Executive summary

Executive summary

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

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

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

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

Implementing a unified payment system for post-acute care

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

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

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

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

Medicare Part B drug payment policy issues

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

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

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

- *Improving ASP data reporting.* CMS relies on manufacturers to submit their sales data in order to calculate ASPs for Part B drugs, but not all manufacturers are required to do so. A policy requiring all Part B drug manufacturers to report ASP data and giving the Secretary the authority to enforce penalties on manufacturers who do not report required data would improve the accuracy of ASP payments.
- *Modifying payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC).* Medicare generally reimburses new, single-source Part B drugs at 106 percent of WAC when ASP data are not available. The WAC is the manufacturer's list price and does not incorporate prompt-pay or other discounts. A policy reducing the payment rate for drugs currently paid at 106 percent of WAC to 103 percent of WAC would help reduce excessive payments for these drugs.
- *Establishing an ASP inflation rebate.* Medicare's ASP + 6 percent payment rates are driven by manufacturers' pricing decisions. In theory, there is no limit on how much Medicare's ASP + 6 percent payment rate for a drug can increase over time. An ASP inflation rebate policy would protect the Medicare program and beneficiaries from rapid price increases for individual products.
- *Establishing consolidated billing codes.* The structure of the ASP payment system—with the reference biologic drug assigned to one billing code and its biosimilar drugs assigned to a different billing code—does not spur price competition among these products. A policy requiring use of consolidated billing codes to group a reference biologic drug with its biosimilar drugs would encourage price competition among these Part B drugs.

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

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

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

Using premium support in Medicare

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Of note:

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

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

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

An overview of the medical device industry

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

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

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

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

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

Stand-alone emergency departments

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

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

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

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

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

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

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

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

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

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

Provider consolidation: The role of Medicare policy

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

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

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

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

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

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

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

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