Executive summary

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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. ■