JUNE 2010

REPORT TO THE CONGRESS

Aligning Incentives in Medicare

MEDPAC Medicare Payment Advisory Commission

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

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

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

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

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Glenn M. Hackbarth, J.D., Chairman
Francis J. Crosson, M.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 15, 2010

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

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
U.S. Capitol
Room H-232
Washington, DC 20515

Dear Mr. Vice President and Madam Speaker:

I am pleased to submit the Medicare Payment Advisory Commission's June 2010 *Report to the Congress: Aligning Incentives in Medicare*. This report fulfills the Commission's legislative mandate to examine issues affecting the Medicare program and to make specific recommendations to the Congress.

In previous reports, we have described the need for Medicare to move away from payment policies that encourage service volume and are indifferent to quality and toward policies that promote better value for Medicare and its beneficiaries. In the course of that work, we have focused largely on changes to payment policies that would affect provider incentives to work toward a reformed delivery system. We continue that work in this report but also begin to develop policies that highlight the role of Medicare beneficiaries and the Centers for Medicare & Medicaid Services in achieving the goal of delivery system reform.

The report consists of eight chapters:

- Two chapters touch on the themes of Medicare payment accuracy and moving away from the volume incentives in fee-for-service Medicare. The chapter on the in-office ancillary exception to the Stark law describes the incentives that induce physicians to provide more ancillary services and develops policy options that could change those incentives. The chapter on Medicare's prospective payment system for inpatient psychiatric facilities begins to explore the accuracy and equity of the payments as well as how the inpatient psychiatric admission fits into the larger spectrum of mental health care.
- Three chapters highlight more systemic changes that better align provider incentives with a reformed delivery system. One chapter discusses new approaches to quality improvement to help providers succeed in an environment of performance-based payments. A second addresses the conflicting incentives between Medicare and Medicaid that impede truly coordinated care for beneficiaries dually eligible for both

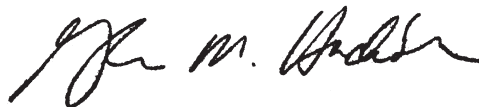
programs. The third provides the Commission's assessment of the nation's system of graduate medical education (GME) and recommendations for improving it. The GME system produces highly technically skilled medical professionals. However, it does not encourage teaching programs to emphasize nonhospital care, care coordination, a focus on quality, and the efficient delivery of care. We make five recommendations on steps Medicare can take to help focus the GME system on producing professionals with the skills needed to practice in a reformed delivery system.

- Two chapters focus on beneficiaries and their potential role in delivery system reform. One chapter discusses redesigning the Medicare benefit to encourage beneficiaries to seek higher value services. Another chapter describes shared decision making, including the use of decision aids and their role in helping to ensure that beneficiaries are fully informed about their health care choices.
- Last, the report includes a chapter that discusses the role of the Centers for Medicare & Medicaid Services in a reformed delivery system. We note that to function like a value-based purchaser (rather than a claims payer) the Secretary of Health and Human Services will likely need additional resources, clearer authority to pay on the basis of value (e.g., quality outcomes), and new authority to test innovative delivery reform ideas and implement promising approaches.

We also acknowledge the passage of the Patient Protection and Affordable Care Act (PPACA) at the end of March 2010, which included provisions that are relevant to some of the issues discussed in this report. Where feasible, given the timing of enactment, we have included appropriate references to the effects of the new law.

The report concludes by fulfilling our statutory obligation to analyze the Centers for Medicare & Medicaid Services' estimate of the update for physician services (Appendix A of this report).

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

Enclosure

Acknowledgments

This report was prepared with the assistance of many people. Their support was key as the Commission considered policy issues and worked toward consensus on its recommendations.

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Finally, the Commission wishes to thank Cay Butler, Hannah Fein, and John Ulmer for their help in editing and producing this report. ■

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Executive summary

Executive summary

The Medicare program enables millions of beneficiaries to obtain health care services but, in its current form, lacks many of the essential elements of a high-quality, high-value, efficient health system: Care coordination is rare, specialist care is favored over primary care, and quality of care is too often poor. Program spending and utilization have increased substantially, without corresponding improvements in beneficiaries' health. If those spending and utilization trends were to continue, they would threaten the long-term sustainability of Medicare.

In previous reports, the Commission has described the need for Medicare to move away from payment policies that encourage service volume and are indifferent to quality and toward policies that promote better value for Medicare and its beneficiaries. In the course of that work, we have focused largely on changes to payment policies that would affect provider incentives to work toward a reformed delivery system. We continue that work in this report but also develop policies that highlight the role of Medicare beneficiaries and CMS in achieving the goal of delivery system reform. The report includes:

- two chapters that touch on the themes of Medicare payment accuracy and moving away from the volume incentives in fee-for-service (FFS) Medicare,
- three chapters that highlight more systemic changes to better align provider incentives with a reformed delivery system,
- two chapters that focus on beneficiaries and their potential role in delivery system reform, and
- one chapter that discusses the role of CMS in a reformed delivery system.

In an appendix, as required by law, we review CMS's estimate of the physician update for 2011. We also acknowledge the passage of the Patient Protection and Affordable Care Act (PPACA) at the end of March 2010, which included provisions that are relevant to some of the issues discussed in this report. Where feasible, given the timing of enactment, we have included appropriate references to the effects of the new law.

Enhancing Medicare's ability to innovate

Innovative purchasing policies could be employed to improve the delivery of health care services, but Medicare currently has legislative limits that constrain it from adopting such policies expeditiously. Furthermore, Medicare might be able to improve health care quality and efficiency if it were given broader authority to demonstrate and implement policy innovations. In Chapter 1, we examine issues related to expanding Medicare's authorities in these two areas.

Medicare has attempted to use several innovative policies that have the potential to increase the value of the program for beneficiaries and taxpayers, but their application has been limited by lack of clear legal authority. Two examples are reference pricing policies, under which a single payment is set for clinically comparable services, and coverage with evidence development, in which CMS requires the collection of clinical data as a condition of Medicare payment. Performance-based risk-sharing strategies, in which Medicare's payment is linked to beneficiaries' outcomes through risk-sharing agreements with product developers, is another innovative policy; allowing Medicare to negotiate with product developers would require a change in law.

Some statutory limits even prevent Medicare from making technical changes to its current payment systems. For example, updating case mix and wage indexes in prospective payment systems would improve payment accuracy, but Medicare often lacks the authority to do so, even when the change is budget neutral. Similarly, a change in law is also necessary for Medicare to implement policies that pay providers based on their quality. Medicare needs authority to make such changes in its current payment systems.

We also examine giving the Secretary more flexibility in testing payment policy and health care delivery improvements and implementing those that prove to be successful in the demonstration stage. Funding and process constraints on Medicare's research and demonstration capacity have hindered how Medicare tests and disseminates policy innovations. We review the significant changes in this area made by the PPACA and present several approaches to increase the Secretary's flexibility to implement new policies that empirical evidence indicates will improve quality and reduce the rate of cost growth in the traditional FFS Medicare program.

Improving traditional Medicare's benefit design

Reforming the design of the traditional Medicare FFS benefit offers an opportunity to align beneficiary incentives with the goal of obtaining high-quality care for the best value. Of particular importance, reforms could also improve financial protection for individuals who have the greatest need for services and currently face very high cost sharing. In Chapter 2, we consider design reform of Medicare's traditional FFS benefit, along with that of supplemental coverage.

The current FFS benefit design has no upper limit on the amount of Medicare cost-sharing expenses a beneficiary could incur. As a result, more than 90 percent of Medicare beneficiaries take up supplemental coverage—for example, medigap policies. The most widely used types of supplemental coverage fill in all or nearly all of Medicare's cost sharing. We have found that when beneficiaries are insured against Medicare's cost-sharing requirements, on average they use more care and Medicare spends more on them.

In the near term, potential improvements to benefit design could, for example, involve adding a cap on beneficiaries' out-of-pocket (OOP) costs and, at the same time, requiring supplemental policies to have fixed-dollar copayments for services such as office visits and emergency room use instead of simply filling in all cost sharing. Such restrictions on supplemental coverage could lead to reductions in the use of Medicare services sufficient to help finance the addition of an OOP cap. These strategies could be coupled with exceptions that waive cost sharing for services in certain circumstances—for example, if evidence identified them as improving care coordination or quality. These strategies could also be coupled with cost-sharing protections for low-income beneficiaries so that they would not forgo needed care.

In the longer term, changes could involve developing the evidence base to better understand which treatments are of higher and lower value. As currently practiced, value-based insurance design lowers cost sharing for services that have strong evidence of substantial clinical benefit. A primary goal of this approach is to improve quality. However, to also achieve net savings, this approach requires careful targeting and willingness to both lower cost sharing for services of high value and raise cost sharing for services of low value.

Medicare's role in supporting and motivating quality improvement

There is wide variation in the quality of health care in the United States, and the pace of quality improvement has been frustratingly slow. The Commission has recommended payment incentives and public reporting to motivate better quality, but they may not be sufficient to induce the magnitude of quality improvement needed. In Chapter 3, we look at two additional ways to motivate quality improvement: offering technical assistance to providers and reforming conditions of participation.

Some providers may need technical assistance in improving care. This assistance could be particularly helpful when improvement requires coordination among many providers during a patient's episode of care, management of a highly complex organization, or coping with the challenges of serving a rural or a low-income population. One source of technical assistance is Medicare's Quality Improvement Organization (QIO) program, but the performance of the QIO program has been variable and its benefits have been difficult to demonstrate. In addition to the QIOs, there may be advantages to allowing other entities (e.g., high-performing providers, professional associations, consulting organizations) to participate as technical assistance agents serving low performers. For example, under an alternative quality improvement model, low performers could choose which entity would be best suited to provide them Medicare-supported technical assistance.

Another way Medicare can stimulate quality improvement is by revisiting its conditions of participation (COPs)—the minimum standards that certain provider types are required to meet to participate in Medicare. Providers, state governments, and the federal government collectively spend millions of dollars annually in preparing for and conducting surveys to ensure compliance with these standards, yet it is unclear how much these efforts have accelerated the pace of change. Various options exist that could reenergize the survey and accreditation process, including updating the COPs to align them with current quality improvement efforts, imposing intermediate sanctions for underperformers, creating higher standards that providers could comply with voluntarily to be designated publicly as a high performer, and using performance on outcomes measures (e.g., mortality rates) as a criterion for providers to be eligible to perform certain procedures.

Modifying the COPs in tandem with providing targeted technical assistance may introduce a new balance of incentives that could accelerate quality improvement and make health care safer for Medicare beneficiaries.

Graduate medical education financing: Focusing on educational priorities

Despite the tremendous advances our graduate medical education (GME) system has brought to modern health care, the Commission finds that it is not aligned with the delivery system reforms essential for increasing the value of health care in the United States. Two specific areas of concern are workforce mix—including trends in specialization and limited socioeconomic diversity—and education and training in skills needed to improve the value of our health care delivery system—including evidence-based medicine, team-based care, care coordination, and shared decision making.

The GME system is influenced not only by how Medicare subsidizes GME but also by how Medicare and other insurers pay for health care services. FFS payment systems reward volume without regard to quality, and the levels of payment for physician services tend to reward performing procedures over patient evaluation, management, and care coordination. These payment signals affect not only physician career choices but also institutional decisions about which residency programs to offer.

The Commission's recommendations in Chapter 4 rest on two principles: decoupling Medicare payments for GME from Medicare's FFS payment systems and ensuring that resources for GME are devoted to meeting educational standards. First, the Commission recommends making a significant portion of Medicare's GME payments contingent on reaching desired educational outcomes and standards. Under this recommendation, the Secretary of Health and Human Services would consult with organizations and individuals with the necessary expertise and perspectives to establish the desired standards. Funding for this initiative should come from the amount that Medicare is currently paying hospitals above their empirically justified costs for indirect medical education—currently estimated to be $3.5 billion. The amount saved from this reduction should be used to fund incentive payments to institutions (such as teaching hospitals, medical schools, and other eligible entities that may sponsor residency programs) that meet educational standards.

The Commission's second recommendation—to make information about Medicare's payments and teaching costs available to the public—also fosters greater accountability for educational activities within the GME community. It is designed to encourage collaboration between educators and institutions on residency program funding decisions.

The final three recommendations call for studies to inform policymakers on better strategies for achieving the workforce we need in the 21st century:

- a rigorous analysis of our 21st century health care workforce needs driven by the requirements of a high-value, affordable health care delivery system;
- a specialty-specific analysis of the costs and benefits of residency programs to institutions, which would inform how Medicare could adjust its payments for residency programs to make them more economically efficient; and
- a study that outlines a strategy for achieving specific health care workforce-diversity goals, which would help optimize federal subsidies for this effort.

Coordinating the care of dual-eligible beneficiaries

Dual-eligible beneficiaries (those enrolled in both Medicare and Medicaid) are, on average, more costly to treat than other beneficiaries. However, we find in Chapter 5 that among dual-eligible beneficiaries are distinct groups of beneficiaries with widely different care needs and spending patterns. They make up disproportionate shares of Medicare and Medicaid spending relative to their enrollment, and yet neither program assumes full responsibility for coordinating all of their care.

The Medicare and Medicaid programs often work at cross-purposes in coordinating care for dual-eligible beneficiaries. Conflicting program incentives encourage providers to avoid costs rather than coordinate care, and poor coordination can raise total federal spending and lower quality. Improving the care for dual-eligible beneficiaries requires two fundamental changes: First, the financing streams need to be more integrated to dampen current conflicting incentives that undermine care coordination; second, an integrated approach to care delivery is needed to ensure quality care for this complex population. Entities that furnish integrated care need to be evaluated by using outcome measures such as risk-adjusted per capita costs, potentially avoidable hospitalization rates, rates of institutionalization, and

emergency room use. In addition, condition-specific quality measures and measures that reflect the level and success of care integration need to be gathered so that the success of care integration for different subgroups of duals can be assessed.

Two approaches currently in use—the Program of All-Inclusive Care for the Elderly and managed care programs that contract with states for Medicaid and with Medicare as Medicare Advantage special needs plans—offer more fully integrated care. These programs combine funding streams so that the conflicting incentives of Medicare and Medicaid are mitigated. Entities are also at risk for all (or most) services, including long-term care, and provide care management services.

While integrated approaches have the potential to succeed, they are few in number and enrollment in some programs is low. Numerous challenges inhibit expanding their numbers and enrollment. Challenges include the lack of experience managing long-term care, stakeholder (beneficiaries, their advocates, and providers) resistance, the initial program investments and financial viability, and the separate Medicare and Medicaid administrative rules and procedures. Also, by statute, Medicare beneficiaries must have the freedom to choose their providers and cannot be required to enroll in integrated care. However, several states have successfully implemented fully integrated care programs, illustrating that it is possible to overcome these obstacles.

Inpatient psychiatric care in Medicare: Trends and issues

Medicare beneficiaries with mental illnesses or alcohol- and drug-related problems who are considered a risk to themselves or others may be treated in inpatient psychiatric facilities (IPFs). To qualify as an IPF for Medicare payment, a facility must meet Medicare's general requirements for acute care hospitals and must be primarily engaged in providing psychiatric services for the diagnosis and treatment of mentally ill persons. In 2008, Medicare spent $3.9 billion on IPF care. About 295,000 beneficiaries had almost 443,000 stays.

In Chapter 6, we survey the current status of IPFs. Using IPF cost reports and claims data from 2008, we find:

- Unlike in other settings, most Medicare beneficiaries treated in IPFs qualify for Medicare because of a disability. As a result, IPF patients tend to be younger and poorer than the typical beneficiary. A majority (56 percent) of IPF patients are dually eligible for Medicare and Medicaid.
- Almost three-quarters of IPF discharges are diagnosed with psychosis and thus receive the same base payment under the prospective payment system. Some patient characteristics that may substantially increase the cost of caring for an inpatient psychiatric patient, such as deficits in activities of daily living and suicidal and assaultive tendencies, are not recognized by the IPF payment system.
- The characteristics of distinct-part IPF units and freestanding IPF hospitals appear to differ, as do some of their patterns of care, sources of admission, discharge destinations, and patients served.
- The number of IPF distinct-part units in acute care hospitals continues to decline; 74 percent of IPFs were distinct-part units in 2008.

Monitoring the adequacy of payments to IPFs is necessary to ensure continued access to care for beneficiaries with severe mental illnesses. In the future, the Commission will analyze IPFs' financial performance under Medicare. As we consider IPFs' costs, it will be important to assess the extent to which any observed cost differences between freestanding IPFs and distinct-part units reflect real differences in service provision, mix of patients, or methods hospitals use to allocate hospital overhead to the unit.

An important variable in assessing provider costs is the quality of care provided. Unfortunately, the development of outcomes measures for IPFs has lagged behind that for nonpsychiatric medical care. Ultimately, improving the quality of care furnished to beneficiaries with serious mental illnesses will necessitate looking beyond the IPF stay to ensure that patients receive adequate and appropriate outpatient mental health services. Such services can reduce severity of illness and improve beneficiaries' productivity and quality of life.

Shared decision making and its implications for Medicare

Medicare beneficiaries face certain challenges when making health care decisions. Although they are insured, Medicare beneficiaries, on average, are more likely to be poorer, less educated, cognitively impaired, faced with multiple chronic conditions, and less health literate than other consumers. All these factors may increase their difficulty understanding the information they receive about

their health conditions and the risks and benefits posed by different treatments. In an effort to mitigate these problems and to make care more patient centered, some clinicians have adopted a model of shared decision making, which we investigate in Chapter 7.

Shared decision making is the process by which a health care provider communicates personalized information to patients about the outcomes, probabilities, and scientific uncertainties of available treatment options and patients communicate their values and the relative importance they place on benefits and harms. It is a way to facilitate patient participation in decision making. Information is conveyed through patient decision aids that provide patients with evidence-based, objective information on all treatment options for a given condition. Physicians, not patients, have the expertise to know which approach to surgery is best, for example, or the side effect profile of different medications; but only patients know what their feelings are toward particular risks and benefits. When the patient understands the risks and the physician understands the patient's concerns, the physician is better able to recommend a treatment that will address the medical problem and respect the patient's values. To date, specialists have been more successful than primary care doctors at implementing shared decision-making programs because they are more likely to engage in shared decision making at a time when it is most useful to patients—before making a decision on procedures like cancer treatment and back surgery.

Medicare could promote the use of shared decision making in a number of different ways: design a demonstration project to test the use of shared decision making for Medicare beneficiaries, provide incentives to practitioners who adopt shared decision making, provide incentives to patients who engage in shared decision making, or require providers to use shared decision making for some preference-sensitive services. These strategies are not mutually exclusive. Each has advantages and disadvantages. Policymakers would have to decide on the design and scope of the policy.

Addressing the growth of ancillary services in physicians' offices

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare patients for "designated health services" (DHS)—such as imaging, radiation therapy, home health, clinical laboratory tests, and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. The in-office ancillary services (IOAS) exception allows physicians to provide most DHS to patients in their offices.

Many physicians have expanded their practices in recent years to provide ancillary services, and these services have experienced rapid volume growth over the last five years. Rapid volume growth, along with the diffusion of new technologies, raises questions about the equity and accuracy of physician payments. Moreover, there is evidence that some diagnostic imaging and physical therapy services ordered by physicians are not clinically appropriate.

On the one hand, proponents of the IOAS exception argue that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. On the other hand, there is evidence that physician investment in ancillary services leads to higher volume through greater overall capacity and financial incentives for physicians to order additional services. In addition, there are concerns that physician ownership could skew clinical decisions.

We used Medicare claims data to examine the frequency with which services covered by the IOAS exception are provided on the same day as an office visit. In Chapter 8, we report that outpatient therapy (such as physical and occupational therapy) is rarely provided on the same day as a related office visit. In addition, half or fewer than half of imaging, clinical laboratory, and pathology services are performed on the same day as an office visit. The finding that many ancillary services are not usually provided during a patient's office visit raises questions about one of the key rationales for the IOAS exception—that it enables physicians to provide ancillary services during a patient's visit.

Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current FFS payment systems, which reward higher volume. Under a different model, however, in which providers received a fixed payment amount for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services. Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Because it will take several years to establish new payment models and delivery

systems, policymakers may wish to consider interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. The Commission does not make any recommendations in Chapter 8, but it does explore several options in more detail:

- excluding therapeutic services such as physical therapy and radiation therapy from the IOAS exception,
- excluding diagnostic tests that are not usually provided during an office visit from the exception,
- limiting the exception to physician practices that are clinically integrated,
- reducing payment rates for diagnostic tests performed under the exception,
- improving payment accuracy and creating bundled payments, and
- adopting a carefully targeted prior authorization program for imaging services.

Review of CMS's preliminary estimate of the physician update for 2011

In CMS's annual letter to the Commission on the update for physician services, the agency's preliminary estimate of the 2011 update was –6.1 percent. This update was to follow a 21.3 percent reduction in physician payment rates required—under the law pertaining when the letter was written—to occur on April 1, 2010. The 21.3 percent reduction was to occur because a series of temporary increases—enacted over several years—were to expire on March 31, 2010. Subsequent congressional action has delayed that expiration date. In Appendix A, we present our required technical review of CMS's estimate.

We find that CMS's calculations are technically correct. The combined effect of the 21.3 percent reduction, were that to occur, and the calculated update in 2011 would be a 26.1 percent decrease in physician payment rates. (The calculation is not strictly a sum; hence, 21.3 combined with 6.1 yields 26.1 percent.) We find that any changes in CMS's forecast of input price changes or spending growth would have a small effect compared with the magnitude of that decrease. ■

CHAPTER 1

Enhancing Medicare's ability to innovate

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Chapter summary

Current statutory provisions limit the flexibility of the Secretary of Health and Human Services and the Administrator of CMS to implement innovative payment, coverage, and delivery system reform policies in Medicare. A range of innovative purchasing policies exists that could be used to improve the delivery of health care services, but Medicare has legislative limits that constrain it from adopting such policies expeditiously. Furthermore, with broader authority to demonstrate (when necessary) and implement policy innovations, Medicare may be able to increase its potential to improve quality and efficiency in the delivery of health care services to beneficiaries.

First, we discuss three innovative policies that Medicare lacks clear authority to implement and that have the potential to increase the value of the program for beneficiaries and taxpayers:

- Reference pricing policies, including least costly alternative determinations, under which a single payment is set for clinically comparable services. The uncertain legal foundation and two recent court decisions limit Medicare to setting the same payment rate for products and services that are clinically comparable.

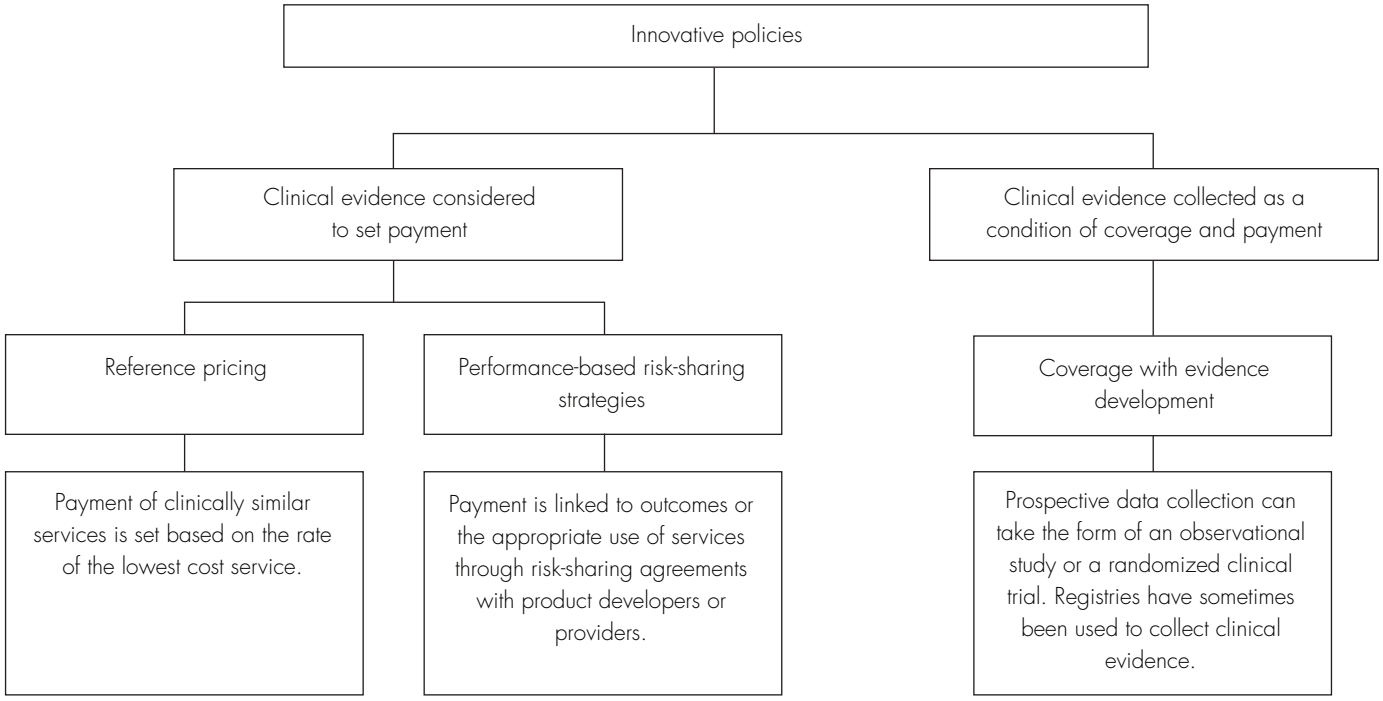
In this chapter

- Performance-based risk-sharing strategies, in which Medicare's payment is linked to beneficiaries' outcomes through risk-sharing agreements with product developers. A change in the law is necessary for Medicare to negotiate with product developers.
- Coverage with evidence development in which CMS requires the collection of clinical data as a condition for Medicare payment. Like reference pricing policies, the program's use of this tool has been hampered because its legal foundation is unclear.

Next, we examine options for giving the Secretary more flexibility to test and implement broader payment policy and health care delivery system improvements through the Medicare demonstration process, including a preliminary analysis of the significant changes made in this area of the program by the Patient Protection and Affordable Care Act of 2010. The Commission has been concerned for several years that funding and process constraints on Medicare's research and demonstration capacity have hindered Medicare's ability to effectively test and rapidly disseminate urgently needed policy innovations. This chapter presents options and reviews changes made by the new law that are designed to increase the Secretary's flexibility and accountability to implement new policies based on empirical evidence to improve the quality of care and reduce the rate of cost growth in the traditional fee-for-service Medicare program. ■

FIGURE 1–1

Clinical evidence is focal point for reference pricing, performance-based risk-sharing strategies, and coverage with evidence development strategies



The Secretary of Health and Human Services and the Administrator of CMS often lack the flexibility to implement innovative payment, coverage, and delivery system reform policies in Medicare. In this chapter, the Commission discusses a continuum of approaches for giving the Secretary and CMS more flexibility to innovate, ranging from applying innovative policies—reference pricing, performance-based risk-sharing strategies, and coverage with evidence development—to testing health care delivery and payment policy improvements, and implementing those approaches that prove to be successful in the demonstration stage. Furthermore, with broader authority to demonstrate (when necessary) and implement policy innovations, Medicare may be able to increase its potential to improve quality and efficiency in the delivery of health care services to beneficiaries. Along with increased flexibility, we consider options for increasing the program's accountability for its performance, including developing a predictable decision-making framework, providing opportunities for public input, and ensuring that the program has sufficient resources to carry out the policy innovations.

Increasing Medicare's flexibility to use selected innovative policies

Reference pricing, performance-based risk-sharing strategies, and coverage with evidence development (CED) are three policies health care purchasers can use to obtain the best value of services purchased (Figure 1-1). The three policies have the potential to improve payment accuracy and decrease knowledge gaps. In addition, they complement the recent federal investment in comparative-effectiveness research (CER). Reference pricing and performance-based risk-sharing strategies use such information in establishing payment for a service or product. CER and CED focus on collecting real-world clinical evidence that patients, providers, and policymakers need to reach better decisions about a service's or product's effectiveness. Medicare's use of each strategy has been hampered because the program's legal foundation is uncertain or lacking (Table 1-1, p. 6). The text box (pp. 8–9) provides four case studies of high-volume or high-growth services for which health policy

TABLE 1–1 **Legal foundation for use of three innovative policies**

	Reference pricing	Performance-based risk-sharing strategies	Coverage with evidence development
Statutory provisions cited to implement policy	A LCA has been applied based on authority 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."* The functional equivalence standard was based on the authority to make adjustments necessary to ensure equitable payments to the transitional pass-through payments of the hospital outpatient PPS.**	None	CED has been applied based on the Secretary's authority to: (1) cover items and services that are reasonable and necessary;* and (2) "conduct and support research [through the AHRQ administrator] with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically…"***
Medicare's application of policy	Since the mid-1990s, Medicare's claims processing contractors applied LCA policies within their geographic region for durable medical equipment and drugs in the local coverage determination process. CMS applied the functional equivalence standard nationally during the rulemaking process for two drugs paid under the outpatient hospital PPS.	No known application by Medicare.	Since 1995, CMS has nationally applied CED through the national coverage determination process for 12 services using observational and randomized research approaches. More recent CED policies have required prospective studies to address patient-oriented health outcomes rather than just changes in physician guided management.

Note: LCA (least costly alternative), PPS (prospective payment system), CED (coverage with evidence development), AHRQ (Agency for Healthcare Research and Quality).
*Social Security Act section 1862(a)(1)(A).
**Social Security Act section 1833(t)(2)(E).
***Social Security Act section 1862(a)(1)(E).

Source: MedPAC analysis of the statute and information from CMS's website at http://www.cms.hhs.gov/CoverageGenInfo/.

experts recommended their use individually or in some combination to improve Medicare efficiency but have yet to be adopted by the program.

Reference pricing strategies

Medicare's reference pricing strategies are called the least costly alternative (LCA) and functional equivalence policies. Both policies achieve the same function—set a single payment rate for a group of clinically similar services assigned to separate payment codes based on the lowest cost item—but are based on a different statutory foundation. Medicare also uses a form of reference pricing when grouping clinically similar services under a single payment code.

The policy's rationale is that Medicare, beneficiaries, and taxpayers should not pay more for a service when a similar service can be used to treat the same condition and produce the same outcome but at a lower cost. While reference pricing strategies establish payment ceilings, they do not control the price that product developers can set for their items or services. For example, under the LCA policy, Medicare's contractors use the prevailing Medicare payment policy to determine Medicare's payment rate for each clinically comparable item or service and then set the payment rate for all the items and services based on the least costly one. However, a beneficiary can gain access to a more costly service if that is his/her preference. Specifically, if the physician informs the beneficiary in advance and in writing that Medicare is likely to deny

payment for the more costly service and if the beneficiary signs an advance beneficiary notice for each service, then the beneficiary can pay Medicare an additional sum if he/she and the physician choose a more costly service (Centers for Medicare & Medicaid Services 2010c). Under these circumstances, the beneficiary's liability cannot exceed the difference in the Medicare payment between the more costly and least costly services (National Government Services 2009).

Medicare's application of least costly alternative determinations

Since the mid-1990s, Medicare's administrative contractors have applied LCA determinations for durable medical equipment and drugs in their geographic jurisdiction. Although the statutory platform for making LCA determinations is based on Medicare's reasonable and necessary authority, the policy affects the payment rate of a service or product (Centers for Medicare & Medicaid Services 2008). LCA determinations are based 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). Examples include manual wheelchair bases, power mobility devices, seat lift mechanisms, supplies for tracheostomy care, and anti-androgen drugs for prostate cancer. However, as this report went to press, several contractors have retired the LCA policy for anti-androgen drugs for prostate cancer. Medicare's contractors consider exceptions to the LCA if documentation of medical necessity is submitted.

A LCA policy is implemented in a local coverage decision (LCD) in which a contractor decides to cover a particular item or service in its geographic jurisdiction (Centers for Medicare & Medicaid Services 2010b, Centers for Medicare & Medicaid Services 2010d). The process of developing LCDs is designed to be transparent with opportunities for public comment. Contractors must follow structured rules, including consulting with physician groups, posting the proposed LCD with a comment period, and publishing the final version, including the evidence used to develop the policy.

There is no statutory provision giving Medicare specific authority to apply LCA determinations nor is there a clear statutory provision prohibiting their use. CMS explains in its interpretive manuals that Medicare's authority to apply LCA determinations is based on the general provision requiring the program to pay the expenses of items and services that are reasonable and necessary (Centers for Medicare & Medicaid Services 2010b, Centers for Medicare & Medicaid Services 2010d) (Table 1-1).

Other federal agencies have recommended that Medicare apply LCA policies. In 2003, the Office of Inspector General (OIG) recommended that CMS encourage all Medicare contractors to apply LCA to a drug used to treat prostate cancer (Office of Inspector General 2003). In another instance, the OIG recommended the use of LCA for the payment of semielectric hospital beds (Office of Inspector General 2002). As described in the text box (pp. 8–9), the Congressional Budget Office suggested the use of LCA to pay for selected Part B drugs.

Two recent court decisions constrain Medicare's future use of LCA determinations. A beneficiary challenged a LCA determination applied to an inhalation drug in U.S. District Court, arguing that Medicare law requires that if the drug is reasonable and necessary, Medicare must pay the statutorily defined payment rate for the drug—106 percent of the average sales price (ASP). The government argued that the reasonable and necessary statutory provision is ambiguous and confers great discretion on the Secretary and that the LCA policy is permissible because the provision explicitly addresses payment and expenses (Table 1-1).

The U.S. District Court agreed with the beneficiary and ruled that Medicare can no longer use LCA policies to pay for Part B inhalation drugs, 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 (U.S. District Court for the District of Columbia 2008). A December 2009 ruling by the U.S. Court of Appeals upheld the lower court's decision (U.S. Court of Appeals 2009). Both court decisions suggest that Medicare can use LCA only when statutory provisions that establish payment rates specifically allow a LCA approach (Arnold & Porter 2010). The Secretary did not ask the D.C. Circuit Court to reconsider its decision or seek review by the Supreme Court.

Medicare's application of a functional equivalence standard

Like a LCA determination, the functional equivalence standard is a form of reference pricing under which payment for clinically comparable services assigned to separate payment codes is based on the least costly item. Medicare has used the functional equivalence standard once to set the payment rates for anti-anemia products.

Use of innovative policies might improve the value of Medicare spending and create better information

The following four case studies demonstrate products and services for which policy experts have proposed using reference pricing and coverage with evidence development (CED), but they have yet to be adopted by Medicare.

Case 1: Products that treat osteoarthritis

The Congressional Budget Office (CBO) included as a policy option use of the least costly alternative approach to pay for five products that physicians use to treat osteoarthritis of the knee. Although each product differs slightly, they are all approved by the Food and Drug Administration for the same indication—osteoarthritis—and they work through the same clinical mechanism. CBO estimated savings of about $200 million between 2010 and 2014 and almost $500 million between 2010 and 2019 if Medicare set the payment for these five products based on the lowest priced product (Congressional Budget Office 2008).

CMS currently covers and pays for each product based on Medicare's method for paying for Part B drugs (106 percent of its average sales price).

Case 2: Wound therapy care

Policy experts have proposed using CED to pay for negative pressure wound therapy (NPWT) pumps—devices used to treat ulcers and wounds (Tunis 2006). Underlining this proposal is the insufficient comparative clinical evidence demonstrating the circumstances in which the pumps are better than conventional wound care (Samson et al. 2004). Medicare's spending for NPWT pumps is substantial and growing: Between 2001 and 2007, spending increased by 583 percent to $164 million (Office of Inspector General 2009b).

Policy experts have also proposed changing how Medicare pays for the pumps. According to the Office of Inspector General (OIG), Medicare's payment is based on the first pump Medicare covered in 2001 even though newer, less costly pumps have become available. A recent assessment concluded that there is insufficient evidence demonstrating differences between the first and the newer pumps (Agency for Healthcare Research and Quality 2009). Considering the finding that suppliers were paying on average about 20 percent of Medicare's fee schedule for the newer pumps, the OIG recommended applying Medicare's inherent reasonableness authority and including the pumps in a competitive bidding program (Office of Inspector General 2009b). Reference pricing is another alternative that might improve program efficiency.

CMS currently covers this device without any requirement to collect clinical evidence, and its payment rate remains based on the most costly one.

Case 3: Cardiac computed tomography angiography

In 2007, CMS proposed CED for cardiac computed tomography (CT) angiography when used to diagnose coronary artery disease. This proposal was based on the lack of sufficient clinical evidence demonstrating that the imaging service improves beneficiaries' health outcomes and was informed by conclusions from CMS's advisory group, the Medicare Evidence Development & Coverage Advisory Committee, and evidence reviews from the Agency for Healthcare Research and Quality and the Blue Cross Blue Shield Technology Evaluation Center. After posting a draft CED, the agency received public comments that overwhelmingly opposed the use of CED, and CMS withdrew the CED proposal in 2008. A key argument by coverage proponents is that Medicare covers other imaging procedures with even less evidence of benefit (Redberg and Walsh 2008).

CMS currently covers cardiac CT angiography without any requirement to collect clinical evidence. Medicare's claims contractors determine coverage through the local coverage determination process or on a case-by-case basis. This service is paid for under the physician fee schedule and hospital outpatient prospective payment system (PPS).

(continued next page)

Use of innovative policies might improve the value of Medicare spending and create better information

Case 4: Treatments for localized prostate cancer

One medical society recommended linking coverage of proton beam therapy used to treat localized prostate cancer to participation in clinical trials because of the lack of research demonstrating its net clinical benefit compared with other existing treatments, including intensity-modulated radiation therapy (IMRT) and brachytherapy (American Society for Radiation Oncology 2009). There also has been a proposal to apply reference pricing. In 2006, a Medicare contractor proposed paying for proton beam therapy at the same rate as IMRT for some conditions and at the same payment rate as conventional radiation for other conditions (TrailBlazer Health Enterprises 2006). Underlining this proposal was the lack of comparative research assessing whether proton beam therapy results in better outcomes than other treatments and the wide variation in costs, ranging from $820 for outpatient surveillance to $20,000 for IMRT and $49,000 for proton beam therapy in 2007 (Institute for Clinical and Economic Review 2008).

Local Medicare contractors that currently cover each treatment strategy (i.e., brachytherapy, IMRT, and proton beam therapy) do so without any requirement to collect clinical evidence. The contractor did not implement the least costly alternative for proton beam therapy. The different treatment strategies are paid for under the physician fee schedule and hospital outpatient PPS. CMS has announced that it is convening the Medicare Evidence Development & Coverage Advisory Committee on April 21, 2010, to review evidence and public testimony and make recommendations to CMS about the sufficiency of evidence on the various radiotherapies for localized prostate cancer. ■

In 2003, 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 clinically comparable because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells.

CMS did not initially set the payment rate of the new product by using the functional equivalence standard. Rather, in the 2003 proposed hospital outpatient prospective payment system (PPS) rule, CMS said that it would continue the new biologic's transitional (higher) pass-through payments.[1] In response, a product developer submitted a comment to CMS arguing that because both the old and the new biologic are substitutes, they should be paid at the same rate (Centers for Medicare & Medicaid Services 2002). In the final rule, CMS reviewed the clinical evidence and concluded that both biologics were functionally equivalent. Noting its authority (under section 1833(t)(2)(E)) to adjust outpatient hospital PPS's transitional pass-through payments that the agency determines are "necessary to ensure equitable payments," CMS determined that the new biologic should be paid for at the same rate as the older one (Centers for Medicare & Medicaid Services 2002).[2] However, CMS also stated that it did "not expect to make nationally-applicable determinations of similarity of drugs or biologicals … on a routine basis. We regard this situation as unusual distinguished by the very strong similarity of the two products and by the size of the potential effects on the Medicare program."

Because the new biologic lost its eligibility for the pass-through payment for new drugs, its payment rate declined from $4.74 per microgram (which included the pass-through payment) in 2002 to $2.37 per microgram (without the pass-through payment) in 2003.[3]

While the marketer of the older biologic supported CMS's action, the developer of the new biologic disagreed with the agency's decision, noting its product's uniqueness and differences from the older product (Amgen 2002, Keenan et al. 2006). The product developer of the new biologic filed suit against CMS's action, but 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).

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limited use of the functional equivalence standard. The Congress prohibited use of this standard for other drugs

TABLE 1–2 **Reference pricing by including two products in a single payment code**

Coding strategy	2005* 1st quarter	2006* 1st quarter	2007* 2nd quarter	2007** 3rd quarter	2008*** 2nd quarter	2009*** 2nd quarter	2010*** 1st quarter
Combined payment code							
Albuterol				$0.53			
Levalbuterol				$0.53			
Separate payment code							
Albuterol	$0.07	$0.06	$0.08		$0.04	$0.05	$0.05
Levalbuterol	1.28	1.34	1.54		0.28	0.26	0.20

Note: 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 the average sales price 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 average sales price for both drugs.
***Beginning in the second quarter of 2008, payment for each drug was based on the lower of: (1) the volume-weighted average of 106 percent of the average sales price for both drugs, or (2) the payment rate based on 106 percent of the average sales price for the specific drug.

Source: The Medicare, Medicaid and SCHIP Extension Act of 2007 (section 112(b)(2)), Office of Inspector General 2009a, and information from CMS's website at http://www.cms.gov/McrPartBDrugAvgSalesPrice/.

and biologics in the hospital outpatient setting. However, the Congress did not preclude the agency from continuing to use the policy for the two biologics in the hospital outpatient setting or for setting the payment rate the same for other clinically comparable services in other settings. Medicare continued to use the functional equivalence standard in 2004 and 2005. In response to passage of the MMA, the payment rate for each biologic was set based on 106 percent of its ASP beginning in 2006.

De facto reference pricing by combining similar services in the same payment code

By grouping clinically similar services in one payment code, Medicare is essentially setting payment based on the volume-weighted average of the program's payment for these services, which creates incentives for providers to furnish the lower priced item.

Medicare has some but not all responsibility for developing and maintaining the standardized codes it assigns to pay for medical services and procedures. Medicare maintains the coding systems for the program's prospective payment mechanisms, such as the clinical categorization system for the inpatient hospital PPS called Medicare severity–diagnosis related groups. Both the American Medical Association (AMA) and Medicare are responsible for the Healthcare Common Procedure Coding System, the classification system of services and procedures performed by physicians and other medical professionals.[4] In general, both the AMA and Medicare assign a unique code for a product or service if, in addition to meeting certain other criteria (e.g., Food and Drug Administration (FDA) approval), clinical evidence suggests that the product or service performs a significantly different function than other available products and services.

An example of de facto reference pricing occurred between July 1, 2007, and March 31, 2008, when CMS established a single payment code for two chemically similar drugs used to treat asthma and chronic obstructive pulmonary disease—levalbuterol (a single-source drug) and albuterol (a multisource drug with generic versions).[5] This de facto reference pricing essentially set the Medicare payment amount based on the volume-weighted ASP for both products. (CMS made this change to comply with provisions of the MMA concerning payment for drugs.)

Including products with divergent acquisition costs into a single payment code could 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 (the multisource product) increased (by 563 percent) while the rate for levalbuterol (the single-source product) decreased (by 66 percent) (Table 1-2) (Office of Inspector General 2009a). To address the concern that the payment rate did not match each product's acquisition cost, the Medicare, Medicaid and SCHIP Extension Act of 2007 reestablished

separate codes for the products starting in the second quarter of 2008 and calculated each product's payment rate based on the lower of: (1) the volume-weighted average of 106 percent of the ASP for both drugs, or (2) the payment rate based on 106 percent of the ASP for the specific drug.

Reactions vary to reference pricing strategies

Proponents of reference pricing argue that it makes patients and their providers more sensitive to the relative prices of different services and to considering cost when choosing among treatment options (Commonwealth Fund 2003). They also argue that such policies, if applied consistently, could stimulate price competition among products and services that are clinically similar.

The potential fiscal advantage must be weighed against several largely unquantified concerns. Some critics argue that physicians should be given discretion in selecting among clinically comparable services, because the effectiveness of those services may vary among patients. The literature on the effect on patients' outcomes when reference pricing is used to set the payment rate of drugs is mixed. An analysis of 10 studies of reference pricing (primarily implemented in Canada) found no evidence of adverse effects on health and no clear evidence of increased health care utilization (Cochrane 2006).[6] By contrast, an uncontrolled study found an increase in complications when patients switched therapies under a system of reference pricing in New Zealand (Thomas and Mann 1998).

Some critics also argue that reference pricing may decrease manufacturers' investment in research and development. Manufacturers might shift their research toward diseases not currently treated by multiple therapies or reduce investment in products that are incremental improvements of other products (Farkas and Henske 2006).[7] Proponents of reference pricing policies counter that such policies might increase manufacturers' incentive to develop truly innovative products and compare their product with other products in the clinical trials they sponsor. Policy analysts noted the lack of empirical evidence documenting the impact of reference pricing policies on the pace of innovation in the drug industry (Kanavos and Reinhardt 2003).

The literature on whether reference pricing may limit the availability of medical products and services is mixed. For example, one study concluded that reference pricing policies of drugs in New Zealand decreased the availability of new compounds, particularly high-priced new products (Danzon and Ketcham 2003). However, another study reported high availability (exceeding 90 percent) of 249 drugs in countries that use reference pricing policies to a greater (e.g., Germany) and lesser (e.g., United States) extent (Danzon and Furukawa 2003).

Reference pricing generally results in lower prices for drugs internationally than in the United States. Using International Monetary System data, the U.S. Department of Commerce reported that, in 2003, prices for all patented drugs were 18 percent to 60 percent lower in Australia, Canada, France, Germany, Greece, Japan, Poland, Switzerland, and the United Kingdom than in the United States (Department of Commerce 2004). However, several factors can affect the international comparison of drugs, including: (1) changes in currency rates between the year the data were published and 2010; and (2) differences in the use of patented drugs and their generic counterparts in the United States and other countries.

Performance-based risk-sharing strategies

Performance-based pricing strategies link payment of a service or a product to patient outcomes through risk sharing with product developers or providers. Examples of risk-sharing agreements include linking a product's payment to whether it is used appropriately (e.g., according to clinical guidelines) or to clinical outcomes (e.g., reduces the occurrence of adverse events or improves clinical outcomes). The reward tied to the desirable use or outcome could be a higher price, while the penalty for undesirable results could be a lower price. Risk-sharing agreements have the potential to improve value for payers, patients, and product developers. Nonetheless, there is limited experience with such sharing strategies and little empirical information evaluating their use (Towse and Garrison 2010). Although some commercial payers in the United States and other countries have begun to use such strategies, they have not been applied by Medicare. A change in law is necessary for the program to implement such strategies.

In most instances, product developers bear the prelaunch risks of developing products; payers bear the postlaunch risks of making poor adoption decisions (Garrison et al. 2007). A product's price is usually established based on the evidence of its clinical effectiveness known prior to its launch. Performance-based arrangements shift some of the risks to the postlaunch period when more information about the clinical effectiveness of the product or service becomes available.

Performance-based strategies might be particularly applicable to products and services that are costly and have different success rates among subgroups of patients. Using such strategies, payers may face less financial risk from the treatment of demographically different patient groups that were not included in clinical trial testing or did not show substantial improvement (Garber and McClellan 2007).

For drug manufacturers in particular, risk sharing provides a means to offer discounts to payers without lowering the list price. From the perspective of a product developer, risk sharing offers the possibility of receiving credit for attributes of a drug not studied in clinical trials such as cost offsets, ease of administration, and adherence (de Pouvourville 2006). It also makes a drug's price more predictable for the product developer and offers the prospect of future financial rewards while additional data are collected postlaunch. On the other hand, it puts pressure on product developers to demonstrate that their claims are well founded.

Several case studies illustrate the workings of performance-based pricing. In each case, a value-based agreement exists between the payer and the product developer. These case studies were developed by the Center for the Evaluation of Value and Risk in Health at the Tufts Medical Center, under contract to the Commission (Neumann et al. 2010).

A drug to prevent and treat osteoporosis

In 2009, two product developers negotiated an agreement with a provider-sponsored payer that links the payment of their drug, which treats and prevents postmenopausal osteoporosis, to the occurrence of nonspinal osteoporotic fractures. (Health Alliance, the payer, entered into a risk-sharing agreement with Procter & Gamble and Sanofi-Aventis, companies that co-market risedronate sodium.) Under this agreement, the payer receives rebates from product developers to cover the costs incurred to treat fractures if patients adhere to their drug regimen. Product developers gain market share when patients adhere to their drug regimen. Thus, the payer and product developers together share the incentive of encouraging patients' adherence to their drug regimen. Under this agreement, the payer placed the drug on a formulary tier with a lower copayment than a competing drug.

To implement this arrangement, pharmacy and medical data were used to calculate patient adherence and fracture rates. The interim results that were announced after nine months suggest that fracture rates were consistent with the rate experienced in the drug's clinical trials (Drug Benefit News 2009).

Two drugs that treat diabetes

In 2009, a product developer entered into a contract with a payer that links the payment of its two diabetes drugs to patients' overall blood sugar control and adherence to therapy. (Cigna, the payer, entered into a risk-sharing agreement with Merck, the product developer of sitagliptin and sitagliptin plus metformin.) Blood sugar control is measured based on hemoglobin A1c levels. (For this measure, lower values, associated with a lower risk of diabetes complications, are better than higher values.) Under the arrangement, the product developer increases the discount for both drugs if there is an increase in the percentage of patients taking any oral antidiabetic therapy who achieve an outcome of a hemoglobin A1c level that is less than 8 percent. The product developer also increases the payer's discount based on the percentage of patients who adhere to their prescribed regimen. The payer already had an active diabetes management program in place and collected both pharmacy data and hemoglobin A1c laboratory results for internal use, so the agreement's infrastructure was established.

From the payers' perspective, this arrangement is advantageous because they are provided larger rebates if patients adhere to their drug regimen and have hemoglobin A1c levels of less than 8 percent. An added benefit is that lowering hemoglobin A1c levels reduces or delays the risk of developing diabetes-related eye, kidney, and nerve disease in people with diabetes. From the product developers' perspective, this arrangement is advantageous because it improves the placement of their drugs on the payer's formulary, meaning a lower copayment than for some other diabetes drugs (Pollack 2009). The agreement also helps increase the product developer's market share.

A molecular diagnostic test that predicts the likelihood of chemotherapy benefit

A product developer and a large payer developed an agreement that links the price of a molecular diagnostic test to patients' subsequent treatment (chemotherapy regimen). (United Healthcare, the payer, entered into a risk-sharing agreement with Genomic Health, which developed and markets Oncotype DX.) The molecular diagnostic test helps identify which women with early-stage breast cancer are more likely to benefit from adding chemotherapy to their hormonal treatment. This test also helps assess the likelihood that a woman's breast cancer will return.

The agreement links the diagnostic test's payment to its impact on treatment patterns. If patients' chemotherapy usage does not follow the recommendations of the diagnostic test, the payer can renegotiate its payment rate (Pollack 2007). By using the payer's claims database, treatment patterns are monitored by comparing patients' test results to chemotherapy usage. The payer views the arrangement as a success thus far. In the agreement's first year, approximately 15 percent of patients were treated contrary to the results of the diagnostic test; in the second year, the rate decreased to 6 percent, obviating the need for contract renegotiations.

Coverage with evidence development

CED is an approach for health care payers to pay for potentially beneficial medical services that lack clear evidence showing their clinical effectiveness in specific patient populations. Some services diffuse quickly into routine medical care with incomplete information about their clinical effectiveness.[8] Under CED, patients have access to medical services while clinical evidence is being collected and analyzed. CED's goal is to reconcile the tension between evidence-based policies and being responsive to the pressure from product developers, providers, and patients to cover new services and new indications of existing services (Iglehart 2009, Tunis and Pearson 2006).

Because CED provides Medicare the opportunity to generate clinical evidence that otherwise may not have been collected, it enables the program to ultimately develop better, more evidence-based policies. CED also provides an opportunity to collect clinical evidence for groups that are often underrepresented in clinical trials, including older beneficiaries and minorities. In the future, there may be opportunities to more closely align Medicare's CED efforts with the FDA's postmarket safety monitoring efforts (Carino et al. 2006).

Since 1995, Medicare has applied CED—linked Medicare coverage and payment to the collection of clinical evidence in the national coverage determination process—to 12 services (Table 1-3, p. 14). The design of each CED effort has varied, depending on the service and the circumstance leading to the CED policy. Some CED efforts were designed as randomized trials and compared alternative treatment approaches (e.g., lung volume reduction surgery compared with medical management) while others used an observational approach and collected clinical evidence for one medical service (e.g., implantable cardioverter defibrillators (ICDs)).

CMS's statutory justification to apply CED has changed over time. Initially, CMS (then called the Health Care Financing Administration (HCFA)) applied the CED concept to the coverage of lung volume reduction surgery through its general authority established by §1862(a)(1)(A) of the Social Security Act, which states that Medicare can pay only for services that are reasonable and necessary for the diagnosis and treatment of illness and injury. With respect to the lung volume reduction surgery, CMS said that the surgical procedure would not be reasonable and necessary when provided in standard clinical practice but would likely "improve health outcomes" when it was provided under the carefully structured circumstances associated with a clinical trial (Mohr et al. 2010). A similar rationale was later used in the coverage decision on the use of radiotracer [^{18}F]fluorodeoxyglucose and positron emission tomography (FDG–PET) for suspected dementia in 2004, the ICD in January 2005, the off-label use of oncology drugs in January 2005, and the first draft of the CED guidance in April 2005.

In 2006, CMS revised its statutory justification to apply CED. In that year, CMS issued final CED guidance that included two different CED tracks: (1) coverage with appropriateness determination (CAD), and (2) coverage with study participation (CSP). In the guidance document, CMS explained that the basis for implementing CAD is that a service is reasonable and necessary but that additional clinical data that are not routinely available on claims are needed to ensure that the service is appropriately provided. For services studied under CAD, observational registries are usually used to collect clinical evidence.

The statutory authority to apply CSP—which generally links coverage to participation in a clinical trial—is more complex. CMS explained that its authority to cover services using CSP is derived from section 1862(a)(1)(E) of the statute that allows Medicare payment for services determined by the Agency for Healthcare Research and Quality (AHRQ) to reflect the research needs and priorities of the Medicare program. Thus, while CMS judges that the clinical evidence does not meet the reasonable and necessary standard, Medicare coverage may be extended to patients enrolled in a clinical research study conducted under section 1862(a)(1)(E). This legal rationale has increased AHRQ's role in implementing CED.

Because its statutory foundation to apply CED is unclear, Medicare's use of CED has been hampered and is limited (Mohr and Tunis 2010). CED has been used on a case-by-

TABLE 1–3 **Medicare's coverage with evidence development studies**

Service	Year CED released	Type of CED	Status of CED effort
Lung volume reduction surgery*	1995	Clinical trial	Publicly funded study completed and main findings published in 2003. Medicare revised its NCD to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit.
Angioplasty of the carotid artery with stenting*	2001	Clinical trial and registry	NINDS (publicly funded) trial ongoing, FDA post-approval studies sponsored by product developers, and privately funded registries.
FDG–PET imaging for dementia	2004	Clinical trial	Trial is ongoing, beginning in 2006 under private sponsorship.
FDG–PET imaging for cancers	2005	Registry	Privately funded registry ongoing. In 2009, CMS removed the clinical study requirement for CED for the initial diagnostic test with PET for most solid tumor cancers. CED will be used for PET scans for subsequent treatment strategies.
Implantable cardioverter defibrillators	2005	Registry	Privately funded registry ongoing. In 2009, an additional effort to collect longitudinal data received private and public funding.
Off-label use of colorectal cancer drugs	2005	Clinical trial	NCI (publicly funded) trials: some ongoing, some completed, some cancelled.
Cochlear implantation	2005	Clinical trial	Study not yet implemented. No source of public or private funding to cover the trial's research costs emerged in response to NCD.
Long-term oxygen treatment	2006	Clinical trial	NHLBI (publicly funded) trial ongoing.
Artificial heart	2008	Clinical trial	Trial ongoing. Manufacturers provide funding for the research costs. A registry of the trial data has received federal funding.
Continuous positive airway pressure therapy for obstructive sleep apnea	2008	Clinical trial	Trial not yet implemented.
Pharmacogenomic testing for warfarin response	2009	Clinical trial	NHLBI (publicly funded) trials ongoing.
PET (sodium-fluoride 18) to identify bone metastasis of cancer	2010	Clinical trial	Study begun or under development.

Note: CED (coverage with evidence development), NCD (national coverage decision), NINDS (National Institute of Neurological Disorders and Stroke), FDA (Food and Drug Administration), FDG–PET ([^{18}F]fluorodeoxyglucose and positron emission tomography), NCI (National Cancer Institute), NHLBI (National Heart, Lung and Blood Institute).
*Although the framework to implement "coverage with evidence development" had yet to be developed, Medicare linked this service's coverage to the collection of clinical evidence.

Source: Mohr et al. 2010, Tunis and Pearson 2006.

case basis in response to specific circumstances at play in each case. In some instances, the lack of clear statutory authority has affected the research questions and study design of the CED effort and the clinical evidence that was collected (Mohr et al. 2010). The absence of a clear statutory foundation has affected Medicare's ability to develop a proactive mechanism to identify potential CED topics (Mohr et al. 2010). Because of the unclear legal foundation, there has been uncertainty, in some instances, about the circumstances under which Medicare can apply CED. This situation is likely to continue to hamper Medicare's ability to implement the policy effectively (Mohr and Tunis 2010).

Some stakeholders argue that CED is beyond Medicare's statutory authority (Dahm 2008). Other concerns cited by stakeholders include: (1) CED may adversely affect manufacturers' incentive to develop new medical services; (2) CED may duplicate or replace FDA's authority in ensuring the safety and efficacy of drugs, biologics, and devices; and (3) CED changes Medicare's threshold for coverage.

Case studies of CED use in Medicare

Taken together, three case studies show the benefits and weaknesses in Medicare's use of CED. On the plus side, they demonstrate that useful clinical evidence can be generated at the same time as providing patients access to a service and that Medicare can use this evidence to refine its coverage policies. On the minus side, the selected cases underscore the lack of a well-defined, consistent approach to (1) designing CED studies, (2) developing methods, and (3) setting a timeline to reevaluate Medicare's payment for the service under study. The Center for Medical Technology Policy under contract to the Commission developed these case studies (Mohr et al. 2010).

In the first case—the use of lung volume reduction surgery for severe emphysema—CMS observed in the mid-1990s that the procedure was increasing among beneficiaries despite extremely limited clinical evidence (Ramsey and Sullivan 2005). The 30-day mortality rates following the procedure ranged between 17 percent and 20 percent. Consequently, CMS, in 1995, issued a national coverage decision (NCD) that paid for the surgery only for beneficiaries treated according to a National Institutes of Health (NIH) clinical trial protocol.

In response to CMS's decision, the Congress mandated that the agency submit a report that: (1) reviewed the treatment of end-stage emphysema and chronic obstructive pulmonary disease and the available studies on lung volume reduction surgery, and (2) made a recommendation about the appropriateness and conditions of Medicare coverage for such a procedure. In addition, the Congress held a hearing about Medicare's coverage decision-making process and beneficiary access to new technologies. Following these congressional activities, in 1997, 17 research centers began enrolling patients (Ramsey and Sullivan 2005). The seven-year trial showed that some patients were more likely to die if they underwent surgery compared with rehabilitation alone, while others achieved a slightly better quality of life or a small survival benefit from the surgery (Tunis and Pearson 2006). Medicare revised its coverage policy to cover all patients who matched the characteristics of patients in the trial who experienced a survival or quality-of-life benefit. Since then, use of this surgery has remained low.

In a second case, in 2002, CMS released a noncoverage decision for FDG–PET in the diagnosis of Alzheimer's disease based on the lack of evidence showing that it would improve beneficiaries' outcomes as well as out of concern that approval of this technology would result in unnecessary exposure to radiation. For this decision, CMS obtained advice from a technology assessment sponsored by AHRQ and an expert panel convened by the National Institute on Aging. After this noncoverage decision, there was considerable pushback from product developers and the clinical and patient communities (Tunis and Pearson 2006). Given the increasing demand from multiple stakeholders, the major burden that dementia represents to the Medicare population, and the lack of conclusive clinical evidence, CMS modified its coverage policy and issued a CED policy in 2004 to cover PET imaging for patients with suspected early dementia if they are enrolled in a large, CMS-approved practical clinical trial. Although researchers developed a CED that met CMS's requirements, they could not obtain public or private funding. As a next step, the lead researchers asked the nine facilities that were originally interested in participating in the CED effort to cover their own research costs; some declined to do so. Most recently, four facilities are participating in the CED effort, although only one of them is currently recruiting patients. A total of 17 patients have been enrolled to date.

In the third case, in 2005, CMS issued a CED for ICDs used to prevent cardiac arrest due to ventricular fibrillation.[9] (ICDs are devices implanted in a patient's chest; when they detect life-threatening heart rhythms, they deliver an electric shock to restore normal rhythm.) An observational registry was used for this CED application to provide access to ICDs across the Medicare population while accumulating large amounts of data for use in subgroup analyses. The registry has been funded by a combination of hospital fees and grants from device companies and payers (Curtis et al. 2009). The American College of Cardiology (ACC) operates the ICD registry; as of June 2009, hospitals have submitted data on 380,000 implants to the registry, representing about 90 percent of all procedures. Information collected by the registry includes the indications for implanting the device, the length of the initial hospital stay, physician training and specialty, the type of device, and the occurrence of in-

hospital complications. For example, using data from the registry, researchers concluded that the risk of in-hospital procedural complication rates was lower for ICD implantations performed by an electrophysiologist than for other physician specialty types (Curtis et al. 2009).

However, the original registry was not designed to answer CMS's questions about beneficiary postdischarge outcomes, including use of the ICD to address life-threatening heart rhythms (i.e., whether the ICD fired) and long-term survival. CMS, the ACC, and other stakeholders later designed a research effort to collect longitudinal firing and survival data over a five-year period; in 2010, AHRQ and the ACC agreed to provide $3.5 million to fund this effort (Agency for Healthcare Research and Quality 2010). The 3.5-year study will follow 3,500 patients with ICDs to determine how often the devices shock (i.e., fire), to establish whether the shocks are appropriate, and to identify the patients who are most likely to require ICD shocks.

Issues in Medicare's use of innovative policies

To improve Medicare's flexibility to use reference pricing, performance-based risk-sharing strategies, and CED, the program would need:

- a clear legal foundation to apply them,
- a transparent process to implement them, and
- sufficient resources to implement them.

The online appendix to this chapter (available at http://www.medpac.gov) discusses additional policy issues associated with implementing each policy.

Reference pricing and performance-based risk-sharing strategies are not the only policies that would promote payment accuracy. There are instances in which the Secretary lacks authority to make technical changes (in a budget-neutral manner) to existing payment methods that would improve payment accuracy. The text box (opposite page) discusses whether Medicare should have more flexibility to maintain existing payment methods or whether the Congress should continue mandating changes on a case-by-case basis.

Creating a clear legal foundation

Over the years, Medicare has had mixed experiences in applying reference pricing strategies and CED. As mentioned previously, despite recommendations from policy experts about the use of these policies for specific services, CMS has not applied them. Medicare lacks a clear legal foundation to implement reference pricing and CED, which has hampered the program's ability to use these tools. A change in law is necessary for the program to implement performance-based risk-sharing strategies.

To improve its ability to promote the efficient delivery of care, Medicare could be given broader authority to implement these innovative policies. Clear statutory authority would enable Medicare to develop a more systematic approach in applying each strategy. Without a change to the statute, the recent two court decisions on LCA may impede CMS's future use of this policy.

Developing a clear and predictable decision-making framework; ensuring transparency and opportunities for public input

To implement these policies, CMS would need to develop a clear and predictable decision-making framework. One example is the process (implemented in 2008) by which CMS considers changes to the list of compendia that identifies medically accepted indications of drugs used in anticancer chemotherapeutic regimens. This process, started in 2008, was developed based on authority from the Deficit Reduction Act of 2005. Each year, beginning on January 15, CMS accepts requests from the public for compendium changes and, no later than March 15, posts the completed requests for public comment. There is a 30-day public comment period, and CMS posts its final decision within 90 days after the close of the comment period. CMS has also posted the criteria that it uses in evaluating compendium requests. Later in this chapter, we discuss the national coverage determination process, another example of a transparent and predictable process that provides opportunities for public input.

One issue is whether the process to implement these policies should be centralized (implemented nationally by CMS officials in Baltimore), decentralized (implemented regionally by Medicare's contractors), or some combination of both. For example, reference pricing policies have been implemented nationally by CMS and regionally by contractors. By contrast, CED has been applied nationally, as it is not clear that the statutory authority to implement local coverage determinations would extend to determinations made under AHRQ's research authority (section 1862(a)(1)(E) of the Social Security Act).

Medicare's flexibility to maintain existing payment methods

In some instances, a change in law is necessary for Medicare to ensure payment accuracy. At issue is whether Medicare should have more flexibility to maintain existing payment methods or whether the Congress should continue mandating changes on a case-by-case basis.

To maintain the payment accuracy of existing payment methods, the Secretary and CMS administrator often need authority from the Congress to make technical changes in a budget-neutral manner. For example, without a change in law, CMS cannot develop an outlier policy for the skilled nursing facility prospective payment system. Such a policy, implemented budget neutral, would improve payment accuracy by defraying the exceptionally high cost of care for some patients.

The Secretary also cannot maintain payment methods when the provisions of the law are very detailed. For example, in 1993, the statute named three drug references (compendia) for the Secretary to consult in determining medically accepted indications of cancer drugs. Over time, only one of these statutorily named compendia was still published. The Secretary could not add new compendia until the Congress, through the Deficit Reduction Act of 2005, gave the Secretary the authority to do so. With the statutory authority, the Secretary, in 2008, implemented a well-defined process, which includes opportunities for public comment, for revising the list of compendia.

Medicare lacks the flexibility to implement policies that pay providers according to their quality or efficiency. As a general rule, providers' payment rates must be applied uniformly across the country. Providers meeting basic conditions of participation cannot be prohibited from billing for covered services. It was necessary for the Congress, through the Patient Protection and Affordable Care Act of 2010, to give authority to the Secretary to implement a pay-for-performance program for acute care inpatient hospitals beginning in fiscal year 2013 and pilot pay-for-performance programs for psychiatric, long-term care, and rehabilitation hospitals; hospice programs; and cancer hospitals exempt from the inpatient hospital prospective payment system. In addition, the law gives the Secretary the flexibility to expand these pilot programs if she determines that they reduce spending and improve quality.

Along with flexibility to maintain payment methods, it is reasonable to consider options for ensuring the program's accountability. As we discuss in this section, added flexibility to make technical changes to existing payment methods would need to be coupled with establishment of a predictable and transparent process by Medicare to implement such changes. ■

Another issue is whether these policies should stem from Medicare's coverage authority or from its payment authority. Although LCAs affect pricing, Medicare's authority to implement them currently stems from its coverage authority (Table 1-1, p. 6). Likewise, Medicare's authority to implement CED partly stems from its coverage authority (as well as AHRQ's research authority). For example, Medicare might implement CED more easily if the program had authority to modify payment while the collection of clinical evidence was under way.

Ensuring transparency and a process for public input would be key if the Secretary and CMS administrator were given flexibility to establish one or all of these strategies. Options for ensuring transparency include consulting with the public issue by issue or establishing an advisory group. CMS's NCD process is an example of an established process that is transparent and provides opportunities for public input. The NCD process determines whether and under what circumstances Medicare will cover and pay for an item or service. Over time, CMS has formalized and strengthened its analytical processes for developing NCDs, which has improved the transparency of the process and increased the opportunity for input and participation by the public. When CMS decides to develop a national coverage policy, the agency provides public notice and seeks input from the general public and clinical evidence from manufacturers and physicians. For example, after CMS posts proposed NCDs, stakeholders may submit written comments to the agency. CMS responds to these comments in its final NCDs.

An example of a way for CMS to gain technical expertise from the public is the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) (originally named the Medicare Coverage Advisory Committee). Established in 1998, it is a 100-member panel that provides independent guidance and expert technical advice to CMS on specific clinical topics considered in the NCD process. This advisory group convenes meetings open to the public in which it evaluates medical literature and technology assessments and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare or that may be eligible for coverage under Medicare. The MedCAC judges the strength of the available evidence and makes recommendations to CMS on the sufficiency of evidence to answer specific questions.

Establishing a committee consisting of interested stakeholders would be another way to provide opportunities for public input. In its 2011 budget request, AHRQ included funding an effort that would comprehensively engage stakeholders. In the United Kingdom, since 2002, a Citizens Council composed of 30 members of the public convenes twice per year and provides advice to the National Institute for Health and Clinical Excellence, an agency that provides guidance to the United Kingdom's National Health Service on public health, health technologies, and clinical practice.

Ensuring sufficient resources

CMS would require additional resources to develop the infrastructure, establish and maintain the administrative processes, and hire individuals with expertise in developing and managing such policies. For example, even with specific statutory authority, CMS lacks sufficient funding to sustain a well-articulated CED approach. For CED to be successful, CMS needs the necessary funds to establish a well-articulated process to identify services to study under CED and to implement well-designed studies.

As we also discuss later in this chapter, some observers argue that CMS's administrative resources are not commensurate with its current responsibilities, let alone new ones, and that the mismatch between the agency's administrative capacity and its mandate has grown enormously over the past two decades. In the federal budget, spending for Medicare administrative activities—with the exception of antifraud and quality improvement activities—is discretionary, determined by the annual appropriations process, while spending for Medicare (entitlement) benefits is mandatory. Former CMS administrators have pointed out the following funding issues for several years: (1) a persistent mismatch between appropriated dollars for program administration and agency responsibilities (e.g., implementing the Balanced Budget Act of 1997 (BBA) and the MMA); (2) requirements to conduct congressionally mandated projects, which may require diverting limited discretionary resources from other efforts; and (3) competition for funding with other Department of Health and Human Services (HHS) programs, such as funding for NIH, during the annual President's Budget and congressional appropriations processes (Butler et al. 1999, Iglehart 2009, Wilensky and Vladeck 2009).

Enhancing Medicare's research and demonstration capacity

The Medicare program has used research and demonstrations for decades to test the conceptual and operational feasibility of new payment policies and health care service delivery models. Over the last several years, the Commission and other observers have noted a growing disconnect between Medicare's urgent need to implement payment and service delivery innovations and the program's limited ability to research, test, and evaluate demonstrations that provide the information policymakers need to implement effective policy changes program wide.

The Commission most recently expressed its concerns about the pace of Medicare's demonstrations in a mandated report to the Congress on improving Medicare chronic care demonstration programs (Medicare Payment Advisory Commission 2009). Its analysis of four recent Medicare demonstrations suggested several larger issues with the structure and funding of research and development in Medicare, including: very low levels of funding for research, demonstrations, and evaluations relative to the overall size of the program; constraints on CMS's ability to redeploy research and demonstration funding as the program's needs change; and the existence of time-consuming and resource-intensive administrative requirements in the executive branch demonstration review process.

The Congress has recently acted to address many of these issues in the Patient Protection and Affordable Care Act of 2010 (PPACA), enacted on March 23, 2010 (Public Law No. 111-148). The PPACA authorizes the creation of a Center for Medicare and Medicaid Innovation (CMI)

within CMS no later than January 1, 2011; specifies several changes in the demonstration approval and implementation process; authorizes new funding for CMS to carry out demonstrations; and creates a process by which the Secretary may expand successful policy innovations under certain circumstances without seeking further congressional approval (see text box, pp. 20–21, for more detail). Throughout this section of the chapter, we discuss our initial analysis of the impact the CMI will have on the research and demonstration issues the Commission has been examining, and we note areas for potential further analysis as the new law is implemented.

Commissioners also have raised concerns about the level of Medicare resources allocated for health services research activities, such as funding and staffing for intramural and extramural research projects and to revamp the agency's data infrastructure to provide external researchers with timely access to program and demonstration data. Until relatively recently, Medicare devoted at least a portion of its research and demonstrations budget and staff to data-driven research projects that informed demonstration designs and development of payment policy reform ideas. It remains to be seen whether and to what extent the significant new resources appropriated for the new CMI may be used to support fundamental research activities.

Background on research and demonstrations

Within the Medicare program, research generally refers to data-driven analyses that are designed to suggest policy options for further exploration.[10] A demonstration is applied research; it changes how Medicare operates in a limited geographic area or for a particular group of beneficiaries. Medicare's research and demonstration activities are connected in that demonstrations usually require research to support their development and to evaluate their results. Before implementing a demonstration, CMS uses research to develop and test the demonstration methodology and the performance measures to be used in the evaluation. After a demonstration is completed, a formal evaluation is conducted to determine whether the demonstration's interventions had any observable effects on the use, costs, and quality of care (Cassidy 2008).

Demonstrations by design are time limited. Most demonstrations have an operational phase that typically lasts from three to five years, but the entire demonstration process usually takes considerably longer than that—more than a decade in some cases—when the time for design, review and approval, solicitation of participants, operation, and evaluation is taken into account (the demonstration process is described in more detail below). Demonstrations most often involve testing payment policy innovations—that is, paying for Medicare-covered services in a different way than under traditional fee-for-service Medicare. Some projects also involve paying for items or services not otherwise paid for by Medicare or allowing health care providers not otherwise providing a particular Medicare-covered service to do so.

Ideally, demonstrations allow CMS to gain practical operational experience with policy changes in a controlled manner that provides statistically reliable and valid data with which to evaluate the quality and cost impacts of the policy and delivery system changes being tested. In practice, however, many demonstrations either are too small, in terms of the size of the population in the experimental and control groups, or have effects that are too subtle to produce results with a reasonable degree of statistical confidence and that can be relied on to make decisions about broader policy implementation.[11] On the other hand, even demonstrations that do not yield actionable policy information can give CMS useful operational experience and knowledge that can inform the administration of subsequent demonstrations or program-wide implementation of a policy if it proceeds to that step. Successful demonstrations have led to several of the most significant changes in Medicare policy over the past 30 years, including the inpatient PPS; the skilled nursing facility and home health PPSs; aspects of the Medicare managed care program, including preferred provider organizations and special needs plans; durable medical equipment competitive bidding; programs to improve care for dual-eligible beneficiaries, such as the Program for All-Inclusive Care for the Elderly and social health maintenance organizations; and the hospice benefit (Cassidy 2008).

Overview of the Medicare demonstration process

The process of initiating, designing, implementing, and evaluating a Medicare demonstration is highly complex, involving multiple stakeholders within the legislative and executive branches of the federal government, providers, beneficiaries, and research institutions (both private and academic). In many ways, each Medicare demonstration is a microcosm of the policy and implementation complexities of the larger Medicare program (Kuhn 2008). The following section describes each of the major steps in the current demonstration process.

Center for Medicare and Medicaid Innovation authorized by the Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010 (Public Law 111–148), enacted on March 23, 2010, creates the Center for Medicare and Medicaid Innovation (CMI) within CMS and directs the Secretary to begin the CMI's operations not later than January 1, 2011 (§3021 as amended by §10306). The new law makes a number of significant changes that will affect the scope, budget, and process by which Medicare tests, evaluates, and expands payment and delivery system reform policies:

- Creates the CMI "to test innovative payment and service delivery models to reduce program expenditures under [Medicare and Medicaid] while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to" Medicare or Medicaid beneficiaries or beneficiaries of both programs (i.e., dual eligibles).
- Directs CMS to "consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management" when operating the CMI.
- Directs the Secretary to select models for testing under the CMI "where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under [Medicare or Medicaid or both] while preserving or enhancing the quality of care received by individuals receiving benefits under" the program(s). The law includes a list of 20 models that may be tested, but the Secretary is not limited to this list. There also are eight general criteria that the Secretary must consider when selecting models to be tested.
- Prohibits the Secretary from requiring, as a condition of initiating a test, that a model be budget neutral during its initial implementation phase. However, the Secretary is required to modify or terminate a test unless she determines (after an unspecified amount of elapsed implementation time) that quality of care will increase without an increase in program spending, will reduce spending without reducing the quality of care, or will reduce spending and increase quality. The CMS chief actuary must certify the spending determination.
- Allows the Secretary to waive any provision of Title 11 and Title 18 of the Social Security Act as necessary for testing models under the CMI. Title 11 includes the federal anti-kickback statute and provider self-

(continued next page)

Initiation of demonstrations

Both the Congress and HHS (typically through CMS) may initiate Medicare demonstration projects. The distribution of congressionally mandated and HHS-initiated projects has varied over time. In the early 1980s, few projects were mandated by the Congress, but this situation changed over the next decade and congressionally mandated demonstrations became the majority (Cassidy 2008). As of April 2010, just over half (17 of 31) of the currently active or upcoming Medicare demonstrations were mandated by the Congress (Table 1-4, p. 22).

Congressional initiation of demonstrations The Congress may mandate particular demonstration projects or research studies when it enacts legislation, typically in a bill that incorporates more extensive changes to the program (e.g., the MMA, which mandated 14 new demonstrations). Because the authorization language for most demonstrations specifies that their implementation must be budget neutral, the provisions typically are scored by the Congressional Budget Office as not increasing the cost of the overall bill and, therefore, few if any budgetary concerns are raised.

Center for Medicare and Medicaid Innovation authorized by the Patient Protection and Affordable Care Act of 2010

referral prohibitions (the Stark law); thus, the ability of the Secretary to waive these provisions would allow testing of payment models that included shared accountability arrangements (also called gainsharing) between participating providers, such as hospitals and physicians. Title 18 includes Medicare's fee-for-service payment and benefit coverage policies, which the Secretary may waive to test alternative provider payment models and coverage of otherwise non-covered benefits or services.

- Exempts from Paperwork Reduction Act review the testing, evaluation, or expansion of models under the CMI.
- Requires the Secretary to evaluate each model tested under the CMI. Each evaluation must include an analysis of the quality of care (including measurement of patient-level outcomes and patient-centeredness criteria) and changes in spending attributable to the model. Evaluations must be made "available to the public in a timely fashion."
- Allows the Secretary to expand, through rulemaking, the duration and the scope of a model that is being tested under the CMI, including implementation on a nationwide basis, if the following criteria are satisfied:
  - the Secretary determines that the expansion is expected to reduce spending without reducing the quality of care, or improve quality without increasing spending;
  - the CMS chief actuary certifies that the expansion would reduce or not increase net program spending; and
  - the Secretary determines that an expansion "would not deny or limit the coverage or provision of benefits" for beneficiaries.
- Directs the Secretary to "focus on models and demonstration projects that improve the quality of patient care and reduce spending" when determining which models or demonstration projects to expand.
- Appropriates $5 million for CMI activities for fiscal year 2010, $10 billion for CMI activities initiated in fiscal years 2011 through 2019, and $10 billion for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period starting in fiscal year 2020). Directs that not less than $25 million of the amounts so appropriated "shall be made available each such fiscal year to design, implement, and evaluate models" under the CMI.
- Directs the Secretary to submit a report to the Congress on the CMI's activities in 2012 and not less than once every other year thereafter. ■

The Congress may also influence the selection and implementation of demonstration projects through the annual appropriations process. The appropriations committees may indicate their support for specific projects in the conference report accompanying the Labor, HHS, and Education Appropriations bill. Appropriators also have been specific in identifying and in some cases allocating exact funding amounts for their preferred projects. Appropriations bills have also included language that prohibits CMS from spending money to implement certain demonstrations, thereby delaying or possibly ending a demonstration (Cassidy 2008).

The Congress also may act to extend projects beyond their original planned timeframe, particularly when a demonstration enjoys strong support from the providers or beneficiaries involved, but expansion of the concept being tested is unlikely (e.g., because savings goals were not reached). An example is the Municipal Health Services Demonstration, which was initiated in 1978 and repeatedly extended by the Congress until it ended in 2006, well beyond its originally planned timeframe of five years (Cassidy 2008). This demonstration was designed to test the effects of increased utilization of municipal

TABLE 1–4 **Active or upcoming Medicare demonstrations, April 2010**

Demonstration project name	Year	Initiated by:
Medicare Physician Group Practice Demonstration	2000	Congress (BIPA 2000)
Informatics for Diabetes Education and Telemedicine Demonstration Project	2000	Congress (multiple acts)
Private, For-Profit Demo Project for the Program of All-Inclusive Care for the Elderly	2001	Congress (BBA 1997)
Medicare Coordinated Care Demonstration	2001	Congress (BBA 1997)
Demonstrations Serving Those Dually-Eligible for Medicare & Medicaid	2002	HHS
ESRD Disease Management Demonstration	2003	HHS
Premier Hospital Quality Incentive Demonstration	2003	HHS
Demonstration Project for Consumer-Directed Chronic Outpatient Services	2003	Congress (MMA 2003)
Rural Community Hospital Demonstration Program	2004	Congress (MMA 2003)
Frequent Hemodialysis Network Clinical Trials	2005	HHS
Care Management for High-Cost Beneficiaries Demonstration	2005	HHS
Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities	2005	Congress (BIPA 2000)
Rural Hospice Demonstration	2005	Congress (MMA 2003)
Demonstration Project for Medical Adult Day Care Services	2005	Congress (MMA 2003)
MMA 646: Medicare Health Care Quality Demonstration Program	2005	Congress (MMA 2003)
Senior Risk Reduction Program	2006	HHS
Medicare Low Vision Rehabilitation Demonstration	2006	HHS
Post Acute Care Payment Reform Demonstration	2006	Congress (DRA 2005)
DRA 5007 Medicare Hospital Gainsharing Demonstration	2006	Congress (DRA 2005)
MMA Section 646 Physician Hospital Collaboration Demonstration	2006	Congress (MMA 2003)
Frontier Extended Stay Clinic Demonstration	2006	Congress (MMA 2003)
Medicare Care Management Performance Demonstration	2006	Congress (MMA 2003)
Home Health Pay for Performance Demonstration	2007	HHS
Medicare Part D Payment Demonstration	2007	HHS
Electronic Health Records Demonstration	2008	HHS
Nursing Home Value-Based Purchasing	2009	HHS
Medicare Acute Care Episode Demonstration	2009	HHS
FQHC Advanced Primary Care Practice Demonstration	2010	HHS
Multi-payer Advanced Primary Care Initiative	2010	HHS
Medicare Imaging Demonstration	2010	Congress (MIPPA 2008)
Medicare Enrollment Demonstration	2011	Congress (BBA 1997)

Note: BIPA (Benefits Improvement and Protection Act of 2000), BBA (Balanced Budget Act of 1997), HHS (Department of Health and Human Services), ESRD (end-stage renal disease), MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), DRA (Deficit Reduction Act of 2005), FQHC (Federally Qualified Health Center), MIPPA (Medicare Improvements for Patients and Providers Act of 2008).

Source: MedPAC analysis of CMS, "Demonstration Projects and Evaluation Reports: Medicare Demonstrations" (www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp#TopOfPage), April 23, 2010.

health centers in four cities by eliminating coinsurance and deductibles for beneficiaries who received care at the participating sites, expanding the range of covered services offered there (e.g., vision and dental care and prescription drugs), and paying the cities the full cost of delivering services at the centers. An evaluation of the cost-effectiveness of the demonstration indicated that a large proportion of the increase in program costs was caused by the rise in the use of services such as prescription drugs, dental care, and vision care and that these costs were not offset by decreases in emergency room and hospital usage (Centers for Medicare & Medicaid Services 2007).

At the other extreme, the Congress has adopted approaches being tested under demonstrations before those demonstrations have even been fully operational, much less evaluated. For example, the Medicare Choices Demonstration tested methods for offering new types of managed care products under Medicare and alternative risk-based payments for managed care. The earliest enrollment in a plan under the demonstration was in February 1997, with most enrollment beginning in spring and summer of that year. However, when the Congress passed the BBA in August 1997, it adopted for the larger Medicare managed care program some of the methods being tested under the Medicare Choices Demonstration (Cassidy 2008), such as preferred provider organizations. Similarly, the Congress authorized the addition of a hospice benefit to Medicare in the Tax Equity and Fiscal Responsibility Act of 1982, only two years after HCFA initiated a hospice demonstration in 1980 (Davis 1988).

HHS initiation of demonstrations The Secretary of HHS has authority to initiate demonstration projects under Section 402 of the Social Security Amendments of 1967 (see text box, pp. 24–25). For more than 40 years, this law has authorized the Secretary to conduct demonstrations that change current Medicare payment policy. This authority generally has been interpreted to limit agency-initiated demonstrations to changes in Medicare payment policy, such as paying providers for services not otherwise covered by Medicare at the time of the demonstration (e.g., care coordination services, remote monitoring, or hospice services before hospice became a covered benefit), or to experiment with changing the basis of provider payments, such as PPSs, bundled payments, or basing a portion of payments on improvements in quality. Such changes must not decrease the quality of care for beneficiaries.

CMS is using Section 402 authority to test the feasibility of bundled hospital and physician payments for certain types of acute care episodes; pay-for-performance policies for inpatient hospitals, skilled nursing facilities, and home health agencies; payments for care management programs serving high-cost beneficiaries with multiple chronic conditions; and Medicare participation with private payers in primary care medical home programs. All of these initiatives could yield insights into program and policy innovations for which the Commission has expressed support in past reports.

However, the Commission and other observers also have raised questions about the Secretary's use of the Section 402 demonstration authority to implement national payment policy changes for certain services or providers, such as ongoing demonstrations affecting Medicare Part D enrollees who also are eligible for the Part D low-income subsidy program, or to make supplemental payments to oncologists who were affected by reduced payments for Part B–covered drugs (Cassidy 2008, Medicare Payment Advisory Commission 2006).

Administration of demonstrations

The current process of designing and implementing demonstrations typically takes several years to complete. The major steps in the process are outlined in Figure 1-2 (p. 26).

The administration of Medicare demonstration projects is handled primarily by the CMS Office of Research, Development, and Information (ORDI). After a demonstration concept has been initiated by the Congress or the agency, the demonstration design is developed by ORDI staff and CMS staff from other parts of the agency as needed (e.g., information technology and fee-for-service operations staff), in some cases with input from outside experts on the relevant subject. The external input may be through informal consultation, advisory panels, or a formal federal contract for development design. The demonstration's design must anticipate and incorporate the data needs of the project's eventual evaluation as well as address how Medicare claims processing systems will be able to identify and correctly process claims under the demonstration model.

Next, CMS staff and policy officials must work with HHS and Office of Management and Budget (OMB) staff and policy officials to gain approval for the proposed design. The HHS Office of the Assistant Secretary for Financial Resources, Office of the Assistant Secretary for

Medicare demonstration authority under Section 402 of the Social Security Amendments of 1967 [excerpts]

Sec. 402 [Title 42 U.S. Code §1395b-1]. Incentives for economy while maintaining or improving quality in provision of health services

(a) Grants and contracts to develop and engage in experiments and demonstration projects

(1) The Secretary of Health and Human Services is authorized, either directly or through grants to public or private agencies, institutions, and organizations or contracts with public or private agencies, institutions, and organizations, to develop and engage in experiments and demonstration projects for the following purposes:

(A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222(a) of the Social Security Amendments of 1972) for health care and services under health programs established by this chapter [i.e., Medicare and Medicaid], including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services;

(B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in

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Planning and Evaluation, and the Office of the Secretary are involved in reviewing and requesting modifications to the demonstration design. The OMB review includes the Office for Intergovernmental and Regulatory Affairs—which is responsible for enforcing the Paperwork Reduction Act (PRA) and therefore, until enactment of the PPACA, reviewed all proposed information collection activities for a demonstration—and the Health Division, which is responsible for reviewing and approving each demonstration's budget-neutrality analysis. According to CMS staff, negotiations with OMB on occasion have increased the length of the demonstration approval process by six to nine months (Magno 2010).

Once a project is cleared internally within the executive branch, CMS issues a public notification and requests participants for the demonstration by publishing a notice in the *Federal Register*, issuing a press release, conducting outreach to relevant provider organizations, or contacting potential applicants. Next, demonstration participants (usually health care providers) are selected, often through an open, competitive contracting process consistent with the requirements of the demonstration. Demonstrations mandated by the Congress may have specific requirements for the types or geographic distribution of the providers selected to participate. For example, the section of the BBA authorizing the Medicare Coordinated Care Demonstration (MCCD) specifically required the Secretary to "implement at least 9 demonstration projects, including—

(A) 5 projects in urban areas;

(B) 3 projects in rural areas; and

(C) 1 project within the District of Columbia which is operated by a nonprofit academic medical center that maintains a National Cancer Institute certified comprehensive cancer center." (Balanced Budget Act of 1997 §4016(b)(2))

Once sites have been selected and contracts with each of them negotiated, the sites are given sufficient lead time to prepare operationally for implementing the demonstration protocol.

Medicare demonstration authority under Section 402 of the Social Security Amendments of 1967 [excerpts]

the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program; …

(b) Waiver of certain payment or reimbursement requirements; advice and recommendations of specialists preceding experiments and demonstration projects

In the case of any experiment or demonstration project under subsection (a) of this section, the Secretary may waive compliance with the requirements of this subchapter and subchapter XIX of this chapter insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or (in the case of physicians) on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment; and costs incurred in such experiment or demonstration project in excess of the costs which would otherwise be reimbursed or paid under such subchapters may be reimbursed or paid to the extent that such waiver applies to them (with such excess being borne by the Secretary). No experiment or demonstration project shall be engaged in or developed under subsection (a) of this section until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already completed or in process. ■

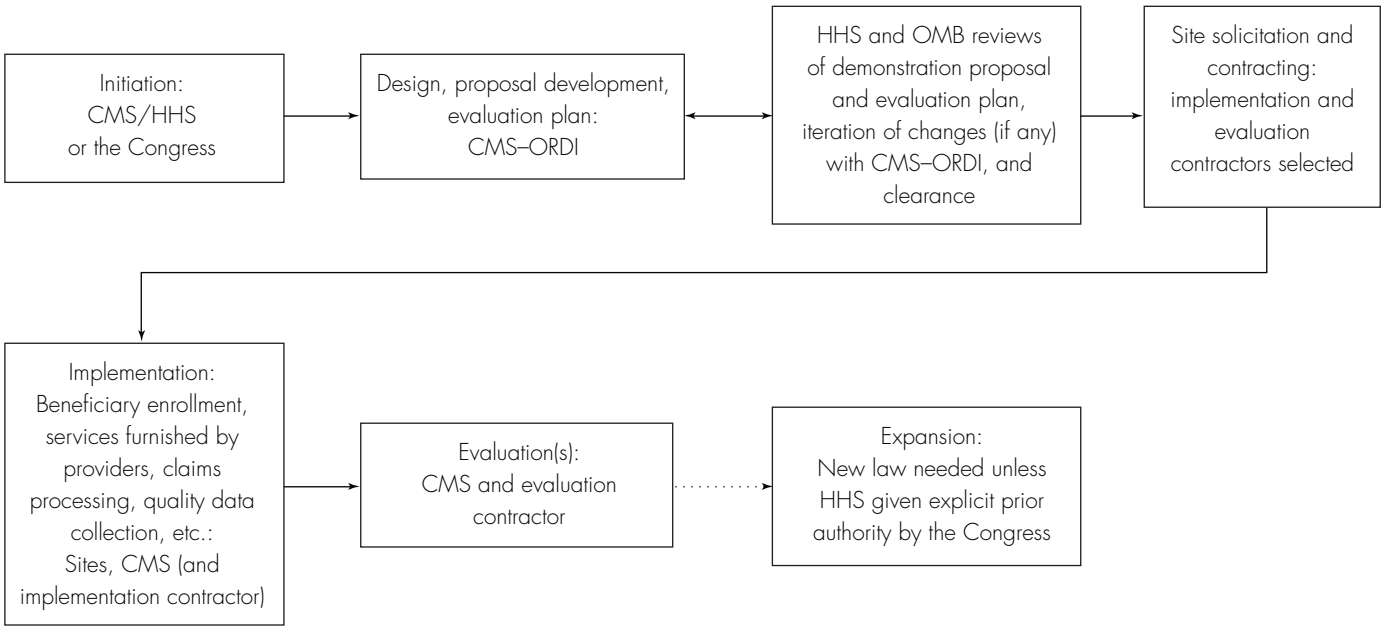
The demonstration is operational for one to five years, depending on the original mandate, if any, and the final study design. Interim evaluations may be conducted during the demonstration, and an overall evaluation is conducted after the demonstration is completed. Evaluations are significant efforts in their own right, typically operating in a separate but parallel design and contracting process from the demonstration. The evaluation must be carefully coordinated with the design and implementation of the demonstration to ensure that CMS and its selected evaluation contractor will have access to claims data, quality measures, and other information needed to complete any required interim reports and the final evaluation. Some demonstrations also involve a refinement stage, in which results are used to refine policies or operational aspects to hone the policy or how it is implemented (Cassidy 2008).

Two recent Medicare demonstrations illustrate how long the demonstration process can take. The MCCD was authorized in the BBA, which was enacted in August 1997 (Figure 1-3, p. 27). The length of the MCCD's design phase was affected by the Congress mandating that the Secretary "evaluate best practices in the private sector of methods of coordinated care for a period of 1 year and design the demonstration project based on such evaluation" (P.L. 105–33, §4016). In mid-2000, CMS solicited competitive proposals for programs to be MCCD sites and made 15 program site awards in early 2002. The sites began enrolling patients in mid-2002 and were initially authorized to operate for four years. The most comprehensive evaluation of the MCCD to date was based on complete Medicare claims data for services rendered through June 2006 (i.e., through the end of the original four-year demonstration period) and this report was delivered to CMS by the evaluation contractor in January 2008 (Peikes et al. 2008).[12]

The Medicare Health Support (MHS) program followed a somewhat more rapid course (Figure 1-4, p. 27). The MHS program was authorized in the MMA, but the design phase was much shorter than in the case of the MCCD because

FIGURE 1–2

Schematic of current Medicare demonstration process



Note: CMS (Centers for Medicare & Medicaid Services), HHS (Department of Health and Human Services), CMS–ORDI (Centers for Medicare & Medicaid Services Office of Research, Development, and Information), OMB (Office of Management and Budget).

CMS had already spent two years developing a large, population-based disease management demonstration that the agency had planned to conduct under its own demonstration authority. CMS staff worked with the Congress to incorporate many of the design parameters from that demonstration design into the statute (Magno 2010). The MMA provision authorizing the program also specified the qualifications of the types of organizations that would be allowed to participate in the program (Section 1807(e) of the Social Security Act, as added by MMA §721). After a competitive solicitation in 2004, CMS awarded three-year contracts to eight program sites that began operations in mid-2005 to early 2006 (McCall et al. 2008).

The MMA required that the evaluation results of the initial three-year phase (Phase I) were to be used by the Secretary to determine whether to proceed to full-scale implementation of the program (Phase II). CMS announced in January 2008 that, on the basis of an interim evaluation of the first 18 months of MHS operations, it would end Phase I as scheduled and not renew the five remaining active MHS contracts beyond their scheduled termination dates in 2008. CMS also announced it would evaluate the results of the final evaluation expected sometime in 2010 or 2011 before making a final decision about whether to proceed to Phase II (Medicare Payment Advisory Commission 2009).

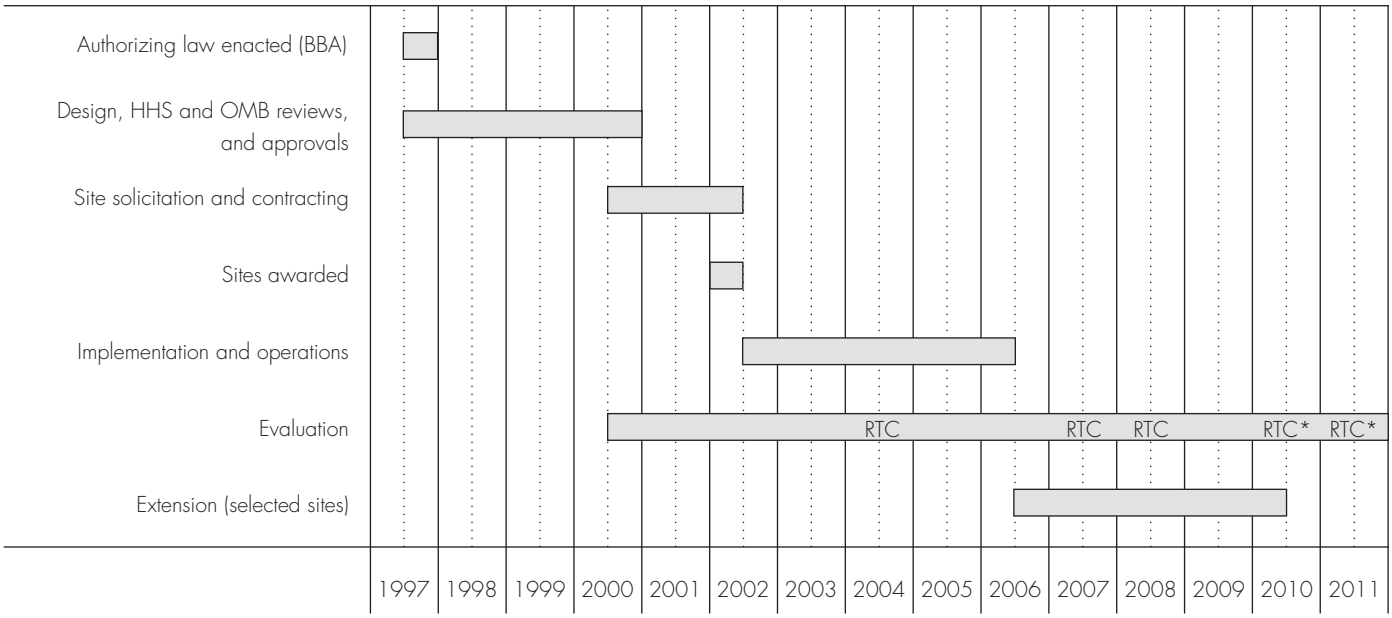
Issues in the current demonstration process

Policymakers began expressing concerns about the timeliness and usefulness of Medicare's research and demonstration activity not long after the Congress granted demonstration waiver authority to the Secretary in 1967. The House Ways and Means Subcommittee on Oversight held a hearing in 1980 "on the relevance and usefulness of the Medicare research and demonstrations projects, the timeliness of reports and feedback to Congress on those projects, the quality of the evaluation of demonstration projects, and the dissemination of demonstration results. Members emphasized that the issues in this hearing were similar to those raised in a 1976 hearing" (Cassidy 2008).

More recently, concerns have been raised from a variety of perspectives about several issues that hinder Medicare's ability to research, experiment, evaluate, and disseminate urgently needed policy innovations in a timely fashion (Crosson et al. 2009, Guterman and Drake 2010, Guterman and Serber 2007, Iglehart 2009, Kuhn 2008,

FIGURE 1–3

Timeline of Medicare Coordinated Care Demonstration, 1997–2011

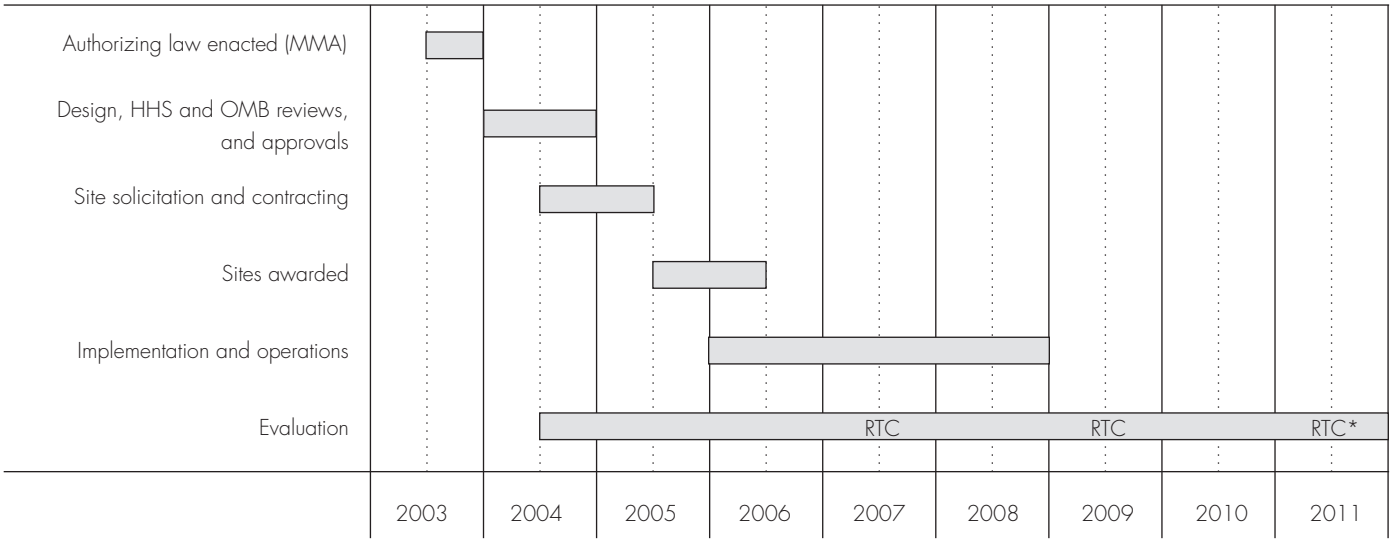


Note: BBA (Balanced Budget Act of 1997), HHS (Department of Health and Human Services), OMB (Office of Management and Budget), RTC (Report to the Congress).
*Planned Reports to the Congress.

Source: MedPAC analysis of demonstration evaluation reports and CMS data.

FIGURE 1–4

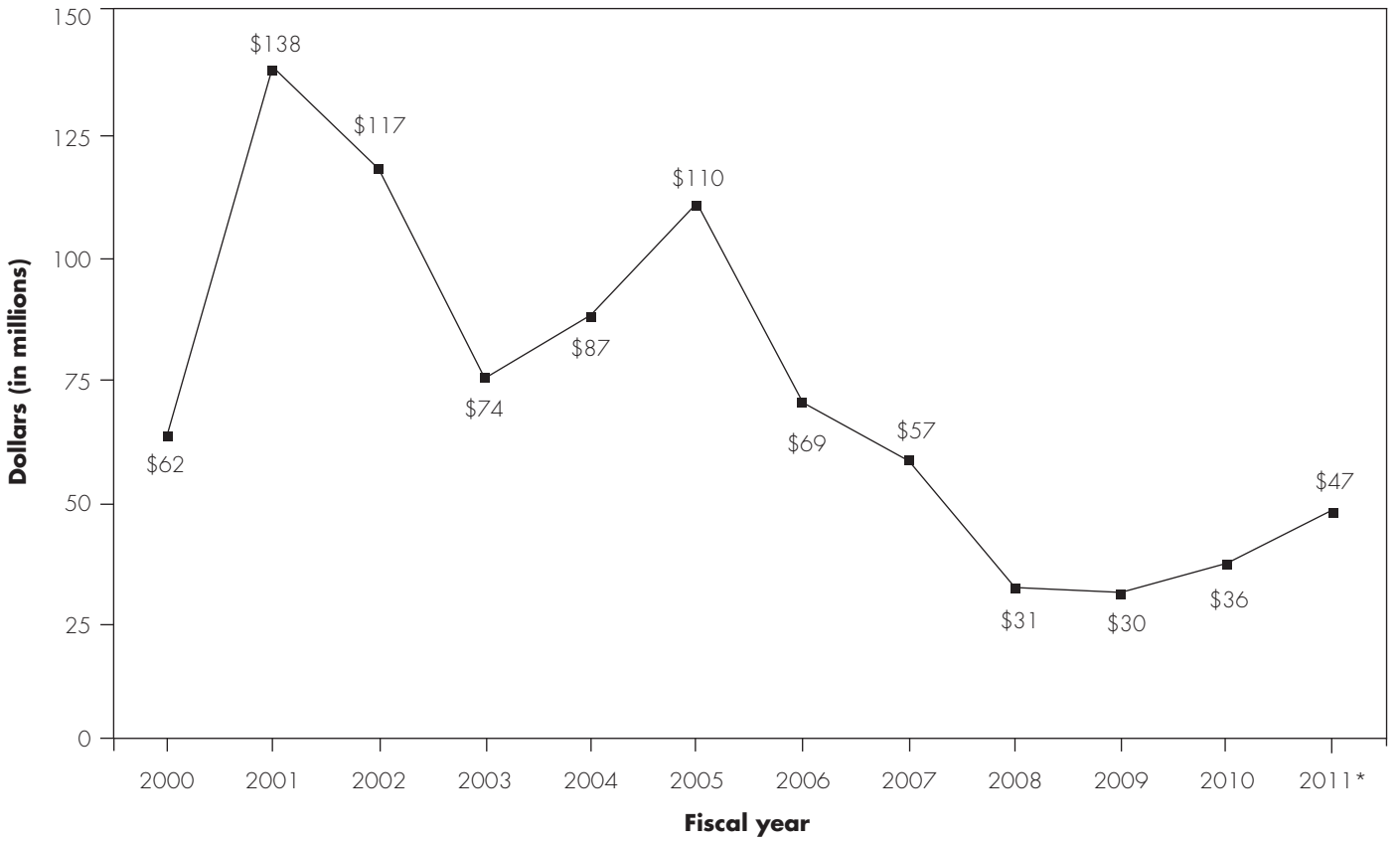
Timeline of Medicare Health Support program, 2003–2011



Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), HHS (Department of Health and Human Services), OMB (Office of Management and Budget), RTC (Report to the Congress).
*Planned Report to the Congress.

Source: MedPAC analysis of Medicare Health Support evaluation reports and CMS data.

FIGURE 1–5 **CMS budget for research, demonstrations, and evaluation, FY 2000–2011**



Note: FY (fiscal year).
*Proposed FY 2011 President's Budget.

Source: MedPAC analysis of the Department of Health and Human Services Budget in Brief for FYs 2000–2011.

Medicare Payment Advisory Commission 2008, Medicare Payment Advisory Commission 2009, Wilensky and Vladeck 2009). These issues can be grouped into three broad categories for purposes of analysis and formulation of policy options: funding, flexibility, and accountability.

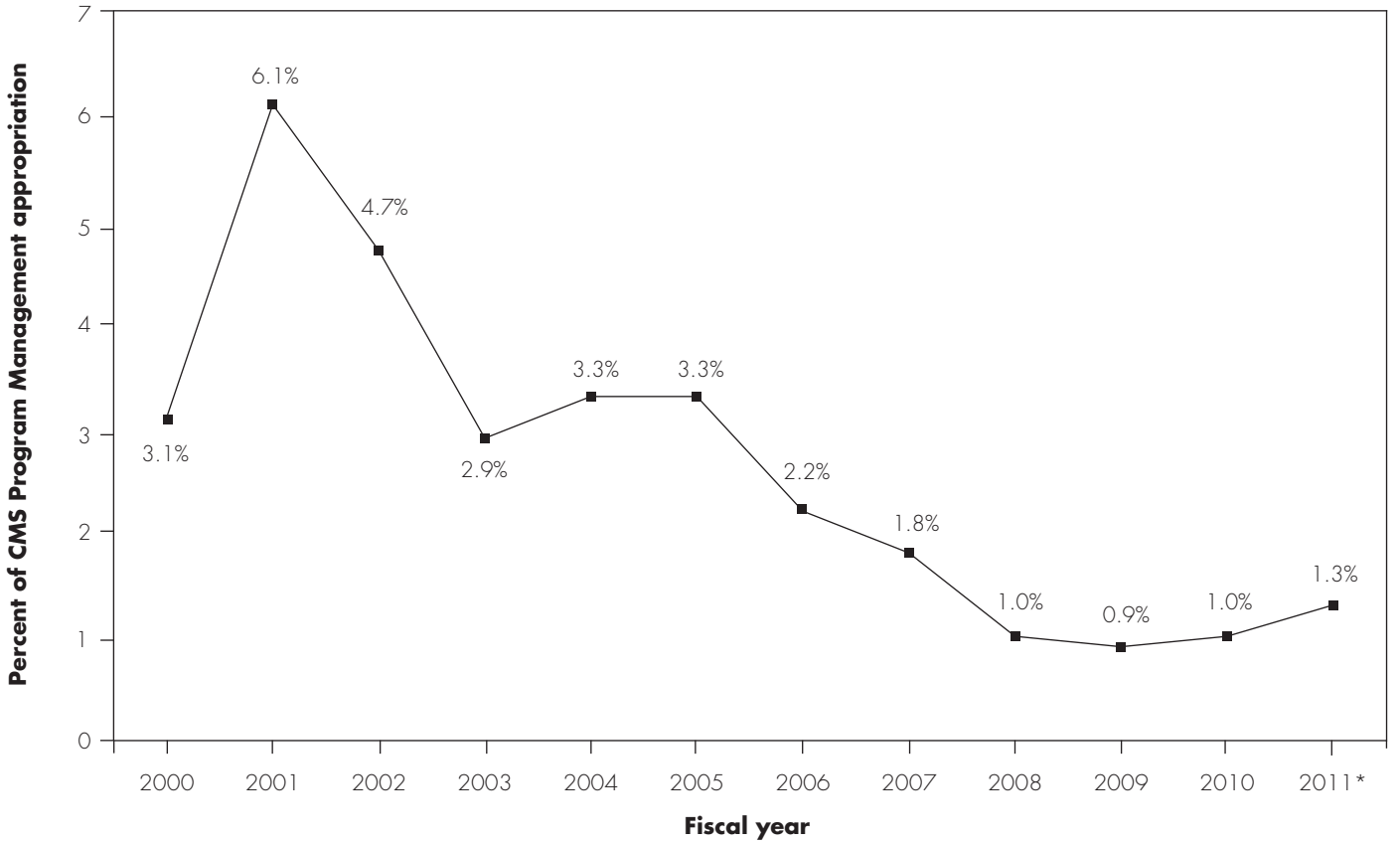
Funding

As shown in Figure 1-5 and Figure 1-6, funding for all CMS research and demonstration activities has declined over the past 10 years, both in nominal dollars and as a percentage of the total amount of discretionary appropriations for CMS program administration. Funding for CMS research, demonstrations, and evaluation activities reached a peak of about $138 million in 2001 (6.1 percent of total discretionary program management funding that year). It declined over the next two years but then increased with enactment of several Medicare demonstrations in the MMA, which included a large short-term increase in funding for CMS administrative activities associated with implementing the MMA. Since 2005, the budget for research and demonstrations has significantly declined to its current level of about $36 million (1.0 percent of total discretionary program management funding in fiscal year (FY) 2010). The FY 2010 funding amount of $36 million is about 0.007 percent of total mandatory spending for Medicare benefits (about $515 billion) projected for the current fiscal year.

Within the current budget, not all the funds are available for implementation and evaluation of demonstration projects. In FY 2010, about 57 percent of the $35.6 million appropriation is allocated to other research activities, most prominently to support ongoing implementation

FIGURE 1–6

CMS budget for research, demonstrations, and evaluation as percent of CMS Program Management discretionary appropriation, FY 2000–2011



Note: FY (fiscal year). Discretionary Program Management appropriation includes Medicare Operations, Federal Administration, Survey and Certification, and Research. *Proposed FY 2011 President's Budget.

Source: MedPAC analysis of the Department of Health and Human Services Budget in Brief for FYs 2000–2011.

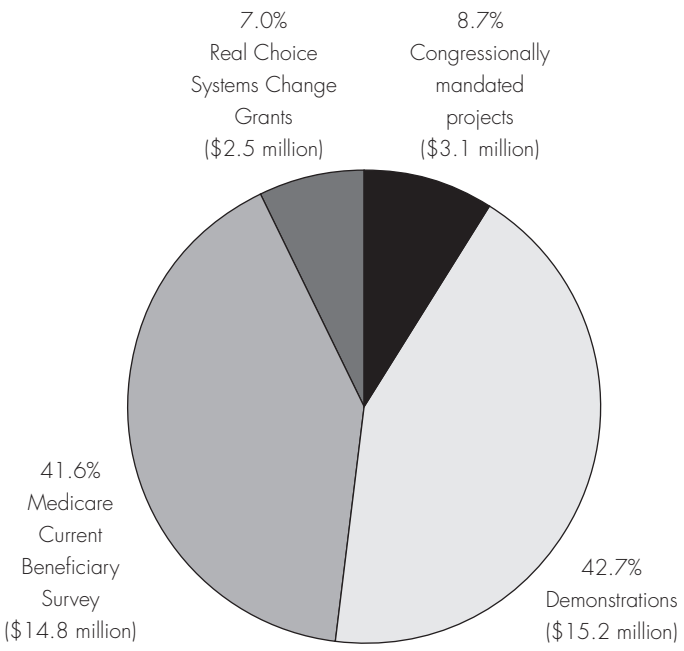
of the Medicare Current Beneficiary Survey (Figure 1-7, p. 30). About 9 percent of the total ($3.1 million) is allocated to congressionally mandated projects (in FY 2008 and FY 2009, about 15 percent of the total research, demonstration, and evaluation budget was directed to congressionally mandated projects). About $15.2 million is available in FY 2010 for all the remaining Medicare and Medicaid research, demonstrations, and evaluation activities.

The impact of limited resources on CMS's ability to implement and evaluate demonstrations has been noted by observers inside and outside the agency (Crosson et al. 2009, Institute of Medicine 2008, Kuhn 2008). In addition to limiting the scope and variety of policy innovations that the program can test, resource constraints also can affect the agency's ability to produce timely evaluations of implemented demonstrations, especially those that are initiated by the Secretary (Love 2010). Funding priority may be given to evaluations of congressionally initiated demonstrations or other required reports to the Congress on demonstration activity.

There also may be a significant return on investment from some of the program's spending on research and demonstrations. For example, CMS estimates that Medicare spent about $13 million on the research and demonstration work underlying the inpatient PPS (IPPS) in the early 1980s, while the program-wide implementation of the IPPS is estimated by the Medicare actuary to have reduced Medicare outlays by about $25 billion over the first 10 years it was in effect—a return of roughly $1,900 over 10 years for every dollar spent on the initial research and demonstration work. Other examples

FIGURE 1–7

Distribution of FY 2010 CMS research, demonstrations, and evaluation budget by activity



Note: FY (fiscal year).

Source: MedPAC analysis of Centers for Medicare & Medicaid Services 2010a.

cited by CMS of large returns on investments in research and demonstrations include the skilled nursing facility PPS, competitive bidding for durable medical equipment, and risk adjustment for payments to Medicare Advantage plans (Love 2010).

To offer CMS a more stable and secure source of funding, funding for CMS research and demonstration activities could be removed from the annual discretionary appropriations process and instead authorized and appropriated directly from the Medicare trust funds, similar to the way the Health Care Fraud and Abuse Control (HCFAC) program[13] and the Medicare Quality Improvement Organization (QIO) program[14] are financed. If Medicare demonstrations were funded through mandatory appropriations, it may be reasonable to apportion the total funding amount between the Hospital Insurance and Supplementary Medical Insurance Trust Funds in proportion to the percentage of Medicare benefit outlays paid from each.

Multiyear funding allocations (e.g., a two-, three-, or five-year mandatory appropriation) also could be used to ensure a stable stream of resources, and this approach may be particularly appropriate for funding multiyear demonstration projects. A particular concern is to ensure that sufficient funds are available at the end of a multiyear demonstration to complete its evaluation. Currently, funding that is initially budgeted for the evaluation of HHS-initiated demonstrations may be unavailable if CMS decides to reallocate resources within its limited total funding to complete evaluations of congressionally mandated demonstrations or other reports to the Congress.

An outstanding issue for further exploration by the Commission is the amount of resources within CMS's research and demonstrations budget that should be devoted by CMS to support basic health services research activities, including enhancing CMS staff capabilities to conduct intramural research projects; funding extramural research; expediting access to Medicare data (which may include data generated from demonstration projects that could be available for external evaluations); and rapidly developing CMS's internal data infrastructure to meet the growing demands of multiple research and demonstration activities. On the latter issue, the agency has included a request for $110 million in two-year funding for a health care data improvement initiative in its proposed FY 2011 budget (Centers for Medicare & Medicaid Services 2010a). The Congress will address this request during the FY 2011 appropriations process later this year.

In the PPACA provision creating the CMI, the Congress authorized the appropriation of $5 million in FY 2010 for the "design, implementation, and evaluation of models" under the new center. It then allocates $10 billion for FY 2011–2019 and for each subsequent decade beginning with FY 2020 for the costs of demonstration programs, presumably to allow for new provider payment and benefits costs under the demonstrations, and further specifies that not less than $25 million in each of those fiscal years (2011–2019) shall be available for designing, implementing, and evaluating the models being demonstrated.

The new funding authorized by the PPACA represents a significant increase in the amount and the stability of resources available to the agency for designing, testing, and evaluating payment policy and health care delivery system innovations. Funding issues include how the Secretary and the Congress will determine the level of annual funding for the center's operations above the

$25 million minimum level authorized in the new law and the distribution of that funding across the center's various activities, including the amount of resources (both funding and staff) devoted to basic research into potential innovations. These issues will become clearer as the law is implemented.

Flexibility

Arguably the most acute problem with the current Medicare demonstration process is the long and resource-intensive process through which demonstrations are designed, implemented, evaluated, and, if warranted, disseminated program wide. Some parts of the process are inherently time-consuming, given the complexity of working through a vast amount of technical detail to design and implement a demonstration, an effort akin to implementing a miniature version of the Medicare program for each demonstration (Kuhn 2008). In addition to the technical design and implementation challenges, the process involves negotiating agreement among all the parties involved, including stakeholders inside the participating executive branch agencies and outside the government (e.g., each demonstration site). During implementation, practical considerations come into play, such as the time it takes for clinical interventions to have measurable effects on service use and quality of care. It may take a longer-than-planned implementation period to determine with sufficient statistical confidence that an intervention in fact had no effect or to detect relatively subtle effects of an intervention in the study population.

Nonetheless, there are other parts of the process, before and after the implementation phase, where changes could be made to shorten the time and resources involved. Policymakers must make a trade-off in deciding how to shorten the time and resources involved in the design, approval, and evaluation phases of a demonstration by finding an appropriate balance between eliminating duplicative or otherwise unnecessary steps in the process while maintaining the due diligence necessary during the design phase (ensuring that the demonstration will produce results that are relevant to the policy questions they wish to investigate) and in the evaluation (ensuring it is as accurate as possible to avoid drawing erroneous conclusions from the demonstration results). Once a demonstration is completed and evaluated, there is the issue of accountability for the decision on whether to expand implementation of the tested policy innovation (assuming expansion is supported by the evaluation) and whether that responsibility should remain with the Congress or be delegated to the Secretary.

While many of the demonstration process issues discussed below are addressed in the CMI provisions of the PPACA, the Commission remains concerned that Medicare demonstrations could continue to have difficulty generating statistically significant cost and quality impacts—in the absence of which the Secretary will not be able to expand the use of an innovation—as long as the experiments are limited in duration and scope to the extent that a sufficient critical mass of providers is unwilling or unable to make the painful and costly organizational changes needed to restructure the delivery system to achieve significant results. This matter is a key implementation issue that the Commission will continue to monitor as the new law is implemented.

Reduce administrative requirements in the demonstration review process In the executive branch review and approval phase, there are at least two areas where it may be possible to shorten the process without adversely affecting the overall quality of the research or putting Medicare funds at any more risk than they already may be under in the current demonstration process.

Exempt demonstrations from PRA review—First, CMS staff have indicated that the PRA requirements imposed by OMB during the internal review process often are time-consuming, resource intensive to respond to, and usually do not result in a commensurate improvement in the design or implementation of the demonstration. These requirements may include review and approval of all forms, surveys, site visit protocols, and other types of information collection that will be used in the demonstration and evaluation.

An option for addressing this issue would be to exempt Medicare demonstrations and evaluations from the otherwise applicable sections of the PRA. The newly enacted PPACA includes such a provision, exempting all demonstrations and evaluations from PRA review if they are implemented under the new CMI. The new law is silent, however, on whether there will be oversight of the PRA exemptions. To provide such oversight, a third-party entity such as the HHS OIG or the Government Accountability Office could periodically review and report to the Congress on CMS's activities under the PRA waiver. This oversight activity could be expanded to include any other areas where the Congress grants CMS clear exemptions from statutory or regulatory requirements that otherwise might apply, such as the Federal Advisory Committee Act.

Modify the application of budget neutrality in demonstrations—Before enactment of the PPACA, virtually all Medicare demonstrations were required to meet a budget-neutrality test as a condition of being allowed to move ahead to implementation. Budget neutrality means that actual or (more frequently) projected costs under the demonstration cannot exceed what costs would be if the demonstration were not implemented. In demonstrations authorized by the Congress, a budget-neutrality requirement often would be included to ensure that the provision authorizing the demonstration would not be scored by the Congressional Budget Office as increasing Medicare outlays. For demonstrations initiated by the Secretary, OMB required HHS to submit estimates showing that each proposed demonstration would be budget neutral. For both types of demonstrations, OMB was responsible for deciding what assumptions would be used to calculate budget neutrality and whether a demonstration proposal satisfied the test.

The use of budget neutrality in the demonstration approval process was criticized for its narrowness and inflexibility (Cassidy 2008, Guterman and Serber 2007). OMB usually required that all demonstrations be estimated to show budget neutrality over their relatively short operational duration, estimates that typically could not take into account any potential longer term savings (or costs) from the proposed intervention. The policy also considered only the estimated costs and savings from a demonstration and usually did not consider cases in which significant quality improvements could be achieved with relatively small net increases in spending.

While the PPACA expressly prohibits the application of budget neutrality as a condition of approving and implementing a demonstration, the new law requires the Secretary to terminate or modify a model at any point after implementation unless she determines that the model is expected to be budget neutral or reduce spending (and the Medicare actuary must independently certify the estimated costs or savings) and that the quality of care for beneficiaries participating in the model also is expected to increase or at least not decrease. An option for implementing this provision would be for the Secretary to establish a spending level or growth rate target for each demonstration and then assess actual costs against the target for the first year or two of operations. The Secretary could immediately terminate or modify a demonstration (or an individual site participating in the demonstration) if the assessment found that the model had costs in excess of the predetermined level or growth rate target.

Accelerating evaluations—Almost all demonstrations, whether initiated by the Congress or by the Secretary, include an evaluation and public report on the findings and recommendations regarding the tested policy changes. CMS enters into a contract for a demonstration's evaluation with research firms through a process separate than that used for design and implementation of the demonstration. The evaluation design often is developed at the same time the demonstration is being developed (Cassidy 2008), and CMS often begins working with the evaluation contractor as soon as the demonstration sites are operational (Magno 2010). The fundamental challenge in designing and executing an evaluation is maintaining the appropriate balance between scientific rigor and policy usefulness.

Most evaluations currently use a full or partial randomized controlled trial (RCT) design to assess the success or failure of interventions. Several concerns have been raised about whether the RCT methodology is an appropriate approach for evaluating Medicare demonstrations. One concern is that RCT-based evaluations may not yield critical information to explain why the intervention succeeded or failed to produce the expected outcomes (Gold et al. 2005). For instance, the demonstration may have imperfect controls and deliver incomplete data, hindering the evaluator's attempts to control for mitigating factors and isolate the effects of the demonstration's intervention. Some experts question whether the RCT approach is poorly suited to demonstrations in which one characteristic that may be critical to the development of successful innovations in the real world—continuous local adaptation in response to learning—violates the fundamental RCT premise of "holding all else constant" (Berwick 2008, Gold et al. 2005, Guterman and Drake 2010, Guterman and Serber 2007).

A separate but related issue is the timeliness of evaluations. The RCT-based evaluation approach requires accurate and complete data, but the process of collecting, cleaning, and analyzing those data is inherently time-consuming and, in the case of the care management demonstrations the Commission examined in 2009, significantly increased the administrative complexity and cost to CMS and participating providers of implementing the interventions (Medicare Payment Advisory Commission 2009). CMS has taken several steps to accelerate evaluations, including concurrent award and implementation of contracts for demonstrations and evaluations, continuous monitoring of demonstration projects and preparation of interim evaluation reports

(when resources are available, which has not always been the case in the past), and the use of alternative evaluation methods (Magno 2010). All these approaches can allow more rapid-cycle feedback to expedite the incorporation of demonstration findings into consideration of policy changes (Gold et al. 2005, Guterman and Serber 2007). A challenge for CMS as it implements the CMI will be to ensure that sufficient resources are deployed to sustain and build on the steps the agency has taken to accelerate evaluations, while maintaining a balance between scientific rigor in evaluations and the information needs of the policymaking process.

In addition to efforts to speed evaluations, efforts could be made to encourage additional evaluations by researchers outside of CMS. One way to do so would be to increase the availability of the Medicare data—such as claims data and quality measures—that are generated during a demonstration. By making these data available as quickly as possible with appropriate privacy protections, policymakers could benefit from alternative analytic perspectives on the outcomes of demonstrations. For example, health services researchers have used data from the Medicare Premier Hospital Quality Incentive Demonstration to evaluate the effect of a hospital pay-for-performance program on quality of care (Glickman et al. 2007, Grossbart 2006, Lindenauer et al. 2007). The largest and most rigorous of these studies found that, when controlling for baseline performance and condition-specific patient volumes, the observed percentage point improvement over a two-year period in composite quality scores for participating hospitals compared with nonparticipating hospitals decreased from 4.3 percentage points to 2.9 percentage points, a statistically significant difference (Lindenauer et al. 2007). This analysis suggests that the incentive program did increase participating hospitals' quality somewhat (as measured by the process metrics used in the demonstration) but not by as much as it initially appeared.

The PPACA's changes to the Medicare demonstration process do not directly address alternative evaluation criteria or publicly releasing Medicare demonstrations data to external researchers. The new law requires the Secretary to evaluate each model tested under the CMI and states that the evaluation must analyze the impacts on cost and quality (specifically including patient outcomes) of the tested interventions. It further directs the Secretary to make each evaluation publicly available "in a timely fashion" but does not define "timely" (§1115A(b)(4)).

Allow successful models to move from demonstration to program policy without further congressional action—The Commission and others have observed that Medicare could speed up its pace of innovation if the Congress gave the Secretary the authority to expand demonstrations, up to and including nationally or program wide, without further congressional action if the Secretary determined that doing so would decrease (or at least not increase) costs, while increasing or maintaining quality of care (Medicare Payment Advisory Commission 2008). The Congress adopted this approach in the MMA provision enacting the Medicare Health Support program and in the BBA provision authorizing the MCCD. The Secretary's determination to expand a demonstration could be based in part on a joint determination with the Medicare actuary that the expansion is expected to be budget neutral and either increase or at least not decrease the quality of care for Medicare beneficiaries.

The PPACA adopts this approach for models tested under the new CMI, with a requirement that expansions of policy innovations must be expected to reduce or at least not increase net program spending (i.e., total spending net of any costs for new benefits or provider payments that are made under the tested model), while also improving or at least not decreasing the quality of care for participating beneficiaries. Because the new law requires the Secretary to use the rulemaking process to implement any policy expansion, there will be an opportunity for external stakeholders to comment on proposed expansions through the usual public "notice-and-comment" process.

Provision of the PPACA increasing the Secretary's flexibility to waive current law and prohibiting administrative or judicial review of demonstrations

In addition to the specific areas of PRA review, budget neutrality, and expansion authority, the PPACA makes two other significant changes to the Secretary's demonstration authority that should increase the program's ability to implement policy innovations more rapidly. First, the Secretary is explicitly allowed to waive the requirements of Title 11 of the Social Security Act (as well as the main Medicare statutes in Title 18) for purposes of carrying out projects under the CMI. Title 11 includes the anti-kickback statute (Section 1128B) and the civil monetary penalty statute (Section 1128A), and therefore the Secretary's ability to waive those provisions appears to allow the use of shared accountability arrangements (also called gainsharing) between physicians and hospitals and potentially other providers in a local delivery system for models tested under the CMI. This provision is consistent

with a 2005 Commission recommendation that the Congress should grant the Secretary the authority to allow shared accountability arrangements between providers to better align financial incentives, with appropriate regulation of those arrangements to protect the quality of care and minimize financial incentives that could inappropriately affect physician referrals (Medicare Payment Advisory Commission 2005). The Secretary's ability to waive the requirements of Title 11 could permit more expansive demonstrations of shared accountability arrangements than it has been possible to implement to date.

Second, the PPACA stipulates that there shall be no administrative or judicial review of the Secretary's decisions on the following aspects of demonstrations under the CMI:

- the selection of models for testing or expansion;
- the selection of organizations, sites, or participants to test the selected models;
- the elements, parameters, scope, and duration of a demonstration;
- the determination regarding budget neutrality in the design and approval process;
- the determination of the cost and quality impacts of an implemented demonstration and the resulting decision (if applicable) to terminate or modify it; and
- the determination about expansion of the scope and duration of a demonstration, including the determination that a model is not expected to reduce program costs and increase or at least not reduce the quality of care.

This provision is significant because the implementation or expansion of some Medicare demonstrations, such as competitive bidding for clinical laboratory services and durable medical equipment, have been delayed by judicial review. This provision also could give the Secretary flexibility to contract with entities such as practice-based research networks (PBRNs) to test policy innovations on a smaller scale before expanding them (if successful) to full-blown demonstrations. The Commission discussed the potential value of PBRNs, or a similar standing network of competitively contracted provider sites, in its 2009 report on a Medicare chronic care practice research network (Medicare Payment Advisory Commission 2009).

Accountability

Along with increased funding and flexibility to design, implement, evaluate, and disseminate Medicare policy innovations, it is reasonable to consider options for increasing the program's accountability for its performance in this area.

First, the Secretary could be required to consult with private sector entities, such as health plans or integrated delivery systems, about the agency's Medicare research agenda and directed to examine and report on the feasibility of adapting private-sector policy innovations for application in Medicare (Lee et al. 2010). The consultation process also could involve creating a formal advisory committee of external experts from other federal agencies, including AHRQ and the Institute of Medicine, academic research institutions, private payers and purchasers, and provider and beneficiary representatives. The Congress also could direct CMS to consult periodically with the Commission to discuss Medicare's research and demonstrations agenda and ongoing projects, including the preliminary operational or evaluation results of demonstrations. The PPACA requires the Secretary, in carrying out the functions of the CMI, to consult with relevant federal agencies and experts in medicine and health care management through the use of open door forums or other mechanisms to be decided by the Secretary.

Medicare may also consider directly engaging in joint demonstration projects with private payers (Crosson et al. 2009, Guterman and Drake 2010, Lee et al. 2010). The Secretary has some ability to do so under the Section 402 demonstration authority, as evidenced by HHS's announcement in September 2009 that CMS would establish a demonstration program that will enable Medicare to join Medicaid and private insurers in state-based advanced primary care initiatives (Department of Health and Human Services 2009). Some analysts argue that a sustained and transparent process of coordination with private-sector payment policy and care delivery innovations would magnify the impact of payment incentive innovations at the provider level, while reducing the administrative barriers for providers to participate in demonstrations, thereby increasing their population size and the statistical power of their results (Guterman and Drake 2010). This process in turn could result in obtaining more actionable information from demonstration evaluations, which would speed the process of disseminating policy innovations from demonstrations into program-wide implementation. On the other hand,

multipayer collaborations involving Medicare would need to be carefully designed, implemented, and evaluated to ensure that the cost and quality of care for participating beneficiaries is appropriately accounted for and closely monitored and that Medicare's research needs are met—for example, by capturing differences in clinical profiles between privately insured participants and Medicare beneficiaries, who are more likely to have multiple chronic conditions.

Another option to increase transparency and accountability would be to require the Secretary to periodically report to the Congress about what is being learned from ongoing demonstrations and what the potential effects could be if they were expanded (Guterman and Serber 2007). The PPACA requires the Secretary to submit a report to the Congress on the activities of the CMI beginning in 2012 and at least every other year thereafter. As specified in the new law, this report must at a minimum include the numbers of Medicare (and Medicaid) beneficiaries participating in ongoing demonstrations, the amounts of program payments made on behalf of participating beneficiaries, and the results of any formal evaluations. It also could be informative to policymakers and reduce the reporting burden on CMS if this biannual report encompassed any Medicare demonstrations operating outside of the CMI and included any preliminary or interim evaluation findings. As noted above, obtaining the information for this kind of report would require a different approach to demonstration evaluations than CMS currently uses. The Commission could submit a comment letter to the Congress after examining this report from the Secretary and communicate its views on the substance and process of Medicare's research and demonstration activity. ■

Endnotes

1 In 2003, epoetin alfa was no longer eligible for a transitional pass-through under the hospital outpatient PPS. (Pass-through payments were paid for two to three years until standard payments could be modified to incorporate the cost of the new technology.) In 2003, payment for epoetin alfa was based on its acquisition cost, which was usually at 68 percent of the average wholesale price (Medicare Payment Advisory Commission 2002). By contrast, a drug in the transitional pass-through payment status was paid based on 95 percent of the average wholesale price for the drug.

2 Section 1833(t)(2)(E) states that under the outpatient hospital PPS, "the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals."

3 Because the biologics are dosed in different units, CMS developed a conversion ratio with assistance from the product developers and an independent contractor.

4 The AMA is responsible for level I of the Healthcare Common Procedure Coding System (HCPCS), more commonly referred to as Current Procedural Terminology, that codes professional services provided by physicians. Medicare is responsible for level II of the HCPCS, which includes codes for services and procedures not included in level I such as durable medical equipment.

5 Albuterol is a racemic mixture containing equal parts of two isomers (the R-albuterol and S-albuterol). Levalbuterol contains only the R-albuterol isomer.

6 Most of the reference pricing studies were for senior citizens in British Columbia, Canada. The use (dispensing) of reference drugs increased in five studies, between 60 percent and 196 percent immediately after introduction of reference drug pricing, whereas the use of cost-sharing (i.e., more costly) drugs decreased by between 19 percent and 42 percent in four studies. In three studies, the reference drug group expenditures decreased (range 19 percent to 50 percent), whereas in the fourth study the expenditures increased by 5 percent in the short term.

7 Some analysts have specifically raised concern about the potential negative incentives for pharmaceutical innovation when brand-name products are covered by reference pricing (Lopez-Casasnovas and Puig-Junoy 2000).

8 For services that go through the FDA regulatory process—drugs, biologics, diagnostic tests, and devices—safety and efficacy evidence obtained through clinical trials is usually not collected for all patient populations. For example, clinical trials often exclude older patients and those with multiple illnesses. For diagnostic tests, such as imaging tests, product developers sponsor clinical studies that often focus on the tests' accuracy rather than the tests' impact on patient outcomes. Moreover, it is difficult to encourage product developers to conduct additional clinical research after obtaining FDA approval (Tunis and Pearson 2006). Surgical procedures do not go through any formal regulatory review process by the FDA.

9 The CED includes patients with class II and class III heart failure and measured left ventricular ejection fraction at or below 35 percent.

10 For example, CMS currently has a contract with the University of Minnesota for a five-year research project entitled "Monitoring Chronic Disease Care and Outcomes Among Elderly Medicare Beneficiaries with Multiple Chronic Diseases," which is using data from the Medicare Chronic Conditions Warehouse and Part D claims to conduct analytic studies designed to better understand the nature of chronic disease among Medicare beneficiaries and to improve the care of these populations (Centers for Medicare & Medicaid Services 2009).

11 A notable exception was the Medicare Health Support program, which was significantly larger than other recent Medicare care coordination and care management demonstrations. Approximately 290,000 chronically ill Medicare beneficiaries were randomly assigned to the program's intervention and control groups in eight geographic areas, with approximately 30,000 intervention and control group members in each area's original target population.

12 CMS expects to submit another report to the Congress in 2010 on the operation of the two remaining MCCD sites, using claims data for services provided through 2008 (Magno 2010).

13 The Health Insurance Portability and Accountability Act of 1996, which created the HCFAC program, appropriates funds from the Hospital Insurance trust fund to an expenditure account, called the Health Care Fraud and Abuse Control Account, in amounts that the Secretary and attorney general jointly certify as necessary to finance antifraud activities. The Tax Relief and Health Care Act of 2006 allowed for yearly increases in the program's annual funding levels, based on the year-to-year change in the consumer price index for all

urban consumers for FY 2007 through FY 2010. For FY after 2010, the program's funding level may not be any less than—and may be more than—the amount appropriated for it in FY 2010. The FY 2010 HCFAC appropriation is about $1.5 billion, of which $1.2 billion is mandatory funding and $0.3 billion is discretionary funding (Centers for Medicare & Medicaid Services 2010b).

14 The Medicare QIO program is funded through an executive apportionment from the Medicare trust funds rather than through the annual congressional appropriation. Every three years, the Secretary and OMB determine the program's statement of work (SOW) and funding level for the following three-year period. The QIO program's ninth SOW began on August 1, 2008, and ends on July 31, 2011; the funding level for the ninth SOW is $1.1 billion (Centers for Medicare & Medicaid Services 2010b).

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CHAPTER 2

Improving traditional Medicare's benefit design

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Chapter summary

Much of the Commission's work focuses on changing Medicare's payment systems to give providers incentives to maintain adequate access to care, improve quality, and use fewer resources. Complementary to this work is research on improving the design of Medicare's traditional fee-for-service (FFS) benefit, along with that of supplemental coverage. Reforming the FFS benefit offers an opportunity to align beneficiary incentives and program goals to obtain high-quality care for the best value. Of particular importance, reforms could improve financial protection for individuals who have the greatest need for services and who currently have very high cost sharing.

The current FFS benefit design includes a relatively high deductible for inpatient stays and a relatively low deductible for physician and outpatient care, and it requires beneficiaries to pay 20 percent of the Medicare-approved amount for most physician care and outpatient services. Under this design, no upper limit exists on the amount of Medicare cost-sharing expenses a beneficiary can incur. If not supplemented with additional coverage, the FFS benefit design makes Medicare beneficiaries face substantial financial risk and may discourage the use of valuable care. One exception is certain preventive services, where Medicare has begun offering greater coverage and reduced cost sharing.

In this chapter

All but about 9 percent of Medicare beneficiaries have supplemental coverage through former employers or medigap policies, or they have additional coverage through Medicare Advantage plans, Medicaid, and other sources. The most widely used types of supplemental coverage such as standard medigap Plan C and Plan F policies fill in all or nearly all of Medicare's cost sharing in return for a monthly premium. Although popular, some forms of secondary insurance are expensive, with administrative costs of 20 percent or more. Supplemental coverage addresses beneficiaries' concerns about the uncertainty of what cost sharing they might owe in the FFS Medicare benefit, but it also dampens financial incentives beneficiaries would otherwise face to control spending.

Commission-sponsored work shows evidence that when elderly beneficiaries are insured against Medicare's cost-sharing requirements, they use more care and Medicare spends more on them. It is the flip side of an extensive body of literature showing that higher cost sharing leads to lower health care spending. Much of this literature also finds that cost sharing can have beneficial and detrimental effects on beneficiaries' health outcomes. Trying to encourage use of high-value care and discourage low-value care are the great challenges of benefit design.

For the near term, proposed incremental improvements to the FFS benefit and to supplemental coverage could begin changing beneficiaries' incentives. The aim of these improvements would be to reduce financial risk for beneficiaries with the highest levels of cost sharing, deter beneficiaries' use of lower value services, and avoid deterring beneficiaries from using higher value care—especially individuals with lower incomes. Potential improvements could include, for example, adding a cap to beneficiaries' out-of-pocket (OOP) costs in the FFS benefit and, at the same time, requiring supplemental policies to have fixed-dollar copayments for services such as office visits and emergency room use. Such restrictions on supplemental coverage could lead to reductions in use of Medicare services sufficient to help finance the addition of an OOP cap. These strategies could be coupled with exceptions that waive cost sharing for services in certain circumstances—for example, if evidence identified them as leading to better health outcomes. The strategies could also include cost-sharing protections for low-income beneficiaries so that they would not forgo needed care. Providing beneficiaries with clear information to help them consider their treatment options with their providers could also be complementary to changes in benefit design.

For the longer term, the Medicare program will need to move toward more sophisticated benefit designs that give individuals incentives to use higher value care and avoid using lower value care. Part of this change will involve developing

the evidence base to better understand which treatments have higher and lower values. As currently practiced, value-based insurance design lowers cost sharing for services that have strong evidence of substantial clinical benefit. A primary goal of this approach is to improve quality of care. However, to achieve net savings, this approach requires careful targeting and willingness to lower cost sharing for services of high value and raise cost sharing for services of low value. ■

Much of the Commission's work focuses on changing Medicare's payment systems to give providers incentives to maintain adequate access to care and improve quality and efficiency. However, the design of fee-for-service (FFS) Medicare's benefits for Part A and Part B services also affects program spending and value through coverage policies and cost-sharing requirements. The treatment recommendations of medical providers strongly influence the amount of care beneficiaries receive. Still, for certain situations and conditions, Medicare's cost sharing can affect beneficiaries' decisions about whether to initiate care, the types of providers to see, and which treatments to use. Reforming the FFS benefit offers an opportunity to align beneficiary incentives and program goals to obtain high-quality care for the best value. Of particular importance, reforms could improve financial protection for individuals who have the greatest need for services and who currently have very high cost sharing.

Introduction

In today's traditional FFS Medicare, neither its payment system nor benefit design is built around incentives that reward delivery and use of high-quality, high-value care. The status quo encourages growth in the volume and intensity of services and has led to care that is often not coordinated, sometimes inappropriate, and occasionally risky to patients. It has also left beneficiaries with rising Part B premiums and out-of-pocket (OOP) costs and left taxpayers with an unsustainable burden for financing the program.

Given these problems, the program needs to be transformed to improve incentives for delivering and using high-value care (see Chapter 1 of the Commission's March 2010 report) (Medicare Payment Advisory Commission 2010). Changes for the long term could include a different benefit design for future cohorts of beneficiaries, the introduction of management tools into traditional Medicare, and incentives for beneficiaries to use high-value therapies based on clinical evidence about the effectiveness of alternative treatments—an approach called value-based insurance design. In the shorter term, other changes in Medicare policy could address some of the problems with beneficiary incentives as they are structured today.

Two key decision points for Medicare beneficiaries

Medicare beneficiaries make decisions about obtaining health care at two key points. First is the decision to choose between enrolling in FFS Medicare or a Medicare private plan. Each has advantages and drawbacks with respect to premiums, scope of benefit offerings, and rules about choice of providers. Second is the beneficiary's decision about whether to use a given health care service—which can be affected substantially by cost-sharing requirements.

Choosing between FFS Medicare and private Medicare plans

Today, about 75 percent of beneficiaries receive health benefits through traditional FFS Medicare. FFS Medicare's benefit design is uniform, with the same Part B premium nationwide despite large regional differences in average use of services and program expenditures.[1] Beneficiaries can use any provider willing to accept Medicare's terms and payment rates. To cover gaps in the FFS benefit, most beneficiaries have supplemental coverage through former employers or individually purchased medigap policies, or they have additional coverage through Medicaid or other sources. Despite Medicare's lower average payment rates to providers compared with private payers' rates, the FFS program has certain desirable characteristics for providers, including little or no utilization management (American Medical Association 2009).[2] Under this arrangement, there are few restrictions on the services providers and patients decide to use, and Medicare bears most of the insurance risk for beneficiaries' health spending.

At the other end of the spectrum are private Medicare plans that receive capitated payments for delivering Part A and Part B (and often Part D) benefits; they bear insurance risk for their enrollees' health spending. Private plans offer a wide variety of benefit packages, and some include a cap on OOP spending.[3] Medicare's private plans vary considerably in how well they manage delivery of care, enrollees' health outcomes, and spending (see Chapter 5 of the Commission's March 2010 report) (Medicare Payment Advisory Commission 2010). However, most private Medicare Advantage (MA) plans form networks of providers (some have an integrated delivery system), use cost sharing to steer enrollees toward contracted providers and preferred therapies, and apply utilization management tools such as prior authorization, concurrent review, and case management to manage care and constrain volume.[4] In exchange for greater constraints on service use, private plans typically offer beneficiaries additional benefits

beyond what is provided in FFS Medicare for low or no premiums, such as lower cost sharing for Part A and Part B services or vision and dental coverage.

For insured consumers outside the Medicare program, premiums act as a signal of the breadth of coverage and available providers. Premiums also reflect the relative health status and average use of services of the insured population. For example, plans with relatively tight networks of providers are expected to have lower premiums—the trade-off for less choice of providers is a lower price. In the Medicare program, however, the various premiums a beneficiary can face are not good signals of cost differences. Despite geographic differences in average use of services, FFS Medicare's Part B premium does not vary (except by income). In addition, many beneficiaries pay premiums for supplemental insurance that covers much of Medicare's cost sharing. While premiums for medigap policies vary widely, that variation reflects the health status of a particular pool of insured individuals and each insurer's ratings method more than breadth of coverage. Premiums for medigap policies can also be expensive because of high administrative costs, largely due to the need for medigap insurers to market directly to individuals (Moon 2006). For private plans that contract with Medicare through MA, premiums are a misleading signal; they are often zero or artificially low because, on average, Medicare pays private plans more for their enrollees' Part A and Part B care than the same beneficiaries would cost in the FFS program.[5] In the choice between FFS Medicare and enrolling in private Medicare plans, the premium signals that consumers typically use to help them make choices do not encourage beneficiaries to use efficiently delivered health care.

Beneficiary decisions about the use of care

Beneficiaries' use of care is strongly affected by the recommendations of medical providers. Still, the amount patients must pay for health care at the point of service can affect whether they seek care, the type of provider they see, and which treatment they use. A benefit design that encourages beneficiaries at the point of service to use care only when it is of high value is ideal but is a great challenge. A related challenge is how to provide beneficiaries with clear information about the potential risks and benefits of treatment options (see Chapter 7 of this report).

Medicare's FFS benefit structure has changed very little since 1965; it has considerable cost-sharing requirements and provides no OOP cap. For Part A services, it includes a relatively high deductible for inpatient stays ($1,100 in 2010) and daily copayments for long stays at hospitals and skilled nursing facilities.[6] Patients with more than one hospital stay can owe more than one hospital deductible for the year. For Part B services, the FFS benefit has a relatively low deductible ($155 in 2010) and requires beneficiaries to pay 20 percent of the Medicare-approved amount for most services. Increases in the deductibles and copayments under Part A and Part B are linked to average annual increases in Medicare spending for those services. There is no upper limit on how much cost sharing a beneficiary could owe under the FFS benefit. (Table 2-1 (p. 52) and Table 2-2 (p. 53) show Part A and Part B premiums and cost sharing.) Analyses suggest that the actuarial value—the percent of medical spending for a standard population paid by an insurer—of the traditional Medicare benefit is significantly lower than typical employer-sponsored health coverage (Peterson 2009, Yamamoto et al. 2008).

More recent changes to the FFS benefit design include greater coverage of and incentives for preventive care. The benefit now covers a "welcome to Medicare" physical within each beneficiary's first six months of enrollment in Part B, and it waives the Part B deductible for certain preventive services such as screening mammography and prostate-specific antigen blood tests. Under the Patient Protection and Affordable Care Act of 2010 (PPACA), beginning in 2011, Medicare's cost sharing will be eliminated for all Medicare-covered preventive services recommended with a grade of "A" or "B" by the U.S. Preventive Services Task Force.

Since the FFS benefit provides indemnity insurance and not managed care, cost sharing is one of the few means by which the Medicare program can provide incentives to affect beneficiaries' behavior. But more than 90 percent of FFS beneficiaries have supplemental coverage that fills in some or all of Medicare's cost sharing, effectively nullifying the program's tool for influencing beneficiary incentives.

Effects of cost sharing on beneficiaries' use of services

There is an extensive literature about the effects of cost sharing on the use of health care services. The research shows that increases in cost sharing can lead to lower utilization and lower spending on health care. More controversial, however, is the effect increases in cost sharing have on health outcomes. Much of this literature is consistent with the notion that cost sharing can have both beneficial and detrimental effects on beneficiaries.

The RAND health insurance experiment (HIE), conducted in the 1970s, is considered the gold standard because its

randomized design permitted analysts to measure the effects of insurance coverage while limiting selection bias—the tendency of sicker individuals to seek out coverage more than healthier persons. However, the HIE excluded elderly individuals. More recent literature, much of which focuses on prescription drugs, confirms that beneficiaries are sensitive to cost sharing, potentially affecting their use of clinically important medications as well as less important drugs. In Part D, private plans have used tiered cost sharing successfully to encourage enrollees to use generic drugs. Two recent studies suggest that higher cost sharing for outpatient visits is associated with increased hospital use. A recent Commission-sponsored study found that when elderly beneficiaries are insured against Medicare's cost sharing, they use more care and Medicare spends more on them.

Moderate sensitivity to price, reductions in effective and ineffective care

RAND HIE results suggest that individuals are moderately sensitive to price: A 10 percent increase in cost sharing led to about a 2 percent decline in patients' use of services (Newhouse and the Health Insurance Experiment Group 1993). This amount is lower than estimates of price sensitivity for gasoline and new car purchases that were evaluated at about the same time (Morrisey 1992). Participants were least sensitive to prices for inpatient services and most sensitive to prices for well care services, with other acute and chronic outpatient care falling in between.

The HIE found that reductions in use of services in response to cost sharing occurred by about the same amount in both effective and ineffective care (Newhouse and the Health Insurance Experiment Group 1993).[7] However, averaged across all participants, higher cost sharing did not affect health outcomes adversely. One exception was participants with both low incomes and poorer health—those individuals in free plans had a clinically significant reduction in blood pressure compared with individuals in plans with cost sharing (Manning et al. 1987).[8]

Most of the options evaluated in the HIE were within the context of indemnity insurance rather than in managed care plans. Among the benefit designs tested, the HIE found that both coinsurance and deductibles had "strong separate effects" (Keeler et al. 1988). The main effect of higher coinsurance was on whether participants initiated care for an episode of illness, but it also had slight effects on the costliness of care. Even small deductibles reduced participants' initiation of care, particularly outpatient care. Using HIE results, Newhouse and colleagues estimated that a well-designed indemnity policy would include (in 1983 dollars) an individual deductible of about $200 and 25 percent coinsurance up to a $1,500 OOP cap (Newhouse and the Health Insurance Experiment Group 1993). In 2006, Newhouse suggested that a deductible of about $1,000 for an individual policy in that year's dollars was roughly in line with prior HIE estimates (Newhouse 2006). However, he also noted there could be ways to improve such a policy, such as lowering cost sharing for services to treat chronic conditions if strong evidence existed that treatments were cost effective.

There are limits to generalizing from the HIE, particularly because it excluded elderly participants. Care that once was provided in the hospital is now delivered in outpatient settings, medical technology includes better diagnostic screening and minimally invasive treatments, and drugs are a more widespread mode of therapy. Policymakers also need to consider whether elderly and disabled beneficiaries, who have higher average health care spending and lower average incomes, might behave differently than the general population in reaction to cost sharing.

More recent literature shows sensitivity to cost sharing within managed care

Over the past several decades, many payers moved from indemnity coverage to managed care—with the notable exception of FFS Medicare. In the early days of managed care, plans lowered cost sharing relative to the indemnity coverage they replaced but established rules and limits on patients' use of providers and technologies. After the managed care backlash of the early 1990s, plans used a "belt and suspenders" approach, loosening managerial rules (the belt) and relying more heavily on differential cost sharing (the suspenders) to steer beneficiaries toward network providers and preferred drugs where they could obtain price discounts (Pauly and Ramsey 1999). Studies completed after the RAND HIE capture changes that have taken place in health care technology and delivery.

Effects of cost sharing on the Medicare population For the general population, there is little direct evidence that increased cost sharing results in worse health outcomes. However, there is reason to believe that the Medicare population's response to cost-sharing requirements may differ from the commercial population's reaction. Price sensitivity to goods and services without substitutes is generally low. Medicare beneficiaries, who tend to have a higher disease burden than other populations, may perceive few substitutes for medical care. Thus, as a group,

TABLE 2–1 **Premiums and cost-sharing requirements for Part A services in 2010**

Category	Amount
Premiums	$0 if entitled to Social Security retirement or survivor benefits, railroad retirement benefits, Social Security or railroad retirement disability benefits, or end-stage renal disease benefits. $461 per month for individuals who are 65 or older and not described above, in addition to the Part B premium (shown in Table 2-2).
Hospital stay	$1,100 deductible for days 1–60 each benefit period. $275 per day for days 61–90 each benefit period. $550 per "lifetime reserve day" after day 90 each benefit period (up to 60 days over lifetime). All costs for each day after lifetime reserve days.
Skilled nursing facility stay	$0 for the first 20 days each benefit period. $137.50 per day for days 21–100 each benefit period. All costs for each day after day 100 in the benefit period.
Home health care	$0 for home health care services. May have Part B cost sharing if durable medical equipment is needed (shown in Table 2-2).
Hospice care	$0 for hospice visits. Up to a $5 copayment for outpatient prescription drugs for pain and symptom management. 5% of the Medicare-approved amount for inpatient respite care.
Blood	All costs for the first 3 pints (unless donated to replace what is used).

Note: A benefit period begins the day a beneficiary is admitted to a hospital or skilled nursing facility and ends when the beneficiary has not received hospital or skilled nursing care for 60 days in a row. If the beneficiary is admitted to the hospital after one benefit period has ended, a new benefit period begins and the beneficiary must again pay the inpatient hospital deductible. Part A cost sharing increases over time by the same percentage update applied to payments to inpatient hospitals and adjusted to reflect real change in case mix.

Source: Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. *Medicare & You 2010*. Baltimore, MD: CMS. January. http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

Medicare beneficiaries may be less sensitive to cost-sharing requirements, although considerable variation in the health status of Medicare beneficiaries suggests that cost sharing could affect the health care decisions of some.

Studies that examine whether cost sharing affects health outcomes among the elderly are few and their findings are mixed.[9] A slightly larger number of studies examine the relationship between cost sharing and use of appropriate care.[10] A majority find evidence that higher cost sharing tends to reduce the use of appropriate services, with more evidence for prescription drugs than for other types of services.

Two recent studies raise concern that increases in cost sharing for outpatient care can cause some beneficiaries to forgo effective care and lead to more hospitalizations and potentially higher costs. One analysis involved retired California public employees who faced increased copayments for physician visits and prescription drugs (Chandra et al. 2010). The study found that increases in copayments for ambulatory care modestly increased hospital use for the average elderly person, but hospital spending increased significantly for chronically ill patients as physician and drug use decreased. A separate study observed enrollees in MA plans that increased ambulatory care copayments and matched them to control plans with no copayment increases (Trivedi et al. 2010). In the year after the copayment increases, researchers found a significant drop in outpatient visits and a significant rise in hospital admissions and inpatient days. Although questions remain about the degree to which their results can be generalized, the two studies suggest the need for attention to cost-sharing changes, as they can have both beneficial and detrimental effects.

Literature on effects of cost sharing for prescription drugs

Similarly, literature on cost sharing for prescription drug benefits shows the potential for good and bad effects. A large number of studies suggest that higher copayments and capped benefits for drugs are associated with lower medication adherence and spending (Hsu et al. 2006, Rice and Matsuoka 2004). An extensive review found moderate price sensitivity ranging from the average levels in the HIE to about three times as much (Gibson et al. 2005, Goldman

TABLE 2–2 **Premiums and cost-sharing requirements for Part B services in 2010**

Category	Amount	
Premiums	$96.40 per month:	Same premium as in 2009 applies if beneficiaries had the SSA withhold Part B premium payments from their Social Security check in 2009 and if income is below the following: Single beneficiaries with incomes of $85,000 or less Couples with incomes of $170,000 or less
	$110.50 per month:	All beneficiaries with incomes below the thresholds shown above and who are new to Part B for 2010 or have premiums paid by state Medicaid programs or Medicare Savings Programs.
	$154.70 per month:	Single beneficiaries with incomes between $85,001 and $107,000 Couples with incomes between $170,001 and $214,000
	$221.00 per month:	Single beneficiaries with incomes between $107,001 and $160,000 Couples with incomes between $214,001 and $320,000
	$287.30 per month:	Single beneficiaries with incomes between $160,001 and $214,000 Couples with incomes between $320,001 and $428,000
	$353.60 per month:	Single beneficiaries with incomes above $214,000 Couples with incomes above $428,000
Deductible	The first $155 of Part B–covered services or items	
Physician and other medical services	20% of the Medicare-approved amount for physician services (including most doctor services during inpatient stays), outpatient therapy (subject to limits), most preventive services, and durable medical equipment	
Outpatient hospital services	A coinsurance or copayment amount that varies by service, projected to average 24% in 2010. These rates are scheduled to phase down to 20% over time. No copayment for a single service can be more than the Part A hospital deductible ($1,100 in 2010).	
Mental health services	45% of the Medicare-approved amount for most outpatient mental health care*	
Clinical laboratory services	$0 for Medicare-approved services	
Home health care	$0 for home health care services	
Durable medical equipment	20% of the Medicare-approved amount	
Blood	All costs for the first 3 pints, then 20% of the Medicare-approved amount of additional pints (unless donated to replace what is used)	

Note: SSA (Social Security Administration). Under Part B's income-related premium, higher income individuals pay monthly premiums equal to 35 percent, 50 percent, 65 percent, or 80 percent of Medicare's average Part B costs for aged beneficiaries. Normally, all other individuals pay premiums equal to 25 percent of average costs for aged beneficiaries. In 2010, however, most beneficiaries pay the same premium as in 2009 because of a provision in law that does not permit the Part B premium to increase by a larger dollar amount than beneficiaries' Social Security checks. CMS estimates that about 5 percent of Medicare beneficiaries pay the higher premiums. The Part B deductible increases over time by the rate of growth in per capita spending for Part B services.
*This coinsurance rate is scheduled to phase down to 20 percent by 2014.

Source: Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. *Medicare & You 2010*. Baltimore, MD: CMS. January. http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

et al. 2007). More recent analysis of the effects of Part D on individuals who previously had no prescription drug coverage suggests that the program has increased use of some clinically important medications (Schneeweiss et al. 2009). At the same time, Part D plans have successfully encouraged enrollees to use generic alternatives when available (Office of Inspector General 2007). Plans' management tools, particularly their use of formularies that help to create competition among therapeutically similar drug treatments for which enrollees pay differential copayments, may also lower rates of growth in prices for drugs with patent protection (Duggan and Morton 2010).

TABLE 2–3 **Medicare cost-sharing liability in 2008**

Range of cost-sharing liability per person	Percent of FFS beneficiaries	Average amount of cost sharing per beneficiary
$1 to $499	42%	$250
$500 to $1,999	36	$1,071
$2,000 to $4,999	16	$3,036
$5,000 to $9,999	4	$6,879
$10,000 or more	2	$15,402

Note: FFS (fee-for-service). Amounts reflect cost sharing under FFS Medicare—not what beneficiaries paid out of pocket. Most beneficiaries have secondary insurance that covers some or all of their Medicare cost sharing.

Source: MedPAC based on data from CMS.

Evidence is mixed on whether lower cost sharing for prescription drugs has "cost offsets"—reduced spending for other medical services such as inpatient stays. Sokol and colleagues found evidence that high adherence among patients with diabetes or with high cholesterol was associated with a net economic benefit in disease-related medical costs (Sokol et al. 2005). For high blood pressure and congestive heart failure, the researchers did not find cost offsets. Another study looked at use of angiotensin-converting enzyme inhibitors among Medicare beneficiaries with diabetes and projected that first-dollar coverage could increase utilization of these medications and arguably lead to lower Medicare expenditures (Rosen et al. 2005). A recent study of the effects of Medicare coverage delivered within an MA prescription drug plan found that among beneficiaries who had no drug coverage before 2006, Part D coverage led to reductions in medical spending that roughly offset the increased spending on drugs (Zhang et al. 2009a). However, among enrollees who had drug coverage before 2006, Part D enrollment was associated with higher medical spending.

Other research has begun analyzing the effect on medication adherence of Part D's coverage gap (the portion of spending between the program's initial coverage limit and the annual out-of-pocket threshold, in which the Part D plan enrollee pays the full discounted price for the drug). Several studies have compared enrollees in MA–prescription drug plans that had a gap in coverage with enrollees in similar plans with no gap or generic-only benefits in the coverage gap (Fung et al. 2009, Zhang et al. 2009b). Drug spending among enrollees with no gap coverage was significantly lower than for those with gap coverage, and the former group had significantly lower medication adherence.[11]

Effects of supplemental coverage on Medicare spending

Researchers agree that Medicare beneficiaries with medigap or retiree health coverage tend to have higher use of services and spending than those with no supplemental coverage. However, they disagree on what proportion of this difference is due to a pure insurance effect (i.e., higher use of care because the patient does not face Medicare's full cost-sharing amount) versus selection bias (i.e., the greater tendency of individuals with higher health care needs to purchase insurance).

Many supplemental plans cover all or nearly all of Medicare's cost-sharing requirements regardless of whether there is evidence that the service is ineffective or, conversely, whether it might prevent a hospitalization. Thus, some portion of the higher spending of these beneficiaries is arguably due to an insurance effect. Studies that attribute at least a portion of higher spending to an insurance effect find a spending increase of about 25 percent, with estimates ranging from 6 percent to 44 percent (Atherly 2001).[12] Estimates for the effects of medigap policies are generally higher than for employer-sponsored retiree coverage, and they tend to show larger effects for outpatient than for inpatient services.

Another set of studies finds small or statistically insignificant induced demand for care resulting from supplemental insurance after controlling for selection bias (Long 1994, Wolfe and Goddeeris 1991). Differences in the methodologies used to control for selection bias have contributed to the wide range of expenditure differences found in the literature. Some researchers believe that previously reported differences in spending might be overstated because supplemental coverage encourages beneficiaries to adhere to medical therapies that prevent hospitalizations or the use of other services (Chandra et al. 2010). Another line of research suggests that the responsiveness of beneficiaries to cost sharing is varied and the effects of supplemental coverage are more modest for individuals in poorer health (Remler and Atherly 2003).

Last year's Commission-sponsored study

Commission-sponsored work showed evidence that when elderly beneficiaries are insured against Medicare's cost sharing, they use more care and Medicare spends more on them (Hogan 2009). That analysis found some notable patterns where supplemental coverage seemed to have

more or less of an effect. For example, having secondary insurance was not associated with higher spending for emergency hospitalizations, but it was associated with higher Part B spending that ranged from 30 percent to over 50 percent more. Overall, beneficiaries with private supplemental insurance spent more on elective hospital admissions, preventive care, office-based physician care, medical specialists, and services such as minor procedures, imaging, and endoscopy.

When looking at beneficiaries within a given category of supplemental insurance—for example, comparing individuals with retiree coverage or comparing medigap policyholders—paying little OOP seemed to be an influential factor associated with higher Medicare spending. The analysis suggests that if supplemental coverage did not fill as much of Medicare's cost sharing, cost sharing could be structured in ways to encourage beneficiaries to choose high-value care. For example, differential copayments between primary and specialty care could be used to encourage more of the former. This approach is used commonly within MA plans and commercial insurance for non-Medicare populations.

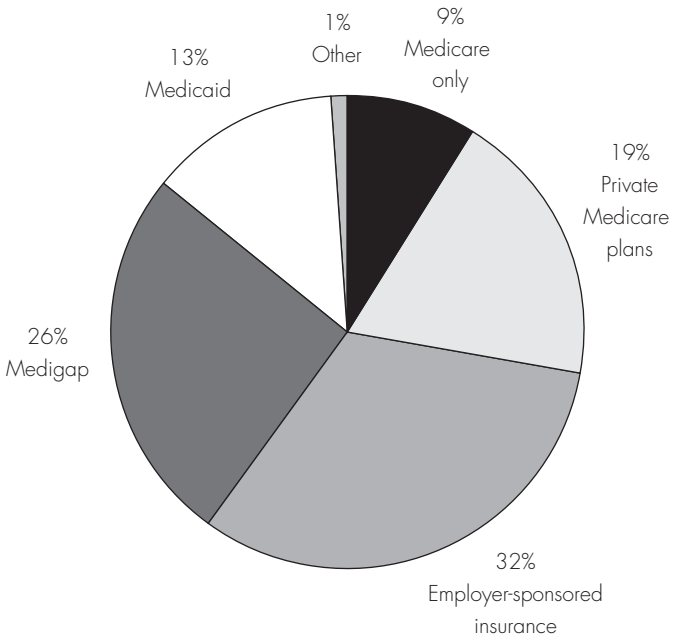
The Commission's analysis also found that lower income beneficiaries were moderately more sensitive to cost sharing than higher income individuals. In general, when either lower income or higher income beneficiaries had supplemental insurance, their Medicare spending was higher than that of individuals without supplemental coverage but with a similar income. However, the presence of secondary insurance had a moderately stronger effect on spending for lower income beneficiaries. This finding is consistent with other research that suggests that differences in price sensitivity to rising copayments for prescription drugs may account for some of the observed disparities in health across socioeconomic groups (Chernew et al. 2008).

Medicare's FFS benefit in a changing context

Medicare's FFS benefit needs to change to discourage use of lower value services, moderate rapid growth in Part B premiums and OOP costs, and rein in unsustainable rates of program spending. These changes must take into account the role of supplemental coverage that currently, for each health care service delivered, shields beneficiaries from the true cost of care. However, when considering potential changes to the FFS benefit, it is also important to bear in mind ways in which beneficiaries' future options for supplemental insurance will differ.

FIGURE 2–1

Most Medicare beneficiaries had supplemental coverage in 2006



Note: Excludes long-term institutionalized beneficiaries.

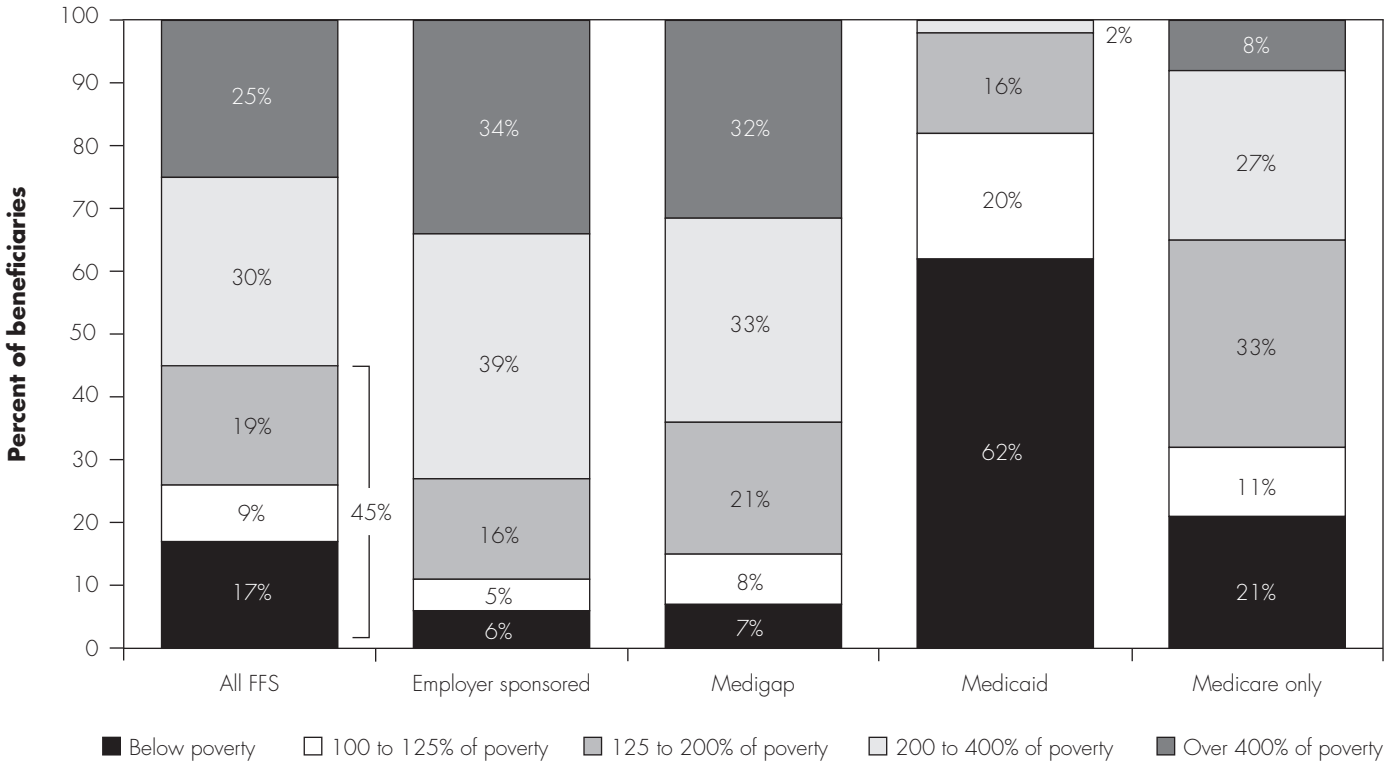
Source: MedPAC analysis of Medicare Current Beneficiary Survey Cost & Use files.

Shortcomings of the FFS benefit and the role of supplemental plans

The Commission and its predecessor commissions have explored problems with traditional Medicare's benefit design for many years (Medicare Payment Advisory Commission 2009, Physician Payment Review Commission 1997). The FFS benefit alone does not provide true insurance—financial protection against very high levels of OOP spending. Compared with other types of coverage, Medicare's benefit has a high inpatient deductible and a low outpatient deductible. These features lead to a small percentage of Medicare beneficiaries incurring the highest levels of cost sharing (Table 2-3).

Shortcomings in the FFS benefit design lead more than 90 percent of beneficiaries to take up supplemental coverage (Figure 2-1). In 2006, employer-sponsored retiree policies that wrap around the Medicare FFS benefit covered the

FIGURE 2–2 **Distribution of FFS beneficiaries' income by type of supplemental coverage in 2006**



Note: FFS (fee-for-service). Excludes long-term institutionalized beneficiaries. In 2006, the federal poverty threshold was $9,996 for people living alone and $12,186 for married couples. Sums may not total to 100 percent due to rounding.

Source: MedPAC analysis of Medicare Current Beneficiary Survey Cost & Use files.

most beneficiaries, followed by individually purchased medigap policies, private Medicare plans, and Medicaid.[13] Nine percent of beneficiaries relied solely on Medicare's benefit.

The economic circumstances of beneficiaries differ significantly across categories of supplemental insurance. Among all FFS beneficiaries, in 2006, about 45 percent had incomes of 200 percent of the poverty threshold or less (Figure 2-2).[14] On average, beneficiaries with employer-sponsored retiree coverage or medigap policies had higher incomes than individuals with no supplemental insurance or with both Medicare and Medicaid benefits.

At the median, Medicare beneficiaries spent about 16 percent of their income on premiums and other OOP health spending in 2005 (Neuman et al. 2009). However, that figure masks considerable variation across individuals. Generally, beneficiaries with higher Medicare spending pay a larger proportion of their income than those with lower Medicare spending, but the relative burden of financial liability depends on the beneficiary's type of supplemental coverage. Two groups tend to pay comparatively more than others: (1) beneficiaries with medigap policies, and (2) those with no supplemental coverage and high use of Medicare services (Medicare Payment Advisory Commission 2009).

Like the FFS benefit, supplemental coverage has some notable problems. The one form of supplemental insurance available to all elderly Medicare beneficiaries—medigap coverage—is popular among beneficiaries but can have high premiums. A 2009 survey found that 88 percent of medigap policyholders are satisfied with their secondary coverage, and 77 percent believe these policies are a good value (America's Health Insurance Plans/Blue Cross Blue Shield 2009). Yet medigap policies can be expensive because they tend to cover individuals with higher health spending and have administrative costs of 20 percent or more (Scanlon 2002).[15] The most popular types of

TABLE 2–4

Benefits offered under standard medigap policies in 2010

	Plan type										
Category	**A**	**B**	**C**	**D**	**F**	**F (high deductible)***	**G**	**K**	**L**	**M**	**N**
Part A hospital costs up to an additional 365 days after Medicare benefits are used up	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Part B cost sharing for other than preventive services	✓	✓	✓	✓	✓	✓	✓	✓** (50%)	✓** (75%)	✓	✓** ($20/$50)
Blood (first 3 pints)	✓	✓	✓	✓	✓	✓	✓	✓** (50%)	✓** (75%)	✓	✓
Hospice care cost sharing	✓	✓	✓	✓	✓	✓	✓	✓ (50%)	✓ (75%)	✓	✓
SNF coinsurance			✓	✓	✓	✓	✓	✓ (50%)	✓ (75%)	✓	✓
Part A deductible		✓	✓	✓	✓	✓	✓	✓ (50%)	✓ (75%)	✓ (50%)	✓
Part B deductible			✓		✓	✓					
Part B excess charges					✓	✓	✓				
Foreign travel emergency (up to plan limits)			✓	✓	✓	✓	✓			✓	✓
Medicare preventive care Part B coinsurance	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Note: SNF (skilled nursing facility). Plan E, Plan H, Plan I, and Plan J will close to further enrollment in 2010. Insurers may begin offering standard Plan M and Plan N in June 2010.
*High-deductible Plan F pays the same benefits as Plan F after one has paid a calendar year deductible of $2,000 in 2010. Applicable expenses for this deductible are expenses that would ordinarily be paid by the policy. These expenses include the Medicare deductible for Part A and Part B but do not include the plan's separate foreign travel emergency deductible.
**Plan K and Plan L require the insured to pay 50 percent and 75 percent, respectively, of Part B coinsurance payments unrelated to hospitalizations and preventive services. After meeting the Part B deductible and an out-of-pocket limit of $4,620 in Plan K or $2,310 in Plan L, the plan pays 100 percent of Medicare cost sharing for covered services for the rest of the calendar year. Plan N has set dollar amounts that beneficiaries pay in lieu of certain Part B coinsurance payments ($20 for office visits and $50 for emergency room visits).

Source: Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2010. *Choosing a medigap policy: A guide to health insurance for people with Medicare*. Additional information from the National Association of Insurance Commissioners.

medigap policies, standard Plan C and Plan F, nearly fill in all of Medicare's cost-sharing requirements, including both the Part A and Part B deductibles (Table 2-4 and Table 2-5 (p. 58)). By effectively masking FFS Medicare's price signals at the point of service, supplemental coverage can influence beneficiaries' choices about whether to seek care and which types of providers and therapies to use.

Premiums for medigap policies can also vary widely, even in the same market. This variation is due in part to different approaches that states allow insurers to use for setting premium rates.[16] But considerable variation in medigap premiums also exists in states that allow only community rating—that is, premiums cannot vary by an individual's age, gender, or health status. For example, in 2009 in Albany, New York, premiums for a medigap Plan F policy (the most popular plan type) varied between $1,940 and $4,130 (Table 2-5). Much of this variation likely reflects the average health status and utilization trends of each medigap insurer's covered population.[17]

TABLE 2–5

Distribution of medigap policies and average premiums

	2008			
Plan type	**Number of policyholders (in thousands)**	**Percent of policyholders**	**Average annual premium**	**Range of premiums in Albany, New York, February 2009***
All	9,492	100%	$2,000	N/A
A	265	3	1,500	$1,230–$2,420
B	516	5	1,800	$1,670–$3,240
C	1,523	16	1,900	$1,830–$3,750
D	399	4	2,000	$1,800–$2,920
E, H, I, J	1,114	12	2,000	$1,810–$2,720
F	3,703	39	2,000	$1,940–$4,130
F (high deductible)	32	0	500	$850–$1,190
G	336	4	1,900	$1,810–$2,720
K	13	0	800	$890–$1,340
L	23	0	1,300	$1,240–$1,900
Waiver-state policies	624	7	2,200	N/A
Pre-1991 policies	842	9	2,600	N/A

Note: N/A (not applicable). Plan E, Plan H, Plan I, and Plan J will close to further enrollment in 2010. Insurers may begin offering standard Plan M and Plan N in June 2010. Waiver states include Massachusetts, Minnesota, and Wisconsin.
*New York state uses community rating, meaning that premiums cannot vary by age, gender, or health status of the insured individual.

Source: MedPAC analysis of 2008 data from the National Association of Insurance Commissioners. Data for premiums from Albany, New York, from New York State Insurance Department website.

Policymakers, insurers, and regulators have taken several steps to develop more affordable types of medigap policies, but so far those products have not attracted much enrollment. Medicare SELECT® plans have the same standard designs as other medigap policies but require beneficiaries to use a provider network in return for lower premiums.[18] A 1997 evaluation found that SELECT plans provide a weak form of managed care in that they recruit hospitals willing to provide a discount for their networks but generally do not form physician networks (Lee et al. 1997). In 2006, insurers had 1.1 million Medicare SELECT plans in force—11 percent of all medigap policies (America's Health Insurance Plans 2008). After 1997, insurers were allowed to sell high-deductible versions of Plan F and Plan J in return for lower premiums.[19]

The Medicare Prescription Drug, Modernization, and Improvement Act of 2003 created two other types of standard products—Plan K and Plan L—that fill in less of Medicare's cost sharing in return for lower premiums. Plan K and Plan L require policyholders to pay 50 percent and 75 percent, respectively, of Part B coinsurance amounts unrelated to hospitalizations and preventive services. Although they have lower premiums than other types of medigap policies, as of 2008, Plan K and Plan L combined made up less than 0.5 percent of all medigap policies.

Effective June 2010, medigap insurers may introduce two new types of policies—Plan M and Plan N. Plan M will cover 50 percent of the Part A deductible but none of the Part B deductible. Plan N will cover all of the Part A deductible but none of the Part B deductible, and it will require copayments of up to $20 for office visits and up to $50 for emergency room visits (National Association of Insurance Commissioners 2010).[20] Both Plan M and Plan N are expected to have lower premiums than other medigap policies.

Further research on why beneficiaries have not taken up lower premium options in greater numbers could help to evaluate potential changes to supplemental coverage. One potential reason may be that newer types of policies such as Plan K and Plan L use percentage coinsurance rather than fixed-dollar copayments, which leaves beneficiaries with uncertainty about the amount of cost

sharing they might owe at the point of service. Because the dollar amounts of cost sharing in Plan N are known to policyholders in advance (i.e., the policies include copayments rather than coinsurance), Plan N may have broader market appeal than Plan K and Plan L. It would also be useful to understand whether the relative size of commissions to insurance agents on the various types of medigap policies affect how those alternatives are marketed to beneficiaries.

Employer-sponsored insurance typically provides beneficiaries with broader coverage for lower premiums than medigap policies. However, employer-sponsored coverage may not fill in all cost sharing and is not available to everyone. Retiree policies through large employers typically include a lower deductible for hospitalizations than Medicare's; a cap on OOP spending; and sometimes benefits that FFS Medicare does not cover, such as dental care (Yamamoto et al. 2008). Employers who offer retiree plans often pay for much of the premium for supplemental coverage. One 2007 survey found that, on average, large employers subsidized 60 percent of the total premium for single coverage; retirees paid 40 percent (Gabel et al. 2008).

Many employer plans require retirees enrolled in Medicare to pay deductibles and cost sharing just as active workers and younger retirees do. But it is unclear whether these cost-sharing arrangements apply to all retirees or primarily those who are in younger cohorts. In 2007, Actuarial Research Corporation analyzed 2005 data from the Medical Expenditure Panel Survey for the Commission. At that time, about 20 percent of Medicare beneficiaries with supplemental coverage through an employer had no OOP spending other than their premiums—their retiree plans paid for their Medicare cost sharing. Last year, Direct Research used 2005 data from the Medicare Current Beneficiary Survey to estimate that 50 percent of FFS beneficiaries with employer-sponsored coverage paid 5 percent or less of their Part B spending OOP. These estimates suggest that today a sizable portion of beneficiaries with employer-sponsored coverage have most of their Medicare cost sharing filled in by secondary insurance.

Expected changes over time

In 2007, the Commission looked at ways in which the profile of Medicare beneficiaries will change over time (Medicare Payment Advisory Commission 2007). We expect that a greater proportion of the Medicare population will be treated for multiple chronic conditions. At the same time, the rate of disability among beneficiaries as measured by limitations in activities of daily living has been declining, although it is not clear that this trend will continue after more of the baby-boom generation joins Medicare. Individuals of Hispanic and Asian ethnicity will make up growing shares of beneficiaries, and changes to the typical family structure will leave fewer adult children available to provide long-term care for their parents.

Similarly, changes in the structure of the economy and continued rapid growth in health care spending will also affect the availability and price of supplemental coverage. Although the percentage of Medicare beneficiaries with employer-sponsored retiree coverage has remained fairly constant since the early 1990s (Merlis 2006), the number of large employers offering such coverage to new retirees has been declining, which will affect future cohorts of Medicare beneficiaries (Employee Benefit Research Institute 2008). Beneficiaries who have aged into Medicare more recently are less likely to have retiree coverage (Stuart et al. 2003). As those cohorts replace older ones in Medicare, employer-sponsored supplemental coverage will play less of a role than it does today.

With less retiree coverage available, more Medicare beneficiaries are likely to turn to MA plans or medigap policies or to remain in traditional Medicare without supplemental coverage. All three alternatives have features that make them generally less attractive to beneficiaries than most forms of retiree coverage that wrap around Medicare's FFS benefit. In the past, beneficiaries in MA plans generally had small or no premiums and additional coverage beyond standard Part A and Part B benefits in exchange for a more restricted choice of providers and managed use of care. Under the PPACA, MA payments will change in ways that could reduce the availability of extra benefits or lead to higher MA premiums. Medigap premiums, which typically cost more than beneficiaries pay for retiree coverage, will rise increasingly with the growth in health care costs. It remains to be seen whether higher premiums will encourage beneficiaries to move into new types of medigap policies that have lower premiums. Finally, beneficiaries without supplemental coverage pay no additional premiums beyond those for Medicare but are exposed to full FFS cost sharing, which increases their risk of becoming impoverished because of a costly illness. To the extent that more beneficiaries become impoverished, more will incur enough medical expenses to "spend down" their income so that they qualify for Medicaid, further straining state and federal budgets.

Employer coverage among the working population is also becoming less comprehensive and includes more cost sharing and higher premiums. In the future, some beneficiaries may be more willing to accept a reformed FFS benefit because they may view a restructured Medicare program as better coverage than what they had during their working years.

Shorter term potential improvements to FFS Medicare

For the near term, incremental steps can be taken to begin changing beneficiaries' incentives. The aims of these nearer term measures include:

- reducing financial risk for beneficiaries who currently have very high cost sharing,
- avoiding cost sharing that may deter beneficiaries—especially those with lower incomes—from using higher value care, and
- redefining the role of supplemental coverage to avoid encouraging beneficiaries' use of lower value services.

Providing beneficiaries with clear information about the potential risks and benefits of their treatment options through shared decision making with their medical providers could also be complementary to changes in benefit design (see Chapter 7 in this report).

Reducing financial risk for beneficiaries with high spending

While most individuals have at least one outpatient physician visit in a year, only about one in five has a hospital stay. The result is that beneficiaries who have a hospitalization during a year can accumulate considerably more cost-sharing expenses than those who are not hospitalized. (Over several years, the odds of having one or more hospital stays go up considerably. For example, among beneficiaries who were in Medicare in 2004 and were alive in 2008, about half had a hospital stay at some point over that five-year period.) Beneficiaries with multiple hospitalizations may need to pay the inpatient deductible repeatedly, and those who require longer stays in hospitals or skilled nursing facilities pay sizable daily copayments. In addition, patients who are hospitalized have little control over care associated with their stay—for example, the professional services of physicians and physical therapists—and pay 20 percent coinsurance for those services. Although much of Medicare beneficiaries' cost sharing is triggered by a hospitalization, ultimately most of the cost sharing they incur stems from coinsurance on their use of Part B services (Medicare Payment Advisory Commission 2009).

If the FFS benefit were redesigned to include an OOP cap, the effects would be mixed—generally lower spending for beneficiaries and higher program spending for the government. Such a policy would benefit individuals who currently pay very high Medicare cost sharing, particularly those with no supplemental coverage, and would tend to lower supplemental premiums for many other beneficiaries. However, Medicare would begin paying for some of the costs now covered by secondary insurers. Because beneficiaries who have medigap policies pay the full premium for the supplemental benefits of everyone in their insurance pool (including some beneficiaries with high Medicare cost sharing), all beneficiaries who had medigap policies would see lower premiums but Medicare spending would grow. An OOP cap would also lead to somewhat higher Part B premiums since they are set as a percentage of Medicare's spending for Part B services.

To illustrate, using conservative assumptions about beneficiary responses to cost sharing: If in 2011 the FFS benefit capped each beneficiary's cost sharing at $4,000, Medicare program spending would increase by nearly $18 billion, or 4 percent, and the monthly Part B premium would increase by about $7, which is $88 per year, or 6 percent (Table 2-6).[21] At the same time, however, the policy would lead to an average $404 annual reduction in medigap premiums (24 percent). (This estimate is a crude approximation of medigap effects based on overall average spending across all beneficiaries with medigap policies. Effects on specific medigap plans would depend on each pool of individuals covered.) It is less straightforward to quantify what would happen with other forms of supplemental coverage such as employer-sponsored insurance. Average costs of those supplemental premiums (including both employer and retiree shares) would decline by an estimated $414 yearly (28 percent). However, some employers might choose to apply those savings toward reducing their contributions to retiree premiums rather than passing along the reduction in retirees' share of the premium.

Having no more cost sharing above an OOP cap would likely lead to higher utilization. One way to counter this tendency would be to follow Part D's example. It has an OOP cap, but above that cap beneficiaries still

TABLE 2–6 **Projected effects of adding an OOP cap to the FFS benefit in 2011**

Category	Baseline	Percentage change associated with adding the following out-of-pocket maximum: $4,000	$5,000	$7,000
Medicare program spending	$431.7 billion	4%	3%	2%
Part B premium	$123	6	5	3
Average medigap "premium"*	$1,693	–24	–19	–12
Average "premium" for employer-sponsored insurance*	$1,486	–28	–23	–17

Note: OOP (out of pocket), FFS (fee-for-service). This analysis excludes Part D.
*These values are simple estimates of the overall change in supplemental benefit spending under the policy change plus a loading factor, divided by the applicable number of beneficiaries with medigap or employer-sponsored policies. Note that the average for employer-sponsored insurance is the whole premium—the share paid for by both employers and beneficiaries. Employers may or may not choose to pass on reductions in spending for supplemental benefits to their retirees.

pay nominal cost sharing to deter the use of lower value services.

One way to reduce Medicare's program costs under an OOP cap would be to combine the FFS deductibles for Part A and Part B services. To remain budget neutral, a combined deductible would need to be high. For example, if today's separate deductibles were replaced in 2011 with a combined deductible under a policy that capped OOP expenses at $4,000, all enrollees in FFS Medicare would need to pay for the first $1,328 of Part A or Part B services. Again using conservative assumptions about beneficiaries' behavioral responses, at this amount, Medicare spending would break even and the new benefit would not worsen the program's financial sustainability. If supplemental policies were permitted to fill in this combined deductible, most beneficiaries would likely see little change or a net lowering of their combined OOP spending, Part B premiums, and premiums for supplemental coverage.

Avoiding cost sharing that deters use of high-value care

Even though most beneficiaries would benefit or see little change under a revised benefit with an OOP cap and a combined deductible, there are legitimate concerns with that approach for beneficiaries without supplemental coverage. In 2009, research conducted for the Commission found that individuals without supplemental coverage, who tended to have lower incomes than others with medigap policies or employer-sponsored coverage, used less care (Medicare Payment Advisory Commission 2009). To the extent that these beneficiaries would forgo necessary care because of a high combined deductible, they could experience poorer health outcomes and higher use of other medical services.

One approach to address this policy challenge would be to refine programs that help beneficiaries with limited incomes pay for Medicare premiums and cost sharing. Three such programs include Medicaid support for individuals dually eligible for Medicare and Medicaid, the Medicare Savings Programs, and Part D's low-income subsidy.[22] Providing assistance with premiums and cost sharing addresses the concern that individuals with low incomes may obtain less necessary care because of the financial burden of OOP costs. At the same time, filling in all cost sharing for low-income enrollees would mean that Medicare would have fewer tools to encourage the use of necessary care and deter the use of ineffective care. For this reason, Part D and many state Medicaid programs ask low-income enrollees to pay smaller cost-sharing amounts.

A related idea is to set cost-sharing obligations relative to each individual's income (Gruber 2006). However, there are significant administrative issues with carrying out this approach, and policymakers would need to come to a consensus on what share of income would be equitable. The PPACA may have set a precedent for such an approach. In new state-based health insurance exchanges, the law calls for reduced cost-sharing amounts and OOP spending limits for individuals younger than 65 with lower incomes (Kaiser Family Foundation 2010).

Another way to discourage unnecessary care would be to set lower copayments for higher value services and higher copayments for lower value services (Chernew et al. 2007). Copayments could be difficult to set at levels that would be budget neutral to current law cost sharing

without being too high for a substantial number of beneficiaries. For this approach to have its intended effect, supplemental coverage could not be permitted to fill in these copayments. An alternative approach that would redefine the role of supplemental coverage is described below. The PPACA uses such an approach (see text box).

Redefining the role of supplemental coverage

Instead of replacing the current Part A and Part B deductibles with a combined deductible, policymakers could focus on redefining the amount of Medicare cost sharing that supplemental insurance could fill in. For example, the Congressional Budget Office (CBO) estimates that if medigap insurers were barred from paying any of the first $525 of a policyholder's cost sharing and if medigap coverage were limited to 50 percent of the next $4,725 in Medicare cost sharing with all further cost sharing covered by the policy, the option would lower federal spending by about $4 billion per year beginning in 2012 (Congressional Budget Office 2008).[23] As estimated by CBO, this option would apply only to medigap policies—it would not affect beneficiaries with employer-sponsored retiree coverage. Given that beneficiaries with retiree coverage outnumber medigap policyholders, including that group in the option might more than double the $4 billion estimate. Our preliminary estimates for 2011 suggest that the magnitude of reduced spending would be approximately enough to add an $8,000 OOP cap to the FFS benefit and keep program spending budget neutral.

Another approach might keep medigap policies and employer-sponsored insurance from filling in fixed-dollar copayment amounts for services such as office visits and use of hospital emergency rooms. Copayments could be set to steer beneficiaries toward certain types of care—by setting copayments for office visits, for example, that were lower for seeing primary care providers according to specialty. This approach is used commonly within MA plans and in commercial insurance.

The methods for carrying out such a change vary by type of supplemental coverage because of the way private insurance is regulated. For example, medigap policies are subject to both state and federal regulation; to ensure that medigap changes were made nationwide, the Congress would need to direct the National Association of Insurance Commissioners (NAIC) to redefine medigap standards.

It is less clear how to carry out restrictions on supplemental coverage obtained through employers. Most individuals who receive retiree health benefits worked for large employers subject to the Employee Retirement Income Security Act (ERISA). ERISA exempts self-insured employers from state laws and regulations but does not set standards for what benefits employers provide to retirees. Therefore, to limit retiree coverage from filling in some of Medicare's cost sharing, policymakers might need to make changes to ERISA or to other laws that are broader than Medicare (e.g., tax treatment of health benefits). Alternatively, one could make such restrictions a condition for employers to receive Part D's retiree drug subsidy, but such an approach deserves careful consideration of the potential effects on continued provision of retiree health benefits.[24]

Estimates of the effects of such copayments can vary substantially depending on the groups of services to which copayments apply. For example, MA plans often apply copayments to face-to-face visits with providers for evaluation and management services as well as other types of services such as X-rays and other imaging, chiropractic care, and physical therapy. By comparison, recent guidance developed by the NAIC in conjunction with CMS suggests that insurers offering the new medigap Plan N will use a narrower interpretation of office visits. The guidance states that Plan N will apply copayments of up to $20 only for services that can be billed under CPT–4 codes 99201–99205 (evaluation and management of new patients), 99211–99215 (evaluation and management of established patients), as well as 92002, 92004, 92012, and 92014 (ophthalmology), and 90805 (psychotherapy) (National Association of Insurance Commissioners 2010). Such an interpretation may not achieve the degree of reduction in use of Part B services that was envisioned with changes to medigap Plan C and Plan F called for in the PPACA (see text box). Other details would need to be evaluated carefully, such as the level of copayment that would apply when a beneficiary receives primary care from a medical specialist.

To illustrate this copayment approach, we assume all medigap and employer-sponsored policies that currently provide first-dollar coverage could no longer fill in $10 copayments for primary care office visits, $25 copayments for visits for specialty care (including certain nonphysician providers such as chiropractors and physical therapists), and $50 copayments for visits to emergency rooms. Our preliminary estimates suggest that this approach would reduce Medicare program spending by about $7 billion

Changes in the Patient Protection and Affordable Care Act of 2010 relevant to benefit design

The recently enacted Patient Protection and Affordable Care Act of 2010 (PPACA) puts in place certain changes that will affect future medigap options and reduce cost-sharing requirements for certain preventive services within Medicare. First, the law directs the National Association of Insurance Commissioners (NAIC) to revise standards for medigap policies classified as Plan C and Plan F. These standard types, which are the only ones that cover all Part B cost sharing, are the most popular plan types, accounting for about 55 percent of all medigap policies in 2008.

The new law requests the NAIC to revise Plan C and Plan F standards to include requirements for nominal cost sharing to encourage the use of appropriate physicians' services under Part B. New standards are to be based on evidence published in peer-reviewed journals or current examples used in integrated delivery systems. NAIC's revised standards are, to the extent practicable, to be in place as of January 1, 2015.

Because the revised standards would apply only to newly issued medigap policies, the law will not affect current policyholders who already have Plan C or Plan F. Nor does the health reform law place any new minimum cost-sharing requirements on retiree policies offered by employers. Over time, however, the use of copayments in medigap plans could change incentives for Medicare beneficiaries as they consider their use of care, particularly as the availability of employer-sponsored insurance declines.

Second, the PPACA allows for an annual wellness exam in which providers create a personalized prevention plan for beneficiaries—a schedule for receiving preventive services tailored to each person's clinical situation. Beginning in 2011, beneficiaries will not owe cost sharing for Medicare-covered preventive services recommended with a grade of "A" or "B" by the U.S. Preventive Services Task Force (USPSTF). The law also gives the Secretary authority to modify Medicare coverage of certain preventive services based on recommendations of the USPSTF. ■

in 2011. This amount of savings could approximately pay for a $9,000 OOP cap added to the FFS benefit. These estimates assume an insurance effect—in this case, a decrease in the use of services as beneficiaries pay more cost sharing—similar in magnitude to assumptions used by CBO in its budget options. For most beneficiaries with medigap policies, the cost of new copayments would be more than offset by the lower premiums for their supplemental coverage.

The copayment approach could be coupled with other changes to the FFS benefit to encourage appropriate use of services and allow a lower OOP cap. Cost sharing could be made more uniform across services and could be applied to services for which no cost sharing is required today, such as laboratory tests and home health care.

A separate approach involves an excise tax on insurers that offer the most complete coverage—supplemental policies that fill in most of Medicare's cost sharing. This approach uses a different philosophy in that it would not forbid supplemental policies from filling in all of Medicare's cost sharing but instead would charge the insurer for at least some of the added costs imposed on Medicare of having such comprehensive coverage. Applying a tax only to supplemental policies that fill in nearly all of Medicare's cost sharing could serve several purposes. First, it would help to recoup some of the additional Medicare spending associated with that more complete coverage.[25] Taxes would be paid by medigap insurers directly to the Medicare trust funds through the same Medicare administrative contractors who already process claims.[26] Presumably, insurers would pass the excise tax along by raising premiums for those more complete plans. In turn, beneficiaries in those plans would have an incentive to voluntarily consider newer types of medigap plans that require paying more of Medicare's cost sharing.

One potential consequence of higher premiums is that rather than switch to a different supplemental plan, some beneficiaries may choose to drop coverage altogether. If dropping all supplemental coverage led beneficiaries to forgo necessary care, it could worsen their health

outcomes and potentially result in higher Medicare spending. To encourage individuals to move into newer types of medigap policies or other sources of additional benefits, policymakers may want to consider reducing hurdles that prevent switching. For example, an option to move into medigap plans without first-dollar coverage that are not subject to the excise tax on a guaranteed-issue basis might limit the numbers of beneficiaries who choose to drop supplemental coverage.

As an example, if an excise tax were applied only to those medigap policies that cover both the Part A and Part B deductibles, a 10 percent excise tax might raise on the order of $1 billion per year. The tax would, in all likelihood, need to be significantly greater than 10 percent to recoup the induced demand attributable to medigap coverage. However, because of the difficulty in disentangling the effects of a pure insurance effect from selection bias (described earlier), the exact percentage is uncertain. If the excise tax encouraged beneficiaries to move into the newer types of medigap policies that require paying more of Medicare's cost sharing at the point of service, that behavior could lead to slower growth in Medicare spending and in premiums for Part B and medigap policies.

Other ideas to explore

The Commission will continue to explore other options. Pilot or demonstration programs may provide a way to try new approaches with supplemental coverage. For example, Medicare might want to encourage new types of Medicare SELECT plans that include physician networks in addition to hospital networks. Insurers might be more interested in establishing physician networks for SELECT products or using more managed approaches in administering medigap benefits if they shared some of the savings from doing so. In addition, the NAIC is beginning to catalog states' approval of "new or innovative benefits" offered by medigap insurers. State insurance regulators have had authority to approve the addition of such benefits to standard medigap policies for some time, but so far relatively little information has been shared. Doing so would allow states and insurance companies to look for best practices.

Another potential subject of a pilot or demonstration could be a value-based insurance design that tailored Part D cost-sharing requirements to individuals' clinical needs (Murphy et al. 2009). It would be an opportunity to test whether value-based insurance design could help achieve lower Part A and Part B spending.

Longer term potential improvements to Medicare

For the longer term, the Medicare program will need to move toward benefit designs that give individuals incentives to use higher value care and discourage using lower value care. Part of this change will involve developing the evidence base to better understand which treatments are of higher and lower value. Several years ago the Commission recommended that policymakers establish an independent, public–private entity that would produce information to compare the clinical effectiveness of a health service with its alternatives (Medicare Payment Advisory Commission 2008). Along the same lines, the PPACA establishes the Patient-Centered Outcomes Research Institute to identify national priorities for comparative clinical effectiveness research and sponsor comparative-effectiveness research efforts. In addition, Medicare may want to begin examining how the incentives of beneficiaries can best be used to help transform the structure of health care delivery.

Moving toward value-based insurance design

In recent years, policymakers have become more aware that not all health care services are of the same value, but identifying which services are of higher or lower value can be difficult. The term "value based" is applied to strategies for reimbursing providers (value-based purchasing) and cost-sharing options designed to encourage beneficiaries to undertake certain high-value behaviors or use high-value treatment options (value-based insurance design). Testing these approaches would help policymakers decide which ones could encourage beneficiaries more effectively to use high-value health care services.

Incentives for selecting among treatment options

Some insurers have begun setting different levels of cost sharing for the same medical intervention based on the clinical benefit a given patient is likely to derive (Chernew et al. 2007, Fendrick et al. 2001). For example, patients with diabetes have lower cost sharing for medical interventions shown to prevent or reduce the long-term complications of the disease, such as drugs that control blood pressure. When there is evidence that specific therapies are comparatively more effective and appropriate for certain patients, lowering their cost sharing to help increase their adherence to the therapy could improve

health outcomes. If higher adherence leads to fewer exacerbations of the patient's condition, this approach could also lower spending. At the same time, where evidence suggests that medical therapies are less effective, increasing beneficiaries' cost sharing could deter use of those services. The extent to which value-based insurance design could reduce Medicare program spending depends on beneficiaries' underlying health risk, the cost of adverse outcomes, beneficiaries' responsiveness to copayments, and the effectiveness of medical therapies at reducing risk (Chernew et al. 2010).

A primary objective of value-based insurance design is to improve beneficiaries' quality of care and encourage high-value care. For some, a separate goal may be to achieve net savings. However, achieving savings requires careful targeting and willingness to lower cost sharing for high-value services and raise cost sharing for low-value services. Many services do not save money even though they are cost effective. Value-based insurance design would lead to overall lower spending only if it helped to reduce medical interventions when the costs outweigh the clinical benefits.

Insurers, large employers, and researchers have tested key elements of value-based insurance design with some success. The University of Michigan, Pitney Bowes, and the municipality of Asheville, North Carolina, have implemented programs that lower copayments for diabetes patients for certain high-value interventions related to their condition, while maintaining lower cost sharing for generic drugs (Chernew et al. 2007). Other employers such as Marriott, Alcoa, Procter & Gamble, and IBM are investigating their own approaches to value-based insurance design, as are major insurers such as Aetna (Fuhrmans 2007, Wojcik 2009). In a study of the nonelderly, researchers found that varying copayments for cholesterol-lowering drugs based on expected therapeutic benefit increased adherence and reduced use of hospital and emergency services (Goldman et al. 2006). Similarly, one program implemented by a large employer increased use of high-value services and arguably broke even from a combined perspective of employer and employees (Chernew et al. 2008, Chernew et al. 2010).

Aiming differential copayments at those patients most likely to benefit clinically would, in principle, achieve better value more effectively than a blunt, across-the-board approach to raising and lowering copayments. However, the targeted approach requires solid evidence about the comparative effectiveness of alternative therapies as well as the ability to accurately identify patients' conditions and their severity. Therapies for some diseases have a more thorough body of evidence than others on comparative effectiveness. To make the value-based insurance approach effective, policymakers and payers would need significantly more investment in comparative-effectiveness research and alternative methods of identifying relevant patient characteristics (such as information typically found in an electronic medical record). There are also administrative hurdles such as higher administrative costs, near-term cost increases associated with lower copayments, legal issues, and the potential for fraud. Beneficiaries might be concerned about the complexity and equity of the benefit design as well as the need to protect the privacy of patient data (Chernew et al. 2007).

Incentives for selecting among providers

As Medicare further develops methods for measuring providers' quality of care and resource use, it could take steps beyond confidentially informing providers of their relative rankings. (These rankings are made through analyses comparing providers' practice patterns with those of their peers after risk adjustment—that is, controlling for differences in patients' health status.) For example, Medicare could use the information to charge higher cost sharing for beneficiaries who use providers identified consistently as resource use "outliers" compared with their peers. Over time, with the accumulation of data, provider payments could be tied to beneficiaries' long-term health outcomes rather than to delivery of individual services. At the same time, however, Medicare would need to ensure that beneficiaries had sufficient access to providers at lower cost sharing. The effectiveness of this approach would depend on the supply of providers in specific markets and their bargaining leverage.

The Commission has been exploring different payment approaches designed to counter the financial incentives under the FFS payment system for providers to increase volume and consequently spending. Accountable care organizations (ACOs) involve an approach in which Medicare would give providers the opportunity to earn bonuses funded by shared savings, withholds, or both, if they met quality and resource use targets (Medicare Payment Advisory Commission 2009). Under some approaches, providers would bear more financial risk for health care spending that the Medicare program now bears, and ACOs would leave decisions about managing care to its group of providers. To foster the development of ACOs, Medicare could encourage beneficiaries to use

ACO providers by offering lower cost sharing or more generous financial protection against high OOP spending.

Similarly, beneficiary incentives could help promote the use of medical homes. In Medicare, a medical home program would encourage beneficiaries to seek or remain with a physician who can manage their overall care. Under such a program, Medicare would direct monthly payments to medical homes to promote the important role that personal physicians and their health care team play in coordinating care delivery, particularly for patients with multiple conditions (Medicare Payment Advisory Commission 2008). Incentives for beneficiaries to use medical homes could include reduced cost sharing or a cap on OOP spending. Such incentives might help to encourage providers to organize themselves in a way that could deliver the combination of primary care and related care management, information technology, and quality improvement services that would better coordinate care.

Future options for newly enrolling Medicare beneficiaries

Today, as individuals become eligible for Medicare, they may either enroll in a private Medicare plan or use FFS Medicare. If the latter, beneficiaries also usually take up supplemental coverage.

For the future, entering cohorts of Medicare beneficiaries could face a somewhat different set of choices. That future could continue to include both the FFS benefit and MA plans, but it would help beneficiaries make clearer choices by presenting them with better price signals through the premiums and cost sharing of those options. MA plan premiums and cost sharing would function better as price signals if benchmarks that CMS uses to evaluate MA plan bids were set at 100 percent of FFS costs, thereby reducing the additional MA subsidies that distort the comparison to FFS Medicare (Medicare Payment Advisory Commission 2010). The PPACA will likely bring MA payments much closer to 100 percent of FFS costs. Redefining the role of supplemental coverage in ways described earlier would also help to send better price signals through cost sharing in the FFS benefit.

The desirability of current Medicare options may differ in the future from what it is today. For example, fewer beneficiaries will have employer-sponsored supplemental coverage available to them. Insurers will continue to offer medigap policies, but premiums for that coverage (as well as for Medicare Part B) will likely take up a larger share of household income. The attractiveness of MA plans to beneficiaries may depend on how well plans are able to manage their benefits and deliver services with fewer resources relative to the cost of providing care to beneficiaries in FFS Medicare. The availability of additional coverage through Medicaid will depend in part on other constraints on state and federal spending.

The future could hold other adaptations to the FFS model. A separate, more managed benefit could be offered to beneficiaries on a voluntary basis (referred to hereafter as a Medicare preferred provider organization (PPO)). In exchange for some form of lower OOP costs, enhanced benefits, or both, a Medicare PPO would set limits on the amount of Medicare's cost sharing that could be filled in by supplemental coverage and would employ management tools to curb the use of inappropriate services.

Among the utilization management tools a Medicare PPO could adopt are prior authorization, concurrent review, and case management. Medicare would incorporate these tools to promote appropriate use of services and to protect patient safety. Pharmacy benefit managers use similar tools routinely to evaluate whether enrollees' prescriptions are covered when they present them at the pharmacy, and some private payers use such measures to manage radiology services and other types of benefits. To adopt such measures, Medicare would need strong evidence behind the treatment guidelines it used as well as a transparent process for setting criteria about when utilization tools would be used. Medicare's administrative costs would grow accordingly.

Medicare would need to give beneficiaries incentives to enroll voluntarily in such a program. Several strategies could be used to encourage enrollment:

- Set a cap on OOP spending and offer easy-to-understand cost sharing in the form of copayments.
- Set premiums for the reformed benefit in a risk pool separate from the traditional FFS program's risk pool. In other words, premiums for the reformed benefit would reflect average costs for enrollees in the reformed package, and premiums for the FFS benefit would reflect average costs for FFS enrollees. To the extent that the reformed Medicare benefit led to lower average costs, premiums under the reformed benefit would be lower than those for traditional FFS Medicare.
- Provide federal subsidies to low-income individuals to help them with premiums and most of their cost

sharing if they enroll in the reformed Medicare option. States might encourage individuals to enroll in the reformed benefit rather than in the current FFS benefit if the revised Medicare option tended, on average, to reduce state Medicaid benefit spending.

Initially, these features might tend to attract sicker and costlier enrollees first into the reformed Medicare option, which could make its premiums high. For example, the opportunity to enroll in a reformed Medicare benefit with an OOP cap might be especially attractive to disabled beneficiaries younger than age 65 who live in states where they are now unable to purchase medigap policies. At a time when Medicaid costs are growing rapidly, states would likely look to a reformed Medicare option as an opportunity to have the federal government pay for 100 percent of assistance with premiums and cost sharing for dual-eligible beneficiaries. These factors suggest that, based on health status alone, average costs of benefits could be high and, at least initially, premiums for a risk pool of enrollees in a reformed Medicare benefit might not be as attractive as intended relative to FFS premiums.

To counter the problem of adverse selection in a new Medicare option, it would be important to enroll as broad a group of beneficiaries as possible from the beginning. This strategy was used when Part D was introduced. Beneficiaries were given a one-time option to enroll during an initial enrollment period. After that period, individuals who chose to wait and enroll later faced a monthly penalty in addition to their Part D premium. ■

Endnotes

1 Higher income beneficiaries pay a higher income-related Part B premium, but a high-income beneficiary in, for example, California pays the same Part B premium as a beneficiary in Maine with the same income.

2 For example, the American Medical Association's 2009 National Health Insurer Report Card shows that Medicare performed similar to or better than private insurers on several claims-processing measures, such as indicators for timeliness, transparency, and accuracy of claims processing (American Medical Association 2009). The report card noted that, although Medicare had higher rates of denied claims (4 percent) than several of the private insurers, Medicare does not require preauthorization for services, as do many private insurers.

3 Beginning in 2011, all Medicare Advantage plans will be required to include an OOP cap ($6,700 for that year). Some Medicare Advantage plans include an OOP cap lower than that required of all plans.

4 An exception is private FFS plans, which use a model that generally does not involve managing care.

5 The Commission estimates that under the Part C payment system, MA plans are currently paid substantially above what the same beneficiaries would cost in FFS Medicare (Medicare Payment Advisory Commission 2010). The health reform law will likely bring MA payments much closer to 100 percent of FFS costs. For more about the Part C payment system, see http://www.medpac.gov/documents/MedPAC_Payment_Basics_09_MA.pdf.

6 In 2007, the Part A deductible was $992 and the Part B deductible was an additional $131. By comparison, in 2007, a typical large employer used a combined deductible for inpatient and outpatient care of $500 per individual ($1,000 per family) for in-network care (Yamamoto et al. 2008). (For out-of-network providers, it was $1,000 per individual ($2,000 per family).) For people younger than 65 who are not enrolled in Medicare, deductibles can be much higher than Medicare's if they purchase insurance in the individual market—that is, without the benefit of a large risk pool like major employers and Medicare have. In a 2009 survey, the median respondent who purchased a single, individual policy with a preferred provider organization or an HMO with a point-of-service option faced a deductible of between $2,000 and $2,500 (America's Health Insurance Plans 2009).

7 Physicians on the RAND HIE team grouped conditions into categories based on their judgment of whether medical treatments tend to be effective (Newhouse and the Health Insurance Experiment Group 1993). For example, treatment for certain acute conditions such as infections (e.g., strep throat or pneumonia) and for traumas (e.g., fractures or lacerations) was categorized as highly effective. Examples of medical care for chronic conditions that was categorized as highly effective include treatment of thyroid disease, diabetes, hypertension, and congestive heart failure. Other conditions were categorized as "medical care rarely effective" or "self-care effective" such as obesity, influenza, and constipation.

8 The sample size was too small to test whether this result was associated with statistically significant differences in mortality.

9 For example, among seven studies reviewed by Rice and Matsuoka, four support the idea that increased cost sharing is correlated with worsened health status, as measured by mortality rates (two studies) or health status (two studies) (Rice and Matsuoka 2004). Two of the remaining three studies that showed no effect on health outcomes focused on myocardial infarction (Magid et al. 1997, Pilote et al. 2002). Individuals' perceptions about being in a life-threatening emergency may have made them less responsive to price changes (Rice and Matsuoka 2004).

10 Among the nine studies examined by Rice and Matsuoka, six found evidence that higher cost sharing tends to reduce the appropriate use of services (Rice and Matsuoka 2004). Evidence was strongest for prescription drugs and less definitive for other services.

11 Cost sharing is one of many factors that can affect medication adherence. For example, beneficiaries who receive Part D's low-income subsidy (LIS) face no coverage gap. A recent CMS-sponsored study found relatively low rates of use of commonly recommended drugs among diabetic patients enrolled in Part D, with lower drug prevalence rates among LIS enrollees (Stuart and Simoni-Wastila 2009).

12 One often-cited estimate based on data from the mid-1990s suggests that use of services ranged from 17 percent higher for those with employer coverage to 28 percent higher for those with medigap policies (Christensen and Shinogle 1997).

13 Some employers offer retiree coverage through MA plans. As of April 2010, about 18 percent of enrollment in MA plans was through employer groups.

14 In 2006, the poverty threshold was $9,669 for single people and about $12,186 for married couples.

15 By comparison, a 2006 survey of Blue Cross Blue Shield plans that covered their own insured business as well as plans run for self-insured employer groups found that administrative costs were typically about 12 percent of premiums (Merlis 2009).

16 Wide ranges in premiums suggest that the market for supplemental coverage is not very efficient. Different ratings methods are one reason for the wide range, and they include the following:

- Community rating—all beneficiaries are charged the same rate for a given plan.
- Issue age rating—all beneficiaries in a plan are charged a set rate based on how old they are when they first purchase the plan.
- Attained age rating—all beneficiaries of a given age are charged the same within a plan.
- Individual medical underwriting—the process that an insurance company uses to decide, based on the applicant's medical history, whether to accept the application for insurance. Except in guaranteed-issue situations, beneficiaries in poorer health may be refused coverage entirely, may have fewer choices of plans available to them (sometimes only higher priced options), and preexisting condition exclusions may apply.

17 While beneficiaries may be confused by the bewildering array of premium choices and lose confidence that they can select the plan that is best for them, there is a safeguard against plans providing poor value. Medigap plans must return a minimum level of benefits relative to their premiums, with a medical loss ratio of not less than 65 percent; that is, each medigap plan must pay out in medical benefits at least 65 percent of the premiums collected from the policyholders. Group policies, which are sold through employers, unions, and other groups and tend to have lower administrative costs, must have a minimum loss ratio of 75 percent. The National Association of Insurance Commissioners reports that for 2008, the average medigap loss ratio was 80 percent (81 percent for group policies and 79 percent for individual policies).

18 Medicare SELECT provider networks are usually just for inpatient care but in some cases include specific physicians. When a policyholder does not use a network provider for nonemergency care, she must pay some or all of Medicare's cost sharing.

19 Under the terms of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, insurers cannot issue new Plan J policies because they would compete with Part D by including prescription drugs in their covered benefits. In 2010, enrollees pay the first $2,000 in Medicare cost sharing under the high deductible of Plan F.

20 After the policyholder meets the Part B deductible, Plan N's cost sharing is the lesser of a $20 copayment or Medicare's coinsurance amount for Part B evaluation and management services for either specialist or nonspecialist office visits. The lesser of a $50 copayment or Part B coinsurance applies for each covered emergency room visit. However, that cost sharing is waived if the beneficiary is admitted and the emergency visit is covered subsequently by Part A (National Association of Insurance Commissioners 2010).

21 The PPACA will create state-based health insurance exchanges that use four benefit categories available to individuals who are not Medicare beneficiaries. Compared with those benefit categories, the $4,000 cap described here is lower than limits on OOP spending for higher income individuals under the new law, but it is significantly higher than limits prescribed for individuals with incomes less than 200 percent of the federal poverty level (Kaiser Family Foundation 2010). Benefits in the health insurance exchanges generally are to follow the OOP limit in current law for health savings accounts ($5,950 for individuals in 2010). However, the PPACA reduces the OOP limits for lower income individuals: $1,983 for individuals with incomes between 100 percent and 200 percent of the federal poverty level, $2,975 for individuals between 200 percent and 300 percent, and $3,987 for individuals between 300 percent and 400 percent.

22 Within the Medicare Savings Programs (MSPs), only qualified Medicare beneficiaries (who have incomes less than 100 percent of the federal poverty level) receive assistance with both Medicare's cost sharing and premiums. Beneficiaries with other designations under MSP—specified low-income Medicare beneficiaries and qualifying individuals—receive assistance with Medicare premiums but not cost sharing.

23 CBO prepared estimates for this option beginning in 2011, with the amounts of restrictions on medigap policies indexed each year to the average annual growth in Medicare costs. Because CBO assumes some ramp up of the policy in 2011, we present their steady-state estimates for 2012.

24 In return for providing primary prescription drug coverage to their former employees, employers receive a tax-free subsidy from Medicare for some of their drug costs. Under the PPACA, employers may still receive this subsidy. However, effective in 2013, they can no longer deduct from income prescription drug expenses for which they receive the subsidy.

25 It is similar in nature to the approach used in Part D, in which beneficiaries who enroll in plans with enhanced benefits must pay premiums that incorporate an assumption about their higher use of services stemming from having supplemental benefits. However, some Part D plans have a relatively healthy mix of enrollees, and the additional premium associated with their enhanced benefits may not cost very much.

26 Insurers are also facing new taxes under the health reform law. Specifically, the law calls for a general fee on health insurance providers and places an excise tax on high-cost employer-sponsored health coverage.

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CHAPTER 3

Medicare's role in supporting and motivating quality improvement

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Chapter summary

There is wide variation in the quality of health care in the United States, and the pace of quality improvement has been frustratingly slow. As the largest single purchaser of health care, Medicare has a responsibility to induce and support quality improvement. The Commission has recommended numerous payment changes to create a business case for quality, which should encourage quality improvement. These changes include pay for performance, payment penalties for excessive hospital readmissions, and a pilot to test medical homes. In addition, the Commission has recommended that performance data be publicly reported to further motivate better quality, both by stimulating professional pride and by enabling beneficiaries to make more informed choices about where they receive their care (Medicare Payment Advisory Commission 2008).

Payment incentives and public reporting alone may not be sufficient to induce the magnitude of quality improvement needed. Some providers simply may not know how to improve care. Quality improvement is difficult, particularly when it requires coordination among various provider types during a patient's episode of care, management of a highly complex organization, or coping with the challenges of serving a rural or a low socioeconomic population. Accordingly, some providers need technical assistance. Medicare is in a position to facilitate an exchange of expertise, so that the innovations and culture of the nation's high-performing providers can be exported to

In this chapter

underperforming providers, who, despite the best of intentions, endanger too many Medicare beneficiaries with substandard care.

Medicare's Quality Improvement Organization (QIO) program recently began an effort to focus on assisting low performers. This focus has several advantages and raises several implementation issues in delivering technical assistance for quality improvement, such as which measures should be used to identify low performers. Other changes to the program could also be contemplated. For example, there may be advantages to allowing entities besides the current QIOs (e.g., high-performing providers, professional associations, consulting organizations) to receive Medicare support as technical assistance agents serving low performers. Under an alternative quality improvement model, low performers could choose which entity would be best suited to provide them Medicare-supported technical assistance.

Another way Medicare can stimulate quality improvement is by reforming its conditions of participation (COPs)—the minimum standards that certain provider types are required to meet to participate in Medicare. Providers, state governments, and the federal government collectively spend millions of dollars annually preparing for and conducting surveys to ensure compliance with these standards, yet it is unclear how much these efforts have accelerated the pace of change. Various options exist that could reenergize the survey and certification process, including updating the COPs to align them with current quality improvement efforts, imposing intermediate sanctions for underperformers, creating higher standards that providers could comply with voluntarily to be designated publicly as a high performer, and using performance on outcomes measures (e.g., mortality rates) as a criterion for providers to be eligible to perform certain procedures.

Modifying the COPs in tandem with providing targeted technical assistance may introduce a balance of incentives that could accelerate quality improvement and make health care safer for Medicare beneficiaries. ■

Whether beneficiaries survive an illness or avoid a preventable, debilitating complication can depend on where and from whom they receive care. Accordingly, Medicare has a responsibility to induce and support improvement in the quality and efficiency with which care is delivered.

Improvement in care has been slow. It takes, on average, 17 years for the results of clinical trials to become standard clinical practice (Balas and Boren 2000). Adoption of the "checklist" approach to reducing central line infections that was implemented successfully in Michigan hospitals and publicized widely has not been fully implemented in the vast majority of hospitals (Leape 2010). Some of the nation's leading physician voices on quality have recently lamented the too frequent reluctance of physicians to rely on proven practice guidelines to inform their practice style and save lives (Swensen et al. 2010). In addition, a recent survey of hospital boards found that none of the boards of low-performing hospitals thought their hospitals were poor performers—in fact, 58 percent thought they had better or much better quality than the average hospital (Jha et al. 2009).

Performance on quality measures varies widely, with differences of two- to threefold across states on many measures, including mortality, morbidity, and complications (Kroch et al. 2007). The Institute of Medicine (IOM) and others estimate that tens of thousands of lives could be saved each year if providers delivered safer care (Kohn et al. 1999).

Medicare has multiple ways to induce quality improvement; one of the most powerful is through payment incentives. The Commission has recommended numerous changes intended to align financial incentives with the provision of high-quality, efficient care. The Commission has also recommended that performance on quality measures be publicly disclosed as a further effort to motivate and support improvement. Some experts argue that publicly disclosing performance data is even more important than financial incentives (Leape 2010). In the last decade, CMS has begun publicly reporting quality data for hospitals, nursing homes, home health agencies, and dialysis providers; these data are submitted by the providers.

Medicare has other levers to support and encourage improvement. First, through its Quality Improvement Organizations (QIOs) in each state, Medicare can give providers technical assistance to help them change practice patterns and improve quality and efficiency. While management of the QIO program continues to evolve to address past problems, the Commission's review of the literature and discussions with stakeholders suggest that alternative approaches to technical assistance may be worth considering.

Second, Medicare could better leverage its conditions of participation (COPs)—standards for provider entry to and continued participation in the program—to accelerate quality improvement. A combination of improved technical assistance from QIOs and the inclusion of regulatory consequences under COPs could introduce a balance in incentives and accountability that lowers the risk of avoidable harm to Medicare beneficiaries.

To simplify the discussion of quality improvement, we use hospitals to illustrate key concepts, but the principles discussed here apply to all provider types. We recognize, however, that quality improvement efforts and COPs (as well as conditions for coverage that apply to nonhospital providers) vary by provider category and that tailoring technical assistance and oversight to specific aspects of the providers' services is appropriate.

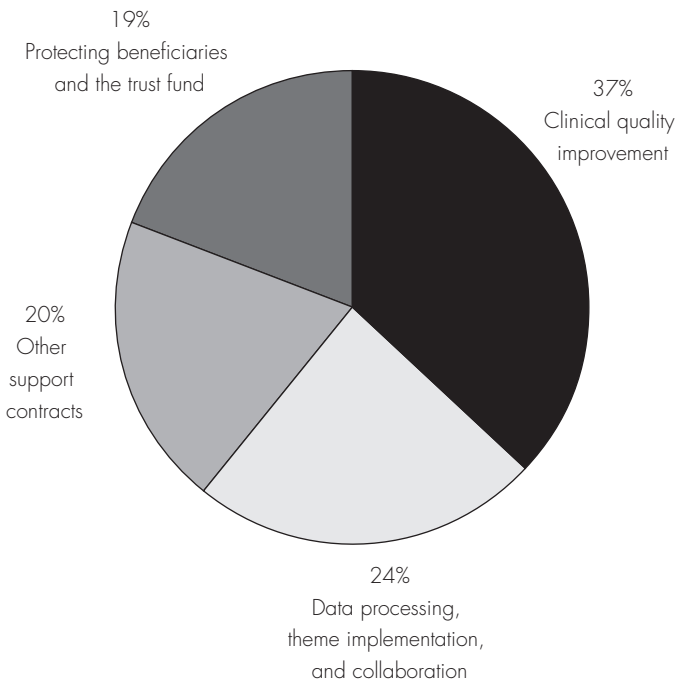
Background

Quality Improvement Organizations

In the current three-year (2008–2011) contracting cycle, Medicare is spending $1.1 billion (about $366 million annually) to support the functions of QIOs, which CMS defines as improving quality of care for beneficiaries, protecting the integrity of the Medicare trust fund by ensuring that Medicare pays only for services that are necessary, and addressing individual beneficiary complaints (Centers for Medicare & Medicaid Services 2008). There are 41 organizations that hold 53 contracts to provide QIO services in all 50 states, Puerto Rico, the Virgin Islands, and the District of Columbia. Most are nonprofit entities. The QIO program also funds several QIO support centers, which serve as national resources to QIOs in carrying out their responsibilities.

The role of QIOs has changed over time. Early on, QIO predecessors (Peer Review Organizations) were responsible for identifying individual cases of unnecessary or substandard care that might be driving up costs. In 1992, the focus changed, partly spurred by the IOM's recommendations, so that their primary role shifted from identifying individual clinical errors to providing technical

FIGURE 3–1 **Allocation of spending in the Quality Improvement Organization budget**



Source: Fiscal year 2011 President's budget.

assistance, particularly in data collection and performance feedback and in fostering internal quality improvement. The sense was that "fear and adversarial relations … [would] cripple quality-improvement efforts" (Jencks and Wilensky 1992). By 1999, every Peer Review Organization was required to produce measurable statewide improvement in select clinical areas (e.g., diabetes, breast cancer, acute myocardial infarction (AMI)). Now, QIOs are largely measured on how they improve the quality of care of the providers they directly assist.

Each scope of work (SOW)—the three-year contracting cycle with QIOs—emphasizes somewhat different tasks or approaches to quality improvement. For example, the eighth SOW cycle focused on four strategies to improve quality: measurement and reporting, health information technology (HIT), redesign of care processes, and change in organization culture and management. It also included projects like preventing hospital admissions from a nursing home and improving transition of care across settings, which were intended to help develop an evidence base for what works.

In the current ninth SOW cycle, QIOs are to focus on beneficiary protection, patient safety, prevention, and care transitions. As part of patient safety, QIOs are focusing on reducing rates of methicillin-resistant *Staphylococcus aureus* infections, pressure ulcers in nursing home patients, and physical restraint use in nursing homes; improving inpatient surgical safety and heart failure treatment in hospitals and drug safety; and providing technical assistance to nursing homes.[1] In addition, QIOs in states that successfully competed for additional work are to focus on the following tasks: reducing disparities in preventive services, promoting seamless transitions across settings, and slowing the progression of chronic kidney disease to kidney failure and improving clinical care to all kidney patients.

In the ninth SOW, CMS changed aspects of its management of the program in response to concerns and problems about the program noted by the IOM, Government Accountability Office, and members of the Congress. It is using management information tools, such as milestones and project tracking, to monitor the effectiveness of QIO activities. In addition, QIOs are expected to focus their interventions across the spectrum of provider types as well as low performers. CMS has also made changes to inject greater competition into the program. It awarded funding for certain subnational tasks competitively. In addition, in seven of the QIO jurisdictions, where the QIOs' prior performance on the eighth SOW contract did not require renewed contracts, CMS conducted an open competition for the contract, in conformity with federal acquisition law. As part of that, CMS awarded a QIO contract to one new contractor (Centers for Medicare & Medicaid Services 2008).

The breadth of the QIO program's mission and budget extends well beyond technical assistance to providers. In the ninth SOW cycle, only 37 percent of total funding is devoted to clinical quality improvement. Another 19 percent is dedicated to protecting beneficiaries and the trust fund. Data processing, theme implementation, and collaboration receive 24 percent and other support contracts receive the remaining 20 percent (Figure 3-1). The IOM has raised concerns about the oversight and evaluation of the effectiveness of spending for support contracts and other quality activities performed outside of QIOs (Institute of Medicine 2006).

QIO funding comes through an apportionment directly from Medicare's Hospital Insurance and Supplementary Medical Insurance trust funds rather than an annual appropriation.

The apportionment process allows the Department of Health and Human Services (HHS) and the Office of Management and Budget to determine the program's needs and how much will be used from the trust funds.

Conditions of participation

COPs are the minimum standards that many types of providers are required to meet to participate in the Medicare program. To ensure that the COPs are met, both initially and periodically, providers are surveyed by either a private accrediting entity (approved by CMS) or state-designated surveyors.

COPs are tailored to each applicable provider type and have been in place since Medicare began covering the relevant service. Most categories of providers are subject to COPs or conditions for coverage; a significant exception is physicians. As initially conceived, the standards were largely statements of what a provider must do or have to make quality possible; they do not guarantee that quality is present (Sprague 2005).

COPs mainly require that certain physical and management structures are in place. For example, requirements for hospitals apply to areas such as the governing body; patients' rights; the medical staff; nursing services; medical records; pharmaceutical, laboratory, and radiology services; utilization review; discharge planning; infection control; and emergency services.

The standards have evolved somewhat. In 1986, less prescriptive but broader COPs were adopted. New conditions included infection control, surgical and anesthesia services, and quality assurance. Despite these improvements, more changes may be needed. The Commission has identified a number of areas where COPs could be strengthened (as discussed in this chapter) and has heard from other experts that COPs have not evolved to reflect the latest thinking on quality improvement, particularly with respect to the importance of provider teamwork, communication across sites of care, and evolution in the management of integrated systems.

The Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) is the largest accrediting organization of the nation's hospitals. It accredits about 80 percent of hospitals, with most of the rest being accredited by state agencies.[2] Its surveys are now unannounced and occur at two- to three-year intervals (between 18 and 39 months). The survey process has several components. Hospitals are required to perform periodic self-evaluation and collect quality data and submit the results of both to the Joint Commission. During the on-site survey, the accrediting staff interviews hospital staff about compliance with the Commission's standards, which largely mirror the COPs but also include national patient safety goals. These goals focus on providers' progress on widely identified safety issues, such as avoiding wrong site surgery, promoting hand washing as part of infection control, and having better communication among the care team.

In addition to interviews of the staff, ascertaining compliance is achieved by selecting "tracer" patients and examining the course of their care while in the hospital. Using tracer patients allows surveyors to view a hospital's practices from the patient's perspective and assess things such as whether lab results are returned to the right physicians in a timely way and whether the pharmacists play an active role in medication reconciliation on a real-time basis. Unfortunately, this approach does not allow a look at the entire discharge planning process because it limits the view to patients hospitalized at the time of the survey.

There is some federal oversight of accreditors. The Secretary of HHS has the authority to conduct "validation" surveys in a random sample of Joint Commission–accredited hospitals each year. In addition, CMS conducts "allegation surveys," or complaint investigations. They are more common than validation surveys but more limited in scope. They look only at the condition relevant to the complaint.

Most hospitals are either accredited or approved by state surveyors. For the Joint Commission, 94.7 percent of hospitals that applied for accreditation received it in 2008. Another 4.6 percent received "conditional accreditation" (Tucker 2010).

How can Medicare best provide technical assistance to providers?

To a great extent, quality improvement should be part of every provider's mission; it is a requirement in Medicare's COPs for hospitals. It should not be considered an "extra" function that needs separate funding. Yet some providers simply may not have the knowledge to undertake the breadth of initiatives that are required, or they may face a particularly challenging environment. The task at hand is made that much more difficult when improvement requires

coordination among various provider types during a patient's episode of care, management of a highly complex organization, or coping with the challenges of serving rural or low socioeconomic patients. Because the consequences of these challenges adversely affect the quality of care for beneficiaries, Medicare has a role in supporting providers' quality improvement efforts. What should this role be and how should it be executed?

Choosing this juncture to consider technical assistance

We raise the issue of technical assistance at this time for three reasons. First, while management of the QIO program has recently been reformed as part of the ninth SOW, it has a history of not being able to demonstrate its effectiveness and even now, based on our interviews with various experts and stakeholders (e.g., hospital administrators, academics, health plan executives, staff of independent quality organizations), the expertise of its contractors is perceived as uneven and, in some cases, unequal to the task. Second, the landscape of quality improvement providers has changed over time, with a growing number and variety. This change raises the opportunity for more types of entities to constructively contribute to quality improvement and possibly merit support from the Medicare program in their efforts to reach low performers. Third, a variety of federal programs exist to improve the quality of care, and in some cases the coordination between them is not at all clear. The recent health care reform law, the Patient Protection and Affordable Care Act of 2010 (PPACA), calls for the Agency for Healthcare Research and Quality (AHRQ) to create a national strategy for quality improvement. The role of QIOs should be considered carefully as to how their efforts can best complement (and be complemented by) other programs, such as patient safety organizations, AHRQ grant programs that fund quality improvement efforts, and the newly created Health Information Technology Regional Extension Centers.

The perception and performance of QIOs

QIOs are partway through implementing the ninth SOW, which includes numerous reforms to address concerns raised in the past, most specifically by the IOM in 2006. While these changes are promising (an evaluation of QIOs' performance under the ninth SOW is not yet available), current perceptions of stakeholders and the history of the program suggest that exploring options for the structure of the program could be constructive.

In the Commission's recent conversations with numerous stakeholders and experts (e.g., hospital administrators, academics, health plan administrators, staff of organizations dedicated to improving quality), many mentioned their concerns that QIO performance is uneven across the nation and that some did not have the staff expertise or analytic infrastructure to take on the assigned role. Some suggested that the QIOs' impact is constrained by their motivation to perform to the terms of the contract and, accordingly, they are less likely to be innovative and a source of energy in their leadership. Future demonstrated success of QIOs could prove these perceptions wrong and alter the image that QIOs have developed, but these perceptions are a factor worth consideration in assessing the potential of the program to drive change, particularly when the vast majority of QIO contractors remains the same from contract to contract.

Historic performance also highlights the challenges of operating the QIO program and producing measurable results. In 2006, an IOM panel, tasked by the Congress with evaluating the QIO program, concluded that "given the lack of consistent and conclusive evidence in scientific literature and the lack of strong findings from the committee's analyses, it is not possible to determine definitively the extent of the impact of the QIOs and the national QIO infrastructure on the quality of health care received by beneficiaries" (Institute of Medicine 2006). The IOM review not only looked at the literature but also included site visits and phone interviews with QIO leaders.

An evaluation of the QIO program by NORC (formerly the National Opinion Research Center) for the HHS Assistant Secretary for Planning and Evaluation in 2007 also painted a troubling picture. For example, it found a "paucity of activity- or intervention-specific information available in public resources, particularly related to the seventh SOW. In several cases, no substantive information on any specific project could be found for a given QIO and subtask … efforts to locate details on projects that were identified by name often proved futile and while most QIOs stated that they currently or have previously participated in national or local quality improvement initiatives, specific details as to the QIOs' scope or role in the initiatives were generally unavailable" (Sutton et al. 2007).

The literature on the effectiveness of the QIO program does not present a consensus (Sutton et al. 2007). Moreover, many of the studies are plagued by

methodologic obstacles, including questionable data, selection bias, spurious attribution due to numerous confounding factors, and the inability to isolate and define experimental and control groups (Sutton et al. 2007). These types of obstacles challenge the evaluation of other quality programs as well and are not singular to the evaluation of QIO interventions (Institute of Medicine 2006).

Studies on the impact of individual QIO quality improvement show that some interventions have been more effective than others and can catalyze improvements in process measures and to a lesser degree outcomes measures in care settings (Sutton et al. 2007). For example, an examination of a pressure ulcer prevention project conducted by the Texas QIO concluded the project's intervention—assigning quality improvement teams to participating facilities—was associated with a reduction in the occurrence of pressure ulcers (Abel et al. 2005).

QIO leaders dispute a perception problem and point to the results of a 2008 survey of 470 hospitals, or about 11 percent of hospitals, where 89 percent of them responded that QIOs had a very positive or somewhat positive influence on their hospitals (Cohen et al. 2008). This level of positive responses exceeded that given to any other type of quality improvement organizations.

Another consideration in the perception of QIOs is the somewhat conflicting role they have as both a quality improvement organization and a regulator. QIOs still have a role in reviewing providers' care and issuing corrective plans when they find problems.[3] The dual nature of their role could make providers less likely to view QIOs as purely collaborative partners in quality improvement.

Emergence of private sector organizations and initiatives focused on quality improvement

More organizations are getting involved in quality improvement, creating the opportunity for more types of entities to possibly merit support from the Medicare program in their efforts to reach low performers. While the efforts of these organizations are promising, like QIOs, many have not demonstrated conclusively that their initiatives have improved care nationally. Many, but not all, charge for their services.

Some of the relatively new entrants in the market are national organizations. The Institute for Healthcare Improvement (IHI), created in 1991, has organized large national campaigns to reduce medical errors (e.g., "5 million lives campaign"), sponsored numerous collaborative efforts on both quality (e.g., transforming care at the bedside) and efficiency (e.g., improving flow through acute care settings), and hosts conferences.

In September 2009, the Joint Commission launched its Center for Transforming Healthcare, which states as its aim "to solve health care's most critical safety and quality problems." It intends to work with select hospitals and health systems to discover underlying causes of problems and develop targeted solutions and to share proven solutions with the more than 16,000 health care organizations it accredits. It began with promoting hand hygiene and has continued with improving hand-off communications (Joint Commission 2009b).

A number of trade associations and provider alliances have also emerged as quality improvement resources for providers. For example, Premier has launched a collaborative of 160 hospitals it calls QUEST to help "springboard hospitals to a new level of performance." QUEST pools data from all participants to establish hospitals' baseline performance and enables sharing of best practices to improve performance (Premier 2010). The University HealthSystem Consortium, with a membership of 107 academic medical centers, also promotes quality improvement among its members by enabling them to benchmark themselves against similar hospitals on a variety of measures, reporting relative performance within the group, and providing technical assistance conferences (University HealthSystem Consortium 2010). As widely reported, the Michigan Hospital Association demonstrated strong leadership in coalescing its members around an initiative to reduce the incidence of central line infections, with great success (Pronovost et al. 2006).

To name a few of the initiatives among physician associations, we note that the American College of Cardiology has initiated a "door to balloon" campaign to improve the efficacy of treatment for heart conditions and a "hospital to home" initiative to reduce readmissions for cardiac patients (Antman and Granger 2010). The American College of Surgeons has the National Surgical Quality Improvement Program, which allows comparisons of hospitals in the program and provides them with the tools, reports, analyses, and support to make quality improvements (American College of Surgeons 2006). The Society of Hospital Medicine, whose membership is

hospitalists, has launched "Project Boost," which helps hospitals exchange information and mentor one another in an effort to reduce preventable readmissions (Society of Hospital Medicine 2010).

Need for coordination among federal quality improvement programs

The recently passed health care reform legislation, PPACA, requires HHS to establish a national strategy to improve the quality of health care services, delivery of health care services, health outcomes, and the health of the overall population. As part of that strategy, HHS will implement these priorities at local, state, and federal levels to ensure that providers utilize best practices that focus on efficiency and quality, reduced medical errors, improved medication management, improved emergency care, reduced hospital readmissions, and increased patient education with regard to treatment options. The law also establishes the Interagency Working Group on Health Care Quality to improve quality measures and increase collaboration between federal departments.

This type of initiative should be an opportunity to assess how other federal health improvement programs and Medicare's QIO program should coordinate with one another. In particular, over the last several years, AHRQ's role in funding facilities and providers to improve quality and spread innovation has increased. For example, in 2006 it launched a program called Accelerating Change and Transformation in Organizations and Networks (ACTION). According to AHRQ, "ACTION promoted innovation in health care delivery by accelerating the development, implementation, diffusion, and uptake of demand-driven and evidence-based products, tools, strategies and findings. ACTION develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems" (Agency for Healthcare Research and Quality 2006).

ACTION is organized around 15 large partnerships between AHRQ and 15 prime contractors (e.g., RAND, RTI, Indiana University). ACTION participants span all states and include health plans, physicians, hospitals, long-term care facilities, ambulatory care settings, and other health care sites. Each partnership includes health care systems with large databases, clinical and research expertise, and the authority to implement health care interventions. Projects are designed, implemented, and evaluated on a rapid cycle basis; they are awarded under separate task orders and are completed within 15 months on average.

As part of this project, AHRQ has recently funded hospital associations in 10 states to reduce central line infections, modeled on the success of the Michigan Hospital Association's initiative. From 2006 to 2008, AHRQ made 58 ACTION project awards with total funding of $30.2 million (Palmer 2008).

Evaluation of a previous AHRQ project that had similar characteristics found that diffusion across sites was rare over the period studied (Gold and Taylor 2007). AHRQ indicates that it has addressed this lack of diffusion in the ACTION program by emphasizing projects with broad applicability and potential scale. How findings are diffused beyond these sites to nonparticipating facilities is also important, however. AHRQ has a website to make its findings publicly available (Palmer 2008).

In addition, AHRQ has the authority to implement the 2005 Patient Safety Act, which created Patient Safety Organizations (PSOs). PSOs are entities that meet certain criteria and apply for the designation. To receive the designation, the entity's primary activity must be conducting activities to improve patient safety and health quality, such as disseminating recommendations, protocols, or information on best practices. A prime motivation for this designation is to allow providers to voluntarily report information on their care delivery on a privileged and confidential basis to allay fears that the information could be used against them in medical liability cases. Seventy-nine organizations are currently listed (Agency for Healthcare Research and Quality 2010). Newly enacted legislation calls on PSOs to work with hospitals with high rates of preventable readmissions.

The PPACA also calls on the Center for Quality Improvement and Patient Safety at AHRQ to study best practices and support their diffusion. This center is also authorized to award technical assistance grants to a variety of organizations (including providers and the Joint Commission) to provide technical assistance for quality improvement.

Opportunities for coordination also exist between the QIO program and the Office of the National Coordinator for Health Information Technology (ONC) at HHS, which is tasked with leading the national effort to support adoption of HIT and promote the exchange of information

to improve care. Among other things, the ONC is implementing the HIT regional extension center program to provide HIT technical assistance to providers on a regional basis. Some QIOs have successfully competed to offer assistance under this program (Department of Health and Human Services 2010).

Another indication that there is an opportunity for more coordination in quality improvement funding is the large percentage of the QIO program budget devoted to support contracts and not to directly support QIO clinical quality improvement activities (as discussed on p. 78). QIOs have noted that, while this type of funding may be supporting worthwhile projects, they object to the Medicare Trust Fund money being diverted to other projects, which reduces funding for their core activities (Reichard 2008). Spending on noncore activities is a growing part of the QIO program budget and the IOM has noted that there is no accountability for how this category of money is spent (Institute of Medicine 2006).

In considering ways to better coordinate quality improvement efforts, it is worth noting that the IOM discussed the option of transferring the QIO program to a different federal entity (i.e., AHRQ, Veterans Administration). Among the advantages of such an approach are that it would free CMS to focus on measurement and payment issues and to pursue a strong regulatory approach (when necessary) without fear of jeopardizing providers' willingness to participate in quality improvement. The IOM also noted that other federal agencies might better manage the program. Disadvantages included "the loss of the QIO apportionment, which supports other quality related projects." The IOM report also observed that moving the QIO program outside of CMS would jeopardize coordination between QIOs and the CMS offices responsible for public reporting, COPs, Medicaid, SCHIP, and Medicare payment (Institute of Medicine 2006).

Policy considerations in provision of technical assistance

In considering how Medicare can encourage diffusion of best practices and a culture of patient safety, this section discusses the advantages of focusing on low performers and explores the implementation issues that arise in pursuing this policy. Second, we reconsider the current infrastructure for delivery of technical assistance and contemplate the possibility that greater flexibility—in who provides the assistance, who chooses the assistance agent, and what the assistance is used for—is needed to stimulate real change. Increased flexibility can precipitate innovation, allow for local needs to be met, generate organizational buy-in, and allow for multiple sources of funds to be used synergistically. Increased flexibility, however, requires strong accountability, and for this reason it is useful (although not necessary) to consider these policy options in tandem with our discussion of conditions of participation.

Focusing assistance on low performers

CMS has introduced a policy of focusing its technical assistance on low-performing providers in the QIOs' latest SOW. The logic for this approach is multipronged, but implementation raises some design issues.

Advantages Focusing technical assistance on low-performing providers has several advantages. First, it helps address the problem of uneven quality that makes some Medicare beneficiaries vulnerable to the hazards of poor care. By informing poor performers of the proven techniques and innovations of the leading edge of providers, QIOs can reduce variation in the quality of care Medicare providers deliver. Moreover, because low-performing providers tend to care for proportionately more minority and poor patients, this focus could be an effective strategy in closing racial and socioeconomic disparities in care (see text box, pp. 84–85).

Second, targeting technical assistance can help providers with resource and knowledge constraints to respond to new payment policies. CMS already reduces payments to hospitals when avoidable complications occur during the inpatient stay and denies payments to hospitals for treatments in which unacceptable errors, known as "serious reportable events" (sometimes also referred to as "never events"), occur.[4] Also, the PPACA will penalize hospitals for high risk-adjusted readmission rates and, in the context of pay for performance, for poor risk-adjusted performance on a range of quality measures starting in 2012. These payment policies are intended to provide a financial incentive for hospitals to improve their quality of care.

The Commission recognizes that caring for patients with certain disadvantages (e.g., low income, low health care literacy, lack of social support, language barriers)—many of whom live in areas with little access to primary care—challenges providers' ability to effectively manage care over time. Targeted technical assistance could help providers address these challenges. This approach—

Targeting low performers may reduce racial and socioeconomic disparities in care

Improving quality of care among the lowest performing providers has the advantage of addressing persistent racial and socioeconomic disparities in care—disparities that have no place in 21st century American medicine.

Minority beneficiaries often receive health care from providers found to deliver lower quality care. For example, the Commission's research finds hospitals that serve relatively high proportions of minority and low-income Medicare beneficiaries have higher readmission rates than hospitals serving fewer minority beneficiaries. Because of the concentration of minority beneficiaries served by poorly performing providers, efforts to improve the performance of low performers should disproportionately benefit minority patients.

However, targeting technical assistance to low-performing providers would not necessarily address racial or socioeconomic gaps in care that arise from the same providers treating their minority and nonminority patients differently. The literature does not suggest this situation is a main source of disparities in care.

Racial patterns in the selection of providers

Minorities tend to receive most of their care from a limited number—20 percent to 25 percent—of the nation's physicians and hospitals (Bach et al. 2004, Jha et al. 2007, Jha et al. 2008). For physician services, Bach and colleagues analyzed Medicare claims data for Part B services provided in 2001 and found that 22 percent of primary care physicians accounted for roughly 80 percent of all physician office visits by African American Medicare beneficiaries, while the remaining 78 percent of primary care physicians accounted for 78 percent of the visits by white patients.

For hospital care, Jha and colleagues found that the top 25 percent of hospitals (about 1,100 hospitals) with the largest volume of African American patients provided care for nearly 90 percent of all elderly African American patients (Jha et al. 2007). There was further concentration within this quartile—the 5 percent of hospitals (222 hospitals) with the highest volume of African American patients accounted for almost 44 percent of the total volume of elderly African American patients. By comparison, the top 5 percent of hospitals with the highest volume of white patients cared for 23 percent of all white patients.

A similar pattern exists for Hispanic beneficiaries. The 5 percent of hospitals (227 hospitals) with the highest volume of elderly Hispanic patients cared for about 51 percent of all patients in that grouping, and the top quartile of hospitals (1,137 hospitals) with the largest proportion of Hispanic patients provided care for more than 90 percent of all elderly Hispanic patients in 2004 (Jha et al. 2008).

Providers serving a high portion of minority and economically disadvantaged populations have lower quality

Physicians treating African American beneficiaries were somewhat (but statistically significantly) less likely to have obtained board certification in their primary specialty than physicians treating white patients (77.4 percent compared with 86.1 percent); these physicians also were more likely to report that they could "not always" provide access for their patients to high-quality subspecialists, diagnostic imaging, nonemergency hospital admissions, and high-quality ancillary services (Bach et al. 2004). These findings are supported by other survey-based research that, while not focused exclusively on Medicare patients (and thus the findings are affected by factors such as patients' insurance status and coverage), shows primary care physicians treating predominantly minority patients were more likely to report difficulties providing high-quality care (e.g., getting referrals to high-quality specialists and spending enough time with patients) (Reschovsky and O'Malley 2008).

In a study of hospital quality of care, Jha and colleagues found that the top 25 percent of hospitals with the largest volume of African American patients had slightly lower performance on acute myocardial infarction quality measures and modestly lower performance on pneumonia quality measures than hospitals with a low volume of African American patients. They found no difference in congestive heart failure measures.

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Targeting low performers may reduce racial and socioeconomic disparities in care

Similarly, hospitals with high proportions of Hispanic patients had lower performance on quality indicators for all three conditions than hospitals with low proportions of elderly Hispanic patients.

Several other studies that examined disparities in the quality of one or more processes of inpatient care also found that large portions of the measured differences in quality between white and minority patients are accounted for by differences in the hospitals where the patients received their care (Barnato et al. 2005, Bradley et al. 2004, Gaskin et al. 2008, Groeneveld et al. 2005, Hasnain-Wynia et al. 2007). Among African American beneficiaries in a market with high racial segregation, the risk of admission to a high-mortality hospital was 35 percent higher than for whites in the same market (Sarrazin et al. 2009). Another study found that risk-adjusted mortality after acute myocardial infarction is significantly higher in hospitals that disproportionately serve African Americans (Skinner et al. 2005). A newly published study examined whether a hospital performs a high volume of 17 services for which a positive volume–outcome relationship has been documented. The researchers found that African American patients of all ages and insurance types in the New York metropolitan area from 2001 to 2002 were significantly less likely than white patients to use a high-volume hospital for all but one of the services examined, and Hispanic patients were less likely than whites to use high-volume hospitals for 15 of the 17 services (Gray et al. 2009). The observed differences in the use of high-volume hospitals did not seem to be accounted for by proximity (minorities actually tended to live closer to the high-volume hospitals) or insurance status (the differences persisted among patients with the same insurance coverage). The authors speculate that the most likely explanation for the observed patterns pertains to the physician a patient first sees for treatment and the referral process that follows.

Socioeconomic status also plays an important role in contributing to racial and ethnic disparities in access to and quality of care. Studies have found that racial and ethnic minorities are generally poorer than whites and are more likely to have family incomes near the federal poverty level. Low socioeconomic status usually is associated with substandard access to care, fewer community resources, and higher mortality (Cohen et al. 2003, Stewart and Napoles-Springer 2003). In an analysis of six common, high-risk surgical procedures for Medicare beneficiaries, researchers found that patients with lower socioeconomic status experienced significantly higher rates of risk-adjusted mortality than patients with higher socioeconomic status. Like racial and ethnic disparities in hospital and surgical care, disparities among beneficiaries from different socioeconomic groups seem to be driven by differences among the hospitals where patients receive treatment. At hospitals whose patients have the lowest average socioeconomic status, patients of both high- and low-status groups are more likely to die, while at hospitals whose patients have the highest average socioeconomic status, patients of both high- and low-status groups are less likely to die (Birkmeyer et al. 2008). Although socioeconomic status and race and ethnicity are related, researchers have found that when they control for socioeconomic status, racial and ethnic health care quality disparities are reduced but not eliminated (Barr 2008, Chassin 2002, Cohen et al. 2003).

Providers with high readmission rates tend to serve a high proportion of minority beneficiaries

In our own analyses of racially disparate care, we found that hospitals with high risk-adjusted readmission rates had a different racial and ethnic patient mix than their lower readmission rate counterparts (see online Appendix 3-A at http://www.medpac.gov). Hospitals in the top quintile of risk-adjusted readmission rates for 2005 through 2007—roughly 400 acute care hospitals and critical access hospitals—have, on average, a significantly higher percentage of minority Medicare patients than all other hospitals (Table 3-1, p. 86). This finding holds true for the aggregate comparison of all minority Medicare admissions by total count of admissions and proportion of admissions. These highest readmitting hospitals also have higher admissions counts and percentages of African American and Hispanic patients.

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Targeting low performers may reduce racial and socioeconomic disparities in care

TABLE 3–1 **Hospital percentage of Medicare admissions by race/ethnicity, 2007**

	Top quintile readmissions (mean)	Bottom four quintiles readmissions (mean)
White	72%*	86%*
Minority	29*	14*
African American	23*	10*
Hispanic	6*	2*

Note: *Statistically significant difference (p = 0.01) between hospitals in the top quintile of risk-adjusted readmission for 2005–2007 and other hospitals.

Source: MedPAC analysis of 2005–2007 MedPAR data.

Hospitals with the highest risk-adjusted readmission rates for the 2005–2007 period also differed from their counterparts on certain socioeconomic characteristics. Hospitals in the top quintile of readmission rates had, on average, a significantly higher percentage of disproportionate share hospital (DSH) funds and a greater likelihood of falling into the top quartile of DSH percentage. Additionally, these hospitals had a greater share of Medicaid days (data not shown). While DSH percentage and share of Medicaid days are imperfect proxies for the socioeconomic status of patients at a given hospital, our findings suggest that hospitals with the highest risk-adjusted readmission rates may serve a lower income population than hospitals with lower readmission rates.

While this seems to support the broad finding that minorities and low-income individuals receive care at lower quality institutions, causality cannot be determined. On one hand, minorities and low-income individuals may receive poorer quality care because they concentrate in low-performing institutions. Conversely, these institutions may report lower quality because they treat a challenging population in a community with a weak outpatient care infrastructure (see online Appendix 3-A at http://www.medpac.gov). ■

maintaining uniform standards and providing technical assistance—stands in contrast to an alternative approach that would lower quality benchmarks for hospitals caring for a high proportion of poor and minority patients as a way to lessen the likelihood they would be financially penalized. Such an approach essentially endorses a lower standard of care for a sizeable portion of poor and minority patients and ultimately may perpetuate care disparities.

Experience of the Medicare Premier Hospital Quality Incentive Demonstration suggests that when low-performing hospitals are provided support and a financial incentive, the performance gap between high and low performers can narrow substantially, if not be eliminated. In 2003—the year before implementation of the demonstration program—hospitals with a high share of poor patients had lower scores than hospitals with a low share on composite quality measures of care for AMI, congestive heart failure (CHF), and pneumonia. In 2007, the scores for the hospitals with a high share of poor patients across all three care composites had increased significantly more than the other hospitals, almost entirely eliminating the quality measure differentials that existed at baseline (Jha et al. 2009). Premier offered technical assistance to providers throughout the demonstration by helping them understand how they compared to other hospitals and informing them of strategies to improve their performance.[5] While encouraging, policymakers should consider these results with some caution, given that the hospitals participating in the demonstration self-selected and may not represent all low-performing hospitals.[6]

A third advantage of focusing on low performers and those with financial constraints is that it may minimize the likelihood that public resources would displace equally effective private sector resources. High-performing providers likely already have the resources necessary to make investments leading to high-quality care. Providing additional assistance to them effectively subsidizes their success using scarce public resources. Poor performers

may be less likely to take advantage of private sector technical assistance because of financial constraints that arise from a challenging environment (e.g., rural setting, low-income population) or a lack of commitment to improving quality.

Similarly, a focus on low performers may avert duplication with other federal initiatives through AHRQ that focus on identifying best practices and encouraging entities to function as technical assistance agents.

Design considerations Several design choices arise in pursuing an approach that focuses technical assistance primarily on poor performers. The first choice concerns the metrics to be used to measure quality or performance for the purposes of identifying which facilities should be eligible for additional assistance. Currently, CMS establishes quality priorities for the QIO program (e.g., nursing home pressure ulcers, improving surgical safety and care for heart failure, the use of physical restraints in nursing homes and hospitals) and identifies poorly performing providers for some of them.[7] The advantage of being specific is that proven quality improvement strategies can be implemented quickly to address these problems and thus save lives immediately, while fostering a culture of quality improvement at the facility. IHI used this type of strategy in its 100,000 Lives Campaign to improve patient safety; it identified six areas for improvement (e.g., rapid response teams, medication reconciliation) and provided practical tools to quickly implement changes (Bodenheimer 2007).

Under an alternative approach, low performers could be identified based on their performance on more general outcomes measures, such as rates of mortality, potentially avoidable complications, infections, and readmissions as well as patient experience measures. Ideally, at least some of these measures would evaluate performance across the hospital and not be specific to a condition or a department. Other measures, such as the community's emergency department use and admission rates, could also be considered, as they are indicators of whether the community has adequate access to primary care. Access to primary care is central to promoting health among beneficiaries and is an aspect of the health care delivery system that pioneering hospitals have been able to influence.[8]

The advantage of using risk-adjusted outcomes measures is that they define quality more broadly and more meaningfully for patients than intermediate outcomes measures or process measures. As Swensen and colleagues noted, "The bureaucracies required to track enough process measures for broad-based transformation of outcomes would be oppressive and expensive. A system that rewards better patient outcomes while encouraging innovation would be more efficient and effective. Furthermore, given that nearly 20% of all medical diagnoses are incorrect, rewarding a correct process (possibly for an incorrect diagnosis) makes less sense than recognizing our ultimate goal: superior outcomes for patients" (Swensen et al. 2010).

Using outcomes measures also allows providers flexibility in which quality improvement strategies they employ. For some, reducing patient mortality may require that they focus on strategies to align hospital and physician incentives in a way that promotes hand washing to prevent infections. For others it may be that certain HIT projects need to move to the top of the queue so that high-risk patients are identified upon admission. And for still others, it may require retraining staff on implementing checklists in the intensive care unit or operating room. A combination of these strategies may be necessary.

In addition, focusing on broad outcomes challenges facilities to work with their data and use self-assessment tools to identify targeted improvement strategies that affect hospital-wide performance. While some may not be accustomed to working with detailed performance data, the ability to do so may be key to precipitating genuine culture change.

There are three potential disadvantages of this approach. First, some facilities may not be sufficiently facile with using their performance data and assessment tools to identify the root causes of their problems, which delays their response in implementing effective improvement strategies. Second, the ability to risk-adjust outcomes measures may not be considered sufficiently precise to accurately compare hospital performance. Third, measuring the effect of Medicare's technical assistance may be difficult to tease out, compromising public oversight of the use of these funds.

A second design issue concerns whether assistance should be directed to low performers that do not face particular challenges, such as financial constraints, a high proportion of poor patients, or operating in a rural setting. Without such challenges, it may be reasonable to expect providers to improve performance without additional federal resources.

A related issue is whether assistance should focus on any particular provider types (e.g., physicians, hospitals, nursing homes). It could be argued that small physician practices and freestanding nursing homes would be good candidates for technical assistance, as they lack the infrastructure and economies of scale to implement quality-improving strategies on their own. Hospitals not part of a system or consortium may also be less likely to implement quality improvement. A counter argument is that Medicare should devote its technical assistance resources to promoting the formation of integrated delivery systems that are more likely to be able to deliver quality care efficiently. The integrated nature of these organizations can allow for better coordination of care and alignment of incentives across providers, particularly if payment changes such as those envisioned under accountable care organization proposals are enacted (Medicare Payment Advisory Commission 2009).

Similarly, another design question is whether Medicare should devote its quality improvement resources to providers that serve a high proportion of Medicare beneficiaries (e.g., hospices vs. ambulatory surgery centers, hospitals that care for a high volume of Medicare beneficiaries vs. hospitals with a low volume of Medicare beneficiaries). Or is Medicare's obligation to improve care regardless of the proportion of beneficiaries receiving care from the provider?

Another design question is whether assistance should be targeted to individual providers or whole communities, including a mix of providers and patient advocates. Targeting assistance to communities would take into account the fact that some quality issues are not specific to an individual provider. All providers in a community would benefit from improvements in communications, for example. Convening providers who normally do not meet to discuss systems issues can be a valuable form of technical assistance. There are limitations, however, to directing assistance to communities instead of providers. First, a "community" cannot be held accountable and many do not identify themselves as an entity with the capacity of collectively organizing quality improvements. Second, performance can vary greatly within the community, which suggests that not all the factors underlying low performance are shared across a community. In addition, technical assistance to one hospital could still lead to convening of providers. For example, reducing a hospital's readmission rate could well require reaching out to post-acute care providers, community physicians, and possibly other hospitals to address coordination issues.

Options for delivery of technical assistance

Who should provide technical assistance to low-performing providers or communities, and who should select which technical assistance agent can best meet their needs? For example, should CMS continue the QIO program as currently structured, relying on its core cadre of organizations that currently function as QIOs? Or should it designate other types of entities to provide the assistance? Or should providers or communities needing the assistance be provided a grant with which to obtain the technical assistance they think might best suit them?

Each option is explored below, but one overarching point is worth making at the outset. Providers need access to data on their performance compared with others. The data are necessary to evaluate whether new ideas produce genuine quality improvements, encourage successful sites of care to continue their work, and challenge slower adopters to make changes. Medicare currently posts performance data on its website that allow hospitals and nursing homes (and certain other types of providers) to compare their performance with others, but it does not report providers' patterns of care by episodes—information that can be key to improving care transitions but not possible for individual providers to ascertain on their own. An expert panel assembled by the Commission on October 22, 2009, to reflect a range of stakeholders strongly voiced the need for Medicare to make episode data available to providers on a timely basis to aid improvement efforts. Concerns about preserving provider and patient privacy would also need to be addressed in making this information a successful tool for quality improvement.

Option for CMS to continue contracting with current types of entities as QIOs Currently, CMS designates QIOs to serve each state through a competitive process. A subset of the QIOs may be competitively designated to focus on additional priorities, such as the 14 QIOs working to reduce preventable readmissions as part of CMS's care transitions initiative. QIOs identify providers to work with and their performance is measured along several different dimensions, depending on the specific task in the SOW.

Despite concerns about the effectiveness of the QIO program, the current approach to technical assistance, in principle, has some distinct advantages. First, the current QIO infrastructure has the appeal of making

available a geographically dispersed source of technical assistance and could be an ideal conduit for national efforts to disseminate quality improvement information. The IHI recruited select QIOs as part of its 100,000 Lives Campaign to function as "nodes" in disseminating quality information. Recent legislation authorizing investment in HIT also creates an extension agent network, presumably to address the need for a standing cadre of independent HIT assistance agents.

Second, the current QIO approach could allow the entities to focus on improving community health and as such address community needs comprehensively across providers and across quality improvement priorities (Brock 2009). A third advantage of the QIO structure is that the types of organizations currently eligible to be QIOs are independent from providers. When strictly adhered to, this independence can help avoid concerns about commingling of funds or the appearance of conflicts of interest.

If policymakers find the advantages of the current structure valuable, they may want to consider aspects of the QIO program that could be strengthened. Perhaps there are ways to stimulate a more entrepreneurial and innovative culture. Some QIOs report feeling restricted in their ability to be innovative and responsive to the needs of the communities due to micromanagement by CMS (Sutton et al. 2007). The challenge, however, is that the current program is also under pressure to demonstrate measureable improvement. This emphasis, while reasonable, can stifle the flexibility needed for the desired cultural change.

Option for CMS to contract with other entities to offer technical assistance Under this option, the Congress would change the law to allow more types of entities to contract as QIOs. Current law requires QIOs to serve an entire state and be either a "physician-sponsored" or a "physician-access" organization. These designations require specific thresholds for the number of physicians in the organization's ownership or membership. If these constraints were lifted, other entities, such as independent quality organizations, high-performing facilities or networks of providers, professional societies, and trade associations, among others, could potentially participate.[9]

Among the advantages of such a change are that these entities could stimulate the competitiveness of the program and allow the program to draw on the expertise in the field broadly, while also stimulating innovation among the current panel of QIOs. It could also allow for a better match between providers and agents of technical assistance. Some entities could provide assistance for a subset of quality problems but not others or for certain regions but not others. Similarly, some new types of QIOs might be able to offer assistance to one type of provider (e.g., rural hospitals) because of their unique qualifications but not others.

This approach has several disadvantages. First, the variability in participants would add complexity to administration of the QIO program. With more participants and more variation among them, measuring performance and comparing it with others would increase evaluation challenges. Second, because these organizations have commercial interests in marketing their services and would not have to maintain the distance from clients currently required in the QIO program, oversight of the integrity with which the funds were used could be more challenging. Third, while this approach reflects a significant shift in management of the program, it retains the current relationship in which providers are passive in assignment of the technical assistant agents. CMS would continue to make the selection in compliance with federal acquisition laws and various other statutory requirements that govern the selection and appeals process.

Option for providers to receive funds and determine the entity to provide technical assistance An alternative approach is for the government to provide a grant for technical assistance directly to the provider instead of funneling funds to QIOs. In turn, providers would be required to use that funding to obtain the assistance from a qualified organization of their choice. Current QIOs could compete with other entities to be the choice of providers in the market for assistance. One advantage of this approach is that it confers responsibility for performance improvement to the provider and, as such, could stimulate providers' commitment to improvement and better engage senior managers whose involvement can be so important to quality improvement (Bodenheimer 2007, Keroack et al. 2007). It also avoids some of the bureaucratic and statutory challenges associated with management of the QIO program, allowing providers more flexibility in identifying the areas they need to improve and choosing the technical assistant agent best able to address their needs.

Ideally, this approach harnesses the power of market forces as technical assistance agents have to prove their worth to consumers (i.e., health care providers) rather than

to the government. Taking out the role of government may appeal to providers uncertain not only of the government's expertise but also of its motivation; the government (directly and through its contractors) plays multiple roles simultaneously—payer, regulator, and quality improvement agent—and these roles can conflict.

To protect the taxpayer investment and provide some assurances that the money is being directed to reputable organizations, some constraints could be placed on what types of entities would be eligible to provide technical assistance. CMS could create a marketplace of technical assistance agents meeting certain standards, providing specific information about their areas of expertise and links to websites for further information. It could also post reviews of technical assistance providers by other providers who have used their services.

Nevertheless, this approach does not guarantee success and offers less ability to formally evaluate the effectiveness of technical assistance funding than the current approach. If the market fails to produce technical assistance agents that can provide a product of genuine value to providers, technical assistance resources will be wasted. This risk may be abated by having financial incentives for providers to improve quality (as have been recently enacted as part of health care reform) or intermediate sanctions as part of the survey process for compliance with the COPs. Under pressure, providers may be more engaged and savvy consumers.

Another issue concerns whether grants to providers sacrifice the economies of scale that QIOs can offer when they conduct conferences or collaboratives to address common quality problems. These economies may allow QIOs under the current structure to assist more providers than under this model where grants go to the low-performing providers or communities. It is possible, however, that providers or communities could opt to work with technical assistance agents that offer collaboratives or other types of group-learning forums and still capture efficiencies.

Under approaches that move away from having a limited, stable mix of QIO contractors, the question remains as to whether QIOs would retain their other responsibilities, such as handling beneficiary complaints, other case reviews, and system-wide quality improvement activities. Responsibility for these activities could be reassigned to other parts of CMS or to claims administration contractors, or it could be maintained with the current QIOs.

Use of conditions of participation to further motivate quality improvement

Although COPs have the potential to influence the quality of care provided to Medicare beneficiaries, the standards and the survey process that enforce them can likely be better leveraged to improve the performance of low performers as well as higher performers. For low performers, particularly those receiving technical assistance, clearly stated expectations and accountability for meeting those expectations can provide additional motivation to improve. For higher performers, the opportunity to meet performance criteria indicative of high quality and efficient care could resonate with their desire to distinguish themselves in the marketplace.

Effectiveness of current COPs and oversight

Several stakeholders we interviewed expressed concern that the COPs reflect a limited aspect of quality. The link between having certain structural requirements and process measures in place and having a culture of patient safety and quality improvement that produces good outcomes is tenuous. For example, the COP requirement for surveyors to affirm that hospitals' plan for patients' discharges may produce a less meaningful view of quality than if the COP required surveyors to review surveys that asked recently discharged patients if they understood what problems to look for, how to take their drugs, and who to call if they had a problem.

Studies have focused on the efficacy of COP enforcement, primarily through the accreditation process, rather than on a correlation between standards and quality outcomes.

Studies on the effectiveness of the accreditation and survey process provide mixed results. Studies have found little correlation between accreditation and general hospital mortality and no differences in rates of medication error between accredited and nonaccredited hospitals (Barker et al. 2002, Griffith et al. 2002). The media have also raised questions about the rigor or value of the surveys, citing a variety of examples where, following a Joint Commission's accreditation of a facility, glaring examples of poor care surfaced (Gaul 2005). Other studies raise relevant concerns, although they do not specifically reference the accreditation process, such as why so few boards are aware of their hospitals' relative performance on quality measures and how so many medication errors have occurred.

On the plus side of accreditation, one study of beneficiaries hospitalized for AMI found that accredited hospitals had higher scores on process measures (more likely to use aspirin, beta-blockers, and reperfusion therapy) and lower 30-day mortality rates than nonaccredited hospitals. (Considerable variation existed within accreditation categories, indicating that accreditation levels, which have since been modified, have limited usefulness (Chen et al. 2003).) Another study found Joint Commission accreditation to be associated with better outcomes for patients with AMI and CHF treated in rural hospitals compared with nonaccredited rural hospitals (Morlock et al. 2005). Researchers have found that the Joint Commission's national patient safety goals have led hospitals to focus on widely identified quality issues (Devers et al. 2004).

A recent opinion piece in *Health Affairs* praised some of the Joint Commission's improvements in the last several years (i.e., the national patient safety goals, the tracer methodology, and unannounced surveys) but expressed concern that "once low-hanging fruit has been picked" its approach is "ill-suited to drive progress in complex, nuanced areas." It cites as evidence the difficulty the Joint Commission had in creating a patient safety goal on medication reconciliation, concluding that the Joint Commission implemented the standard prematurely (Wachter 2010).

Because the Joint Commission accredits such a large share of the nation's hospitals while variation continues to exist in the level of quality provided, accreditation standards could be considered too inclusive to sufficiently promote quality care. This situation in part reflects the nature of the COPs, which do not cover accountability for health outcomes. It may also reflect the Joint Commission's educational role, as providers have up to 60 days to correct infractions detected in the course of a survey to earn accreditation status.

Policy options to maximize COP effectiveness

Several options exist for modifying the COPs in ways that could encourage providers to improve health care quality and value and enable beneficiaries to make more informed choices. These options include updating COPs to align them with current quality improvement efforts, creating interim sanctions, and developing voluntary or mandatory outcome-oriented requirements.

Update COPs to align them with current quality improvement efforts

If the COPs were updated in line with current quality improvement efforts, there would be greater opportunity to influence providers' adoption of recommended clinical practices and processes of care. The National Quality Forum recommends that CMS and the Joint Commission continue to review and update their accreditation standards for "currency, consistency, and alignment" (National Quality Forum 2004). Some possible areas for updating are discussed below.

The challenge of updating the COPs would be to avoid making the requirements so prescriptive that they did not allow for productive innovation. In addition, as a practical matter, promulgating regulatory changes is time-consuming and costly, while CMS is understaffed and underfunded. Therefore, to make COPs a more effective tool for quality improvement, consideration should be given to investing in a new process for making timely updates to both the COPs and their accompanying guidance on implementation and allowing input from the public on their development.

Encourage boards of directors to focus on quality improvement A recent study found that 66 percent of hospital boards thought their quality scores on the Joint Commission core measures or with Hospital Quality Alliance measures were better or much better than the typical U.S. hospital. As noted earlier, none of the boards of low-performing hospitals thought that their hospitals' quality was worse than the typical hospital: 58 percent of low-performing hospitals reported their performance to be better or much better (Jha et al. 2009). This finding is alarming, particularly because the COPs require that the board be involved in quality improvement. One solution could be for the COPs to be more specific and binding to encourage boards to better embrace their responsibilities. For example, board members could be required to document that they are aware of their hospital's relative performance on quality measures. Both National Quality Forum and the HHS Office of Inspector General (together with the American Health Lawyers Association) have published papers calling for greater board involvement (Callender et al. 2007, National Quality Forum 2004).

As part of this reform, it may also be important to focus responsibility on the boards of systems in addition to boards of the individual hospitals. The governing body at the system level may have control over more resources that could be devoted to quality improvement than individual hospitals.

Improve the discharge process For example, the COPs could require that hospital staff go over a discharge checklist with patients to increase the likelihood that they know how to care for themselves at discharge and decrease the chance they will be readmitted. They could require that follow-up appointments for community care be arranged before the patient is discharged or that providers use the teach-back approach to promote greater knowledge about self-care. These requirements would be in addition to existing ones that require a hospital to counsel patients and family members and prepare them for post-hospital care; supply lists of local Medicare-participating post-acute care providers; transfer or refer patients, along with appropriate medical records, for follow-up and ancillary care as needed; and reassess its discharge plans to ensure they are responsive to patients' needs at the time of discharge.

Demonstrate that physicians are participating in patient safety activities and are accountable Physician leaders have called for more accountability and consequences for physicians, saying that "as long as transgressions carry no risk of penalty, some providers ignore the rules, believing that they are not at risk for the mistake the practices are designed to prevent, that they are too busy to bother, or that the practice is ineffective" (Wachter and Pronovost 2009). To encourage hospitals to monitor physician actions in the hospital for appropriateness, the COPs could require hospitals to demonstrate that physicians are accountable for patient safety.

This type of requirement can vary in its stringency. On one side of the spectrum, the COPs could require that the hospital demonstrate that physicians participate in activities such as using checklists or team-based training (Livingston 2010). Further along the spectrum in rigor, the COPs could require that hospitals develop their own penalties for clinicians' failure to adhere to safe practices, such as failure to practice hand hygiene, marking the surgical site to prevent wrong-site surgery, or using the checklist when inserting central venous catheters (Wachter and Pronovost 2009).

The COPs could be strengthened to ensure that surveyors review hospitals' commitment to implementing an effective physician peer review process. Given how few doctors are reported to the National Practitioner Data Bank and the persistent culture of concealing medical errors, there is reason for concern that hospitals do not adequately monitor whether their physicians are practicing appropriate medicine (Levine and Wolfe 2009). Examples of physicians in Redding, California, and more recently in Towson, Maryland, performing unnecessary cardiac surgeries are reminders that monitoring is necessary.

Expand COPs to directly address efficiency Currently, the COPs require hospitals to perform quality improvement projects and demonstrate improvement. The standards are not prescriptive about the focus of the projects (e.g., reducing infections, better communication) but require that projects have objectives that surveyors can verify. One option would be to create a similarly structured requirement that hospitals perform process reengineering projects that are intended to reduce waste of hospital resources. Among other things, process improvements can achieve efficiencies by improving throughput and avoiding duplication of services (e.g., multiple imaging) or avoidable expenses (e.g., opening sterilized surgical supplies that ultimately are not used). Such improvements are likely to improve quality as well as efficiency but may not appear a priority among quality projects.

While, in theory, providers already have an incentive to reduce waste during patients' inpatient stays under Medicare's payment policy, it may not always be achieved. This outcome may in part be because hospitals are complex organizations with many competing priorities. It may be that the goal to maintain or increase the revenue stream requires that facilities focus on launching new service lines or buying state-of-the-art equipment rather than analyzing the inner workings of front-line staff to identify process improvements (e.g., a better maintenance schedule for portable oxygen machines, moving the supply cabinet) that eliminate resource-intensive (and quality compromising) "work arounds." Equipment failures and facility limitations have been identified by front-line staff as one of the most significant impediments to efficient and quality care, yet these types of deficiencies tend to attract little attention (Tucker et al. 2008).

IHI has launched programs on improving efficiency and reducing waste to complement its more quality-focused initiatives. It finds that changes in the current economic environment and mounting evidence that better care can come at lower cost provides the case for "the systemic identification and elimination of waste, while maintaining or improving quality." The aim therefore is "primarily financial; any positive impact on quality, while desired is secondary." Incorporated in IHI's vision of waste reduction is the need for organizations to establish a specific waste reduction aim in cost reduction terms (e.g., 1 percent to 3 percent of operating expenses per year). IHI calls hospitals that systematically address waste "industry pioneers" and

offers examples of strategies to reduce waste, including improvements in staffing (e.g., lower turnover, higher productivity, safer care), patient flow, and supply chain management, as well as as ways to reduce mismatched services (e.g., offering palliative care in the intensive care unit) (Martin et al. 2009).

Create intermediate sanctions

One problem with enforcement under the current survey and accreditation process is that the consequence for failing to pass the accreditation or survey criteria is so extreme—exclusion from the Medicare program—that such action is rarely taken. Intermediate consequences or sanctions that had a real possibility of being imposed could induce providers to improve care and make the accreditation and survey process more effective. A 1990 IOM study recommended that intermediate sanctions be adopted (Institute of Medicine 1990).

There are a range of types of intermediate measures. Under one approach, low-performing providers could be identified publicly, either solely through their performance on process or outcomes measures or in tandem with survey results. Already, under Medicare's Special Focus Facility program, nursing homes designated as deficient are identified publicly.[10]

Under another approach, COPs could require low performers to receive technical assistance. With respect to hospitals, for example, if insufficient improvement was found after some period of time the COPs could require that hospital boards submit a corrective action plan and require each member to verify the board's role in its implementation. The plan would need to be approved by CMS to avert exclusion from the program. Corrective action plans could describe the types of activities the hospital would pursue as well as any management changes the hospital was planning. More aggressive steps could also be contemplated. For example, CMS could prohibit hospitals from performing elective procedures in a given service line for some period.[11]

Given that the research suggests leadership is central to cultivating a quality culture and the evidence that boards of low-performing hospitals are unaware, requiring board involvement may trigger the needed cultural change. This combination of carrots (i.e., technical assistance, particularly if it comes in the form of a grant) and sticks (e.g., board implementation of a correction action plan or a moratorium on elective procedures) would strengthen the motivation of providers to adopt the quality innovations suggested through technical assistance.

Create voluntary higher standards

A more rigorous set of standards for which compliance was voluntary could be created that would allow providers meeting these standards to publicly distinguish themselves as high performers. Ideally, these standards could rely heavily on outcomes measures. If providers found the designation as a high performer valuable, more could be induced to meet a higher standard of care. Over time, depending on providers' response, the higher standard could become the new floor. To the extent that beneficiaries used this information in selecting their providers, more beneficiaries could receive higher quality care.

Several organizations have experimented with creating standards that providers could meet voluntarily to earn a designation that could be used publicly for marketing. Generally, the organizations reported improvements in quality.

- The Blue Cross Blue Shield Association (BCBSA) operates a Blue Distinction program for select conditions, including bariatric surgery, cardiac care, complex and rare cancers, knee and hip replacement, spine surgery, and transplants. Voluntarily, facilities can demonstrate they meet the quality criteria, composed of structure, process, and outcomes measures by reporting their own data to BCBSA. BCBSA has made more than 1,600 designations of distinction across 46 states, including about 500 designated centers for knee and hip replacement, 420 for cardiac care, and 83 for transplants. The program has not been formally assessed, but BCBSA reports anecdotes of facilities responding to the incentives by allocating more resources to quality improvement of certain departments and new participation in national registry programs, such as the Society of Thoracic Surgeons or the American College of Cardiology programs. Facilities that meet the Blue Distinction criteria have lower mortality rates and lower episode costs for the selected conditions (Izui and Flamm 2010).
- UnitedHealthcare has a Premium Designation Program for cardiac care and designates high-quality, efficient specialty physicians and hospitals. It reports that preliminary data indicate an average savings of $3,500 per cardiac episode at these hospitals compared with other hospitals in the area.

This program builds on the success of the Premium Network program, which focuses on transplants, rare cancers, and congenital heart disease and is managed by an affiliate of UnitedHealthcare. Patients who received care from designated providers under that program were found to have higher survival rates and less costly care (UnitedHealthcare 2010).

- The National Committee for Quality Assurance (NCQA) has used voluntary standards in the past, allowing its members to demonstrate coordination-of-care efforts. NCQA reports that the health plans that met the standards found the distinction valuable. As evidence, one of these plans took out a full-page ad in the *New York Times* touting the distinction. Subsequently, those standards were incorporated into the health plan accreditation requirements (Torda 2010).

- The Joint Commission has a Disease-Specific Care Coordination Program (for more than 29 conditions) as well as an "advanced level of certification" in seven clinical areas (e.g., primary stroke center, chronic kidney disease). To be certified, programs must demonstrate compliance with consensus-based national standards and safety goals, effective use of clinical practice guidelines, and an organized approach to performance measurement and improvement activities (Joint Commission 2009a).

Two levels of COP designation, such as gold and platinum, could be advantageous to consumers, who are less likely to distinguish among providers by poring over statistics on various performance measures. One important design consideration would be whether the higher standards should be service-line specific, hospital wide, or system wide. Having publicly reported performance data available on an aggregated basis (in addition to more disaggregated data) could attract the attention of senior managers with the most control over allocation of resources and ultimately encourage them to invest in ways to export innovations to other parts of the organization. This approach to performance reporting would help minimize the chances that innovations stay isolated in just one unit of a hospital or in just one flagship hospital of a multihospital system.

Create mandatory outcomes-oriented standards for select services

The COPs could possibly be used to address the concern that Medicare fails to adequately direct patients to better quality providers for certain high-cost and complicated procedures. One option would be to amend the COPs to incorporate outcomes or volume criteria for select services, much like it does for transplant centers, restricting payment for certain services to providers that demonstrate sufficient volume and quality.

The COPs for transplant services differ from COPs for other services and are more proactive in ensuring quality. In addition to requirements for quality improvement programs and notifying patients about their rights, transplant centers also have requirements for their clinical experience and patient outcomes. Transplant centers must generally perform an average of 10 transplants per year. In addition, CMS will compare each transplant center's observed number of patient deaths and graft failures one year post transplant with the center's expected number using the most recent Scientific Registry of Transplant Recipients center-specific report. If observed patient survival or graft survival rates are below expected (and fail certain other statistical tests), CMS will not consider survival rates acceptable.

CMS issued the outcomes-based COPs for transplant centers in 2007 in an effort to maintain state-of-the-art practice and standardize requirements for transplant centers nationwide. Previously, performance standards for a transplant center were organ specific and based on localized outcomes in each service area. This situation raised concerns about variation in a localized outcomes measure, which prompted the requirement for uniform transplant center COPs in the Organ Procurement Organization Certification Act of 2000 (Centers for Medicare & Medicaid Services 2005).

Mandatory higher standards, such as outcomes and volume criteria, would likely be most appropriate for complex and costly procedures, which are not normally needed on an urgent basis. Certain cardiac procedures, such as coronary artery bypass graft, and certain orthopedic procedures may be the types of procedures for which this approach may be appropriate.

The possible disadvantages to this option are that it requires consensus about the evidence governing the criteria, beneficiaries may have to travel farther to access certain services, and such restrictions create barriers to entry for new providers and could therefore stymie a competitive marketplace. ■

Endnotes

1 In January 2009, CMS announced that it was concluding QIO work on reducing pressure ulcers in hospitals. It noted that all 53 QIOs recruited hundreds of hospitals to work to reduce pressure ulcers, but after 18 months of work overall rates of pressure ulcers "remained relatively low across the nation"—a rate too low for this initiative "to bring about a substantial national-level impact on hospital safety" (Centers for Medicare & Medicaid Services 2010).

2 The American Osteopathic Association and DNV Healthcare, Inc. accredit a small portion of the nation's hospitals.

3 As part of their work under the beneficiary protection theme in the SOW, QIOs are required to conduct case reviews on quality-of-care complaints by beneficiaries and conduct certain utilization reviews, among other things. QIOs are also required to perform quality improvement activities (QIAs). A QIA is defined as an activity initiated by the QIO that requires: (a) an identified provider to articulate a plan or activity to improve an identified quality concern and (b) the QIO to follow up to ensure that the plan is complete or the action has been taken (Centers for Medicare & Medicaid Services 2008). QIOs must identify at least one QIA with an impact that is system wide. As an example, IPRO, the QIO serving New York, has found "that many of the issues identified and confirmed through the case review process relate to concerns that impact/can impact a patient's readiness for discharge as well as increase the potential for readmission. [The] findings include such things as failure to address abnormal laboratory results obtained prior to discharge as well as unclear or incomplete discharge instructions" (IPRO 2009).

4 As of October 1, 2008, Medicare does not assign an inpatient hospital discharge to a higher paying Medicare severity–diagnosis related group (MS–DRG) if the only secondary diagnosis on the claim for the stay is one or more of eight selected hospital-acquired conditions (HACs) and if the condition was not present at admission. In those cases only, Medicare will pay the hospital as though the secondary diagnosis (the HAC) were not present, in effect not paying the hospital to treat the HAC. However, the nonpayment applies only when the specified HACs are the only secondary diagnoses on the claim; if the claim has at least one non-HAC secondary diagnosis that qualifies as a complication or comorbidity (CC) or a major complication or comorbidity (MCC), the claim is paid under a higher paying MS–DRG classification.

The Commission has expressed its concern that Medicare's current HAC payment policy does not give a strong enough incentive for hospitals to eliminate the subset of HACs known as "serious reportable adverse events" (also referred to as "never events"), such as a foreign object retained after surgery, air embolism, blood incompatibility, stage 3 or stage 4 pressure ulcers, and falls or other injury trauma. For these HACs, the Commission suggests that the presence of the HAC upon discharge should bar assignment to a higher paying MS–DRG regardless of whether any other CCs or MCCs are on the claim for that inpatient stay.

5 One independent evaluation of the experience of four hospitals participating in the Medicare Hospital Quality Incentive Demonstration (HQID) noted that the local QIOs worked with the participating hospitals on the HQID project. According to this study, the four hospitals participating in the demonstration formed a collaborative workgroup in the early stages of the project that included the hospital system's corporate quality management department, representatives from Premier, and representatives from the QIOs that worked with the four participating hospitals in Kentucky and Ohio (Grossbart 2006).

6 Another program that could offer insights about the effectiveness of targeting assistance to low performers is the Nursing Homes in Need initiative, which is part of the ninth SOW and requires that QIOs work with a poor-performing nursing home each year of the three-year contract. A final evaluation is not available.

7 For other quality priorities in the ninth SOW, CMS does not identify low performers or require QIOs to focus on low performers. These priorities include improving drug safety, reducing methicillin-resistant *Staphylococcus aureus* infections, care transitions, and prevention.

8 See the Commission's March 2010 meeting transcript at http://www.medpac.gov for the testimony by Denver Health and Parkland Hospital for examples on how they have improved outpatient and community care.

9 One possible model could be similar to the proposed Medicare Chronic Care Practice Research Network, a group of 12 health care provider and research organizations, which stated its mission as "to serve as the leading national resource available to advance the science and operational standards of care management for the chronically ill Medicare population, with special focus on their widespread adoption and relevance to new and improved payment policies." This model was discussed in the Commission's June 2009 report, and while the Commission found problems with the policy design of the specific proposal, the notion of a network of providers being funded directly as a change agent represents an alternative way for QIOs to fund improvements.

10 The Special Focus Facility program provides for close monitoring of poorly performing nursing homes across the country.

11 Other aggressive approaches have been authorized for deficient nursing homes. When a nursing home is cited with one or more deficiencies that constitute immediate jeopardy to resident health or safety, the law allows for "federal temporary management." The temporary management appointed by CMS has full authority to hire, terminate, or reassign staff; spend nursing home funds; alter nursing home procedures; and otherwise manage a home to achieve its objectives. In reviewing the program, the Government Accountability Office found that most homes under temporary management (15 between 2003 and 2008) corrected deficiencies in the short term, although some continued to have compliance issues in the longer term.

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CHAPTER 4

Graduate medical education financing: Focusing on educational priorities

RECOMMENDATIONS

4-1 The Congress should authorize the Secretary to change Medicare's funding of graduate medical education (GME) to support the workforce skills needed in a delivery system that reduces cost growth while maintaining or improving quality.

- The Secretary should establish the standards for distributing funds after consultation with representatives that include accrediting organizations, training programs, health care organizations, health care purchasers, patients, and consumers.
- The standards established by the Secretary should, in particular, specify ambitious goals for practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice, including integration of community-based care with hospital care.
- Performance-based GME funding under the new system should be allocated to an institution sponsoring GME programs only if that institution met the new standards established by the Secretary, and the level of funding would be tied to the institution's performance on the standards.

The indirect medical education (IME) payments above the empirically justified amount should be removed from the IME adjustment and that sum would be used to fund the new performance-based GME program. To allow time for the development of standards, the new performance-based GME program should begin in three years (October 2013).

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

4-2 The Secretary should annually publish a report that shows Medicare medical education payments received by each hospital and each hospital's associated costs. This report should be publicly accessible and clearly identify each hospital, the direct and indirect medical education payments received, the number of residents and other health professionals that Medicare supports, and Medicare's share of teaching costs incurred.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

4-3 The Secretary should conduct workforce analysis to determine the number of residency positions needed in the United States in total and by specialty. In addition, analysis should examine and consider the optimal level and mix of other health professionals. This work should be based on the workforce requirements of health care delivery systems that provide high-quality, high-value, and affordable care.

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

4-4 The Secretary should report to the Congress on how residency programs affect the financial performance of sponsoring institutions and whether residency programs in all specialties should be supported equally.

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

4-5 The Secretary should study strategies for increasing the diversity of our health professional workforce (e.g., increasing the shares from underrepresented rural, lower income, and minority communities) and report on what strategies are most effective to achieve this pipeline goal.

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

CHAPTER 4

Graduate medical education financing: Focusing on educational priorities

Chapter summary

Our nation's system of medical education and graduate training produces superbly skilled clinicians while contributing to stunning advances in medical science. Yet, it is not aligned with the delivery system reforms essential for increasing the value of health care in the United States. Research discussed in our June 2009 report, for example, found that internal medicine residency programs had limited focus on skills such as quality measurement and improvement, evidence-based medicine, multidisciplinary teamwork, care coordination across settings, and health information technology. These skills are important for producing the health professionals we need for a high-performance delivery system—one that provides high quality, high value, and efficiently delivered services.

Medicare is the single largest payer of graduate medical education (GME)—$9.5 billion in 2009—but requires minimal accountability from its recipients for achieving education and training goals. Approximately $3 billion of Medicare's payments is intended to support Medicare's share of the direct costs of running GME programs. The other $6.5 billion is intended to support Medicare's share of the indirect clinical costs associated with the presence of GME. Commission analysis has shown that this amount is $3.5 billion higher than the empirically calculated indirect clinical costs associated with teaching (Medicare Payment Advisory Commission 2010).

In this chapter

This chapter presents the Commissions' summary assessment of gaps in the current GME system—with particular attention to financing issues—and makes a set of recommendations to address some of the identified concerns. Two principles underlying these recommendations are: the need to decouple Medicare's GME payments from fee-for-service (FFS) payment systems, and the need to ensure that resources for GME are devoted to meeting educational standards and outcomes that can improve the value of our health care delivery system. We also discuss the importance of understanding workforce requirements for improved health care delivery in the 21st century.

Commission's summary assessment of the GME system

Despite the tremendous advances that our GME system has brought to modern health care, the Commission finds it is not consistently producing physicians and other health professionals who can become leaders in reforming our delivery system to substantially improve its quality and value. Two specific areas of concern are workforce mix—including trends in specialization and limited socioeconomic diversity—and education and training in skills needed for improving the value of our health care delivery system—including evidence-based medicine, team-based care, care coordination, and shared decision making.

We cannot accomplish delivery system reform without simultaneously ensuring that the providers we need have the skills necessary to integrate care across settings, improve quality, and use resources efficiently. In a recent *New England Journal of Medicine* article, prominent physicians assert that not only do residents need to learn relatively new skills, they need to develop a new perspective on what it means to be a "good doctor"—shifting emphasis, for example, from independent and autonomous practice to more patient-centered, team-based care (Swensen et al. 2010).

Our GME system is influenced not only by how Medicare subsidizes it but also by how Medicare and other insurers pay for health care services. FFS payment systems reward volume without regard to quality and their levels of payment for physician services tend to reward performing procedures over patient evaluation, management, and care coordination. These payment signals likely affect not only physician career choices but also institutional decisions about which residency programs to offer.

Commission recommendations to address gaps in the GME system

First, the Commission recommends increasing accountability for Medicare's GME payments. We recommend establishing a performance-based incentive program with payments to institutions contingent on reaching desired educational outcomes and standards. Eligible institutions would include teaching hospitals, medical

schools, and other entities that may sponsor residency programs. In determining the criteria for evaluating performance under this program, the Secretary of Health and Human Services would consult with organizations and individuals with the necessary expertise and perspectives—specifically, representatives from organizations such as program accrediting bodies, certifying boards, training programs, health care organizations, health care purchasers, and patient and consumer groups. From these deliberations, the Secretary would develop a GME payment system that fosters greater accountability for Medicare's GME dollars and rewards education and training that will improve the value of our health care delivery system. Although accrediting standards for residency programs are moving in this direction, the Commission recommends that Medicare institute financial incentives to accelerate these efforts.

Funding for this initiative should come from reducing Medicare's indirect medical education (IME) payments to eliminate the amount currently paid above empirically justified IME costs. Although some could assert that this amount should not be expended at all, the Commission determined that Medicare should use this amount to fund incentive payments to institutions meeting specified educational standards. Only those institutions meeting these educational standards specified by the Secretary should be eligible for such incentive payments; conceivably, therefore, all, some, or none of this amount could be distributed, depending on performance. Future assessment of the GME payment system might consider making even larger portions of Medicare's GME payments contingent on performance.

Second, the Commission recommends making information about Medicare's payments and teaching costs available to the public to foster greater accountability for educational activities within the GME community. To encourage collaboration between educators and institutions on residency program funding decisions, Medicare should make information about GME payments and costs more accessible. Although interpreting reported cost data may require some caveats, the transparency of this payment and cost information will recognize Medicare's significant investment in residency (and some nursing) training and education.

The final three recommendations in this chapter call for studies to examine specific aspects of health workforce training. Currently, Medicare's payments for GME generally subsidize the specialty choices of both teaching hospitals (in their program offerings) and residents (in their career choices). The resulting physician mix of specialties is unlikely to ensure that the nation has an efficient supply of health professionals for well-functioning delivery systems, as evidenced by falling shares of physicians practicing primary care after their residencies. The Commission recommends that a rigorous, independent analysis of our health

care workforce be conducted regularly. This analysis should be driven by the requirements of a high-value, affordable health care delivery system. Analyses that simply extrapolate demand projections based on current patterns of care could compromise the nation's chances of fostering high-value health care systems. An improved delivery system will influence the total number of physicians and the mix of professionals needed in our health workforce. Consequently, any decisions about Medicare's funding of new residency positions should await the results of such a study.

Also in question is the optimal level of Medicare GME payments by resident specialty type. Institutional costs and benefits of supporting residency programs are likely to vary significantly by specialty. For example, some specialties may require greater supervision costs, while others may attract higher volumes of more profitable services to the institution. There is little research on these differences. To learn how Medicare could adjust its subsidies for residency programs to make them more economically efficient, a specialty-specific analysis of net institutional costs and benefits would be useful.

A third workforce goal that deserves concerted attention is to find the most effective strategies for increasing the diversity of our pipeline of health professionals (i.e., increasing the share of professionals from underrepresented racial and ethnic minorities, from lower income families, and from rural hometowns). Research has found that a diverse health care workforce is associated with better care quality and access for disadvantaged populations, greater patient choice and satisfaction, and better educational experience for students in health professions. A number of programs, administered by the Health Resources and Services Administration, are designed to address this goal. While research on several specific programs shows some positive impacts, comprehensive evaluation of these programs' longitudinal effectiveness is not well studied. Therefore, a study that outlines a strategy for achieving specific health care workforce-diversity goals is essential to optimize federal subsidies for this effort. ■

Over the last two years, as the Commission examined ways to improve graduate medical education (GME) financing, it became clear that delivery system reform cannot be accomplished without simultaneously ensuring that the physicians and other health professionals we need have the skills necessary to integrate care across settings, improve quality, and use resources efficiently. Although the nation's GME system produces superbly skilled clinicians and stunning advances in medical science, greater attention is needed to align its educational goals with the nation's delivery system needs. This chapter presents the Commission's assessment of problems in the GME system and offers a set of recommendations. Two principles underlying these recommendations are: the need to decouple Medicare's GME payments from fee-for-service (FFS) payment systems, and the need to ensure that resources for GME are devoted to meeting educational standards and outcomes that can improve the value of our health care delivery system. We also discuss the importance of understanding and meeting health care workforce goals for the 21st century.

Commission's summary assessment of the GME system

Our nation's system of GME is, in some respects, the best in the world: U.S. teaching hospitals produce thousands of new physicians each year—physicians who are superbly skilled and able to apply cutting-edge technology and techniques to aid severely ill or injured patients. Teaching hospitals often serve as linchpins of their local health care systems, and many contribute to stunning advances in medical science.

The GME system is not, however, consistently producing the physicians and other health professionals needed for a 21st century health care delivery system, one focused on high-quality, high-value, and affordable care. That is not just our assessment but also the assessment of some active participants in GME as well as many health care delivery organizations, insurers, corporate purchasers, and organizations representing patients and consumers (Blumenthal 2002, Council on Graduate Medical Education 2007b, Holmboe et al. 2005, Institute of Medicine 2008, Ludmerer and Johns 2005, Meyers et al. 2007, Mullan 2009, Swensen et al. 2010).

Gaps in the current GME system

We find gaps in the mix of physicians being produced (including their specialty, their geographic distribution, and their socioeconomic diversity) and in the content of their education and training. (In addition, there are distinct, but complementary, problems in the education and training of other health professionals, which are critical as well. However, this chapter focuses principally on the training of physicians, as does Medicare's GME funding.)

Physician mix

The specialty mix of physicians coming through the GME pipeline is not well matched to the needs of an efficient, high-quality, high-value delivery system. As discussed in our June 2009 report, a reformed delivery system that focuses on effective chronic care and keeping patients from needing to be hospitalized will require primary care physicians who can function with other health care professionals and specialists as part of a patient's health care team. These primary care providers are essential to a well-functioning delivery system, yet the mix of specialists and primary care graduates from residency programs has been tilting more toward specialists (American College of Physicians 2006, Colwill et al. 2008). Specifically, the proportion of third-year internal medicine residents becoming generalists is declining because a growing share is choosing to subspecialize or become hospitalists after residency (Bodenheimer 2006).[1]

In addition, there is insufficient socioeconomic diversity among physicians entering the pipeline, and too few are drawn from rural areas and inner cities, which may mean a reduced propensity to practice in these often underserved areas. Studies show that residents tend to select practice locations that are similar to where they grew up and where they trained (Brooks et al. 2002, Phillips et al. 2009). Yet, medical schools and residency programs are concentrated in certain areas of the country and draw students from families with considerably higher incomes than the population at large has (Association of American Medical Colleges 2008). Socioeconomic diversity in the physician workforce is crucial for improving patient access to culturally responsive care. In addition to programs sponsored by the Health Resources and Services Administration (HRSA), efforts to increase physician workforce diversity have been undertaken by private foundations and other organizations such as the Association of American Medical Colleges, but diversity is still insufficient, suggesting that we need to examine the effectiveness of current strategies.

Additionally, prudent workforce strategies need to address other health professionals, such as nurse practitioners and physician assistants, who provide essential patient care and enhance the effectiveness and efficiency of physician time and expertise.

Content and outcomes of physician training

The GME system should embrace a more systematic effort to instill the skills and perspectives needed to accelerate the development of a high-quality, high-value, and efficient delivery system, including (but not limited to) evidence-based medicine, team-based care, care coordination, and shared decision making. A recent article authored by numerous well-regarded physicians asserts that not only do residents need to learn relatively new skills, they also need to develop a new perspective on what it means to be a "good doctor"—shifting emphasis, for example, from independent and autonomous practice, to more patient-centered, team-based care (Swensen et al. 2010).

A reformed delivery system will require health care professionals trained to provide coordinated care across institutional boundaries and trained in the skills required to promote patient safety and quality. Yet, studies show that this kind of training is not routinely provided in residency programs today (Cordasco et al. 2009, Council on Graduate Medical Education 2007a, Council on Graduate Medical Education 2007b, Lucien Leape Institute 2010, Medicare Payment Advisory Commission 2009). These findings suggest that although the Accreditation Council for Graduate Medical Education (ACGME) has begun instituting outcome-based standards for some of these newer skills and competencies, progress on them has been slow. Some of these shortfalls are compounded by a GME system focused too heavily on inpatient care. Although experience in caring for hospital inpatients is an indispensable part of a physician's education, greater focus on providing ambulatory care for chronically ill patients with complex health care needs is essential for preventing avoidable hospitalizations and improving overall care delivery.

Payers' role in fostering gaps in GME system

The GME system is not solely responsible for these gaps and problems. Medicare has played a large role in shaping—some would say distorting—the GME system. GME is influenced not only by how Medicare subsidizes it but also by how Medicare pays for health care services. In making decisions about their clinical and training priorities, teaching hospitals likely consider financial signals from Medicare about what types of care are most valued. Those signals are embedded in the methods used to pay for services and the relative rates paid for different services. For example, Medicare's FFS payment system rewards volume without regard to quality. At the same time, the physician payment system has tended to reward procedural over cognitive care. While the Congress and CMS have increased payments for some cognitive services, the rewards for high volumes of lucrative procedures cannot help but influence hospitals' choices of which specialty residency programs to support and the programs' relative sizes.

Payment levels are also an important influence—although not the only influence—on the specialty preferences of physicians in training. Although lifestyle factors and the nature of the clinical and administrative work affect career choices, residents—many of whom face large debt levels for their education—reasonably look at future earnings prospects when choosing a specialty. Medicare payment rates can influence that choice. The payment methods used by other insurers, which are often based on Medicare's system, intensify these signals.

Medicare's role in GME reform

Aside from changes in the way Medicare pays for services, Medicare can modify its GME financing structure to support and accelerate delivery system reforms. Currently, some GME payments are calculated as a percentage add-on to inpatient hospital admissions and others are calculated based on Medicare's share of patient days; neither of these methods is an effective means for encouraging hospitals to foster ideal educational programs and environments. Thus, where possible, Medicare's subsidies for GME should be decoupled from its payment for services and instead directed toward educational goals (see the text box for a description of Medicare's current GME payments in more detail).

Delivery system reform cannot be accomplished without simultaneously ensuring that the physicians and health care professionals we need across this country have the skills necessary to integrate care across settings, improve quality, and use resources efficiently. The Commission considered whether federal subsidies for GME should be removed from Medicare and instead distributed through general revenues. Although a case could be made for this approach—considering that GME is thought by many to be a public good that benefits the nation as a whole—there were concerns with GME funding stability among other issues. On balance, the Commission determined that significant improvements can be accomplished through adjustments to current Medicare payment policies.

Medicare's payments for graduate medical education

Since its inception, Medicare has provided substantial support for graduate medical education (GME) in the United States. Its primary mechanism for these subsidies is through payments to teaching hospitals to support their higher patient care costs and physician residency programs. Medicare's GME payments for 2009 totaled an estimated $9.5 billion—averaging more than $100,000 per resident. These payments are divided into direct and indirect GME payments.

Direct GME (DGME) payments are intended to support the teaching aspects of residency programs, such as resident stipends and benefits, supervisory physician salaries, and administrative overhead expenses. DGME payments are based on a hospital-specific per resident payment amount that was determined in 1984, updated for inflation. This amount is applied to Medicare's share of the hospital's inpatient days (both fee-for-service and Medicare Advantage). Subspecialty fellowship positions are funded at half the amount of core-year residency positions. The total number of residents supported by Medicare is capped per hospital at 1996 levels. Medicare also provides some education funding to hospitals to support direct costs of hospital-based education and training programs for nursing and various allied health professions. Medicare's DGME payments totaled an estimated $3 billion in 2009.

Indirect medical education (IME) payments are designed to support the higher costs of patient care associated with teaching, such as residents' "learning by doing," greater use of emerging technologies, and patient severity. Based on a formula, IME payments are an adjustment—a percentage increase—to Medicare's inpatient payment rates and vary based on hospitals' "teaching intensity" (as measured by the ratio of residents to hospital beds). Therefore, hospitals' IME payments are tied to their Medicare inpatient volume and case mix as well as the size of their residency programs (subject to their resident cap number). Medicare makes separate adjustments for operating and capital payments. Hospitals also receive IME payments from Medicare for Medicare Advantage patients.

Medicare's IME payments totaled an estimated $6.5 billion in 2009, but repeated Commission analysis finds that only 40 percent to 45 percent of these payments can be analytically justified to cover the higher patient care costs of Medicare inpatients. In essence, the current adjustment is set at more than twice what can be empirically justified, resulting in an estimated $3.5 billion directed to teaching hospitals with little accountability for their use of these funds.

Federally qualified health centers, rural health clinics, and Medicare Advantage plans that sponsor residency training programs can also receive Medicare DGME payments. In the future, teaching health centers (established in the Patient Protection and Affordable Care Act of 2010 as community-based, ambulatory patient care centers that support primary care residency programs) will receive payments to support direct and indirect costs, but funding will be authorized in a manner similar to that for the Children's Hospital GME program (CHGME) and will not come from Medicare. The Health Services and Resources Administration manages the CHGME program and will manage the teaching health centers program. ■

Physician mix

The single most important way Medicare can influence the mix of physicians being produced by the GME system is to reform how it pays for services. The Commission discussed the importance of promoting primary care and testing other payment models, such as medical homes, in its June 2008 report. The Congress and CMS have also taken steps toward these goals. If Medicare changes its signals about what care is valued, the GME system will likely respond.

Given the fiscal challenges confronting the federal government, current federal subsidies for physician and other health professional training should ideally be redesigned, not increased. If there is any increase in the number of residents Medicare supports, it should be founded on a careful analysis of future workforce needs that is driven by the needs of an efficient, high-quality, high-

value system. An extrapolation of workforce needs based on current patterns of care would not just fail to meet the future needs of a high-quality, high-value, efficient delivery system, it could compromise the nation's chances of developing such a system by producing increasing numbers of providers who have a stake in the status quo.

Content and outcomes of physician training

Medicare should move toward a more accountable GME payment system that focuses on improving educational performance among institutions and residency programs. Such reforms likely will result in redistribution of current Medicare GME payments. Accordingly, changing how Medicare subsidizes GME should catalyze improvements in the content of GME instruction and resident experience. Although ACGME's outcome-based standards for residency programs are moving in this direction (as described later in this chapter) the Commission recommends that Medicare institute financial incentives to accelerate these efforts.

Medicare should not unilaterally presume to prescribe curricular content or teaching method. Any criteria for educational content should be the product of deliberation among parties with the necessary expertise and perspective, including accrediting organizations, certifying boards, government advisory bodies, teaching institutions, residency program directors, leading health care delivery systems, insurers, purchasers, and patients. Through ensuring that such deliberations proceed with the necessary speed and focus, Medicare can specify the results it expects from its substantial investment in GME and structure payment incentives that help align the educational process to those outcomes.

Role of other federal programs

Federal programs other than Medicare could also contribute to improving the output of the GME system as well as to the development of other important health professionals. Several HRSA programs are designed to attract individuals—particularly from minority, rural, and low-income communities—to health careers through a variety of incentives, ranging from early education (grade school) programs to loan repayment programs. HRSA programs are also focused on promoting primary care access, particularly in underserved areas, and enhancing the cultural competence of this workforce by funding opportunities for medical students and residents to train in diverse settings and locations. These programs have the potential to improve the mix of health professionals (through increases in socioeconomic diversity, rural access, and primary care providers) and should be subject to rigorous evaluation and improvement.

Second only to Medicare, Medicaid is another financer of GME. Because many states currently base their GME payments on Medicare's structure, changes in Medicare GME payment policies may also affect Medicaid policies. The Department of Veterans Affairs (VA) is also an active participant in GME, with more than one-third of residents rotating through VA facilities during their training. Research has shown that residents who rotate through the VA system gain delivery system skills, such as competencies in comprehensive health information technologies and multidisciplinary teamwork (Byrne et al. 2010, Congressional Budget Office 2007, Cordasco et al. 2009). Thus, the VA is likely to be an important partner in improving the GME system.

Commission recommendations to address gaps in the GME system

In consideration of these identified concerns, the Commission makes a set of recommendations to address fundamental weaknesses in Medicare's system of GME subsidies. Two principles inherent in these recommendations are: the need to decouple Medicare's GME payments from FFS payment systems and the need to ensure that resources for GME are devoted to meeting educational standards and outcomes that can improve the value of our health care delivery system. The recommendations include linking GME payments to performance on educational standards and outcomes, increasing the transparency of and accountability for these payments, examining how best to assess health care workforce needs, assessing the impact of residency programs on hospitals' financial performance, and identifying strategies for increasing the diversity of the nation's physician workforce.

Link payments to performance to meet education and training goals for delivery system reform

Financial incentives that link GME payments to performance on educational standards and outcomes—such as resident competencies and adequate faculty support—can be important tools for encouraging more rigorous educational agendas among institutions and residency programs. Particular focus should be on skills

essential for delivery system reform, such as quality measurement and improvement, evidence-based medicine, multidisciplinary teamwork, care coordination across settings, and health information technology. Although accreditation standards are moving in this direction, the Commission recommends that Medicare institute GME financing policies to accelerate these efforts. Funding for performance-based incentives should come from a significant reduction in IME payments.

Accelerate the progress of improving GME outcomes

Currently, Medicare's only method for ensuring accountability for educational standards is its requirement that residents be in accredited residency programs. Most physician residency programs are accredited—by ACGME, the Commission on Osteopathic College Accreditation, or both.[2] These accrediting bodies are private, nonprofit councils that evaluate and accredit residency programs in the United States. In addition to Medicare financing, program accreditation is a requirement for other aspects of GME, including board certification and state licensure. It is rare for programs to lose their accreditation status.[3]

The ACGME recently transitioned to an outcome-based evaluation process for its residency programs. This initiative took an important step forward in defining core competencies not only in medical knowledge and patient care but also in skills that are consistent with those required to support health care delivery reform. These skills include practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice.[4] They are described in further detail in the text box (pp. 112–113).

Many within the medical education community state that ACGME's Outcomes Project and evaluations are moving in the right direction (Chaudhry et al. 2008, Holmboe et al. 2006, Papadakis et al. 2008). However, studies show that progress toward these goals is slow. For example, examining 26 internal medicine residency programs (selected from a nationally representative sampling frame), RAND researchers found that, overall, internal medicine residency programs were not placing attention on formal instruction and experience in skills essential for delivery system reform—such as teamwork, quality measurement, and cost awareness (Cordasco et al. 2009, Medicare Payment Advisory Commission 2009). These researchers noted that overall programs' curricula on these topics fell far short of recommendations from the Institute of Medicine and other experts. A number of physicians in a recent article stated that a reformed delivery system will require physicians who are trained in relatively new skills that will enable them to provide more patient-centered, team-based care that is coordinated across institutional boundaries (Swensen et al. 2010). Reports from other experts have noted that training in these topics is not routinely provided in residency programs today (Council on Graduate Medical Education 2007a, Council on Graduate Medical Education 2007b, Lucien Leape Institute 2010).

Other educational efforts are beginning to address deficits

Several educators and specialty-based organizations have embarked on comprehensive projects to help medical schools and residency programs improve their teaching methods and curricula. For example, through its "Milestones Project" the American Board of Internal Medicine is aiming to teach educators successful methods for engaging residents in ACGME competencies and measuring their observable progress, but current Medicare payment policies do not provide incentives for these endeavors. Other specialties, such as general surgery, are engaged in similar milestones projects to facilitate outcome-based evaluations. Certifying boards are also influential in residency programs' curriculum development.[5]

An educational goal that is particularly pertinent to Medicare is the growing need for basic geriatric competency among almost all our physicians, as called for by many experts, clinicians, and researchers (Boult et al. 2010, Institute of Medicine 2008, Leipzig et al. 2009). While many specialties require some form of geriatric instruction for ACGME accreditation, and several organizations have collaborated to develop a set of geriatric competencies for all medical students and residents, Medicare's GME financing does not place any requirements on geriatric skills and experience.[6] Encouraging basic knowledge in geriatric care among graduating residents would have important benefits for elderly Medicare beneficiaries.

Particular focus needed to increase experience in nonhospital settings

Another concern about current residency education and training is its limited residency experience in nonhospital settings, as found in the previously mentioned RAND research. Hospital inpatient experience is a vital component of residency education to gain exposure to

The Accreditation Council for Graduate Medical Education (ACGME) common program requirements: General competencies

Approved by the ACGME Board February 13, 2007

The residency program must integrate the following ACGME competencies into the curriculum:

Patient care

Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.

Medical knowledge

Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and social–behavioral sciences as well as the application of this knowledge to patient care.

Practice-based learning and improvement

Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning. Residents are expected to develop skills and habits to be able to meet the following goals:

- identify strengths, deficiencies, and limits in one's knowledge and expertise.
- set learning and improvement goals.
- identify and perform appropriate learning activities.
- systematically analyze practice using quality improvement methods, and implement changes with the goal of practice improvement.
- incorporate formative evaluation feedback into daily practice.
- locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems.
- use information technology to optimize learning.
- participate in the education of patients, families, students, residents, and other health professionals.

Interpersonal and communication skills

Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. Residents are expected to:

- communicate effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds.

(continued next page)

acute, serious illnesses, but it is equally essential for residents to have adequate time and experience outside the hospital in settings such as physician practices, nursing facilities, and nonhospital clinics. Benefits include greater experience with the clinical management of chronic conditions and exposure to the need for good care coordination across settings. Improving residents' comfort level with care in ambulatory settings could increase their desire to practice community-based care, particularly when their experiences in these nonhospital settings are positive. GME payment policies should create incentives for institutions and residency programs to maintain strong community-based, ambulatory rotations for their residents.[7] Recent legislative changes provide some Medicare payment flexibility to promote clinical nonhospital residency experience as described in the text box (p. 114).

Increase accountability through performance-based payments

To create stronger incentives for providing residents with the education, training, and experiences necessary to

The Accreditation Council for Graduate Medical Education (ACGME) common program requirements: General competencies (cont.)

- communicate effectively with physicians, other health professionals, and health-related agencies.
- work effectively as a member or leader of a health care team or other professional group.
- act in a consultative role to other physicians and health professionals.
- maintain comprehensive, timely, and legible medical records, if applicable.

Professionalism

Residents must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. Residents are expected to demonstrate:

- compassion, integrity, and respect for others;
- responsiveness to patient needs that supersedes self-interest;
- respect for patient privacy and autonomy;
- accountability to patients, society, and the profession; and
- sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

Systems-based practice

Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care as well as the ability to call effectively on other resources in the system to provide optimal health care. Residents are expected to:

- work effectively in various health care delivery settings and systems relevant to their clinical specialty.
- coordinate patient care within the health care system relevant to their clinical specialty.
- incorporate considerations of cost awareness and risk–benefit analysis in patient or population-based care as appropriate.
- advocate for quality patient care and optimal patient care systems.
- work in interprofessional teams to enhance patient safety and improve patient care quality.
- participate in identifying system errors and implementing potential systems solutions. ■

Source: ACGME

achieve desired educational goals and outcomes, Medicare should create payment incentives based on institutional and program performance. The development of standards for measuring performance in topics essential for delivery system reform should be a collaborative process whereby the Secretary of Health and Human Services consults with representatives from organizations, such as program accrediting bodies, certifying boards, training programs, health care organizations, health care purchasers, and patient and consumer groups.

The standards established by the Secretary should specify ambitious goals for practice-based learning and improvement (including quality measurement), interpersonal and communication skills (including cultural sensitivity), professionalism (including patient-centered care), and systems-based practice (including integration of care across community- and hospital-based settings). Standards should address educational outcomes as well as clinical environments. These standards may vary depending on the types of institutions to which they apply, including hospitals, medical schools, and other entities

Recent payment changes provide payment flexibility to promote clinical nonhospital residency experience

The Patient Protection and Affordable Care Act of 2010 made three changes to Medicare payment policies to make it easier for residency time in certain nonhospital settings to be eligible for direct graduate medical education (DGME) payments and indirect medical education (IME) payments, starting July 1, 2010. First, supporting institutions (including hospitals that may share in supporting the costs of residents) will no longer need to cover more than the residents' stipends and benefits to qualify for DGME and IME when they rotate outside the hospital. (Previously, hospitals needed to pay the nonhospital sites for their supervision.) Second, for DGME payments, institutions will now be able to count the time residents spend on didactic and scholarly activities outside the hospital provided they are in clinical settings. (Previously, such didactic time could be counted only if it occurred in the hospital.) Third, for IME payments, hospitals will also now be able to count the time residents spend in non–patient care activities (except research not related to a particular patient) if they take place in the hospital, including provider-based hospital outpatient departments.

Although these provisions relax the nonhospital regulations, teaching hospitals have expressed concern that some administrative barriers will continue to exist. Resident time spent in didactic or scholarly activities in nonhospital settings will continue to be ineligible for IME payments. Time that residents spend in settings that are not primarily devoted to patient care—such as state public health departments, county jails, and medical schools—will continue to be ineligible for Medicare DGME and IME payments. ■

that support residency programs. The topics of interest are also part of ACGME's current program evaluations as discussed earlier (text box, pp. 112–113); therefore, Medicare's assessment of residency programs and institutional performance would build on topics familiar to residency programs, teaching hospitals, and other affiliated institutions.

This new program will increase the accountability of Medicare subsidies for GME. Funding for the program should come from a substantial reduction in current IME payments. Repeated Commission analysis shows that Medicare's current IME payments—paid as add-ons to hospitals' case-based payments—are in excess of empirical costs (by an estimated $3.5 billion in 2009). Although some could assert that this amount should not be expended at all (and thus remain in the Medicare trust fund), the Commission determined that Medicare should use this amount to fund a new performance-based program.

As described above, this new program would establish payment incentives that reward institutions—including teaching hospitals, medical schools, and other entities that may support residency programs—which meet specified educational standards and outcomes. Only those institutions meeting these criteria should be eligible for such incentive payments; conceivably, therefore, all, some, or none of this amount could be distributed, based on program and institutional performance. Future assessment of the GME payment system might consider making even larger portions contingent on performance.

By rewarding successful teaching on topics such as quality measurement, teamwork, and cost awareness, Medicare would support efforts to produce a health care workforce with the skills needed for delivery system reform. Accordingly, institutions that offered greater support for educators' teaching time would likely experience better educational outcomes and thus could earn higher payments from Medicare. Additionally, standards for achieving higher payments could include hospitals' protection of faculty teaching time and investment in faculty expertise and development.

To allow adequate time for the development of educational standards and criteria, Medicare's new, more accountable payment approach should begin in three years—October 2013. This implementation date would also give hospitals and other qualified institutions some time to consider ways to improve their medical education programs and alter their operations in line with anticipated IME payment

changes to manage this new system. CMS will require additional resources to assess institutions' performance and eligibility for incentive payments.

RECOMMENDATION 4-1

The Congress should authorize the Secretary to change Medicare's funding of graduate medical education (GME) to support the workforce skills needed in a delivery system that reduces cost growth while maintaining or improving quality.

- **The Secretary should establish the standards for distributing funds after consultation with representatives that include accrediting organizations, training programs, health care organizations, health care purchasers, patients, and consumers.**
- **The standards established by the Secretary should, in particular, specify ambitious goals for practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice, including integration of community-based care with hospital care.**
- **Performance-based GME funding under the new system should be allocated to an institution sponsoring GME programs only if that institution met the new standards established by the Secretary, and the level of funding would be tied to the institution's performance on the standards.**

The indirect medical education (IME) payments above the empirically justified amount should be removed from the IME adjustment and that sum would be used to fund the new performance-based GME program. To allow time for the development of standards, the new performance-based GME program should begin in three years (October 2013).

RATIONALE 4-1

Medicare's investment in GME should demand accountability for reaching specified standards and meeting the needs of high-value health systems. This new program would establish payment incentives that reward institutions—including teaching hospitals, medical schools, and other entities that may support residency programs—that meet specified educational goals and outcomes. Only those institutions meeting these specified criteria should be eligible for such incentive payments. Funding for this new program would come from a reduction in Medicare's IME payment—currently estimated to be twice the amount empirically attributable to higher patient care costs associated with a teaching environment.

IMPLICATIONS 4-1

Spending

- No Medicare program spending increase would occur; there would be some administrative costs.

Beneficiary and provider

- There would be no direct impact on beneficiaries.
- Payments to individual teaching hospitals would increase or decrease, depending on their performance.

Improve collaboration between educators and teaching hospitals by increasing the transparency of Medicare payments

During our examination of GME financing issues, some residency program directors voiced concerns that they have difficulty gaining information about their teaching hospitals' GME revenues because GME payments go directly to hospitals. Consequently, it can be challenging for them to judge whether Medicare's GME payments—as well as other revenues from other payers to support GME activities—are being distributed appropriately and equitably.

To improve information exchange between residency programs and provider institutions, Medicare could provide more transparent information on Medicare direct GME (DGME) and IME payments and hospital costs. This information, in the form of a short, public report, could prompt deliberations and collaborations among residency programs and hospitals about the distribution of these funds toward educational goals and community workforce needs. In addition, it would provide for greater public transparency in Medicare's role in supporting GME.

Specifically, the public report should include the following information, by institution:

- DGME revenues from Medicare
- IME revenues from Medicare
- number of residents counted by Medicare for direct GME payments
- number of residents counted by Medicare for IME payments
- Medicare's share of GME costs

Medicare could produce this information with little administrative burden, albeit with about a two-year lag. The payment information is already published by CMS on its website, but it is not necessarily in a user-friendly format or easy to find.[8] CMS could start producing these reports relatively quickly with the data it already has available. The institutions listed in these reports should include all those that received Medicare's DGME and IME funds in the reporting year.[9]

In response to a similar concern, New York State, in 2009, started requiring that residency training directors and teaching hospital administrators jointly submit an annual institutional budget for GME activities, reflecting both GME revenues and expenses, to the New York State Commissioner of Health.[10] This reporting is intended to foster greater dialogue between hospitals and their sponsoring institutions' designated academic affairs director to ensure that hospitals are aware of current and expected program needs and incorporate them into hospital budgets and that the academic affairs director is aware of how hospitals use these different sources of GME revenues.

Payment data

Payment data should include all DGME and IME payments that hospitals receive from Medicare, for both fee-for-service and Medicare Advantage. Also, for applicable institutions, this report should include relevant information on Medicare payments that support hospital-based nursing and other health professional training programs ($300 million in 2009).

Resident count data

The resident count data should be the count of residents used for Medicare DGME and IME payments. As the resident count used for DGME and IME payments can differ, separate DGME and IME resident counts need to be included in the report. Ideally, the report would also include data on the number of other types of health professionals that Medicare supports through its direct medical education payments for nursing and allied health professionals. The hospital cost reports, however, do not provide this level of detail; thus, a reporting mechanism would need to be developed to include such data.

Cost data

To make the cost data commensurate with the payment data, both DGME and IME costs reflecting Medicare's share of these expenses need to be reported. Although reporting Medicare payments and resident counts is relatively straightforward, some of the cost data are more complicated and would need to be computed. Medicare's report would need to cite issues concerning the accuracy and comparability of DGME cost data across providers (e.g., DGME cost data are not audited, hospitals may account for certain costs differently, and benefits hospitals receive from resident services are not reflected). Further work to refine, validate, and standardize the direct cost data may be necessary. Medicare could calculate and list IME costs as the institution's empirically justified share of Medicare IME revenues, but it would be important to also include caveats that these amounts are estimates that are based on national calculations and not reflective of a hospital's actual, specific indirect costs. Currently, hospitals do not compute hospital-specific IME costs. Although this approach would be an estimate, omitting any Medicare indirect costs from the report could leave the false impression that there are no indirect costs or that indirect costs equal the indirect payment.

Other issues

While this report would include both Medicare GME revenue and institutional cost information, it needs to make clear that these data cannot be used to perform a profit-and-loss analysis of GME activities. As noted above, there are a number of issues with the potential completeness and accuracy of the direct cost data and considerable uncertainty as to a hospital's actual indirect costs. Moreover, the financial benefits of residency training programs to the hospital and its physicians are not captured in these data; thus, any comparison of costs and revenues would provide an incomplete picture. We discuss these net financial impacts in a later section of this chapter related to Recommendation 4-4.

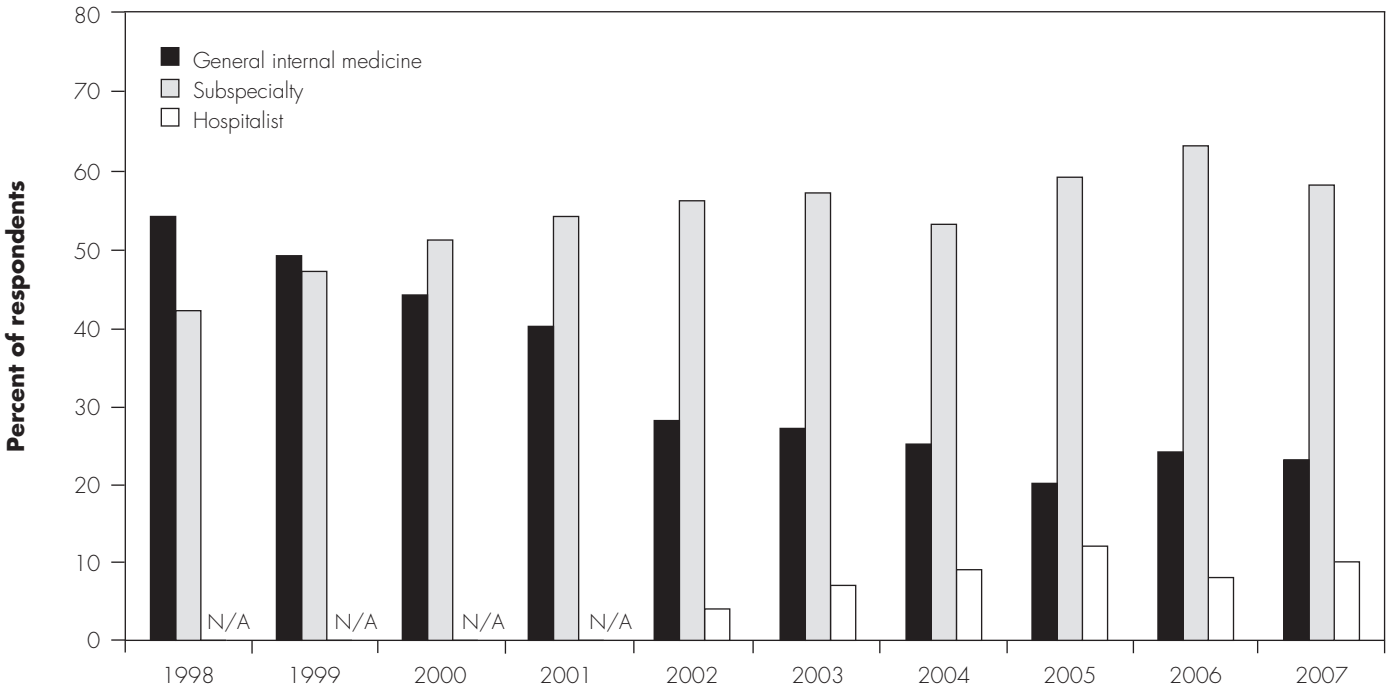
The proposed report would not divide payments and costs by specialty or list residents by specialty because these data are not readily available to Medicare. Nonetheless, residency program costs are likely to vary by specialty, as would their financial benefits to the hospital. Accordingly, some cross-subsidization is likely to occur across programs within an institution. Residency programs and hospitals would likely discuss this issue in their budgetary collaborations.

RECOMMENDATION 4-2

The Secretary should annually publish a report that shows Medicare medical education payments received by each hospital and each hospital's associated costs. This report should be publicly accessible and clearly

FIGURE 4–1

Proportions of third-year internal medical residents becoming subspecialists or hospitalists are growing



Note: N/A (not available).

Source: Bodenheimer, T. 2006. Primary care—Will it survive? *The New England Journal of Medicine* 355:861–864. *Copyright © 2006 Massachusetts Medical Society. All rights reserved.* Updated to include years 2006 and 2007, supplied by Thomas Bodenheimer, who obtained the relevant data from The American College of Physicians.

identify each hospital, the direct and indirect medical education payments received, the number of residents and other health professionals that Medicare supports, and Medicare's share of teaching costs incurred.

RATIONALE 4-2

Publication of this information is intended to prompt an informed dialogue between residency programs and hospitals on the resources that are required to support high-quality educational experiences for residents and fellows. It would also provide for greater public transparency on Medicare's role in supporting GME.

IMPLICATIONS 4-2

Spending

- No program spending increase would occur; there would be small administrative costs.

Beneficiary and provider

- There would be no direct impact on beneficiaries.
- There would be no direct impact on providers.

Determine health workforce needs for a reformed delivery system

Medicare's payments for GME generally subsidize the specialty choices of both teaching hospitals (in their program offerings) and residents (in their career choices). As discussed earlier, these choices are strongly influenced by the payment rates of the services these specialties provide. The resulting physician mix of specialties is unlikely to ensure that the nation has an efficient supply of health professionals for well-functioning delivery systems. For example, the share of third-year internal medicine residents choosing to practice primary care (rather than subspecialize or become hospitalists) has fallen from roughly 55 percent to 25 percent over the last decade (Figure 4-1).[11] Considering

the significant financial investment that Medicare and other federal programs make in GME, a commitment to rigorous, independent workforce analysis is imperative to inform the most efficient use of these public funds. Such analysis should be conducted regularly to account for evolving clinical and health system factors.

Workforce studies are multifaceted, requiring not only creating projections of how many physicians, nurses, physician assistants, and others will be needed many years in the future but also what education and training the workforce will require. Some studies have projected there will be unmet demand unless the supply of physicians is greatly increased (Dill and Salsberg 2008); others have found current total numbers may be in the right range but specialty mix and geographic distribution issues may need adjustments (Mullan 2009); and still others find that efficient, high-quality systems can have lower physician-to-population ratios (Goodman 2004). The Bureau of Health Professions within HRSA periodically reports on health care workforce supply and demand issues, including physicians, nursing, and public health care workers, but these reports are not regularly updated.

The Commission strongly recommends that an analysis of our 21st century health care workforce needs be driven by the requirements of a high-value, affordable health care delivery system. In calculating benchmarks for physicians and specialty mix, this study should take into account successful examples of high-performing, integrated delivery systems (McCarthy and Mueller 2009).

Analyses that simply extrapolate demand projections based on current patterns of care could compromise the nation's chances of fostering a high-value health care system by producing increasing numbers of physicians who have a stake in the status quo. Alternatively, an improved delivery system will influence the total number of physicians needed in the workforce as well as the mix of professionals (e.g., the mix of primary care physicians, specialists, advanced practice nurses, and physician assistants).

Several existing workforce models assume the market is roughly in equilibrium in the base year. This assumption implies inefficiencies in current utilization and delivery patterns would transfer into the future (Bureau of Health Professions 2008). Even departures from the baseline in the models tend to assume only modest changes in the delivery system. A study is needed to assess how major improvements in the delivery system would affect the demand for physicians. If Medicare is unsustainable without delivery system reform, as the Commission maintains, a health care workforce that is consonant with a reformed delivery system is essential.

Recognizing the need for systematic health care workforce analysis, the Congress enacted several workforce and primary care provisions in the Patient Protection and Affordable Care Act of 2010 (PPACA) as described in a text box at the end of this chapter (p. 121). For example, the act establishes a National Health Workforce Commission tasked with examining workforce issues and charges HRSA's National Center for Health Care Workforce Analysis with data collection, analysis, and other reporting activities. The act also establishes state and regional centers for health workforce analysis to work in conjunction with this HRSA center. To carry out the workforce analyses that we recommend in this chapter, the Secretary could potentially collaborate with this new workforce commission and HRSA's workforce centers.

RECOMMENDATION 4-3

The Secretary should conduct workforce analysis to determine the number of residency positions needed in the United States in total and by specialty. In addition, analysis should examine and consider the optimal level and mix of other health professionals. This work should be based on the workforce requirements of health care delivery systems that provide high-quality, high-value, and affordable care.

RATIONALE 4-3

Considering the investment that Medicare and other federal programs make in GME subsidies, a commitment to rigorous, independent workforce analysis is imperative to inform the most efficient use of these funds. Any change in the number of residents Medicare supports should be founded on an analysis of the health care workforce needs of a high-quality, high-value health care delivery system. Such an analysis should consider optimal care integration among physicians and other health professionals.

IMPLICATIONS 4-3

Spending

- No program spending increase would occur; there would be some administrative costs.

Beneficiary and provider

- There would be no direct impact on beneficiaries.
- There would be no direct impact on providers.

Examine the net impact of residency program costs and benefits on hospitals' financial performance

Medicare's GME payment policies do not specifically consider the costs and benefits (together the net cost) of residency training programs or whether the net cost of training differs by specialty. IME payments, for instance, count all residents the same regardless of their experience. Although some broad-based payment differentials are built into the DGME payment rates—payments for primary care residents are slightly higher than for residents in other core specialties, and payments for subspecialty residents are set at half the rate for other residents—these payment differentials were the result of policy considerations and were not based on actual cost differences. The costs and benefits of sponsoring residency programs, however, are likely to vary significantly by specialty—potentially making certain specialty programs financially more attractive to an institution than others. Understanding how the net cost of training varies by specialty may help the Medicare program target its limited resources to support GME more effectively. Such an analysis would consider not only the net cost of training but also other factors, such as educational outcomes (see Recommendation 4-1) and the workforce needs of the health care system (see Recommendation 4-3). Determining the net costs of a given specialty residency training program will be challenging, as it is made up of a complex mix of educational expenses and potentially forgone revenues on the cost side and potentially increased patient care revenues and other effects on the benefit side. To date, there has been limited research on this issue.

Costs of supporting residency programs

Although residents' stipends are similar across specialties, the cost of supervising residents varies by specialty. For instance, not only do faculty salaries vary by specialty, but the opportunity cost of supervision (forgoing greater clinical productivity) also varies, depending on reimbursement levels for the hospitals' different service lines. Program administrative costs may also be higher for certain types of residencies in which training needs to be coordinated across multiple sites, supervision requirements are more intensive, or space needs are greater. Supervision costs are likely highest for first-year residents and fall as residents become more experienced. Indirect costs also may decline with increases in residents' experience, as more experienced residents likely have greater throughput (i.e., patient care productivity), order fewer unnecessary tests, and require less supervision.

Benefits of supporting residency programs

In addition to qualifying for higher payment rates, hospitals benefit from supporting residency programs in other ways—several of which vary by specialty. As part of their clinical education, residents provide services that otherwise would need to be provided by other health care professionals—often at higher wages (Rich et al. 2002). To the extent that certain types of services are more profitable for hospitals than others, residency programs in some specialties would offer more positive financial benefits than others. Additionally, in principle, more experienced residents should be able to perform services with greater independence and less supervision—resulting in a lower cost and greater benefit to the facility.

Another factor that may make some residency programs more attractive to teaching hospitals than others is their ability to draw in leaders in specialty fields that will enhance the prestige of the hospital and potentially lead to higher market share, patient volume, and revenues in select hospital departments. The value of resident services may also differ across settings, with hospital inpatient and outpatient departments potentially providing the highest return, as the services provided are generally reimbursed at higher rates. Given that a number of teaching hospitals train more residents than Medicare supports, some residency programs, particularly in subspecialties, may be financially self-sustaining. The Commission's analysis of Medicare data show, for instance, that hospitals that have exceeded the capped number of residents that Medicare subsidizes tend to have more subspecialty residents than those that are under the cap.[12] Also, the number and share of residents in subspecialties have grown (Salsberg et al. 2008).

In principle, Medicare's payments to institutions for resident education and training could reflect not only differences in performance but also differences in the net costs of supporting residency programs. While determining costs and benefits by specialty is complex, such research is needed to inform efficient distribution of Medicare GME funding.

RECOMMENDATION 4-4

The Secretary should report to the Congress on how residency programs affect the financial performance of sponsoring institutions and whether residency programs in all specialties should be supported equally.

RATIONALE 4-4

The net impact that residency programs have on their hospitals' financial performance is likely to vary by

specialty. Some residency programs may improve hospitals' financial performance (because of the ability to garner higher market share and be associated with higher revenue-producing services), while other residency programs may not. Although determining costs and benefits is a complex task, a better understanding of these financial impacts could inform a more efficient distribution of GME dollars among residency programs.

IMPLICATIONS 4-4

Spending

- No program spending increase would occur; there would be some administrative costs.

Beneficiary and provider

- There would be no direct impact on beneficiaries.
- There would be no direct impact on providers.

Increase diversity among future physicians

Our June 2009 report discussed the underrepresentation of medical school students and residents from minority, lower income, and rural communities. Multiple research studies show that a diverse health care workforce is associated with better access to and quality of care for disadvantaged populations, greater patient choice and satisfaction, and better educational experience for students in health professions (Cooper et al. 2003, Health Resources and Services Administration 2006, Institute of Medicine 2004, Komaromy et al. 1996, Mertz and Grumbach 2001, Moy and Bartman 1995). Factors that increase the likelihood of students choosing careers in primary care and caring for underserved populations include being from a rural hometown and being an ethnic or racial minority (Brooks et al. 2002, Phillips et al. 2009).

Medicare's GME system is not able to address pipeline goals for increasing the economic, racial, or geographic diversity of the nation's physicians and other health professionals because Medicare's GME payments are focused on graduate-level physician training—much too late to influence individuals in their career choices. Interest in pursuing and preparing for careers in health professions (and specialty choices among those health professions) occurs along a continuum of stages in peoples' lives.

A number of HRSA programs are designed to recruit individuals—particularly from minority, rural, and low-income communities—into health careers. These programs (namely, those authorized by the Public Health Service Act, such as the National Health Service Corps (NHSC) and other programs under Title VII and Title VIII) include a variety of incentives, ranging from early education (grade school) programs to loan repayment programs. HRSA programs are also focused on promoting primary care access, particularly in underserved areas, and enhancing the cultural competence of this workforce by funding opportunities for medical students and residents to train in diverse settings and locations. These programs reach to a broader workforce than just physicians—including nurses, dentists, and other clinicians who focus on primary care. Recently, the PPACA reauthorized these HRSA programs and increased funding for several of them.

While the goals of these programs are on target with increasing the number and diversity of the nation's primary care workforce, and studies on selected HRSA programs find positive impacts, empirical research that comprehensively evaluates the longitudinal effectiveness of these programs is limited (Government Accountability Office 2006, Phillips et al. 2009, Rittenhouse et al. 2008). A more systematic approach for assessing impact across all programs is essential for determining the best way to invest resources to improve workforce diversity.

The Secretary should, therefore, complete a study that outlines a strategy for achieving specific goals related to workforce diversity in the nation's pipeline of health professionals. Potentially, this study could be conducted in collaboration with the new workforce Commission and HRSA workforce centers (mentioned earlier in this chapter) established by the PPACA. This study could also consider strategies that include partnerships with other federal departments, such as the Department of Education and the Department of Labor. Other important considerations in this study should be the need for both immediate and ongoing assessment of the effectiveness of HRSA's Title VII and Title VIII programs and to make available increased funding for the NHSC programs. Also, as recently recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry, HRSA should create a central data repository to collect and track information on HRSA program grantees (Advisory Committee on Training in Primary Care Medicine and Dentistry 2010).

Ultimately federal dollars that subsidize the nation's health care workforce should foster an optimal mix of clinicians—from different specialties, racial and

Summary of health workforce and primary care provisions in the Patient Protection and Affordable Care Act of 2010

- Establishes a National Health Workforce Commission, which would report and make recommendations to the Congress and the Administration on the current state and projected needs of the U.S. health care workforce (Section 5101).
- Creates a competitive grant program for states to develop workforce planning strategies (Section 5102).
- Charges Health Resources and Services Administration's National Center for Health Care Workforce Analysis with data collection, analysis, and reporting on workforce programs and establishes state and regional centers for health workforce analysis (Section 5103).
- Reauthorizes and increases funding for several Public Health Service Act programs including Title VII and Title VIII, makes available increased funding for the National Health Service Corps, and establishes scholarship and loan repayment programs for a range of health care and public health professionals (Sections 5201 to 5207, and Sections 5308 to 5313).
- Establishes a primary care extension program through the Agency for Healthcare Research and Quality to educate primary care providers about preventive medicine, health promotion, chronic disease management, mental health service, and evidence-based therapies (Section 5405).
- Authorizes grants to geriatric education centers to support training for clinical faculty and family caregivers in geriatrics, chronic care management, and long-term care (Section 5305).
- Authorizes development grants and payments to support teaching health centers as community-based, ambulatory patient care centers eligible for sponsoring physician residency programs in primary care (Section 5508).
- Directs the Secretary to redistribute 65 percent of currently unused residency slots and directs 75 percent of those slots for training primary care and general surgery and to states with the lowest resident physician-to-patient ratios, to states with the highest ratio of the population living in a health professional shortage area relative to the general population, and to states with rural hospitals (Section 5503).
- Modifies rules governing indirect medical education to promote resident training in ambulatory settings and in didactic and scholarly activities (Sections 5504 and 5505).
- Directs the Secretary to establish a demonstration program for hospitals to increase graduate nurse education training under Medicare (Section 5509).
- Provides a 10 percent payment bonus to primary care practitioners and general surgeons (pertains only to general surgeons in health professional shortage areas) for services provided under Medicare; makes Medicaid's payments for primary care services match Medicare's (Section 5501).
- Creates Center for Medicare and Medicaid Innovation to research, develop, test, and expand innovative payment and delivery service models, including the medical home (Section 3021). ■

ethnic backgrounds, rural and urban communities, and income levels—to achieve good access to a 21st century health care delivery system in all areas of the country. Determining the best strategy for reaching this objective should be a high priority to inform future spending decisions.

RECOMMENDATION 4-5

The Secretary should study strategies for increasing the diversity of our health professional workforce (e.g., increasing the shares from underrepresented rural, lower income, and minority communities) and report on what strategies are most effective to achieve this pipeline goal.

RATIONALE 4-5

Research has found that a diverse health care workforce is associated with better access to and quality of care for disadvantaged populations, greater patient choice and satisfaction, and better educational experience for students in health professions. Currently, Medicare's GME system is not designed to influence progress toward the goal of greater diversity among health professionals. A number of HRSA programs are designed to address relevant objectives under this goal, and research on specific programs shows some positive impacts, but comprehensive evaluation of these programs' longitudinal effectiveness is not well studied. An analysis that outlines a strategy for achieving specific health care workforce diversity goals and objectives is essential to optimize federal subsidies for this effort.

IMPLICATIONS 4-5

Spending

- No program spending increase would occur; there would be some administrative costs.

Beneficiary and provider

- There would be no direct impact on beneficiaries.
- There would be no direct impact on providers. ■

Endnotes

1 Although the Government Accountability Office found that the number of physician residents in primary care programs increased 6 percent over the last decade, research by Bodenheimer and colleagues suggests that an increasing share of these residents sought further subspecialty training or became hospitalists (Bodenheimer 2006, Government Accountability Office 2008). The number of family medicine residents increased by 3 percent for 2010 but decreased by the same percentage in 2009 (National Resident Matching Program 2010). This specialty has lower rates of subspecialization than internal medicine.

2 Medicare also recognizes—for purposes of GME and IME funding—residency programs accredited by the American Dental Association and the Council on Podiatric Medical Education. ACGME also evaluates and accredits residency programs' institutional sponsors (mainly teaching hospitals) from an educational perspective.

3 Specifically, ACGME reports that for the 2008–2009 academic year, 1 percent of residency programs had a "withdrawal of accreditation" status and fewer than 1 percent had a "probationary accreditation status." A more frequent action that ACGME takes when programs are not performing at high enough levels is to shorten the time between program evaluations.

4 ACGME began to implement these outcome-based standards in 2001 and required full integration of them in residency programs beginning in 2006.

5 ACGME-endorsed milestone projects are currently moving forward in internal medicine, pediatrics, general surgery, urology, ophthalmology, family medicine, and transitional year programs. Internal medicine, pediatrics, and general surgery have already defined milestones and are currently looking at ways to operationalize milestones in practice. Subspecialty societies like the American College of Cardiology and the American Gastroenterological Association are also developing milestones.

6 With support from private foundations, the Association of American Medical Colleges, the American Medical Association, the Council of Medical Specialty Societies, and the American Geriatrics Society have launched a competency-based education and training initiative to ensure that all medical students and residents achieve basic competence in the care of older adults. The competencies, initially for graduating medical students, include measurable tasks associated with evidence-based geriatric care and patient safety. They fall into four main categories, those that: (1) are critical to patient safety and quality of care (medication management, self-care capacity, falls, balance and gait disorders, and hospital care for elders); (2) address the prevalence and underrecognition of cognitive impairment; (3) address the complexity of diagnosis (atypical presentation of disease); and (4) address prioritizing care based on patient preference and function.

7 Some have raised concerns, however, that promoting more nonhospital residency experience is less relevant for Medicare GME policies because the share of Medicare patients in many of these settings is smaller.

8 See http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp#TopOfPage.

9 In the future, the report could also include federally qualified health centers, rural health clinics, teaching health centers (established in the Patient Protection and Affordable Care Act of 2010), and other places that receive Medicare or other federal support to cover direct and indirect costs of residency training programs. Data for such training sites, however, would need to come from sources other than the Medicare cost reports.

10 The initial idea for a joint budget came from the New York Council on Graduate Medical Education, which recommended that these budgets should be generated by individual residency program directors for the hospital leadership team. With one year of reporting completed, the comparability of expense data across providers has proven somewhat problematic as not all GME expenses, such as those made for malpractice and simulation laboratories, are accounted for in the same way across institutions.

11 Although the Government Accountability Office found that the number of physician residents in primary care programs increased 6 percent over the last decade, Figure 4-1 suggests that many of these residents sought further subspecialty training or became hospitalists (Government Accountability Office 2008). The number of family medicine residents increased by 3 percent for 2010 but decreased by the same percentage in 2009 (National Resident Matching Program 2010). This specialty has lower rates of subspecialization than internal medicine.

12 Medicare caps the number of residents a hospital can count for direct and indirect GME payments at 1996 levels. There are also certain subspecialties that do not have ACGME accreditation that train fellows, but hospitals receive no direct GME or IME payments for these residents (e.g., gynecologic oncology, reproductive endocrinology and infertility), providing further evidence that some residency programs may be self-sustaining.

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CHAPTER 5

Coordinating the care of dual-eligible beneficiaries

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Chapter summary

Dual-eligible beneficiaries (those enrolled in both Medicare and Medicaid) have higher medical expenses than other beneficiaries. While they make up disproportionate shares of Medicare and Medicaid spending relative to their enrollment, neither program assumes full responsibility for coordinating all of their care. The Medicare and Medicaid programs often work at cross-purposes in ways that impede the coordination of care for dual-eligible beneficiaries. Conflicting program incentives encourage providers to avoid costs rather than coordinate care, and poor coordination can raise spending and lower quality.

Within the dual-eligible population, there are distinct groups of beneficiaries with widely different care needs. They vary considerably in the prevalence of chronic conditions, their physical and cognitive impairments, and whether they are institutionalized. Many have multiple chronic conditions that make care coordination especially important. Other duals have no or one physical impairment and no chronic conditions. Reflecting this wide range in care needs, spending varies by a factor of four according to physical and cognitive impairment. Likewise, spending on specific types of services differs by subgroup, with some having higher spending on nursing home or hospital services than others. Care coordination activities, and the need for them, should reflect these differences, tailoring specific activities to each beneficiary.

In this chapter

Improving the care for dual-eligible beneficiaries requires two fundamental changes in financing and delivering care to them. First, the financing streams need to be more integrated so that the current conflicting incentives between Medicaid and Medicare no longer undermine care coordination. Second, an integrated approach to care delivery is needed to ensure quality care for this complex population. An integrated approach could involve a single entity at financial risk for the care furnished to beneficiaries with the responsibility for coordination of all care furnished to dual-eligible beneficiaries.

In integrated approaches, beneficiaries are regularly assessed for their risk for hospitalization or institutionalization and a multidisciplinary team manages a beneficiary's care according to an individualized care plan. Entities that furnish integrated care need to be evaluated by using outcome measures such as risk-adjusted per capita costs, potentially avoidable hospitalization rates, rates of institutionalization, and emergency room use. In addition, condition-specific quality measures and indicators that reflect the level and success of care integration need to be gathered so that the success of care integration for different subgroups of duals can be assessed.

Two approaches currently in use—managed care programs implemented through Medicare Advantage special needs plans that contract with states and the Program of All-Inclusive Care for the Elderly—offer more fully integrated care. These programs combine funding streams so that the conflicting financial incentives of Medicare and Medicaid are mitigated. Entities are also at full financial risk for all (or most) services, including long-term care, and provide care management services. Given the diversity of the care needs of the dual-eligible population, a common approach to full integration and care coordination may not be best suited for all beneficiaries.

While integrated approaches have the potential to be successful, they are few in number and enrollment in some programs is low. Numerous challenges inhibit expanding their numbers and enrollment. Challenges include a lack of experience managing long-term care, stakeholder resistance (from beneficiaries and their advocates, and from providers), the costly initial program investments and uncertain financial viability, and the separate Medicare and Medicaid administrative rules and procedures. Also, by statute Medicare beneficiaries must have the freedom to choose their providers and cannot be required to enroll in a health plan that could integrate care. However, several states have successfully implemented fully integrated care programs, illustrating that it is possible to overcome these obstacles. ■

Dual-eligible beneficiaries (those enrolled in both Medicare and Medicaid) have, on average, higher medical expenses than other beneficiaries and the care they receive is likely to be uncoordinated. They make up 16 percent of Medicare's enrollment but one-quarter of its spending (Medicare Payment Advisory Commission 2009a). On the Medicaid side, they make up 18 percent of Medicaid enrollment but almost half (46 percent) of its spending (Lyons and O'Malley 2009). However, there are distinct groups of beneficiaries with widely different care needs. Given the multiple chronic conditions of many dual-eligible beneficiaries, care coordination is paramount but often lacking.

The Medicare and Medicaid programs often work at cross-purposes in ways that impede the coordination of care for dual-eligible beneficiaries. Conflicting program incentives in Medicare and Medicaid encourage providers to avoid costs rather than coordinate care, and poor coordination can raise total federal spending and lower quality. Neither program assumes full responsibility for coordinating the care furnished to dual-eligible beneficiaries.

This chapter describes the dual-eligible beneficiaries and spending on them. It then describes examples of fully integrated programs in which an entity receives revenue from Medicaid and Medicare, assumes full (or most of the) financial risk for the enrollees, and manages all the services furnished to them. It discusses performance measures that would be relevant to the dual-eligible population, which are particularly important if enrollment in integrated plans is to expand.

The chapter discusses approaches being used to coordinate the care for dual-eligible beneficiaries—Medicare Advantage (MA) special needs plans (SNPs) that contract with the state Medicaid agencies to provide integrated managed care programs, and the Program of All-Inclusive Care for the Elderly (PACE). These programs make two fundamental changes to the financing and delivery of care to dual-eligible beneficiaries. First, entities are at financial risk for all (or most) of the care furnished to duals, so that the current conflicting incentives no longer undermine care coordination. Second, a single entity takes responsibility for care coordination. Few beneficiaries are enrolled in these programs and the last section discusses the challenges to expanding their enrollment.

Background

Dual-eligible beneficiaries are people who receive health care coverage through both Medicare and Medicaid. In 2005, approximately 16 percent of Medicare beneficiaries were also enrolled in Medicaid. Of these dual-eligible beneficiaries, almost two-thirds were aged 65 or older and one-third were disabled and under age 65 (Medicare Payment Advisory Commission 2008). Many beneficiaries who would otherwise qualify for Medicaid do not enroll in the program.[1] Most dual-eligible beneficiaries remain eligible for state coverage over time because they typically do not experience large changes in assets or income. About 5 percent of dual-eligible beneficiaries lose their eligibility each year; about 40 percent of them reenroll within a year (Stuart and Singhal 2006).

Within the dual-eligible population, there are different levels of assistance through what are called Medicare Savings Programs. Most "duals" (almost 80 percent) qualify for full Medicaid benefits, including long-term care (often referred to as "full benefit duals"). Medicaid also pays their Medicare premiums and cost-sharing expenses. Medicare beneficiaries with higher incomes (often referred to as "partial duals") do not receive Medicaid benefits other than assistance with Medicare premiums and cost sharing.[2]

Medicare is considered the primary payer for dual-eligible beneficiaries and pays for all Medicare-covered services (such as hospital and physician services; see Table 5-1, p. 132). For Medicaid, all states are required to cover certain services, including nursing home care, Medicare cost sharing (the Part A and Part B deductibles, the Part B premiums, and the Part B coinsurance), coverage for inpatient hospital and skilled nursing facility services when Part A coverage is exhausted, and home health care for those dual-eligible beneficiaries who would otherwise qualify for nursing home services. States have the option to cover other services—such as dental, vision, and hearing; home- and community-based services; personal care services; and home health care (for those duals who do not qualify as needing nursing home services). Not surprisingly, there is considerable variation across states in the services covered and in eligibility rules, resulting in different benefits for duals, depending on where they live. States can cap their payments for Part B cost sharing to what they would pay for the service if the beneficiary had only Medicaid coverage.[3] As a result, most states do

TABLE 5–1 **Services paid for by Medicare and Medicaid for dual-eligible beneficiaries**

Medicare	Medicaid
• Acute care (hospital) services • Outpatient, physician, and other supplier services • Skilled nursing facility services • Home health care • Dialysis • Prescription drugs • Durable medical equipment • Hospice	• Medicare cost sharing (Part A and Part B deductibles, Part B premiums and coinsurance) • Coverage for hospital and skilled nursing facility services if Part A benefits are exhausted • A portion of the cost of prescription drugs • Nursing home care • Home health care not covered by Medicare when the beneficiary qualifies as needing nursing home care • Transportation to medical appointments • Optional services: dental, vision, hearing, home- and community-based services, personal care, and home health care (when the beneficiary does not qualify for Medicare and does not need nursing home care) • Durable medical equipment not covered by Medicare

not, in effect, pay for cost-sharing expenses (Mitchell and Haber 2004).

Over the last three decades, programs delivering home- and community-based services (HCBS) such as home health care and personal care have become an attractive alternative to institutional care for persons who require long-term care. Between 1995 and 2007, Medicaid spending on HCBS as a percentage of its total long-term care obligations has more than doubled from 19 percent to 41 percent (Kaiser Family Foundation 2009b). Demand is high because many beneficiaries prefer to remain at home and receive support services that allow them to avoid being institutionalized. States fund such programs because they believe the services will reduce facility-based expenditures on long-term care, which is the single largest spending item for Medicaid, constituting a third of its total spending (Kaiser Family Foundation 2009a). Differences in state policies to fund these services contribute to the considerable variation in average per capita HCBS spending. In 2006, per capita spending on HCBS ranged from $5,407 in Texas to $33,862 in Rhode Island (Kaiser Family Foundation 2009b).

Although Medicaid is a state-run program, there is considerable federal support. The federal government contributes to each state's Medicaid program based on a formula that yields higher matching funds for poorer states. The average "match rate" is 57 percent, but it ranges from 50 to 76 percent. To provide short-term fiscal relief to states, the Congress included a provision in the American Recovery and Reinvestment Act of 2009 that temporarily (through 2010) raised the minimum match rate to 65 percent and the maximum to 83 percent (Department of Health and Human Services 2009).

Characteristics of dual-eligible beneficiaries

On average, dual-eligible beneficiaries differ from other beneficiaries. They are more likely to be young and disabled and to have multiple chronic conditions. But the dual-eligible population is not homogeneous. Duals differ considerably in their physical and cognitive impairments, their abilities to perform activities of daily living, and whether they are institutionalized. Some duals have multiple chronic conditions that will raise their spending year after year. Others—the essentially well duals—have minimal care needs. These factors will shape the amount and type of services that need to be coordinated and the opportunities and benefits of integration.

Dual-eligible beneficiaries differ from other beneficiaries

To qualify for Medicaid, dual-eligible beneficiaries must have low incomes. More than half of duals have incomes below the poverty line (in 2006, poverty was defined as $10,294 for an individual and $13,167 for married couples) compared with 8 percent of non-dual-eligible beneficiaries. Their poverty shapes their basic living needs. If they have inadequate housing or cannot afford heat and food, they cannot focus on and manage their health care

TABLE 5–2

Demographic differences between dual-eligible beneficiaries and non-dual-eligible beneficiaries

	Percent of beneficiaries	
Characteristic	**Dual eligible**	**Non-dual eligible**
Disabled	41%	11%
Report poor health status	20	7
Race		
White, non-Hispanic	58	82
African American	18	7
Hispanic	15	6
Other	9	4
Limitations in ADLs		
No ADLs	49	71
1–2 ADLs	23	19
3–6 ADLs	29	10
Living arrangement		
In an institution	19	3
With a spouse	17	55
Education		
No high school diploma	54	22
High school diploma only	24	31
Some college or more	18	45

Note: ADLs (activities of daily living). Totals may not sum to 100 percent due to rounding and the exclusion of an "other"category.

Source MedPAC analysis of Medicare Current Beneficiary Survey Cost and Use file, 2006.

needs. For example, the lack of adequate heating can delay recovery from illness.

Compared with other Medicare beneficiaries, dual-eligible beneficiaries are, on average, more likely to be young and disabled, report poor health status, and be a member of a racial or ethnic minority group (Table 5-2). Dual-eligible beneficiaries are almost three times more likely than other beneficiaries to have three or more limitations in their activities of daily living (such as dressing, bathing, and eating), with 29 percent reporting this level of physical impairment. Dual-eligible beneficiaries are more than six times more likely to be living in an institution, with 19 percent living in one compared with 3 percent of other beneficiaries. Compared with other beneficiaries, duals are much less likely to live with a spouse. More than half of dual-eligible beneficiaries did not complete high school, compared with fewer than one-quarter of other beneficiaries.

The disabled group make up about one-third of dual-eligible beneficiaries. Among them, 44 percent are mentally ill, one-third have one or no physical impairment, and 18 percent are developmentally disabled (Table 5-3). A small share have dementia, reflecting their younger age.

The group of beneficiaries entitled based on their age make up about two-thirds of dual-eligible beneficiaries. Among them, more than half have one or no physical impairment, 26 percent are mentally ill, and 16 percent have dementia. A small fraction of the aged dual-eligible beneficiaries have two or more physical impairments.

Beneficiaries in these impairment groups vary considerably in what share are institutionalized, which will have a large impact on per capita spending. High proportions of aged duals with dementia or with at least two physical impairments are institutionalized (Figure 5-1, p. 134).[4] But only a small fraction (2 percent) of those with no or one physical impairment are institutionalized. The rates of institutionalization among the other groups—the mentally ill, the developmentally disabled, and the disabled with

TABLE 5–3

Physical and cognitive impairments vary considerably among dual-eligible beneficiaries

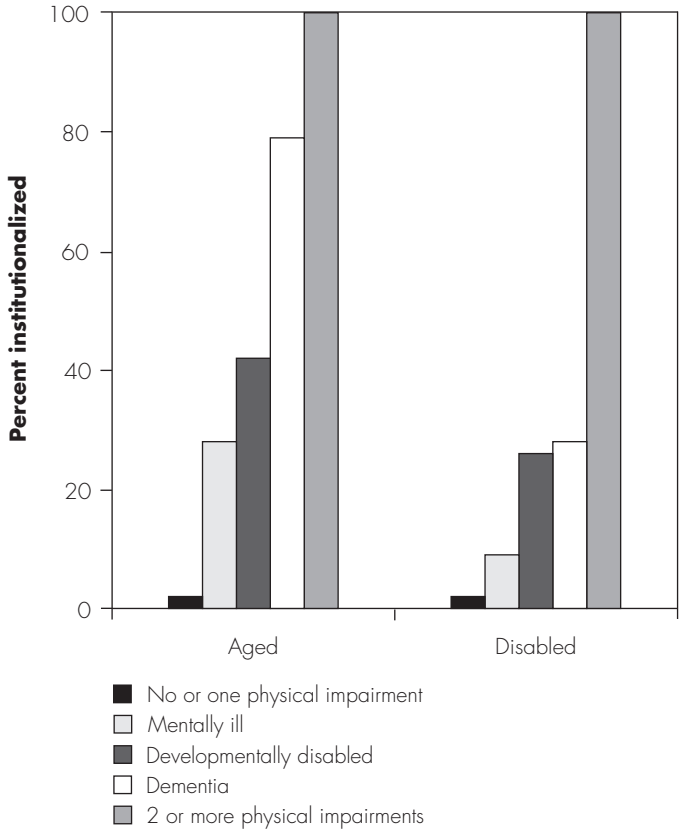
Dual-eligible group	Aged	Disabled
Mentally ill	26%	44%
Dementia	16	3
Developmentally disabled	2	18
One or no physical impairments	54	33
Two or more physical impairments	3	3

Note: Beneficiaries were grouped into the "aged" and "disabled" groups based on how they qualified for Medicare coverage. The grouping uses a hierarchy that first divides dual-eligible beneficiaries by their original eligibility into the Medicare program. Beneficiaries are then assigned to a cognitive impairment group and, if none, are assigned to a physical impairment group (a beneficiary with both would be assigned to a cognitive impairment group). Physical impairment refers to a limitation to perform activities of daily living such as bathing, dressing, or eating. Beneficiaries with end-stage renal disease were excluded.

Source: MedPAC analysis of Medicare Current Beneficiary Survey Cost and Use file, 2004–2006.

FIGURE 5–1

Rate of institutionalization varies by group of dual-eligible beneficiaries



Note: Beneficiaries were grouped into the "aged" and "disabled" groups based on how they qualified for Medicare coverage. The grouping uses a hierarchy that first divides dual-eligible beneficiaries by their original eligibility into the Medicare program. Beneficiaries are then assigned to a cognitive impairment group and, if none, are assigned to a physical impairment group (a beneficiary with both would be assigned to a cognitive impairment group). Physical impairment refers to a limitation to perform activities of daily living such as bathing, dressing, or eating. Beneficiaries with end-stage renal disease were excluded.

Source: MedPAC analysis of Medicare Current Beneficiary Survey Cost and Use file, 2004–2006.

dementia—are more variable, ranging from 9 percent to 42 percent. In general, aged duals are more likely to be institutionalized than disabled duals.

Using CMS's chronic conditions warehouse data, we found that many dual-eligible beneficiaries have three or more chronic conditions—41 percent of duals who do not have end-stage renal disease (ESRD) and 74 percent of those who do. The most common chronic conditions include cardiovascular, diabetes, Alzheimer's and related disorders, rheumatoid arthritis or osteoarthritis, and depression (Mathematica Policy Research 2010).

The frequency of chronic conditions varied considerably among the disabled and the aged groups (Table 5-4). More than one-quarter of the aged dual-eligible beneficiaries had the five most frequent chronic conditions—ischemic heart disease, heart failure, Alzheimer's and related conditions, diabetes, and rheumatoid arthritis or osteoarthritis. Except for diabetes, many fewer of the under 65 and disabled dual-eligible population had these conditions. For example, only 17 percent had ischemic heart disease, compared with 43 percent of the aged dual-eligible beneficiaries. Among those under 65 and disabled, only two conditions—depression and diabetes—were as prevalent (at least 20 percent of duals had the condition). It is likely that the under 65 and disabled population has other conditions not included in the Chronic Conditions Warehouse (CCW), such as schizophrenia, other psychosis, serious neurosis, and substance abuse, which are not captured in the data. The vast majority of dual-eligible beneficiaries admitted to inpatient psychiatric hospitals had a diagnosis of psychosis (see Chapter 6). The unreported conditions will understate the prevalence of mental illness among duals.

TABLE 5–4

Five most frequent chronic conditions vary among the aged and the under 65 and disabled dual-eligible beneficiaries

	Percent of group with the condition	
Chronic condition	**Aged**	**Under 65 and disabled**
Alzheimer's and related conditions	30%	5%
Chronic obstructive pulmonary disease	18	10
Depression	18	28
Diabetes	36	23
Heart failure	33	11
Ischemic heart disease	43	17
Rheumatoid arthritis/osteoarthritis	31	13

Note: The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

Duals also vary in the number of chronic conditions they have (Figure 5-2). While 19 percent had five or more chronic conditions, a large share (38 percent) had none or one. Half of the 22 percent with dementia also had four other chronic conditions.

Dual-eligible beneficiaries' health status characteristics—whether they are aged or disabled, their physical and cognitive impairments, and their chronic conditions—shape the amount of care coordination they require, the mix of providers serving them, and their inclination and ability to seek timely care. Those with minimal physical impairments are likely to require much less support than dual-eligible beneficiaries with serious impairments. Care needs will also vary according to the chronic condition. Beneficiaries with conditions particularly at risk for hospitalization, such as heart failure and chronic obstructive pulmonary disease, should be closely monitored to avert unnecessary hospitalization. Beneficiaries who live alone are at risk for institutionalization, which HCBS may be able to delay or avoid.

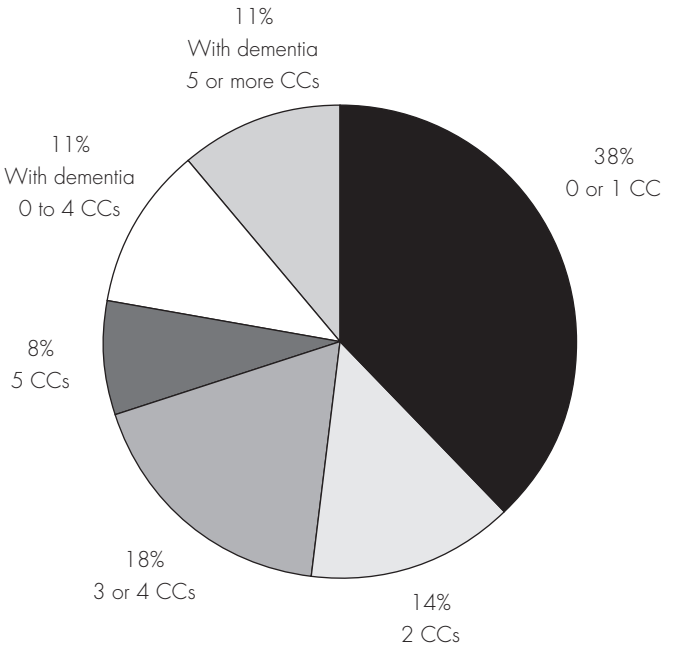
Mentally ill and cognitively impaired dual-eligible beneficiaries are typically limited in their abilities to understand instructions and adhere to them. In addition, although mental health care providers often serve as the central health care resource for mentally ill beneficiaries, they may not routinely screen their patients for general health problems or adequately monitor health effects of medications that are frequently prescribed. Furthermore, the network of mental health care providers treating a dual-eligible beneficiary is often separate from that furnishing general health care, requiring mentally ill duals to navigate yet another system of care. This landscape should shape care coordination activities for this group of dual-eligible beneficiaries.

Per capita spending on dual-eligible beneficiaries varies by subgroup

The variation in health status, cognitive and physical impairments, and living arrangements across dual-eligible beneficiaries is reflected in the large differences in per capita spending across these beneficiaries' subgroups. A large factor is whether the beneficiary is institutionalized, which affects Medicaid spending and combined program spending. Chronic conditions also contribute to higher spending levels, particularly for patients with dementia, as do cognitive and physical impairments.[5]

FIGURE 5–2

Number of chronic conditions and presence of dementia vary considerably among dual-eligible beneficiaries



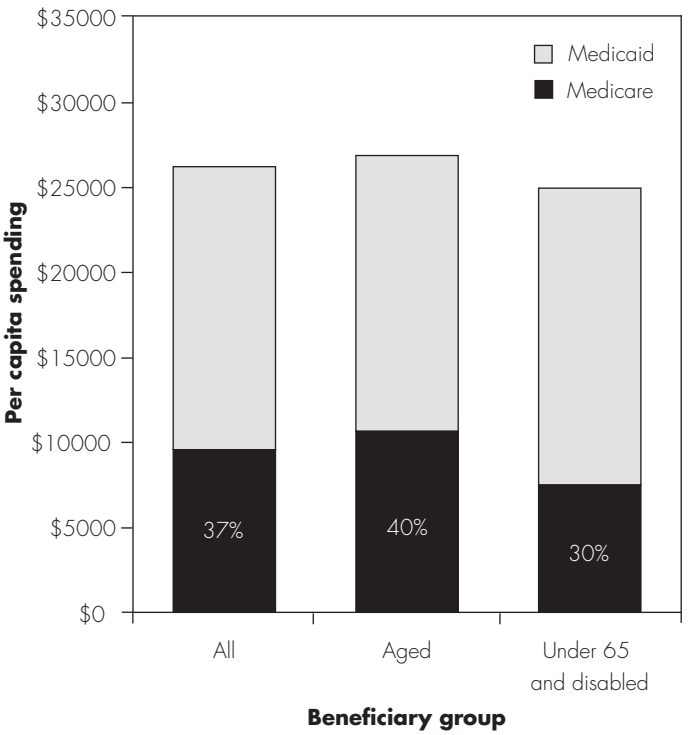
Note: CC (chronic condition). The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

Medicaid and Medicare per capita spending on dual-eligible beneficiaries totaled $26,185 in 2005, with Medicare spending accounting for 37 percent of the total (Figure 5-3, p. 136). Combined per capita spending was slightly higher (3 percent) than average for the aged dual-eligible beneficiaries, while per capita spending for the under 65 and disabled was 5 percent less than the average. Medicare's share of the combined varied from 30 percent (under 65 and disabled) to 40 percent (aged), largely reflecting the share of beneficiaries receiving Medicaid-financed long-term care and prescription drugs. These data predate the implementation of Medicare's drug benefit, so prescription drug spending is included in Medicaid's spending.

FIGURE 5–3

Medicare and Medicaid per capita spending on dual-eligible beneficiaries in 2005



Note: The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans. Spending on prescription drugs is included in Medicaid spending (the data predate Part D). Percents are Medicare share of combined spending.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

Per capita spending varies by nursing home use

The differences in per capita spending for the aged and the under 65 and disabled groups of dual-eligible beneficiaries were more pronounced once we controlled for nursing home use (Table 5-5). For duals with no nursing home spending (i.e., living in the community), combined Medicare and Medicaid per capita spending for the under 65 and disabled was one-third higher ($22,530) than that for the aged ($16,916). For duals with the highest nursing home spending (those in the 20th percentile of nursing home spending), the difference between the groups was smaller. Combined per capita spending was 13 percent higher for the under 65 and disabled group ($84,339) than the spending for the aged group ($74,439).

Nursing home use has a large impact on total combined spending. Combined per capita spending for dual-eligible beneficiaries with the highest per capita nursing home spending was about four times that of duals with no nursing home spending.

Impact of chronic conditions on per capita spending

Considerable differences in combined per capita spending also exist by category of chronic condition (Table 5-6 and online Appendix 5-A, available at http://www.medpac.gov). Among the most frequent conditions, combined per capita spending ranged from 20 percent higher than average for dual-eligible beneficiaries with diabetes or with rheumatoid arthritis or osteoarthritis to 80 percent higher than average for duals with Alzheimer's disease and related conditions. Per capita spending for duals with five or more chronic conditions was almost double the per capita spending for all duals. Because beneficiaries can have more than one chronic condition, the differences reported here are not the additional spending associated with the condition alone. For example, many beneficiaries in the diabetes group have other chronic conditions that raise program spending. Twenty percent of duals had none of the chronic conditions recorded in the CCW.

Dementia plays a key role in per capita spending differences. Across the most prevalent chronic conditions, combined per capita spending for dual-eligible beneficiaries with dementia was 30 percent to 60 percent higher than for duals without it.

Spending also varied considerably by the number of chronic conditions the beneficiary had (Figure 5-4, p. 138). Combined per capita spending for duals with one chronic condition was just over $16,000 but with dementia it increased to more than $31,000. Spending for duals with five or more chronic conditions was $43,000; combined spending on those with dementia was more than $55,000.

Physical and mental impairments influence per capita spending

To examine spending differences by physical and mental impairments, we examined Medicare Current Beneficiary Survey data and used a hierarchy that first divides dual-eligible beneficiaries by their original eligibility into the Medicare program. Then, it assigned beneficiaries first into cognitive impairment groups and then, if not already

TABLE 5–5

Controlling for nursing home use, per capita spending for under 65 and disabled duals is higher than for aged duals, 2005

	Total	No nursing home spending	Top nursing home spending
All dual eligibles	$26,185	$19,171	$75,469
Aged	26,841	16,916	74,439
Under 65 and disabled	24,924	22,530	84,339

Note: The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans. Top nursing home spending includes the top 20th percentile of spending for beneficiaries who used nursing home services.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

assigned, into physical impairment groups. A beneficiary with both types of impairments is assigned to a mental impairment group.[6]

Within the aged and disabled groups, Medicare and Medicaid per capita spending ranged by a factor of four (Figure 5-5). In both the disabled and aged groups, spending on duals with no or one impairment was about half of the average; in contrast, the highest spending groups (those with two or more physical impairments and those with dementia) were about double the average. Other differences were difficult to discern. Groups with high rates of institutionalization tended to have high spending, but not always. For example, while spending was about twice the average for duals with two or more physical impairments (groups with high institutionalization rates, see Figure 5-1), spending was about 20 percent above average for the developmentally disabled aged group (a group in which fewer than half were institutionalized). For any given impairment group, spending for the aged groups

TABLE 5–6

Total Medicare and Medicaid per capita spending for dual-eligible beneficiaries varied for most frequent chronic conditions

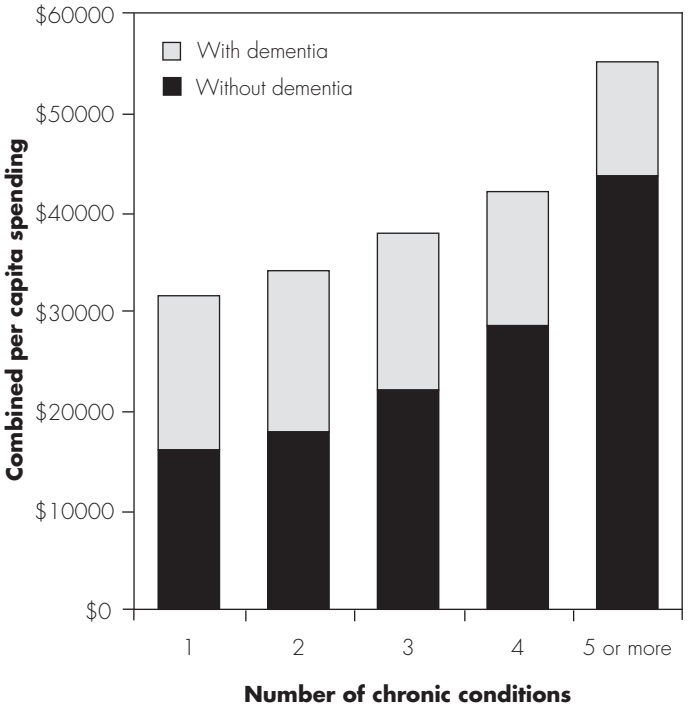
Select chronic condition	Share of all duals with condition	Medicare and Medicaid spending	Spending relative to average
All dual-eligible beneficiaries	100%	$26,185	1.0
Alzheimer's and related conditions	22	46,578	1.8
COPD	15	40,645	1.6
Depression	21	38,829	1.5
Diabetes	32	32,188	1.2
Heart failure	26	40,632	1.6
Ischemic heart disease	34	34,568	1.3
Rheumatoid arthritis & osteoarthritis	25	31,864	1.2
4 or more chronic conditions	30	43,986	1.7
5 or more chronic conditions	19	50,278	1.9

Note: COPD (chronic obstructive pulmonary disease). The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

FIGURE 5–4

Combined per capita spending increases with dementia and number of chronic conditions



Note: The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

tended to be higher than for the disabled groups, but not always. Spending was higher for the aged groups with cognitive impairments, but the disabled group with two or more physical impairments had higher spending than its aged counterpart.

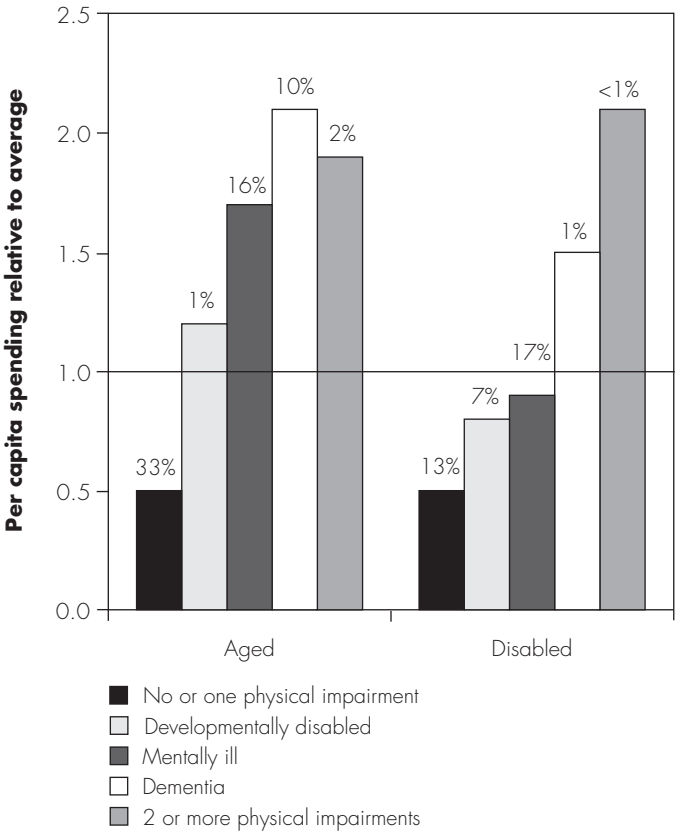
Mix of service spending varies by clinical condition

The impairments and chronic conditions shape the mix of services beneficiaries use. Dual-eligible beneficiaries who are institutionalized have a high proportion of combined per capita spending on nursing home services. Those with minimal impairments, living at home, and without a hospitalization are likely to have a greater share of combined program spending on physician and other community-based services. Those with conditions that are susceptible to frequent hospitalizations, such as chronic obstructive pulmonary disease (COPD) and heart failure, have a high share of combined spending on hospital services.

Among the most prevalent chronic conditions, the share of total per capita spending devoted to nursing home services ranged from 20 percent for dual beneficiaries with heart failure or COPD to 45 percent for duals with Alzheimer's disease and related conditions (Figure 5-6 and online Appendix 5-A, available at http://www.medpac.gov). Per

FIGURE 5–5

Per capita spending by cognitive and physical impairment group

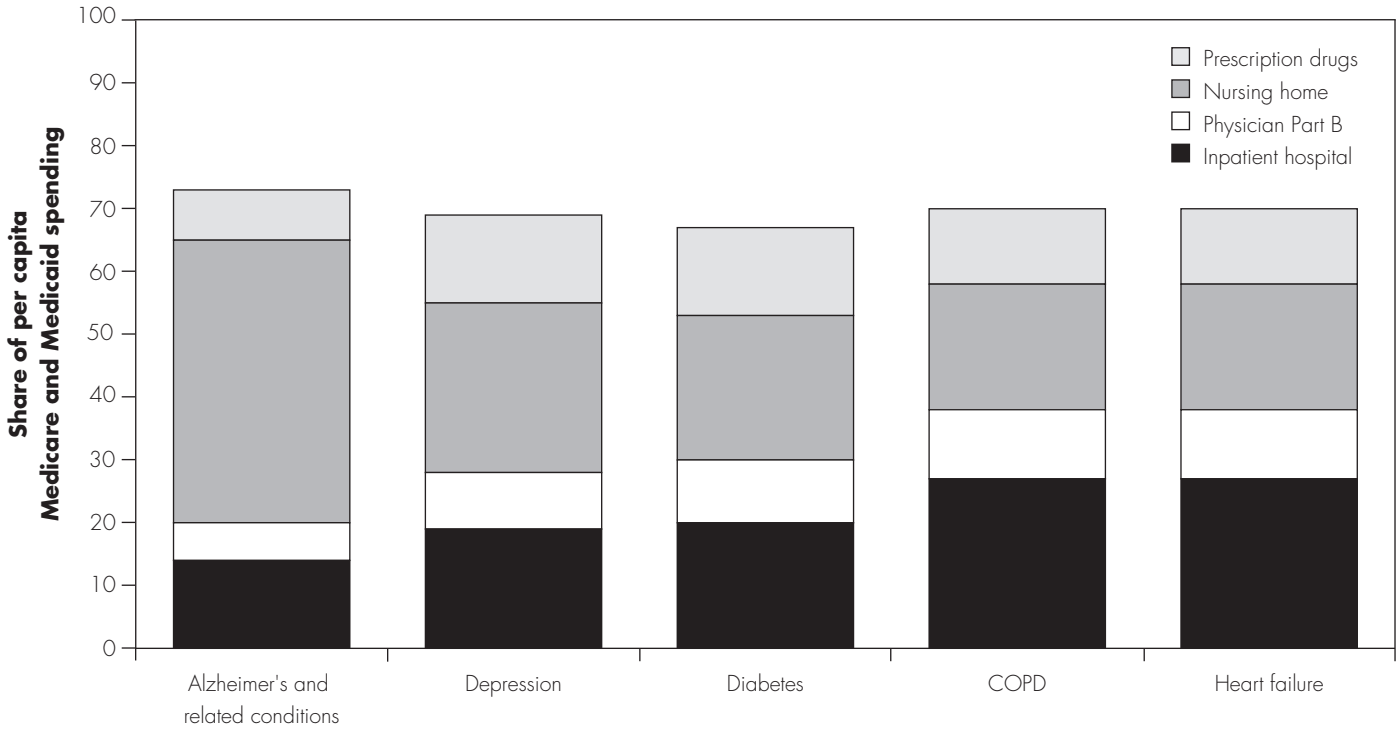


Note: Beneficiaries were grouped into the "aged" and "disabled" groups based on how they qualified for Medicare coverage. The grouping uses a hierarchy that first divides dual-eligible beneficiaries by their original eligibility into the Medicare program. Beneficiaries are then assigned to a mental impairment group and, if none, are assigned to a physical impairment group (a beneficiary with both would be assigned to a mental impairment group). Physical impairment refers to a limitation to perform activities of daily living such as bathing, dressing, or eating. The percentages represent the share of all duals included in the group. Beneficiaries with end-stage renal disease were excluded.

Source: MedPAC analysis of Medicare Current Beneficiary Survey Cost and Use file, 2004–2006.

FIGURE 5–6

Differences in per capita spending by select chronic condition



Note: COPD (chronic obstructive pulmonary disease). The analysis includes duals who were eligible for full Medicaid benefits and were enrolled during all 12 months of the year or were enrolled from January through their date of death. Data from Maine were incomplete and were excluded. Analysis excludes beneficiaries with end-stage renal disease and beneficiaries enrolled in Medicare Advantage plans or Medicaid managed care plans.

Source: Mathematica Policy Research 2010; CMS merged Medicaid (MAX) and Medicare summary spending files for 2005.

capita spending for inpatient services was more concentrated (27 percent of per capita spending) for duals with heart failure or COPD compared with duals with any chronic condition (17 percent of per capita spending). Across the most common chronic conditions, per capita spending on prescription drugs ranged from 8 percent (Alzheimer's disease and related conditions) to 14 percent (depression and diabetes). Per capita spending on physician and other Part B services ranged from 6 percent (Alzheimer's disease and related conditions) to 11 percent (COPD, heart failure, ischemic heart disease, and rheumatoid arthritis and osteoarthritis).

Implications for coordinating care

The design and targeting of care coordination approaches could be tailored to match the care needs of different groups of dual-eligible beneficiaries. Given the variation in the level and mix of spending, a uniform way to coordinate care for all dual-eligible beneficiaries is unlikely to be as effective as more targeted approaches for individual subgroups. For example, coordinating the care for dual-eligible beneficiaries living in the community will require managing services across a wide array of providers, especially for beneficiaries with multiple chronic conditions. In contrast, for beneficiaries residing in nursing homes, care coordination might be best based at the facility. It might be possible to avoid premature institutionalization of some dual-eligible beneficiaries with minimal care needs if they are managed appropriately.

Beneficiaries with certain clinical conditions are at greater risk of hospitalization than others. Care management approaches that emphasize preventing unnecessary hospitalizations would avoid the unnecessary spending and care transitions that undermine good quality of care. Such techniques would differ for community-dwelling and institutionalized beneficiaries. In addition, specific medication management approaches

could be used for beneficiaries with high spending on prescription drugs or with certain diagnoses, similar to the medication therapy management programs that prescription drug plans and Medicare Advantage–Prescription Drug plans are required to implement for high-risk beneficiaries. There has been considerable variation in how these programs were implemented and CMS strengthened plan requirements for 2010 (Medicare Payment Advisory Commission 2009b, Medicare Payment Advisory Commission 2010).

Conflicting incentives of Medicare and Medicaid

Care coordination is hampered by the conflicting incentives of Medicare and Medicaid. The two programs can work at cross-purposes that undermine cost control and good patient care. At the payer level, Medicaid and Medicare have incentives to minimize their financial liability by avoiding costs through coverage rules. Medicare covers services that are restorative or improve a beneficiary's functional status, denying payment for services that are considered "maintenance." In contrast, Medicaid may pay for services that prevent further deterioration. At times there is ambiguity about whether a service helps maintain the status quo or is restorative.

Examples of these conflicting incentives include the financial incentive to hospitalize nursing home residents, shift costs to the next provider ("downstream") in an episode of care, and shift coverage for home health care from one program to another (see text box on conflicting incentives). States' longstanding use of "Medicare maximization" strategies—raising a state's federal match dollars through illusory financial arrangements—underlines the importance of designing financially integrated approaches that successfully balance state flexibility with adequate fiscal controls and the need for carefully specified policies.

Fee-for-service payment methods discourage care coordination

Medicare and Medicaid pay for post-acute care (PAC) by using fee-for-service (FFS) payment methods that typically limit spending per visit, day, or episode. These payment methods create incentives to hospitalize patients with above-average costs rather than invest in the resources (such as skilled nursing staff) to manage patients in-house. Estimates of the rates of potentially avoidable rehospitalizations vary from 18 percent to 40 percent, depending on the PAC setting, the risk adjustment method, and the clinical conditions considered (Grabowski et al. 2007, Medicare Payment Advisory Commission 2010, Saliba et al. 2000).

Hospitalization rates appear to be sensitive to the level of payments. One study of nursing homes found that for every additional $10 in Medicaid daily payment above the mean, the likelihood of hospitalization declined 5 percent (Intrator et al. 2007). Another nursing home study found that Medicaid residents were more likely than other higher payment patients to be rehospitalized, with risk-adjusted hospitalization rates that were 15 percent lower for Medicare and private pay patients (Konetzka et al. 2004).

As a result of the FFS payment methods, providers typically have no incentive to take into account the impacts of their own practices on total spending over time. What may be in a provider's own financial interest in the short term may result in higher federal spending over the longer term. Medicare's PAC transfer policy under the hospital inpatient prospective payment system counters the financial incentive to prematurely discharge inpatients to PAC settings. However, PAC settings do not have transfer penalties. PAC providers can lower their own costs by shifting patients to other PAC settings or to the community. Although bundling Medicare payments for hospital and PAC services could encourage more efficient use of Medicare resources, it would not address the incentive to shift costs to another program.

Further discouraging care coordination is the lack of a care coordination benefit in Medicare. Although care coordination per se is not covered, certain providers are required to conduct some of these activities, such as discharge planning by hospitals. Because MA plans are required to provide only those services covered in FFS, they are not required to furnish care coordination. However, these activities may improve a plan's quality indicators and its financial performance, particularly plans that enroll high-cost beneficiaries. Plans enrolling an essentially well mix of beneficiaries may have little financial incentive to offer care coordination activities.

Conflicting incentives may lower quality of care

Because Medicaid and Medicare have no incentive to improve overall efficiency and care coordination for duals, each program focuses on minimizing its own payments instead of investing in initiatives that would lower overall

Examples of conflicting incentives

Three examples illustrate how providers and states can shift the responsibility for beneficiaries from one program to another and, at the same time, raise total federal spending (Grabowski 2007).

- *Nursing home transfer to hospitals*—Transferring dual-eligible beneficiaries receiving long-term care in nursing homes to hospitals is financially advantageous to facilities and states but raises Medicare spending. A nursing home benefits first by avoiding the high costs associated with care the hospital had to provide. State bed-hold policies that pay nursing homes a daily amount while a resident is in the hospital can also affect hospitalization rates. States with bed-hold policies had hospitalization rates that were 36 percent higher than states without them (Intrator et al. 2007). Second, the facility may qualify for a higher payment under Medicare when the beneficiary is readmitted and requires skilled nursing facility (SNF) services.[7] The state also benefits when beneficiaries qualify for Medicare-covered SNF stays because its financial liability is to pay only for the copayments and deductibles for Medicare-covered services.
- *Hospital transfer to nursing home*—Hospitals do not have a financial incentive to consider the "downstream" costs of long-term care. Rather, their financial incentive is to lower their own costs by transferring patients to nursing facilities, which increases state and federal spending.
- *Home health care*—As a result of a 1988 U.S. Supreme Court decision, Medicare broadened the coverage guidelines for home health care.[8] Medicare's home health benefit expanded from covering mostly short-term, post-acute care to one that can cover patients over longer periods of time (Government Accountability Office 2000). Because Medicare and Medicaid home health care coverage can be ambiguous (does the patient qualify for skilled care, is the patient homebound), Medicare and Medicaid can jockey to avoid paying for care by asserting the beneficiary does or does not meet Medicare's criteria for coverage (being homebound, requiring skilled care, or receiving part-time or intermittent services).[9] ■

spending and improve quality. States are more inclined to invest in programs to lower their long-term care spending than in programs that avoid unnecessary hospitalizations because these benefits accrue to Medicare. Reflecting the ambivalence to lower rehospitalization rates, none of the four state nursing home pay-for-performance programs (Iowa, Kansas, Minnesota, and Ohio) uses hospital readmissions as a performance measure (Grabowski 2007).

The patterns of care that result from shifting patients for financial, rather than clinical, reasons can lead to suboptimal care for beneficiaries. Nursing homes have little incentive to provide preventive care and avoid acute flare-ups of chronic conditions if their efforts raise their costs. Moreover, to the patient's detriment, unnecessary hospitalizations expose beneficiaries to hospital-acquired disease that can delay patients' recovery or erode their health status. We found that dual-eligible beneficiaries make up the majority of beneficiaries with repeat hospitalizations (four or more within two years). Multiple transitions between settings increase the likelihood that a patient will experience fragmented care, medical errors, medication mismanagement, and poor follow-up care. The Health and Human Services Office of Inspector General found that more than one-third of episodes of patients with multiple hospital skilled nursing facility stays were associated with quality-of-care problems (Office of Inspector General 2007).

Care can also be fragmented when dual-eligible beneficiaries are enrolled in multiple plans for their health care coverage. Some dual-eligible beneficiaries are enrolled in different Medicaid and Medicare managed care plans or in a managed care plan under one program and FFS in the other, in addition to a separate plan for prescription drug coverage. Duals in these circumstances do not have a single person or entity taking responsibility

for their care. Such fragmentation can lead to medication mismanagement, poor coordination of treatment plans, and low patient adherence to medical instructions.

For cognitively impaired dual-eligible beneficiaries, efforts to effectively coordinate care are further complicated. Focus groups have revealed that dual eligibles often do not understand their benefits and coverage (Ryan and Super 2003). This complexity of coverage can result in discontinuities in care, involuntary disenrollment, and inappropriate charges for cost sharing. These experiences were echoed in focus groups on prescription drug coverage conducted by the Commission in 2009. We found that some low-income beneficiaries were confused about coverage of the various programs they were enrolled in.

Fragmentation can occur even when beneficiaries are enrolled in SNPs, the MA plans that focus on special needs populations, including dual-eligible beneficiaries. Until 2010, SNPs were not required to contract with states to provide Medicaid benefits and most did not. In 2008, the Commission recommended that the Secretary require SNPs to contract with the states of their service areas (Medicare Payment Advisory Commission 2008). The Medicare Improvements for Patients and Providers Act of 2008 required SNPs to contract with states to provide Medicaid benefits (for a summary of the legislative changes to SNP provisions, see online Appendix 5-B, available at http://www.medpac.gov).

Approaches to integrate the care of dual-eligible beneficiaries

There are approaches to coordinate the care for dual-eligible beneficiaries that combine the financing of Medicare and Medicaid and make a single entity (such as a provider or managed care plan) responsible for coordinating all services. Two approaches are being used to integrate the care for dual-eligible beneficiaries: Medicare Advantage special needs plans (SNPs) that contract with the state Medicaid agencies to provide all services and PACE. These approaches shift the current silos of financing and care delivery to one entity that is responsible for all services and at full financial risk. While the models integrate the financing and care coordination, they differ in whether the entity is acting essentially as an insurer (managed care plans) or primarily as a set of providers assuming risk (PACE). They also vary considerably in their target populations and enrollment, the services they manage, and how they organize and integrate services.

Some policy analysts have proposed approaches that integrate the financing of the two programs (but do not coordinate the care) as a way to help overcome the programs' conflicting incentives. Financial integration approaches include giving block grants to the states or shifting the responsibility of dual-eligible beneficiaries to the Medicare program. In block grants, a state would be given a funding allotment each year (a block grant) to pay for all services covered by Medicaid and Medicare.[10] If a state's spending is less than the block grant, the state would keep the difference; if spending exceeds the grant amount, the state would be financially liable. Block grants would require enforcement to ensure that state programs maintained beneficiary access to services and that states funded the intended services.[11] Financial integration could also be achieved if Medicare assumed primary administrative responsibility for the services furnished to the dual-eligible population (Bruen and Holahan 2003, Government Accountability Office 1995, Holahan et al. 2009, Moon 2003). Although approaches to financially integrate Medicaid and Medicare would mitigate the conflicting incentives of the programs, they would not, by themselves, result in coordinated care.

Features of a fully integrated model of care

Fully integrated models of care manage both Medicare and Medicaid services and benefits. Many other efforts manage either Medicaid or Medicare services (but not both), and those that manage only Medicaid services typically exclude long-term care. However, given the incentives to shift costs between the programs, fully integrated models of care should consider including both programs and extend to all services.

Integrated care has the potential to offer enrollees enhanced, patient-centered, and coordinated services that target the unique needs of the dual-eligible enrollees (Table 5-7). Case management, individualized care plans, assistance with accessing community services, and care transition services are intended to lower total program costs by averting hospitalizations, institutional care, medication mismanagement, and duplicative care.

Care coordination begins by assessing patients to identify their level of risk and matching coordination efforts to the person's needs. Then, a multidisciplinary team develops a patient-specific plan of care that is regularly updated

TABLE 5–7 **Sample activities of an integrated model of care**

Feature	Coordinated care activity
Assess patient and assign to a risk group	• Use protocols, service use (e.g., hospital and SNF admissions, ER and specific prescription drugs), referrals from community service and medical care providers, and predictive models to identify high-risk beneficiaries • Care coordination plan reflects the patient's level of risk
Devise and update individualized care plan	• Design a plan of care for each beneficiary; share plan with patient and all providers; update plan periodically to reflect changes in health status or service provision • Educate patients about their prescription drugs and how to manage their disease • Visit at home those patients who are at risk for falls; identify and coordinate installation of safety measures • Socially isolated beneficiaries may be enrolled in adult day care • Adapt patient education and counseling activities for cognitively impaired beneficiaries so that patient/family member recognizes warning signs of the need for prompt medical attention
Assist beneficiary in negotiating health care and community services systems	• Schedule appointments • Arrange for prescriptions, DME, and transportation • Link beneficiary to community services (such as heating assistance programs) that could undermine medical regimen if left unattended
Manage nursing home use	• Visit patients in nursing homes to monitor and treat conditions that if left untreated could result in hospitalization
Coordinate behavioral and primary health care	• Clinical social workers may screen patient population for mental health care needs • Behavioral health providers update primary care physicians on a quarterly basis
Multidisciplinary teams manage care	• Teams may consist of primary care physician, clinical social worker, pharmacist, behavioral health provider, and medical assistant

Note: SNF (skilled nursing facility), ER (emergency room), DME (durable medical equipment).

Source: Lukens et al. 2007.

so that it remains a current map of the care each patient should receive. A comprehensive provider network ensures that patients have access to the full spectrum of services that address the special care needs of dual-eligible patients. Ideally, a beneficiary would have one plan card with one set of rules for Part A, Part B, and Part D coverage. Data are shared across providers so that all participants know the care plan, the services furnished to beneficiaries, and the outcomes and results so that care can be optimally managed.

Performance measures for fully integrated care

Performance measures for fully integrated plans should include outcome-based measures of quality that span all providers over an episode of care as well as metrics specific to the clinical conditions prevalent among the dual-eligible population. In addition, measures should gauge the level and success of care coordination and case management. Tying providers' performance on these types of measures to payments can give them an incentive to collaborate.

One set of outcome measures could be used to gauge the overall performance of all types of fully integrated programs, which would allow for comparison of plans along comparable dimensions of care. Quality measures for managed care plans (such as MA plans) currently assess the extent to which patients receive appropriate preventive care, medication, and acute care and also assess patient satisfaction. In addition, outcome measures could include hospital readmission rates, rates of hospital

admissions for ambulatory-care-sensitive conditions, potentially preventable emergency department visits, and mortality rates for specific conditions. Changes over time in functional and cognitive status may also be appropriate measures for the dual-eligible population. For all outcome measures, it is important to use risk adjustment as much as technically feasible to control for patient characteristics that can affect outcomes but are beyond the providers' influence.

Furthermore, some metrics should be tailored to the care needs of the relevant population, defined by specific factors such as diagnoses, cognitive state, disability status, and institutional status. For example:

- *Nursing home residents:* Although publicly reported Nursing Home Compare measures report on many aspects of institutional long-term care, they do not assess the appropriateness of the admission, medication errors, or rates of potentially avoidable hospitalizations. Ideally, quality measures would detect, for example, if patients were prematurely institutionalized or if their medical condition or functioning deteriorated more quickly than expected once they were institutionalized. In addition to measures for the elderly, measures should include those specifically designed to gauge the quality of care furnished to beneficiaries with physical or cognitive disabilities.
- *Beneficiaries living in the community:* Measures could gauge whether beneficiaries who need supportive care and other social services receive them and the degree of care coordination (e.g., does the patient have a primary care physician who is regularly seen and are medications being managed). CMS established a quality framework for HCBS that included the following categories of measures: beneficiary access, patient-centered service planning and delivery, provider capacity and capabilities, beneficiary safeguards, patient rights and responsibilities, outcomes and patient satisfaction, and system performance.[12] Because a large fraction of the disabled live in the community, measures specifically designed for adults with disabilities would need to be able to gauge the quality of care furnished to this population.
- *Duals with significant mental health care needs:* Given the chronic nature of some severe mental illness, outcome measures for many duals will be hard to develop (see Chapter 6). In the interim, process measures could gauge whether the care coordination identifies persons needing mental health services, ensures beneficiaries receive care in a timely manner, checks that patients' medications are reconciled periodically and every time they transition from one care setting to another and that the medications are being taken, and facilitates communication between a beneficiary's mental health professional and his or her primary care physician. Hospitalization rates for selected psychiatric conditions would provide feedback on the success of managing beneficiaries on an outpatient basis.

Fully integrated care programs should also assess the degree of care coordination and care management provided. As of 2009, SNPs are required to report on structure and process measures of case management, care transitions, and dual-eligible integration. For example, one measure looks at how frequently an organization identifies members who need case management services, while another measure counts how many processes focused on reducing unplanned transitions. Regarding Medicare–Medicaid coordination, SNPs must report whether they have, or are working toward, an agreement with the relevant state Medicaid agency. An inherent shortcoming of these structure and process measures is that they do not assess the effectiveness of these care coordination efforts. Patient and physician surveys on care transitions and case management efforts may be helpful in assessing how much managed care programs facilitate patient understanding of postdischarge plans and improve provider collaboration.

Examples of fully integrated care programs

There are two main types of fully integrated care programs: state–SNP integrated managed care programs and PACE. These programs receive capitated Medicare and Medicaid payments to cover all Medicare and Medicaid services including all or some long-term care services. The programs are at full financial risk for all (or most) of the services they cover. This risk structure gives the programs the incentive to coordinate the Medicare and Medicaid services they offer to reduce unnecessary utilization or high-cost services that programs would otherwise have to pay for.

The type of entity that receives the capitated payments and manages the benefits differs in the two approaches. In the state–SNP programs, the integration is through a managed care plan; under PACE, these functions are carried out by a PACE provider. All the state–SNP programs and PACE target dual-eligible beneficiaries, although the specific subgroups of dual-eligible beneficiaries that

are targeted for enrollment differ across programs. In addition, while the intensity of care coordination varies across programs, this variation may reflect the level of needs of the programs' target population. For example, the PACE program offers an intense care management structure with frequent monitoring and management of participants; however, PACE serves the frail elderly living in the community who require this level of care. A program serving a healthier dual-eligible population may require a less intense form of care management than PACE provides.

A number of states are considering other models to improve care coordination for the dual-eligible population. These alternative models include state-administered managed care plans and medical homes. Each has the potential to improve the care coordination for the dual-eligible population but, for different reasons, may have limited success and one model could raise significant concerns about adequate fiscal controls and accountability (see text box, p. 147).

State–SNP integrated managed care programs

To date, at least eight states—Arizona, Massachusetts, Minnesota, New Mexico, New York, Texas, Wisconsin, and Washington—have fully integrated Medicare and Medicaid programs for dual-eligible beneficiaries through SNPs (all of which are MA plans) or through MA plans that are not SNPs (see text box on SNPs, p. 148). Under these programs, a managed care organization, often operating in MA as a SNP, receives capitated payments from both Medicare and Medicaid. The plans are then responsible for establishing provider networks and implementing the model of care, including care coordination or case management services. An estimated 120,000 dual-eligible beneficiaries nationwide are enrolled in fully integrated managed care programs (Center for Health Care Strategies 2009). These individuals represent less than 1.5 percent of the dual-eligible population and about 8 percent of the dual-eligible beneficiaries enrolled in MA plans (SNP and non-SNP MA plans) (Center for Health Care Strategies 2010).[13]

Integrated managed care programs through SNPs could be an option for all subgroups of the dual-eligible beneficiaries—the nonfrail aged, the nursing-home certifiable, the institutionalized, the physically disabled, and the mentally retarded and developmentally disabled. Currently, programs exist to serve these individual subgroups, but few programs serve all subgroups in the same program.

The state programs vary in their eligibility requirements (their target populations), their enrollment, covered services, risk structures, and models of care. There is also variability in results, if any, to date. The key characteristics and differences across state–SNP integrated managed care programs are discussed below (Table 5-8). A brief description of each state–SNP integrated managed care program is provided in a text box (see text box on state–SNP integrated managed care program descriptions, pp. 150-151).

Eligibility While the programs vary in the subgroups of dual-eligible beneficiaries they serve, the two broadest groups of dual-eligible beneficiaries—the aged and disabled—are eligible to enroll in almost all of the programs. Six of the programs (Arizona, New Mexico, New York, Texas, Wisconsin, and Washington) enroll the aged and disabled in the same program. Minnesota has separate programs for the aged and disabled. Some programs exclude large subgroups of duals, such as the non–nursing home certifiable (beneficiaries who are healthy or not frail enough to require a nursing home level of care), institutionalized duals, or the mentally retarded and developmentally disabled. The programs that do not restrict eligibility to the nursing home certifiable can enroll both beneficiaries who are healthy or not frail enough to require nursing home services and frail dual-eligible beneficiaries who require a nursing home level of care.

Fully integrated state–SNP programs appear to more selectively target subgroups of the disabled duals compared with the aged duals. Regarding the disabled populations, some programs exclude the non–nursing home certifiable and institutionalized disabled, while others restrict eligibility to the physically disabled, thus excluding the mentally retarded and developmentally disabled population. Regarding the aged, the non-nursing home certifiable is the most common subgroup of the aged duals that is excluded from these programs, and one program also excludes the institutionalized aged. These restrictions may be indicative of the challenges in designing and implementing multiple models of care in a single program to serve the distinct subgroups of dual-eligible beneficiaries.

Enrollment Most states with strong enrollment in their integrated care programs had statewide Medicaid managed care programs in place before adding the integrated programs. Other states' programs, such as the one in New York, struggled with enrolling large numbers of eligible duals. In New York, voluntary program enrollment and

TABLE 5–8 **Characteristics of fully integrated care programs**

State	Program name	Eligible population: Aged	Eligible population: Disabled	Mandatory or voluntary enrollment
Arizona	Arizona Long-Term Care System (ALTCS)	Nursing home certifiable only	Nursing home certifiable only	Mandatory enrollment in ALTCS for Medicaid long-term care services, but voluntary enrollment in a Medicare managed care plan
Massachusetts	Massachusetts Senior Care Options	Yes	No	Voluntary
Minnesota	Minnesota Senior Health Options (MSHO)	Yes	No	Voluntary for MSHO, but mandatory for aged Medicaid beneficiaries to enroll in a managed care plan. MSHO is one of the managed care options.
	Special Needs Basic Care	No	Yes	Voluntary; disabled are not required to enroll in a managed care plan
New Mexico	Coordination of Long-Term Services	Yes	Yes, but excludes beneficiaries with developmental disabilities who are enrolled in a 1915(c) waiver	Mandatory
New York	Medicaid Advantage Plus	Nursing home certifiable only	Nursing home certifiable only	Voluntary
Texas	Texas Star+Plus	Yes, except for beneficiaries residing in nursing facilities	Yes, except for beneficiaries residing in intermediate care facilities for the mentally retarded	Mandatory
Washington	Washington Medicaid Integration Partnership	Yes	Yes	Voluntary
Wisconsin	Wisconsin Partnership Program	Nursing home certifiable only	Physically disabled only	Voluntary

Source: Center for Health Care Strategies 2010, Centers for Medicare & Medicaid Services 2007, Edwards et al. 2009, Frye 2007, Korb and McCall 2008, and Osberg 2009.

competition from nonintegrated SNPs contributed to the program's low enrollment (Korb and McCall 2008). In addition, most programs operate in select regions within each state rather than across the entire state, which can also limit enrollment.

Covered services and risk structure The nine state–SNP fully integrated programs cover Medicare acute care benefits, Medicaid acute care wraparound benefits, and Medicaid long-term care services. Most also cover behavioral health services. A few of these programs, however, place limits on the amount or type of long-term care services that are covered. For example, Minnesota's programs, Minnesota Senior Health Options (MSHO) and Special Needs Basic Care, cover nursing home utilization up through 180 days and 100 days, respectively. Any nursing home utilization incurred after these limits is paid through Medicaid FFS although enrollees remain in the program. New York's Medicaid Advantage Plus program also caps

Alternative models may be limited in their ability to effectively control spending and coordinate care

Some states are considering other ways to improve the care coordination for dual-eligible beneficiaries, including state-administered managed care plans and medical homes. In state-administered managed care plans, a state entity would receive special needs plan–like payments from Medicare and Medicaid and would be responsible for all health care benefits for dual-eligible beneficiaries. One model considers state-administered Medicaid Advantage plans in which participating states contract with competing health plans to manage the care for dual-eligible beneficiaries (Turner and Helms 2009). The state would have the option of managing the care itself, if its state capacities were sufficiently developed, or contracting with private health plans. Each state could tailor benefit packages to target specific groups of dual-eligible beneficiaries, use performance-based payments, and encourage plans to engage in active care management.

This model may have potential in some states but may not result in adequate beneficiary access to care and proper use of federal spending in every state. Policymakers should note a long history of state financial strategies to maximize federal support while minimizing the state's own contributions. Such strategies generated considerable controversy because the higher federal spending did not always expand coverage or get used to furnish or improve health care (Coughlin and Zuckerman 2002). The strategies underline the importance of adequate fiscal controls and accountability to ensure that spending remains focused on target populations and services.

A number of states are considering the use of medical homes to manage care for dual-eligible beneficiaries. In this model, primary care practitioners are paid (typically on a per member per month basis) to coordinate care for patients between visits and across providers. In 2008, the Commission recommended that Medicare establish a pilot program for medical homes that pays qualified medical practices to coordinate the care of beneficiaries with multiple chronic conditions.

In January 2010, the North Carolina Community Care Networks, an existing medical home and shared savings program serving the Medicaid population, began providing dual-eligible beneficiaries with care management in return for a portion of the savings that may eventually accrue. Any Medicare savings beyond a certain threshold will be reinvested in other services, including home-based services, health information technology, and coverage expansions (Community Care of North Carolina 2009). According to CMS, at least half of the shared savings payments will be contingent on those providers meeting certain quality goals.

Under current payment policies, because medical homes do not assume full risk for their patients' care, their effectiveness at controlling spending will be limited. Medical homes operate within the context of fee-for-service (FFS) medicine and their ability to control total spending will be limited by the portion of payments attached to performance measures. That said, medical homes represent a potentially effective way to bridge the unmanaged world of FFS and more fully integrated care. ■

covered nursing home utilization at 100 days. Texas's program covers community-based long-term care services but not institutional nursing home care (Center for Health Care Strategies 2010, Edwards et al. 2009, Osberg 2009, Texas Health and Human Services Commission 2010b).

Model of care for state–SNP programs The state–SNP programs manage the Medicare medical services and Medicaid medical and support services for the dual-eligible beneficiaries. For example, in addition to managing the Medicare and Medicaid medical services, care coordinators typically consider the need for nonmedical services and supports that facilitate beneficiaries living in the community. These services include HCBS, transportation, heating, food, and housing-related supports; they can help beneficiaries function at home so they can more effectively seek medical attention and adhere to treatment regimens, resulting in appropriate service use.

Special needs plans

Special needs plans (SNPs) are Medicare Advantage (MA) plans that target enrollment to certain groups of Medicare beneficiaries. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized SNPs to target enrollment to the following types of beneficiaries with special needs: those dually eligible for Medicare and Medicaid services, the institutionalized, and beneficiaries with severe or disabling chronic conditions. SNPs were originally authorized through December 2008; first extended through 2009 by the Medicare, Medicaid, and SCHIP Extension Act of 2007; extended again through 2010 by the Medicare Improvements for Patients and Providers Act of 2008; and again through 2013 by the Patient Protection and Affordable Care Act (H.R. 3590).

SNPs receive capitated payments from Medicare to offer Part A and Part B services as well as prescription drug coverage under Part D. Medicare pays SNPs through the same payment method as other MA plans. Payments are risk adjusted for factors that include dual-eligibility status, health condition, disability status, and residence in an institution. SNP per capita payments tend to be higher than payments to other MA plans in the same geographic area because of the risk-adjustment factors and the populations SNPs enroll.

SNPs can also contract with states to receive Medicaid payments to offer Medicaid benefits for dual-eligible beneficiaries. Beginning in 2010, new and expanding dual-eligible SNPs are required to have contracts with states; however, existing dual-eligible SNPs that are not expanding have until January 1, 2013, to establish state contracts (see summary of main legislative changes in online Appendix 5-B, available at http://www.medpac.gov). SNPs can offer a range of Medicaid services for the dual-eligible beneficiaries including coverage of Medicare cost sharing, supplemental acute care services that are not offered by Medicare (such as vision, dental, and transportation), and institutional and community-based long-term care services and supports. SNPs that offer all Medicare and Medicaid acute and long-term care services are considered fully integrated programs. More information on SNPs is available in online Appendix 5-B, available at http://www.medpac.gov. ■

Source: Saucier et al. 2009, Verdier 2006

Each program has a single care coordinator or a care management team to oversee the enrollee's care. For example, in Minnesota's MSHO program for the aged, enrollees are assigned a care coordinator who works with the enrollee's primary care physician and coordinates the enrollee's health care and social services. In the Massachusetts Senior Care Options program for the aged, care management teams coordinate the care for enrollees and authorize the services that enrollees can receive. Similarly, in the Wisconsin Partnership Program, which enrolls both the nursing home certifiable aged and physically disabled adults, the managed care plans employ staff who work together as care coordination teams and nurse practitioners who are responsible for overseeing enrollees' care (Centers for Medicare & Medicaid Services 2007).

Programs also include other coordination activities in their models of care. Arizona's program, for example, focuses on rebalancing nursing home– and community-based long-term care. Institutionalized enrollees are reassessed every six months to see if they can be placed in the community (Centers for Medicare & Medicaid Services 2007). Some integrated care programs have adopted elements of the Evercare Nursing Home Program, a model of managing Medicare benefits for long-stay nursing home patients. The goal of the program is to provide better Medicare primary care services in order to lower Medicare spending by reducing hospitalizations and emergency services. The health plans employ nurse practitioners who work with nursing home residents' primary care physicians to provide enhanced primary care, care coordination, and customized care planning.

Results Outcomes research on the integrated programs is limited; however, analyses of some of the programs demonstrate their ability to reduce institutional and inpatient utilization. The Massachusetts Senior Care Options and Minnesota Senior Health Options program reduced nursing home utilization. Specifically, the

Massachusetts program reduced the number of nursing home admissions and nursing home lengths of stay. Under the Minnesota program, nursing facility utilization declined over a recent five-year period by 22 percent and the number of seniors receiving HCBS increased by 48 percent (JEN Associates 2009, Osberg 2009). An analysis of Evercare demonstration sites found that patients had a lower incidence of hospitalizations, fewer preventable hospitalizations, and less emergency room utilization compared with two control groups (Kane et al. 2002).

Program of All-Inclusive Care for the Elderly

PACE is a Medicare benefit and an optional Medicaid benefit that fully integrates care for the frail elderly, most of whom are dual eligible. To qualify for coverage, beneficiaries must be at least 55 years of age, nursing-home certified, and live in a PACE service area. Enrollees attend an adult health day care center where they receive medical attention from an interdisciplinary team of health care and other professionals. States vary in their licensing requirements for PACE entities—as day care centers, home care providers, outpatient clinics, or some combination of them.

Under capitation with both Medicare and Medicaid, the PACE organization is responsible, and at full risk, for providing all medically necessary care and services, including primary care, occupational and recreation therapy, home health care, and hospital and nursing home care. The interdisciplinary team consists of a physician, registered nurse, social worker, physical therapist, occupational therapist, recreational therapist or activity coordinator, dietician, PACE center manager, home care coordinator, personal care attendants, and drivers. PACE sites directly employ the majority of PACE providers and establish contracts with providers such as hospitals and nursing facilities. If an enrollee needs nursing home care, the PACE program pays for it and continues to coordinate his or her care, even though the beneficiary resides in the facility. Beneficiaries are provided transportation to attend the day care center during the week.

Evaluations of this program have been positive. In its demonstration phase, the program demonstrated higher rates of ambulatory service utilization and significantly lower rates of nursing home utilization and hospitalization relative to those of a comparison group (Chatterji et al. 1998). Concurrently, quality measures were good—enrollees reported better health status and quality of life, and mortality rates were lower. The Balanced Budget Act of 1997 authorized the coverage of PACE benefits in the Medicare program, and PACE programs began expanding across the country.

Overall enrollment in PACE programs is low, although the number of PACE organizations has more than doubled since 1999. The number of PACE programs grew from 30 in 1999 to 72 in 2009, and as of February 2010, 18,000 beneficiaries in 30 states were enrolled in PACE (National PACE Association 2010).[14] In a survey of PACE program officers and researchers, one study identified a number of barriers to expansion (Lynch et al. 2008). First, many beneficiaries did not find the program appealing, given that they would have to frequently attend the adult day care center and change their existing provider relationships. Second, the program had significant upfront costs that nonprofit entities often could not afford. Third, it is more difficult to make PACE programs financially viable in rural areas. The distances raise transportation costs and place a greater premium on information technology to integrate the care coordination and centralize medical records. Despite these challenges, officials from the National PACE Association mentioned that 14 programs are operating in rural areas. Some of these programs use teleconferencing for team meetings and information technology to facilitate the sharing of medical charts from multiple locations.

The PACE model is not a match for some beneficiaries. The program targets the frail elderly who live in the community and are eligible for nursing home care. Patients who have modest care needs are not appropriate for this level of care.

Challenges to expanding enrollment in integrated care

States and managed care entities have faced a number of challenges when implementing integrated care programs. While some states and entities have overcome these factors, they still remain as challenges to more wide-scale implementation of these programs.

Lack of experience with long-term care

Most states, Medicare managed care plans, and medical homes do not have experience with managed care for long-term care services. Only 10 states had some form of Medicaid managed long-term care by January 2009 (Edwards et al. 2009). The remaining states either do not have Medicaid managed care programs for the aged

State–special needs plan integrated managed care program descriptions

Arizona Long-Term Care System

The Arizona Long-Term Care System (ALTCS) program is an example of a mandatory Medicaid managed care program in which the state contracts with managed care plans to also offer enrollees Medicare benefits. It is one of the programs within the Arizona Health Care Cost Containment System—a statewide mandatory 1115 waiver demonstration program for Medicaid beneficiaries. ALTCS provides long-term care services. Participation in ALTCS is mandatory for the elderly and disabled who are nursing home certifiable; however, enrollees can choose to enroll in one of the Medicare managed care plans or special needs plans (SNPs) for their Medicare benefits or they can receive their Medicare benefits through fee-for-service (FFS). Most ALTCS members reside in the community and receive home- and community-based services (HCBS) such as home health, attendant care, personal care, transportation, adult day care, and homemaker services. Institutionalized enrollees are reassessed every six months to see if they can be placed in the community (Centers for Medicare & Medicaid Services 2007).

Massachusetts Senior Care Options

The Massachusetts Senior Care Options (SCO) program began in 2004 as a demonstration program and converted to SNP authority. All aged Medicaid beneficiaries, both nursing home certifiable and non–nursing home certifiable, are eligible to enroll in the program on a voluntary basis. The program covers all Medicare and Medicaid benefits, including institutional and community-based long-term care services. Care management teams coordinate the care for enrollees and the teams authorize the services that enrollees can receive. An evaluation of SCO published in 2009 found that the program reduced both the number of nursing home admissions and nursing home length of stay (Centers for Medicare & Medicaid Services 2007, JEN Associates 2009).

Minnesota Senior Health Options

Minnesota's program, Minnesota Senior Health Options (MSHO), originally began in 1997 under Medicare demonstration authority. The managed care plans participating in MSHO are now required to be SNPs. MSHO is a voluntary program for dual-eligible seniors who are nursing home certifiable and non-nursing home certifiable. Although the program is voluntary, it has been mandatory since 1983 for Minnesota's elderly Medicaid population to enroll in a managed care plan for primary and acute Medicaid services, and the elderly Medicaid beneficiaries must choose from MSHO and another plan that offers only Medicaid services. All Medicare and Medicaid acute care services are integrated in MSHO as well as behavioral health and community-based long-term care services and up to 180 days of nursing home care. Nursing home utilization after 180 days is paid for through FFS. Each enrollee has a care coordinator who works closely with the enrollee's primary care physician and coordinates the enrollee's health care and social services. MSHO data show that nursing facility utilization for MSHO members declined by 22 percent from 2004 to 2009 and the number of seniors receiving HCBS increased by 48 percent (Centers for Medicare & Medicaid Services 2007, Edwards et al. 2009, Osberg 2009).

Minnesota Special Needs Basic Care

The Minnesota Special Needs Basic Care program (SNBC), is a voluntary program for all dual-eligible beneficiaries with disabilities. SNBC coordinates all Medicare and Medicaid acute services and Medicaid behavior health services. The program covers the first 100 days of nursing home care, but all other HCBS and long-term care services are FFS (Center for Health Care Strategies 2010, Osberg 2009).

New Mexico Coordination of Long-Term Services

New Mexico's Coordination of Long-Term Services (CoLTS) program began in 2008. CoLTS is a mandatory program for dual-eligible beneficiaries, Medicaid beneficiaries living in nursing facilities, and Medicaid beneficiaries enrolled in New Mexico's disabled and elderly waiver program. The program excludes Medicaid beneficiaries with developmental disabilities who are enrolled in New Mexico's 1915(c) waivers. CoLTS offers all Medicare acute care benefits and

(continued next page)

State–special needs plan integrated managed care program descriptions

Medicaid acute and long-term care services through SNPs (Edwards et al. 2009, Korb and McCall 2008).

New York Medicaid Advantage Plus

The Medicaid Advantage Plus program (MAP) is a Medicare and Medicaid managed care program for dual-eligible beneficiaries who are nursing home certifiable. MAP offers Medicare acute and Medicaid long-term care services, including up to 100 days of care in a nursing home and HCBS such as personal care, case management, adult day care, and social support services. New York contracts with a SNP to offer the program. MAP is voluntary; however, beneficiaries must enroll in the SNP to receive their Medicare benefits before they are permitted to enroll in the SNP for their Medicaid benefits (Edwards et al. 2009).

Texas Star+Plus

Texas Star+Plus is a mandatory program for elderly Medicaid recipients and nonelderly Medicaid beneficiaries with a physical or mental disability who reside in the community. Current nursing home residents, beneficiaries in intermediate care facilities for the mentally retarded, and Star+Plus enrollees who spend more than 120 days in a nursing facility are not allowed to participate in the program. The state contracts with some SNPs to offer both Medicare and Medicaid benefits for the dual-eligible enrollees, and by 2010 contractors will be required to be SNPs. The program covers community-based long-term care but does not cover nursing facility care. Star+Plus health plans are still responsible for members who enter a nursing facility and must work with service coordinators to assess the member at 30 days and 90 days after admission to determine whether the individual can return to the community. However, nursing facility services are paid by the state directly to the nursing facility and after four months of nursing facility utilization, Star+Plus members are disenrolled from the program and return to Medicaid fee-for-service (Center for Health Care Strategies 2010, Texas Health and Human Services Commission 2010a, Texas Health and Human Services Commission 2010b).

Washington Medicaid Integration Partnership

The Washington Medicaid Integration Partnership (WMIP) is a voluntary pilot project for elderly and nonelderly disabled dual-eligible beneficiaries. The program began in 2005 and operates in one county through a SNP. WMIP offers both Medicare acute and Medicaid acute and long-term care services (Korb and McCall 2008).

Wisconsin Partnership Program

The Wisconsin Partnership Program (WPP) began in 1999 under Medicare demonstration authority and now operates through SNPs. The program is voluntary and targeted to adults with physical disabilities and the nursing home certifiable elderly. WPP covers all Medicare services and all Medicaid acute services, community-based long-term care services, and nursing home services. The managed care plans employ staff to function as care coordination teams for enrollees, and a nurse practitioner is responsible for overseeing each enrollee's care. WPP also integrates the services of independent physicians who participate in the program's network (Centers for Medicare & Medicaid Services 2007, Frye 2007). ■

and disabled or carve long-term care services out of their managed care programs. Although institutional SNPs have relationships with long-term care providers, they offer Medicare benefits to the institutional population and are not required to contract with states for Medicaid long-term care services. All dual-eligible SNPs are required by 2013 to have contracts with states. These contracts are likely to initially cover Medicaid cost-sharing, wraparound, or supplemental services but not long-term care services. Managed care entities also may not be willing to cover institutional or community-based long-term care services if they lack experience establishing a provider network for those services. Some states are considering various risk-sharing agreements to give plans incentives to include long-term care services in their benefits packages.

Stakeholder resistance

Many states faced resistance from stakeholders during the development of integrated care programs for dual-eligible beneficiaries. In some states, stakeholder opposition has derailed implementation of integrated managed care programs or expansion of these programs to additional dual-eligible populations. Resistance has come from provider groups concerned about payment rates, the loss of clients and autonomy, and dealing with managed care organizations.

Beneficiaries and their advocates are concerned with the impact of the programs on enrollee benefits, freedom of choice, and quality of care (Korb and McCall 2008). In addition, beneficiaries often are not interested in selecting managed care options for their care. They prefer seeing their current set of providers and do not want to switch physicians. Furthermore, because Medicaid currently covers the cost-sharing requirements of Medicare, dual-eligible beneficiaries are not likely to benefit financially (i.e., reduced cost-sharing obligations) by joining a managed care option.

Such resistance could be overcome with program designs that accommodate stakeholder concerns and better understanding of the benefits of the program. For example, in Minnesota and New Mexico, support for these programs grew as the states addressed some of the advocates' concerns through the program design and as advocates understood the benefits of the programs, especially the increased access to community-based long-term care. New Mexico asked for input on program design elements such as enrollment and quality from stakeholder groups including advocates, providers, and Native Americans (Edwards et al. 2009).

Initial program investments and program financial viability

Integrated care programs require initial program investments. Managed care plans, for example, have to dedicate resources to managing the care of enrollees and may hire health care professionals to coordinate care. Plans would also have to invest in technology, such as electronic medical record systems. New PACE program sites incur the initial capital costs of establishing a day care and outpatient clinic and of hiring professional staff. Surveys of PACE sites show that lack of start-up capital limited the expansion of existing nonprofit organizations (Lynch et al. 2008).

In addition, there is concern among states about Medicaid program investments generating Medicare program savings. States must secure a waiver from the federal government to implement mandatory Medicaid managed care programs, offer beneficiaries additional services under voluntary or mandatory Medicaid managed care, expand Medicaid eligibility, or test a new payment system. As part of the waiver application, states must demonstrate to the Office of Management and Budget (OMB) that federal Medicaid expenditures under the waiver will be budget neutral. Yet states may incur costs as they invest in care management services designed to lower rehospitalizations, emergency room and skilled nursing facility use, and nursing home placements. Thus, although state Medicaid programs fund care management services (many are not Medicare-covered services), the savings accrue to Medicare. States cannot use expected savings in Medicare to offset any increases in Medicaid spending when demonstrating budget neutrality. These budget-neutrality rules are longstanding OMB policy, not statutory or regulatory requirements (Rosenbaum et al. 2009).

Waiver rules also require that budget neutrality be achieved within two to five years, depending on the waiver. Savings are likely to accrue more quickly from lower hospital, emergency room, and skilled nursing facility use than from averted nursing home admissions. However, under current policies as noted, savings from one program cannot be used to underwrite costs from the other in an integrated managed care program.

Separate Medicare and Medicaid administrative rules and procedures

Medicare and Medicaid have separate and often different procedures for administrative tasks, such as enrollment, disenrollment, eligibility, marketing, appeals, and performance reporting. Navigating and trying to align the two programs' administrative rules and processes is challenging for states, managed care entities, and dual-eligible individuals with limited resources. In addition, states can take many years to obtain federal approval for a Medicare and Medicaid managed care program. Further, each program cannot access health care claims from the other, and lack of data sharing in real time can inhibit care management and coordination between SNPs and states on covered services. SNPs and states can address some of the administrative barriers through close collaboration. For example, all but one of the SNPs participating in Minnesota's integrated care program contract with the state to be responsible for the plans' Medicare enrollment (Edwards et al. 2009).

The Patient Protection and Affordable Care Act established the Federal Coordinated Health Care Office within CMS. The Federal Coordinated Health Care Office goals include simplifying processes for dual-eligible beneficiaries and eliminating regulatory conflicts between Medicare and Medicaid and may help alleviate the administrative burdens of integrated care programs.

Low program enrollment

States can obtain waivers from CMS to mandate enrollment into Medicaid managed care; however, in contrast to states' authority over Medicaid benefits, states cannot require dual-eligible beneficiaries to enroll in a SNP to receive Medicare benefits. Under Medicare, beneficiaries have freedom of choice to select providers. Dual-eligible beneficiaries are permitted to receive their Medicare benefits through any MA plan (and can change plans monthly) or through any FFS provider. Duals may not recognize the advantages of an integrated care program (such as enhanced care coordination) and therefore may not choose to enroll in integrated care programs for their Medicare benefits.

Concluding observations

Approaches to better care coordination for dual-eligible beneficiaries need to combine financing streams and actively manage the care that beneficiaries receive. Without combined finances, an approach will not fully align provider and program incentives. A strategy to coordinate care is also needed. Likewise, care coordination alone would not align financial interests across providers and programs. Conflicting financial incentives could continue to result in unnecessary and fragmented care. Excluding long-term care from any approach will make it difficult to control federal spending for these services and result in less optimal coordinated care.

This review has not concluded whether one or more approaches to care integration are more or less likely to be successful. We have not assessed whether provider-based models (such as PACE) or health plan-based models (such as a state–SNP approach) will have better results. State–SNP arrangements appear to be successful at coordinating care for dual-eligible beneficiaries, but such arrangements were often initiated by states with a history of Medicaid managed care. States vary in their experience with and aversion to managed care and this model will not be equally replicable in all states. Future work will consider the characteristics of successful fully integrated programs and how enrollment might be expanded.

Care coordination activities should be tailored to patients' characteristics and their relative risk for costly undermanagement—potentially avoidable hospitalizations, medication mismanagement, and premature institutionalization. Beneficiaries at risk for institutionalization will need to be more closely monitored than the essentially well dual-eligible beneficiaries. Approaches for dual-eligible beneficiaries with several chronic conditions will need to emphasize communication and data sharing across the multiple providers and appropriate primary care to avert unnecessary facility-based care. Care management activities for cognitively impaired beneficiaries (a high-spending group) will need to be tailored to their ability to understand and adhere to care plans.

Integrated models of care should, like all beneficiary care, be evaluated with measures that gauge their relative efficiency—such as risk-adjusted hospitalization rates, nursing home use, emergency use, and per capita costs. Other measures should capture the extent to which and how well programs integrate the care dual-eligible beneficiaries receive using measures of care coordination and care transitions. Tying provider payment to these measures will put them at risk for achieving good patient outcomes.

Even if best models are identified, implementing full care integration for all dual-eligible beneficiaries will require a transition from the essentially uncoordinated world to one with active care management. There are multiple ways it could be accomplished. Integration could begin with certain services, such as cost sharing and optional Medicaid services. After successfully integrating these services, the models could be expanded to take on the more difficult (but more important, given the dollars at stake) set of long-term care services. Integration could also start with certain subgroups—either the high cost, those most at risk for costly undermanagement, or those with the most beneficiaries. Partial integration efforts need to be designed with enough flexibility so that other services and groups of beneficiaries can be folded in over time. ■

Endnotes

1 One study found that fewer than half of all Medicare beneficiaries with incomes at or below 100 percent of the federal poverty level were enrolled in Medicaid (Pezzin and Kasper 2002). Reasons for low participation rates include welfare stigma, a lack of information about program and eligibility criteria, and cumbersome enrollment processes.

2 There are four ways to be eligible for the Medicare Savings Program (MSP). Beneficiaries whose income is less than 100 percent of the federal poverty level (FPL) qualify for the qualified Medicare beneficiaries (QMBs) benefit, and Medicaid pays for their Medicare premiums and cost sharing. Some QMBs do not qualify for full Medicaid benefits (and are referred to as "QMB only"). In some states, higher income beneficiaries do not qualify for cost-sharing benefits but they do qualify for other Medicaid benefits. If their income is between 100 and 120 percent of FPL, then they qualify for the specified low-income Medicare beneficiaries benefit, and Medicaid pays for their Medicare Part B premiums. If their income is between 120 and 135 percent of FPL, then they qualify for the qualifying individuals benefit, and Medicaid pays for their Medicare Part B premium. If beneficiaries are working, disabled individuals with an income up to 200 percent of FPL, then they qualify for the qualified working disabled individuals benefit, and Medicaid pays their Medicare Part A premium. Under the provisions of the Medicare Improvements for Patients and Providers Act of 2008, for all these programs, beneficiary assets cannot exceed twice the Supplemental Security Income limit—$6,600 for individuals and $9,910 for couples (Centers for Medicare & Medicaid Services 2009). In 2008, the Commission recommended that the Congress raise the MSP income and asset criteria to those of the low-income drug subsidy criteria, which the Congress adopted beginning in 2010. This alignment updated the criteria (they were last revised in 1989) and will simplify the application process for beneficiaries and lower administrative costs of the programs.

3 The Balanced Budget Act of 1997 permitted states to not pay Medicare cost sharing if the Medicare rate minus the cost sharing is higher than the Medicaid rate for those services.

4 It is possible that there are community-dwelling duals with two or more physical impairments who, given our hierarchical categories, have been assigned to a cognitive impairment group.

5 Dual-eligible beneficiaries with end-stage renal disease (ESRD) were excluded from the analysis. They make up a small share of all dual-eligible beneficiaries (2 percent) and the very high spending on them would distort the underlying picture for the majority of dual-eligible beneficiaries. The average spending for ESRD dual-eligible beneficiaries is about three times that for other duals. In addition, physicians caring for beneficiaries with ESRD receive a monthly fee to manage their patients' dialysis. Therefore, ESRD patients have, to varying degrees, at least one of their underlying conditions managed by a physician.

6 The subgroups draw directly on the approach of Foote and Hogan in their analysis of the Medicare disabled population (Foote and Hogan 2001).

7 Most facilities are dually certified for both Medicaid and Medicare. To be covered under Medicare, a skilled nursing facility stay must be preceded by a three-day hospitalization and the patient must require skilled care (such as therapy or skilled nursing services). Medicare Advantage plans may waive the three-day hospital stay requirement and cover skilled care in a nursing facility as a Medicare-covered benefit.

8 In Duggan v. Bowen, beneficiaries and providers charged that Medicare's interpretation that services be "part-time or intermittent" was too narrow and denied care to eligible beneficiaries.

9 Many states have pursued Medicare maximization strategies to increase federal payments. When coverage for services is ambiguous for some beneficiaries—such as nursing home and home health services—states may require providers to first bill Medicare for services (or to pay the providers directly and then pursue Medicare reimbursement) as a way to have Medicare be the primary payer. States and providers prefer to have Medicare pay the claim: Providers prefer the higher payments generally paid by Medicare, while states can avoid paying for the service. Claims that are rejected by Medicare are then submitted to Medicaid for payments. This back-and-forth between payers can leave beneficiaries with unpaid bills until the coverage is sorted out. Some states have used contingency fee consultants to implement strategies—such as new methods to maximize federal reimbursements, state staff training in the claims submission process, and preparation of claims for federal reimbursement—designed to maximize federal reimbursements to state Medicaid programs (Government Accountability Office 2005).

10 Block grants to cover Medicaid services are not a new idea. A proposal to move Medicaid to block grants was made in 1981; they were again proposed in 1995 and 2003. These proposals outlined options for coverage and populations who had to be covered and included federal spending limits and annual increases. Although the limits on federal spending and the expanded state autonomy were attractive, a strong commitment to cover a vulnerable population and concerns about the fiscal impact on states have kept Medicaid as an entitlement program (Lambrew 2005).

11 For example, in 2003 the Bush Administration's block grant proposal included a provision that states show "maintenance of efforts" to receive federal funds—a kind of reverse matching funds (Mann 2004).

12 Application to §1915(c) HCBS Waiver Version 3.4. Appendix H. Available from http://www.hcbs.org/browse.php/sby/Date/type_tool/146/Waiver%20templates.

13 Commission calculations: estimated number of dual-eligible beneficiaries in integrated care programs and estimated number of dual-eligible beneficiaries in MA plans, including SNPs (Center for Health Care Strategies, Inc. 2009).

14 The 30 states with PACE programs are Arizona, California, Colorado, Florida, Hawaii, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Missouri, Montana, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. Source for states with PACE programs: MedPAC analysis of CMS, MA enrollment by state/county/contract, March 2010; source for PACE enrollment estimate: MedPAC calculation of CMS MA and Part D contract and enrollment data, February 2010.

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CHAPTER 6

Inpatient psychiatric care in Medicare: Trends and issues

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Chapter summary

Medicare beneficiaries with serious mental illnesses or alcohol- and drug-related problems may be treated in specialty inpatient psychiatric facilities (IPFs). Beneficiaries who use IPFs are among the most vulnerable in Medicare. A majority are disabled and low income. They tend to be heavy users of health care services, in part because their mental illnesses may undermine their willingness or ability to comply with recommended care. Often, they have additional medical needs that may complicate their treatment.

The services furnished by IPFs are intended to meet the urgent needs of patients experiencing an acute mental health crisis. To qualify as an IPF for Medicare payment, a facility must meet Medicare's general requirements for acute care hospitals and must be primarily engaged in providing psychiatric services for the diagnosis and treatment of mentally ill persons. In 2008, Medicare spent $3.9 billion on IPF care. About 295,000 beneficiaries had almost 443,000 stays. Medicare discharges make up about one-quarter of IPFs' total discharges.

In January 2005, CMS changed the method of payment for IPFs from a cost-based system to a prospective payment system (PPS). The change to a PPS creates financial incentives for providers and may therefore affect patterns of care, including the types of cases admitted to IPFs, services furnished, and

In this chapter

lengths of stay. The Commission's analysis of IPF cost reports and claims data from 2008 found:

- Unlike in other settings, most Medicare beneficiaries treated in IPFs qualified for Medicare because of a disability. As a result, IPF patients tended to be younger and poorer than the typical beneficiary. A majority (56 percent) of IPF patients were dually eligible for Medicare and Medicaid.
- Almost three-quarters of IPF discharges were assigned to one Medicare severity–diagnosis related group (psychoses) and thus received the same base payment under the PPS. Some patient characteristics that may substantially increase the cost of caring for an inpatient psychiatric patient, such as deficits in activities of daily living and suicidal and assaultive tendencies, are not recognized by the IPF payment system.
- In 2008, 74 percent of IPFs were distinct-part psychiatric units in acute care hospitals, but that share is falling as the number of psychiatric units declines. We noted some distinct differences between psychiatric units and freestanding IPFs. On average, psychiatric units were much smaller than freestanding IPFs and were more likely to be nonprofit. Psychiatric units also were somewhat more likely to be located in rural areas and to be teaching institutions. Although about three-quarters of patients in both types of IPFs were diagnosed with psychoses, psychiatric units cared for a smaller share of patients with substance-abuse diagnoses and a larger share of patients with degenerative nervous system disorders than did freestanding IPFs. Average lengths of stay in non-government-owned psychiatric units and freestanding IPFs were 11.2 days and 12.4 days, respectively. A much larger share of psychiatric units' patients were admitted through the emergency department, while a smaller share of their patients were discharged to the home. Psychiatric units were three times as likely as freestanding IPFs to discharge patients to skilled nursing facilities and twice as likely to discharge patients to intermediate care facilities, which care for patients with mental retardation and related conditions.

It is not clear if differences between psychiatric units and freestanding IPFs stem from differences in practice patterns or in the mix of patients and services furnished. Given the implications for access to and quality of care, it will be important to determine whether the payment system adequately captures relevant differences in costliness across patients. If payment rates do not vary consistently with expected variation in patient costs, facilities that treat many patients with a need for high levels of nursing and staff time could be disadvantaged. In addition, access problems might develop for patients who are identified as having high nursing and staff time needs before admission. To the extent that payments do not accurately

reflect patient costs, some IPFs could receive substantial overpayments relative to the expected costs of their mix of patients, while others could be underpaid.

In the future, the Commission intends to analyze IPFs' costs to assess the adequacy of payments to IPFs and providers' financial performance under Medicare. It will be important to assess the extent to which any observed cost differences between freestanding IPFs and distinct-part psychiatric units reflect real differences in service provision and mix of patients and how much is due to methods acute care hospitals use to allocate overhead to their psychiatric units.

The development of outcomes measures to evaluate quality of care in IPFs has lagged behind that for nonpsychiatric medical care. Outcomes assessment in IPFs is complicated by the fact that IPFs may have only a short-term impact on a patient's course of illness. They can successfully stabilize a mentally ill patient in crisis, but changing the patient's course of illness following the inpatient stay often requires ongoing treatment on an ambulatory basis. However, established protocols exist for the treatment of acute episodes of mental illnesses such as major depression, bipolar disorder, and schizophrenia. Clinical process measures can therefore be used in IPFs to evaluate providers' assessment, treatment, coordination, and safety protocols.

Ultimately, improving the quality of care furnished to beneficiaries with serious mental illnesses will necessitate looking beyond the IPF stay to ensure that patients receive adequate and appropriate outpatient mental health services. Such services can reduce severity of illness and improve beneficiaries' productivity and quality of life. ■

Medicare beneficiaries with serious mental illnesses or alcohol- and drug-related problems may be treated in specialty inpatient psychiatric facilities (IPFs). The services furnished by IPFs are intended to meet the urgent needs of those experiencing an acute mental health crisis. Patients in crisis may present with behavior that poses a risk to themselves—either intentional or as the result of impaired self-care—or to others. The goal of IPF care is mood stabilization and restoration of the ability to live independently. In addition, IPFs provide supervision and behavioral management to minimize risk of harm to self or others. Most IPF patients receive drug therapy in the form of antipsychotics, mood stabilizers, antidepressants, and anticonvulsants. Patients also may receive individual and group therapy, psychosocial rehabilitation, illness management training, family therapy, electroconvulsive therapy (ECT), and other treatments. In addition, patients may receive care for medical comorbidities such as diabetes, infectious disease, wounds, and cardiac conditions.

Beneficiaries treated for psychiatric conditions in IPFs are covered for 90 days of care per spell of illness, with a 60-day lifetime reserve.[1] Beneficiaries are responsible for the Part A deductible—$1,100 in 2010—for the first admission during a spell of illness, and for a copayment—$275 per day—for the 61st through 90th days. A higher copayment ($550 per day) applies for each lifetime reserve day. Over their lifetimes, beneficiaries are limited to 190 days of treatment in freestanding psychiatric hospitals.[2] In 2008, the average length of a stay in a psychiatric facility was 13.1 days.

In 2008, almost 295,000 beneficiaries had about 443,000 discharges from IPFs (Table 6-1). Since a prospective payment system (PPS) was implemented in January 2005, the number of cases in IPFs has fallen, on average, about 2 percent per year. Controlling for the number of beneficiaries enrolled in fee-for-service (FFS) Medicare, IPF cases fell about 1 percent per year between 2004 and 2008.

Medicare spending for IPF services in 2008 was $3.9 billion. Both before and after implementation of the IPF PPS, spending per beneficiary grew at the same rate—about 3.5 percent annually. By comparison, the average Medicare payment per IPF case grew 4.5 percent per year between 2004 and 2008. This growth was due in

TABLE 6–1

The number of IPF cases has fallen under PPS

	TEFRA	PPS				Average annual change	
	2002	2004	2006	2007	2008	2002–2004	2004–2008
Cases	464,780	483,271	474,417	456,045	442,759	2.0%	–2.2%
Cases per 1,000 FFS beneficiaries	13.3	13.2	13.1	12.8	12.7	–0.2	–0.9
Spending (in billions)	$3.2	$3.5	$3.8	$3.8	$3.9	5.6	2.3
Spending per FFS beneficiary	$90.6	$97.0	$104.7	$106.7	$111.4	3.4	3.5
Payment per case	$6,822	$7,328	$7,989	$8,315	$8,742	3.6	4.5
Payment per day	$570	$627	$677	$698	$728	4.9	3.8
Length of stay (in days)	13.0	12.7	13.0	13.0	13.1	–1.2	0.7
Unique beneficiaries	299,888	311,146	312,949	301,672	294,574	1.9	–1.4

Note: IPF (inpatient psychiatric facility), PPS (prospective payment system), TEFRA (Tax Equity and Fiscal Responsibility Act of 1982), FFS (fee-for-service). Numbers of cases and patients reflect Medicare fee-for-service utilization of services furnished in inpatient psychiatric facilities. Scatter bed cases and spending are excluded, as are cases and spending for beneficiaries enrolled in Medicare Advantage plans.

Source: MedPAC analysis of MedPAR data from CMS.

part to an increase in the average length of stay. Because Medicare pays IPFs on a per diem basis, providers have some incentive under the PPS to increase lengths of stay (although Medicare mitigates this incentive by reducing per diem payments for later days of the IPF stay). But even controlling for the number of days of care, payments have risen 3.8 percent per year, on average, since 2004.

In this chapter, we provide an overview of Medicare's PPS for inpatient psychiatric services, the providers who furnish those services, and the beneficiaries who use them. We report on the Commission's analysis of claims for IPF services, including the types of diagnoses most commonly coded in IPFs and differences in coded diagnoses and patient characteristics across IPFs. Finally, we review issues related to the adequacy of Medicare's payments for IPF services and the development of quality measures.

Medicare pays for care in IPFs under the IPF PPS

When the inpatient PPS (IPPS) for general acute care was implemented in 1983, IPFs were excluded largely because the diagnosis related group (DRG) classification system used in the IPPS was thought to be a poor predictor of resource use for psychiatric patients. Research had found that DRGs generally explain less than 10 percent of the variation in inpatient psychiatric resource use based on length of stay or cost per admission (Thompson 2002).[3] Diagnosis alone does not reliably describe the reasons for hospitalization or the types of services typically received, in part because psychiatric diagnoses are less well defined than diagnoses in general medicine and surgery. In addition, treatment patterns within diagnoses may be more variable depending on the nature of the crisis that precipitated the inpatient psychiatric stay as well as on patient characteristics such as deficits in activities of daily living and a predilection for dangerous behavior.

Until 2005, IPFs were paid based on their Medicare-allowable costs per discharge, subject to limits established in the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Medicare paid each IPF either its average cost per discharge or its target amount, whichever was less. The target amount equaled the facility's costs per discharge in its base year, updated to the current year. Facilities with costs below their target amounts received bonus payments. This policy created opportunities for profit for new facilities and thus fueled growth in the number of IPFs. A newly established IPF could inflate its costs in its base year to establish a high target amount. The facility could then reduce its costs in subsequent years and be reimbursed its full costs, plus a bonus payment for keeping its costs below the target.

The Balanced Budget Refinement Act mandated that the Secretary of Health and Human Services develop a per diem PPS for inpatient services furnished in psychiatric hospitals and units that included an adequate patient classification system reflecting the differences in patient resource use and cost among providers. Developing an adequate patient classification system for use in an IPF PPS proved to be challenging, because the administrative data collected by CMS do not include some of the patient and clinical characteristics and functional status indicators that are predictive of resource use and costs in IPFs. In other Medicare PPSs developed for services for which diagnosis is not an adequate predictor of resource use—such as inpatient rehabilitation facility services and skilled nursing facility (SNF) services—data on relevant patient and clinical characteristics and functional status indicators are collected via assessment instruments. But time limitations and industry opposition led CMS to move forward with the IPF PPS without an assessment tool (Centers for Medicare & Medicaid Services 2004, Thompson 2002).

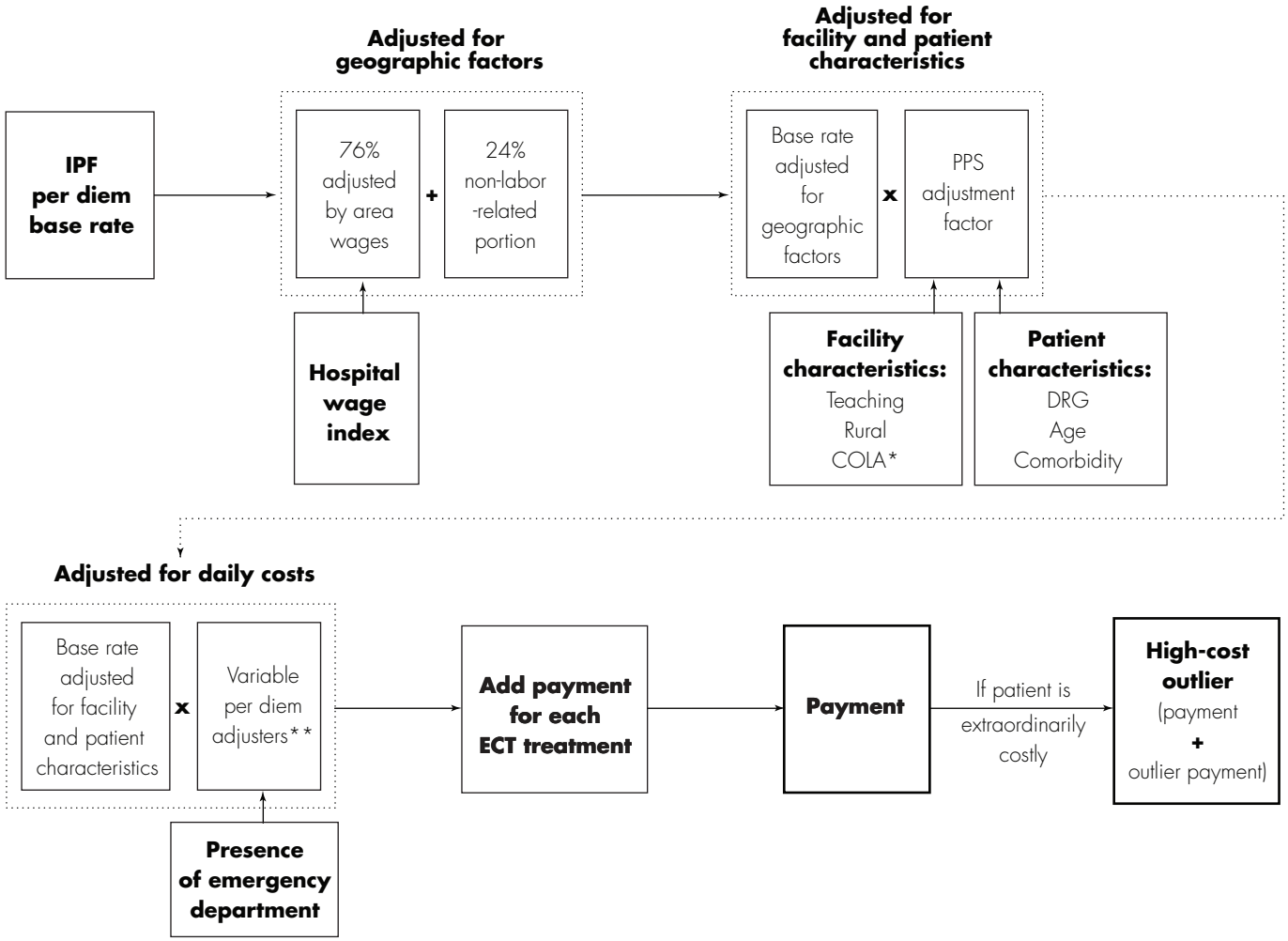
In January 2005, CMS began a three-year phase-in of the IPF PPS. Under the PPS, Medicare pays for the per diem costs associated with furnishing covered inpatient psychiatric services. The base payment rate for each patient day in an IPF is based on the national average daily routine operating, ancillary, and capital costs in IPFs in 2002.[4] For rate year (RY) 2010 (beginning July 1, 2009), the base payment rate is $652 per day.

The base rate is adjusted to account for patient and facility characteristics that can be collected from administrative data and that are associated with cost differences in IPF patients (Figure 6-1). Cases receive all applicable adjustments; generally, adjustments to the base rate are multiplicative. Patient adjustments are made for:

- ***Diagnosis***—Patients are assigned to 1 of 17 psychiatric Medicare severity–diagnosis related groups (MS–DRGs), such as psychoses, depressive neuroses, and degenerative nervous system disorders. Medicare assigns a weight to each of the MS–DRGs reflecting the average costliness of cases in that group compared with that for the most frequently

FIGURE 6–1

PPS for psychiatric services delivered by IPFs



Note: PPS (prospective payment system), IPF (inpatient psychiatric facility), COLA (cost of living adjustment), DRG (diagnosis related group), ECT (electroconvulsive therapy).
*A cost of living adjustment to the non-labor-related portion is made for facilities in Alaska and Hawaii.
**The variable per diem adjusters decline from 1.31 for the first day of stay in an IPF with an emergency department (1.19 for stays in IPFs without an emergency department) to 0.92 for day 22 and beyond. Table 6-2 shows the adjusters.

reported diagnosis in fiscal year 2002. A diagnosis of psychoses has an adjustment factor of 1.0. The adjustment factors range from 0.88 for MS–DRGs 896 and 897 (alcohol/drug abuse without rehabilitation) to 1.22 for MS–DRG 876 (operating room procedure with a principal diagnosis of mental illness). If a patient is assigned to a nonpsychiatric MS–DRG, the case does not receive a diagnosis adjustment (or, rather, the case receives the same adjustment as does a psychoses case).[5]

- ***Age***—In general, payment increases with increasing age over 45. The adjustment factors range from 1.00 for patients under 45 to 1.17 for patients age 80 or over.
- ***Comorbidities***—This adjustment recognizes the increased costs associated with 17 specific patient conditions—such as renal failure, diabetes, and cardiac conditions—that are secondary to the patient's principal diagnosis and that require treatment during the stay.[6] Adjustment factors range from 1.03 to 1.13.

TABLE 6–2 **The adjusted rate for IPFs is higher for initial days of the patient stay**

Day of patient's stay	Per diem adjustment
1 Facility:	
with a full-service emergency department	1.31
without a full-service emergency department	1.19
2	1.12
3	1.08
4	1.05
5	1.04
6	1.02
7	1.01
8	1.01
9	1.00
10	1.00
11	0.99
12	0.99
13	0.99
14	0.99
15	0.98
16	0.97
17	0.97
18	0.96
19	0.95
20	0.95
21	0.95
22 or more	0.92

Note: IPF (inpatient psychiatric facility). The per diem adjustment is applied to the base rate that is already adjusted for geographic, facility, and patient characteristics.

Source: Centers for Medicare & Medicaid Services 2009.

- ***Length of stay***—Per diem payments decrease as patient length of stay increases (Table 6-2).

Facility-based adjustments are made for:

- ***Area wage index***—The labor-related share (76 percent) of the base per diem payment is adjusted by an area wage index to reflect the expected differences in local market prices for labor.[7]
- ***Rural location***—IPFs in rural areas are paid 17 percent more than urban IPFs.
- ***Teaching***—Teaching hospitals have an adjustment based on the ratio of interns and residents to average daily census.
- ***Cost of living***—IPFs in Alaska and Hawaii are paid up to 25 percent more than IPFs in other areas, reflecting the disproportionately higher costs in those states.
- ***Presence of an emergency department***—All freestanding IPFs with qualifying emergency departments and all distinct-part psychiatric units located within acute care hospitals that maintain qualifying emergency departments are paid 12 percent more for their patients' first day of the stay.

IPFs receive an additional payment for each ECT treatment furnished to a patient. In RY 2010, the ECT payment is $281.

For cases that have extraordinarily high costs, the IPF PPS allows for outlier payments, drawn from an outlier pool of 2 percent of total payments (funded by lowering payments for all cases). Medicare makes outlier payments when an IPF's estimated total costs for a case exceed a threshold ($6,565 in RY 2010, adjusted for the facility characteristics outlined above) plus the total payment amount for the case. Medicare covers 80 percent of the costs above this amount for days 1 through 9 and 60 percent of the costs above this amount for the remaining days. The different risk-sharing rates are intended to counteract the financial incentives to keep outlier cases longer.

Patients who are readmitted to the IPF within three days of discharge are considered to have an uninterrupted stay. In such cases, Medicare treats the readmission as a continuation of the original stay, with lengths of stay adjustments applied accordingly.

Inpatient psychiatric care may also be furnished in so-called "scatter beds"—that is, in acute care hospital beds not within distinct-part psychiatric units. Medicare pays for scatter bed services under the acute care hospital PPS (see text box). In 2008, there were almost 250,000 admissions to scatter beds for inpatient psychiatric care, representing 36 percent of all inpatient psychiatric admissions that year. Controlling for FFS enrollment, total admissions to scatter beds have increased 2 percent since 2004.

Different types of IPFs meet the diverse needs of seriously mentally ill patients

Inpatient psychiatric providers include freestanding psychiatric hospitals and distinct-part psychiatric units in

Scatter beds

Patients experiencing an acute mental health crisis can also be treated on an inpatient basis in acute care hospital beds that are not within distinct-part psychiatric units. These beds are called "scatter beds." Medicare pays for inpatient psychiatric services furnished in scatter beds under the per discharge inpatient prospective payment system for acute care hospitals.The patients served in scatter beds may not be directly comparable to those served in freestanding inpatient psychiatric facilities (IPFs) and psychiatric units. First, the typical diagnoses in scatter beds differ from those seen in IPFs. Although substance abuse and degenerative nervous system disorders were among the most common admissions to IPFs in 2008, most Medicare beneficiaries hospitalized for substance abuse are admitted to scatter beds, as are most beneficiaries hospitalized with degenerative nervous system disorders. Freestanding and hospital-based IPFs cared for many more patients diagnosed with psychoses, including schizophrenia, major depression, and bipolar disorder. This situation may be due in part to the inability of many acute care hospitals to provide in scatter beds the adequate security and supervision required for patients at risk of harming themselves or others.

Second, patients may be admitted to scatter beds instead of IPFs because they have underlying medical conditions that are more appropriately treated in the acute care hospital. Beneficiaries diagnosed with degenerative nervous system disorders or substance abuse, for example, are more likely to be admitted to scatter beds if they have a major comorbidity or complication. Beneficiaries age 80 or older, who may be more likely to have underlying medical conditions, are almost twice as likely to be admitted to scatter beds as their under-45 counterparts.

Beneficiaries admitted to scatter beds are more likely than those in IPFs to be admitted through the emergency department (60 percent vs. 35 percent). Average length of stay is 6.6 days, compared with 13.1 days in IPFs. Upon discharge, they are far more likely to be transferred to skilled nursing facilities (19 percent vs. 11 percent).

Some beneficiaries may be admitted to scatter beds because they have exhausted their allotment of days in freestanding IPFs or because beds in psychiatric hospitals and units are unavailable. In some cases, a patient may be admitted to a scatter bed because payment is more favorable, although the extent to which these cases occur is unknown. More research is needed to compare types of patients, payments, costs, quality of care, and outcomes across the settings in which beneficiaries can receive inpatient psychiatric care and to determine whether payments in each setting are appropriate. ■

acute care hospitals.[8] The sector has undergone dramatic changes over the last several decades, driven by a number of factors. Beginning in the 1960s, the downsizing and closure of many state- and county-owned mental hospitals resulted in a large decrease in the total number of inpatient psychiatric beds and shifted capacity to the private sector (Salinsky and Loftis 2007).[9] The introduction in 1983 of the IPPS for acute care hospital services created incentives for acute care hospitals to open psychiatric units, which continued to be paid on a cost basis under the rules established by TEFRA. (As mentioned above, the payment rules under TEFRA also encouraged the growth of psychiatric hospitals and units.) The number of nongovernment IPFs increased substantially in the 1980s and early 1990s and then began to decline. In 2008, about 400 freestanding IPFs and about 1,100 psychiatric units provided care to Medicare beneficiaries (Table 6-3, p. 170). Approximately 35 percent of the nation's acute care hospitals had distinct-part psychiatric units.

Historically, different types of facilities developed to meet the diverse needs of the seriously mentally ill (Lave 2003, RTI International 2005, Salinsky and Loftis 2007). For example, government-owned IPFs frequently function as providers of last resort, often serving patients with severe and persistent mental illness who are difficult to place in other IPFs because of insurance status, diagnosis, or need for specialized services (such as security for forensic

TABLE 6–3

Inpatient psychiatric facilities, 2002–2008

	TEFRA			PPS				Average annual change	
Type of IPF	2002	2003	2004	2005	2006	2007	2008	2002–2004	2004–2008
All	1,724	1,704	1,657	1,622	1,591	1,584	1,535	–2.0%	–1.9%
Urban	1,318	1,298	1,277	1,283	1,268	1,263	1,226	–1.6	–1.0
Rural	406	406	378	339	323	321	309	–3.5	–4.9
Freestanding	347	353	352	366	396	413	408	0.7	3.8
Hospital-based units	1,377	1,351	1,305	1,256	1,195	1,171	1,127	–2.7	–3.6
Nonprofit	993	974	949	909	877	848	818	–2.2	–3.6
For profit	363	349	327	344	344	358	346	–5.1	1.4
Government	368	381	381	369	370	378	371	1.8	–0.7

Note: IPF (inpatient psychiatric facility), TEFRA (Tax Equity and Fiscal Responsibility Act of 1982), PPS (prospective payment system). Numbers are facilities that submitted valid Medicare cost reports in the given fiscal year.

Source: MedPAC analysis of Medicare cost report files from CMS.

patients). These providers are distinguished by their longer average lengths of stay. Daily intensity of services tends to be relatively low. By comparison, nongovernment psychiatric units and freestanding IPFs generally serve patients who are expected to return to the community relatively quickly. Because lengths of stay are shorter, the daily intensity of care may be greater than that provided in government-owned IPFs. Distinct-part psychiatric units in acute care hospitals (regardless of ownership) also can offer medical and surgical capabilities that may be lacking in many freestanding IPFs. Research conducted for CMS by RTI International found that these differences in types of patients served and patterns of care across provider types were reflected in staffing levels. Freestanding IPFs generally had lower staffing levels than psychiatric units, and their patients generally used less nursing and staff time. The highest use of nursing time, by far, was seen in nongovernment psychiatric units. It is not clear if the differences in staffing levels are indicative of greater patient need for services, greater availability of nursing staff, or differences in the quality of care provided.

The Commission's analysis of IPF claims from 2008 found that, overall, Medicare discharges made up about one-quarter of IPFs' total discharges, but this rate differed across the types of facilities. About 29 percent of psychiatric units' discharges were covered by Medicare, compared with 19 percent of freestanding IPF discharges.

We found that freestanding IPFs differed from psychiatric units in a number of ways. On average, freestanding IPFs were much larger, averaging 113 beds in 2008 compared with psychiatric units' average 32 beds. In fact, 57 percent of psychiatric units had fewer than 25 beds. By comparison, 71 percent of freestanding facilities had more than 50 beds. In addition, about two-thirds of psychiatric units were nonprofit, compared with 18 percent of freestanding IPFs. Psychiatric units also were somewhat more likely to be located in rural areas (22 percent of units compared with 15 percent of freestanding) and to be teaching institutions (18 percent of units compared with 11 percent of freestanding).

Between 2002 and 2004, the number of freestanding IPFs remained fairly steady (Table 6-3). Beginning in 2005, when the IPF PPS began to be implemented, the number of freestanding IPFs grew an average of 3.8 percent per year. By comparison, the number of distinct-part psychiatric units in acute care hospitals fell at an average annual rate of 2.7 percent between 2002 and 2004, a decline that accelerated beginning in 2005. Much of the decline occurred among nonprofit and rural facilities.

Examination of the supply of IPF beds shows a similar, but more striking, pattern. Overall, the number of IPF beds remained relatively stable between 2004 and 2008 (Table 6-4). However, there was a marked shift in the location of those beds. The number of psychiatric unit beds fell

more than 12 percent over the period, while the number of freestanding IPF beds increased 11 percent. At the same time, the number of rural and nonprofit IPF beds declined almost 15 percent, while the number of for-profit beds rose 12 percent.

A growing share of Medicare IPF users have been discharged from freestanding IPFs. Between 2004 and 2008, that number increased, on average, 2 percent per year. At the same time, the number of IPF discharges from psychiatric units declined an average 4 percent per year.

The drop in the number of psychiatric unit beds likely has several causes. Psychiatric units may not be as profitable as they once were, particularly when compared with other hospital services. Other factors, such as the purported unwillingness of psychiatrists to serve inpatients or provide on-call services in emergency departments and the impact of psychiatric cases on emergency department overcrowding, may also play a role in decisions to close, maintain, or open IPFs (Salinsky and Loftis 2007). How psychiatric unit closures will affect access to care for Medicare beneficiaries remains to be seen.

TABLE 6–4 **Supply of inpatient psychiatric facility beds, 2008**

Type of IPF	Number of beds 2008	Percent change in beds 2004–2008
All	81,610	–0.6%
Urban	72,122	1.7
Rural	9,488	–14.7
Freestanding	45,982	11.0
Hospital-based units	35,628	–12.5
Nonprofit	27,063	–14.5
For profit	18,252	12.3
Government	36,295	6.1

Note: IPF (inpatient psychiatric facility),

Source: MedPAC analysis of Medicare cost report files from CMS.

Most Medicare patients treated in IPFs are assigned to one MS–DRG

Medicare patients in IPFs generally are assigned to 1 of 17 psychiatric MS–DRGs. In 2008, the most frequently occurring IPF diagnosis—accounting for 73 percent of IPF discharges—was psychoses (Table 6-5, p. 172). The next most common discharge, accounting for almost 8 percent of IPF cases, was degenerative nervous system disorders.[10]

That almost three-quarters of IPF patients are grouped into one diagnosis category, with an adjustment factor of 1.0, illustrates the limitations of diagnosis as a predictor of patient resource use and cost. Diagnosis alone does not differentiate among the majority of IPF patients in any meaningful way. In fact, the psychoses diagnosis group generally comprises two psychiatric conditions—schizophrenia and mood disorders (including bipolar disorder and major depression)—that from a clinical perspective are considered quite distinct and that may require different mixes of services and therefore generate different resource costs (see text box, pp. 174–175). Under the IPF PPS, almost three-quarters of patients can be differentiated from one another only by virtue of their age, length of stay, and the presence or absence of 17 secondary medical conditions that require treatment during the IPF stay. (As mentioned above, IPF PPS payments also vary depending on the type of facility in which treatment is provided, but these are facility, not patient, descriptors.) The Commission examined claims for IPF patients diagnosed with psychoses in 2008 and found that only 17 percent had any of these secondary medical conditions.[11] Overall, then, almost 60 percent of IPF patients can be differentiated from one another only by their age and length of stay.[12]

The coded diagnoses of Medicare patients treated in IPFs have changed somewhat since the IPF PPS was implemented (Table 6-6, p. 172). Among the top diagnoses, the Commission's analysis of IPF claims data shows disproportionate growth between 2004 and 2007 in the number of degenerative nervous system disorder cases, which climbed more than 9 percent per year, on average. Between 2007 and 2008, the number of these cases fell by 1 percent. Recent growth in the number of patients with degenerative nervous system disorders may reflect increased incidence of Alzheimer's disease and other dementias among the Medicare population. But it may also reflect a growing use of inpatient psychiatric facilities by patients with these conditions. Some patient advocates report that nursing facilities increasingly are transferring difficult dementia patients to IPFs for stabilization. The Commission's analysis found that admissions to IPFs from SNFs remained small in number but increased 25 percent between 2004 and 2008, even as total IPF admissions fell

TABLE 6–5

Distribution of MS–DRGs in IPFs, 2008

MS–DRG	Description	Share of total
885	Psychoses	72.8%
057	Degenerative nervous system disorders without MCC	7.6
884	Organic disturbances & mental retardation	5.7
897	Alcohol/drug abuse or dependency, no rehabilitation, without MCC	4.3
881	Depressive neurosis	3.3
882	Neurosis except depressive	1.1
895	Alcohol/drug abuse or dependency with rehabilitation, without MCC	0.9
056	Degenerative nervous system disorders with MCC	0.8
880	Acute adjustment reaction & psychosocial dysfunction	0.7
883	Disorders of personality & impulse control	0.5
886	Behavioral and developmental disorders	0.5
894	Alcohol/drug use—left AMA	0.2
896	Alcohol/drug abuse or dependency without rehabilitation, with MCC	0.2
876	OR procedure with principal diagnosis of mental illness	0.1
887	Other mental disorders	0.1
081	Nontraumatic stupor & coma without MCC	0.1
080	Nontraumatic stupor & coma with MCC	0.0
	Nonpsychiatric MS–DRGs	1.0
	Total	100.0

Note: MS–DRG (Medicare severity–diagnosis related group), IPF (inpatient psychiatric facility), MCC (major complication or comorbidity), AMA (against medical advice), OR (operating room).

Source: MedPAC analysis of MedPAR data from CMS.

TABLE 6–6

Most common types of cases in IPFs, 2008

Description	Number of cases	Percent change 2004–2008
Psychoses	322,415	–7.7%
Degenerative nervous system disorders	37,264	28.1
Organic disturbances & mental retardation	25,383	–36.2
Alcohol/drug abuse	24,888	–3.4
Depressive neurosis	14,796	–17.3
Top five case types	424,746	–8.1
All IPF cases	442,759	–8.4

Note: IPF (inpatient psychiatric facility), MS–DRG (Medicare severity–diagnosis related group). Degenerative nervous system disorders include MS–DRGs 56 and 57. Alcohol/drug abuse includes MS–DRGs 894, 895, 896, and 897.

Source: MedPAC analysis of MedPAR data from CMS.

9 percent. These transfers may be due to a lack of nursing facility staff to provide the close observation and other care needed by some patients with dementia. It should also be noted, however, that nursing facilities may have a financial incentive to discharge patients to IPFs, because upon return to the nursing facility, patients may qualify for Medicare payment under the SNF PPS, if the IPF stay is at least 3 days.[13] In response to increased demand, many IPFs now have specialty geropsychiatric units, which provide care specifically for elderly patients with mental illnesses. These patients frequently have deficits in activities of daily living (ADLs) and often require a more intensive level of care than other psychiatric inpatients (Cromwell et al. 2004).

In 2008, 18 percent of IPF patients were admitted with one or more of the comorbidities recognized by the IPF payment system as increasing the cost of care. Younger IPF patients and, among the most common diagnoses, those with substance abuse disorders and depressive

TABLE 6–7 **Most frequent IPF discharges, by MS–DRG and type of IPF, 2008**

MS–DRG	Description	Type of IPF: Freestanding	Type of IPF: Hospital-based unit
885	Psychoses	75.6%	72.4%
897	Alcohol/drug abuse or dependence without rehabilitation without MCC	8.2	2.7
57	Degenerative nervous system disorders without MCC	3.5	8.8
884	Organic disturbances & mental retardation	3.4	6.5
881	Depressive neuroses	3.2	3.4
	Total number of discharges	128,888	305,041

Note: IPF (inpatient psychiatric facility); MS–DRG (Medicare severity–diagnosis related group), MCC (major complication or comorbidity).

Source: MedPAC analysis of MedPAR data from CMS.

neuroses were more likely to have these comorbidities, which include eating disorders, renal failure, and diabetes. Among the 17 percent of psychoses patients with comorbidities, the most common was infectious disease (7 percent of psychoses patients), followed by developmental disabilities (3 percent of psychoses patients).[14] Overall, about 2 percent of IPF patients received at least one ECT treatment during their stay. This percentage has remained the same since 2002. Most patients (94 percent) receiving ECT were diagnosed with psychoses.[15]

Other patient characteristics may increase the cost of caring for an inpatient psychiatric patient but are not recognized by the IPF payment system (RTI International 2005). These characteristics include the presence of deficits in ADL and dangerous behavior (e.g., suicidal and assaultive tendencies, likelihood of escaping). These characteristics are not submitted on provider claims for Medicare reimbursement and so cannot be used as a basis for payment under the current claims-based IPF PPS.

In 2008, the average length of stay in an IPF was 13.1 days. Among the most common IPF diagnoses, patients with degenerative nervous system disorders without complications and those with organic disturbances and mental retardation typically had somewhat longer stays (13.6 days and 14.1 days, respectively). Overall, in 2008, patients diagnosed with depressive neuroses had shorter stays, averaging 7.8 days. Patients with substance abuse disorders also tended to have shorter stays. Regardless of diagnosis, patients who receive ECT had average stays almost twice as long as patients who did not receive that treatment.

Differences in MS–DRGs across IPF providers

In 2008, the distribution of patient diagnoses differed somewhat across distinct-part psychiatric units and freestanding IPFs (Table 6-7). Psychiatric units were less likely than freestanding IPFs to care for patients with substance-abuse diagnoses. These diagnoses accounted for less than 3 percent of units' cases, compared with 8 percent in freestanding IPFs.[16] At the same time, psychiatric units were more likely to care for patients with degenerative nervous system disorders such as Alzheimer's disease. Such patients made up 9 percent of psychiatric units' patients, compared with 3.5 percent of freestanding IPFs' patients. However, in both types of facilities, about three-quarters of patients were admitted with psychoses.[17]

There was relatively little difference across provider types in the share of patients admitted with comorbidities. Nineteen percent of patients admitted to psychiatric units had one or more comorbidities, compared with 16 percent in freestanding IPFs.

The average length of stay was longer in freestanding IPFs than in psychiatric units, largely due to long lengths of stay in government-owned freestanding IPFs. When we excluded government-owned IPFs, we found that in 2008 the average stay in nongovernment freestanding IPFs was 12.4 days, compared with 11.2 days in nongovernment psychiatric units and 12.2 days in government-owned psychiatric units. Length of stay in government-owned freestanding IPFs averaged 28.7 days.

Common conditions in IPFs: Mood disorders and schizophrenia

In 1999, the Surgeon General released a comprehensive report on mental health and mental illness that synthesized available research on common mental disorders, describing diagnostic criteria and identifying treatments that have proven to be effective (Department of Health and Human Services 1999). Drawing from this report, we summarize below the two most common conditions treated in inpatient psychiatric facilities (IPFs)—mood disorders and schizophrenia.

Mood disorders

RTI estimated that approximately 40 percent of the Medicare beneficiaries receiving IPF treatment in 2002 were admitted for treatment of a mood disorder such as major depression or bipolar disorder (RTI International 2005). The causes of mood disorders are not fully known. They may be triggered in susceptible individuals by stressful life events and enduring stressful social conditions such as poverty. Mood disorders often coexist with other mental and somatic disorders such as anxiety, substance abuse, hypertension, and arthritis. Hospitalization for acute treatment of depression is necessary for about 5 percent to 10 percent of major depressive episodes and for up to 50 percent of the manic episodes of bipolar disorder. The principal reasons for hospitalization are overwhelming severity of symptoms, functional incapacity, and suicidal or other life-threatening behavior. Because treatment response to medication may take up to 8 weeks, very few severely depressed or manic patients are in remission upon discharge from the IPF. As a result, aftercare services are generally necessary.

Mood disorders can be treated with a host of effective pharmacologic and psychosocial treatments. Severe depression seems to resolve more quickly with pharmacotherapy than without it and may be helped further by a combination of pharmacotherapy and psychotherapy. Overall, the effectiveness of active treatment for major depression typically ranges from 20 percent to 40 percent, after accounting for a placebo response rate of 30 percent. Success rates for treatment of active-phase mania with lithium may range from 40 percent to 50 percent, but discontinuation of therapy is common due to side effects and may accelerate the risk of relapse. A number of other medications initially developed for other indications, such as anticonvulsants and benzodiazepines, are increasingly used for manic patients.

(continued next page)

Source of admission and discharge destination

Overall, in 2008, 44 percent of Medicare beneficiaries admitted to IPFs were referred by a physician or clinic, but the share differed widely by provider type. Freestanding IPFs admitted 59 percent of their Medicare patients on referral from a physician or clinic, while only 37 percent of patients admitted to psychiatric units come from this source (Table 6-8, p. 176). Almost half (46 percent) of the beneficiaries admitted to units were admitted through the emergency department.[18]

Generally, the distribution of case types admitted did not vary by source of admission. The exception, although small at 7 percent, was among beneficiaries admitted from SNFs. They were far more likely than those admitted from other sources to be diagnosed with degenerative nervous system disorders and organic disturbances and mental retardation and far less likely to be diagnosed with psychoses.

In 2008, beneficiaries admitted from nursing homes had longer lengths of stay (14.6 days compared with 13.1 for all IPF patients). The longest lengths of stay were seen in patients admitted through the legal system; they averaged 23.7 days in 2008.[19]

Almost three-quarters (70 percent) of IPFs' Medicare patients were discharged to their homes, but differences in the share of these discharges were seen across provider types. Freestanding IPFs discharged 81 percent of their patients to the home, compared with 66 percent of the patients cared for in psychiatric units. Units were three times as likely as freestanding IPFs to discharge patients

Common conditions in IPFs: Mood disorders and schizophrenia

Schizophrenia

RTI estimated that about a third of Medicare beneficiaries treated in IPFs in 2002 were admitted for treatment of schizophrenia (RTI International 2005). Schizophrenia is characterized by profound disruption in cognition and emotion, affecting language, thought, perception, affect, and sense of self. Symptoms frequently include hallucinations and delusions. The course of illness in schizophrenia is quite variable, with most people having periods of exacerbation and remission. The course of illness may be influenced by timeliness of treatment, patient motivation, and presence or absence of family support. Most patients do not return to their prior state of mental function, but longitudinal studies have shown that a substantial number of people with schizophrenia do significantly improve over time, and some recover completely. Patients with schizophrenia also have high rates of comorbid medical illness, including hypertension, diabetes, sexually transmitted diseases, and substance abuse. Although the causes of schizophrenia are not fully known, research points to genetic factors and adverse environmental influences during early brain development.

Treatment of schizophrenia generally involves antipsychotic medication, which has been shown to be highly effective both in treating acute symptoms and in long-term maintenance and prevention of relapse. Older antipsychotics often cause a host of pervasive, uncomfortable, and sometimes disabling and dangerous side effects. Newer "atypical" antipsychotics have been introduced. These atypical drugs seemed promising at first, but recent research has questioned the assumption that they are more effective than older antipsychotics (Jones et al. 2006, Rosenheck et al. 2003, Wang et al. 2009). Most antipsychotics, whether conventional or atypical, appear to have high rates of discontinuation due to intolerable side effects (Lieberman et al. 2005).

Treatment of schizophrenia usually includes psychosocial interventions, family interventions, and vocational and psychosocial rehabilitation. Patients with schizophrenia often also need assistance with housing, transportation, and general medical care. Ideally, the treatment of patients who are high service users is coordinated by an interdisciplinary team to ensure continuity of services. Studies have found, however, that fewer than 50 percent of patients actually receive recommended treatment. ■

to SNFs and twice as likely to discharge patients to intermediate care facilities (Table 6-9, p. 176). This disparity is not unexpected given that a greater share of psychiatric units' patients are admitted for degenerative nervous system disorders and organic disturbances and mental retardation.

Beneficiaries' discharge destinations also varied depending on their IPF diagnosis. More than 77 percent of beneficiaries with psychoses, substance abuse, and depressive neuroses were discharged home, compared with fewer than 30 percent of beneficiaries with degenerative nervous system disorders and organic disturbances and mental retardation (Table 6-10, p. 177). These beneficiaries were much more likely to be discharged to SNFs or intermediate care facilities.

Source of admission and discharge destination varied somewhat by race. Medicare beneficiaries who were transferred to IPFs from SNFs and acute care hospitals were more likely to be white, while those admitted through the emergency room were more likely to be African American. Referrals from the legal system were more likely to be minorities. Upon discharge, African American beneficiaries were more likely to be sent home, while whites were more likely to be discharged to an acute care hospital, a SNF, a home health agency, or an intermediate care facility. These patterns appeared to be strongly influenced by patient age and diagnosis. Minority beneficiaries admitted to IPFs were much more likely to be under age 45 and much less likely to be over age 80. And, as discussed below, minority beneficiaries were more likely than whites to be admitted for psychoses and less likely to be admitted for degenerative nervous disorders.

TABLE 6–8

Share of IPF cases, by source of admission and type of IPF, 2008

	Type of IPF	
Source of admission	Freestanding	Hospital-based unit
Physician/clinic referral	58.6%	37.1%
Transfer from acute care hospital	11.1	6.7
Transfer from skilled nursing facility	1.6	2.1
Transfer other/unknown	11.4	6.4
Emergency room	11.4	46.2
Court/law enforcement	5.8	1.6

Note: IPF (inpatient psychiatric facility). IPF cases in critical access hospitals were excluded from this analysis. Some IPF cases admitted through the emergency room may have been directly discharged from another facility, such as a skilled nursing facility. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of MedPAR data from CMS.

Beneficiaries using IPF services tend to be younger and poorer than the typical beneficiary

Unlike in other types of facilities, most Medicare beneficiaries treated in IPFs qualify for Medicare because of a disability (Table 6-11). As a result, IPF patients tend to be younger and poorer than the typical beneficiary. In 2008, 65 percent of IPF discharges were for beneficiaries under age 65; almost 29 percent were for beneficiaries under age 45. As the baby boomers have aged, the number of IPF beneficiaries between age 45 and 64 has grown, rising 18 percent between 2002 and 2009, compared with declines of 13 percent to 15 percent for other age groups (Figure 6-2, p. 178). Overall, 2.6 percent of disabled beneficiaries had at least one IPF stay in 2006, compared with only 0.4 percent of aged beneficiaries.

A majority of IPF users are dually eligible for Medicare and Medicaid. In 2008, 56 percent of Medicare beneficiaries with at least one IPF discharge were dually eligible for at least one month of the year (see text box, p. 181).[20]

In 2008, 28 percent of beneficiaries admitted to an IPF had more than one admission during that 12-month period.[21] This share has remained relatively steady over the past several years. Beneficiaries with multiple IPF stays were more likely than other IPF patients to be under age 65 (70 percent compared with 52 percent), to be diagnosed with psychoses (78 percent compared with 66 percent), and to be admitted through the emergency department (40 percent compared with 33 percent).

The racial composition of the group of beneficiaries admitted to IPFs in a given year echoes that of Medicare's under-65 (disabled) population. In 2008, African American beneficiaries represented 17.4 percent of IPF patients. Seventy-seven percent of Medicare IPF patients were white, and 2.6 percent were of Hispanic origin (non-white, non-African American).

Diagnosis patterns differed by age and race. Younger beneficiaries tended to present with different diagnoses than older beneficiaries. Among the top IPF diagnoses in 2008, degenerative nervous system disorders and organic disturbances and mental retardation were much more common in older patients (Table 6-12, p. 179). Psychoses were far more common in younger patients. Fewer than 1 percent of IPF beneficiaries under age 65 were diagnosed with degenerative nervous system disorders. By comparison, 35 percent of IPF beneficiaries over age 80 received that diagnosis. A diagnosis of psychoses

TABLE 6–9

Share of IPF cases, by discharge destination and type of IPF, 2008

	Type of IPF	
Discharge destination	Freestanding	Hospital-based unit
Home	81.2%	65.8%
Transfer to acute care hospital	3.4	4.5
Transfer to skilled nursing facility	4.2	13.0
Transfer to intermediate care facility	2.8	5.7
Discharged to home health agency care	0.6	3.7
Left against medical advice	1.5	1.3
Died	0.1	0.1
Transfer to long-term care facility	0.1	0.6
Transfer to nursing facility (Medicaid)	0.6	0.6
Transfer other	5.5	4.7

Note: IPF (inpatient psychiatric facility).

Source: MedPAC analysis of MedPAR data from CMS.

TABLE 6–10 **Discharge destination by IPF diagnosis, selected MS–DRGs, 2008**

Discharge destination	Psychoses	Degenerative nervous system disorders	Organic disturbances and mental retardation	Substance abuse	Depressive neurosis
Home	77.0%	27.4%	29.4%	84.6%	77.5%
Transfer to acute care hospital	3.4	7.9	8.9	2.9	4.5
Transfer to skilled nursing facility	6.4	42.7	34.9	1.8	6.5
Transfer to intermediate care facility	3.6	16.6	11.9	1.0	2.3
Discharged to home health agency care	2.4	5.8	6.3	0.8	2.7
Left against medical advice	1.3	0.3	0.5	4.1	2.3
Died	0.1	0.5	0.5	0.0	0.1
Transfer other	5.8	9.1	7.7	4.8	4.1

Note: IPF (inpatient psychiatric facility), MS–DRGs (Medicare severity–diagnosis related group).

Source: MedPAC analysis of MedPAR data from CMS.

was also strongly age related. Eighty-five percent of IPF beneficiaries under age 45 were diagnosed with psychoses, compared with 35 percent of IPF beneficiaries age 80 or older.

Minorities were more likely than whites to be admitted for psychoses and less likely to be admitted for degenerative nervous disorders. Among Hispanic and African American beneficiaries who were admitted to IPFs in 2008, 86 percent and 81 percent, respectively, were diagnosed with psychoses, compared with 70 percent of white Medicare IPF patients. Five percent of African American and 3 percent of Hispanic IPF beneficiaries were diagnosed with degenerative nervous system disorders, compared with 10 percent of whites.

IPF users as a group consume more health care services and are more costly than other beneficiaries (Table 6-13, p. 179). In 2007, Medicare spending for all hospital inpatient services was more than five times higher for IPF users than for all FFS beneficiaries, due in part to the IPF stay. But Medicare spending for SNF services was also five times higher for IPF users than for all FFS beneficiaries. At the same time, Medicare spending for hospital outpatient, physician and supplier, and Part D-covered drugs was more than twice as high for beneficiaries who had IPF stays than for all FFS beneficiaries. Closer analysis of Part D claims from 2007 found that IPF users filled an average of 64 prescriptions per year at a cost of about $6,100, compared with 44 prescriptions at almost $2,400 for all Part D enrollees and 51 prescriptions at almost $3,300 for Part D enrollees who receive low-income subsidies (Table 6-14, p. 180). In addition, the drugs used by beneficiaries with IPF stays tended to be more costly than those used by other beneficiaries. Average spending per prescription was $92 for IPF users, compared with $54 for all Part D enrollees and $65 for Part D low-income subsidy enrollees.

TABLE 6–11 **IPF discharges by beneficiary characteristics, 2008**

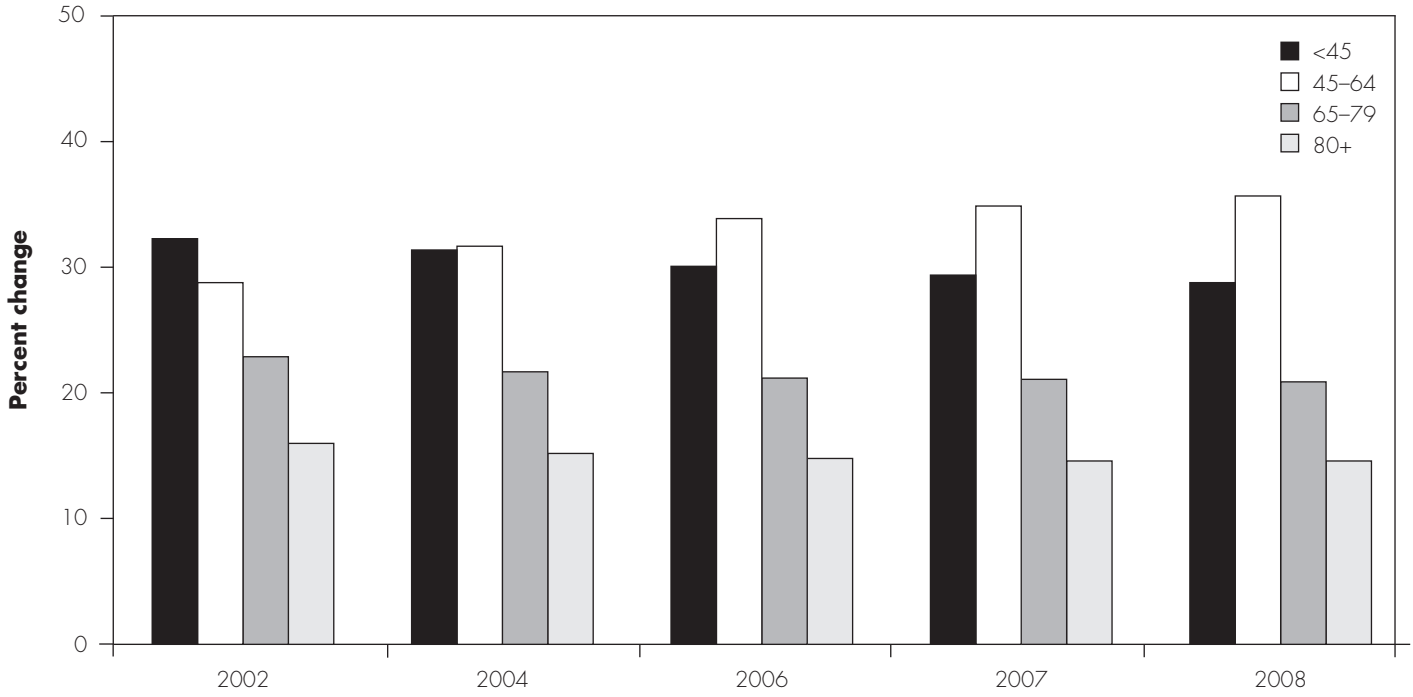
Characteristic	Share of total
Current eligibility status*	
Aged	35.1%
Disabled	64.8
ESRD only	0.1
Age	
<45	28.8
45–64	35.6
65–79	20.9
80+	14.6
Race	
White	77.0
African American	17.4
Hispanic	2.6
Other	3.0

Note: IPF (inpatient psychiatric facility), ESRD (end-stage renal disease).
*Some aged beneficiaries are also disabled.

Source: MedPAC analysis of MedPAR data from CMS.

FIGURE 6–2

The share of IPF users age 45–64 has grown under PPS



Note: IPF (inpatient psychiatric facility), PPS (prospective payment system).

Source: MedPAC analysis of MedPAR data from CMS.

Assessing the adequacy of Medicare's payments to IPFs

The Commission's assessment of payment adequacy generally includes analysis of Medicare payments and providers' costs to determine the extent to which providers are able to continue furnishing high-quality inpatient psychiatric care to beneficiaries who need it. In the future, the Commission intends to analyze IPFs' claims and Medicare cost reports to calculate margins for the industry as a whole and for IPFs by type of facility, ownership, and location.

Since a large share of IPFs are located in acute care hospitals as distinct-part psychiatric units, an important part of this analysis will be an assessment of whether any observed cost differences between freestanding IPFs and psychiatric units are due to methods hospitals use to allocate hospital overhead to the unit or whether they reflect real differences in the mix of services or patients.

The Commission's assessment of payment adequacy also considers the accuracy of payments under the IPF PPS. Medicare's payments for IPF services need to be well calibrated to patient costliness to avoid favoring certain types of providers and creating incentives for providers to admit certain types of patients. However, there is reason to believe that Medicare's payments do not track closely to patient costs because the claims data used to develop the IPF PPS case-mix weights do not describe differences in routine nursing and staff time across patients. The costs associated with tasks and services such as patient assessment, counseling, drug management, nursing care, and behavioral monitoring represent more than 80 percent of the direct costs of furnishing inpatient psychiatric care (Garrett et al. 2009, RTI International 2005, Thompson 2002). But without the necessary data, CMS based its estimates of routine costs in the IPF PPS on an average daily cost across all patients in a facility, thereby understating, or compressing, patient-specific cost differences for some patients and overstating them for others. Medicare's payments for patients requiring high levels of nursing and staff time may be too low, while payments for patients requiring relatively little nursing and staff time may be too high. This situation could disadvantage facilities that treat many patients with the

TABLE 6–12 **Patient characteristics by IPF diagnosis, selected MS–DRGs, 2008**

Characteristic	Psychoses	Degenerative nervous system disorders	Organic disturbances and mental retardation	Substance abuse	Depressive neurosis
Age					
<45	85	0%	1%	6%	3%
45–64	84	1	1	8	4
65–79	63	14	10	5	3
80+	35	35	21	2	3
Race					
White	70	10	6	6	4
African American	81	5	4	5	3
Hispanic	86	3	2	4	2
Other	80	5	4	5	3

Note: IPF (inpatient psychiatric facility), MS–DRG (Medicare severity–diagnosis related group). Sums may not total to 100 due to rounding.

Source: MedPAC analysis of MedPAR data from CMS.

need for high levels of nursing and staff time and could create access problems for patients who are identified as having high nursing and staff time needs before admission.

A related issue concerns variation within MS–DRGs. As we have shown, almost three-quarters of patients are assigned to MS–DRG 885 (psychoses). In its analysis of IPF patients and the costs of treating them in different types of IPFs, RTI found that patients assigned to the psychoses group generally had schizophrenia or a mood disorder, such as major depression or bipolar disorder. However, the costs associated with treating these disorders may differ significantly. If so, providers may have an incentive to avoid admitting psychoses patients with certain types of mental illnesses or those who are perceived to have a greater need for nursing and staff time. It is important to note that, depending on their site of service and mission, as well as on available mental health care alternatives in the market area, IPF providers may differ in their ability to act on this payment incentive.

Outlier payments may reduce but not eliminate the incentive to avoid admitting certain types of patients. Payment relief is not available in cases where costs systematically exceed payment but not by enough for the case to qualify for outlier patients (Garrett et al. 2009). In addition, outlier payments do not address the problem of systematic overpayments for low-cost cases.

Facility characteristics, day of stay, age, degree of social support, need for assistance with ADLs, illness severity, legal status and referral source, and dangerous behavior (suicidal and assaultive tendencies) are stronger predictors of costs in IPFs than diagnosis. Some of these variables—for example, the presence of an emergency department

TABLE 6–13 **Beneficiaries who use IPF services have higher spending for other health services, 2007**

	Inpatient hospital	Outpatient hospital	Physician and suppliers	Skilled nursing facility	Part D drugs
All IPF users	$16,935	$2,308	$4,350	$3,003	$6,103
All FFS beneficiaries	$3,065	$988	$2,023	$581	$2,383

Note: IPF (inpatient psychiatric facility), FFS (fee-for-service).

Source: MedPAC analysis of Medicare Part D PDE data, denominator file, and MedPAR claims data from CMS.

TABLE 6–14 **Part D spending and use for beneficiaries with an IPF stay, 2007**

	Part D enrollees		
	IPF users	All	LIS
Average spending per prescription	$92	$54	$65
Per beneficiary per year			
Total spending	$6,103	$2,383	$3,288
Number of prescriptions*	64	44	51

Note: IPF (inpatient psychiatric facility), LIS (low-income subsidy). Spending and use statistics are for beneficiaries who were enrolled in Part D at any time during 2007 and were not adjusted to account for differences in the number of part-year enrollees.
*Number of prescriptions standardized to a 30-day supply.

Source: MedPAC analysis of Medicare Part D PDE data, denominator file, and MedPAR claims data from CMS.

and differential payments depending on the day of stay and age—were included in the IPF PPS. Including other elements that significantly affect routine nursing and staff time likely would improve the accuracy of Medicare's payments to IPFs. But doing so would require IPFs to submit additional information about their patients. IPF claims currently allow IPFs to specify so-called "social" codes describing patient characteristics that affect care delivery and management, such as problems with sight or hearing. CMS reported that too few claims included these codes in 2002, preventing analysis of the association of these codes with higher per diem costs. The agency has encouraged IPFs to code all relevant diagnoses that affect resources associated with their patient population for future analysis. The Commission's analysis of claims data found that the number of claims with social codes more than doubled between 2002 and 2008 but remains very small—just 2.1 percent of discharges in 2008.

When the Congress mandated implementation of a per diem PPS for IPFs in 1999, CMS began to pursue the development of an assessment instrument that would yield a richer source of data. However, time limitations and industry opposition led CMS to move forward with the PPS without an assessment tool (Centers for Medicare & Medicaid Services 2004, Thompson 2002). The lack of this tool in IPFs undermines payment accuracy. Improving the payment system may require collecting additional information about patient characteristics.

Measuring the quality of care in IPFs

The development of quality measures for IPFs has lagged behind that for medical care. Quality of mental health care can be difficult to measure because there are few meaningful, frequent, and easily collected clinical outcome measures—such as mortality—that have been assessed for validity and reliability. Unlike in medical care, objective laboratory tests generally cannot be used to measure severity of mental illness or the effectiveness of treatment (Hermann et al. 2004, Hermann et al. 2007).

Developing outcomes measures for IPFs is complicated by the length of treatment required during the acute phase of mental illnesses. For example, successful treatment of an acute episode of major depression typically requires six to eight weeks, but patients typically require inpatient care for only a fraction of that period (Department of Health and Human Services 1999). Most beneficiaries discharged from IPFs will need ongoing treatment after their inpatient stay. Further, the nature of mental illness makes it particularly difficult to determine whether providers have furnished treatment of the appropriate duration and intensity. Many mentally ill patients are nonadherent. Some do not perceive a need for care or, if they do, have difficulty navigating the health care system and maintaining a treatment regimen. These difficulties may be exacerbated in depressed patients, who may feel worthless, have excessive guilt, and lack motivation—feelings that are common to the disease (Department of Health and Human Services 1999). Patients with severe mental illness have no-show rates for scheduled appointments as high as 50 percent. A high rate of comorbid illness and substance abuse in seriously mentally ill patients may inhibit compliance (Hermann and Palmer 2002).[22] At the same time, some people with mental illnesses opt not to pursue or continue treatment because of intolerable or undesirable side effects of medication. The stigma associated with psychiatric diagnosis and treatment also prevents many people with mental health disorders from pursuing care.[23] Unlike in the acute care hospital, a readmission to IPF care within a short period of time after the initial discharge may not indicate anything meaningful about the quality and extent of care provided during the initial stay.

Nevertheless, established protocols exist for the treatment of acute episodes of several mental illnesses, including major depression, bipolar disorder, and schizophrenia (Department of Health and Human Services 1999). Clinical process measures can therefore be used in IPFs to

Dual-eligible inpatient psychiatric facility users, 2008

- Represented 56 percent of all Medicare inpatient psychiatric facility (IPF) users.
- Were somewhat more likely to have more than one IPF stay during the year (1.6 stays per year compared with 1.3 stays per year for non-dual-eligible users).
- In aggregate, were much younger than non-dual-eligible IPF users. Seventy-nine percent of dual-eligible IPF users are under age 65, compared with 43 percent of non-dual-eligible users. Almost 40 percent of dual-eligible IPF users are under 45, compared with 13 percent of non-dual-eligible users.
- Were more likely to be non-white. Whites represented 85 percent of non-dual-eligible IPF users compared with 72 percent of dual-eligible users.
- Were far more likely to be eligible for Medicare due to a disability (79 percent compared with 43 percent of non-dual-eligible users).
- Were more likely to be diagnosed with psychoses (79 percent compared with 64 percent) and less likely to be diagnosed with degenerative nervous system disorders (5 percent vs. 14 percent) and organic disturbances and mental retardation (4 percent compared with 9 percent).
- Were generally more likely to be admitted with comorbidities (such as developmental disabilities and infectious disease) that increased payment (5 percent compared with 1 percent).[24]
- Were somewhat more likely to be admitted through the emergency department (37 percent compared with 33 percent)
- Were somewhat more likely to be discharged to home (73 percent compared with 66 percent)
- Were somewhat more likely to be admitted to freestanding IPFs (31 percent compared with 27 percent) ■

evaluate providers' assessment, treatment, coordination, and safety protocols. For example, IPFs might be required to report:

- admission screening for violence risk, substance use, and psychological trauma history;
- proper handoff procedures between emergency room and IPF unit;
- prescribed medications;
- medication errors;
- adverse reactions to medications;
- daily assessment of suicide risk;
- hours of physical restraint use;
- hours of seclusion;
- patients discharged on multiple antipsychotic medications;
- patients discharged on multiple antipsychotic medications with appropriate justification;
- postdischarge continuing care plan; and
- postdischarge continuing care plan transmitted to next level of care provider upon discharge.

The Joint Commission uses some of these IPF process measures in its Hospital-Based Inpatient Psychiatric Services (HBIPS) Core Measure Initiative. Freestanding IPFs can satisfy the Joint Commission's accreditation requirements for performance measurement by adopting the HBIPS measures.[25] The Joint Commission encourages acute care hospitals with distinct-part psychiatric units to use them as well.

The Patient Protection and Affordable Care Act of 2010 mandates the development of a quality reporting program for IPFs by 2014. A similar program is already being used for acute care hospitals, which are required to participate in Medicare's Reporting Hospital Quality Data for

Medicare's coverage of outpatient mental health care services

Most Medicare beneficiaries with mental health problems never use inpatient psychiatric services. Mental health professionals generally agree that patients are better served by quality outpatient care that prevents, to the extent possible, acute mental health crises requiring hospitalization. Beneficiaries may receive outpatient mental health services, including partial hospitalization services and psychotropic drugs. But the extent to which mentally ill Medicare beneficiaries have access to quality psychiatric care on an outpatient basis is unknown—and difficult to measure.

Outpatient mental health services

Medicare covers outpatient mental health services such as psychiatric evaluation, diagnostic testing, psychotherapy, and medication management furnished by physicians or certain other licensed mental health professionals. Until recently, Medicare required cost sharing of 50 percent for outpatient mental health therapy services. The Medicare Improvement for Patients and Providers Act of 2008 requires that cost sharing for Medicare beneficiaries using mental-health-related treatments be reduced to 20 percent by 2014 (the same level set for physician services).[26] This reduction in out-of-pocket spending requirements may allow more beneficiaries to seek mental health services.[27]

Partial hospitalization

Partial hospitalization refers to intensive psychiatric outpatient treatment designed for patients with serious mental health conditions requiring care that is not typically available in an ambulatory setting. Partial hospitalization may provide a "step-down" alternative for patients following an inpatient psychiatric facility (IPF) discharge or may be used as an alternative to inpatient care for patients who need more services than can be provided on a typical outpatient basis but who are not so ill that they need 24-hour care and supervision. Medicare covers partial hospitalization services connected with the treatment of mental illnesses under Part B. Partial hospitalization programs must be hospital based, hospital affiliated, or administered by a community mental health center (CMHC). Services may include diagnostic services, individual and group therapy, occupational therapy, family counseling, and drugs and biologicals furnished for therapeutic purposes that cannot be self-administered. A physician must certify that the

(continued next page)

Annual Payment Update program. Under this program, originally mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS pays a higher annual payment update rate to acute care hospitals that report designated quality measures. In addition to giving hospitals a financial incentive to report the quality of their services, the program provides CMS and Medicare beneficiaries with data to assess the quality of care in acute care hospitals.

Ultimately, improving the quality of care furnished to beneficiaries with serious mental illnesses requires looking beyond the IPF stay. Adequate and appropriate outpatient mental health care services can reduce severity of illness, improve patient productivity and quality of life, and limit the need for higher intensity, more costly services (see text box). In addition, because adults with severe mental illness have higher rates of chronic general medical conditions (including hypertension, HIV/AIDS, and diabetes), a higher frequency of multiple general medical conditions, and a higher rate of premature mortality, improving the quality of mental health care could have positive consequences for medical care and general health (Horvitz-Lennon et al. 2006). ■

Medicare's coverage of outpatient mental health care services

beneficiary would otherwise need inpatient treatment or has been recently discharged from inpatient care and needs partial hospitalization to avoid a relapse and that less intensive treatment options would be inadequate. Medicare pays for a specified bundle of services under a partial hospitalization prospective payment system.[28] The Commission's analysis of partial hospitalization claims from 2008 found that Medicare payments to CMHCs for partial hospitalization services totaled about $360 million. An additional $68 million was paid to hospital outpatient departments for these services.

Psychotropic drugs

Psychotropic drugs—those capable of affecting psychological function, including antidepressants, antipsychotics, and anti-anxiety agents—are the predominant form of treatment for many mental health and substance abuse disorders. Use of prescribed psychotropic drugs has grown rapidly. In recent years, total national spending on psychotropic drugs rose from $5.9 billion in 1996 to $14.7 billion in 2001 (Zuvekas 2005). This growth was driven both by more people using the drugs and by increases in spending per user. About 80 percent of the growth in psychotropic drug spending during the 1996–2001 period was driven by increased use of newer antidepressants (52 percent) and so-called atypical antipsychotics (28 percent).[29] For children and adults under age 65 with a mental health diagnosis, the rate of growth in prescription drug use slowed between 2001 and 2006 (Glied and Frank 2009). Among the elderly, however, prescriptions for psychotropic drugs continued to rise so that, by 2006, 15 percent of seniors reported having such a prescription—twice the share as in 1996 (Glied and Frank 2009). Preliminary analysis by the Commission has found that Medicare Part D spending on these drugs reached $12 billion in 2007.

Dramatic growth in the use of psychotropic drugs to treat mental illnesses could indicate improved access to care. But severely mentally ill patients using psychotropic drugs—especially those with coexisting medical or mental health conditions—often require close supervision. Treatment may require considerable trial and error before an effective medication or medication combination can be identified. Changes or disruptions in medications can be dangerous, resulting in rapid deterioration, impaired functioning, and increased use of mental health services, including inpatient hospital care (Loftis and Salinsky 2006). ■

Endnotes

1 The number of covered inpatient days in the first benefit period is reduced for individuals who are in a Medicare participating IPF on their first day of entitlement to Medicare Part A.

2 This restriction, which was intended to limit the federal government's role in paying for long-term custodial support of beneficiaries with mental illnesses, applies only to services furnished in a freestanding psychiatric hospital. The limitation does not apply to inpatient psychiatric services furnished in a distinct-part psychiatric unit of an acute care hospital, nor does it apply to psychiatric stays paid for under the acute care hospital prospective payment system (i.e., in scatter beds). It is not clear how much the 190-day limit restricts access to inpatient psychiatric care, as few beneficiaries reach the lifetime limit. To the extent that access problems do exist, they could be exacerbated by the ongoing closures of hospital-based distinct-part units.

3 By comparison, DRGs were found to account for 30 percent to 50 percent of the variation in length of stay for nonpsychiatric cases.

4 The Congress required that the IPF PPS be budget neutral. CMS expected that once the IPF PPS was implemented, IPFs might experience utilization patterns that differed significantly from those experienced under TEFRA. For example, since the IPF PPS is a per diem system, IPFs would have an incentive to keep patients in the facility longer to maximize their use of beds or their payments (although decreasing per diem base payments may reduce these incentives). In addition, the former TEFRA payment system did not depend on coding a principal diagnosis; under PPS, payment depends on properly coding the principal diagnosis and associated comorbidities. To offset expected payment increases due to longer stays and improved coding and documentation, CMS reduced the standardized federal per diem base rate by 2.66 percent.

5 A Commission analysis of Medicare claims data found that in 2008 about 1 percent of patients are assigned to a nonpsychiatric MS–DRG.

6 The comorbidity categories are: developmental disabilities, coagulation factor deficits, tracheotomy, eating and conduct disorders, infectious diseases, acute renal failure, chronic renal failure, need for oncology treatment, uncontrolled diabetes, severe protein malnutrition, drug- and/or alcohol-induced mental disorders, cardiac conditions, gangrene, chronic obstructive pulmonary disease, digestive and urinary artificial openings, severe musculoskeletal and connective tissue diseases, and poisoning.

7 CMS uses the prefloor, prereclassification hospital wage index to adjust the base per diem payment.

8 A small number of psychiatric units are located in critical access hospitals (CAHs), which are small hospitals primarily located in rural areas. Beginning in 2004, the number of psychiatric units in CAHs has grown dramatically, following a provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that allowed CAHs to establish distinct-part psychiatric units of up to 10 beds. (Before this time, CAHs were prohibited from having distinct-part units.) In 2007, 70 CAHs (about 5 percent of all CAHs) had psychiatric units. These units may allow some rural beneficiaries to receive inpatient care closer to home and may help retain mental health professionals in rural areas, but little research exists regarding how well the services furnished in these units match rural communities' needs (Medicare Payment Advisory Commission 2005). Covered services provided to Medicare beneficiaries in CAH-affiliated psychiatric units are paid under the IPF PPS.

9 The "deinstitutionalization" movement of the 1960s and 1970s was partly in response to growing public concern about the inhumane treatment of long-term patients in government-owned psychiatric institutions and was aided by the emergence of new pharmacologic agents for the treatment of mental illnesses (Salinsky and Loftis 2007). But the driving force behind deinstitutionalization was states' efforts to shift the financial burden of care for the seriously mentally ill to the federal government (Sharfstein and Dickerson 2009).

10 Degenerative nervous system disorders include Alzheimer's disease, Huntington's disease, amyotrophic lateral sclerosis, and Parkinson's disease.

11 In 2008, the most frequently coded comorbidity secondary to psychoses diagnosis was infectious disease.

12 The use of ECT distinguishes a small number of patients diagnosed with psychoses. The Commission found that 2.8 percent of patients with psychoses had ECT in 2008.

13 The number of nursing facility patients with degenerative nervous system disorders who are discharged to hospice has also been growing in recent years.

14 Patients may have more than one comorbidity.

15 Most patients who receive ECT do so as part of treatment for major depression.

16 Some freestanding IPFs specialize in treating substance abuse.

17 The patient population cared for in psychiatric units in critical access hospitals differs markedly from that seen in other IPFs. Slightly fewer than half the patients in CAH IPFs are diagnosed with psychoses, while more than a quarter are diagnosed with degenerative nervous system disorders. CAHs also care for a disproportionately large share of patients with organic disturbances and mental retardation.

18 Some patients admitted through the emergency department may have been transferred from other providers, such as nursing facilities, intermediate care facilities, and home health agencies.

19 Patients admitted through the legal system are those admitted on the direction of a court of law or on request of a law enforcement agency's representative.

20 We found that 76 percent of the IPF claims for dual-eligible beneficiaries were for patients who had 12 months of dual eligibility.

21 This proportion includes only those beneficiaries who had more than one admission to an IPF in 2008 and does not include patients who had psychiatric admissions to both an IPF and a scatter bed.

22 Compared with people without mental disorders, adults with severe mental illness have higher rates of chronic general medical conditions, including hypertension, HIV/AIDS, and diabetes; a higher frequency of multiple general medical conditions; and a higher rate of premature mortality resulting from these conditions (Horvitz-Lennon et al. 2006).

23 The extent to which such stigma is perceived may vary across ethnic, racial, and cultural groups. Ethnicity, race, culture, and language can also play a role in patients' ability to access care. These factors may affect behavior and description of symptoms as well as reporting of symptoms and the interpretation of those symptoms by others. These factors, in turn, can affect diagnosis and treatment decisions. Differences in ethnicity, race, and culture often frustrate attempts to measure racial and ethnic disparities in mental health care. For example, several recent studies have found that African Americans and other minorities reported overall lower rates of lifetime mental disorders than whites (Breslau et al. 2006, Heeringa et al. 2004, McGuire and Miranda 2008). At the same time, African Americans appear to have higher rates of schizophrenia, while American Indians are at heightened risk for posttraumatic stress disorder and alcohol dependence (Beals et al. 2005, Kendler et al. 1996, Kessler et al. 2005)). And some researchers have found that African Americans who do have mental health disorders tend to have more persistent illness, compared with their white counterparts (Breslau et al. 2006, Williams et al. 2007). It is not clear if these findings reveal differences across racial and ethnic groups in the type or quality of treatments furnished in the reporting and interpretation of symptoms, the ability to access care, the willingness to seek care, real incidence of disease, or some combination of these factors.

24 Non-dual-eligible beneficiaries who were admitted to IPFs in 2008 were about 50 percent more likely to have chronic renal failure than were their dual-eligible counterparts.

25 If the National Quality Forum endorses the measures, HBIPS will become mandatory for freestanding IPFs. Acute care hospitals will not be required to use HBIPS in their IPF units.

26 The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, which requires that group health plans must treat mental health and substance abuse benefits (if offered) the same as standard medical and surgical coverage for purposes of copayments, benefit limits, and prior authorization and utilization review, does not apply to the Medicare program.

27 However, in addition to psychotherapy and medication, people with severe mental illnesses often require psychosocial and supportive services such as employment and housing support. These services can be difficult to obtain because they are often not covered by insurance and because there is limited availability of evidence-based psychosocial programs.

28 Payments for partial hospitalization services skyrocketed almost 500 percent between 1993 and 1997, climbing from $60 million to $349 million. In an analysis of payments for partial hospitalization services made to community mental health centers in five states, the Office of Inspector General found that 91 percent of payments in fiscal year 1997 had been made for unallowable or highly questionable claims (Office of Inspector General 1998). In response to these findings, CMS intensified scrutiny and decertified many providers nationwide (Loftis and Salinsky 2006). Implementation of prospective payment for partial hospitalization in 2000 has helped to control spending growth.

29 Atypical antipsychotics include olanzapine and aripiprazole, which are used to treat mental disorders such as schizophrenia. Beginning in the 1990s, these drugs have been introduced as replacements for drugs like clozapine, which can have undesirable side effects, including involuntary muscle movements, muscle spasms, weight gain, and Parkinsonian-like symptoms such as muscular rigidity and resting tremor. However, recent research has questioned the assumption that atypical antipsychotics are more effective or have fewer side effects than conventional antipsychotics (Jones et al. 2006, Lieberman et al. 2005, Rosenheck et al. 2003, Wang et al. 2009).

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CHAPTER 7

Shared decision making and its implications for Medicare

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Chapter summary

Medicare beneficiaries face certain challenges when making health care decisions. Although they are insured, on average, they are more likely to be poorer, less educated, cognitively impaired, faced with multiple chronic conditions, and less health literate than other consumers. All these factors may increase their difficulty understanding the information they receive about their health conditions and the risks and benefits posed by different treatments. In an effort to mitigate these problems and to make care more patient centered, some clinicians have adopted a model of shared decision making.

Shared decision making is the process by which a health care provider communicates personalized information to patients about the outcomes, probabilities, and scientific uncertainties of available treatment options, and patients communicate their values and the relative importance they place on benefits and harms. The goal of shared decision making is to improve patients' knowledge of their condition and give them a more realistic perception of treatment outcomes so that they can arrive at treatment decisions with their physicians that reflects their values and preferences. Information is conveyed through patient decision aids that provide patients with evidence-based, objective information on all treatment options for a given condition. Decision aids are generally used when the choice among treatment options depends heavily on patient assessment of risks and benefits. Some policymakers

In this chapter

believe shared decision making has the potential to help diverse populations take an active role in managing their health.

Shared decision making must be distinguished from patient decision making. Physicians, not patients, have the expertise to know what approach to surgery is best, for example, or the side effect profile of different medications. Only patients know what their feelings are toward particular risks and benefits. When the patient understands the risks and the physician understands the patient's concerns, the physician is better able to recommend a treatment that will address the medical problem and respect the patient's values.

Effective shared decision-making programs require physician leadership and support, although physicians are not generally involved in daily operation of the programs. In fact, to enlist physician support, shared decision-making protocols must fit seamlessly into clinical practice and not increase the time physicians spend during appointments. To date, specialists have been more successful in implementing shared decision-making programs than primary care doctors because they are more likely to engage in shared decision making at a time when it is most useful to patients—before making a treatment decision on procedures like cancer treatment or back surgery. In contrast, patients may not invest the same amount of effort to understand the advantages and disadvantages of decisions like cancer screening options that they must make with their primary care physician.

Medicare beneficiaries have had limited experience with shared decision making. Some Medicare Advantage plans have begun implementing shared decision-making programs. Clinicians attempting to introduce shared decision making into traditional fee-for-service (FFS) Medicare face many challenges. Most physicians treating Medicare beneficiaries do not have the office infrastructure or functioning clinical information technology system to easily integrate these programs into their practice. In addition, the FFS payment structure does not compensate for this behavior.

Medicare could promote the use of shared decision making in a number of ways: design a demonstration project to test the use of shared decision making for Medicare beneficiaries, provide incentives to practitioners who adopt shared decision making, provide incentives to patients who engage in shared decision making, or require providers to use shared decision making for some services. These strategies are not mutually exclusive. Each has advantages and disadvantages. Policymakers would have to decide on the design and scope of the policy.

In future work, we will discuss some of the challenges Medicare faces trying to communicate with beneficiaries about how their health care services will be delivered and financed. Can the principles and techniques of shared decision making be used to help beneficiaries make choices about plans and providers as well?

The Patient Protection and Affordable Care Act of 2010 includes provisions to promote the development of shared decision making within Medicare and the health system in general. ■

Glossary

Health literacy: The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

Patient activation: A person's ability to self-manage his or her health and health care.

Patient decision aid: A tool that provides patients with evidence-based, objective information on all treatment options for a given condition. Decision aids present the risks and benefits of all options and help patients understand how likely it is that those benefits or harms will affect them. There are many kinds of decision aids, including written material, web-based programs, videos, and multimedia programs.

Preference-sensitive care: Care that depends on patient preferences when two or more medically acceptable options exist.

Shared decision making: The process by which a health care provider communicates personalized information to patients about the outcomes, probabilities, and scientific uncertainties of available treatment options and patients communicate their values and the relative importance they place on benefits and harms. ■

Introduction

Like all health care consumers, Medicare beneficiaries have many decisions to make about the health care services they use and how those services will be delivered and financed. They also must decide where to go for care. Along with the information provided by their personal physicians and health plans, consumers receive multiple—and often conflicting—messages from the media, Internet sources, and advertisements from manufacturers of health care products.

In an effort to mitigate these problems and to make care more patient centered, some clinicians have adopted a model of shared decision making. Shared decision making is defined as an integrative process by which a health care provider gives patients necessary information about their clinical alternatives and patients have the opportunity to express their preferences.

Shared decision making must be distinguished from patient decision making. Physicians, not patients, have the expertise to know what approach to surgery is best, for example, or the side effect profile of different medications. Only patients know what their feelings are toward particular risks and benefits. For example, surgical treatment of prostate cancer may lead to impotence. Men will differ on the importance they attach to this harm compared with other results of treatment. Shared decision making is designed to help patients clarify their values relative to the risks and benefits of different treatment options. When patients understand the risks and physicians understand patients' concerns, they are better able to come to a treatment decision that will address the medical problem and respect the patients' values (Kaplan et al. 2004).

To examine how shared decision making works in practice, the Commission conducted four site visits to institutions engaged in shared decision-making programs: Dartmouth Hitchcock Medical Center, Massachusetts General Hospital, Group Health Cooperative of Puget Sound, and Health Dialog, a company that provides shared decision-making services to health plans. Except for Health Dialog, the programs we examined are conducted in integrated delivery systems. We also conducted structured interviews with individuals implementing programs and companies that produce materials and services needed for shared decision making.

Roots of shared decision making

Many individuals must make medical decisions frequently, although they may have little knowledge of their conditions or the risks and benefits of different treatments. A University of Michigan survey found that in the past two years: 56 percent of respondents discussed with their

How did recent legislation affect shared decision making?

The Patient Protection and Affordable Care Act of 2010 adds Sec. 936, titled Program to Facilitate Shared Decision Making, to the Public Health Service Act. Under terms of the law, the Secretary is required to:

- contract with a consensus-based organization to develop and identify standards for patient decision aids, review patient decision aids, and develop a certification process for determining whether decision aids meet the standards;
- award grants or contracts to entities to develop, update, and produce patient decision aids; to test aids to ensure that they are balanced and evidence based; and to educate providers on their use;
- award grants to establish shared decision-making resource centers to develop and disseminate best practices to speed adoption and use of shared decision making; and
- award grants to providers to develop and implement shared decision-making techniques with patient decision aids.

In addition, the law establishes a Center for Medicare and Medicaid Innovation within CMS. The Center may test models that assist individuals in making health care choices by paying providers of services and suppliers for using patient decision support tools. ■

doctors starting or stopping medications for hypertension, hyperlipidemia, or depression; 72 percent discussed a screening test for cancer; and 16 percent discussed one of four operations. Clinical experts identified four or five facts a person should know, such as the common side effects of medications or surgery. Survey respondents were asked the "knowledge questions" related to their decision. For 8 of the 10 decisions, fewer than half of respondents could answer more than one knowledge question correctly (Couper 2009).

Communication between patients and their physicians is a crucial component of medical decision making, but physicians and patients may not always share all the pertinent information. The same University of Michigan survey found that, among patients who had discussed an intervention with their health care provider, the provider tended to emphasize the pros over the cons and frequently recommended getting more tests or treatment (Couper 2009). While providers tended to focus on the benefits of an intervention, patients were interested in both benefits and harms. Researchers surveyed patients and providers to assess their rankings of key facts and goals for 14 treatment decisions. When providers were asked to choose the top three things patients should know about chemotherapy and hormonal therapy for breast cancer, not one selected side effects or risks, whereas almost one-quarter of patients wanted to know about serious side effects. When patients and providers were asked to choose their top three goals and concerns for the 14 treatment decisions, none of the conditions had the same items in the top three. Providers had a tendency to cluster on a few goals; for example, for breast cancer decisions, they focused on keeping the breast, living as long as possible, and looking natural without clothes, whereas patients were more diverse in their goals (Sepucha 2009).

The goal of shared decision making is to improve patients' knowledge of their condition and give them a more realistic perception of treatment outcomes so that they can arrive at a treatment decision with their physicians that reflects their values and preferences. Shared decision making is generally used when choice among treatment options depends heavily on patient assessment of risks and benefits. However, it is clearly not appropriate for all medical decisions. It cannot be used in emergency situations. It also has limited utility when the medical evidence about a treatment recommendation is unambiguous. In the programs that we studied, a small, discrete set of conditions were identified as appropriate for shared decision making, although the conditions differed somewhat in different programs. Some of the most common conditions were breast cancer, lumbar spine disease, and knee osteoarthritis.

Much of the impetus for the development of shared decision-making programs has been to reduce unwarranted variation in "preference-sensitive" care—that is, care

that depends on patient preferences when two or more medically acceptable options exist. Researchers argue that widespread regional variation in rates for preference-sensitive procedures like hysterectomy is unwarranted if they do not correspond to a similar distribution in patient preferences. The goal is to ensure that these procedures are chosen by informed patients who value their possible benefits more than the potential harms (O'Connor et al. 2004).

Health literacy and shared decision-making tools

Commission-sponsored research shows that, contrary to commonly held assumptions that older people defer to their physicians, elderly patients are interested in participating in their health care treatment options (Gerteis et al. 2008). Yet other evidence shows that health literacy decreases and decision-making processes change with age (Finucane et al. 2002, Kutner et al. 2006). The drop in health literacy suggests that Medicare should explore alternative beneficiary education and communication strategies that take into account the cultural and learning style differences of the population.

Health literacy

Health literacy is defined by the Institute of Medicine as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Institute of Medicine 2004). Estimates quantifying limited health literacy find that nearly half the population has low or marginal health literacy (Paasche-Orlow et al. 2005).[1] Health literacy is lower for certain subgroups, including the elderly, racial minorities, and low-income adults (Kutner et al. 2006).

Statistical literacy is a component of health literacy and considerable evidence suggests that many adults fall short on basic levels. In one study, researchers found that in a nationally representative sample of adults aged 35 to 70, only 25 percent could convert 1 in 1,000 to 0.1 percent; 70 percent of the sample could convert 1 percent to 10 in 1,000; and roughly a quarter of the sample could correctly estimate how many times a coin would likely come up heads in 1,000 flips (Gigerenzer et al. 2008). It is not surprising that this difficulty understanding probabilities leads to confusion about the risks and benefits of health care procedures.

A review of experimental studies suggests that many patients do not understand the difference between statements about reduced risk expressed in relative terms and such statements expressed in absolute terms. They tend to evaluate a treatment alternative more positively if the benefits are expressed as a relative risk reduction (Covey 2007). To illustrate the difference between relative and absolute risk presentations, saying that "a cancer screening test every two years will reduce the chance of dying from that cancer by around one third over the next ten years" is a statement of relative risk reduction, whereas "a cancer screening test every two years will reduce your chance of dying from that cancer from around 3 in 1,000 to around 2 in 1,000" is a statement of absolute risk reduction (Gigerenzer et al. 2008). Generally, patients overestimate the benefits of screening procedures while underestimating the harms. They also confuse early detection with prevention and seek certainty from tests or treatments (Gigerenzer et al. 2008). This finding emphasizes the importance of carefully considering the optimal presentation of risk when educating patients and encouraging them to make informed decisions.

Health and statistical literacy levels affect how individuals gather health information. In one study, adults with high levels of health literacy got most of their information on health issues from written sources such as newspapers, magazines, brochures, and the Internet. Adults with low health literacy got most of their information on health issues from radio and television (Kutner et al. 2006).

Low health literacy is associated with poor health outcomes, controlling for demographic and socioeconomic factors, including income. Researchers found that elderly adults with inadequate health literacy were more likely to be in poor physical and mental health (Wolf et al. 2005). Low levels of health literacy were associated with worsened diabetes outcomes, fewer self-management behaviors, and decreased knowledge about one's chronic disease (Cavanaugh et al. 2008, Gazmararian et al. 2003, Schillinger et al. 2002). Among elderly managed care enrollees, those with lower health literacy were also less likely to receive preventive services, such as influenza vaccines and mammograms. For this group, inadequate health literacy was a risk factor for hospitalization (Baker et al. 1998, Baker et al. 2002). Finally, one study found that low health literacy was one factor contributing to racial disparities in the rates of preventive services among the elderly (Bennett et al. 2009).

Tools to improve doctor–patient communication

Low health literacy among Medicare beneficiaries argues for the use of tools such as patient activation, decision aids, and health information technology (IT) as a way to improve communication between doctors and patients.

Patient activation

Researchers find that patient activation—a person's ability to self-manage his or her health and health care—is positively associated with health care outcomes (Remmers et al. 2009). Someone with high patient activation is more likely to receive preventive care and engage in preventive health behaviors, such as seeking relevant information on their health condition, implementing lifestyle changes, adhering to treatment plans, and asking questions about their health care (Seubert 2009).

Some research suggests that high patient activation may help mediate the adverse effects of low health literacy. One study tested patient comprehension and ability to choose the best hospital based on hypothetical quality information. Researchers found that survey respondents with low health literacy and high activation had better comprehension and made better choices than their low-literacy and low-activation counterparts. For example, given hypothetical quality information about a few hospitals, respondents scoring poorly on literacy and activation made the high-quality choice slightly more than half the time. However, respondents scoring poorly on literacy and well on activation made the high-quality choice roughly 70 percent of the time (Hibbard et al. 2007, Seubert 2009). Additionally, increasing patient activation may help address racial and ethnic disparities because social–environmental factors are associated with activation and, in turn, activation is correlated with healthy behaviors and positive health outcomes. Researchers modeled racial parity in patient activation levels and predicted health outcomes that substantially narrowed the disparities (Hibbard et al. 2008). These findings indicate that improving patient activation may improve decision making among patients.

Decision aids

Patient decision aids are an essential element of shared decision making. They are tools that provide patients with evidence-based, objective information on all treatment options for a given condition. They present the risks and benefits of all options and help patients understand how likely it is that those benefits or harms will affect them. Patients are asked to weigh their personal attitudes toward those risks and benefits and take an active role in the treatment choice. By helping patients to identify their concerns, the decision aid helps them formulate questions to discuss with their physicians.

In recent years, decision aids have proliferated. One recent compendium found more than 500 decision aids, including 200 that meet minimum quality standards (Ottawa Hospital Research Institute 2009).[2] Developers include the Agency for Healthcare Research and Quality; the National Cancer Institute; Healthwise, a nonprofit organization that produces patient education content for health plan web sites; the Foundation for Informed Decision Making; and the Mayo Clinic. In addition, many pharmaceutical companies and manufacturers of other products advertise discussion guides for patients to take to their physician appointments; these guides may not meet standards for objectivity.

To produce an effective decision aid, developers need two kinds of expertise. They must understand complex medical conditions and treatments and keep current with changes in the evidence base. They must also have the ability to translate this information into everyday language comprehensible to people with no medical training. The aids they develop must provide for patients to express their values and preferences. A substantial number of medical experts and communication specialists may be needed to develop and maintain multiple decision aids.

In 2003, the International Patient Decision Aids Standards Collaboration—a group of researchers, practitioners, patients, and policymakers from 14 countries—established a process to develop quality criteria for patient decision aids (Elwyn et al. 2006). The resulting framework called for evaluating decision aids on the basis of content, presentation, and effectiveness. The collaboration also developed a checklist that decision aid developers and evaluators can use to test whether the decision aid meets the criteria. The Patient Protection and Affordable Care Act of 2010 authorizes the Secretary to contract with a consensus-based standards-setting organization to develop quality metrics for decision aids used in shared decision-making programs and to develop a certification process to determine whether decision aids meet the standards (see text box, p. 196).

Health IT

Health IT facilitates the use of shared decision making. At both Dartmouth Hitchcock Medical Center and

Massachusetts General, program organizers use IT to track patients who could benefit from specific decision aids; allow physicians to order aids by clicking a button on the patient's medical record; disseminate aids; and, at times, track patient survey responses. Evidence suggests that an IT infrastructure may be critical to success.

Ideally, and at some places we visited, a physician can initiate the shared decision-making process with one click of a button. The technology already exists to incorporate standardized access to patient-specific educational resources into an electronic medical record system. As a result of the American Recovery and Reinvestment Act of 2009, CMS will implement Medicare and Medicaid payment incentives to providers, totaling an estimated $36 billion over the next six years to encourage the adoption and use of certified electronic health record technology by hospitals and physicians (Blumenthal 2010, Congressional Budget Office 2009). Including provisions for access to patient-specific educational resources in common primary languages would streamline the shared decision-making process during a patient visit and facilitate the infrastructure for broader implementation of shared decision making.

Adoption and evaluation of shared decision-making programs

Shared decision-making programs continue to expand, but the challenges to broader dissemination remain significant. Initially, shared decision-making programs were established at academic medical centers. More recently, demonstration programs have been implemented at community-based clinics. For example, the Foundation for Informed Medical Decision Making currently sponsors demonstrations at 13 primary care clinics and 8 specialty care practices (Foundation for Informed Medical Decision Making 2010). In addition, some health plans provide shared decision-making services to their enrollees.

While evaluation of shared decision-making programs as a whole is still in a formative stage, the International Cochrane Collaboration has analyzed 55 randomized controlled trials of shared decision making with patient decision aids relating to 23 different medical decisions. Studies generally relate to preference-sensitive surgical decisions and testing or screening decisions. The studies have consistently shown that decision aids used along with counseling increase patients' knowledge, give them a more realistic perception of treatment outcomes, reduce the proportion of patients who are passive in decision making, and improve agreement between patients' values and the options they choose. In general, the studies also showed a reduction in more invasive treatment options without adverse effects on health outcomes (O'Connor et al. 2004, O'Connor et al. 2009).

Although supporters of shared decision making emphasize its role in improving the quality of patient care, others believe it also has the ability to lower medical costs. However, data on cost savings are inconclusive. Although patients may choose less-invasive options, these treatments are not always less expensive than other options.

Adoption of shared decision making has been particularly high at breast cancer centers. Currently, about 50 centers are actively distributing decision aids as part of shared decision-making programs. One innovative program has been implemented at the University of California, San Francisco, breast cancer center. Premedical students distribute decision aids before physician visits and provide question listings, audio recordings, and note-taking services to help patients prepare for, participate in, and remember their visits (Belkora 2010, Foundation for Informed Medical Decision Making 2010).

One issue that could limit future adoption of shared decision-making programs is the lack of payment incentives. Physicians at Dartmouth Hitchcock Medical Center and Massachusetts General mentioned that shared decision-making programs in their institutions were implemented despite the negative incentives created by a fee-for-service (FFS) payment system. For example, surgeons can expect to see fewer patients electing back surgery if they engage in shared decision making. Specialists at Dartmouth Hitchcock Medical Center did not consider that a problem but believed a different payment structure would facilitate wider dissemination of these programs.

A number of states are promoting shared decision-making initiatives. In May 2007, Washington became the first state to enact legislation on shared decision making. The legislature directed the state Health Care Authority to enact a demonstration project at one or more multispecialty group practice sites providing state-purchased care. These sites must incorporate decision aids into areas of preference-sensitive care and evaluate the aids' impact. The ongoing demonstration project is based at Group Health Cooperative of Puget Sound. Group Health has been implementing a program for 12

preference-sensitive conditions related to elective surgical procedures.[3]

The law also includes legal protections for physicians who engage in shared decision making with their patients. Current standards of informed consent are ambiguous and vary by state. Thus, a physician applying evidence-based medicine may still be vulnerable to lawsuits (King and Moulton 2006). Under the terms of the law, if a patient or his or her representative signs an acknowledgment of shared decision making, that document serves as prima facie evidence that the patient gave informed consent to the treatment. Plaintiffs would face a high burden of proof to argue otherwise. A number of other states are considering similar statutes.[4]

Although failure to obtain informed consent is not the primary cause of many malpractice suits, some legal scholars have argued that poor risk communication in the informed consent process is an underlying factor in much litigation. For example, a patient may not understand the risks that a treatment entails (despite signing an informed consent form) and then sue when harms result from the procedure (Sharpe and Faden 1998).

To evaluate the demonstration project, Group Health will track the following outcomes:

- decision aid viewing
- patient satisfaction with decision aids
- procedure rates
- overall health care use of patients (number of physician visits, hospitalizations, medications)
- cost of program implementation and delivery
- impact of program implementation on providers and staff

Group Health began implementing the program January 2009. Implementation proceeded slowly. Organizers spent more than a year talking to physicians about shared decision making, trying to convince them to adopt it in their practices. They found that adoption rates of shared decision making varied among specialties, with orthopedists most receptive to the program.

Group Health recently provided some preliminary results. Over the past year, 3,200 decision aids have been distributed to patients, most ordered by their physicians. Patients have reported a high degree of satisfaction and six of nine orthopedists also expressed satisfaction. (Two orthopedists were neutral and one was negative.) Physicians found no change in the amount of time they spent with patients, although some reported that the quality of the visit was better (Arterburn 2010).

More recently, Maine and Vermont passed legislation to study the feasibility of incorporating shared decision making within clinical practice. Other states considering initiatives include Florida, Connecticut, Minnesota, California, Oklahoma, and Massachusetts. In proposed legislation, Minnesota would require clinicians treating state-insured employees and Medicaid recipients to use shared decision making to receive payment for certain procedures, including chronic back pain, early-stage breast cancer, and benign prostatic hyperplasia (Kuehn 2009). Some initiatives (e.g., in Maine and Minnesota) include collaborations between the state and private employers to test shared decision making as an element in broader health delivery system reform.

Lessons learned to date on physicians' use of shared decision making

Effective shared decision-making programs require physician leadership and support, although physicians are not generally involved in the daily operation of programs. In fact, to enlist physician support, shared decision-making protocols must fit seamlessly into clinical practice and not increase the time physicians spend during appointments. In well-designed programs, patient appointment times remain the same but the conversation differs.

Optimal conditions for physicians' use

Studies have shown that physicians generally support the concept of better informed patients and have a positive attitude toward shared decision making but have not implemented its use in their practices. For example, most orthopedic surgeons responding to a 2004 member survey of the American Academy of Hip and Knee Surgeons said that shared decision making was a good or excellent idea. The most important benefit of decision aids used in the programs was increased patient comprehension. The major barrier they reported was that it would interfere with office work (Weinstein et al. 2007). Similarly, in a recent national survey of primary care physicians, 93 percent reported that

shared decision making sounded like a positive process. Nearly all said they would use patient decision aids if they met physicians' standards. They named lack of time with patients as the most important barrier to engaging in shared decision making (Foundation for Informed Medical Decision Making 2009b). Our site visits suggest key principles for obtaining physician participation in shared decision making.

- ***Programs require physician support.*** At both Dartmouth Hitchcock Medical Center and Massachusetts General Hospital, organizers stressed the importance of having physician support before trying to implement a shared decision-making program. Unlike the disease management programs we have examined in the past, physicians in these practices have taken the lead in shaping their institutions' use of shared decision making. In the programs developed at Massachusetts General, they are responsible for prescribing patient decision aids. At Dartmouth Hitchcock Medical Center, decision aids are prescribed automatically in a program designed by physicians. At both sites, physicians have the opportunity to review the material and they know that each decision aid is updated frequently by their peers.

  Organizers of a demonstration project at Group Health of Puget Sound (see above) spent months informing physicians about the program and addressing their concerns before implementing a shared decision-making demonstration. They found that physician receptivity was not uniform. As at other sites we visited, physician response differed by specialty. One interviewee found more positive reactions from individuals in high-volume specialties. For example, orthopedists—a high-volume specialty—were more likely to appreciate shared decision making because it resulted in fewer patients who were poor candidates for back surgery or knee replacement. Additionally, they said that patients had more realistic expectations about treatment results.

  Physicians may differ in their use of specific decision aids. In at least one case, a decision aid on colon cancer screening was not used initially at Dartmouth Hitchcock Medical Center. The institution's gastroenterologists were concerned that the aid might bias patients against screening because it presented not getting screened as a valid option. As a result, a small randomized trial was done that showed patients chose screening at the same rate after watching the version that included one expert describing his decision, as a patient, not to be screened compared with a revised version that deleted his commentary. On the basis of these results, this decision aid is now in use at Dartmouth Hitchcock. Gastroenterologists at Massachusetts General did not object to use of this decision aid.

- ***Programs are designed to fit into the way physicians practice.*** Although most early programs resulted from physician initiatives, physicians are typically not involved in the program's day-to-day operation. At the sites we visited, program organizers took a team-based approach to shared decision making. Nurses, social workers, and others provided materials, counseling, and other assistance to patients to prepare them for their physician visits. The directors of the Center for Informed Choice and the Center for Shared Decision Making at Dartmouth Hitchcock Medical Center emphasized that these programs could work only if they fit into the way physicians practiced. If the program created more work for physicians or interrupted the work flow in the office, shared decision making was unlikely to be widely adopted. The Dartmouth Hitchcock Medical Center shared decision-making program is part of a comprehensive, coordinated care system for newly diagnosed breast cancer patients. It requires no additional work for the surgeons. Patients are automatically prescribed video-based decision aids upon diagnosis and asked to complete a survey after viewing the aid. Counselors are available to help patients with the material as well as other issues. When the surgeon sees the patient, she has the survey results indicating the patient's values and preferences as well as measures of how well the patient understood the information covered in the decision aid. Further aids are available to help patients decide about reconstructive surgery (Collins 2009).

  The importance of designing systems that accommodate practice styles also was illustrated during our visit to Massachusetts General. Decision aids were disseminated to patients from two different primary care practices affiliated with the hospital. In each case, physicians received a list of the relevant materials they could prescribe to their patients. The list was incorporated into the patients' electronic medical record. Doctors could click on the ones they wanted their patient to receive and a department in the

hospital would mail them directly to the patient. This procedure worked in one practice but not in the other. Organizers discovered that in the second practice, physicians were accustomed to sending patients to a hospital patient library to obtain relevant information. They reorganized their system so that the list of decision aids was added to the other materials patients received in the library. As a result, physician use of the aids in the second practice increased.

- ***Programs have more impact when a feedback loop ensures that physicians meet with patients after they have seen decision aids.*** Primary care physicians at Dartmouth Hitchcock Medical Center described two models of shared decision making for the cancer screening programs they tested. In one case, all eligible patients were sent the decision aids before their scheduled preventive care visit. In the other case, patients received the aids when they arrived for their appointment. Evaluators concurred that the second model was less successful. To act on the information they received during their visit, patients would have to follow up with their physicians, although they may have had no further appointment scheduled. Ongoing demonstrations in a number of primary care clinics are testing the most effective way to deliver decision aids to patients at a time when they are likely to act on the information they receive.

Distinctions between specialty and primary care in use of shared decision making

Researchers stress the importance of implementing shared decision-making programs in primary care, and physician associations like the American Academy of Family Physicians have endorsed the model. However, intrinsic differences between primary and specialty care highlight the danger of assuming the broad applicability of shared decision-making programs without adaptations.

- ***Specialists are more likely to have a limited number of decision aids to prescribe for their patients.*** For example, breast cancer surgeons prescribe a decision aid that helps patients decide about lumpectomy or mastectomy for early-stage breast cancer. Primary care physicians deal with a wider range of issues. Organizers at Massachusetts General identify 22 decision aids that are available for use by primary care physicians. Programs include decisions about cancer screening, diabetes, heart disease, depression, end-of-life care, and general health. Primary care physicians are less likely to know before a patient visit which decision aids may be appropriate. Many of the decisions they discuss with their patients are about strategies to diagnose patient symptoms rather than treatment options. At Massachusetts General, the most prescribed programs are aids about PSA testing, colon cancer screening options, advanced directives, and chronic lower back pain.

- ***Patients may find decision aids provided by specialists more salient than those provided in primary care practices.*** Specialists prescribe decision aids at a time when the information is most useful to patients—before meeting with the physician to decide on a procedure like cancer treatment or back surgery. The physician can then spend more time with the patient answering questions and discussing the options and less time explaining the basics of the diagnosis and treatment options. In contrast, patients may not be willing to invest the same amount of time to understand the advantages and disadvantages of different cancer screening options that they may receive from their primary care physician.

- ***In specialty care programs, physicians are more likely to receive the results of their patients' response to the decision aid.*** In the Dartmouth Hitchcock Medical Center breast cancer program, patients are not only surveyed about their values and preferences after using the decision aid, they are also asked questions to test their knowledge of the material they have viewed. Physicians receive copies of these surveys before the patient's appointment. They can assess patient values and preferences and also whether those preferences are based on an understanding of the decision trade-offs. In the primary care setting, patients may not have another appointment to see their physicians soon after they receive a decision aid, which may limit the utility of the decision aid.

Despite these difficulties, many proponents of shared decision making emphasize the importance of implementing the model in primary care settings before decisions about tests and treatments are made. For example, patients who are referred to surgeons are likely to choose surgery. If they discussed their treatment options with their primary care physician, they might choose other options like medical management, watchful waiting, or physical therapy depending on the condition.

Use of shared decision making for certain populations

The Commission has expressed considerable interest in the application of shared decision making to elderly, minority, and low-income patients. Conceptually, shared decision making represents an opportunity to improve knowledge and informed consent among groups that may have lower health literacy—including the elderly, racial and ethnic minorities, and low-income adults. To compensate for low levels of health literacy, some decision aids are consciously crafted at a fifth-grade reading level. Risks are presented in absolute terms instead of relative terms. Some decision aids are translated into Spanish and will soon be translated into other languages to apply to patient populations who may not speak English at home.

Despite efforts to make decision aids useful to vulnerable populations, the empirical evidence on shared decision making within minority and low-income populations is limited. Many sites implementing shared decision making programs do not have diverse populations or do not track results by demographic characteristics. For example, Group Health Cooperative of Puget Sound in Seattle does not record the race of patients who access decision aids through their personal health records. Dartmouth Hitchcock Medical Center serves a population that is fairly homogeneous racially but diverse socioeconomically, ranging from patients affiliated with Dartmouth University to rural patients for whom Dartmouth Hitchcock Medical Center is the only source of care. The Dartmouth Hitchcock Medical Center breast cancer program records the results of its patients' knowledge and preferences survey but has not analyzed the results by socioeconomic status.

The commercial sector has made somewhat more progress targeting shared decision making to minority and low-income populations. For example, Health Dialog, the for-profit company contracting with health plans to market shared decision making as a component of a health coaching service, uses demographic data to target its patient outreach by classifying patients in 60 population segments. Health Dialog uses a combination of demographic data (race/ethnicity, census ZIP code–level income, age, and family structure) and clinical data to identify which population segment a patient belongs to. Once that determination has been made, colors, photos, and taglines of the marketing material are adjusted to optimize outreach success. The head of the Consumer Segmentation and Engagement Strategies group told us that they vary taglines on mailed outreach materials to resonate with different population segments, such as cost sensitivity, empowerment, and convenience. They adjust photos to depict members of the targeted patient's population segment. They also change color themes based on the results of extensive focus group testing that suggest that different populations respond differently to earth tones versus bright colors. Currently, these demographic targeting strategies aim only to increase participation in the health coaching service and not to influence the content of health coaching or shared decision-making materials. Measuring the success of this outreach targeting is difficult because most health plans that are Health Dialog clients do not collect race/ethnicity data on health coaching participation, much less share it with researchers. While efforts to date concentrate on encouraging participation, Health Dialog plans to implement population-specific content in 2010, including outreach aimed to lower dietary salt intake among African American and Hispanic populations (Costello 2009).

Improving outreach through targeting answers only part of the Commission's question about how shared decision making applies to vulnerable populations. There is still a dearth of information on the application and challenges of shared decision making among racial and ethnic minorities, low-income populations, and low health literacy populations, but promising initiatives are under way:

- ***Developing and testing educational materials to improve decision making for patients with advanced chronic kidney disease (CKD).*** A group of researchers at Johns Hopkins University School of Medicine is developing and testing educational materials to improve decision making for patients with advanced CKD, a condition that disproportionately affects African Americans. As patient decisions about treatments for end-stage renal disease (ESRD) are preference sensitive, these audiovisual and computer-based educational resources are designed to enhance shared decision making with regard to the choice of ESRD treatment. Researchers are working toward decision aids to assist incident ESRD patients and their families make informed decisions about live kidney donation and transplantation. To date, they have conducted focus groups with African American CKD patients and their family members. These groups have discussed the level of baseline understanding about treatment options, perceptions of advantages and disadvantages for each treatment choice, important elements of the patient experiences relative

to treatment choice, and the degree to which patients feel informed about insurance coverage for kidney transplantation (Foundation for Informed Medical Decision Making 2009a).

- ***Testing an intervention to improve activation among patients in the waiting room of a community health center.*** Researchers from City College in New York are implementing and testing interventions to boost patient activation among patients at a community health center with a diverse and low-income population. Project staff will test three strategies to assess their impact on patient activation scores compared with a control group. One group of patients will receive an intervention designed to help patients develop their question-asking skills and link those skills to health care decision making; a second group will view the video-based patient decision aid—Getting the Healthcare That's Right for You—designed to make individuals more aware of how to be active participants in their care; a third group will be exposed to both interventions. These interventions will take place in the waiting room. The study will measure patient activation before and after the intervention (Gold 2010).

- ***Impact of health literacy on outcomes and effectiveness of shared decision-making programs in patients with chronic diseases***. Recognizing that low health literacy may present an additional challenge in the management of chronic disease, researchers at the University of Cincinnati are implementing and testing the booklet and video version of a shared decision-making program for patients with coronary artery disease. Researchers will measure the effect of the video versus the booklet intervention on knowledge scores to assess whether the resulting difference is most pronounced for patients with low health literacy. Additionally, they will record relevant clinical outcomes six months after the intervention to assess whether patients with low health literacy became more or less involved in the management of their disease than their more literate counterparts (Foundation for Informed Medical Decision Making 2009a).

Shared decision making in Medicare

Medicare beneficiaries have had limited experience with shared decision making. Some health plans contract with Health Dialog to provide shared decision-making services to their enrollees, including Medicare beneficiaries. In addition, some Medicare Advantage plans have begun implementing shared decision-making programs. One approach involves plans contracting with individuals serving as coaches to contact selected enrollees to discuss medical decisions as well as more traditional disease management services. Our interviews with nurse coaches and a health plan program coordinator suggest that Medicare beneficiaries are very receptive to their services. However, because they generally rely on claims data, the programs have difficulty identifying and contacting beneficiaries in time to prepare them to make a preference-sensitive decision.

Medicare could promote the use of shared decision making in a number of ways:

- Design a demonstration project to test the use of shared decision making for Medicare beneficiaries,
- Provide incentives to practitioners who adopt shared decision making,
- Provide incentives to patients who engage in shared decision making, and
- Require providers to use shared decision making for some preference-sensitive services.

These strategies are not mutually exclusive. Each has advantages and disadvantages. Policymakers would have to decide on the design and scope of any policy choice.

Medicare demonstration project

Clinicians attempting to introduce shared decision making into FFS Medicare face many challenges. Most physicians treating Medicare beneficiaries do not have the office infrastructure or functioning clinical IT system to easily integrate these programs into their practice. As mentioned earlier, incentives in the FFS payment structure do not compensate this behavior. However, the Commission has discussed two health system delivery initiatives in Medicare that have the structure and incentives to engage in shared decision making: medical homes and accountable care organizations (ACOs). CMS could initiate a shared decision-making demonstration project based on one of these delivery system models.

Medical homes

A medical home is a delivery system innovation designed to coordinate a patient's health care through a central

clinical contact. In our June 2008 report, the Commission recommended that the Congress initiate a medical home pilot project in Medicare. We noted that eligible medical homes must meet stringent criteria, including at least the following capabilities:

- furnish primary care (including coordinating appropriate preventive, maintenance, and acute health services)
- use health IT for active clinical decision support
- conduct care management
- maintain 24-hour patient communication and rapid access
- keep up-to-date records of patients' advance directives
- be accredited/certified from an external accrediting body

Medical homes that meet these criteria have the infrastructure and the incentive to engage in shared decision making. A number of recent commentators have noted that shared decision making in primary care is a key element of patient-centered medical care (Berwick 2009, Mirabito and Berry 2010).

Accountable care organizations

ACOs represent another delivery system structure that has the potential to develop shared decision-making programs. The Commission and others have discussed the potential of ACOs, a set of providers who are responsible for the health care of a population of Medicare beneficiaries (Congressional Budget Office 2008, Fisher et al. 2009, Medicare Payment Advisory Commission 2008). Under an ACO structure, a group of physicians is teamed with a hospital that is given joint responsibility for the quality and cost of care provided to a large group of patients. By making providers jointly responsible for the quality of care and cost of a population, ACOs are designed to improve the coordination of care and reduce duplication of services. Because ACOs would take responsibility for resource use, Medicare could constrain spending for its beneficiaries with a system of withholds and bonuses. Such a system is intended to counterbalance the incentives in the FFS system to increase volume.

ACOs would have the financial incentive and the infrastructure to implement shared decision making. Because ACOs include physicians with multiple specialties, they would be best positioned to incorporate shared decision making for preference-sensitive conditions as determined by the physicians within the practice.

Medicare could initiate demonstration projects in medical homes or ACOs to test the feasibility of shared decision making with the Medicare population. There are advantages and disadvantages to this approach. These organizations would have the infrastructure to implement shared decision making. They would need physicians within their organization who were willing adopters of the process. However, as these demonstrations introduce many innovations in the delivery system, Medicare might not want to include shared decision making as an additional element in the medical home or ACO model. As in other primary care settings, shared decision making in medical homes could be difficult.

Provide incentives to practitioners who use shared decision making

Some policy analysts have suggested that Medicare and other health care payers could provide incentives to physicians and other practitioners to use shared decision making with their patients. Incentives could be structured in a variety of ways, from allowing physicians to bill for shared decision making through the Medicare fee schedule to offering rewards or bonuses to physicians who distribute patient decision aids. Each strategy has advantages and disadvantages.

- The Medicare fee schedule includes add-on codes to evaluation and management visits that physicians can bill for prolonged visits when medically necessary. These time-based codes can be used only when more than half the duration of the visit is spent on counseling. Documentation must include a time estimate and a brief description of what condition and treatments were discussed. Time is measured by direct face-to-face contact between the physician and the patient. The codes are most often used by surgeons, oncologists, nephrologists, and other specialists (*Part B News* 2010a, *Part B News* 2010b). CMS could specify that these codes can be used by physicians who engage in shared decision making.

  This approach has advantages and disadvantages. It could provide an incentive for physicians within FFS Medicare to engage in shared decision making. CMS would have to provide guidance on the criteria needed to document that shared decision making took place because use of this code could lead to increased Medicare spending. CMS would also need metrics to

evaluate the outcome of shared decision making in this setting.

- Criteria used to determine eligibility for pay-for-performance bonuses could include distributing relevant decision aids to patients. Wennberg and colleagues suggest that most performance incentives are designed to encourage the provision of more services (Wennberg et al. 2007). Bonuses for shared decision making would be one of the few performance incentives that could result in fewer services being performed over the course of an episode of care. After consideration of the risks and benefits of a treatment, a beneficiary may decide not to receive a service that otherwise would have been provided.

  At least two private insurers have included documented use of shared decision making as a requirement for certain recognition or incentive programs. Blue Cross Blue Shield requires facilities seeking a designation as a Blue Distinction Center for knee and hip replacement or spinal surgery to offer shared decision making and preoperative patient education (BlueCross BlueShield Association 2010). A program called MedEncentive provides incentives to patients and physicians to use patient decision aids (Greene 2008).

  For Medicare to use this approach, CMS would have to define criteria to ensure that shared decision making met quality criteria. For example, it would need to verify that patient decision aids were objective, evidence based, and up to date. It would also need metrics to evaluate the effects of the strategy.

Provide incentives to patients to engage in shared decision making

Incentives for patients may also facilitate the use of shared decision making by encouraging the use of decision aids and improving patient activation. A challenge for any incentive system targeting Medicare beneficiaries is tailoring it to the benefit structure and supplemental insurance patterns.

- Patient incentives may be effective among elderly, low-income, and diverse populations. Researchers at the University of California, Los Angeles, tested the effect of a small financial incentive on the likelihood that seniors at two community senior centers would attend screenings of videos about managing chronic diseases. One senior center served a low-income, predominantly African American community and the other served a diverse middle-income community. Researchers found the highest rate of participation occurred among seniors receiving a $50 gift card to attend three of the five screenings. These participants differed from their counterparts on some demographic characteristics (somewhat younger, more likely to be female, moderately more likely to be African American, moderately more likely to have lower household incomes) but not others (number of chronic conditions, baseline patient activation scores). Seniors who attended three or more screenings reported somewhat more physical activity postintervention and had significantly higher patient activation scores, both immediately after the intervention and six months later (Foundation for Informed Medical Decision Making 2009a).

- Patient incentives would have to accommodate benefit structure and supplemental insurance. The MedEncentive program promotes shared decision making by simultaneously incentivizing physicians and offering financial rewards (in the form of copay rebates ranging from $10 to $30) to patients who use web-based decision aids (Greene 2008). This incentive would need adjustment to account for the large percentage of Medicare beneficiaries who have supplemental coverage, but there is some evidence that it yields higher participation rates and cost savings (Greene 2009). Any incentive program would be an added cost but could decrease spending on net if patients opt for less-invasive and less-expensive treatment options.

Require providers to offer shared decision making for some services

Some analysts have suggested that shared decision making be a requirement rather than an option for some preference-sensitive decisions. They argue that patients should not receive preference-sensitive treatments unless they understand the potential risks and benefits the treatment entails. However, implementing payment or coverage restrictions might be difficult if physicians do not have the office infrastructure to facilitate shared decision making within FFS Medicare.

- The Commonwealth Fund (Schoen et al. 2007) proposes requiring FFS Medicare beneficiaries to use patient decision aids for certain high-cost, preference-sensitive conditions, including coronary revascularization for angina and lumbar spine surgery for low-back pain. Providers who perform

the procedure or are accountable for the patient's care would be held responsible for ensuring that the patient has complied. Providers who do not document that this process took place would be subject to a 10 percent reduction in Medicare payments for claims related to the procedure.

- Medicare could link coverage for some preference-sensitive conditions to use of shared decision making. Similar to coverage with evidence development, Medicare would cover specified procedures only with documentation that the patient has engaged in shared decision making with her physician.

As with performance incentives, CMS would have to define criteria to ensure that shared decision making met quality criteria. For example, it would need to verify that patient decision aids were objective, evidence based, and up to date. It would also need metrics to evaluate the effects of the strategy. It would need to account for cases in which beneficiaries are offered shared decision making but refuse to participate. One disadvantage is that this strategy would penalize physicians who do not have the office infrastructure to implement an efficient program of shared decision making. It could also penalize practices serving non-English-speaking populations. Currently, decision aids are not widely available in languages other than English. Finally, as noted earlier, if physicians are required to offer shared decision-making tools but do not support their use, the model is less likely to be effective.

Future work pertinent to shared decision making in Medicare

In future work, we plan to examine some of the challenges Medicare faces trying to communicate with beneficiaries about how their health care services are delivered and financed. In addition to decisions facing all consumers, Medicare beneficiaries must learn about the program and choose whether to obtain benefits from the traditional FFS program or enroll in a Medicare Advantage plan. They must decide whether to enroll in a separate drug plan. They also must determine whether they need supplemental coverage or whether they qualify for additional financial help from the government. They may find the amount of information they receive on all these issues abundant but difficult to synthesize.

Fraenkel and McGraw note that consumers tend to have a broader understanding of medical decision making than that encompassed by shared decision-making programs (Fraenkel and McGraw 2007). For example, they consider choice of provider a key decision they routinely make. In previous work, the Commission has documented the difficulties Medicare beneficiaries faced trying to choose a drug plan when Part D was implemented (Medicare Payment Advisory Commission 2007). An instrument like a decision aid, if recognized as objective and balanced, may help beneficiaries with this sort of choice. Consumers also consider whether to take a prescribed medication an aspect of personal choice. Thus, a broader definition of shared decision making may provide a useful perspective on issues like plan and provider choice and patient nonadherence to medication regimens. ■

Endnotes

1 This estimate of health literacy is based on a review of roughly 85 studies that measured health literacy using the Rapid Estimate of Adult Literacy in Medicine test or the Test of Functional Health Literacy in Adults.

2 To meet minimal inclusion criteria, the patient decision aid must:

- Satisfy the Cochrane definition of a patient decision aid: Patient decision aids are interventions designed to help people make specific deliberative choices by providing information about options and outcomes that are relevant to a patient's health status and by clarifying personal values. They are intended to be adjuncts to counseling.
- Have a development process that includes expert review.
- Have an update policy.
- Support statements with scientific evidence.
- Disclose funding sources and conflicts of interest.

3 Conditions chosen include herniated disc, spinal stenosis, knee and hip osteoarthritis, prostate enlargement, prostate cancer, prostate-specific antigen (PSA) testing, uterine fibroids, abnormal uterine bleeding, chronic stable angina, early-stage breast cancer, and reconstructive surgery after a mastectomy. For more information, see http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/Article/data/02FEB2010/1002HHN_FEA_power&domain=HHNMAG.

4 The use of decision aids to help inform patients' decisions about PSA testing may be gaining traction. In February, the American Cancer Society issued revised guidelines for PSA testing that recommend that men use patient decision aids to help them make an informed choice about testing. The guidelines identify the type of information that should be included in these aids.

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CHAPTER 8

Addressing the growth of ancillary services in physicians' offices

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Chapter summary

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare patients for "designated health services" (DHS)—such as imaging, radiation therapy, home health, durable medical equipment, clinical laboratory tests, and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. The in-office ancillary services (IOAS) exception allows physicians to provide most DHS to patients in their offices under certain conditions.

Many physicians have expanded their practices in recent years to provide diagnostic imaging, clinical laboratory testing, physical therapy, and radiation therapy. These services—particularly diagnostic imaging—account for a significant share of Part B revenue for certain specialties. Many ancillary services have experienced rapid volume growth over the last five years, which contributes to Medicare's growing financial burden on taxpayers and beneficiaries. Rapid volume growth, along with the diffusion of new technologies, also raises questions about the equity and accuracy of physician payments. Moreover, there is evidence that some diagnostic imaging and physical therapy services ordered by physicians are not clinically appropriate (Hendel et al. 2010, Office of Inspector General 2006, Pham et al. 2009).

In the proposed rule for the 2008 physician fee schedule, CMS noted the migration of expensive imaging equipment, pathology services, and therapy

In this chapter

services to physicians' offices and asked for comment on whether the IOAS exception should be changed (Centers for Medicare & Medicaid Services 2007a). Specifically, CMS asked whether certain services should continue to qualify for the exception, such as services that are not needed at the time of the office visit to help the physician with a diagnosis or plan of treatment.

Proponents of the IOAS exception argue that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. On the other hand, there is evidence that physician investment in ancillary services leads to higher volume through greater overall capacity and financial incentives for physicians to order additional services (Baker 2008, Gazelle et al. 2007, Medicare Payment Advisory Commission 2009a, Mitchell and Sass 1995). In addition, there are concerns that physician ownership could skew clinical decisions.

We used Medicare claims data to examine the frequency with which certain services covered by the IOAS exception are provided on the same day as an office visit. We found that outpatient therapy (such as physical and occupational therapy) is rarely provided on the same day as a related office visit. In addition, fewer than half of advanced imaging, ultrasound, and clinical laboratory and pathology services are performed on the same day as an office visit, and about half of standard imaging studies (such as X-rays) are performed on the same day as an office visit. The finding that many ancillary services are not usually provided during an office visit raises questions about a key rationale for the IOAS exception—that it enables physicians to provide ancillary services during a patient's visit.

Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service payment systems, which reward higher volume. However, under a model in which providers receive a fixed payment in advance for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services. Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Integrated delivery systems that are able to coordinate care and manage resource use are likely to perform better under such a payment model than unaffiliated individual providers. Because it will take several years to establish new payment models and delivery systems, policymakers may wish to consider interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. Such strategies should be careful to not limit the development of accountable care organizations that could generate savings for Medicare and

improve quality. Interim policies could include restricting the ability of practices to self-refer for ancillary services, improving payment accuracy, and ensuring the appropriate use of ancillary services. This chapter does not make recommendations but explores several options in more detail:

- excluding therapeutic services such as physical therapy and radiation therapy from the IOAS exception,
- limiting the exception to physician practices that are clinically integrated,
- excluding diagnostic tests that are not usually provided during an office visit from the exception,
- reducing payment rates for diagnostic tests performed under the exception,
- improving payment accuracy and expanding payment rates to include multiple related services, and
- adopting a carefully targeted prior authorization program for advanced imaging services.

In future work, the Commission plans to further examine these strategies with the goal of crafting policy recommendations. ■

Background

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare patients for "designated health services" (DHS)—such as imaging, hospital services, radiation therapy, home health, durable medical equipment (DME), and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. For example, physicians are prohibited from referring patients to an imaging center or clinical lab that they own. However, a provision in the law—called the in-office ancillary services (IOAS) exception—allows physicians and group practices to provide most DHS in their own offices as long as certain requirements are met (42 CFR § 411.355(b)) (see text box, pp. 218–219).[1]

According to a summary of the bill that became the Stark law, the IOAS exception was expected to apply mostly to in-office laboratory tests or X-rays, based on the need for a quick turnaround time on crucial tests (*Congressional Record* 1989). However, the exception applies to almost all DHS, including therapeutic services and services that are delivered on a different day from the patient's office visit. The exception may also cover certain arrangements in which physicians share testing equipment with or lease equipment from other providers (see text box, pp. 218–219).

In the proposed rule for the 2008 physician fee schedule, CMS noted the migration of expensive imaging equipment, pathology services, and therapy services to physicians' offices and asked for comment on whether the IOAS exception should be changed (Centers for Medicare & Medicaid Services 2007a). Specifically, CMS asked whether certain services should continue to qualify for the exception, such as services that are not needed at the time of the office visit to help the physician with a diagnosis or plan of treatment. To date, CMS has not proposed a specific policy change.

The Commission has also noted the rapid growth of services covered by the IOAS exception and evidence that these services are sometimes furnished inappropriately. Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service (FFS) payment systems, which reward higher volume. However, under a model in which providers receive a fixed payment in advance for a group of beneficiaries (capitation) or an episode of care (bundling), they would not be able to generate additional revenue by ordering more services. Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Under such a payment model, integrated delivery systems that are able to coordinate care and manage resource use are likely to perform better than unaffiliated individual providers. Because it will take several years to establish new payment models and delivery systems, policymakers may wish to consider interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. Such strategies should be careful to not limit the development of accountable care organizations that could generate savings for Medicare and improve quality.

This chapter explores several options, including limiting the ability of physician practices to self-refer for ancillary services, improving payment accuracy, and ensuring the appropriate use of imaging services, but does not make recommendations. These strategies could be considered individually or in combination. In future work, the Commission plans to further examine these options with the goal of crafting policy recommendations.

In the sections that follow, we

- describe the increased investment by physicians in services covered by the IOAS exception and the potential benefits and risks of physician self-referral,
- discuss the volume growth of these services and questions about clinical appropriateness,
- present results of our analysis of how frequently diagnostic tests and outpatient therapy services are provided on the same day as an office visit, and
- map out several policy options.

Physicians have increased the provision of ancillary services in their offices

Many physicians have expanded their practices in recent years to provide diagnostic imaging, clinical laboratory testing, physical therapy, and radiation therapy (Anscher et al. 2010, Centers for Medicare & Medicaid Services 2007a, Medicare Payment Advisory Commission 2006a, Pham et al. 2004, Pham and Ginsburg 2007, Saul 2006).[2] According to a survey sponsored by the Commission in 2006, about 27 percent of physicians reported that they expanded in-office testing and lab services in the past year and almost 20 percent reported that they increased their use of in-office imaging (Medicare Payment Advisory Commission 2007a). An analysis by the Government

The in-office ancillary services exception

The in-office ancillary services (IOAS) exception to the Stark self-referral law has three key criteria known as the supervision, building (or location), and billing requirements: (1) The designated health services (DHS)—such as imaging or outpatient therapy—must be personally supervised by the referring physician, a physician who is a member of the group practice, or an individual who is supervised by the referring physician or another physician in the group (the supervision requirement). (2) The services must be furnished in the same building where the referring physician provides services that are not DHS; alternatively, groups may furnish services in a centralized facility that the group uses for ancillary services (the building requirement). (3) The services must be billed by the physician performing or supervising the service, the group practice, an entity that is wholly owned by the performing or supervising physician or by that physician's group practice, or a third-party billing company acting as an agent of the physician or group (the billing requirement) (42 CFR § 411.355 (b)).

The definition of a group practice is important because it allows physicians greater flexibility to provide ancillary services in their offices. Physicians who are in a group may order services that are furnished or supervised by other physicians in the group, and groups may also provide services in a centralized facility. The Stark law defines a group practice as one in which "substantially all" of the services provided by members of the group are furnished through the group and billed by the group. The Stark regulations interpreted "substantially all" as requiring that at least 75 percent of the patient care services provided by members of the group be provided and billed by the group (42 CFR § 411.352 (d)). Members include owners and employees of the group. The 75 percent rule applies to all the services collectively provided by physicians who are group members; individual members do not have to meet the 75 percent threshold. Nevertheless, this rule can make it difficult for groups to qualify as a group practice under the Stark law if they have many part-time physician members who also work for other groups. However, the Stark regulations created a new category called "physicians in the group" that applies to physicians who independently contract with the group. These physicians are not counted toward the 75 percent rule. Thus, groups can contract with physicians

(continued next page)

Accountability Office found that physicians' offices accounted for 64 percent of spending on imaging under the physician fee schedule in 2006, compared with 58 percent in 2000 (Government Accountability Office 2008).

Ancillary services—particularly diagnostic imaging—account for a significant share of Part B revenue for certain specialties (Figure 8-1, p. 220).[3] Imaging accounted for 38 percent of cardiology's Part B revenue in 2008, up from 35 percent in 2003, and it represented 23 percent of vascular surgery's Part B payments in 2008, compared with 20 percent in 2003. In 2008, imaging, clinical lab tests, pathology services, outpatient therapy, and radiation therapy collectively accounted for 12 percent of Part B revenue for orthopedic surgery (no change from 2003), 11 percent for urology (up from 5 percent in 2003), and 10 percent for internal medicine (no change from 2003).

Potential benefits and risks of physician investment in ancillary services

Although physician investment in imaging equipment and other ancillary services may improve access and convenience for patients, it may also lead to higher volume through additional capacity and financial incentives for physicians to order more services (Casalino 2008, Kouri et al. 2002). Proponents argue that allowing physicians to provide tests and other ancillary services in their offices enables them to better supervise quality of care, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations. According to CMS, a key rationale for the IOAS exception was to permit physicians to provide ancillary services in their offices during patient visits to enhance patients' convenience (Centers for Medicare & Medicaid Services 2001). The ability to provide tests and

The in-office ancillary services exception

on a part-time basis to provide or supervise ancillary services without affecting their ability to comply with the 75 percent rule.

The IOAS exception prohibits group practices from compensating their physicians in a manner that directly or indirectly reflects their referrals for DHS (42 CFR § 411.352 (g)). However, the Stark regulations allow practices to allocate profits from DHS to physicians in the practice using certain indirect methods, such as on a per capita basis or based on the practice's distribution of revenue from services that are not DHS.[4]

In addition to group practices that provide imaging in their own offices, arrangements exist in which a practice shares a facility with another practice or leases a block of time from a separate imaging provider. Under a block-of-time lease arrangement, a physician practice sends its patients to another provider for imaging and bills Medicare for the services, profiting from the difference between Medicare's payment rate and the fee paid by the practice to the provider that performs the services. According to data from a California health plan, more than 60 percent of the physicians who billed the plan for MRI or computed tomography (CT) scans engaged in a block lease or similar arrangement (Mitchell 2007). Shared facility or block lease arrangements may comply with the IOAS exception as long as the supervision, building, and billing requirements are met (e.g., the imaging study is performed in the same building where the referring physician furnishes services that are not DHS).[5] Under a CMS rule, however, imaging providers that are enrolled in Medicare as fixed-site independent diagnostic testing facilities (IDTFs) may not lease their operations to or share testing equipment with other organizations (42 CFR § 410.33). This rule does not apply to mobile IDTFs. Although this rule prohibits leasing arrangements between group practices and IDTFs, physician groups may still engage in block-of-time leases with each other.

The Patient Protection and Affordable Care Act of 2010 requires physicians who provide MRI, CT, or positron emission tomography services under the IOAS exception to inform their patients that they may obtain these services from another provider and to provide patients with a list of alternative providers in their area. ■

other services during an office visit may help physicians initiate treatment more quickly.

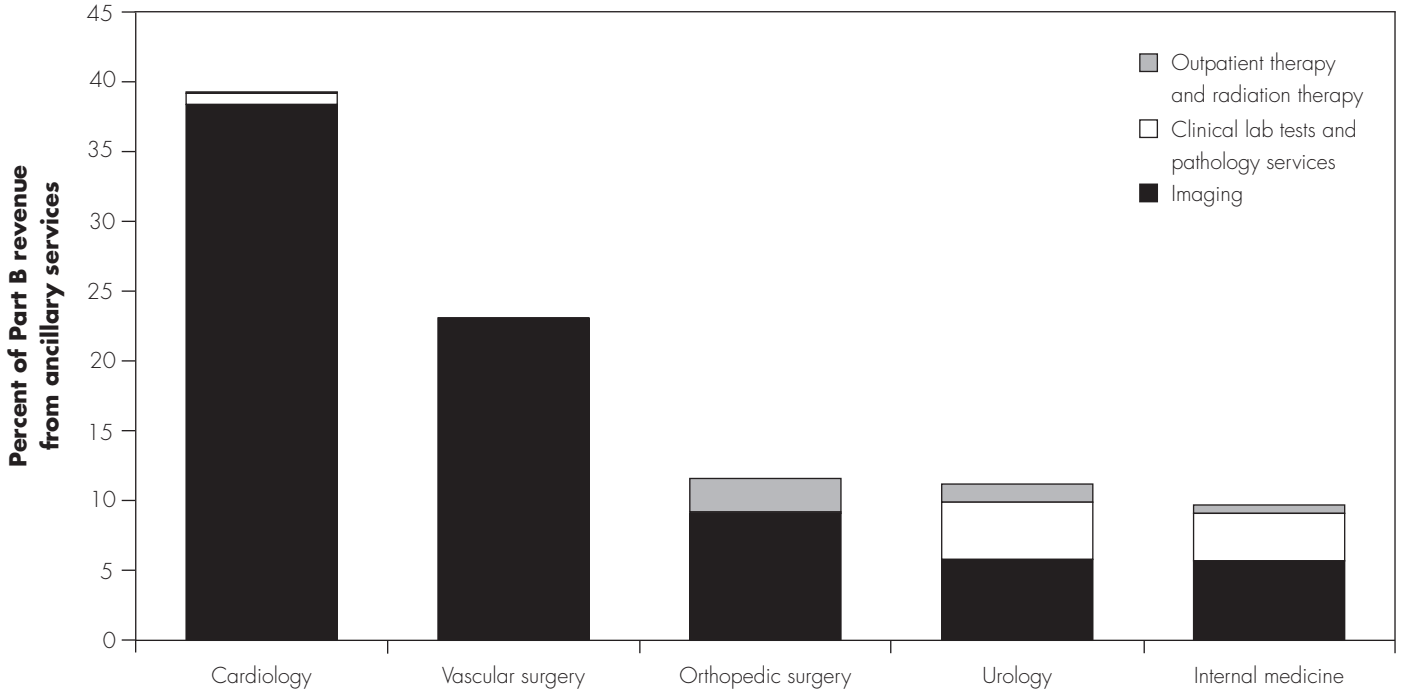
On the other hand, physician investment in ancillary services could lead to higher volume through greater overall capacity and financial incentives for physicians to order additional services. A study by Baker and colleagues estimated that each additional MRI scanner in a market is associated with 733 additional MRI scans among Medicare beneficiaries, and each additional computed tomography (CT) machine is associated with 2,224 additional CT scans (Baker et al. 2008). It is unclear whether the growth in scans is driven by changes in demand for medically necessary care or changes in the supply of machines. Several studies—including recent research conducted by the Commission—have found that physicians who furnish imaging services in their offices refer patients for more imaging than other physicians (Baker 2008, Gazelle et al. 2007, Government Accountability Office 1994, Hillman et al. 1990, Hillman et al. 1992, Kouri et al. 2002, Litt et al. 2005, Medicare Payment Advisory Commission 2009a). Researchers also found that physicians with a financial interest in physical therapy initiated therapy for patients with musculoskeletal injuries more frequently than other physicians and that physical therapy clinics with physician ownership provided more visits per patient than non-physician-owned clinics (Mitchell and Sass 1995, Swedlow et al. 1992).

Volume of ancillary services has grown rapidly

Many services covered under the IOAS exception experienced rapid volume growth under the physician fee schedule from 2003 to 2008.[6] The volume of diagnostic imaging services increased by 7.2 percent per beneficiary per year during this period. Also during this period, the

FIGURE 8–1

Percent of Part B revenue derived from imaging and other services, for selected specialties, 2008



Note: The services in this figure are considered designated health services under the Stark self-referral law. Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. The figure only includes outpatient therapy services that were furnished "incident to" a physician's service; it does not include therapy services furnished by therapists employed by physician groups who bill Medicare independently. Clinical lab tests are paid under the clinical lab fee schedule and pathology services are paid under the physician fee schedule. Part B spending does not include Part B drugs. The specialties in the figure are those with the highest share of Part B payments derived from ancillary services, excluding specialties and facilities that predominantly perform imaging or radiation therapy, such as radiology, radiation oncology, and independent diagnostic testing facilities.

Source: MedPAC analysis of 100 percent physician supplier procedure summary file from CMS, 2008.

volume of outpatient therapy services (which includes physical therapy, occupational therapy, and speech–language pathology services) rose by an average of 11.4 percent per beneficiary per year, and radiation therapy services increased by 7.8 percent per year. By comparison, all physician services grew by 4.6 percent per year.

Although the volume growth of all imaging services slowed to 3.3 percent per beneficiary from 2007 to 2008, some types of imaging grew more rapidly. For example, the volume of echocardiography and CT scans of parts of the body other than the head increased by 4.6 percent, and CT scans of the head rose by 4.4 percent. Moreover, as described below, there are reasons to be concerned that some of the increased use of imaging in recent years may not be appropriate.

Rapid volume growth contributes to Medicare's rising financial burden on taxpayers and beneficiaries. Many factors appear to be driving the growth of imaging, outpatient therapy, and radiation therapy, including:

- technological innovation and new clinical applications,
- changes in the population and disease prevalence,
- incentives in Medicare's FFS payment systems to increase volume,
- potential mispricing of services,
- defensive medicine,
- consumer demand, and
- the expansion of services offered in physicians' offices (Baicker et al. 2007, Iglehart 2009, Medicare Payment Advisory Commission 2009a, Medicare Payment Advisory Commission 2009b).

In addition, collaborative relationships between hospitals and physicians—such as joint ventures and hospital employment of physicians—have become increasingly common and contribute to volume growth of profitable admissions and outpatient services. This issue is discussed in a prior Commission report (Medicare Payment Advisory Commission 2008).

In this chapter, we focus on two factors driving volume growth: the expansion of services offered in physicians' offices and the potential mispricing of services in the physician fee schedule.

Questions about the clinical appropriateness of some ancillary services

There is evidence that some diagnostic imaging and physical therapy services ordered by physicians are not clinically appropriate. A pilot study conducted by the American College of Cardiology Foundation (ACCF) and United Healthcare of six practices that perform nuclear cardiology procedures found that 14 percent of the procedures performed at these sites were inappropriate, based on criteria developed by the ACCF and the American Society of Nuclear Cardiology (Hendel et al. 2010). Another study examined the appropriateness of cardiac imaging stress tests conducted at the Mayo Clinic and found that between 14 percent and 18 percent of the tests were inappropriate (Gibbons et al. 2008). A significant proportion of noncardiac imaging studies may also be inappropriate. For example, one study found that nearly 30 percent of Medicare beneficiaries with uncomplicated low back pain received an imaging service within 28 days, even though imaging is rarely indicated for this condition in the absence of specific complications or comorbidities (Pham et al. 2009). A recent analysis reviewed imaging orders from primary care physicians at a large urban hospital and found that 26 percent did not meet appropriateness criteria developed by a radiology benefit management program (Lehnert and Bree 2010). Inappropriate orders included CT for chronic headache, spine MRI for acute back pain, and knee or shoulder MRI for osteoarthritis. It is important to point out that inappropriate use is not limited to imaging services provided in physicians' offices; it also occurs in hospitals. Therefore, policy approaches to address this problem may need to consider multiple settings.

Questions have also been raised about the medical necessity of physical therapy services (Medicare Payment Advisory Commission 2006a). An Office of Inspector General (OIG) investigation estimated that 26 percent of physical therapy services billed by physicians that were provided during the first half of 2002 were not medically necessary (Office of Inspector General 2006).

The growth of imaging has also sparked concerns about the long-term impact of radiation exposure. Certain types of imaging expose beneficiaries to ionizing radiation, which is associated with an increased risk of developing cancer (Brenner and Hall 2007, Center for Devices and Radiological Health 2010, Smith-Bindman et al. 2009). A recent report estimates that the United States population's per capita dose of radiation from medical imaging increased almost 600 percent from the early 1980s to 2006, primarily due to higher use of CT and nuclear medicine studies (National Council on Radiation Protection and Measurements 2009). Although an individual's risk of developing cancer from a single test is small, these risks are applied to a growing number of patients. A recent study projected that approximately 29,000 future cancers could be related to CT scans performed in the United States in 2007 (Berrington de Gonzalez et al. 2009).

Most diagnostic tests and outpatient therapy services are not usually provided on the same day as an office visit

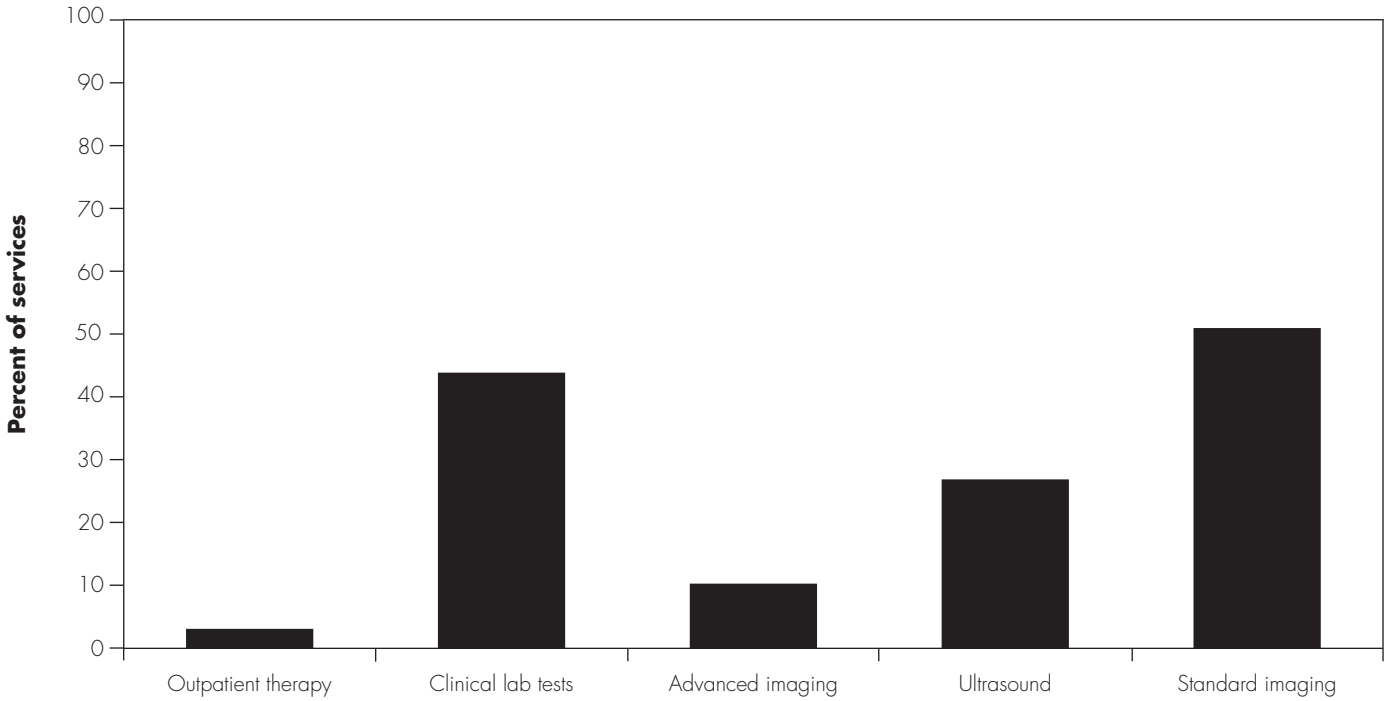
A key—but not the only—rationale for the IOAS exception is that patients should be able to receive ancillary services during their office visits (Centers for Medicare & Medicaid Services 2001). We explored this rationale by examining the share of ancillary services received by patients on the same day as a visit. Our analysis of Medicare claims data indicates that several types of ancillary services are infrequently provided on the same day as a patient's visit. Specifically, we found that outpatient therapy is rarely provided on the same day as a related evaluation and management (E&M) or consultation office visit; fewer than half of advanced imaging, ultrasound, and clinical lab tests are performed on the same day as an office visit; and about half of standard imaging studies are performed on the same day as an office visit. These findings raise questions about one of the primary rationales for the IOAS exception.

Methodology

We used Medicare claims from 2007 and 2008 to examine outpatient therapy (which includes physical therapy, occupational therapy, and speech–language pathology

FIGURE 8–2

Percent of ancillary services performed on the same day as a related office visit varies by type of service, 2008



Note: The services in this figure are considered designated health services under the Stark self-referral law. This figure excludes services performed in hospitals and the professional component of imaging services. Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. Clinical lab tests include pathology services paid under the physician fee schedule and tests paid under the clinical lab fee schedule. Advanced imaging includes MRI, computed tomography, and nuclear medicine. Ultrasound includes echocardiography and other echography. Standard imaging includes chest, breast, musculoskeletal, and other X-rays. Office visits include evaluation and management and consultation services provided in physicians' offices.

Source: MedPAC analysis of 5 percent carrier Standard Analytic File from CMS, 2008.

services), clinical lab tests, anatomic pathology tests, and diagnostic imaging. We focused on these services because they are covered by the IOAS exception and are frequently provided in physicians' offices or other nonhospital settings.[7] For the purposes of the Stark law, CMS includes anatomic pathology tests—in which a tissue sample is acquired through a biopsy or other procedure—in the category of clinical lab tests. Although radiation therapy is also covered by the IOAS exception, we excluded it from our analysis because radiation oncologists do not bill for E&M services during an episode of radiation treatment. Instead, they bill for a radiation treatment management code that covers patient management related to a week's worth of treatment sessions (Centers for Medicare & Medicaid Services 2009c).[8]

Because the goal of our analysis was to focus on office-based services, we excluded ancillary services provided in inpatient or outpatient hospital settings. For imaging services, we included both global and technical component (TC) claims for tests that were performed in a physician's office or an independent diagnostic testing facility (IDTF) but excluded professional component claims for interpreting the studies to avoid double-counting the number of examinations. A global or TC claim indicates that the study was conducted in a physician's office or IDTF.

We determined whether each claim for outpatient therapy, a clinical lab test, or diagnostic imaging could be linked to an E&M or consultation visit in a physician's office for the same beneficiary.[9] Next, we examined whether the ancillary service was performed on the same date as the visit, within 7 days after the visit, or within 14 days after the visit.

A visit was assumed to be related to an imaging or clinical lab service if:

- the office visit appeared on the same claim as the imaging or clinical lab service, or

- the same physician who provided the office visit also ordered the test.

We used a different algorithm for outpatient therapy services because claims for these services do not indicate which physician ordered the service. An office visit was assumed to be related to an outpatient therapy service if:

- the office visit appeared on the same claim as the outpatient therapy service, or
- the office visit shared the same diagnosis category as the outpatient therapy service.

We used Clinical Classifications Software from the Agency for Healthcare Research and Quality to group the diagnosis codes from the International Classification of Diseases, Ninth Revision, into broader diagnosis categories.

We examined ancillary services provided in both self-referral and non-self-referral situations, because we wanted to assess how frequently these services were performed on the same day as an office visit, regardless of whether the service was provided by a self-referring physician. In addition, it is difficult to identify whether an outpatient therapy service was performed by a therapist employed by a physician group (see pp. 225–226). In addition to analyzing imaging across all specialties, we performed the analysis separately for radiologists and IDTFs, which are generally not permitted by Medicare to order diagnostic imaging, and for other specialties, which are permitted by Medicare to order and perform imaging studies.[10]

Results

Outpatient therapy services are not generally associated with a related office visit. In 2008, only 3 percent of outpatient therapy services were provided on the same day as an office visit, 9 percent within 7 days after a visit, and 14 percent within 14 days after a visit (Figure 8-2). These results are not surprising; under Medicare's coverage rules, a beneficiary does not need to receive an office visit with each outpatient therapy service. Instead, a physician must certify the initial plan of care within 30 days of the initial therapy service and must recertify the plan of care every 90 days (Centers for Medicare & Medicaid Services 2007b). In addition, patients tend to receive multiple sessions of therapy within an episode of care (Ciolek and Hwang 2004).

Slightly fewer than half of clinical lab tests and anatomic pathology services were performed on the same day as a related office visit.[11] The share of these services linked to an office visit increased from 44 percent to 52 percent when we expanded the time window to 14 days. Our analysis may overstate the proportion of these services performed on the same day or within 14 days of a visit, because Medicare rules require that the date of service on a claim reflect the date on which the specimen was collected from the patient, not the date when the test was actually performed (42 CFR § 414.510). In other words, if the specimen for a clinical lab or pathology test was collected on the same day as an office visit but the test was performed the following day, this test would be counted as having been performed on the same day as the visit.

Advanced imaging services—MRI, CT, and nuclear medicine—were less commonly provided on the same day as an office visit than ultrasound and standard imaging, such as chest, musculoskeletal, and other X-rays (Figure 8-2). Only 10 percent of advanced imaging services were performed on the same day as a related office visit. This proportion increased to 33 percent of services within 7 days after a visit, and 41 percent within 14 days after a visit. Slightly more than one-quarter of ultrasound studies (which include echocardiography and other ultrasound) were performed on the same day as an office visit, 40 percent within 7 days after a visit, and 46 percent within 14 days after a visit. Just over half of standard imaging services were performed on the same day as an office visit; this share increased to 59 percent when we expanded the time window to 14 days. The lower rate at which advanced imaging studies were performed on the same day as an office visit may reflect the need to schedule certain imaging procedures in advance. For example, patients may need to fast for several hours before receiving CT studies with contrast material (Mayo Foundation for Medical Education and Research 2008, Radiological Society of North America 2009).

Within the category of advanced imaging, there was variation in how frequently different modalities were furnished on the same day as an office visit, ranging from 8.2 percent of studies in the category of "MRI: other" to 23.8 percent of "CT: head" studies (Table 8-1, p. 224). Also worth noting is that the proportion of all imaging studies performed on the same day as an office visit declined by 1.6 percentage points (4.2 percent) from 2007 to 2008, even though the total volume of imaging increased by 3.3 percent per beneficiary. For example, from 2007 to 2008, the rate of nuclear medicine studies furnished on the same day as a visit fell from 9.7 percent to 8.5 percent and the rate of "MRI: brain" studies declined from 9.7 percent to 8.4 percent.

TABLE 8–1 **Wide variation in how frequently different types of imaging services were performed on same day as a related office visit, 2008**

Type of imaging	Proportion of services performed on same day as office visit
Advanced imaging	
MRI: brain	8.4%
MRI: other	8.2
CT: head	23.8
CT: other	13.1
Nuclear medicine	8.5
Echocardiography	25.9
Other echography	28.4
Standard imaging	50.9
All imaging	35.4

Note: CT (computed tomography). All imaging services in the table are considered designated health services under the Stark self-referral law. Table excludes the professional component of imaging services (unless it is part of a global service) and imaging performed in hospitals. Office visits include evaluation and management and consultation services provided in physicians' offices.

Source: MedPAC analysis of 5 percent carrier Standard Analytic File from CMS, 2008.

When we separately examined imaging studies by specialty, we found that imaging services were more likely to be provided on the same day as a visit when they were performed by a nonradiologist than by a radiologist or an IDTF.[12]

Options to address concerns about the growth of ancillary services

We examine three types of options to address concerns about the growth of ancillary services:

- limiting the types of services or physician groups covered by the IOAS exception,
- developing payment tools to mitigate incentives to increase volume, and
- adopting a targeted prior authorization program for advanced diagnostic imaging services.

Limiting the types of services or physician groups covered by the in-office ancillary services exception

We describe three ways in which the types of services or physician groups covered by the IOAS exception could be limited:

- exclude outpatient therapy and radiation therapy from the exception,
- limit the exception to physician practices that are clinically integrated, and
- exclude diagnostic tests that are not usually provided during an office visit from the exception.

In prior work, the Commission has examined various aspects of the Stark regulations and recommended ways to strengthen them but has not recommended changes to the IOAS exception (Medicare Payment Advisory Commission 2005b). To address concerns about rapid volume growth, we recommended that CMS add nuclear medicine services to the list of DHS, which CMS subsequently did (Centers for Medicare & Medicaid Services 2005, Medicare Payment Advisory Commission 2005b). The Commission also recommended that CMS expand the definition of physician ownership to include investments in an entity that derives a substantial proportion of its revenue from another provider, such as physician ownership of imaging equipment that is leased to a hospital (Medicare Payment Advisory Commission 2005b).

In response to this recommendation, CMS expanded the definition of an "entity" under the Stark law to include an entity that performs DHS in addition to an entity that bills Medicare for DHS (Centers for Medicare & Medicaid Services 2008a). This change prohibited physicians from referring Medicare patients to an entity that performs DHS if they are owners or investors in that entity. CMS also prohibited "per click" leasing arrangements in which physicians lease equipment or office space to or from a DHS provider on a per service basis (Centers for Medicare & Medicaid Services 2008a).

Excluding outpatient therapy and radiation therapy from the in-office ancillary services exception

Under this option, outpatient therapy (physical therapy, occupational therapy, and speech–language pathology services) and radiation therapy would be excluded from the IOAS exception. They are the primary therapeutic services covered by the exception that are provided in

physicians' offices.[13] Physician investment in therapeutic services may differ from investment in diagnostic services because of its potential to skew clinical decisions about the treatment of patients. For example, some have suggested that financial incentives may influence how cancer patients are treated. One study found that physicians who were paid more generously than the national average for chemotherapy drugs prescribed more costly chemotherapy regimens for certain types of cancer patients (Jacobson et al. 2006). In addition, therapeutic services are not typically ancillary to a patient's office visit. Outpatient therapy and radiation therapy generally involve multiple sessions and are rarely initiated on the same day as an office visit.[14]

Changes in self-referral of radiation therapy The IOAS exception applies to radiation therapy services when a physician who is not a radiation oncologist refers a patient for radiation therapy that is performed in his or her office. According to the Stark law, it is not considered a self-referral when a radiation oncologist orders radiation therapy for a patient as long as the consultation was initiated by another physician and the radiation oncologist supervises the treatment.

In 2008, specialties other than radiation oncology and radiology (such as urology, general surgery, and medical oncology) received $104 million in Medicare payments for radiation therapy, an 84 percent increase from 2003.[15] Because of the rapid overall growth in spending on radiation therapy, however, these specialties accounted for about the same share of total physician fee schedule payments for radiation therapy in 2008 (5.1 percent) as in 2003 (4.7 percent). However, the actual share of spending on radiation therapy delivered under self-referral arrangements may be higher than 5 percent because some of the services billed by radiation oncologists may be provided in a self-referral situation. For example, a physician group may employ a radiation oncologist and refer patients to him or her for radiation therapy. In these cases, the radiation oncologist may bill Medicare directly and reassign payments to the physician group that employs him or her. Unfortunately, Medicare claims data do not indicate whether the payment was reassigned to another provider.

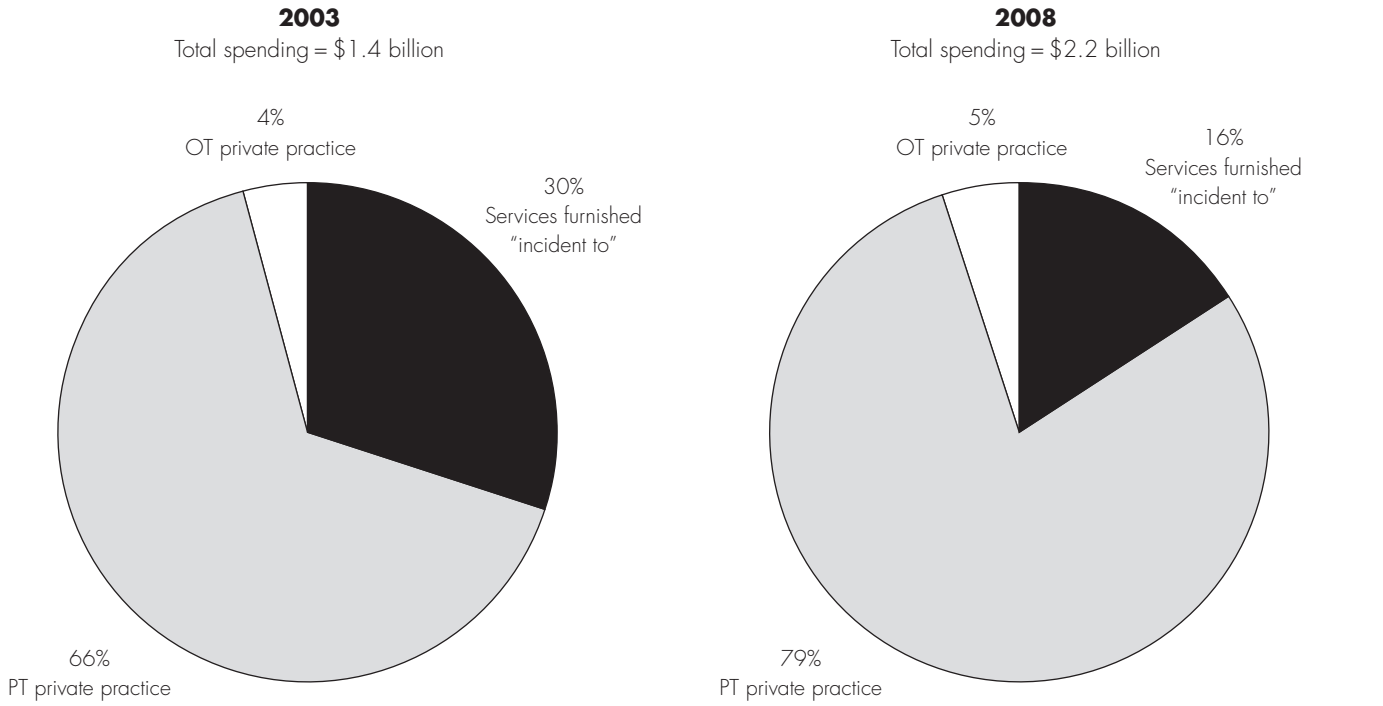
Changes in self-referral of outpatient therapy The IOAS exception applies to outpatient therapy when a physician orders therapy for a patient and the services are provided by therapists who are employed by the physician's practice. Therapists who work in a physician's office may provide services as "incident to" a physician service or may bill Medicare independently under their own billing number and reassign the payments to the physician group. "Incident to" services must meet certain requirements, including that they be supervised by a physician who is in the same office suite when the services are performed (Office of Inspector General 2006). However, therapists who bill Medicare independently (called therapists in private practice (TPP)) do not require physician supervision. Physicians who employ therapists may prefer that the therapists bill Medicare independently because a physician is not required to be in the office suite when therapy is provided. Therapists who bill independently may also work in their own offices rather than in a physician's office; the IOAS exception does not apply in these situations.

Overall, spending for outpatient therapy services paid under the physician fee schedule grew from $1.4 billion to $2.2 billion between 2003 and 2008 (Figure 8-3, p. 226). These figures exclude outpatient therapy provided in hospital outpatient departments, outpatient rehabilitation facilities (ORFs), comprehensive outpatient rehabilitation facilities (CORFs), and skilled nursing facilities (SNFs). The share of spending for therapy services that were provided incident to a physician's service declined by nearly half between 2003 and 2008, from 30 percent to 16 percent. "Incident to" services are provided by therapists employed by a physician's practice. Meanwhile, the share of payments for therapy services delivered by physical or occupational TPP, who bill Medicare independently, grew from 70 percent to 84 percent. Several factors help explain the growth of services provided by TPP:

- In 1999, CMS allowed licensed employee therapists to begin billing Medicare independently; previously, owners of therapy practices had to be on site and do all the billing for services furnished by employed therapists.
- Also in 1999, CMS eliminated payment disparities between settings for therapy services; as a result, many therapists changed their practice from an ORF to an independent practice to avoid the survey and certification requirements of institutional settings.
- CMS clarified in 2003 that therapists could be employees of physicians' practices but still be considered in independent practice, which allowed physicians to employ therapists without being responsible for supervising their work (Medicare Payment Advisory Commission 2006a).

FIGURE 8–3

Physician fee schedule spending for outpatient therapy services shifted to therapists in private practice, 2003–2008



Note: PT (physical therapy), OT (occupational therapy). Outpatient therapy includes physical therapy, occupational therapy, and speech–language pathology services. "Incident to" therapy services must meet certain requirements, including that they be supervised by a physician who is in the same office suite when the services are performed. Physical and occupational therapists in private practice bill Medicare independently and do not require physician supervision. Medicare claims data do not indicate if therapists in private practice are employed by a physician group or work in their own offices. These numbers exclude outpatient therapy provided in hospital outpatient departments, outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, and skilled nursing facilities.

Source: MedPAC analysis of 5 percent carrier file from CMS, 2003–2008.

We are unable to estimate the proportion of the payments for TPP that was related to self-referral because Medicare claims do not indicate whether TPP are employed by a physician group or work in their own offices (Medicare Payment Advisory Commission 2006a).

Concerns about excluding outpatient therapy and radiation therapy from the in-office ancillary services exception There may be a concern that excluding outpatient therapy and radiation therapy from the IOAS exception would inconvenience patients by forcing them to receive care at hospitals. However, physical and occupational therapists can deliver therapy in private practices that are separate from physician groups. Patients can also receive therapy in ORFs, CORFs, and SNFs. In addition, patients may receive radiation therapy from radiation oncologists who practice outside hospitals. According to data from IMV, a market research firm, 30 percent of radiation therapy sites were outside of hospitals in 2004 (IMV Medical Information Division 2005).

There may also be a concern that this policy change would have an impact on rural providers. However, this change would not affect rural providers who are exempt from self-referral restrictions under the rural exception to the Stark law. The rural exception covers providers who furnish at least 75 percent of their DHS to beneficiaries who live in rural areas (42 CFR § 411.356(c)). However, a concern has been raised that some rural beneficiaries may receive outpatient therapy and radiation therapy at physician practices in urban areas, which could be affected by this policy change.

Another issue is that this change would affect clinically integrated groups that care for a wide variety of cancers using a range of modalities, including radiation therapy. For example, practices that include both medical and radiation oncologists would not be able to perform radiation therapy on patients referred by a medical oncologist in the group to a radiation oncologist in the same group.

Limiting the in-office ancillary services exception to physician practices that are clinically integrated

Under this approach, the IOAS exception would be limited to physician groups that can demonstrate clinical integration. The goal of this strategy is to balance the risks of higher volume associated with self-referral with the potential benefits of clinically integrated practices, such as the capacity to provide comprehensive and coordinated care. However, under the current FFS payment system, even clinically integrated groups have a financial incentive to increase volume. Thus, Medicare should begin developing new payment models that reward providers for restraining volume growth while improving quality.

A key issue under this approach would be defining "clinical integration" in a way that could be measured. One option would be to require that each physician in the group provide a substantial share of his or her services—such as 90 percent—through the group. Such a rule would increase the likelihood that the physicians in the practice interact with each other frequently, share information about patients, and follow similar clinical pathways. Practices that employ or contract with a physician on a part-time basis to supervise or interpret diagnostic tests or to supervise radiation treatment would no longer qualify for the IOAS exception if the part-time physician also works for other groups. Arrangements with part-time physicians create a financial incentive to increase volume without the potential benefits of a clinically integrated practice.

Currently, the IOAS exception requires that physicians who are members of a group must provide at least 75 percent of their services through the group (see text box, pp. 218–219. This rule applies only to members of the group (owners and employees) and takes into account all the services provided by all members of the group. In other words, an individual group member could furnish 50 percent of his or her services through the group as long as the aggregate percentage for the entire group (based on all the members) equals or exceeds 75. In addition, physicians who independently contract with the group are not considered "members" of the group and therefore do not count toward the 75 percent rule. Thus, groups may contract with physicians on a part-time basis to provide or supervise ancillary services without affecting their ability to comply with the 75 percent rule. Under the option described above, each physician in the group—whether a member of the group or an independent contractor—would have to provide a substantial share of his or her individual services through the group.

Restricting the IOAS exception to clinically integrated groups would limit the number of practices that qualify for the exception, but the groups that qualify would still have a financial incentive to order more ancillary services under Medicare's FFS payment systems. Thus, it is important for the program to move toward payment models that reward providers for constraining volume growth while improving the quality of care. Examples include paying providers a fixed amount for a group of beneficiaries (capitation), paying providers for an episode of care (bundling), and paying bonuses to accountable care organizations that achieve both quality and cost targets (Medicare Payment Advisory Commission 2009a). Restricting the IOAS exception to clinically integrated groups could encourage the development of integrated practices, which could be well-positioned to succeed under a new payment model.

Excluding diagnostic tests that are not usually provided during an office visit from the in-office ancillary services exception

Under another approach, diagnostic tests that are generally not provided on the same day as an office visit would be excluded from the IOAS exception. The rationale for this option is that certain tests are rarely used by physicians to make a diagnosis at the time of the patient's office visit, which is a key justification for the exception. Among imaging services, there was wide variation in how frequently different modalities were furnished on the same day as an office visit in 2008, ranging from 8.2 percent of "MRI: other" studies to 50.9 percent of standard imaging tests (Table 8-1, p. 224). There was also wide variation in how frequently different high-volume clinical lab tests were furnished on the same day as an office visit in 2008, ranging from 9.6 percent for parathyroid hormone tests (Healthcare Common Procedure Coding System (HCPCS) code 83970) to 49.9 percent for natriuretic peptide tests (HCPCS 83880).

Options for defining which diagnostic tests should be covered by the IOAS exception include an empirical approach based on the frequency with which certain services are provided on the same day as an office visit or a clinical approach based on which tests do not generally require advance patient preparation. Under the empirical approach, CMS could calculate the percent of the time each test (or category of tests) is performed on the same day as an office visit and then set a threshold for services that would be covered by the IOAS exception, such as 50 percent. CMS could rebase this threshold every few years to account for changes in technology and practice. Under a clinical approach, CMS could consult with clinical experts

to determine which tests require patient preparation and are therefore scheduled in advance; these services would be excluded from the IOAS exception. For example, patients may need to fast for several hours before receiving CT studies with contrast material (Mayo Foundation for Medical Education and Research 2008, Radiological Society of North America 2009).

Excluding tests that are generally provided on a different day from an office visit would present several challenges. The rate at which services are provided on the same day as an office visit may vary by type of condition, patient severity, and other factors, which could make it difficult for CMS to apply a common rule to all providers. The empirical approach for determining which services should qualify for the IOAS exception may involve setting an arbitrary threshold. In addition, physicians may begin billing for office visits when they perform diagnostic tests in their offices to reach the threshold to qualify for the exception.

Payment tools to mitigate incentives to increase volume

Potential payment changes that could dampen incentives to increase the volume of ancillary services include:

- reducing payment rates for diagnostic tests performed by self-referring physicians, and
- improving payment accuracy for ancillary services in the physician fee schedule and eventually creating larger payment bundles that include ancillary services often furnished during the same encounter or the same episode of care.

Reducing payment rates for diagnostic tests performed by self-referring physicians

Medicare could reduce payment rates for diagnostic tests performed by self-referring physicians to offset additional Medicare spending related to self-referral, while continuing to allow physicians to provide these services in their offices. Studies by the Commission and other researchers have found that physicians who furnish imaging services in their offices refer patients for more imaging than other physicians (Baker 2008, Gazelle et al. 2007, Government Accountability Office 1994, Hillman et al. 1990, Hillman et al. 1992, Kouri et al. 2002, Litt et al. 2005, Medicare Payment Advisory Commission 2009a). Two of these studies are described further in the text box. In addition, OIG found that, on average, patients of physicians who owned clinical labs received 45 percent more lab tests than all Medicare beneficiaries (Office of Inspector General 1989). A series of OIG audits of 2004 Medicare claims from three group practices found that these groups increased their ordering of pathology services after they established their own labs (Office of Inspector General 2007a, Office of Inspector General 2007b, Office of Inspector General 2007c). For example, one practice increased the average number of tissue examinations it ordered per claim from one to nine after opening its own lab. However, these results may not be generalizable because they are based on only three practices.

Design options Reducing payment rates for diagnostic tests performed by self-referring physicians would involve several design choices. One issue is whether to apply this policy to all diagnostic tests covered by the IOAS exception or only to certain tests. Reducing payments for all diagnostic tests would be simpler to implement but would affect many more providers as well as services frequently provided in physicians' offices, such as low-cost X-rays and lab tests. Alternatively, this policy could be limited to high-cost imaging services and lab tests or those tests that are not commonly performed on the same day as an office visit (such tests may be less likely to lead to rapid diagnosis and treatment). For example, certain advanced imaging procedures—such as CT with contrast or nuclear medicine studies—are scheduled in advance because the patient needs to fast before the procedure or the provider needs to prepare radiopharmaceuticals for the study.

Another issue is how to determine the size of the payment reductions that would be applied to self-referred diagnostic tests. One option is to base the reduction on empirical estimates of the effects of self-referral. However, such estimates vary widely for imaging services, depending on the methodology, type of condition, and type of imaging (Medicare Payment Advisory Commission 2009a). For example, a recent study estimated that acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists (Baker 2008) (see text box). An analysis conducted by the Commission found that episodes with a self-referring physician had spending on imaging that was higher than expected given the patient's severity of illness, geographic market, and physician specialty (Medicare Payment Advisory Commission 2009a) (see text box). Conversely, episodes with no self-referring physician had lower-than-expected spending on imaging. The differences between the adjusted spending for episodes with and without a self-referring physician ranged from 5 percent

Recent studies show that physician self-referral is associated with additional use of imaging services

Two recent studies show that physician self-referral is associated with additional use of imaging services. In the first study, the Commission used 2005 Medicare claims for beneficiaries in six markets to analyze whether physician self-referral affected the use of imaging within an episode of care, adjusting for differences in patients' clinical conditions and the type of imaging (Medicare Payment Advisory Commission 2009a). Our primary definition of a self-referring physician was one who referred more than 50 percent of the imaging studies that he or she ordered to his or her practice. We examined 22 combinations of different types, or modalities, of imaging (such as computed tomography and MRI) and conditions (such as migraine headache, ischemic heart disease, and joint degeneration of the back). Our methodology allowed us to compare the observed cost of a given episode with the average cost of similar types of episodes (adjusting for severity of illness, physician specialty, and market area). There were two key results:

- Compared with episodes with no self-referring physician, a higher proportion of episodes with a self-referring physician received at least one imaging service. The magnitude of the variation ranged from 2 to 23 percentage points depending on the condition and modality; in all but one comparison, the differences were statistically significant. The magnitude of the variation was 10 percentage points or more for 14 of the 22 condition–modality pairs.

- Episodes with a self-referring physician had a higher mean ratio of observed-to-expected spending for an imaging modality than episodes with no self-referring physician. The differences between the ratios ranged from 5 percent to 104 percent, depending on the condition and modality. (For all the comparisons, the differences were statistically significant.) For example, the mean spending ratio for nuclear medicine for ischemic heart disease was twice as high for episodes with a self-referring physician as for episodes with no self-referring physician. Across all condition–modality pairs, the mean difference between ratios was 68 percent (weighted by the number of episodes in each pair).

In a study presented at a Commission meeting, Laurence Baker found that patients of neurologists and orthopedic surgeons who owned MRI machines were more likely to receive an MRI scan within seven days of an office visit than patients of neurologists and orthopedic surgeons who did not own MRI machines (Baker 2008). For example, 14.5 percent of patients who saw a neurologist who owned a machine received an MRI scan within seven days of their visit, compared with 9.3 percent of patients who saw other neurologists. This analysis used Medicare claims data from 1999 through 2005. Baker also used a regression model to examine the impact of acquiring an MRI machine on a physician's likelihood of ordering MRI studies, controlling for physician and patient characteristics. Acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists. ■

to 104 percent, depending on the condition and type of imaging (modality). Across all condition–modality pairs that we examined, spending for episodes with a self-referring physician was 68 percent higher than spending for episodes without a self-referring physician, on average, adjusted for differences in severity of illness, geographic market, and physician specialty.

Another option for determining the payment reductions for self-referred diagnostic tests would be to consider whether some of the payment for a test includes activities that have already been performed by the referring physician or his or her practice. For example, payment for the professional component of an imaging service generally includes preservice activities such as reviewing the patient's history, prior studies, medical records, and indications for the test. If the physician who supervised or interpreted the study is the same physician who ordered the service, this physician should have already obtained and reviewed much of this information during a prior E&M service. The payment for

an imaging study also includes post-service activities such as discussing the findings with the referring physician; this activity is unnecessary when the referring and interpreting physician are the same. Therefore, it may be appropriate to remove some of these preservice and postservice activities from the payment rate for imaging studies performed by self-referring physicians.

Depending on the size of the payment reduction for diagnostic tests performed by self-referring providers and physicians' behavioral responses to such a change, a reduction could offset some or all of the additional Medicare spending associated with self-referral. Physicians who already own testing equipment may respond by increasing their volume to offset the payment reduction. On the other hand, a payment reduction may discourage physicians from investing in new equipment for their offices.

Implementation issues This option could be implemented by adding a field to the Medicare claim form that records whether a diagnostic test was billed by a physician group that provided the test under the IOAS exception. If so, the payment reduction would be applied. This approach would rely on practices to accurately report whether the test was provided under the exception rather than requiring CMS to survey individual practices. Physicians would have a strong incentive to accurately report this information to avoid submitting false claims. Under the False Claims Act, the government may levy substantial penalties on those who submit a false claim to the government. To further encourage compliance, OIG could audit a random sample of practices that bill Medicare for diagnostic tests.

Improving payment accuracy and combining discrete services into larger units of payment

This section describes two related approaches: improving the accuracy of payments for discrete services in the physician fee schedule and combining discrete services into larger units of payment (packaging or bundling). The Commission has expressed concerns about the mispricing of services in the physician fee schedule and the inequity of a payment system that allows some physicians to generate volume and revenue more easily than others (Medicare Payment Advisory Commission 2010). The rapid growth of many services covered by the IOAS exception, combined with the use of newer technologies such as MRI and intensity-modulated radiotherapy equipment, suggests that payment rates for these services may need to be reexamined.

Improving payment accuracy for discrete services We have made several recommendations to address mispricing of discrete services. Some of these recommendations affect a broad range of physician services, while others focus on a specific set of services. The Commission has recommended ways to improve the process through which CMS reviews the fee schedule's relative values for accuracy (Medicare Payment Advisory Commission 2006b). Although CMS—with advice from the American Medical Association Specialty Society Relative Value Scale Update Committee—has improved the review process since our recommendations, there are still areas that should be addressed. For example, many procedures have never been reexamined to check whether the average time and intensity of effort to perform them has decreased due to advances in technology, technique, and other factors.

Other Commission recommendations relate to specific types of services. For example, we recommended that Medicare increase the equipment use rate assumption for expensive diagnostic imaging equipment from 25 to 45 hours per week, or 90 percent of the time that providers are assumed to be open for business (Medicare Payment Advisory Commission 2009b). This policy was adopted by CMS for 2010 with a four-year phase in. It reduced practice expense payments for costly imaging services and increased such payments for other physician services. The Patient Protection and Affordable Care Act of 2010 (PPACA) sets the equipment use rate assumption for expensive imaging equipment at 75 percent beginning in 2011; the savings from this policy will return to the Part B trust fund.

The Congress and CMS have made other payment changes that have affected imaging services in recent years.

- The Deficit Reduction Act of 2005 (DRA) capped physician fee schedule rates for the TC of imaging services at the level of hospital outpatient rates. This provision reduced the fee schedule amounts for many imaging services.
- In 2007, CMS made major changes to the method for calculating practice expense relative value units (RVUs) under the physician fee schedule. These changes—which were phased in over four years—shifted practice expense payments from imaging services and major procedures to E&M services and nonmajor procedures (Medicare Payment Advisory Commission 2007b).

- For 2010, CMS began using more current practice expense data from a new, privately sponsored, voluntary survey of physician and nonphysician specialties (Centers for Medicare & Medicaid Services 2009d). This change is redistributing practice expense RVUs among specialties and services over a four-year period. Several of the specialties experiencing a decline in RVUs (such as radiology, cardiology, and IDTFs) perform many imaging services.
- The PPACA reduced the TC payment for imaging services by 50 percent when providers furnish multiple studies on contiguous body parts during the same session.[16]

The Commission plans to continue addressing mispricing issues in the future. For example, we will consider the validity of estimates of the typical amount of time a physician spends furnishing physician fee schedule services (Medicare Payment Advisory Commission 2010). These time estimates explain much of the variation in payments for physician work, and questions have been raised about them. The Commission will investigate the availability of data that CMS could use to validate the time estimates.

Combining discrete services into larger units of payment

In addition to improving payment accuracy for individual services, Medicare could combine multiple services often furnished together during the same encounter or the same episode of care into a single payment rate, which could create incentives to use ancillary services more efficiently. The Commission has expressed concern that the relatively small units of payment for many physician services could give physicians a financial incentive to increase volume (Medicare Payment Advisory Commission 2005a).

Under an approach known as packaging, all the services provided during one encounter with a provider are combined into a single payment rather than each discrete service receiving a separate payment. For example, the hospital outpatient prospective payment system packages radiopharmaceuticals and certain imaging services with their associated procedures. This concept could be applied to the physician fee schedule by providing physicians a single payment for an office visit that covers the cost of the visit as well as all lab tests and X-rays provided during the visit. In its proposed rule for physician fee schedule services for 2009, CMS expressed interest in payment approaches that would account for efficiencies when services are provided together, such as packaging services into a single payment unit or discounting payments for the additional service(s) (Centers for Medicare & Medicaid Services 2008b).

Under a concept known as bundling, all the services furnished during multiple encounters are combined into a single payment. Under the physician fee schedule's global surgical policy, for example, many surgical procedures are subject to a global payment rate that includes some preoperative care, the surgery, and postoperative visits in the hospital and office (for 10 days or 90 days after the surgery, depending on the type of surgery). Bundling may be limited to services furnished by a single provider or could include services delivered by multiple providers. For example, the Commission has recommended that CMS conduct a pilot program to test bundled payment for all services associated with a hospitalization episode (Medicare Payment Advisory Commission 2008).

Packaging and bundling are not mutually exclusive. Bundling policies may build on packaging policies as Medicare moves from a disaggregated payment system to one that is more integrated and focused on efficiency. For example, CMS may start by creating payment rates that encompass multiple services provided during a single encounter (packaging) and then develop episode-based rates that incorporate multiple encounters related to common, high-cost chronic illnesses.

The advantage of a packaging or bundling approach with respect to ancillary services is that it could encourage all physicians—whether or not they benefit financially from performing ancillary services—to use tests and other ancillary services more prudently. Further, it would not disrupt self-referral arrangements that improve convenience and care coordination for patients. However, much analytic work would need to be done to identify and price cohesive bundles of services and to address situations in which multiple providers furnish services within a bundle.

Require certain self-referring physicians to participate in a prior authorization program for advanced diagnostic imaging

Under a prior authorization approach, Medicare could require self-referring physicians who order many more advanced imaging services (MRI, CT, nuclear medicine, and positron emission tomography (PET)) than their peers to participate in a prior authorization program for these services. Such a policy could involve two steps. First, CMS would identify self-referring physicians who are outliers in terms of their use of advanced imaging for a

given set of conditions (such as use of MRI for low back pain). Second, Medicare would require these physicians to participate in a prior authorization program, in which CMS or a contractor would review their requests to use imaging services to ensure that they are clinically appropriate before they are provided. As an interim step, CMS could provide confidential feedback to outlier physicians about their use of imaging for a period of time before requiring prior authorization.

Many private plans have initiated prior authorization programs to control the growth of high-cost imaging services (such as CT, MRI, nuclear medicine, and PET) and improve the appropriate use of these studies (Congressional Budget Office 2008, Government Accountability Office 2008, Iglehart 2009). According to radiology benefit managers, the vendors who operate these programs, the programs are based on appropriateness criteria developed by specialty groups such as the American College of Radiology and American College of Cardiology, literature reviews, and clinician panels. Some plans report that these programs significantly reduce the volume growth of expensive modalities, but there are no independent studies that measure the impact of prior authorization using a control group (Government Accountability Office 2008, Levin et al. 2010, Mitchell and Lagalia 2009, Tynan et al. 2008).

In prior authorization programs, physicians who wish to order certain studies must first obtain approval from the plan. The ordering physician submits a request that includes clinical information to the plan or the plan's contractor. The plan checks whether the request is consistent with its clinical criteria and, if so, approves the test. If not, the plan may request additional clinical information or deny the test. Some plans use a variation of preauthorization called prior notification. In these programs, ordering physicians provide clinical information to plans about studies they wish to order and receive feedback on whether the studies are appropriate. If the request does not meet guidelines set by the plan, it suggests an alternative approach but does not deny payment if the physician decides to order the original study.

The main benefit of a prior authorization approach is that it would ensure the appropriate use of advanced imaging by self-referring physicians who order many more studies than their peers, rather than imposing a blanket prohibition on physicians' performing advanced imaging services in their offices. The downsides of this policy include the potentially high administrative costs of establishing and managing a prior authorization program, the administrative burden on providers who are required to submit requests for prior approval, additional waiting time for patients to receive imaging, the perceived challenges to physicians' clinical autonomy, concerns about whether the clinical guidelines are based on sound evidence, the need for a public program like Medicare to have transparent criteria, and questions about the level and sustainability of spending reductions over time. Under a demonstration program authorized by the Medicare Improvements for Patients and Providers Act of 2008, CMS is in the process of developing appropriateness criteria for imaging services in consultation with specialty societies (Centers for Medicare & Medicaid Services 2009a).[17] Although the demonstration is not testing prior authorization, these criteria could eventually become the basis for a prior authorization or prior notification program focused on self-referring physicians.

Conclusion

This chapter has described the rapid growth of services covered by the IOAS exception—such as imaging, clinical lab tests, radiation therapy, and outpatient therapy—and evidence that imaging and physical therapy services are sometimes ordered inappropriately. Physician self-referral of ancillary services creates incentives to increase volume under Medicare's current FFS payment systems, which reward higher volume. Therefore, the preferred long-term approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care. Because it will take several years to establish new payment models and delivery systems, we have explored several interim approaches to address concerns raised by the growth of ancillary services in physicians' offices. These strategies could be considered individually or in combination, and each has strengths and weaknesses and the potential for unintended consequences. In future work, the Commission plans to further examine these options with the goal of crafting policy recommendations. ■

Endnotes

1 The Congress excluded most DME and parenteral and enteral nutrients, equipment, and supplies from the IOAS exception because there was no clear justification for referring physicians to offer these services (Medicare Payment Advisory Commission 2005c). CMS determined that physicians may provide a limited number of DME items required for a patient to ambulate from the physician's office—such as canes, wheelchairs, walkers, and crutches—as well as blood glucose monitors.

2 It is difficult to estimate the magnitude of self-referral involving outpatient therapy and radiation therapy services because the ordering physician is not listed on the claims for these services. Moreover, it is difficult to identify whether an outpatient therapy service was performed by a therapist employed by a physician group or one who works independently (Medicare Payment Advisory Commission 2006a).

3 We excluded specialties from our analysis that predominantly perform imaging or radiation therapy, such as radiology, radiation oncology, and independent diagnostic testing facilities.

4 In addition, practices may create separate pools of profits from imaging and other DHS services for separate subgroups of physicians, as long as each subgroup has five or more physicians. Physician subgroups may be based on specialty, practice location, level of referrals for ancillary services, or other factors (Johnson and Keegan 2006). The pool of profits may be distributed to each physician in the subgroup on a per capita basis or by another indirect method.

5 Such arrangements would have to comply with at least two other federal requirements: (1) the anti-kickback statute, which prohibits the offer, payment, or receipt of anything of value to induce the referral of patients for services reimbursed by federal health programs; and (2) the anti-markup rules, which apply to a physician who bills Medicare for diagnostic tests that are performed (or supervised) by a physician who does not share a practice with the billing physician. In such cases, Medicare will not pay more than the performing provider's net charge to the billing physician. The anti-markup rules do not apply to tests performed or supervised by a physician in the same building where the billing physician regularly furnishes patient care (42 CFR § 414.50).

6 Volume is measured as the units of service multiplied by each service's relative weight (relative value units) from the physician fee schedule. Thus, volume growth accounts for changes in both the number of services and the complexity, or intensity, of those services.

7 We used a file from CMS to determine which Healthcare Common Procedure Coding System codes are considered DHS.

8 However, radiation oncologists bill for an initial E&M service or consultation before treatment begins to evaluate the need for radiation therapy and its likely results (American Society for Therapeutic Radiology and Oncology and American College of Radiology 2010).

9 We excluded inpatient and outpatient hospital, nursing home, and emergency room visits because these visits would be unlikely to generate office-based ancillary services on the same day as the visit. We also excluded visits to federally qualified health centers or rural health clinics because Medicare pays an all-inclusive rate for these visits that includes preventive care and services that are provided incident to a physician's service.

10 All diagnostic tests must be ordered by the physician who is treating the beneficiary, and a radiologist performing a diagnostic procedure is not considered a treating physician (Centers for Medicare & Medicaid Services 2009b). There are limited situations in which a radiologist may alter the test ordered by the treating physician, such as determining whether to use contrast material.

11 We separately examined a common pathology service, tissue exam by a pathologist (Healthcare Common Procedure Coding System code 88305), and found that it was performed 33 percent of the time on the same day as an office visit.

12 Overall, nonradiologists accounted for 69 percent of imaging services performed outside of hospitals, while radiologists and IDTFs accounted for 31 percent.

13 Although other types of therapeutic services and products are covered by the Stark law, most of them are either excluded from the IOAS exception or are not provided in physicians' offices. For example, most types of DME and supplies are specifically excluded from the exception (42 CFR § 411.355 (b)). In addition, the exception covers home health services for physicians who treat patients in their homes.

14 Before radiation treatment begins, for example, a radiation oncologist generally provides an initial E&M service or consultation to evaluate the need for radiation therapy, followed by clinical treatment planning and therapeutic radiology simulation (American Society for Therapeutic Radiology and Oncology and American College of Radiology 2010).

15 Some radiation oncologists might identify themselves as radiologists because both specialties are certified by the American Board of Radiology.

16 Under this policy, Medicare will pay the full amount for the most expensive study but reduce payment for other studies performed during the same session by 50 percent.

17 The purpose of the demonstration is to test the impact of providing feedback to physicians about their use of imaging.

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APPENDIX A

Review of CMS's preliminary estimate of the physician update for 2011

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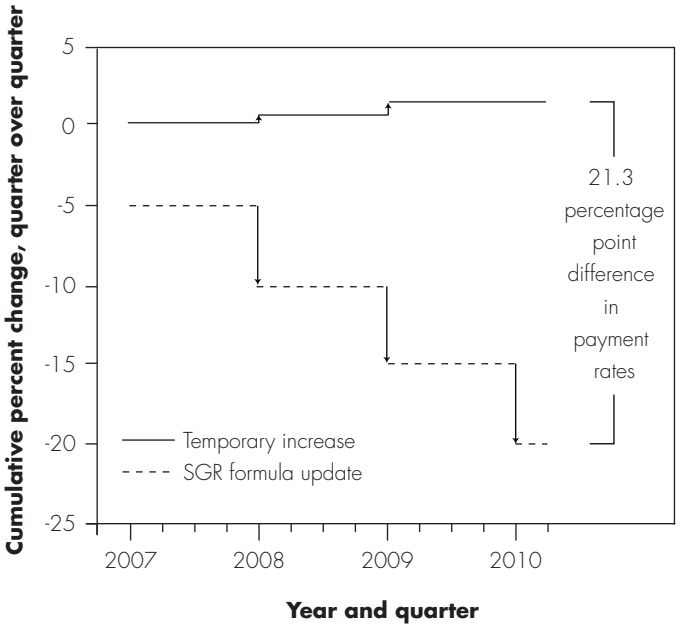
Review of CMS's preliminary estimate of the physician update for 2011

In CMS's annual letter to the Commission on the update for physician services, the agency's preliminary estimate of the 2011 update is –6.1 percent (Blum 2010). This update would follow a 21.3 percent reduction in physician payment rates required under law that was to occur on April 1, 2010, after a series of temporary increases—enacted over several years—expired.[1] Such increases have prevented negative updates under the sustainable growth rate (SGR) formula—the statutory formula for updating Medicare's payment rates for physician services—that would have occurred at the beginning of each of four years: 2007, 2008, 2009, and 2010. Combined, the 2011 update and the expired temporary increases equal a reduction in payment rates of 26.1 percent.[2]

This appendix provides our mandated technical review of CMS's estimate. We find that—absent a change in law—the combined effect of the expired increases and the 2011 update is very unlikely to differ substantially from –26.1 percent. The temporary increases—by far, the largest factor influencing the payment reduction—were specified in law. When they expire, payment rates go down by an amount that is not subject to change. The SGR update for 2011 could change between now and when CMS implements the update in January, but only by a small amount. According to the formula, the update is the projected change in input prices for physician services, adjusted by a factor to align spending with a target.[3] While CMS's estimate of a 0.1 percent change in input prices may change, the agency's estimate of an update adjustment of –6.2 percent is the dominant factor. By law, the update adjustment is limited to –7.0 percent, so it can go no lower than that even if spending goes up faster than projected by CMS. Alternatively, the update adjustment could lead to a somewhat smaller reduction in payment rates if spending goes up more slowly than CMS anticipates. For instance, if spending in 2010 were 1 percent lower than CMS projects, the update adjustment for 2011 would be −5.3 percent instead of −6.2 percent. In turn, the 2011 update would go from −6.1 percent to −5.2 percent. Still, such changes in the 2011 update—whether higher or lower than CMS now estimates—appear small when the context is an overall decrease in payment rates of 26.1 percent.

Before presenting the details of our technical review, we remind readers that the Commission is not satisfied with the current physician payment update mechanism. It does not provide incentives for individual physicians to control volume growth, and it is inequitable to those physicians who do not increase volume unnecessarily. Our report *Assessing Alternatives to the Sustainable Growth Rate System* examined several approaches for updating physician payments and made suggestions to improve the accuracy of Medicare's payments, create incentives for physicians to provide better quality of care, coordinate care across settings, and use resources judiciously (Medicare Payment Advisory Commission 2007).

FIGURE A–1 **Temporary increases prevented the SGR formula's negative updates**



Note: SGR (sustainable growth rate). The 21.3 percentage point difference is the ratio of the cumulative SGR formula updates to the cumulative temporary bonuses (0.79946/1.01606 = 0.78682 or –21.3 percent).

Source: Blum 2010 and Office of the Actuary 2009.

How temporary increases and other legislative provisions have affected payments for physician services

The SGR formula is intended to limit growth in Medicare spending for physician services. If aggregate spending—accumulated since 1996—exceeds a specified target in a given year, the formula calls for a downward adjustment in the physician fee schedule's conversion factor.

In recent years, the Congress has overridden the formula's updates. Spending has exceeded the target, and updates calculated with the formula have been negative. However, except for the negative update implemented in 2002, the Congress has passed specific legislation for each year to prevent further negative updates.

Initially, the legislative overrides prescribed a positive update for a given year but did not allow the spending target to rise. The result was a growing gap between spending and the target. The formula could have recouped the difference, but the process would have required many years of negative updates. In response, the Congress instituted a new method. Starting with the update for 2007, legislation prescribed temporary increases. When the increases expire, updates are calculated—with the formula—as if the increases had never been applied.

From 2007 through the first quarter of 2010, the temporary increases totaled a cumulative increase in payment rates of 1.6 percent (Figure A-1).[4] Had the Congress not overridden the formula with these increases, the cumulative change in payments would have been –20.1 percent. The difference is the 21.3 percent reduction in payment rates mentioned earlier.

In addition to the temporary increases, legislation has raised payments for physician services in other ways. For instance, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) increased bonuses under the Physician Quality Reporting Initiative (PQRI) to 2 percent of allowed charges for 2009 and 2010. Previously, the bonuses were 1.5 percent of allowed charges. MIPPA also established incentives for electronic prescribing. This program allowed physicians to receive a 2 percent bonus on their allowed charges in 2009 and 2010 if they met the program's requirements. And MIPPA extended through 2009 higher payments for some areas through the floor on the physician fee schedule's geographic practice cost index for physician work.

How CMS estimated the SGR formula's update for 2011

Calculating the physician update is a two-step process. CMS first estimates the SGR—the target growth rate for allowed spending on physician services—for the coming year. The agency then computes the update using that SGR and historical information on actual and allowed spending.

SGR for 2011

The SGR is a function of projected changes in:

- input prices for physician services—an allowance for inflation,[5]
- real gross domestic product (GDP) per capita—an allowance for growth in the volume and intensity of services,[6]

- enrollment in fee-for-service (FFS) Medicare—an allowance for fluctuations in the number of FFS beneficiaries, and
- spending attributable to changes in law and regulation—an allowance for policy changes that affect spending on physician services.

Allowing for these four factors, CMS's preliminary estimate of the SGR for 2011 is –0.4 percent (Table A-1).

The first of these factors—the estimated change in input prices of 0.2 percent—is lower than the figure for previous years. Given economic conditions, CMS projects relatively modest increases in physician compensation, staff earnings, rent, and the prices of other inputs.

The next factor in the 2011 SGR—growth in real GDP per capita—is a 10-year moving average. It includes estimates of economic growth for 2002 through 2009 and projections for 2010 and 2011. CMS's estimate of 0.8 percent for this factor is the same as the estimate we calculate when we use Congressional Budget Office projections for 2010 and 2011 to calculate a 10-year moving average of growth in real GDP per capita (Congressional Budget Office 2010).

For the factor on the change in FFS enrollment, CMS projects an increase of 3.1 percent, a growth rate higher than the projected 2.0 percent growth in overall Medicare Part B enrollment. Higher growth in FFS enrollment is projected because the rapidly growing private FFS plans in the Medicare Advantage program will have a new requirement in 2011 to form provider networks, which likely will reduce the availability of these plans. In turn, the growth in enrollment in these plans could diminish, leading to a shift in enrollment from Medicare Advantage to Medicare FFS.

The remaining factor in the 2011 SGR is a –4.4 percent change in spending due to law and regulation. For this factor, CMS's preliminary estimate—subject to change when information on actual spending becomes available—is that some changes in policy will have relatively small effects on spending: expiring PQRI bonuses and a change in payment for certain laboratory services. Expiration of the temporary increases is the primary source of CMS's estimate of the –4.4 percent change in spending.

How does a change in spending of less than 5 percent account for a 21.3 percent reduction in payments that occurred when the temporary increases expired? There are several reasons for the difference. First, because the temporary increases did not expire at the beginning of 2010, the change in spending is not uniform for all 12 months of 2011 compared with all 12 months of 2010. Instead, the change in spending is a weighted average: a decrease in spending for three months—comparing the first three months of 2011 and the first three months of 2010—and no change in spending for nine months. Second, the expiring increases would not affect all the spending accounted for by the SGR. About 9 percent of that spending is for laboratory services. Third, the law and regulation factor in the SGR is not an estimate of a change in payment rates; it is an estimate of a change in spending. A change in payment rates would not necessarily equal a change in spending if the change in payment rates were accompanied by a change in the volume of services. Indeed, when projecting a decrease in payment rates, CMS offsets the decrease by almost a third to account for a volume increase, consistent with the agency's research (Codespote et al. 1998). In other words, if volume goes up when the temporary increases expire, spending will fall by less than the reduction in payment rates.

TABLE A–1

Preliminary estimate of the sustainable growth rate, 2011

Factor	Percent
2011 change in:	
Input prices for physician services*	0.2%
Real GDP per capita	0.8
Fee-for-service enrollment	3.1
Change due to law or regulation	–4.4
Sustainable growth rate	–0.4

Note: GDP (gross domestic product). Percentages are converted to ratios and multiplied, not added, to produce the sustainable growth rate. Estimates shown are preliminary.
*The change in input prices includes inflation measures for services furnished by a physician or in a physician's office. As defined for the sustainable growth rate, those services include services billable under the physician fee schedule and laboratory services.

Source: Blum 2010.

Calculating the SGR formula's update for 2011

After estimating the SGR, CMS calculates the update, which is a function of:

- the change in productivity-adjusted input prices for physician services, as measured by the Medicare Economic Index (MEI); and

TABLE A–2

Preliminary estimate of the SGR formula's update for 2011

Factor	Percent
Change in input prices*	0.1%
Update adjustment factor	–6.2
Update	–6.1

Note: SGR (sustainable growth rate). Percentages are converted to ratios and multiplied, not added, to produce the update. Estimates shown are preliminary.
*For the update, physician services include only those services billable under the physician fee schedule.

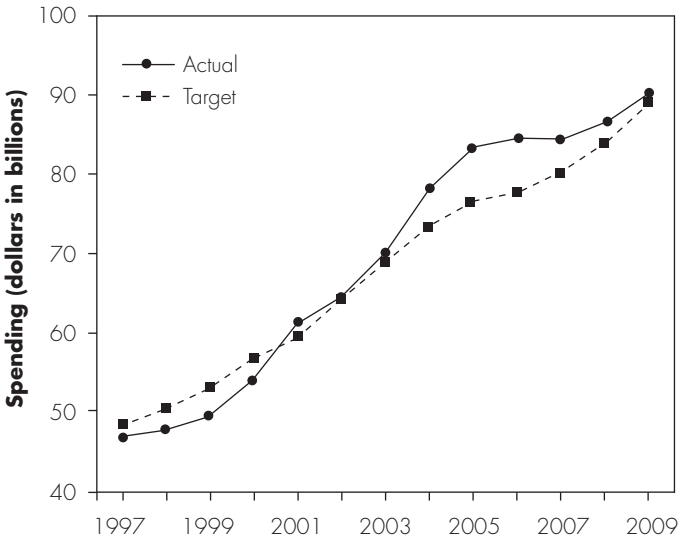
Source: Blum 2010.

- an update adjustment factor (UAF) that increases or decreases the update as needed to align actual spending, cumulated over time, with target spending determined by the SGR.

The estimate of the change in input prices for use in the 2011 update is 0.1 percent (Table A-2). The part of the update calculation that has the larger effect, however, is the UAF. For 2011, CMS estimates a UAF of –6.2 percent. Combining this adjustment with the estimated change in input prices results in an update estimate of –6.1 percent. The UAF is negative because actual spending for physician services has exceeded the target every year since 2001 (Figure A-2).[7] In the meantime, the deficit has continued—despite the formula's calls for payment reductions—because the Congress has overridden the formula.

FIGURE A–2

Since 2001, actual spending for physician services has exceeded the target



Note: Estimates shown are preliminary. Data for 1997 and 1998 are for the last three quarters of each of those years and the first quarter of the following year.

Source: Centers for Medicare & Medicaid Services 2009 and Blum 2010.

As discussed earlier, both factors that go into the update calculation—the MEI and the UAF—could change by November 2010 when CMS finalizes the update for 2011. By then, the MEI could be somewhat higher or lower than 0.1 percent as further data become available on changes in input prices for physician services. And the UAF could be higher or lower than –6.2 percent. The UAF is partly a function of actual spending for physician services. When calculating the preliminary estimate of the 2011 update, CMS had data on actual spending that were nearly complete for the first three quarters of 2009 but less so for the last quarter of that year. As more data become available, the estimate of actual spending in 2009 may change somewhat before CMS issues a final rule on the update in November. The estimates of actual spending for 2010 could change also. Regardless, such changes in the update calculations are very unlikely to have a large impact in the context of an overall reduction in payment rates—combining both the SGR formula's update for 2011 and expiration of the temporary increases—estimated to total –26.1 percent. ■

Endnotes

1 After CMS sent the letter, another temporary increase was enacted that delayed the reduction until June 1, 2010.

2 For the update calculations discussed in this appendix, percentages are not added. Instead, they are converted to ratios and multiplied. For instance, the decrease in payment rates of 26.1 percent is the arithmetic product of the 2011 update (–6.1 percent, or 0.939) and the expiration of the temporary increases (–21.3 percent, or 0.787). The multiplication is $0.939 \times 0.787 = 0.739$, or –26.1 percent.

3 For the update, physician services include only those services billable under the physician fee schedule.

4 For 2007, the Tax Relief and Health Care Act of 2006 maintained payment rates at 2006 levels. For the first six months of 2008, the Medicare, Medicaid, and SCHIP Extension Act of 2007 raised payment rates by 0.5 percent. For the second six months of 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) maintained payment rates at the levels for the first six months of that year. For 2009, MIPPA raised payment rates by 1.1 percent. For January and February of 2010, the Department of Defense Appropriations Act of 2010 maintained payment rates at their 2009 levels. For March 2010, the Temporary Extension Act of 2010 maintained payment rates at the levels for the first two months of the year. The Continuing Extension Act of 2010 continued the zero update for physician services through May 2010.

5 For calculating the SGR, physician services are services commonly performed by a physician or in a physician's office. In addition to services in the physician fee schedule, these services include diagnostic laboratory tests.

6 As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the real GDP per capita factor in the SGR is a 10-year moving average.

7 For 2010, CMS removed physician-administered drugs from the SGR's definition of physician services (Centers for Medicare & Medicaid Services 2009). This change narrowed the gap between actual spending and the target.

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APPENDIX B

Commissioners' voting on recommendations

APPENDIX B

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: Enhancing Medicare's ability to innovate

No recommendations

Chapter 2: Improving traditional Medicare's benefit design

No recommendations

Chapter 3: Medicare's role in supporting and motivating quality improvement

No recommendations

Chapter 4: Graduate medical education financing: Focusing on educational priorities

4-1 The Congress should authorize the Secretary to change Medicare's funding of graduate medical education (GME) to support the workforce skills needed in a delivery system that reduces cost growth while maintaining or improving quality.

- The Secretary should establish the standards for distributing funds after consultation with representatives that include accrediting organizations, training programs, health care organizations, health care purchasers, patients, and consumers.
- The standards established by the Secretary should, in particular, specify ambitious goals for practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice, including integration of community-based care with hospital care.

- Performance-based GME funding under the new system should be allocated to an institution sponsoring GME programs only if that institution met the new standards established by the Secretary, and the level of funding would be tied to the institution's performance on the standards.

The indirect medical education (IME) payments above the empirically justified amount should be removed from the IME adjustment and that sum would be used to fund the new performance-based GME program. To allow time for the development of standards, the new performance-based GME program should begin in three years (October 2013).

Yes: *Behroozi, Berenson, Bertko, Borman, Butler, Castellanos, Chernew, Crosson, Dean, Hackbarth, Hansen, Kane, Kuhn, Miller, Milstein, Scanlon, Stuart*

4-2 The Secretary should annually publish a report that shows Medicare medical education payments received by each hospital and each hospital's associated costs. This report should be publicly accessible and clearly identify each hospital, the direct and indirect medical education payments received, the number of residents and other health professionals that Medicare supports, and Medicare's share of teaching costs incurred.

Yes: *Behroozi, Berenson, Bertko, Borman, Butler, Castellanos, Chernew, Crosson, Dean, Hackbarth, Hansen, Kane, Kuhn, Miller, Milstein, Stuart*
Not voting: *Scanlon*

4-3 The Secretary should conduct workforce analysis to determine the number of residency positions needed in the United States in total and by specialty. In addition, analysis should examine and consider the optimal level and mix of other health professionals. This work should be based on the workforce requirements of health care delivery systems that provide high-quality, high-value, and affordable care.

Yes: *Behroozi, Berenson, Bertko, Borman, Butler, Castellanos, Chernew, Crosson, Dean, Hackbarth, Hansen, Kane, Kuhn, Miller, Milstein, Scanlon, Stuart*

4-4 The Secretary should report to the Congress on how residency programs affect the financial performance of sponsoring institutions and whether residency programs in all specialties should be supported equally.

Yes: *Behroozi, Berenson, Bertko, Borman, Butler, Castellanos, Chernew, Crosson, Dean, Hackbarth, Hansen, Kane, Kuhn, Miller, Milstein, Scanlon, Stuart*

4-5 The Secretary should study strategies for increasing the diversity of our health professional workforce (e.g., increasing the shares from underrepresented rural, lower income, and minority communities) and report on what strategies are most effective to achieve this pipeline goal.

Yes: *Behroozi, Berenson, Bertko, Borman, Butler, Castellanos, Chernew, Crosson, Dean, Hackbarth, Hansen, Kane, Kuhn, Miller, Milstein, Scanlon, Stuart*

Chapter 5: Coordinating the care of dual-eligible beneficiaries

No recommendations

Chapter 6: Inpatient psychiatric care in Medicare: Trends and issues

No recommendations

Chapter 7: Shared decision making and its implications for Medicare

No recommendations

Chapter 8: Addressing the growth of ancillary services in physicians' offices

No recommendations

Appendix A: Review of CMS's preliminary estimate of the physician update for 2011

No recommendations

Acronyms

Acronyms

AAMC	Association of American Medical Colleges
ACC	American College of Cardiology
ACCF	American College of Cardiology Foundation
ACGME	Accreditation Council for Graduate Medical Education
ACH	acute care hospital
ACO	accountable care organization
ACP	American College of Physicians
ACR	American College of Radiology
ACTION	Accelerating Change and Transformation in Organizations and Networks
ACTPCMD	Advisory Committee on Training in Primary Care Medicine and Dentistry
ADL	activity of daily living
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
ALTCS	Arizona Long-Term Care System
AMA	against medical advice
AMA	American Medical Association
AMI	acute myocardial infarction
ASP	average sales price
ASTRO	American Society for Therapeutic Radiology and Oncology
AUA	American Urological Associates
BBA	Balanced Budget Act of 1997
BCBSA	Blue Cross Blue Shield Association
BHIX	Brooklyn Health Information Exchange
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAD	coverage with appropriateness determination
CAH	critical access hospital
CBO	Congressional Budget Office
CC	chronic condition
CC	complication or comorbidity
CCW	Chronic Conditions Warehouse
CDRH	Center for Devices and Radiological Health
CED	coverage with evidence development
CEO	chief executive officer
CER	comparative-effectiveness research
CHF	congestive heart failure
CHGME	Children's Hospital Graduate Medical Education [program]
CKD	chronic kidney disease
CMHC	community mental health center
CMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
COGME	Council on Graduate Medical Education
COLA	cost of living adjustment
CoLTS	Coordination of Long-Term Services
COO	chief operating officer
COP	condition of participation
COPD	chronic obstructive pulmonary disease
CORF	comprehensive outpatient rehabilitation facility
CPT	Current Procedural Terminology
CSP	coverage with study participation
CT	computed tomography
DGME	direct graduate medical education
DHS	designated health services
DME	durable medical equipment
DRA	Deficit Reduction Act of 2005
DRG	diagnosis related group
DSH	disproportionate share hospital
E&M	evaluation and management
EBRI	Employee Benefit Research Institute
ECT	electroconvulsive therapy
ED	emergency department
EHR	electronic health record
EMR	electronic medical record
ER	emergency room
ERISA	Employee Retirement Income Security Act of 1974
ESRD	end-stage renal disease
FDA	Food and Drug Administration
FDG–PET	[^{18}F]fluorodeoxyglucose and positron emission tomography
FDHG	First Diversity Healthcare Group
FFS	fee-for-service
FIMDM	Foundation for Informed Medical Decision Making
FPL	federal poverty level
FQHC	federally qualified health center
FY	fiscal year
GAO	Government Accountability Office
GDP	gross domestic product
GME	graduate medical education
HAC	hospital-acquired condition

HBIPS	Hospital-Based Inpatient Psychiatric Services
HCBS	home- and community-based services
HCFA	Health Care Financing Administration
HCFAC	Health Care Fraud and Abuse Control
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
HIE	health insurance experiment
HIT	health information technology
HQID	[Medicare] Hospital Quality Incentive Demonstration
HRSA	Health Resources and Services Administration
ICD	implantable cardioverter defibrillator
ICER	Institute for Clinical and Economic Review
IDTF	independent diagnostic testing facility
IHI	Institute for Healthcare Improvement
IME	indirect medical education
IMRT	intensity-modulated radiation therapy
IOAS	in-office ancillary services
IOM	Institute of Medicine
IPF	inpatient psychiatric facility
IPPS	inpatient prospective payment system
IRF	inpatient rehabilitation facility
IT	information technology
KFF	Kaiser Family Foundation
LCA	least costly alternative
LCD	local coverage decision
LIS	low-income [drug] subsidy
LTCH	long-term care hospital
MA	Medicare Advantage
MAP	Medicaid Advantage Plus
MA–PD	Medicare Advantage–Prescription Drug [plan]
MCC	major complication or comorbidity
MCCD	Medicare Coordinated Care Demonstration
MedCAC	Medicare Evidence Development & Coverage Advisory Committee
MedPAC	Medicare Payment Advisory Commission
MedPAR	Medicare Provider Analysis and Review [file]
MEI	Medicare Economic Index
MHS	Medicare Health Support
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007
MR	mental retardation
MRI	magnetic resonance imaging
MS–DRG	Medicare severity–diagnosis related group
MSCO	Massachusetts Senior Care Options
MSHO	Minnesota Senior Health Options
MSP	Medicare Savings Program
MSP	Medicare Support Program
NAIC	National Association of Insurance Commissioners
NC–CCN	North Carolina Community Care Network
NCD	national coverage decision
NCI	National Cancer Institute
NCQA	National Committee for Quality Assurance
NCRP	National Council on Radiation Protection and Measurements
NHLBI	National Heart, Lung and Blood Institute
NHPF	National Health Policy Forum
NHSC	National Health Service Corps
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NORC	(formerly) National Opinion Research Center
NPWT	negative pressure wound therapy
NRMP	National Residency Matching Program
OECD	Organisation for Economic Co-operation and Development
OIG	Office of Inspector General
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OOP	out-of-pocket
OR	operating room
ORDI	Office of Research, Development, and Information [CMS]
ORF	outpatient rehabilitation facility
PAC	post-acute care
PACE	Program of All-Inclusive Care for the Elderly
PBGH	Pacific Business Group on Health
PBRN	practice-based research network
PET	positron emission tomography
PPACA	Patient Protection and Affordable Care Act of 2010
PPRC	Physician Payment Review Commission
PPO	preferred provider organization
PPS	prospective payment system
PQRI	Physician Quality Reporting Initiative
PRA	Paperwork Reduction Act

PSA	prostate-specific antigen
PSO	Patient Safety Organization
QIA	quality improvement activity
QIO	Quality Improvement Organization [Medicare]
QMB	qualified Medicare beneficiary
RCT	randomized controlled trial
RTC	Report to Congress
RUC	Relative Value Scale Update Committee
RVU	relative value unit
RY	rate year
SCHIP	State Children's Health Insurance Program
SCO	Senior Care Options
SGR	sustainable growth rate
SNBC	Special Needs Basic Care
SNF	skilled nursing facility
SNP	special needs plan
SOW	scope of work
SOW	statement of work
SSA	Social Security Administration
TC	technical component
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982
TPP	therapists in private practice
UAF	update adjustment factor
U.S.	United States
U.S.C.	United States Code
USPSTF	U.S. Preventive Services Task Force
VA	Department of Veterans Affairs
VBID	value-based insurance design
WMIP	Washington Medicaid Integration Partnership
WPP	Wisconsin Partnership Program

More about MedPAC

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Robert A. Berenson, M.D., F.A.C.P., is an Institute Fellow at the Urban Institute. From 1998 to 2000 he served as Director of the Center for Health Plans and Providers in the Centers for Medicare & Medicaid Services overseeing provider payment policy and managed care contracting. Dr. Berenson was founder and medical director of the National Capital Preferred Provider Organization from 1986 to 1996. He served as an Assistant Director of the White House Domestic Policy staff in the Carter Administration. Dr. Berenson has authored many articles in nationally recognized journals and several books, and he most recently co-authored *Medicare Payment Policy and the Shaping of U.S. Health Care*. Dr. Berenson is a board-certified internist who practiced for 20 years. He received his B.A. from Brandeis University and his M.D. from the Mount Sinai School of Medicine.

John M. Bertko, F.S.A., M.A.A.A., serves as adjunct staff at RAND and as a visiting scholar at the Brookings Institution. He recently retired as the chief actuary for Humana Inc., where he managed the corporate actuarial group and coordinated the work of actuaries on Medicare Advantage, Part D, and consumer-directed health care products. Mr. Bertko has extensive experience with risk adjustment and has served in several public policy advisory roles, including design of prescription drug programs. He is also a member of the panel of health advisors of the Congressional Budget Office. He served the American Academy of Actuaries as a board member from 1994 to 1996 and as vice president for the health practice area from 1995 to 1996. He was a member of the Actuarial Board for Counseling and Discipline from 1996 through 2002. Mr. Bertko is a fellow of the Society of Actuaries and a member of the American Academy of Actuaries. He has a B.S. in mathematics from Case Western Reserve University.

Karen R. Borman, M.D., F.A.C.S., is the General Surgery Residency Program Director and an attending physician at Abington Memorial Hospital, Abington, Pennsylvania. She is board certified in surgery and in surgical critical care. Her clinical focus is on endocrine surgery and her research focus is on surgical education. She is a member of the General Surgery CPT/RUC Committee of the American College of Surgeons. She is a director and an executive committee member of the American Board of Surgery. She is the President of the Association of Program Directors in Surgery. She is a test development committee member for the National Board of Medical Examiners. She has worked with the Centers for Medicare & Medicaid Services on issues related to physician payment and service coverage. Dr. Borman was a member of the executive committee and vice-chair of the American Medical Association's Current Procedural Terminology Editorial Panel. She also served on the AMA Diagnostic and Therapeutic Technology Assessment Panel. Dr. Borman earned her medical degree from Tulane University. Her undergraduate degree in chemistry is from the Georgia Institute of Technology.

Peter W. Butler, M.H.S.A., is a nationally recognized health care executive with more than 25 years of experience in teaching hospitals and health care systems. In addition to being executive vice president and chief operating officer of Rush University Medical Center in Chicago, Illinois, Mr. Butler is an associate professor and chairman of the Department of Health Systems Management at Rush University. Before joining Rush in 2002, he served in senior positions at The Methodist Hospital System in Houston and the Henry Ford Health System in Detroit. Mr. Butler holds an undergraduate degree in psychology from Amherst College and a master's degree in health services administration from the University of Michigan.

Ronald D. Castellanos, M.D., has practiced urology for more than 30 years. For the past four years Dr. Castellanos has been a member, and for the last year the chair, of the Practicing Physicians Advisory Council on issues related to physician payment. Dr. Castellanos was president of the Florida Urologic Society and has worked with several other organizations on health policy, including the American Urologic Association and the American Lithotripsy Society. Dr. Castellanos earned his medical degree from Hahnemann Medical College. His undergraduate degree is from Pennsylvania State University.

Michael Chernew, Ph.D., is a professor in the Department of Health Care Policy at Harvard Medical School. Dr. Chernew's research activities focus on several areas, most notably the causes and consequences of growth in health care expenditures and value-based insurance design (VBID). Professor Chernew is a member of the Congressional Budget Office's Panel of Health Advisors and Commonwealth Foundation's Commission on a High Performance Health System. In 2000 and 2004, he served on technical advisory panels for the Centers for Medicare & Medicaid Services that reviewed the assumptions used by the Medicare actuaries to assess the financial status of the Medicare trust funds. Dr. Chernew is a Faculty Research Fellow of the National Bureau of Economic Research. He co-edits the *American Journal of Managed Care* and is a Senior Associate Editor of *Health Services Research*. Dr. Chernew earned his undergraduate degree from the University of Pennsylvania and a doctorate in economics from Stanford University.

Francis J. Crosson, M.D., is the associate executive director of the Permanente Medical Group. He was previously senior medical director of the Permanente Federation of medical groups that make up the physician component of Kaiser Permanente. He joined Kaiser Permanente in 1977. He was the founder and executive director of the Federation from 1997 to 2007. He also has experience with prescription drug arrangements and has led efforts on comprehensive public report cards on clinical quality, management of a drug formulary, and adoption of a state-of-the-art electronic medical record. He serves on the boards of the California Medical Association Foundation, the American Medical Group Foundation, and the Advisory Board of the Mayo Health Policy Institute. Dr. Crosson received his undergraduate degree in political science from Georgetown University and his M.D. degree from Georgetown's School of Medicine.

Thomas M. Dean, M.D., is a board-certified family physician who has practiced in Wessington Springs, South Dakota, since 1978. He is chief of staff at Avera Weskota Memorial Medical Center. Dr. Dean is on the board of directors of Avera Health Plan, the Bush Foundation Medical Fellowship, and the South Dakota Academy of Family Physicians. He was president of the National Rural Health Association, and he published articles and presented on health care in rural areas. Dr. Dean received the Dr. Robert Hayes Memorial Award for outstanding rural health provider, received the Pioneer Award from the South Dakota Perinatal Association, and was awarded a Bush Foundation Medical Fellowship. Dr. Dean earned his medical degree from the University of Rochester School of Medicine and Dentistry. His undergraduate degree is from Carleton College.

Glenn M. Hackbarth, J.D., M.A., chairman of the Commission, lives in Bend, OR. He has experience as a health care executive, government official, and policy analyst. 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 currently serves as the vice chairman of the board of the Foundation of the American Board of Internal Medicine. He is also a board member at the National Committee for Quality Assurance (NCQA) and at the Commonwealth Fund. He is also a member of the Commonwealth Fund's Commission on a High Performance Health System. Mr. Hackbarth received his B.A. from Pennsylvania State University and his J.D. and M.A. from Duke University.

Jennie Chin Hansen, R.N., M.S.N., F.A.A.N., is CEO of the American Geriatrics Society, and previously was the immediate past president of AARP and a senior fellow at University of California's Center for the Health Professions. Ms. Hansen was executive director of On Lok Senior Health Services, the prototype for the Program of All-Inclusive Care for the Elderly (PACE)—a capitated program for frail elders that integrates Medicare and Medicaid financing and care delivery and was signed into federal legislation as a provider type in the BBA of 1997. PACE now operates in over 30 states. She has practiced

and taught nursing in both urban and rural settings. She currently serves in leadership roles on the National Academy of Social Insurance, the SCAN Foundation, the Robert Wood Johnson Foundation Initiative on the Future of Nursing at the Institute of Medicine, and the Executive Nurse Fellows Program—the latter also funded by the Robert Wood Johnson Foundation. Ms. Hansen consults with other foundations on leadership development and independent reviews. She is a Fellow in the American Academy of Nursing. Ms. Hansen received her B.S. and an honorary doctorate from Boston College and her M.S.N. from the University of California, San Francisco.

Nancy M. Kane, D.B.A., is professor of management in the Department of Health Policy and Management and associate dean of education at the Harvard School of Public Health. Dr. Kane directs the Masters in Healthcare Management Program, an executive leadership program for mid-career physicians leading healthcare organizations. She has taught health care accounting, payment systems, financial analysis, and competitive strategy. Her research interests include measuring hospital financial performance, quantifying community benefits and the value of tax exemption, the competitive structure and performance of hospital and insurance industries, and nonprofit hospital governance. Professor Kane consults with federal and state agencies involved in health system design, oversight, and payment. She is an outside director of Press Ganey, which provides patient satisfaction surveys and comparative performance reports to health care providers. Prior to obtaining her business training, she practiced as a hospital-based physical therapist. Dr. Kane earned her master's and doctoral degrees in business administration from Harvard Business School.

Herb B. Kuhn is the current president and CEO of the Missouri Hospital Association, the trade association serving the state's 176 hospitals and health systems. Prior to joining MHA, Mr. Kuhn served in multiple roles at the Centers for Medicare & Medicaid Services, including as Deputy Administrator from 2006 to 2009 and as 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. In 2008 Mr. Kuhn was named by *Modern Healthcare* magazine as one of the 100 Most Powerful People in Healthcare in the United States. Mr. Kuhn received his bachelor of science in business from Emporia State University.

George N. Miller, Jr., M.H.S.A., over the last two decades, has managed a series of hospitals, leading financial turnarounds at four of them. Since 2008, Mr. Miller has been the Managing Partner and COO of First Diversity Healthcare Group (FDHG). FDHG is a national healthcare consulting firm helping healthcare organizations improve their operations. He was the president and CEO of Community Mercy Health Partners and senior vice president of Catholic Health Partners, a hospital chain in the Springfield, Ohio, area. Previously, he ran hospitals in Illinois, Texas, and Virginia and is the immediate past president of the National Rural Health Association. Mr. Miller has been an adjunct professor in health services administration at Central Michigan University since 1998. He has an undergraduate degree in business administration from Bowling Green State University and a master of science in health services administration from Central Michigan University.

Arnold Milstein, M.D., M.P.H., is the medical director of the Pacific Business Group on Health (PBGH) and the chief physician at Mercer Health & Benefits. PBGH is the largest employer–health care purchasing coalition in the U.S. His work and publications focus on health care purchasing strategy, the psychology of clinical performance improvement, and clinical innovations that reduce total health care spending and improve quality. He co-founded both the Leapfrog Group and the Consumer-Purchaser Disclosure Project. He heads performance measurement activities for both initiatives. The *New England Journal of Medicine*'s series on employer sponsored health insurance described him as a "pioneer" in efforts to advance quality of care. Citing his nationally distinguished innovation in health care cost reduction and quality gains, he was selected for the highest individual award of the National Business Group on Health, and of the American College of Medical Quality. He was elected to the Institute of Medicine of the National Academy of Sciences and is a faculty member at the University of California at San Francisco's Institute for Health Policy Studies. Dr. Milstein has a B.A. in economics from Harvard, an M.D. degree from Tufts University, and an M.P.H. in health services evaluation and planning from the University of California at Berkeley.

William J. Scanlon, Ph.D., is a consultant to the National Health Policy Forum. Dr. Scanlon is a member of the National Committee on Vital and Health Statistics. Before his current positions, Dr. Scanlon was the managing director of health care issues at the U.S. General

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Bruce Stuart, Ph.D., is a professor and executive director of the Peter Lamy Center on Drug Therapy and Aging at the University of Maryland in Baltimore. An experienced research investigator, Mr. Stuart has directed grants and contracts with various federal agencies, private foundations, state governments, and corporations. Mr. Stuart joined the faculty of the University of Maryland's School of Pharmacy in 1997 as the Parke-Davis endowed chair in geriatric pharmacy. Previously, he taught health economics, finance, and research methods at the University of Massachusetts and the Pennsylvania State University. Earlier, Mr. Stuart was director of the health research division in the Michigan Medicaid program. Mr. Stuart was designated a Maryland eminent scholar for his work in geriatric drug use. His current research focuses on the policy implications of the Medicare prescription drug benefit. Mr. Stuart received his economics training at Whitman College and Washington State University.

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