatient claims that are subsequently rebilled as outpatient claims will increase. Spending implications of the withdrawal of the two-midnight rule are unclear, but spending may increase if the Secretary decides to restore the 0.2 percent reduction made in the fiscal year 2014 IPPS final rule to account for the implementation of the two-midnight rule.

Beneficiary and provider

- We do not expect that this recommendation will adversely affect Medicare beneficiaries with respect to access to care. The withdrawal of the two-midnight rule may have a mixed effect on beneficiary cost sharing because some stays would likely shift between inpatient and outpatient stays, and these settings have different cost-sharing structures. For providers, this recommendation may reduce administrative burden. Hospitals in aggregate also will experience an increase in revenues due to increased rebilling opportunities following inpatient claim denials. The impact on individual providers will depend on their utilization patterns. A subset of hospitals with high rates of short inpatient stays will receive increased scrutiny from RACs and may therefore experience increased claim denials and administrative burden. For the remainder of hospitals, this recommendation will reduce RAC scrutiny and thus decrease claim denials and administrative burden.

Hospital payment penalty on short inpatient stays

Policymakers should continue to identify long-term options for reducing hospitals' administrative burden, lowering hospitals' costs, and reducing hospitals' financial incentive to admit patients while not discouraging clinical innovations that lead to shorter stays. The Commission

believes it is essential that the Secretary maintain adequate oversight of Medicare payments and that this oversight system be as efficient as possible. Concurrent with the RAC-related policies included in the previous section of the chapter, the Commission has discussed the concept of a payment penalty on hospitals with excessive short inpatient stays and believes there should be further study of this concept. Ultimately, a policy such as this could be implemented as either a replacement for or a supplement to RAC program audits of short inpatient stays.

The Secretary should evaluate establishing a penalty for hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for recovery audit contractor review of short inpatient stays.

The current RAC program has been effective in generating financial recoveries for the Medicare Hospital Insurance Trust Fund and inducing behavioral change in providers. However, the RAC program adds to the administrative burden of individual hospitals and increases the cost of the appeals process for the federal government. To alleviate these concerns, the Commission has considered a formula-based penalty on excess short inpatient stays that could serve to substitute, in whole or in part, for RAC reviews of short inpatient stays. This concept should be evaluated further because there are several design issues that could alter the penalty's potential effectiveness. As part of this study, the Secretary could consider gathering public feedback on this concept in future IPPS rulemaking. The Commission also intends to continue to explore the concept of the formula-based payment penalty on short inpatient stays.

Design of the formula-based penalty

In designing a formula-based penalty, policymakers would need to address several fundamental design questions. For example, policymakers would need to determine how to define short stays, how to determine a short-stay penalty threshold, and how to determine the penalty amount.

Defining short inpatient stays Policymakers must decide on the definition of a short inpatient stay. The Commission has defined short inpatient stays as those with a single overnight stay and those that are admitted and discharged on the same day. In addition, policymakers must decide whether utilization should be

measured by a simple count of short stays, by a count of excess short stays, or by another metric. To date, the Commission has considered a measure that counts excess short stays, which can be defined as the number of actual short stays minus the number of expected short stays. The Commission defines expected short stays as the product of a hospital's count of all inpatient stays multiplied by the national mean short-inpatient-stay utilization rate for each DRG (taking into account both inpatient and outpatient stays).

Defining the short inpatient stay utilization threshold The penalty threshold for relatively high use of short stays could be determined in a number of ways. For example, a hospital could be determined to be high use if its one-day inpatient stays accounted for 20 percent or more of its inpatient and outpatient stays. In calculating each hospital's short-inpatient-stay utilization, the Secretary would need to examine variation in hospitals' case mix and account for differences through risk adjustment because short-stay volume is affected by a hospital's mix of cases. The established threshold for high use could be adjusted over time based on changes in hospital short-stay utilization rates. For example, policymakers may wish to adjust the utilization rate threshold in subsequent years if hospitals, on average, begin reducing their use of short inpatient stays.

Determining the payment penalty amount A payment penalty amount could be determined in several ways. For example, the penalty could be a percentage reduction in the hospital's inpatient payment amount. Alternatively, the penalty could be valued as the average excess inpatient payment per one-day stay times the number of excess one-day stays above a certain threshold of stays.

Consequences of a short-stay payment penalty

The design decisions made by policymakers would determine the outcome of a formula-based payment penalty, but in general, this policy would have positive and negative consequences.

Positive consequences

- A formula-based payment penalty could be a more efficient method of providing oversight of short inpatient stays. It could reduce hospitals' RAC-related administrative burden and reduce CMS's administrative burden in managing the RAC program. Hospitals may be able to reduce the number of staff they employ to handle RAC medical record requests or to track appeals through the appeals process.

- The penalty could be as effective as the RAC program at providing hospitals with the incentive to limit their use of short inpatient stays.

- In contrast to the existing RAC program, a payment penalty might be more transparent for hospitals. The penalty would have clearly defined thresholds compared with the more subjective RAC auditing process and ALJ appeals process.

Negative consequences

- Triggered by excess rates of one-day stays, the penalty would not distinguish between appropriate and inappropriate short inpatient stays on a case-by-case basis. Short inpatient stays can be broken down into two groups: appropriate admissions that are of short duration because of hospital efficiency and inappropriate admissions that could have been served in the outpatient setting. Because the penalty would be driven by a formula-based measure, utilization patterns of all one-day stays would determine the penalty. However, a formula-based measure may not be capable of differentiating between appropriate and inappropriate short stays. By contrast, the RAC program conducts a case-by-case review of appropriateness and is better able to differentiate these two types of one-day stays. Unlike the RAC claims review, a formula-based penalty could discourage clinically appropriate one-day stays that resulted from greater efficiency.

- Similar to the two-midnight rule, the penalty could provide hospitals with the incentive to avoid one-day inpatient stays by either increasing the use of observation status or lengthening inpatient stays beyond one day.

IMPLICATIONS 7-2

Spending
- We do not expect this recommendation to increase Medicare program spending at this time because the Commission recommends exploring the concept of a payment penalty rather than implementing a final policy.

Beneficiary and provider
- We do not expect this recommendation to adversely affect Medicare beneficiaries or providers because the Commission recommends further exploration rather than implementation.

Beneficiary protections

The recent increase in outpatient observation stays has exposed some Medicare beneficiaries—those who are discharged to a SNF without qualifying for SNF coverage and those who receive self-administered drugs—to greater financial liability. Beneficiaries treated in outpatient observation are not always aware of the key coverage and liability consequences of being served as an outpatient.

Revise the SNF three-day prior hospitalization policy

Revising the SNF coverage eligibility requirement would permit time spent in outpatient observation status to count toward the three-day prior hospitalization threshold, but to protect the Hospital Insurance Trust Fund, such a revision would need to require that at least one of the three days be an inpatient day.

R E C O M M E N D A T I O N   7 - 3

The Congress should revise the skilled nursing facility three-inpatient-day hospital eligibility requirement to allow for up to two outpatient observation days to count toward meeting the criterion.

R A T I O N A L E   7 - 3

This policy seeks to balance reducing beneficiary liability for cases that currently do not qualify for SNF coverage with preventing the current SNF post-acute care benefit from expanding to a long-term care benefit. Allowing time spent in observation to count toward the three-day-stay requirement, while still requiring at least one of the three days to be an inpatient day, would allow more beneficiaries to qualify for SNF coverage and would limit the potential for a large increase in SNF use that might result from allowing observation to count for the entire three days. Beneficiaries who are never admitted or who are not in the hospital for three days would remain ineligible for SNF coverage. Overall, a partial reduction of the requirements for SNF coverage would increase SNF utilization.

In recent years, certain risk-bearing arrangements such as Medicare Advantage plans and some accountable care organizations (ACOs) within fee-for-service (FFS) Medicare have had the SNF three-day rule waived with the assumption that admitting patients directly to a SNF could reduce unnecessary hospitalizations. CMS should assess the need for the SNF three-day rule with regard to risk-bearing arrangements in general, including risk-bearing ACOs within FFS.

I M P L I C A T I O N S   7 - 3

Spending

- The Commission anticipates that this recommendation would increase program spending. An additional several thousand beneficiaries would qualify for SNF coverage, increasing the overall level of annual SNF spending. The overall impact of this policy on spending would also depend on the behavioral reaction of beneficiaries and providers. By establishing a lower threshold for Medicare SNF coverage, this policy could encourage further changes in behavior. For example, the lower threshold might encourage nursing facilities to return more beneficiaries to the hospital to requalify for the SNF benefit.

Beneficiaries and providers

- The Commission anticipates that this policy would have a positive impact on the relatively small group of beneficiaries who are served in SNFs without Medicare SNF coverage. Such beneficiaries would see their out-of-pocket liability reduced dramatically. We anticipate that this policy would increase Medicare use and resulting payments to freestanding and hospital-based SNFs.

Advanced beneficiary notification about observation status

Beneficiaries are often unclear about the differences between inpatient status and outpatient observation. Further, beneficiaries are occasionally surprised to learn that they failed to qualify for Medicare SNF coverage and are financially liable for the costs of SNF care. Thus, the Commission is concerned that some beneficiaries are not notified by the hospital treating them that they are being served in outpatient observation status rather than inpatient status.

To clarify beneficiary status, CMS has included some beneficiary education regarding observation services in recent publications. For example, the 2015 edition of *Medicare & You* directs beneficiaries (or family members on the beneficiary's behalf) to ask whether they are an inpatient or outpatient on each day of their hospital stay because their status may affect their financial liability. Further, a May 2014 CMS publication for beneficiaries called *Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!* provides details on the difference between inpatient and outpatient stays, including examples of what Medicare Part A and Part B cover and the coverage criteria for SNF care. The document also advises

beneficiaries to "always ask your doctor or hospital staff if Medicare will cover your SNF stay" (Centers for Medicare & Medicaid Services 2015b).

The Commission contends that the difficulty beneficiaries have in making distinctions between inpatient and outpatient coverage calls for requiring hospitals to notify Medicare beneficiaries, both orally and in writing, that their observation status could affect their cost-sharing liability and their coverage eligibility for SNF care as part of the discharge planning process.

RECOMMENDATION 7-4

The Congress should require acute-care hospitals to notify beneficiaries placed in outpatient observation status that their observation status may affect their financial liability for skilled nursing facility care. The notice should be provided to patients in observation status for more than 24 hours and who are expected to need skilled nursing services. The notice should be timely, allowing patients to consult with their physicians and other health care professionals before discharge planning is complete.

RATIONALE 7-4

Medicare currently does not require hospitals to notify beneficiaries of their outpatient observation status, regardless of the time these beneficiaries spend in the hospital. Medicare beneficiaries and beneficiary advocates often cite this lack of notification as a source of confusion for beneficiaries regarding SNF eligibility and cost-sharing liability. The Commission maintains that this notification should be provided at a time when a patient can best plan for posthospital care.

Several states now have laws or are considering laws that require hospitals to inform patients about their status in observation. Each state's law includes at least one of the following parameters: how the notification is communicated (written or orally), when the notification is provided, and what coverage information the notification contains. The changes in discharge destination, admission patterns, and length of stay resulting from these policies remain uncertain given the recent implementation of the state laws. Further, given the narrow scope of the Commission's recommendation for beneficiary notification, any changes that occur across the limited number of Medicare beneficiaries affected by this notification will be difficult to detect.

IMPLICATIONS 7-4

Spending

- This recommendation will have no significant effect on Medicare spending.

Beneficiaries and providers

- This recommendation will help provide beneficiaries with the basic coverage information they need to be able to work with discharge planners to determine the optimal post-acute care setting for their needs. Hospitals will have to make administrative changes to accommodate this policy and will incur an administrative cost to implement this policy.

Liability for self-administered drugs

Beneficiaries served in outpatient observation status can face high out-of-pocket costs for prescription medications they take while they are in the hospital. Specifically, if a hospital provides a self-administered drug (SAD) to a hospital outpatient, the drug is considered noncovered. The hospital bills the beneficiary for the drug at the full charge (approximately $200, on average, for observation stays), which is typically substantially above the cost of the drug (approximately $40, on average, for observation stays). By contrast, Medicare covers these drugs for hospital inpatient beneficiaries. As a result, beneficiaries face unexpected and occasionally large out-of-pocket costs for the SADs they received during their outpatient observation stay. The extent to which beneficiaries are affected by this issue varies by hospital. Some hospitals reportedly do not charge beneficiaries for SADs. Other hospitals contend that they must charge beneficiaries for SADs because of laws prohibiting beneficiary inducements. Some hospitals report that SAD charges are a source of patient dissatisfaction and that administrative resources, which are limited, are spent addressing these issues.

To address these concerns, Medicare should cover SADs under the OPPS, in a budget-neutral manner, for beneficiaries who are ordered to receive outpatient observation services. Under this approach, the Secretary would increase the outpatient payment rates associated with observation care—whether paid through the observation ambulatory payment classification (APC) or packaged into payment for other separately paid APCs on the claim—to reflect coverage of SADs, while the payment rates for other outpatient services under the OPPS would decrease slightly to offset the coverage, resulting in no additional Medicare spending.

The Congress should package payment for self-administered drugs provided during outpatient observation on a budget-neutral basis within the hospital outpatient prospective payment system.

This recommendation would reduce beneficiary liability substantially. Beneficiaries in observation would no longer be liable for noncovered SADs at full charges. The beneficiary would face higher cost sharing for outpatient observation (reflecting Medicare's increased payment rate for observation), but this higher cost sharing would be counterbalanced by lower cost sharing on other nonobservation outpatient services. This recommendation would also make cost sharing for SADs more uniform across beneficiaries and OPPS hospitals. Payment for SADs should be packaged, rather than paid separately, to avoid creating the financial incentive to overprovide these drugs.

Spending

- This recommendation would cover SADs under the outpatient hospital payment system in a budget-neutral manner, so it would not increase program spending.

Beneficiaries and providers

- Overall, this recommendation would reduce beneficiary liability for SADs. Hospitals would experience a small decrease in revenues obtained through beneficiary liability. This policy could also reduce hospital administrative burden associated with cost-sharing collections and beneficiary complaints regarding payment for SADs. ∎

Endnotes

1   One-day stays include stays that crossed one midnight or no midnights. The length of inpatient stays is measured by the number of midnights a stay crossed. For example, a two-day stay is a stay that crossed two midnights.

2   Medicare beneficiaries typically enter into observation status through the hospital emergency department, but can enter through outpatient clinics or by direct referral. Hospitals manage observation patients either by placing them within an observation unit with staff specifically devoted to observation or by serving these patients in any available inpatient bed, with staff assigned to a broad range of patients.

3   Commercial insurers use a variety of strategies to encourage providers to avoid hospital admissions. In addition to policies requiring prior authorization and notification, some insurers clearly define admission criteria in provider contracts, implement care coordination programs, encourage hospitals to use hospitalists, and sign risk-based contracts with providers to give the provider an incentive to control patients' costs and keep the patient out of the hospital.

4   The length of inpatient stays is calculated by measuring the number of midnights the stay crossed. However, one-day stays include stays that crossed one midnight as well as stays that were discharged on the same day admission occurred.

5   Medicare's IPPS includes an outlier payment policy that provides hospitals with extra payments in cases where the costs of a case significantly exceed payments. Analyses of Medicare payment reported in this chapter include outlier payments.

6   The IPPS contains two different transfer policies that reduce payment for inpatient stays when a patient is transferred early in the stay to either another acute care hospital (hospital-to-hospital transfer policy) or certain post-acute care settings (post-acute transfer policy). Only 12 percent of one-day stays are affected by transfer policies (5 percent by the hospital-to-hospital transfer policy and 7 percent by the post-acute care transfer policy).

7   A few MS–DRGs in the top 15, such as septicemia and heart failure, had a substantial number of stays lasting one day because of deaths.

8   More information about Medicare's inpatient and outpatient prospective payment systems is available at http://www.medpac.gov/documents/payment-basics/hospital-acute-inpatient-services-payment-system-14.pdf?sfvrsn=0 and http://www.medpac.gov/documents/payment-basics/outpatient-hospital-services-payment-system.pdf?sfvrsn=0.

9   To translate outpatient observation claims into inpatient MS–DRGs, we linked claims' outpatient Current Procedural Terminology (CPT) codes or Healthcare Common Procedure Coding System (HCPCS) codes to corresponding inpatient International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) procedure codes. We grouped the resulting outpatient claims into inpatient MS–DRGs using standard grouping software. Because the development of CPT to ICD–9–CM crosswalks is a clinically subjective exercise, we used several different versions of this crosswalk in our analyses.

10   This analysis is based on 2012 data, and changes were made to increase the payment rates moderately for observation in 2014. Observation care meeting certain criteria is eligible for payment through a composite APC for extended evaluation and management. The 2012 payment rate for the composite APC was $394 or $720, depending on how the patient entered observation (with the higher paid APC being the most prevalent). The total amount Medicare paid for observation in 2012 was more than the composite APC rate because certain services, such as imaging and clinical labs, received additional payment. In 2014, CMS established a single composite APC for observation and packaged some additional ancillary services into the APC, with the resulting 2014 APC payment rate being $1,199. Some services remained separately billable in 2014, so total payment for observation would be more than this APC rate. In 2015, the observation APC payment rate increased to $1,235.

11   Payment differences between short inpatient stays and comparable outpatient stays also exist for surgical stays, but the differences are generally smaller. For example, in 2012, payments for stays with MS–DRG 247 (percutaneous cardiovascular procedure with drug-eluting stent without MCC) were $13,748, on average, when the case was a one-day inpatient stay and $9,966, on average, when the case was a one-day outpatient stay.

12   The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 first established the Medicare RAC program as a demonstration project limited to California, Florida, and New York.

13   The Medicare appeals process has five levels, but RAC appeals are largely resolved after the first three levels. The process begins after the RAC makes a denial determination. The hospital has 120 days (4 months) to decide to appeal to the Medicare administrative contractor (MAC) (the first level of appeal). The MAC then has 60 days (2 months) to make a ruling. After the MAC's ruling, the hospital has 180 days (6 months) to decide whether or not to appeal to the qualified independent contractor (QIC) (the second level of appeal).

If so, the QIC has 60 days (2 months) to make a ruling. Both the MAC and QIC appeal determinations involve an element of automation. After the QIC's ruling, the hospital has 60 days (2 months) to decide whether or not to appeal to the administrative law judge (ALJ) (the third level of appeal). The ALJ has 90 days (3 months) to make a ruling. This is the point at which the appeals process has experienced the most significant backlog. After the ALJ's ruling, the hospital has 60 days (2 months) to decide to appeal to the Medicare Appeals Council (the fourth level of appeal). The Council has 90 days (3 months) to make a ruling. After the Council's ruling, the hospital has 60 days (2 months) to decide whether or not to appeal to the federal court system (the fifth and final level of appeal). There is no established time line for the federal court's ruling, but assuming all these time lines are met, the process could take as long as 750 days (26 months). Hospitals control the pace of the appeal for 16 months (60 percent), and the other entities control the pace of appeal for 10 months (40 percent).

14 Audit accuracy rates represent how often RACs accurately determine overpayments or underpayments based on the validation of an independent contractor. The calculation of these rates is separate from the appeals process.

15 A hospital may not replace denied inpatient care with what it contends is equivalent outpatient care because CMS intends for these beneficiaries to retain their inpatient status. CMS specifically excludes the following outpatient-only services from the hospital rebilling program: diabetes self-management training, physical therapy, speech–language pathology, occupational therapy, outpatient visits generally, emergency department visits, and observation. The hospital is also not permitted to alter the beneficiary's status from inpatient to outpatient.

16 In addition to outpatient observation stays, the two-midnight rule has potentially had an impact on outpatient stays that do not contain observation status, such as surgical stays or other stays originating in the emergency department. We estimate that in 2012, there were about 200,000 of these nonobservation outpatient stays.

17 CMS instructs physicians that, in deciding whether an inpatient admission is warranted, they should assess whether the beneficiary will require hospital services for two or more midnights (including time spent in the inpatient setting and the outpatient setting, such as in observation or the emergency department).

18 In the fiscal year 2014 IPPS final rule, CMS estimated that the two-midnight policy would shift 360,000 stays from inpatient status to outpatient status and another 400,000 stays from outpatient status to inpatient status, a net increase of 40,000 inpatient stays. These cases represent less than 5 percent of all outpatient observation cases. As a result, CMS adjusted the

inpatient base payment rates down by 0.2 percent for fiscal year 2014.

19 Between 2012 and 2013, the utilization of one-day inpatient stays declined more rapidly (6 percent per beneficiary) than all other inpatient stays (3 percent per beneficiary).

20 Between 2006 and 2012, surgical discharges declined 20 percent per fee-for-service Part A beneficiary, and medical discharges declined 11 percent per beneficiary. From 2011 to 2012, the decline of medical and surgical discharges was equal, at 6 percent, demonstrating the general migration of services to the outpatient setting.

21 Between 2012 and 2013, the utilization of outpatient observation stays increased more than 4 percent per Medicare Part B beneficiary. Collectively, from 2006 to 2013, the number of visits per 1,000 beneficiaries increased 96 percent.

22 In 2012, approximately 200,000 stays were between 48 hours and 71 hours in length, and nearly 50,000 stays were 72 hours or more.

23 Six of the most common MS–DRGs across all outpatient observation stays in 2012 were chest pain (MS–DRG 313); esophagitis (MS–DRG 392); syncope (MS–DRG 312); cardiac arrhythmia (MS–DRG 310); disorders of nutrition (MS–DRG 641); and circulatory disorders except acute myocardial infarction, with cardiac catheterization (MS–DRG 287).

24 The formula for the one-day-inpatient-stay ratio equals the number of one-day inpatient stays over the sum of all inpatient stays, all outpatient observations stays, all outpatient emergency department visits, and all outpatient surgical stays. The formula for the outpatient-observation-stay ratio equals the number of outpatient observation stays over the sum of all inpatient stays, all outpatient observations stays, all outpatient emergency department visits, and all outpatient surgical stays. The formula for the long-outpatient-observation-stay ratio equals the number of outpatient observation stays lasting 48 or more hours over all outpatient observation stays.

25 The 55 MS–DRGs used for this analysis include the 6 MS–DRGs identified as common to both inpatient and outpatient observation stays. To translate outpatient observation claims into inpatient MS–DRGs, we linked outpatient CPT codes to corresponding inpatient ICD–9–CM procedure codes and then grouped the resulting outpatient claims into inpatient MS–DRGs using standard grouping software. We used several proprietary crosswalks of CPT to ICD–9–CM procedure codes because an official Medicare crosswalk does not exist.

26 For inpatient stays, beneficiaries are responsible for a deductible amount in each benefit period ($1,216 for fiscal year 2014) and a coinsurance payment amount if their stay

is exceptionally long. For outpatient stays, beneficiaries are responsible for both a deductible amount and coinsurance. Medicare Part B beneficiaries are responsible for coinsurance of roughly 20 percent of the allowed amount, billed charges, or preset rate of the service, depending on the type of service received.

27 In 2012, approximately 85 percent of Medicare FFS beneficiaries had some form of supplemental coverage that shielded them from some or all of their inpatient deductibles and also outpatient Part B deductible coinsurance (Medicare Payment Advisory Commission 2014).

28 Most of the remaining beneficiaries (84 percent) were discharged home, and a small share (11 percent) were discharged to other post-acute care settings.

29 For example, Connecticut (2014), Maryland (2013), New York (2013), and Pennsylvania (2014) have state laws mandating hospitals to notify patients that they are in observation status. These laws vary in what exactly they require of hospitals. Two require notification be given to all patients in observation status and two require notification be given to patients after they have been in observation status for 24 hours.

30 Between 2009 and 2012, the volume of these cases increased 61 percent, from 63,000 cases to 102,000 cases, or about 20 percent growth per year.

31 Under a modified SNF three-day policy, a modest behavioral response such as increasing the length of stays might also result in SNF coverage for beneficiaries who had an inpatient admission and spent between 48 and 71 hours in the hospital. There were 46,000 of these stays in 2012.

32 We focused on observation patients since the length of observation stays (on average more than 24 hours) can result in patients needing to get their regular medications from the hospital. We also included ED and outpatient surgeries in the analysis since these services can sometimes involve lengthy hospital outpatient stays, which might result in the need for SADs.

33 Anecdotally, some hospitals report not charging beneficiaries for SADs, which might in part account for the lack of reporting of SAD charges in the observation claims for one-third of hospitals.

34 In this example, observation stays of less than 24 hours would be paid a lower outpatient rate, and inpatient stays of 2 or more days would be paid a higher inpatient rate.

35 Without length-of-stay criteria, Medicare would pay comparable rates for patients with similar diagnoses who received inpatient medical stays and outpatient observation stays (including outpatient stays that involved only a few hours of observation). This policy may not be desirable since the intensity and cost of these stays may not be similar.

36 The relative weight for an inpatient DRG is based on the relative cost of inpatient cases in that DRG compared with the cost of cases in other DRGs. If, over time, a DRG experiences a reduction in inpatient length of stay, the relative weight—and resulting payment rate for that DRG—may decline. Because the inpatient DRG relative weight is based on the cost of all inpatient cases in the DRG (short and long), inpatient payments are likely to always remain higher than the outpatient payment after recalibration. Also, to the extent that, over time, short inpatient stays for a DRG shift from the inpatient to outpatient setting, average length of the stay and average cost for the remaining inpatient cases in that DRG could increase, possibly increasing the payment cliff between an inpatient and outpatient hospital stay for that condition.

37 The Medicare claims used to recalibrate the relative weights for a payment year are based on claims for two fiscal years prior. These claims include those processed by Medicare during the given year (12 months) and the 6-month period after the close of that year. Inpatient claims denied by a RAC within that 18-month period are not included in the recalibration process. Claims denied outside of that 18-month period would be included in the recalibration process and would be reflected in the claims file as paid claims. Therefore, many short inpatient stay claims denied by RACs and currently in the appeals process may be included in the data used in the recalibration process.

References

American Hospital Association. 2014a. *Exploring the impact of the RAC program on hospitals nationwide: Results of the AHA RACTrac Survey, 1st quarter 2014.* Chicago, IL: AHA.

American Hospital Association. 2014b. *Exploring the impact of the RAC program on hospitals nationwide: Results of the AHA RACTrac Survey, 3rd quarter 2014.* Chicago, IL: AHA.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015a. Hospital participant: Settlement instructions. http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/HospitalParticipantSettlementInstructions_updated09092014.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015b. *Medicare & you 2015.* National Medicare Handbook. Baltimore, MD: CMS. http://www.medicare.gov/Pubs/pdf/10050.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014a. *Medicare benefit policy manual: Chapter 1—Inpatient hospital services covered under Part A.* Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014b. *Medicare benefit policy manual: Chapter 6—Hospital services covered under Part B.* Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014c. *Medicare benefit policy manual: Chapter 8—Coverage of extended care (SNF) services under hospital insurance.* Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014d. *Recovery auditing in Medicare for fiscal year 2013.* Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013a. CMS administrator's ruling: Part A to Part B rebilling of denied hospital inpatient claims. *MLN Matters* no. MM8185. Baltimore, MD: CMS. http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm8185.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013b. *Frequently asked questions: 2 midnight inpatient admission guidance & patient status reviews for admissions on or after October 1, 2013.* Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013c. Medicare program; Part B inpatient billing in hospitals. Proposed rule. *Federal Register* 78, no. 52 (March 18): 16632–16646.

Feng, Z., B. Wright, and V. Mor. 2012. Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Affairs* 31, no. 6 (June): 1251–1259.

Government Accountability Office. 2014. *Medicare: Further action could improve payment prevention and recoupment efforts.* GAO–14–619T. Washington, DC: GAO.

Medicare Payment Advisory Commission. 2014. *A data book: Health care spending and the Medicare program.* Washington, DC: MedPAC.

Office of Inspector General, Department of Health and Human Services. 2013. Memorandum report: Hospitals' use of observation stays and short inpatient stays for Medicare beneficiaries. OEI–02–12–00040. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2012. *Improvements are needed at the administrative law judge level of Medicare appeals.* OEI–02–10–00340. Washington, DC: OIG.

Office of Medicare Hearings and Appeals, Department of Health and Human Services. 2015. Adjudication timeframes. http://www.hhs.gov/omha.

Office of Medicare Hearings and Appeals, Department of Health and Human Services. 2014. Office of Medicare Hearings and Appeals workloads. Statement of Nancy J. Griswold, Chief Administrative Law Judge, before the Subcommittee on Energy Policy, Health Care, and Entitlements, Committee on Oversight and Government Reform, U.S. House of Representatives. 113th Congress, 2nd sess. July 10.

Next steps in measuring quality of care in Medicare

Next steps in measuring quality of care in Medicare

Chapter summary

In its June 2014 report to the Congress, the Commission put forth a concept for an alternative to Medicare's current system for measuring the quality of care provided to the program's beneficiaries. For reasons explained in that report, the Commission believes that there is a fundamental problem with Medicare's current quality measurement programs, particularly in fee-for-service (FFS) Medicare, which is that they rely primarily on clinical process measures for assessing the quality of care provided by hospitals, physicians, and other types of providers. Tying a portion of a providers' payment to their performance of specific clinical processes may exacerbate incentives in FFS to overprovide services. Such measures also may contribute to uncoordinated and fragmented care, while burdening providers and CMS with costs of gathering, validating, analyzing, and reporting on process measures that have little value to beneficiaries and policymakers.

Under the alternative policy discussed in the Commission's June 2014 report, Medicare would use a small set of population-based outcome measures to evaluate quality of care at the population level in a local area under each of Medicare's three payment models—traditional FFS, Medicare Advantage (MA), and accountable care organizations (ACOs). Examples of such outcome measures include rates of potentially preventable hospital admissions, emergency department visits, and readmissions; mortality; and patient experience measures. Both achievement (performance levels)

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- Introduction

- Concept for a new approach to quality measurement

- How population-based outcome measures could be applied to traditional FFS, ACOs, and MA plans in a local area

- Measuring "healthy days at home"

- Further directions

and improvement (changes in performance levels over time) could be measured, affording Medicare useful tools to evaluate quality.

The Commission's report drew a distinction between using this small set of population-based outcome measures for public reporting versus using it for payment policy. Public reporting of a local area's performance on these measures could be done for all three of the payment models operating in the area (traditional FFS in total, MA plans, and ACOs, if any) and for each individual MA plan and ACO in the area. However, the results could not be used for traditional FFS payment adjustments because there is no single accountable entity that would represent all of the traditional FFS providers in an area. The Commission does support using population-based outcome measures to adjust payments to the MA plans and ACOs in a local area. For example, by using the ambient level of quality in FFS Medicare as a minimum threshold, CMS could determine whether any of the MA plans and ACOs qualified for quality-based payment adjustments.

This chapter examines two measurement concepts that we are evaluating to determine whether they could eventually fit into the small set of population-based outcome measures: a "healthy days at home" (HDAH) measure and health-related quality of life measures such as patient-reported outcomes. Our initial analysis of an HDAH measure using Medicare claims data suggests that such a concept may be a meaningful way to compare differences in relative health status across populations in a way that would be relatively easy for beneficiaries, policymakers, and other stakeholders to understand. The preliminary analysis found that the measure's ability to detect differences among populations is magnified when it is focused on beneficiaries who are diagnosed with one or more chronic conditions and that the results are sensitive to the types of service use included in the measure, specifically post-acute care and, more particularly, home health services.

The Commission plans to continue exploring the HDAH measure concept, including several issues that were not included in this initial analysis such as risk adjustment, geographic variation, and relative importance of different types of service. The Commission plans to examine additional issues related to the development of the HDAH measure, including HDAH specific to beneficiaries with certain clinical conditions and an analysis of HDAH results for the beneficiary populations attributed to ACOs.

Patient-reported outcome measures also may have value in distinguishing quality among FFS Medicare, MA, and ACO populations within a local area, but more research is needed before reaching conclusions about their use in Medicare. ∎

Introduction

In its June 2014 report to the Congress, the Commission presented evidence that has accumulated over the past few years, underscoring several concerns with Medicare's current approach to measuring the quality of care for beneficiaries, particularly in the traditional fee-for-service (FFS) program (see that report for details) (Medicare Payment Advisory Commission 2014).[1] The key points from that report are as follows:

- While Medicare has made improvements in the past couple of years, it currently relies on too many clinical process measures that are weakly correlated with health outcomes such as mortality and readmission rates, which are more meaningful to and understandable by beneficiaries and policymakers.

- Tying a portion of a provider's payment to that provider's performance of specific clinical processes is likely to increase the volume of, and Medicare spending for, the services encompassing those processes, which is concerning when there is evidence that such services are not associated with improved health outcomes.

- The current system is overly burdensome and complex for providers and for CMS to administer, both because it uses process measures that require labor-intensive data extractions from medical records and because Medicare's quality measures are not aligned with those required by private payers.[2,3]

- Providers are given incentives to focus their limited resources on the care processes that Medicare is measuring, whether or not those quality issues are the most significant for a particular provider or local area. As a result, providers have fewer resources available for determining their own ways to improve more relevant outcomes such as reducing potentially preventable hospital admissions and emergency department (ED) visits, readmissions, and deaths, and improving beneficiaries' experience of care.

Concept for a new approach to quality measurement

The Commission's June 2014 report explored a new approach to measuring and reporting on the quality of care within and across the three main payment models in Medicare: traditional FFS, Medicare Advantage (MA), and accountable care organizations (ACOs). This alternative would deploy a small set of population-based outcome measures, such as potentially preventable hospital admissions, ED visits, and readmissions; mortality; and patient experience surveys, to assess a local area's quality of care delivered by providers paid under Medicare's three payment models. Other experts have proposed a similar quality measurement approach that is concise and focused on the outcomes of care, explicitly giving more flexibility and more responsibility to providers and organizations to assess their own needs to improve performance on the selected outcome measures (Meyer et al. 2012).

The Commission's vision is that, over the next several years, Medicare would move away from publicly reporting on dozens of clinical process measures and toward reporting on a small set of population-based outcome measures for the beneficiary populations served by traditional FFS, ACOs, and MA plans. For payment policy, Medicare could use the same population-based outcome measures to compare a local area's quality of care in ACOs and MA plans with the quality assessed for the area's traditional FFS providers; using the area's FFS quality level as a minimum threshold, Medicare could determine quality-based payment adjustments for the ACOs and MA plans. Such adjustments would not be appropriate for payments to traditional FFS providers because they are not organized under any accountable entity such as an MA plan or an ACO. Medicare would have to continue to use other, provider-based quality measures to make traditional FFS payment adjustments—but in a much more focused and succinct way than it does today.

The Commission has considered using population-based outcome measures to assess the quality of care instead of relying on provider-based process measures, as in current practice for traditional FFS. Under this approach, Medicare would use a small set of population-based outcome measures to assess the quality of care provided under each of the program's three payment models—traditional FFS, ACOs, and MA plans—within a local area. As much as possible, these areas should be defined in a way that is consistent with the organization of local health care delivery markets and with Medicare payment policy, such as those that the Commission has recommended for local MA payment areas (Medicare Payment Advisory Commission 2005). We also note that, even if Medicare were to use population-based outcome measures to evaluate and compare quality across traditional FFS, ACOs, and MA plans in a local area, the use of these population-based measures would not preclude each area's

TABLE
8–1

Population-based outcome measures for measuring quality in an area

Outcome measure	Specifications	Examples of existing metrics that could be used
Potentially preventable admissions for inpatient hospital care	Risk-adjusted rates of potentially preventable admissions for beneficiaries diagnosed with ambulatory care–sensitive conditions (e.g., diabetes, CHF, COPD); may also include admissions for procedures subject to clinical appropriateness criteria (e.g., spinal fusion surgery) and admissions for short-term or long-term complications of chronic diseases	• 3M™ Potentially Preventable Admissions • AHRQ Prevention Quality Indicators
Potentially preventable ED visits	Risk-adjusted rates of potentially preventable ED visits for beneficiaries diagnosed with specified ambulatory care–sensitive conditions for the treatment of that condition; visits for conditions for which beneficiary could have been treated in a community setting (e.g., physician office)	• 3M Potentially Preventable Visits • Billings/New York University algorithm of potentially avoidable ED visits (Billings 2003)
Mortality rates after an inpatient hospital stay	Risk-adjusted 30-day postdischarge mortality rates for condition-specific (AMI, CHF, pneumonia, stroke, and COPD) and all-condition measures	• CMS/Yale 30-day risk-standardized mortality rates
Readmission rates after an inpatient hospital stay	Risk-adjusted 30-day postdischarge readmission rates for condition-specific (AMI, CHF, pneumonia, stroke, and COPD) and all-condition measures	• CMS/Yale 30-day risk-standardized readmission rates • 3M Potentially Preventable Readmissions
Healthy days at home	Risk-adjusted number of days per year (expressed as a rate, such as per thousand beneficiaries) that individuals in a population met specified criteria for "healthy and at home." Definition could include days during which a beneficiary was alive and neither was an inpatient nor had an ED visit	• Conceptual design under development by Commission staff
Patient experience	Performance on standardized patient experience surveys (e.g., CAHPS®), specifically including CAHPS Item Set for Addressing Health Literacy	• FFS CAHPS, MA CAHPS, and CG CAHPS (for ACOs)

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease), AHRQ (Agency for Healthcare Research and Quality), ED (emergency department), AMI (acute myocardial infarction), CAHPS® (Consumer Assessment of Healthcare Providers and Systems®), FFS CAHPS (fee-for-service CAHPS), MA CAHPS (Medicare Advantage CAHPS), CG CAHPS (CAHPS Clinician & Group Surveys), ACO (accountable care organization).

Source: Medicare Payment Advisory Commission 2014.

individual providers, medical groups, and health systems from continuing to use other quality measures.

The population-based outcome measures proposed in the June 2014 report, including "healthy days at home" (highlighted in gray), are summarized in Table 8-1.

Patient-reported outcome measures, such as health-related quality of life (HRQOL) measures, also may have value in distinguishing quality among traditional FFS, MA, and ACO populations within a local area, but more research is needed before reaching conclusions about their use in Medicare (see text box, pp. 214–215).

How population-based outcome measures could be applied to traditional FFS, ACOs, and MA plans in a local area

Figure 8-1 depicts a simplified illustration of a local area in which Medicare's three payment models are active: traditional FFS, two ACOs, and three MA plans. Under the Commission's concept for using population-based outcomes to measure an area's quality, Medicare would calculate benchmark rates of outcome measures such as potentially preventable admissions, potentially preventable ED visits, mortality, and patient experience, and then at

**FIGURE
8–1**

Conceptual diagram of quality reporting for Medicare payment models in a local area

Medicare publicly reports and compares population-based outcomes for traditional FFS and ACOs combined (the benchmark*), each individual ACO, and each MA plan in a local area.

ACO 1

ACO 2

Benchmark* =

Total of ACOs + FFS Medicare

MA Plan 1

MA Plan 2

MA Plan 3
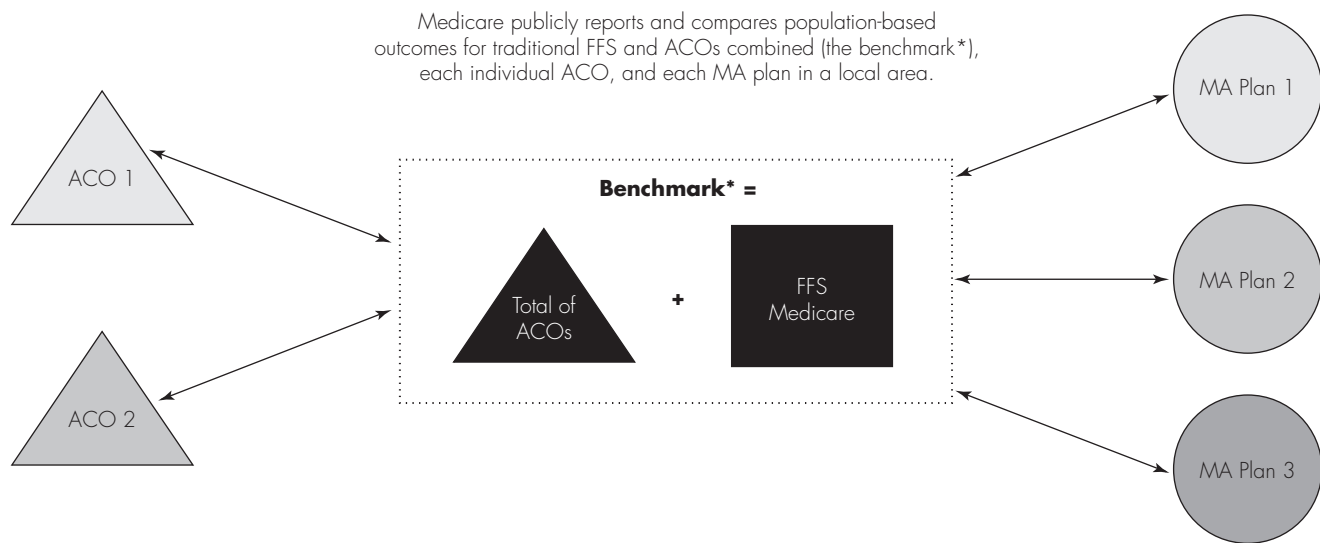
Note: FFS (fee-for-service), ACO (accountable care organization), MA (Medicare Advantage).
          *The benchmark shown here includes the combined results for all ACOs and FFS Medicare in the local area.

the end of a performance year, calculate rates on the same outcome measures for each of the MA plans, the ACOs, and FFS Medicare in the local area. The benchmark would be calculated with combined data from the area's traditional FFS providers and ACOs since providers in the current ACO program continue to be paid through traditional FFS. The benchmarks for each outcome measure could be calculated and published in advance of the performance year so that all parties could know them before the performance period starts.

The Commission would distinguish between using the performance results for public reporting and for payment policy. For public reporting, Medicare would publish the benchmark and the results of each outcome measure for the area's ACOs and MA plans.[4] In this way, beneficiaries, providers, policymakers, and other stakeholders would be able to compare each ACO and MA plan's outcomes with the benchmark (Figure 8-1).

For payment purposes, the area's benchmark for each measure would be the threshold that the area's ACOs and MA plans would have to exceed to qualify for a quality-based bonus payment (Figure 8-2a, p. 212). Medicare could impose payment penalties on the ACOs and MA plans that performed below the FFS benchmark. The amount of quality-based bonus payments to individual

ACOs and MA plans would be determined by comparing relative quality among the ACOs and, separately, among the MA plans (Figure 8-2b, p. 212). As discussed in the June 2014 report, the Commission believes that making payment adjustments to traditional FFS providers based on population-based outcome measures is not appropriate at this time.[5] Instead, Medicare will need to keep measuring quality in traditional FFS using provider-based measures to make quality-based payment adjustments. A more thorough discussion of this rationale is included in the Commission's June 2014 report to the Congress.

Measuring "healthy days at home"

Chapter 3 of the Commission's June 2014 report mentioned the concept of a quality measure that would count the number of days per year (expressed as a rate, such as per thousand beneficiaries) that the individuals in a given population met specified criteria for "healthy and at home," for example, days during which a beneficiary was alive and was neither an inpatient of a health care facility nor had an ED visit (Medicare Payment Advisory Commission 2014). The Commission has begun work constructing such a measure.

FIGURE
8–2

Conceptual diagram of quality-based payment for Medicare payment models in a local area

Figure 8-2a: Qualifying for quality-based bonus payment or penalty

ACOs and MA plans in a local area are compared against a benchmark* calculated by combining data for FFS Medicare and all of the ACOs in the area.
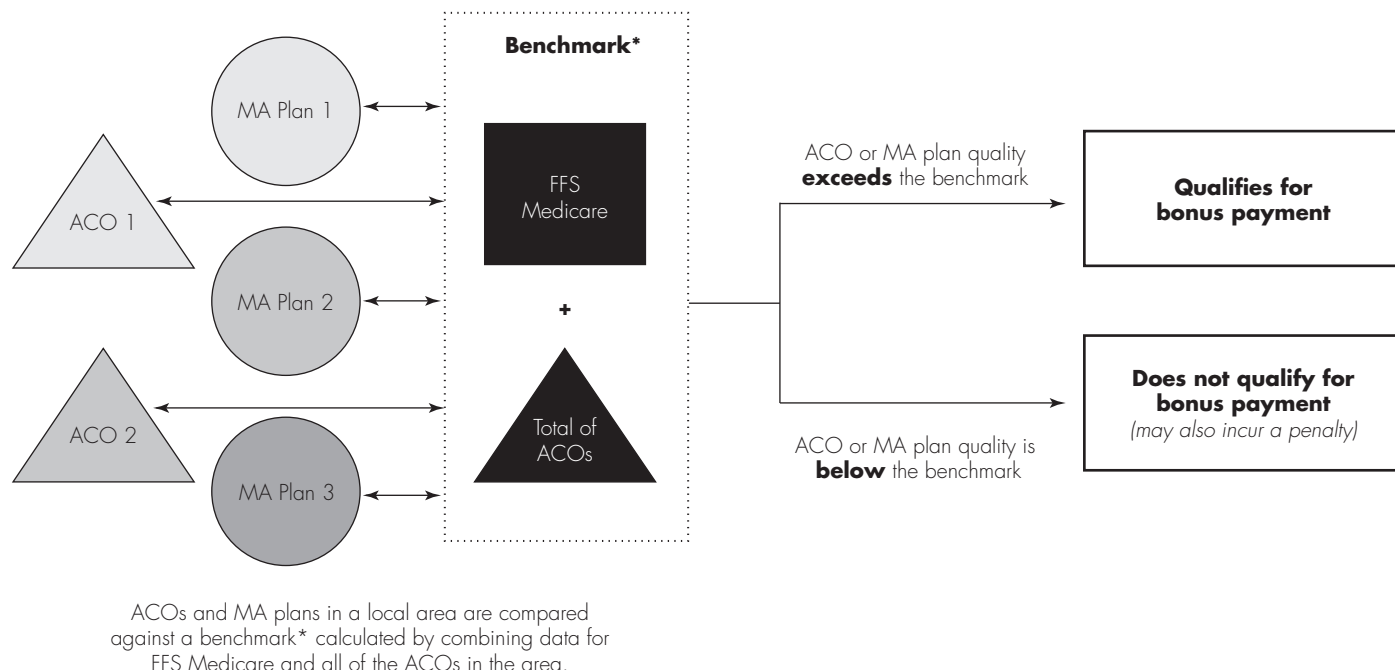
Figure 8-2b: Determining the value of quality-based bonus payment or penalty

FFS Medicare uses **provider-based measures** to determine bonuses or penalties for FFS providers.

• Measures not available for all provider types, so not all providers measured
• Each provider measured separately, if measures are available
• Bonuses or penalties determined within each provider type

Each ACO that qualifies for a bonus (or penalty) is compared against other ACOs using **population-based measures** to determine bonus (or penalty) amount.

Each MA plan that qualifies for a bonus (or penalty) is compared against other MA plans using **population-based measures** to determine bonus (or penalty) amount.

Note: ACO (accountable care organization), MA (Medicare Advantage), FFS (fee-for-service).
         *As shown here, the benchmark includes the combined performance of all ACOs and FFS Medicare.

"Days alive and out of the hospital" clinical trial measure

"Days alive and out of the hospital" (DAOH) is a measure that has been used in heart failure (HF) clinical trials. Researchers record hospitalizations and death in the period after an intervention such as pulmonary artery catheterization. In some trials, the recording period is for a set time—for instance, six months—and is the period defining the DAOH measure (Binanay et al. 2005). For others, DAOH is defined as the number of days before such an incident occurs, regardless of how long that takes. For instance, the Candesartan in Heart Failure–Assessment of Reduction in Mortality and Morbidity (CHARM) trial followed patients for a median of 38 months and used a linear regression of DAOH and percentage of DAOH to adjust for the differences in follow-up time (Ariti et al. 2011). These studies compare the DAOH of the intervention group with a control group; higher DAOH after an intervention compared with the control implies that the impact of the therapy was positive.

Historically, evaluation of HF interventions looked at mortality and hospitalizations independently. DAOH has become a popular endpoint for clinical trials because it captures the broader morbidity of the disease and two aspects of the potential benefits to patients (lower mortality rate and fewer hospital days) of the intervention being studied. However, some researchers caution that the composite measure may be skewed by the relative weights assigned to hospitalizations versus mortality in calculating the combined measure. That is to say, by accounting for both hospitalizations and mortality in the same measure, there is an inherent judgment call in deciding how to weight them relative to one another. If the measure is to be effective, one or the other outcome must be recognized as the primary driver of the composite score. This determination may be especially crucial when providers and patients are using the information to make a choice about the course of treatment (Cleland 2002). Furthermore, as the Commission has discussed previously in relation to readmission rates, mortality and hospitalization can be inversely correlated, acting in a way as substitutes for one another (Medicare Payment Advisory Commission 2013).

Cleland (2002) notes that a study that uses a finite time period may be more useful than those that run until an outcome endpoint is reached because patients observed in a defined time period have "an equal period of exposure to the risk of events and can attain the same potential maximum score" (p. 247). He further explains that this period could be lengthened or compressed based on patient severity, with those with acute HF being monitored for a couple of days or weeks, moderate HF patients monitored for 100–200 days, and mild HF patients followed for a year or more.

Broader concept of "healthy days at home"

The intent of a "healthy days at home" (HDAH) measure is to capture the number of days within a set period (e.g., per month, quarter, or year) that a local area's given population of beneficiaries (e.g., those in FFS Medicare, enrolled in an MA plan, or attributed to an ACO) are alive and did not have interactions with the health care system that imply less than optimal health. This concept appears consistent with the Commission's statements that Medicare ought to focus on quality metrics that are intuitively easy to understand and meaningful for beneficiaries (such as mortality and readmission rates). The HDAH concept also is in keeping with the Commission's position that measurement of quality in Medicare should be more comprehensive (that is, should encompass care delivered across settings) and more focused on evaluating care outcomes, and it should include few, if any, clinical process measures for one provider type. A comprehensive outcome measure such as HDAH eventually may be able to help beneficiaries make better informed choices about the delivery model (FFS, MA, or ACO) through which they decide to receive their care.

In developing and refining the HDAH measure, the Commission will need to grapple with which services to include in the measure to best capture the population's health over the given time period. For instance, a primary care evaluation and management visit would not necessarily suggest an unhealthy beneficiary, but a stay in a skilled nursing facility (SNF) almost always would. For the purposes of measuring population health, HDAH expresses the rate of an average beneficiary's interactions with the most therapeutically intensive parts of the health care system, that is, primarily inpatient and post-acute care. While it would not be accurate to conclude that all beneficiaries who did not have such an intensive interaction were completely healthy (e.g., many still could have chronic conditions that are treated and managed by ambulatory care providers), we sought to explore whether it was feasible to construct a measure that would allow us to compare risk-adjusted rates of HDAH across population groups.

The underlying goal is to build a measure of a population's relative health as reflected in the effectiveness of an ACO, MA plan, or local FFS Medicare delivery system in keeping its population healthy enough to avoid needing

One type of population-level outcome measure used in some clinical and health policy research environments is the "health-related quality of life" (HRQOL) measure. The Centers for Disease Control and Prevention (CDC) defines HRQOL as "functioning and well-being in physical, mental, and social domains of life" (Hays et al. 2009) or simply "perceived physical and mental health and function" (Centers for Disease Control and Prevention 2000). Assessed through surveys completed by patients, such as the 12-item or 36-item Medical Outcomes Study Short Forms (SF-12 or SF-36) or the National Institutes of Health (NIH) Patient-Reported Outcome Measurement Information System® (PROMIS®) Global Health Scale, an HRQOL measure attempts to quantify multiple dimensions of health and their effects on a patient's daily life (Centers for Disease Control and Prevention 2000).

CDC Healthy Days Core Module

The CDC has defined an HRQOL metric called the "Healthy Days Core Module" (HRQOL-4), which consists of four questions relating to physical and mental health:

1. Would you say that in general your health is excellent, very good, good, fair, or poor?

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

Using these four questions, the CDC defines "healthy days" as the number of days in the past 30 days in which patients indicated that both their physical and mental health were good. (A longer form of the survey, the HRQOL-14, is also available.) Furthermore, "because people generally seek healthcare only when they feel unhealthy, self-perceptions are also predictive of the future burden on the healthcare delivery system" (Centers for Disease Control and Prevention 2000). These questions have been incorporated into the CDC's Behavioral Risk Factor Surveillance System telephone survey and are in the public domain (Moriarty et al. 2003).

National Institutes of Health's PROMIS Global Health Scale

Researchers at Dartmouth recently suggested that "an outcome-focused approach could plausibly be built on the foundation established by NIH's PROMIS initiative, which is developing health status and domain-specific nonproprietary instrument banks that can be efficiently administered through computer-adaptive testing that markedly reduces respondent burden" (Colla and Fisher

(continued next page)

to access intensive health care services. If implemented, an HDAH measure would need to be used together with the other kinds of outcome measures described in the Commission's June 2014 report (e.g., patient experience surveys and rates of potentially preventable admissions and ED visits) so as not to create undesirable incentives for MA plans, ACOs, and FFS providers to underprovide or discourage beneficiaries from seeking needed care in an ambulatory setting.

Preliminary analysis results

Commission staff worked with a team led by Ashish Jha, MD, at the Harvard School of Public Health to

develop an illustration of one potential version of an HDAH measure. Instead of beginning the measurement period with a triggering event such as a hospitalization, HDAH was measured for all beneficiaries for the full year. Dr. Jha's team began with a 20 percent sample of Medicare beneficiaries from 2011, which included about 10.3 million beneficiaries. Because encounter data are not yet available for MA, those enrollees could not be included. Once beneficiaries who were enrolled in MA and those who were not enrolled in Medicare continuously throughout the year were excluded, about 6.8 million beneficiaries remained in the sample. About 4.1 million of

2014). The PROMIS Global Health Scale is a 10-item survey developed to create an efficient self-reported health assessment using "global health items," which ask respondents to evaluate their health in general rather than in terms of specific elements of health (Hays et al. 2009). It asks respondents for global ratings of their physical and mental health, physical function, fatigue, pain, emotional distress, and social health (Hays et al. 2009). It was included in the 2010 National Health Interview Survey (NHIS), and the National Center for Health Statistics also plans to include it in the 2015 and 2020 NHIS (Barile et al. 2013).

Concerns about HRQOL measures

The Commission has expressed concerns about the usefulness of a particular health status assessment instrument that CMS currently uses as one piece of quality measurement in the Medicare Advantage (MA) program: the Health Outcomes Survey (HOS). In its March 2010 report to the Congress, the Commission observed that, as applied to detect changes over time in MA plan enrollees' self-reported physical and mental health status, the HOS often produced results showing no significant outcome differences among MA plans. The Commission recommended that the HOS be used as a quality measure for fee-for-service (FFS) Medicare, as well as continuing its use in MA, only if the Secretary determined that its use as a quality measure could be improved to meaningfully differentiate quality between FFS Medicare and MA, and among individual MA plans (Medicare Payment

Advisory Commission 2010a, Medicare Payment Advisory Commission 2010b).

Another challenge in assessing HRQOL is that older survey tools such as the SF–36 are time-consuming to administer and, therefore, may not be practical to build into day-to-day clinical practice. A shorter, less burdensome survey might be a preferable data collection tool. Some researchers have questioned whether any HRQOL or functional status indicators can adequately reflect quality of care, at least for older adult patients with multiple chronic conditions (Dy et al. 2013). If this is a valid concern, then a HRQOL measure may not be appropriate to hold providers accountable for preventing or reversing functional decline for this population of Medicare beneficiaries. Other researchers cite evidence that responses on "global" health items, which are self-evaluations by an individual of his or her health in general rather than of specific elements of health, are predictive of future health care utilization and mortality (Hays et al. 2009).[6]

If a link between patient-reported outcomes and clinical outcomes could be established and if the statistical and administrative concerns that the Commission raised in the context of the HOS could be mitigated, then a tool like the 10-item PROMIS Global Health Scale may have value as a population-based outcome measure to compare performance across FFS Medicare, accountable care organizations, and MA plans. Further research is needed before reaching conclusions about the use of HRQOL measures in Medicare. ∎

those had a diagnosis of at least one chronic condition.[7] About 1.5 million beneficiaries, or 18.4 percent of the sample, were under age 65.

For the purposes of these analyses, HDAH was defined algorithmically as follows:

Healthy days at home = 365 days – (days in short-term acute care hospital + days in inpatient rehabilitation facility (IRF) + days in long-term care hospital (LTCH) + days in inpatient psychiatric facility + days in SNF + days in observation status + days of ED use + days of home health use + mortality days)

The analysis was performed for two populations: all qualifying beneficiaries and only beneficiaries with at least one diagnosed chronic condition. For each of these populations, the Harvard team compared HDAH geographically across Dartmouth Atlas hospital referral regions (HRRs). The Commission is sensitive to the incentives that may result from excluding or including home health care from the measure since it may be argued that some of the days of home health care use cannot be clearly categorized as either "healthy and at home" or "unhealthy and not at home." Because of this ambiguity, we could consider whether some types of home health use

might not be used to indicate an "unhealthy day." For this reason, and because the analysis found that days of home health use accounted for such a large share of total days, we report the HDAH results with and without home health days separately. We will continue to consider which types of home health use, if any, should be included in an HDAH measure.

HDAH results for all beneficiaries

In 2011, about 19 percent of beneficiaries had some type of hospitalization, with an average length of stay of about five days. This results in a mean length of stay of 2.3 days in the hospital when averaged across the entire population.[8] About 5.5 percent of beneficiaries had a SNF claim, resulting in an average of 3.1 days of SNF care across the entire population. About 5 percent of beneficiaries died during 2011, which translated to about 8.1 "mortality days," defined as the average number of days between a beneficiary's death and the end of the year, across the entire population.

The total HDAH measure was built progressively, beginning with DAOH and then adding other types of service use that suggested a beneficiary was neither at home nor healthy on the day of the service. For all beneficiaries in 2011:

Days alive and out of the hospital:

= 365.0 days – 2.3 days in the hospital – 8.1 mortality days

= 354.6 days

Days alive and out of the hospital and not in a SNF:

= 354.6 days – 3.1 days in SNF

= 351.5 days

Days alive and out of the hospital and not in a SNF and without an ED visit:

= 351.5 days – 0.9 days with at least one outpatient ED visit

= 350.6 days

Days alive and out of the hospital and not in a SNF and without an ED visit or an outpatient observation stay:

= 350.6 days – 0.2 days with at least 1 outpatient observation stay

= 350.4 days

In summary, in 2011, the average Medicare beneficiary was at home 350.4 days out of the year. Note that "at home" at this point cannot be assumed to mean "healthy and at home." Certain other services provided to beneficiaries at home, such as home health care and some outpatient procedures, may be indicators that a beneficiary at home is not healthy. As the Commission further develops this work, we will examine options for incorporating these types of services, when appropriate.

Like almost all other health care quality and resource-use measures, HDAH varies geographically. Table 8-2 shows the variation in HDAH across HRRs for all beneficiaries in 2011. The use of HRRs as the geographic unit of analysis, rather than a smaller area such as the Dartmouth Health Service Areas, was driven by consideration of the limits of statistical reliability of results for areas smaller than HRRs, given the underlying dataset of a 20 percent sample of Medicare claims. In further research on the HDAH measure, the Commission will use 100 percent claims data files, which will allow for reliable analysis of smaller geographic areas.

Table 8-2 shows that, setting aside the outliers, there was not much variation in the initial HDAH results, which did not include home health use. In the lowest performing HRR, the average beneficiary was at home 344.4 days; in the highest performing HRR, 355.4 days (a 3 percent difference). In contrast, the difference between the 25th and 75th percentile was only 2.5 days. When home health use is incorporated in the measure, the variation between the minimum and maximum increases to 21 percent (from 291.1 days to 353.2 days). Again, the variation in the interquartile range is relatively small, suggesting that the wide distribution is due to outliers. Beneficiaries were healthy and at home a mean of 350.4 days, and when home health use is considered an indication of an "unhealthy day," that mean drops to 341.6 days.

By considering the distribution of each component of HDAH, we can see how each type of "unhealthy day" contributes to the overall variation (Table 8-3). Differences in post-acute care appear to drive about half of the HDAH variation across geographic regions. Excluding days associated with beneficiaries who died, at the mean, post-acute care (LTCH, IRF, SNF, and home health) accounts for about 80 percent of the remaining days not healthy and at home.

Perhaps unsurprisingly, home health use is the single largest contributor to the observed variation in HDAH across HRRs, in part because home health care tends to be used

TABLE
8–2

Little variation appears in healthy days at home across hospital referral regions for all beneficiaries, 2011

	Days						
	Mean	Standard deviation	Minimum	25th percentile	Median	75th percentile	Maximum
Healthy days at home, no home health use	350.4	1.9	344.4	349.0	350.2	351.5	355.4
Healthy days at home	341.6	8.4	291.1	339.3	343.8	347.0	353.2

Note: Results are not risk adjusted. The number of hospital referral regions included in this analysis is 306. Analysis includes all fee-for-service beneficiaries.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

for a longer period of time than other services and because patterns of home health utilization vary so widely across the country. This finding is consistent with previous work by the Commission and Institute of Medicine on geographic variation in health care delivery (Institute of Medicine 2013, Medicare Payment Advisory Commission 2011). The large impact of the variation in home health use on HDAH rates suggests some areas for further research as we refine the HDAH measure concept. First, would the precision of the HDAH measure be improved by treating different types of home health services differently in the measure's calculation? For example, one option could consider whether home health use that follows an inpatient stay (i.e.,

post-acute care) should be counted as "non-healthy days," while home health days *without* a preceding inpatient stay should count as "healthy days," with a presumption that the latter type of home health could be substituting for more intensive inpatient treatment. Second, is it feasible to parse the known variation in home health use between that which captures a positive outcome of care, in the form of the least intensive clinically appropriate care, and undesirable factors that drive some of the variation, for instance, clinically inappropriate use or fraud and abuse? Finally, how would the inclusion or exclusion of different types of home health services affect providers' incentives when they are selecting a patient's site of care?

TABLE
8–3

Post-acute care accounts for much of the variation in types of unhealthy days at home across hospital referral regions, 2011

	Days						
Type of unhealthy day	Mean	Standard deviation	Minimum	25th percentile	Median	75th percentile	Maximum
Acute care hospital	1.8	0.4	1.0	1.5	1.8	2.0	3.1
Long-term care hospital	0.0	0.0	0.0	0.0	0.0	0.0	0.3
Inpatient rehabilitation facility	0.2	0.1	0.0	0.1	0.1	0.2	0.6
Inpatient psychiatric facility	0.2	0.1	0.0	0.1	0.2	0.2	0.6
Skilled nursing facility	3.1	1.0	0.7	2.4	3.0	3.8	7.8
Outpatient observation	0.2	0.1	0.0	0.1	0.2	0.2	0.8
Emergency department	0.9	0.2	0.4	0.8	0.9	1.1	1.7
Home health	8.8	7.9	1.0	4.1	6.2	10.5	62.3
Mortality	8.1	0.8	6.1	7.6	8.2	8.6	10.8

Note: Results are not risk adjusted. The number of hospital referral regions included in this analysis is 306.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

**TABLE
8–4**

**Total healthy days at home, all beneficiaries and beneficiaries
with at least one chronic condition HCC, 2011–2012**

	Days in 2011		Days in 2012	
	All beneficiaries	**Beneficiaries with at least one chronic condition HCC**	**All beneficiaries**	**Beneficiaries with at least one chronic condition HCC**
Type of unhealthy day				
Acute care hospital	1.8	2.8	1.7	2.6
Long-term care hospital	0.0	0.0	0.0	0.0
Inpatient rehabilitation facility	0.2	0.2	0.1	0.2
Inpatient psychiatric facility	0.2	0.3	0.1	0.2
Skilled nursing facility	3.1	4.9	2.9	4.7
Outpatient observation	0.2	0.3	0.2	0.3
Emergency department	0.9	1.3	0.9	1.3
Home health	8.8	13.3	8.6	13.3
Mortality	8.1	10.8	7.9	10.0
Healthy days at home	**341.6**	**331.0**	**342.5**	**331.9**
Healthy days at home, no home health use	**350.4**	**344.3**	**351.2**	**345.7**

Note: HCC (hierarchical condition category). Figures shown are averages across 306 hospital referral regions. Results are not risk adjusted. "Type of day" components
plus healthy days at home do not sum to 365 due to rounding.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

Focusing on healthy days at home for beneficiaries with chronic conditions

An evident challenge with the initial analysis that included all beneficiaries was that over 75 percent of the population had 365 healthy days at home, making it difficult, for example, to see much variation across geographic areas. To further explore whether the HDAH measure might be able to detect significant differences among beneficiary subpopulations, we next limited the sample to include only those diagnosed with at least one chronic condition. This analysis reduced the number of beneficiaries in the sample from about 6.8 million to about 4.1 million (i.e., 60 percent of all continuously enrolled FFS beneficiaries had at least one diagnosed chronic condition). The use of "at least one diagnosed chronic condition" as a criterion to limit the population being measured is only one of several options that could be used if policymakers decided the measurement population should be limited at all. The Commission will continue not only to explore the incentives that might be created from limiting versus expanding the population included in the measure but also to look at other options for more precisely defining the measured population, such as including only beneficiaries with specific chronic conditions that are responsive to high- or low-quality care

(e.g., congestive heart failure, chronic obstructive pulmonary disease, and chronic kidney disease).

As may be expected, beneficiaries with chronic conditions were healthy and at home fewer days than the total population.[9] Twenty-seven percent had at least one inpatient admission, as opposed to 18 percent of the general population. Likewise, beneficiaries with chronic conditions were more likely to experience a SNF stay (8.2 percent vs. 5.2 percent), an ED visit (32.0 percent vs. 23.8 percent), or death within the study year (6.0 percent vs. 4.3 percent). Table 8-4 shows the differences in HDAH for these populations in more detail, for both 2011 and 2012.

Similar to the DAOH measure, one challenge in defining the measure is that, for different populations, different components of the measure may contribute more to variation than others. For this reason, we show all components of the measure in the tables that follow.

As Table 8-4 shows, having 1 or more chronic conditions is associated with about 11 fewer HDAH when home health is included in the measure and 6 fewer HDAH when home health is not included. This trend is consistent for both years analyzed. In all categories, beneficiaries with at least

TABLE
8–5

Healthy days at home by age, for beneficiaries with at least one chronic condition HCC, 2011

| | Days, by age group | | | |
	Younger than 65	**65–69**	**70–79**	**80 or older**
Number of beneficiaries	831,703	728,448	1,379,070	1,289,630
Percent of beneficiaries	20%	17%	33%	30%
Type of unhealthy day				
Acute care hospital	3.1	2.2	2.6	3.6
Other inpatient	1.2	0.3	0.4	0.5
Skilled nursing facility	2.1	1.9	3.3	9.8
Outpatient observation	0.3	0.2	0.2	0.3
Emergency department	2.4	0.9	0.9	1.1
Home health	10.8	7.6	11.3	21.6
Mortality	5.0	5.2	7.9	20.6
Healthy days at home	**340.0**	**346.6**	**338.2**	**307.4**
Healthy days at home, no home health use	**350.9**	**354.3**	**349.7**	**329.1**

Note: HCC (hierarchical condition category). "Other inpatient" includes long-term care hospital, inpatient rehabilitation facility, and inpatient psychiatric facility. Figures shown are averages across 306 hospital referral regions. Results are not risk adjusted. "Type of day" components plus healthy days at home do not sum to 365 due to rounding.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

one chronic condition are more likely than the general population to have an "unhealthy day."

Table 8-5, Table 8-6 (p. 220), and Table 8-7 (p. 221) look at HDAH for beneficiaries in terms of different demographic characteristics: age, race/ethnicity, and Medicare–Medicaid dual eligibility. For these analyses, only beneficiaries who had at least one chronic condition were included.

With the exception of beneficiaries under age 65 (which includes beneficiaries entitled to Medicare on the basis of disability, end-stage renal disease, or both), younger beneficiaries in general had fewer unhealthy days, although it must be noted that these results are not risk adjusted (Table 8-5). The greatest variation occurred among days of SNF and home health use, and mortality. The under-65 population used home health care at about the same rate as beneficiaries ages 70 to 79 and used observation stays at the same rate as the population ages 80 and older. Beneficiaries under age 65 had more ED visits and other kinds of hospitalization days (e.g., days in LTCHs and inpatient psychiatric facility days) than other age groups.[10] The age 80-and-above population had significantly more days of SNF and home health use and mortality than other age groups.

Table 8-6 (p. 220) shows that beneficiaries whose race was identified as Asian, Other, or Unknown had the highest number of HDAH. Beneficiaries identified as African American or Hispanic had the lowest total HDAH, but the underlying utilization patterns differed. African Americans had more acute inpatient hospital days than any other group, with nearly four days on average. Hispanics on average used home health care for 27.6 days, the highest by far. African Americans' home health use was also relatively high (23.2 days). Both Whites and African Americans had relatively high SNF use, with about five days for each group. However, Hispanics used more than twice as much home health care as Whites. African Americans used nearly as much home health care as Hispanics in 2011. Variation in home health use explains much of the difference in healthy days between these groups. In fact, when home health use is excluded, Hispanics experienced on average more healthy days at home than Whites. These differences could be in part a function of geography and the existing geographic distribution of FFS Medicare beneficiaries with certain race/ethnicity characteristics.

Whites also had the highest number of mortality days (11.1), a result that is consistent with other studies that Jha and colleagues have conducted (Joynt and Jha 2011,

	White	African American	Asian	Hispanic	Native American	Other	Unknown
			Days, by race/ethnicity				
Number of beneficiaries	3,523,331	453,491	68,851	90,753	23,311	57,649	11,465
Percent of beneficiaries	83%	11%	2%	2%	1%	1%	0.3%
Type of unhealthy day							
Acute care hospital	2.8	3.9	2.3	3.2	3.3	2.3	2.5
Other inpatient	0.5	0.8	0.4	0.7	0.5	0.4	0.6
Skilled nursing facility	4.9	5.0	3.0	3.5	3.4	2.5	2.8
Outpatient observation	0.3	0.3	0.2	0.2	0.3	0.2	0.5
Emergency department	1.2	1.8	0.7	1.5	1.9	0.8	1.0
Home health	12.3	23.2	10.4	27.6	14.8	9.6	8.9
Mortality	11.1	9.7	7.5	8.4	9.8	6.7	7.1
Healthy days at home	**331.8**	**320.3**	**340.5**	**319.9**	**330.8**	**342.6**	**341.5**
Healthy days at home, no home health use	**344.1**	**343.5**	**350.9**	**347.6**	**345.7**	**352.2**	**350.5**

Note: HCC (hierarchical condition category). "Other inpatient" includes long-term care hospital, inpatient rehabilitation facility, and inpatient psychiatric facility. Results are not risk adjusted. "Type of day" components plus healthy days at home do not sum to 365 due to rounding.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

Joynt et al. 2011). Possible explanations suggested by this research include differences in diagnostic coding across race/ethnicity categories, differences in the percentage of the population over age 80 by race/ethnicity, and the trade-off between readmission rates and mortality.[11]

The quarter of Medicare beneficiaries in the sample who were dually eligible for Medicare and Medicaid also had substantially fewer HDAH than those who were Medicare-only beneficiaries (Table 8-7). Dual-eligible beneficiaries received twice as much home health care, had twice as many ED and outpatient observation days, and spent twice as many days in a SNF compared with beneficiaries who were not dual eligible.

Variation in HDAH across HRRs for beneficiaries with one or more chronic conditions (Table 8-8) follows a similar pattern to that of the general population (shown in Table 8-3, p. 217), but beneficiaries with one or more chronic conditions overall had more unhealthy days. On average, the biggest differences between the general population and the chronic conditions subgroup were home health use days

(8.8 vs. 13.3, respectively) and mortality days (8.1 vs. 10.8, respectively). Similarly to HDAH for the entire population, HDAH for beneficiaries with chronic conditions has outliers on both ends of the distribution and less variation between the 25th percentile and 75th percentile. However, there is more variation in this range for this subgroup.

Further directions

Our exploratory analysis thus far suggests that an HDAH measure may be a meaningful way to compare differences in relative health outcomes across populations and could be conveyed in a way that would be relatively easy for beneficiaries, policymakers, and other stakeholders to understand. The analysis found that the measure's ability to detect differences between groups is magnified when focused on beneficiaries diagnosed with one or more chronic conditions and that it is sensitive to the types of service use included in the measure, particularly the use of home health services. Risk adjustment is a critical

TABLE 8–7

Dually eligible beneficiaries with at least one chronic condition HCC generally had fewer healthy days at home than Medicare-only beneficiaries, 2011

	Days, by dual eligibility for Medicare and Medicaid	
	Dual eligible	**Not dual eligible**
Number of beneficiaries	1,043,466	3,185,385
Percent of beneficiaries	25%	75%
Type of unhealthy day		
Acute care hospital	3.8	2.7
Other inpatient	1.0	0.4
Skilled nursing facility	8.2	3.7
Outpatient observation	0.4	0.2
Emergency department	2.2	1.0
Home health	20.8	11.4
Mortality	11.9	10.4
Healthy days at home	**316.7**	**335.2**
Healthy days at home, no home health use	**337.6**	**346.6**

Note: HCC (hierarchical condition category). "Other inpatient" includes long-term care hospital, inpatient rehabilitation facility, and inpatient psychiatric facility. Results are not risk adjusted. "Type of day" components plus healthy days at home do not sum to 365 due to rounding.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

component missing from this preliminary analysis and must be developed and included in the measure before it could be used to make comparisons between geographic areas or accountable entities. Risk adjustment will also shed light on the nature of the variation in HDAH and whether those differences are clinically meaningful.

In future work, the Commission will continue to refine the measure based on:

- appropriate risk adjustment;

- stability of the measure;

- geographic variation, including level of analysis (e.g., HRR, hospital service area, etc.);

- inclusion or exclusion of service types;

- weighting of measure inputs (mortality and service types); and

- feasibility of detecting statistically significant differences among subgroups.

The Commission plans to examine additional issues related to the development of the HDAH measure, including:

- *Beneficiaries with certain clinical conditions.* The Commission's contractor has identified 15 conditions for further investigation, using a hospital discharge

TABLE 8–8

Healthy days at home across hospital referral regions, for beneficiaries with at least one chronic condition HCC, 2011

	Days						
	Mean	**Standard deviation**	**Minimum**	**25th percentile**	**Median**	**75th percentile**	**Maximum**
Type of unhealthy day							
Acute care hospital	2.8	0.5	1.6	2.5	2.8	3.1	4.5
Long-term care hospital	0.0	0.0	0.0	0.0	0.0	0.0	0.5
Inpatient rehabilitation facility	0.2	0.2	0.0	0.1	0.2	0.3	0.8
Inpatient psychiatric facility	0.3	0.2	0.0	0.2	0.2	0.3	0.9
Skilled nursing facility	4.9	1.6	1.2	3.8	4.6	5.9	12.9
Outpatient observation	0.3	0.2	0.0	0.2	0.3	0.3	1.3
Emergency department	1.3	0.3	0.6	1.1	1.3	1.5	2.6
Home health	13.3	11.3	1.7	6.5	9.4	15.4	86.8
Mortality	10.8	1.0	8.1	10.1	10.8	11.4	13.9
Healthy days at home	**331.0**	**11.8**	**262.5**	**328.2**	**334.9**	**338.5**	**347.0**

Note: HCC (hierarchical condition category). Results are not risk adjusted. The number of hospital referral regions included in this analysis is 306.

Source: MedPAC contractor analysis of 20 percent sample of Medicare claims data.

associated with the condition as the starting point of the measurement period.

- *An analysis of HDAH results for the beneficiary populations attributed to ACOs.* Because the claims used for the analyses in this chapter were from 2011 (before ACOs had begun operating), we did not feel it was appropriate to report simulated HDAH for ACOs at this time. Further, the 20 percent sample raises questions about the effects that random variation may have on the performance of ACOs on the measure. In future work, the Commission will analyze 100 percent claims data for the beneficiaries attributed to ACOs in more recent years.

- *A comparison of the updated aggregate ACO results with the results for the HRRs (or other geographic area) in which an ACO is located.* We are interested in examining whether—and, if so, to what extent— beneficiaries attributed to ACOs have different types of healthy days at home compared with beneficiaries in traditional FFS in the same local area. ∎

Endnotes

1 The Commission's June 2014 report (Chapter 3) also explored the feasibility of applying measures of potentially inappropriate service use ("overuse" measures) to FFS Medicare and described short-term steps that could be taken to improve FFS Medicare's existing provider-based quality measurement programs. Commission staff members are continuing to develop analyses in those policy areas, but they are not discussed in this report.

2 Medical record review is expensive because it requires trained personnel to abstract data from medical records in a standard format for analysis (Hicks 2003). Medical reviewers, who are typically either nurses or physicians, must interpret each record and input data findings into a standardized format collection tool. Medical records provide detailed clinical data that are required for some types of quality measures such as those that rely on laboratory values (e.g., hemoglobin A1c or cholesterol levels) or a record of a specific treatment being given within a specific time frame (e.g., primary percutaneous coronary intervention received within 90 minutes of hospital arrival or discharge instructions provided to the patient at time of discharge) (Agency for Healthcare Research and Quality 2014).

3 This evaluation is not meant to imply that Medicare would always defer to private payers' quality measures or vice versa, but the possibility of aligning measures and their specifications ought to be explicitly considered when Medicare adopts quality measures. There may be specific factors, such as certain comorbidities or age limits, that Medicare would use in its versions of outcome measures (e.g., mortality or potentially preventable admission and ED use rates) but that would not be appropriate to apply when measuring those outcomes for a commercial insurance population.

4 Defining the quality benchmark as the combined performance of a local area's FFS Medicare providers and ACOs would be necessary to create an ongoing incentive for the ACOs and MA plans in the area to continue improving quality over time. If the benchmark were defined to include *only* beneficiaries in traditional FFS Medicare, which could become smaller and less representative over time as ACOs and MA plans grow, then the resulting benchmark could be an increasingly unreasonable standard against which to evaluate the quality of the ACO and MA plans. Another approach that Medicare could consider would be to use (or phase in) national or regional performance benchmarks instead of (or combined with) the local area FFS + ACO benchmark. Under the current Medicare Shared Savings Program, CMS standardizes the risk-adjusted outcome measures for ACOs (such as the all-condition readmission measure and three acute unplanned admission

measures) nationally (Centers for Medicare & Medicaid Services 2015a). In addition to greatly increasing the size of the population represented in the benchmark, a national benchmark that is phased in over time could be used to gradually eliminate regional differences in risk-adjusted outcomes that are found to reflect local or regional quality shortfalls.

5 The primary reason is that population-based quality measurement would aggregate the performance of an area's individual FFS providers to determine the area's overall FFS Medicare quality, which would combine the quality of high-performing and low-performing providers and thereby unfairly reward low performers if overall performance was high, and would penalize high performers in areas where overall performance was low (Institute of Medicine 2013).

6 Examples of global health items in PROMIS include: "In general, would you say your health is: Excellent / Very good / Good / Fair / Poor?"; "To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair? Completely / Mostly / Moderately / A little / Not at all?"; "In the past 7 days, how would you rate your pain on average? From 0 (no pain) to 10 (worst pain imaginable)." The PROMIS global health items include ratings of physical health and mental health, overall quality of life, physical function, fatigue, pain, emotional distress, and social health (National Institutes of Health 2015).

7 Diagnoses were determined from claims data, and chronic conditions were defined using CMS hierarchical condition category (HCC) diagnosis definitions.

8 For this analysis, "days in the hospital" describes acute care hospital stays only. Subsequent analyses also include stays in LTCHs, inpatient psychiatric facilities, and IRFs.

9 "Chronic condition" in this case is defined as beneficiaries with at least one chronic condition HCC that results in the risk adjustment of MA payments. These 27 chronic conditions are the following: acquired hypothyroidism; acute myocardial infarction; Alzheimer's disease; Alzheimer's disease, related disorders, or senile dementia; anemia; asthma; atrial fibrillation; benign prostatic hyperplasia; cancer/colorectal; cancer/endometrial; cancer/breast; cancer/lung; cancer/prostate; cataract; chronic kidney disease; chronic obstructive pulmonary disease; depression; diabetes; glaucoma; heart failure; hip/pelvic fracture; hyperlipidemia; hypertension; ischemic heart disease; osteoporosis; rheumatoid arthritis/osteoarthritis; stroke/transient ischemic attack (Centers for Medicare & Medicaid Services 2015b).

10 The high rate of "other inpatient" hospital days for the under-65 population may be due in part to the high proportion of those beneficiaries diagnosed with mental disorders.

11 This analysis considers only those beneficiaries with at least one chronic condition HCC. Because certain groups may be more likely than others to receive diagnostic codes, it is possible that some comparable beneficiaries were excluded from this analysis. If so, this could contribute to the observed differences in service use and mortality rates because the level of illness across groups is not comparable.

References

Agency for Healthcare Research and Quality. 2014. *Selecting quality and resource use measures: A decision guide for community quality collaboratives.* Rockville, MD: Agency for Healthcare Research and Quality. http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/perfmeasguide/index.html.

Ariti, C. A., J. G. Cleland, S. J. Pocock, et al. 2011. Days alive and out of hospital and the patient journey in patients with heart failure: Insights from the Candesartan in Heart Failure: Assessment of Reduction in Mortality and Morbidity (CHARM) program. *American Heart Journal* 162, no. 5 (November): 900–906.

Barile, J. P., B. B. Reeve, A. W. Smith, et al. 2013. Monitoring population health for Healthy People 2020: Evaluation of the NIH PROMIS® Global Health, CDC Healthy Days, and satisfaction with life instruments. *Quality of Life Research* 22, no. 6 (August): 1201–1211.

Binanay, C., R. M. Califf, V. Hasselblad, et al. 2005. Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness: The ESCAPE trial. *Journal of the American Medical Association* 294, no. 13 (October 5): 1625–1633.

Centers for Disease Control and Prevention, Department of Health and Human Services. 2000. *Measuring healthy days: Population assessment of health-related quality of life.* Altanta, GA: CDC.

Centers for Medicare & Medicaid Services. 2015a. Medicare shared savings program quality measure benchmarks for the 2015 reporting year. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-QM-Benchmarks-2015.pdf.

Centers for Medicare & Medicaid Services. 2015b. Chronic conditions data warehouse: Chronic condition categories. https://www.ccwdata.org/web/guest/condition-categories.

Cleland, J. G. 2002. How to assess new treatments for the management of heart failure: Composite scoring systems to assess the patients' clinical journey. *European Journal of Heart Failure* 4, no. 3 (June): 243–247.

Colla, C. H., and E. S. Fisher. 2014. Beyond PCMHs and accountable care organizations: Payment reform that encourages customized care. *Journal of General Internal Medicine* 29, no. 10 (October): 1325–1327.

Dy, S. M., E. R. Pfoh, M. E. Salive, et al. 2013. Health-related quality of life and functional status quality indicators for older persons with multiple chronic conditions. *Journal of the American Geriatrics Society* 61, no. 12 (December): 2120–2127.

Hays, R. D., J. B. Bjorner, D. A. Revicki, et al. 2009. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Quality of Life Research* 18, no. 7 (September): 873–880.

Hicks, J. 2003. *The potential of claims data to support the measurement of health care quality.* Dissertation for the Pardee RAND Graduate School. Santa Monica, CA: RAND Corporation.

Institute of Medicine. 2013. *Interim report of the committee on geographic variation in health care spending and promotion of high-value care: Preliminary committee observations.* Washington, DC: The National Academies Press.

Joynt, K. E., and A. K. Jha. 2011. Who has higher readmission rates for heart failure, and why? Implications for efforts to improve care using financial incentives. *Circulation Cardiovascular Quality and Outcomes* 4, no. 1 (Jan 1): 53–59.

Joynt, K. E., E. J. Orav, and A. K. Jha. 2011. Thirty-day readmission rates for Medicare beneficiaries by race and site of care. *Journal of the American Medical Association* 305, no. 7 (February 16): 675–681.

Medicare Payment Advisory Commission. 2014. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

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

Medicare Payment Advisory Commission. 2011. *Report to the Congress: Regional variation in Medicare service use.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2010a. *Report to the Congress: Aligning incentives in Medicare.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2010b. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2005. *Report to the Congress: Issues in a modernized Medicare program.* Washington, DC: MedPAC.

Meyer, G. S., E. C. Nelson, D. B. Pryor, et al. 2012. More quality measures versus measuring what matters: A call for balance and parsimony. *BMJ Quality & Safety* 21, no. 11 (November): 964–968.

Moriarty, D. G., M. M. Zack, and R. Kobau. 2003. The Centers for Disease Control and Prevention's Healthy Days Measures: Population tracking of perceived physical and mental health over time. *Health and Quality of Life Outcomes* 1: 37.

National Institutes of Health. 2015. Domain frameworks: PROMIS adult self-reported health—Global health. http://www.nihpromis.org/Measures/domainframework1.aspx#gh.

Commissioners' voting
on recommendations

Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation and to document the voting record in its report. The information below satisfies that mandate.

Chapter 1: Synchronizing Medicare policy across payment models

No recommendations

Chapter 2: The next generation of Medicare beneficiaries

No recommendations

Chapter 3: Part B drug payment policy issues

No recommendations

Chapter 4: Value-based incentives for managing Part B drug use

No recommendations

Chapter 5: Polypharmacy and opioid use among Medicare Part D enrollees

No recommendations

Chapter 6: Sharing risk in Medicare Part D

No recommendations

Chapter 7: Hospital short-stay policy issues

7-1 The Secretary should:

- direct recovery audit contractors (RACs) to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay,
- modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate,
- ensure that the RAC look-back period is shorter than the Medicare rebilling period for short inpatient stays, and
- withdraw the "two-midnight" rule.

Yes: *Armstrong, Buto, Christianson, Coombs, Crosson, Gradison, Hackbarth, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Uccello*
Absent: *Baicker*

7-2 The Secretary should evaluate establishing a penalty for hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for recovery audit contractor review of short inpatient stays.

Yes: *Armstrong, Buto, Christianson, Coombs, Crosson, Gradison, Hackbarth, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Uccello*
Absent: *Baicker*

7-3 The Congress should revise the skilled nursing facility three-inpatient-day hospital eligibility requirement to allow for up to two outpatient observation days to count toward meeting the criterion.

Yes: *Armstrong, Buto, Christianson, Coombs, Crosson, Gradison, Hackbarth, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Uccello*
Absent: *Baicker*

7-4 The Congress should require acute-care hospitals to notify beneficiaries placed in outpatient observation status that their observation status may affect their financial liability for skilled nursing facility care. The notice should be provided to patients in observation status for more than 24 hours and who are expected to need skilled nursing services. The notice should be timely, allowing patients to consult with their physicians and other health care professionals before discharge planning is complete.

Yes: *Armstrong, Buto, Christianson, Coombs, Crosson, Gradison, Hackbarth, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Uccello*
Absent: *Baicker*

7-5 The Congress should package payment for self-administered drugs provided during outpatient observation on a budget-neutral basis within the hospital outpatient prospective payment system.

Yes: *Armstrong, Buto, Christianson, Coombs, Crosson, Gradison, Hackbarth, Hall, Hoadley, Kuhn, Naylor, Nerenz, Redberg, Samitt, Thomas, Uccello*
Absent: *Baicker*

Chapter 8: Next steps in measuring quality of care in Medicare

No recommendations

Acronyms

Acronyms

AAC	actual acquisition cost		**EPC**	Evidence-Based Practice Center
ACO	accountable care organization		**ESRD**	end-stage renal disease
ADE	adverse drug event		**FAQ**	frequently asked question
ADL	activity of daily living		**FDA**	Food and Drug Administration
AHA	American Hospital Association		**FE**	functional equivalence
AHRQ	Agency for Healthcare Research and Quality		**FFS**	fee-for-service
ALJ	administrative law judge		**FFS CAHPS**	fee-for-service Consumer Assessment of Healthcare Providers and Systems®
AMI	acute myocardial infarction		**FIM™**	Functional Independence Measure™
AMP	average manufacturer price		**GAO**	Government Accountability Office
APC	ambulatory payment classification		**GDP**	gross domestic product
ASP	average sales price		**GDR**	generic dispensing rate
ASP + 6	average sales price plus 6 percent		**HCC**	hierarchical condition category
BLS	Bureau of Labor Statistics		**HCPCS**	Healthcare Common Procedure Coding System
BRFSS	Behavioral Risk Factor Surveillance System		**HDAH**	healthy days at home
CAH	critical access hospital		**HF**	heart failure
CAHPS®	Consumer Assessment of Healthcare Providers and Systems®		**HEDIS®**	Healthcare Effectiveness Data and Information Set®
CBO	Congressional Budget Office		**HHS**	Department of Health and Human Services
CBSA	core-based statistical area		**HI**	Hospital Insurance (Medicare Part A)
CC	complication or comorbidity		**HIV/AIDS**	human immunodeficiency virus/ acquired immune deficiency syndrome
CDC	Centers for Disease Control and Prevention		**HMO**	health maintenance organization
CERT	Comprehensive Error-Rate Testing		**HOPD**	hospital outpatient department
CG CAHPS®	Consumer Assessment of Healthcare Providers and Systems® Clinician & Group Surveys		**HOS**	Health Outcomes Survey
CHARM	Candesartan in Heart Failure–Assessment of Reduction in Mortality and Morbidity		**HRET**	Health Research and Educational Trust
			HRQOL	health-related quality of life
CHF	congestive heart failure		**HRR**	hospital referral region
CMI	case-mix index		**HRSA**	Health Resources and Services Administration
CMMI	Center for Medicare and Medicaid Innovation		**HSA**	health service area
CMS	Centers for Medicare & Medicaid Services		**ICD–9–CM**	International Classification of Diseases, Ninth Revision, Clinical Modification
CMS–HCC	CMS–hierarchical condition category		**ID**	identification
COME HOME	Community Oncology Medical Home		**IME**	indirect medical education
COPD	chronic obstructive pulmonary disease		**IOM**	Institute of Medicine
CPI–U	consumer price index for all urban consumers		**IPPS**	inpatient prospective payment system
CPT	Current Procedural Terminology		**IRF**	inpatient rehabilitation facility
CPT–4	Current Procedural Terminology–4		**LCA**	least costly alternative
DAOH	days alive and out of the hospital		**LIS**	low-income [drug] subsidy
DEA	Drug Enforcement Administration		**LOCM**	low osmolar contrast material
DIR	direct and indirect remuneration		**LOS**	length of stay
DRG	diagnosis related group		**LTCH**	long-term care hospital
DSH	disproportionate share		**MA**	Medicare Advantage
E&M	evaluation and management			
ED	emergency department			

MA CAHPS®	Medicare Advantage Consumer Assessment of Healthcare Providers and Systems®		**OPPS**	outpatient prospective payment system
MAC	Medicare administrative contractor		**PAC**	post-acute care
MA–PD	Medicare Advantage–Prescription Drug [plan]		**PBM**	pharmacy benefit manager
MCC	major complication or comorbidity		**PBPM**	per beneficiary per month
MedPAC	Medicare Payment Advisory Commission		**PCI**	percutaneous coronary intervention
MEI	Medicare Economic Index		**PDE**	prescription drug event
mg	milligram		**PDMP**	Prescription Drug Monitoring Program
ml	milliliter		**PDP**	prescription drug plan
MLR	medical loss ratio		**PLATO™**	Predictive Learning Analytics Tracking Outcomes™
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003		**PMPM**	per beneficiary per month
MRI	magnetic resonance imaging		**PPACA**	Patient Protection and Affordable Care Act of 2010
MSA	metropolitan statistical area		**PPO**	preferred provider organization
MS–DRG	Medicare severity–diagnosis related group		**PPS**	prospective payment system
MS–LTC–DRG	Medicare severity long-term care diagnosis related group		**PROMIS®**	Patient-Reported Outcome Measurement Information System®
MSSP	Medicare Shared Savings Program		**PVP**	Prime Vendor Program
MTM	medication therapy management		**QIC**	qualified independent contractor
MV	mechanical ventilation		**QIP**	quality incentive program
N/A	not applicable		**RAC**	recovery audit contractor
N/A	not available		**OMHA**	Office of Medicare Hearings and Appeals
NDC	national drug code		**RRC**	rural referral center
NHIS	National Health Interview Survey		**RxHCC**	prescription drug hierarchical condition category
NHSN	National Healthcare Safety Network		**SAD**	self-administered drug
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases		**SCH**	sole community hospital
NIH	National Institutes of Health		**SMI**	Supplementary Medical Insurance (Medicare Part B)
NORC	(formerly) National Opinion Research Center		**SNF**	skilled nursing facility
NSAID	nonsteroidal anti-inflammatory drug		**SNP**	special needs plan
OCM	Oncology Care Model		**SSA**	Social Security Act
OIG	Office of Inspector General		**SSDI**	Social Security Disability Insurance
OMHA	Office of Medicare Hearings and Appeals		**URA**	unit rebate amount
OMS	Overutilization Monitoring System		**ZPIC**	zone program integrity contractor
OOP	out-of-pocket			
OPD	hospital outpatient department			

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Katherine Baicker, Ph.D., is C. Boyden Gray Professor of Health Economics and Chair of the Department of Health Policy and Management at the Harvard School of Public Health, where her research focuses on health insurance finance and the effect of reforms on the distribution and quality of care. From 2005 to 2007, Professor Baicker served as a Senate-confirmed member of the President's Council of Economic Advisers. She is a research associate at the National Bureau of Economic Research, is on the Congressional Budget Office's Panel of Health Advisers, is chair of the Group Insurance Commission of Massachusetts, and is an elected member of the Institute of Medicine. She also served as a commissioner of the Robert Wood Johnson Foundation's Commission to Build a Healthier America, was a member of the Institute of Medicine's Committee on Health Insurance Status and Its Consequences, and served on the faculty of the Economics Department at Dartmouth College. She received her B.A. in economics from Yale University and her Ph.D. in economics from Harvard University.

Kathy Buto, M.P.A., is an expert in U.S. and international health policy. She has recently been involved in a range of volunteer professional engagements, including with the National Academy of Social Insurance, the Robert Wood Johnson Foundation's Healthcare Legacy Forum, and the National Science Foundation's Study of Women in Policy Making. Her previous positions include vice president of global health policy at Johnson & Johnson, senior health adviser at the Congressional Budget Office, deputy director of the Center for Health Plans and Providers at the Health Care Financing Administration (now Centers for Medicare & Medicaid Services), and deputy executive secretary for health at the Department of Health and Human Services. Ms. Buto received her master's in public administration from Harvard University.

Jon B. Christianson, Ph.D., is the James A. Hamilton Chair in Health Policy and Management in the Division of Health Policy and Management at the School of Public Health at the University of Minnesota. His research has addressed the areas of health finance, payment structures, rural health care, managed care payment, and the quality and design of care systems. Dr. Christianson serves on the Institute of Medicine's Board on Health Care Services and on the editorial board of the *American Journal of Managed Care*. He recently served on the Institute of Medicine's Committee on Geographic Adjustment Factors in Medicare Payment and has chaired AcademyHealth's annual research meeting. Dr. Christianson received his Ph.D. in economics from the University of Wisconsin.

Alice Coombs, M.D., is a critical care specialist and an anesthesiologist at Milton Hospital and South Shore Hospital in Weymouth, MA. She is board certified in internal medicine, anesthesiology, and critical care medicine. Dr. Coombs is past president of the Massachusetts Medical Society (MMS) and a member of MMS's Committee on Ethnic Diversity. She chaired the Committee on Workforce Diversity that is part of the American Medical Association's (AMA's) Commission to Eliminate Health Care Disparities and on the Governing Council for the AMA Minority Affairs Consortium and the AMA Initiative to Transform Medical Education. She helped to establish the New England Medical Association, a state society of the National Medical Association that represents minority physicians and health professionals. Dr. Coombs has served as a member and vice chair of the Massachusetts Board of Registration in Medicine Patient Care Assessment Committee. In addition, she was a member of the Massachusetts Special Commission on the Health Care Payment System.

Francis "Jay" Crosson, M.D., spent 35 years as a physician and physician executive at Kaiser Permanente. In 1997 he founded and then led for 10 years the Permanente Federation LLC, the national umbrella organization for the physician half of Kaiser Permanente. Later he served as senior fellow at the Kaiser Permanente Institute for Health Policy and director of public policy for The Permanente Medical Group. From July 2012 through October 2014, he was group vice president of the American Medical Association in Chicago, IL, where he oversaw work related to physician practice satisfaction, efficiency, and sustainability. He currently serves on the National Advisory Council of the Agency for Healthcare Research and Quality. He previously served on MedPAC from 2004 to 2010, including as vice chair from 2009 to 2010. Dr. Crosson received his medical degree from the Georgetown University School of Medicine.

Bill Gradison, Jr., M.B.A., D.C.S., was a scholar in residence in the Health Sector Management Program at Duke's Fuqua School of Business. He was a member of the U.S. Congress (1975–1993) where he served on the House Budget Committee and the Health Subcommittee of the Committee on Ways and Means. Mr. Gradison was a founding board member of the Public Company Accounting Oversight Board and was vice chairman of the U.S. Bipartisan Commission on Comprehensive Health Care ("Pepper Commission"). Prior positions also include assistant to the Secretary of Health, Education, and Welfare; president of the Health Insurance Association of America; and vice chair of the Commonwealth Fund Task Force on Academic Health Centers. Mr. Gradison received his B.A. from Yale University and an M.B.A. and doctorate from Harvard Business School.

Glenn M. Hackbarth, J.D., M.A., chairman of the Commission, lives in Bend, OR. He was chief executive officer and one of the founders of Harvard Vanguard Medical Associates, a multispecialty group practice in Boston that serves as a major teaching affiliate of Harvard Medical School. Mr. Hackbarth previously served as senior vice president of Harvard Community Health Plan and president of its Health Centers Division, as well as Washington counsel of Intermountain Health Care. He has held various positions at the U.S. Department of Health and Human Services, including deputy administrator of the Health Care Financing Administration (now known as CMS). He is also a past chairman of the board of the Foundation of the American Board of Internal Medicine. Mr. Hackbarth received his B.A. from Pennsylvania State University and his J.D. and M.A. from Duke University.

William J. Hall, M.D., M.A.C.P., is a geriatrician and professor of medicine at the University of Rochester School of Medicine where he directs the Highland Hospital Center for Healthy Aging. He previously served as a member of the board of directors of AARP. His career has focused on systems of health care for older adults. He was instrumental in establishing the Program of All-Inclusive Care for the Elderly and developing many senior prevention and wellness programs. Dr. Hall's prior service and positions include president of the American College of Physicians and leadership positions in the American Geriatrics Society. He received his bachelor's degree from the College of the Holy Cross and his medical degree from the University of Michigan Medical School and pursued postdoctoral training at Yale University School of Medicine.

Jack Hoadley, Ph.D., is research professor at the Health Policy Institute of Georgetown University in Washington, DC. Dr. Hoadley previously served as director of the Division of Health Financing Policy for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation; as principal policy analyst at MedPAC and its predecessor organization, the Physician Payment Review Commission; and as senior research associate with the National Health Policy Forum. His research expertise includes health financing for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP); pharmaco-economics and prescription drug benefit programs; and private sector insurance coverage. Dr. Hoadley has published widely on health care financing and pharmaco-economics and has provided testimony to government panels.

Herb B. Kuhn is current president and chief executive officer of the Missouri Hospital Association (MHA), the trade association serving the state's 176 hospitals and health systems. Before joining MHA, Mr. Kuhn served in multiple roles at the Centers for Medicare & Medicaid Services, including deputy administrator from 2006 to 2009 and director of the Center for Medicare Management from 2004 to 2006. From 2000 to 2004, Mr. Kuhn served as corporate vice president for the Premier Hospital Alliance, serving 1,600 institutional members. From 1987 through 2000, Mr. Kuhn worked in federal relations with the American Hospital Association. Mr. Kuhn received his bachelor of science in business from Emporia State University.

Mary D. Naylor, Ph.D., F.A.A.N., R.N., is the Marian S. Ware Professor in Gerontology and director of the NewCourtland Center for Transitions and Health at the University of Pennsylvania School of Nursing. For the past two decades, Dr. Naylor has led an interdisciplinary program of research designed to improve the quality of care, decrease unnecessary hospitalizations, and reduce health care costs for vulnerable community-based elders. Dr. Naylor is also the national program director for the Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative, which is aimed at generating, disseminating, and translating research to understand how nurses contribute to quality patient care. She was elected to the National Academy of Sciences, Institute of Medicine in 2005. She also is a member of the RAND Health Board and the National Quality Forum Board of Directors and was the founding chair of the Board of the Long-Term Quality Alliance.

David Nerenz, Ph.D., is director of the Center for Health Policy and Health Services Research at the Henry Ford Health System in Detroit, MI, as well as director of outcomes research at the Henry Ford Neuroscience Institute and vice chair for research in the Department of Neurosurgery at Henry Ford Hospital. He has served on the National Committee for Quality Assurance's Culturally and Linguistically Appropriate Services Workgroup, the Accountable Care Organization Technical Advisory Committee of the American Medical Group Association, and most recently as co-chair of the National Quality Forum's Expert Panel on Risk Adjustment for Sociodemographic Factors. Dr. Nerenz has served in various roles with the Institute of Medicine, including as chair of the Committee on Leading Health Indicators for Healthy People 2020. He serves on the editorial boards of *Population Health Management* and *Medicare Care Research and Review*.

Rita Redberg, M.D., M.Sc., is professor of clinical medicine at the University of California at San Francisco (UCSF) Medical Center. A cardiologist, Dr. Redberg is also core faculty at the UCSF Philip R. Lee Institute of Health Policy Studies and adjunct associate at Stanford University's Center for Health Policy/Center for Primary Care and Outcomes Research. She is editor of *JAMA Internal Medicine* and chairperson of CMS's Medicare Evidence Development and Coverage Advisory Committee. Dr. Redberg serves in numerous positions on committees of the American Heart Association and the American College of Cardiology and was a Robert Wood Johnson Health Policy Fellow. She did her undergraduate

work at Cornell University and has graduate degrees from the University of Pennsylvania Medical School and the London School of Economics.

Craig Samitt, M.D., M.B.A., is a partner and the Global Provider Practice Leader in Oliver Wyman's Health & Life Sciences Practice. He has led major health systems for 20 years, most recently serving as the president and CEO of HealthCare Partners, a division of DaVita HealthCare Partners. From 2006 through 2013, Dr. Samitt served as president and CEO of Dean Health System in Madison, WI, and previously held senior executive roles at Fallon Clinic, Harvard Pilgrim Health Care, and Harvard Vanguard Medical Associates. He is chair-emeritus of the Group Practice Improvement Network and previously served as an advisory and faculty member of the Centers for Medicare & Medicaid Services' Accountable Care Organization Accelerated Development Learning Sessions. Dr. Samitt received his B.S. in biology from Tufts University; his M.D. from Columbia University, College of Physicians and Surgeons; and his M.B.A. from the Wharton School.

Warner Thomas, M.B.A., is president and CEO of the Ochsner Health System in New Orleans, LA. He oversees a network of 10 hospitals, 45 health centers and clinics, and 2,200 affiliated physicians. The Ochsner system includes the Ochsner Medical Center in New Orleans, the Ochsner Clinic group practice, rurally based and subacute care hospitals, skilled nursing and rehabilitation facilities, and hospice. The Ochsner Medical Center operates one of the largest accredited non-university-based graduate medical education programs in the United States. It is also one of the largest Medicare risk contractors in the region and offers an accountable care organization for Medicare. Mr. Thomas's prior positions include chief operating officer of the Ochsner Clinic, vice president of managed care and network development at the Southern New Hampshire Medical Center, and senior auditor and consultant at Ernst & Young. He received his master's of business administration from Boston University Graduate School of Management.

Cori E. Uccello, F.S.A., M.A.A.A., M.P.P., is senior health fellow of the American Academy of Actuaries, serving as the actuarial profession's chief public policy liaison on health issues. Ms. Uccello focuses on issues related to health insurance financing, coverage and market reforms, and risk-sharing mechanisms. She recently served as a member of the Technical Review Panel on the Medicare Trustees' report. Before joining the academy in 2001,

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