JUNE 2008

REPORT TO THE CONGRESS

Reforming the Delivery System

MEDPAC Medicare Payment Advisory Commission

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

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

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
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 13, 2008

The Honorable Richard B. Cheney
President of the Senate
U.S. Capitol
Washington, DC 20510

Dear Mr. Vice President:

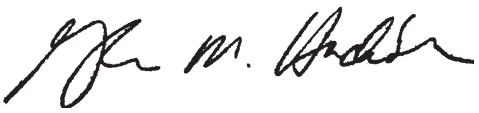
I am pleased to submit the Medicare Payment Advisory Commission's June 2008 *Report to the Congress: Reforming the Delivery System*. This report fulfills the Commission's legislative mandate to examine issues affecting the Medicare program and to make specific recommendations to the Congress.

Without change, the Medicare program is fiscally unsustainable over the long term and is not designed to produce high-quality care. The Commission has focused its work on fundamental payment and delivery system reforms to improve quality, coordinate care, and reduce cost growth. In this report, the Commission:

- describes a direction for Medicare payment and delivery system reform,
- makes recommendations to promote primary care,
- examines hospital–physician collaborative relationships,
- recommends a new payment design bundling payments around hospitalization episodes,
- explores issues in creating an entity to develop information on the comparative effectiveness of alternative therapies,
- examines public reporting of physicians' financial relationships with manufacturers and facilities,
- recommends a revised payment system and improved data reporting for skilled nursing facilities, and
- evaluates Medicare's hospice benefit.

The report concludes by fulfilling our statutory obligation to analyze the Secretary of the Department of Health and Human Services' estimate of the update for physician services (Appendix A of this report).

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

Enclosure

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June 13, 2008

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

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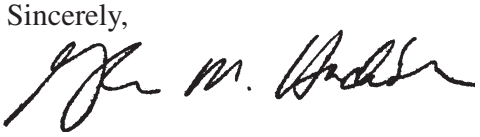

Glenn M. Hackbarth, J.D.
Chairman

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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Table of contents

Executive summary

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Fundamental changes are needed in health care delivery in the United States and in Medicare. Although on average life expectancy is increasing and certain measures of health care outcomes are improving, there is still much room for improvement. Recent studies show that the U.S. health care system is not buying enough of the recommended care, is buying too much unnecessary care, and is paying prices that are very high, resulting in a system that costs significantly more per capita than in any other country. As a major payer, the Medicare program shares in these problems.

Medicare fills a critical role in our society—ensuring that the elderly and disabled have good access to medically necessary care. Along with that role comes a responsibility to make sure the resources entrusted to the program by taxpayers and beneficiaries are used wisely. Without change, the Medicare program is fiscally unsustainable over the long term. Moderating projected spending trends requires fundamental reforms in payment and delivery systems to improve quality, coordinate care, and reduce cost growth.

In this report, we investigate what direction these reforms should take, recognizing the limitations of current Medicare fee-for-service (FFS) payment systems and the need for greater accountability and care coordination. We consider a wide range of issues, including hospital–physician relationships and financial disclosure, and make the following recommendations: First, we recommend a new payment design around hospitalization episodes that holds providers accountable for care delivered over time and provides them an incentive to work together. It incorporates:

- reporting to hospitals and physicians about resource use around hospitalization episodes;
- reduced payments to hospitals with relatively high readmission rates for select conditions, coupled with gainsharing between hospitals and physicians; and
- a pilot program of bundled payments.

We also recommend promoting the use of primary care by establishing a payment adjustment within the physician fee schedule and initiating a medical home pilot project, which will increase care coordination for beneficiaries with multiple chronic conditions. Finally, we recommend revising the prospective payment system (PPS) for skilled nursing facilities (SNFs) and requiring SNFs to provide better diagnosis, service use, and cost information to improve the accuracy of the SNF PPS. Our intent is to continue to improve the accuracy of current FFS payment systems such as the SNF PPS and hospice payment system, while creating new payment designs that will help coordinate care and overcome some of the limitations of current FFS payment systems—moving Medicare in the direction of payment and delivery system reform.

Direction for delivery system reform

In Chapter 1, we examine what long-term direction reforms should take. Medicare reforms should increase value, which means maintaining or increasing access to care, quality, and equity while controlling resource use. To increase value, reforms need to promote accountability and care coordination, create better information and tools to use it, change incentives to encourage efficiency and higher quality rather than increases in volume, and set accurate payment rates. Reforms should also protect beneficiaries from the catastrophic costs of needed care and promote alignment with the private sector and other government payers.

In previous reports, the Commission has recommended that Medicare adopt tools for increasing efficiency and improving quality within the current Medicare payment systems, including: encouraging the use of comparative-effectiveness information, linking payment to quality (pay for performance (P4P)), measuring resource use and providing feedback, and improving payment accuracy within Medicare payment systems. However, in the current Medicare FFS payment system environment, the benefit of these tools is limited for two reasons. First, they may not be able to overcome the strong incentives inherent in any FFS system to increase volume. Second, paying for each individual service and staying within current payment systems (e.g., the physician fee schedule or the inpatient PPS) inhibit changes in the delivery system that might result in better coordination across services and lead to efficiencies or better quality across these systems.

To increase value for beneficiaries and taxpayers, the Medicare program must overcome the limitations of its current payment systems. A reformed Medicare payment system would pay for care that spans across provider

types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of that care and the resources used to provide it. This direction would create payment system incentives for providers that reward value and encourage closer provider integration, which in turn would maximize the potential of tools such as P4P and resource measurement to improve quality and efficiency.

Promoting the use of primary care

Patient access to high-quality primary care is essential for a well-functioning health care delivery system. Research suggests that improving access to primary care and reducing reliance on specialty care may improve the efficiency and quality of health care delivery. Despite these findings, primary care services—which rely heavily on cognitive activities such as patient evaluation and management (E&M)—are being undervalued and risk being underprovided relative to procedurally based services. Consequently, physicians may view primary care services as less valued and less profitable and hence careers in primary care as less desirable. In fact, the share of U.S. medical school graduates entering primary care residency programs has declined in the last decade, and internal medicine residents are increasingly choosing to subspecialize rather than practice as generalists. Additionally, the Commission found that among beneficiaries looking for a new physician in 2007, those looking for a new primary care physician (a small number of beneficiaries) were more likely to report difficulty finding one than those looking for a new specialist.

To improve payment for and access to primary care services, the Commission has explored incentives for encouraging desired services, activities, and the choice of primary care as a career. In our March 2006 report to the Congress, the Commission recommended improvements to the process for reviewing the relative value of physician services. These recommendations sought to address concerns that cognitive services—mainly E&M services—were being devalued over time, regardless of which type of practitioner was furnishing them. Although the formal process for reviewing the service values has not changed, CMS substantially increased the work component of certain E&M codes in 2007, following the recommendations of the Relative Value Scale Update Committee (RUC), and increased the practice expense component of E&M codes as well.

In Chapter 2, we recommend two new initiatives for promoting primary care. The first initiative increases fee schedule payments for primary care services furnished by clinicians focused on delivering primary care. This budget-neutral adjustment would redistribute Medicare payments toward those primary care services provided by practitioners—physicians, advanced practice nurses, and physician assistants—whose practices focus on primary care. A fee schedule adjustment for primary care would help overcome the undervaluation of primary care services. This adjustment, together with CMS's increase in the work and practice expense components for E&M services, would add up to a significant change promoting primary care. Nonetheless, other factors (e.g., on-call schedules) would still affect physicians' career choices.

The second initiative to promote primary care is to establish a medical home pilot program in Medicare. A medical home is a clinical setting that serves as a central resource for a patient's ongoing care. Qualifying medical homes could include primary care practices as well as specialty practices that focus on care for certain chronic conditions, such as endocrinology for people with diabetes. A medical home pilot would create incentives for eligible medical practices to conduct care management and care coordination. This medical home pilot would include monthly, per beneficiary payments to qualifying medical practices for infrastructure and activities that promote ongoing comprehensive care management. To be eligible for these monthly payments, medical homes would be required to meet stringent criteria, including:

- furnish primary care (including coordinating appropriate preventive, maintenance, and acute health services);
- conduct care management;
- use health information technology (IT) for active clinical decision support;
- have a formal quality improvement program;
- maintain 24-hour patient communication and rapid access;
- keep up-to-date records of beneficiaries' advance directives; and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

In rural areas, the pilot could test the ability for medical homes to provide high-quality, efficient care with fewer structural requirements, particularly with respect to health IT.

Beneficiaries with multiple chronic conditions would be eligible to participate because they are most in need of improved care coordination. Beneficiaries would not incur any additional cost sharing for the medical home fees. Medical home practitioners would discuss with beneficiaries the importance of seeking guidance on selecting appropriate specialty services, although participating beneficiaries would retain their ability to see specialists and other practitioners of their choice. Medicare should also provide medical homes with timely data on patients' Medicare-covered utilization outside the medical home, including services under Part A and Part B and drugs under Part D.

The medical home pilot should be on a large enough scale to provide statistically reliable results to test the hypothesis that qualifying medical homes can improve the quality and efficiency of patient care, particularly for those with multiple chronic conditions. A pilot of this scale can also accelerate the speed with which innovations are tested and implemented and provides an excellent opportunity to implement and test physician P4P. However, increasing the scale of the pilot also increases its costs and the difficulty of discontinuing it—should that be indicated. Therefore, there must be clear and explicit results-based thresholds for determining whether the pilot should be expanded into the full Medicare program or discontinued entirely.

Examining hospital–physician collaborative relationships

Medicare's FFS payment systems create economic incentives for providers to increase the volume of medical services they perform. By paying piecemeal for each service, a FFS payment system will increase providers' revenues as long as they increase the number of services delivered. Providers' clinical decision-making authority and a FFS payment system combine to create powerful financial incentives for providers to increase volume. Hospitals and physicians, as well as other providers, have rationally responded to these incentives by implementing various financial and organizational arrangements that enable, encourage, or reward volume growth.

In Chapter 3, we explore a range of financial arrangements between hospitals and physicians and how they contribute to volume growth. By exploring the specific strategies that hospitals and physicians are using to organize the delivery system, and how the drive to increase service volume becomes ingrained in the delivery system's structures, we underscore the need to reform current Medicare payment policies that contribute to this dynamic.

A path to bundled payment around a hospitalization

Medicare's FFS payment systems fail to encourage providers to cooperate with one another to improve coordination of beneficiaries' care and appropriately control the volume and cost of services delivered across an episode of care. In Chapter 4, we recommend changes in FFS payment for care provided around a hospitalization to start to address these failures. Bundling Medicare payment to cover all services associated with an episode of care can improve incentives for providers to deliver the right mix of services at the right time.

While bundling payment holds great potential, the Commission recognizes the complexity associated with it. Accordingly, the Commission recommends an incremental approach, composed of three separate, but related, policies.

- First, it recommends that the Secretary confidentially report to hospitals and physicians information about readmission rates and resource use around hospitalization episodes (e.g., 30 days postdischarge). This information would allow a given hospital and the physicians who practice in it to compare their risk-adjusted performance relative to other hospitals and physicians. Once equipped with this information, providers may consider ways to adjust their practice styles and coordinate care to reduce service use. After two years of confidential disclosure to providers, this information should be publicly available.
- Second, the Commission recommends changing payment to hold providers financially accountable for service use around a hospitalization episode. Specifically, it would reduce payment to hospitals with relatively high readmission rates for select conditions. The Commission recommends that this payment change be made in tandem with a previously recommended change in law to allow hospitals and physicians to share in the savings that result from reengineering inefficient care processes during the episode of care. Recognizing that readmissions account for only part of the variation in practice patterns around an admission, the Commission also recommends that the Secretary explore other

broader payment changes to encourage efficiency around hospitalization episodes and report back to the Congress within two years.

- Third, the Commission recommends that CMS conduct a voluntary pilot program to test bundled payment for all services around a hospitalization for select conditions. This pilot program would be concurrent with information dissemination and a change in payment for high rates of readmissions. Bundled payment raises a wide set of implementation issues. It requires not only that Medicare create a new payment rate for a bundle of services but also that providers decide how they will share the payment and what behavior they will reward. A pilot allows CMS to resolve the attendant design and implementation issues, while giving providers who are ready the chance to start receiving a bundled payment.

Producing comparative-effectiveness information

Comparative-effectiveness analysis evaluates the relative value of drugs, devices, diagnostic and surgical procedures, diagnostic tests, and medical services. By value, we mean the clinical effectiveness of a service compared with its alternatives. Comparative-effectiveness information has the potential to promote care of higher value and quality in the public and private sectors.

In our June 2007 report, the Commission recommended that the Congress establish an independent entity to produce and provide information about the comparative effectiveness of health care services. The entity's primary mission would be to sponsor, compile, and disseminate studies that compare the clinical effectiveness of a service with its alternatives.

In Chapter 5, we explore a number of issues that must be addressed in creating such an entity. The Commission supports a dedicated, broad-based financing mechanism to help ensure the entity's stability and independence. The funding should be from federal and private sources because the research findings will benefit all users—patients, providers, private health plans, and federal health programs. To ensure that the research is objective, an independent board of experts should oversee the entity's efforts. In designing a board, key issues will include the board's composition and size, the appointment process, the duration of terms, and rules governing conflicts of interest. Finally, we explore several options for the entity's structure and location: a federally funded research and development center, an independent federal agency within the executive branch, an independent federal agency within the legislative branch, and a congressionally chartered nonprofit organization.

Public reporting of physicians' financial relationships

Physicians influence both the volume and type of health care services Medicare beneficiaries receive. They recommend when patients should receive a specific drug or medical device or use a specific facility. Physicians are also involved in developing clinical protocols and researching new drugs and devices. Medicare depends on physicians, in carrying out these responsibilities, to act in the best interest of patients. However, physicians may have financial relationships with drug and device manufacturers and facilities that could compromise their independence and objectivity.

Financial relationships between physicians and pharmaceutical and device manufacturers are pervasive. A physician survey conducted in 2003 and 2004 found that more than three-quarters of physicians received meals or drug samples from drug manufacturers in the last year and more than one-quarter were paid for consulting, giving lectures, or enrolling patients in clinical trials. Manufacturers of medical devices, such as artificial joints and spinal implants, frequently pay physicians consulting fees and royalties to develop new products, and subsidize their trips to attend conferences.

In addition, the number of physician-owned specialty hospitals more than doubled from 2002 to 2006 and the number of Medicare-certified ambulatory surgical centers (ASCs)—most of which have at least some physician ownership—grew by 31 percent over the same period. There has also been an increase in joint venture facilities owned by physicians and hospitals.

Payers, plans, patients, and the general public are often not aware of these potential conflicts of interest. If information about financial relationships between physicians and manufacturers, hospitals, and ASCs were publicly available, it would shed light on these interactions and could be used to examine the influence of these relationships on referral patterns and the overall volume of services.

In Chapter 6, we explore options for collecting data on physicians' financial relationships with manufacturers, hospitals, and ASCs. We describe three key design

questions for a potential federal law requiring drug and device companies to report their financial ties with physicians: How comprehensive should the reporting system be? What size and types of payments should be reported? How can the data be made readily accessible to the public? Next, we examine possible reporting requirements for hospitals and ASCs. Under the approaches we describe, the responsibility for public reporting would rest with pharmaceutical and device manufacturers, hospitals, and ASCs rather than physicians. Even if a reporting system were implemented, individual physicians, manufacturers, and facilities would continue to be responsible for ensuring that their financial relationships are ethical and further the best interests of patients.

A revised prospective payment system for SNFs

There are two key problems with Medicare's PPS for SNF services. First, it does not adequately adjust payments to reflect the variation in facility costs for nontherapy ancillary (NTA) services (e.g., intravenous (IV) medications, respiratory therapy, and drugs). Second, payments vary with the amount of therapy furnished, creating an incentive to furnish therapy services for financial rather than clinical reasons. In addition, the PPS does not include an outlier policy to defray the exceptionally high costs of some patients, which could make some providers reluctant to admit certain types of patients.

In Chapter 7, the Commission recommends implementing a revised PPS design that incorporates a separate NTA payment component, a revised therapy payment component, and an outlier policy based on exceptionally high ancillary costs per stay. Compared with the existing PPS, such a revised design would better target payments to stays with high NTA costs, more accurately calibrate therapy payments to therapy costs, and afford some financial protection to SNFs that treat stays with exceptionally high ancillary costs. Because the revised PPS would establish more accurate payments, SNFs would be less likely to avoid patients whom hospital discharge planners report having difficulty placing—those who require IV antibiotics, expensive medications, and ventilator care. For these beneficiaries, access would be improved.

The Commission also recommends directing CMS to require facilities to provide information on patient diagnoses, service use during the SNF stay, and nursing costs. CMS could implement the revised PPS without these data, but better data would simplify implementation, further improve payment accuracy, and enable the value of care to be assessed by linking payments, costs, service use, and patient outcomes.

One drawback common to all prospectively set payments is that facilities may be encouraged to furnish fewer services inside an episode of care—in this case, less therapy than is clinically appropriate during a SNF stay. Under a revised PPS, CMS would need to monitor therapy provision and patient outcomes, underscoring the need to require SNFs to assess patients at discharge. A P4P program that links SNF payments to patient outcomes, as recommended by the Commission, would help counter incentives to stint on services, as poor beneficiary outcomes would result in lower payments.

Evaluating Medicare's hospice benefit

Hospice care has changed significantly in the 25 years since Medicare implemented the hospice benefit, with the most significant changes occurring in the last seven years. The hospice benefit provides palliative care and support services for terminally ill patients as an alternative to conventional care at the end of life. Now, nearly 40 percent of Medicare decedents had elected hospice, and the profile of the beneficiary population electing hospice is very different from when it originated in 1983. The profile of hospice providers has also changed. In 1983, most hospice providers were nonprofits, affiliated with religious or community organizations; now, for-profit hospices make up a majority of providers, with for-profit hospices constituting most of the new entrants into the Medicare benefit since 2000. CMS's Office of the Actuary estimates that Medicare spending under the hospice benefit exceeded $10 billion in fiscal year 2007 and projects that Medicare spending for hospice will more than double again in the next 10 years.

In Chapter 8, we explore what has driven the growth in Medicare spending for hospice and what that implies about the hospice payment system. Spending increases have been driven by increased numbers of beneficiaries using the hospice benefit and increases in average length of stay in hospice. Part of this increase in length of stay reflects a change in the mix of patients electing hospice, from those with cancer and other relatively acute diagnoses to patients with diagnoses such as Alzheimer's disease, nonspecific debility, and congestive heart failure, which typically have long stays in hospice. However,

hospices with longer lengths of stay are more profitable, and for-profit hospices have a length of stay about 45 percent longer than nonprofit hospices. Certain hospices have an average length of stay greater than other hospices across all diagnoses—in particular, those exceeding the "hospice cap," almost 90 percent of which are for profit. The hospice cap is an aggregate per beneficiary limit on Medicare payments to hospices implemented at the beginning of the benefit to ensure that hospice care would be an alternative to intense, costly, and intrusive end-of-life care and not become a de facto long-term care benefit.

Overall, Medicare payments to hospices appear adequate, but this assessment masks considerable variation. In 2005, nonprofit and provider-based hospices had small negative margins, while for-profit and freestanding hospices had large positive margins. Hospices that exceeded the cap had the highest Medicare margins in 2005 (before the return of overpayments—if overpayments were returned their margins would become slightly negative), as longer stays under this payment system led to larger profits. These findings suggest the presence of financial incentives in Medicare's hospice payment system to provide long stays. Such incentives run counter to the intent of Medicare's hospice benefit—to provide an alternative that is less intrusive and costly than conventional treatment.

During this period of major change, Medicare's payment system for hospice care has changed relatively little. Payments have been updated over time, but otherwise the basic structure is much as it was in 1983, with per diem reimbursements for four types of care and few reporting requirements to assist in refinement or evaluation of the benefit. Substantially more data will be needed—data that have historically been uniquely lacking in hospice—to address these concerns about how the hospice benefit is being used and to modernize Medicare's payment system for hospice.

Review of CMS's preliminary estimate of the physician update for 2009

Appendix A fulfills the Commission's requirement to review CMS's estimate of the 2009 update for physician services. CMS's preliminary estimate of the 2009 payment update for physician services is –5.4 percent. A negative update in 2009 would be in addition to a 10.6 decrease to occur on July 1, 2008, at the end of a temporary, six-month bonus that was included in the Medicare, Medicaid, and SCHIP Extension Act of 2007. The sustainable growth rate (SGR) formula has called for negative updates since 2002 because of continued growth in expenditures on physician services and increased spending associated with legislative overrides to avert payment cuts for physician services.

In reviewing the technical details involved in estimating the update under current law (in accordance with the SGR formula), we find that CMS used estimates in calculating the update that are consistent with recent trends. Moreover, the Commission anticipates that no alteration in the factors of CMS's estimates would be large enough to eliminate application of the statutory limit the SGR formula imposes. That limit is –7.0 percent, which, combined with expected inflation in input prices of 1.7 percent, yields the preliminary update estimate of –5.4 percent. The inflation estimate may change between now and January 1 when the update takes effect. ■

CHAPTER 1

Direction for delivery system reform

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Chapter summary

Fundamental changes are needed in health care delivery in the United States. Although on average life expectancy is increasing and certain measures of health care outcomes are improving, there remains much room for improvement. Recent studies show that the U.S. health care system is not buying enough of the recommended care, is buying too much unnecessary care, and is paying prices that are very high, resulting in a system that costs significantly more per capita than in any other country. As a major payer, the Medicare program shares in these problems.

Medicare fills a critical role in our society—ensuring that the elderly and disabled have good access to medically necessary care. Along with that role comes a responsibility to make sure the resources entrusted to the program by taxpayers and beneficiaries are used wisely. Without change, the Medicare program is fiscally unsustainable over the long term. Moderating projected spending trends requires fundamental reforms in the payment and delivery systems to improve quality, better

In this chapter

coordinate care, and reduce cost growth. What direction should those reforms take?

Medicare reforms should increase value, which means maintaining or increasing access to care, quality, and equity while controlling resource use. As the Commission has explored what prevents the Medicare program from increasing value, it has determined that, to be effective, reforms need to:

- promote accountability and care coordination,
- create better information and tools to use it,
- change providers' incentives to encourage efficiency and higher quality rather than increases in volume, and
- set accurate payment rates.

Reforms should also protect beneficiaries from the catastrophic costs of needed care and promote alignment with the private sector to make policies more effective while monitoring the burden on providers.

In previous reports, the Commission has recommended that Medicare adopt tools to increase efficiency and improve quality within current Medicare payment systems. These tools include:

- encouraging the use of comparative-effectiveness information,
- linking payment to quality,
- measuring resource use and providing feedback, and
- improving payment accuracy.

However, in the current Medicare fee-for-service payment system environment, the benefit of these tools is limited for two reasons. First, they may not be able to overcome the strong incentives inherent in any fee-for-service system to increase volume. Second, paying for each individual service and staying within current payment system "silos" (e.g., the physician fee schedule or the inpatient prospective payment system) inhibits changes in the delivery system that might result in better coordination across services and lead to efficiencies or better quality across these systems.

To increase value for beneficiaries and taxpayers, the Medicare program must overcome the limitations of its current payment systems. A reformed Medicare payment system would pay for care that spans across provider types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of that care and the resources used to provide it. This new direction would create payment system incentives for providers that reward value and encourage closer provider integration, which would maximize the potential of tools such as pay for performance and resource measurement to improve quality and efficiency. We introduce three concepts that may move the delivery system in the desired direction:

- medical homes
- bundled payments
- accountable care organizations

The first two of these concepts are developed further in Chapters 2 and 4, and the last one will be developed in future work.

These changes could be complemented by changes to medical education programs to encourage adequate geriatric training, teamwork, primary care, and quality training as well as adoption of innovative production technologies such as process reengineering.

As these concepts and other payment system reforms are developed, several fundamental issues must be addressed:

- How can incentives at the individual physician, group, and joint physician and hospital level be coordinated to obtain the best value for the Medicare program?
- What responsibilities do beneficiaries have? Should cost sharing be designed to motivate patients to use certain providers?

- Is changing the financial incentives enough, or should society demand greater influence over what types of specialty training physicians receive and place tighter restrictions on which facilities and equipment physicians both own and refer their patients to?

These issues will play a major role in determining how far and how fast reform can progress. We need to start the process of reform as soon as possible, even though the final destination is unknowable and years in the future. ■

Why is fundamental change needed?

Fundamental changes are needed in health care delivery in the United States. Although on average life expectancy is increasing and certain measures of health care outcomes are improving, there remains much room for improvement.[1] Recent studies show that the U.S. health care system is not buying enough of the recommended care (McGlynn et al. 2003), is buying too much unnecessary care (Fisher et al. 2003a, Fisher et al. 2003b, Wennberg et al. 2002), and is paying prices that are very high (Anderson et al. 2006, Anderson et al. 2003), resulting in a system that costs significantly more per capita than in any other country. As a major payer, the Medicare program shares in these problems.[2]

Several recent studies show serious quality problems in the American health care system. One study showed that participants received about half (55 percent) of the recommended care across types of care (preventive, acute, chronic) and functions (screening, diagnosis, treatment, follow-up). It found greater variation across conditions; for example, 79 percent received the recommended care for senile cataract, but only 11 percent received it for alcohol dependence (McGlynn et al. 2003). This variation across conditions could reflect incentives in the payment systems and cost sharing or a lack of agreement among clinicians on what constitutes appropriate care. Another study shows wide variation across states in hospital admissions for ambulatory-care-sensitive conditions (i.e., admissions that are potentially preventable with improved ambulatory care) (Schoen et al. 2006).

At the same time that Americans are not receiving enough of the recommended care, they may be receiving too much ineffective care. For 30 years, researchers at Dartmouth's Center for the Evaluative Clinical Sciences have documented the wide variation across the United States in Medicare spending and rates of service use. For example, they find that rates of use for certain kinds of care, referred to as supply-sensitive services (i.e., use is likely driven by a geographic area's supply of specialists and technology), differ greatly from one region to another (Wennberg et al. 2002). The higher rates of use are often not associated with better outcomes or quality and instead suggest inefficiencies. In fact, a recent analysis shows at the state level that no relationship exists between health care spending per capita and mortality amenable to medical care, that an inverse relationship exists between spending and rankings on quality of care, and that high correlations exist between spending and both preventable hospitalizations and hospitalizations for ambulatory-care-sensitive conditions (Davis and Schoen 2007). These findings point to inefficient spending patterns and opportunities for improvement.

Medicare has some control over pricing (i.e., the rates it sets administratively for health care services) but much less control over getting recommended care or avoiding unnecessary care. Fee-for-service (FFS) payment systems encourage service volume growth regardless of the quality or appropriateness of care. Even if the payment rates in the systems were made as accurate as possible (the Commission has made many recommendations toward improving payment accuracy), the existing FFS payment systems will nevertheless reward providers who increase the volume of services they furnish. Because of this strong incentive for volume growth, a fundamental restructuring of Medicare payment systems toward quality and accountability is needed to improve the value of health care spending.

Another indicator that fundamental reform is needed is that providers who are recognized as being innovative and cost effective are not rewarded by FFS payment systems and can in fact be disadvantaged. For example, the Virginia Mason Medical Center in Washington state reported to the Commission that its lower back pain initiative greatly reduced insurance companies' cost for members with lower back pain but, under standard FFS payment rules, decreased the center's revenues (Kaplan 2006).

The Commission is not alone in concluding that fundamental change is needed in Medicare FFS payment systems and the way care is delivered.[3] A recent survey of 214 health care leaders sponsored by the Commonwealth Fund found that 95 percent of those opinion leaders agree that fundamental payment reform is needed. They agree that delivery system reform is needed as well: Three-fourths support fostering integrated delivery systems, and 73 percent support Medicare payment reform to promote medical homes. In addition, 90 percent favor Medicare mandating the use of electronic health records, and 47 percent think pay for performance (P4P) is an important transitional step (Shea et al. 2007).

In *Crossing the Quality Chasm*, the Institute of Medicine also concluded that "The American health care delivery system is in need of fundamental change" (IOM 2001). It set six aims for improvement, proposing that health care should be: safe, effective, patient centered, timely, efficient, and equitable. It pointed out that there were

TABLE 1–1 **Determinants of value in the Medicare program**

Determinant	
Access	Beneficiaries need to be able to obtain care, and the care that is delivered should be appropriate.
Quality	Beneficiaries should receive care that is safe, effective, patient centered, and timely.
Resource use	Care should be provided efficiently; that is, it should produce a given quality outcome with the fewest inputs.
Equity	Payments should be adequate for the efficient provider and not make some services significantly more financially attractive than others. Out-of-pocket costs should not unduly burden particular classes of beneficiaries.

serious shortcomings in quality as well as the absence of real progress toward restructuring heath care systems to address both quality and cost concerns.

How should reform proposals be evaluated?

To help analyze different approaches to payment and delivery system reform, the Commission has created a framework for evaluating reform proposals that sets the goal of reform as achieving value for the Medicare program and defines operational objectives for reform proposals to achieve.

The goal of reform should be to increase the value of the Medicare program to beneficiaries and taxpayers—that is, to improve the efficiency of health care delivery without lowering access or quality. The determinants of the program's value are access to care, quality of care, resource use, and equity (Table 1-1). These concepts are not mutually exclusive. For example, beneficiaries cannot receive high-quality care if they lack access to care. Similarly, access and equity are interrelated; if some services are overpaid relative to others, there may be excessive provision of those services and lessened access to services that are relatively underpaid.

Policymakers can use these determinants of value to help assess the merits of reform proposals. For example, does a given proposal increase access or quality? Does it encourage efficient resource use and increase equity? Reform proposals should make these links explicit when possible, which will help policymakers judge how far a reform proposal moves toward the goal of improving value for the Medicare program.

In addition to the overall goal of improving value, it is also useful to set operational objectives that reform proposals should achieve. We derive these objectives from an analysis of the problems that prevent Medicare from achieving value in the current program.

Barriers to achieving value in Medicare

Medicare, as well as other public and private health care payers, faces fundamental problems that create barriers to getting the best value for its expenditures. In an ideal health care system, providers would be accountable for both the quality of the care they provide and the Medicare resources their patients use—even if those resources were provided by others. Providers would have the information they need to furnish better care and reduce or limit growth in resource use, Medicare administrators and policymakers would have sufficient data to create tools to give information to beneficiaries and providers in usable form and to formulate better policies, and beneficiaries would have the information they need to maintain a healthy lifestyle and to choose the highest quality care at the lowest cost. Payment rates would be accurate and send the right signals to providers about which services are of high value, and new technology would be used only when it generates outcomes of greater value than the alternatives. However, Medicare and the health care system nationwide fall dramatically short of this ideal.

Lack of accountability and care coordination

Fragmented delivery systems, lack of information, and perverse incentives are barriers to full accountability. Most providers have some degree of accountability for the care they furnish. They may provide quality care to uphold professional standards and to satisfy patients. In most instances, they may also want to control their own costs to improve their financial performance. But providers are not accountable for the full spectrum of care a beneficiary may use, even when they make the referrals that dictate resource use. For example, physicians ordering tests or

hospital discharge planners recommending post-acute care do not have to consider the financial implications of the care that other providers may furnish. This fragmentation of care puts both quality of care and efficiency at risk.

Beneficiaries may not be sufficiently accountable for the choices they make among providers or therapies because insurance may insulate them from the financial consequences of health care and lifestyle choices.

Finally, the Medicare program could do more to be accountable to beneficiaries, taxpayers, and the Congress for the program's value. Although the Medicare program has made important strides in becoming not just a payer of claims but a prudent purchaser (examples are the program's investment in developing and reporting quality measures and launching of demonstration programs to test P4P and care coordination), many payments do not reflect the true value of the service being bought. Duplicative tests or imaging, for example, may seldom add much value.

Lack of information and the tools to use it

Profound gaps in information on providers' costs and quality and appropriate clinical practices pose major barriers to fundamental health care reform. The program and its providers lack the information and tools needed to improve quality and use program resources efficiently. For example, Medicare lacks quality data from many settings of care, does not have timely cost or market data to set accurate prices, and does not report resource use back to providers. Individually, providers may have clinical data, but they may not have the information in electronic form, leaving them without an efficient means to process it or an ability to act on it. Crucial information on clinical effectiveness and standards of care either may not exist or may not have wide acceptance. In this environment, it will be a difficult challenge to determine what health care treatments and procedures are needed, and hence what resource use is appropriate, particularly for Medicare patients, many of whom have multiple comorbidities.

Information is also needed to improve the efficiency of hospitals and health care plans. For example, optimized operating room scheduling can increase capacity without new construction. Although systems-engineering tools for designing and analyzing the operations of such complex systems exist, those tools need information that is best supplied by sophisticated information technology (IT) systems. Where investment in IT systems has lagged, use of those tools may be stymied.

The Commission has often decried the lack of current data on which to make policy judgments. Sources of information for policy analysis on the Medicare Part D prescription drug program and the Medicare Advantage program are not available. Basic data sources such as cost reports and claims need to be improved, and a set of quality measures that reflect evidence-based medicine should be developed. This information development is needed to support provider and beneficiary choices as well as payment policy.

Beneficiaries are now being called on to make complex choices among delivery systems, drug plans, and providers. But information for beneficiaries that could help them choose higher quality providers and improve their satisfaction is just beginning to become available.

Inaccurate payment rates

Within Medicare's payment systems, the payment rates for individual products and services may not be accurate. The basic concept of accuracy is the efficient provider's average cost of furnishing a service. However, it is difficult to observe this price in the market because of the market failures in the current health care system, such as asymmetric information, moral hazard, imperfect risk adjustment, and a lack of competition in some markets.[4]

In markets that are noncompetitive or where competition is based on amenities and technology (i.e., a medical arms race), dominant providers may be able to set prices for private-sector payers well above the efficient providers' costs. Yet, in some of those markets Medicare may be able to set rates that all providers have to accept because of the share of the market Medicare represents. The tension between these two phenomena may mean an accurate payment rate is one just high enough to ensure access for Medicare beneficiaries—whatever its relation to costs or prices paid by other payers. This is a challenging concept to put into operation both because there is a lack of information about access across myriad health care markets and because simply defining what constitutes adequate access to appropriate care is difficult.

Inaccurate payment rates in Medicare's payment systems can lead to unduly disadvantaging some providers and unintentionally rewarding others. For example, under the physician fee schedule, fees are relatively low for primary care and may be too high for specialty care (see Chapter 2). This payment system bias has signaled to physicians that they will be more generously paid for procedural, specialty care, resulting in higher volume growth in this

area. In turn, these signals could influence the supply of providers, resulting in oversupply of specialized services and inadequate numbers of primary care providers—which would be an example of perverse incentives in the payment systems.

Poorly targeted technology diffusion

Technology diffuses rapidly across the health care system without sufficient analysis or guidelines that target its use to the patients who will benefit the most. Technologies—like prescription drugs, surgeries, and devices—are typically developed to focus on a specific problem, and the evidence supporting their use is generally based on studies using carefully selected patient populations. However, their diffusion can be based on financial incentives rather than efficiency. Manufacturers have strong marketing programs, physicians have incentives (including ownership of imaging equipment) to provide care that generates revenues, and insurance may pay for the technologies with few restrictions. This interaction of insurance coverage and asymmetric information between physicians and patients tends to result in technologies expanding into patient populations where the benefits of therapies are less clear.

Technology diffusion is exacerbated in some cases by Medicare's coverage and payment policies and has clear implications for efficient resource use. The rapid increase in imaging may be an example of modalities valuable for some patients being used on a wider population and in more settings (perhaps exacerbated by the pricing problems mentioned earlier). Our imaging recommendations have called for setting quality standards for providers, improving coding edits, and encouraging payment accuracy and higher quality (MedPAC 2005a).

At the same time that revenue-increasing technologies disseminate rapidly, some innovations in care that improve quality seem to disseminate slowly. For example, checklists to improve quality in intensive care units have been shown to substantially reduce central line infections, yet they are not in use uniformly (Gawande 2007, Provonost et al. 2006). Understanding why the rate of dissemination for beneficial delivery changes is so slow is essential; increasing that rate could have substantial payoffs for the health care system and Medicare. Lack of sufficient financial incentives to adopt these technologies is part of the problem.[5] Medicare could create clear financial incentives to directly reward hospitals that deliver therapies effectively (e.g., reducing central line infections to target levels) and penalize hospitals that do not. In addition to direct financial incentives and P4P, another approach could be to charge a comparative-effectiveness entity (which the Commission recommended in its June 2007 report) with developing and disseminating evidence-based information on therapies and processes, such as checklists for controlling central line infections (MedPAC 2007c).

Objectives for reform proposals

To be effective in overcoming these barriers that prevent the Medicare program from achieving value, the Commission has determined that reforms should:

- ***Promote accountability and care coordination.*** Providers should be held accountable for the Medicare resources used by the beneficiaries they treat. The autonomy that providers value must be accompanied by accountability to increase value in the Medicare program. Making providers more accountable should improve quality and achieve more efficient resource use. Providers should be encouraged to coordinate care with other providers and break down some of the barriers that current payment systems may create.
- ***Create better information and tools to use it.*** Reforms should encourage the collection and dissemination of clinical and resource information and tools to make collection, dissemination, and analysis of the information easier. The reforms should not place an undue burden on CMS, providers, and beneficiaries. Better information combined with changes to the benefit structure could increase equity among beneficiaries and promote more efficient resource use and quality.
- ***Improve incentives.*** Reforms should encourage higher efficiency—both lower cost production and higher quality—rather than increases in volume. In addition, a policy should address the problem it is intended to solve efficiently. For example, an intervention should focus on the providers or beneficiaries for which it creates the most value.
- ***Set accurate payment rates.*** Reforms should send the correct signals to providers, beneficiaries, and purchasers and avoid unduly favoring some services and beneficiaries with certain characteristics over others.[6]

It is vitally important that reforms hold true to the basic tenet of the Medicare program—ensuring that beneficiaries have affordable access to needed care. This

is the original purpose of the program, even though it may be imperfectly carried out in the current benefit design. As in other health insurance programs, cost sharing is a policy tool to make beneficiaries aware of the resources used in their care and to signal to them which choices of health plans, providers, or treatments may provide better value. (Supplemental insurance that covers cost sharing may make this tool less effective and thus raises other policy issues.) At the same time, a cost-sharing policy should protect beneficiaries from medical bills that exceed their reasonable ability to pay.

Policies should also promote alignment with the private sector. For example, using the same quality measures in public and private P4P programs would greatly simplify and reduce the cost of gathering data. Coordinating programs across all payers would provide greater leverage to influence providers' behavior and at the same time decrease their administrative burden.

Direction for delivery system reform

Without change, the Medicare program is fiscally unsustainable over the long term. In the Commission's view, a fundamental change in the organization and delivery of health care is needed to make care more affordable and of higher quality. However, structural changes may not be enough to achieve sustainability; other actions, such as financing alternatives, may be needed as well, as discussed in Chapter 1 of our March 2007 report (MedPAC 2007a). Many agree that change is needed and that Medicare should seek ways to encourage a more coordinated and clinically integrated care delivery system. But there is less agreement about what such a system should look like and what steps are needed to get there.

Payment system evolution

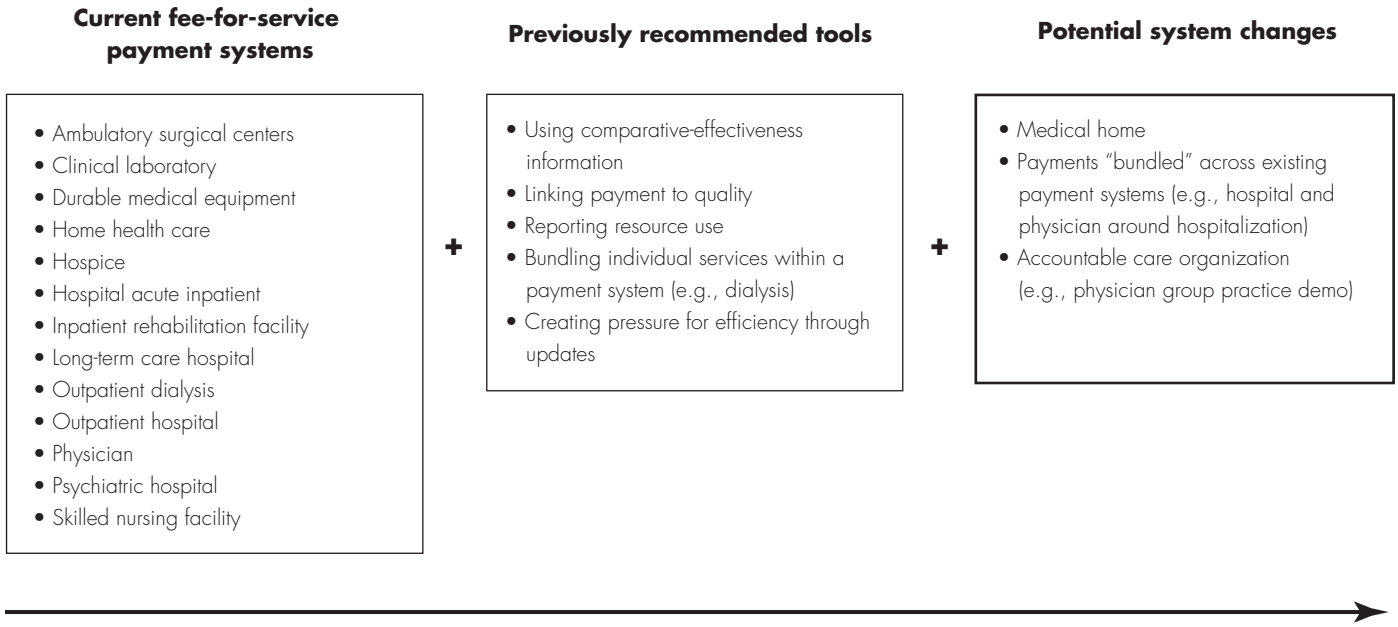
In previous years, the Commission has recommended tools for increasing efficiency and improving quality within existing Medicare payment systems. These include encouraging the use of information on the comparative effectiveness of medical services and procedures, linking providers' payment to quality measures, measuring resource use and providing feedback, improving payment accuracy within Medicare payment systems, and maintaining sufficient economic pressure on providers to encourage cost control. (The text box, pp. 13–15, provides a detailed description of these tools.) However, in the current Medicare FFS payment system environment, the benefit of these tools is limited for two reasons. First, they may not be able to overcome the strong incentives inherent in any FFS system to increase volume. Second, paying for each individual service and staying within current payment system silos (e.g., the physician fee schedule or the inpatient prospective payment system) inhibits changes in the delivery system that might result in better coordination across services and lead to efficiencies or better quality across these systems. For example, in current payment systems, there is no reward for providing timely physical therapy instead of expensive imaging for low back pain, even if it is of higher value and leads to greater patient satisfaction (Kaplan 2006).

To increase value for the Medicare program, its beneficiaries, and the taxpayers, we are looking at payment policies that go beyond the current payment system boundaries of scope and time. The new direction contemplated would pay for care that spans across provider types and time and would hold providers accountable for the quality of that care and the resources used to provide it. It would create integrated payment systems that reward value and encourage closer provider integration, which, in turn, would make the use of tools such as P4P even more beneficial. For example, if Medicare held physicians and hospitals jointly responsible for outcomes and resource use, new efficiencies such as standardization of operating room supplies could be pursued. In the longer term, joint responsibility could lead to closer integration across these two parts of the health care delivery system, which in turn could allow more comprehensive measures of quality—including outcome measures—and potentially more powerful P4P programs.

This chapter outlines three delivery system reform concepts: a medical home that provides a beneficiary with a single place to go for primary care and care coordination; bundling hospital and physician payments for a hospital admission; and accountable care organizations (ACOs), which would create incentives to control costs and coordinate care across a large set of providers and allow accountability for care over time. This evolution is illustrated in Figure 1-1 (p. 12). These three concepts are not the end point for reform and further reforms could move the payment systems farther away from FFS and toward systems of providers who accept some level of risk.

One consideration is whether changes in the incentives in the payment systems will lead to changes in the delivery system. We look at evidence of how physicians and hospitals have responded to changing incentives in Chapter 3. Another consideration is whether the current

FIGURE 1–1 **Direction for payment and delivery system reform**



benefit design and cost sharing need to be reformed to modify the demand for services, which could reinforce the supply-oriented reforms we discuss here. Changes to benefit design and cost sharing are an important consideration and essential to protect beneficiaries from catastrophic costs, but are outside the scope of this chapter.

Potential system changes

We discuss three concepts that might move the program in the direction of better coordination and more accountable care: the medical home, bundled hospital and physician payments, and ACOs. Implementing any of these concepts will present many thorny issues and will require careful consideration of unintended consequences and possible interactions with the incentives in other payment systems. Nonetheless, because these concepts have the potential to improve quality and reduce cost growth, the Commission considers them worthy of serious study and investigation and recommends pursuing them expeditiously.

Concept 1: Medical home

One concept for achieving greater care coordination, particularly for people with multiple chronic conditions, is the medical home. A medical home is a clinical setting with the capability to improve care coordination and follow evidence-based guidelines; it serves as the central resource for a patient's ongoing care. Medical homes should have at least the following capabilities:

- furnish primary care (including coordinating appropriate preventive, maintenance, and acute health services);
- conduct care management;
- use health IT for active clinical decision support;
- have a formal quality improvement program;
- maintain 24-hour patient communication and rapid access;
- keep up-to-date records of beneficiaries' advance directives; and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

A medical home in Medicare would coordinate care not only among providers but also between visits (e.g., through e-mail and telephone reminders), encouraging beneficiaries to adhere to care guidelines and track

Tools the Commission has recommended for increasing efficiency and quality

The Commission has devoted much of its work to increasing efficiency and quality in the Medicare program. In this text box, we review our recommendations on encouraging the development and dissemination of comparative-effectiveness information, measuring and rewarding higher quality, measuring resource use, and creating pressure to control costs by constraining payment updates. The Commission's many recommendations on improving payment accuracy are not reiterated here.

Tool 1: Encouraging the use of comparative-effectiveness information

Comparative-effectiveness analysis compares the clinical effectiveness of a service (drugs, devices, diagnostic and surgical procedures, diagnostic tests, and medical services) with its alternatives. In our June 2007 report, we found that not enough credible, empirically based information is available for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions (MedPAC 2007c). Many new technologies disseminate quickly into routine medical care with little or no basis for knowing whether they outperform existing treatments. Information about the value of alternative health strategies could improve quality and reduce variation in practice styles.

Although several public agencies conduct comparative-effectiveness research, it is not their main focus and their efforts are not conducted on a large enough scale. For private-sector groups, conducting this type of research is costly and, when it is made publicly available, the benefits accrue to all users, not just to those who pay for it. Because the information can benefit all users and is a public good, it is underproduced by the private sector; a federal role is necessary to produce unbiased information and make it publicly available.

Consequently, the Commission recommended that the Congress charge an independent entity to sponsor credible research on comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers. Specific aspects of such an entity, including funding and governance, are developed further in Chapter 5 of this report.

The entity's primary mission would be to sponsor, compile, and disseminate studies that compare the clinical effectiveness of a service with its alternatives. The entity would not make decisions on payment or coverage. Payers, including Medicare, could use this information to inform coverage and payment decisions and actively promote more effective treatments. Although cost effectiveness is not the primary mission, the Commission recognized that the entity would produce such analyses in some instances. In the simplest case, cost may be an important factor to consider for two services that are equally effective for a given population. Even when clinical effectiveness differs, it may be important for end users to be aware of costs.

For a complete discussion of the Commission's views on the use of comparative-effectiveness analysis in Medicare, see our June 2007, 2006, and 2005 reports to the Congress (MedPAC 2007c, MedPAC 2006, MedPAC 2005b).

Tool 2: Linking payment to quality

Medicare has a responsibility to ensure that its beneficiaries have access to high-quality care that is of value to the beneficiary and the program. The Commission has made a series of recommendations to tie payments to quality. Measures of quality and guidelines for appropriate care are becoming increasingly available. The Medicare program has been a leading force in efforts to develop and use quality measures, often leading initiatives to publicly disclose quality information, standardize tools for data collection, and give feedback to providers for improvement. CMS has also revised its regulatory standards to require that providers, such as hospitals and home health agencies, have quality improvement systems in place. In addition, CMS is conducting a number of demonstrations to explore whether financial incentives can improve the quality of care.

Nevertheless, Medicare's existing payment systems continue to reward providers for the volume but not the

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Tools the Commission has recommended for increasing efficiency and quality (cont.)

quality of the care they provide. Under the incentives in these payment systems to generate volume, poor care that results in complications requiring additional treatment is often rewarded. The same negative or neutral incentives toward quality exist in the private sector. Many private purchasers and health plans are experimenting with mechanisms to counterbalance these forces and reward those who provide high-quality care. Yet they agree that Medicare's participation in these efforts is critical because of its market power (MedPAC 2003).

In a series of reports, we have recommended that Medicare change payment system incentives by basing a portion of provider payment on performance. In our June 2003 report to the Congress, we established criteria for measures to determine whether pay-for-performance (P4P) initiatives were feasible in Medicare and developed guidance on how to administer and fund a P4P program (MedPAC 2003).

In other reports to the Congress, we evaluated available measures and measurement activities and recommended that the Congress establish a quality incentive payment policy for physicians, Medicare Advantage plans, dialysis facilities, hospitals, and home health agencies (MedPAC 2005a, MedPAC 2004a). We also recently recommended linking payments for skilled nursing facilities to quality (MedPAC 2008). The Institute of Medicine echoed our earlier recommendations.

To implement P4P, the Congress must first give the Medicare program the ability to pay providers differentially based on performance. To minimize major disruptions, the program should be funded initially by setting aside a small portion of budgeted payments—for example, 1 percent to 2 percent. The financing of P4P should be budget neutral; all monies set aside should be redistributed to those providers who perform as required.

The Commission will continue to examine P4P initiatives in future work. The complete list of the Commission's recommendations on P4P can be found in our March 2005, March 2004, and June 2003 reports to the Congress (MedPAC 2005a, MedPAC 2004a, MedPAC 2003).

Tool 3: Measuring resource use and providing feedback

In its March 2008 and 2005 reports to the Congress, the Commission recommended that CMS measure physicians' resource use over time and share the results with physicians (MedPAC 2008, MedPAC 2005a). Those who used comparatively more resources than their peers could assess their practice styles and modify them as appropriate, relying on evidence-based research or otherwise recommended clinical practices. Moreover, by linking this information with information on quality of care, Medicare will have a better basis for payment and for improving the value of care beneficiaries receive.

Private payers increasingly measure resource use to help contain costs and improve quality (MedPAC 2004b). Evidence on payers' cost savings resulting from analysis of resource use is mixed and varies depending on how the payer uses the results. Providing feedback on use patterns to physicians alone has been shown to have a statistically significant, but small, downward effect on resource use (Balas et al. 1996, Schoenbaum and Murray 1992). However, when paired with additional incentives, the effect on physician behavior can be considerably larger (Eisenberg 2002). Our recent site visits found considerable interest and effort in measuring resource use by private plans but few documented results thus far.

Medicare's feedback on resource use has the potential to be more successful than previous experience in the private sector. Because Medicare's reports would be based on more patients than private plan reports, they may have greater statistical validity. This, in turn, could lead to greater acceptance from physicians. Confidential feedback of the results to physicians may be sufficient to induce some change. Typically, physicians are highly motivated individuals who strive for excellence and peer approval (Tompkins et al. 1996). If identified by CMS as having an unusually resource-intensive style of practice, some physicians

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Tools the Commission has recommended for increasing efficiency and quality (cont.)

may respond by reducing the intensity of their practice. However, confidential information alone may not be sufficient to have a sustained, large-scale impact on physician behavior. This information may have to be linked to payment to change physician behavior. Over time, information on physician or group resource use and quality could be made available publicly to help beneficiaries make choices and decisions. Doing so would require determining what information would be most useful to beneficiaries and how it could be made available in an understandable form.

The Commission's recommendations on this topic can be found in our March 2005 report to the Congress (MedPAC 2005a). Detailed analysis of resource utilization software is presented in our March 2007 sustainable growth rate report and in our June 2006 report (MedPAC 2007b, MedPAC 2006).

Tool 4: Creating pressure for efficiency through payment updates

One of the Commission's primary roles is to recommend to the Congress how much Medicare fee-for-service payment systems should be updated each year. An update is the amount (usually expressed as a percentage change) by which the base payment for all providers in a prospective payment system is changed. The Commission considers a number of factors in its deliberations each year to determine payment adequacy in each sector and how much providers' costs are likely to change. One factor is whether providers in the sector are under enough financial pressure to be efficient and contain costs. If not, costs may be growing faster than the Medicare program can accommodate and the update may be constrained to create the pressure to restrain cost growth.

Although the update is a somewhat blunt tool for constraining cost growth (updates are the same for all providers in a sector, both those with high costs and those with low costs), constrained updates will create more pressure on those with higher costs. Updates as a cost-containment tool can have limited effectiveness, however, when providers continue to have strong incentives to increase service volume even when payment rates are constrained. ■

their progress. The home would be responsible for the health of the beneficiary over time and would receive a monthly fee for each beneficiary in the medical home program. Chapter 2 provides a more complete description of the medical home concept and the Commission's recommendation to establish a medical home pilot in Medicare. To participate in this pilot, medical homes would need to meet stringent criteria including the capabilities listed above. The Commission recommends that the pilot include a physician P4P program to encourage quality and efficiency. Additionally, the pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or be discontinued.

This concept could be expected to improve quality; quality measurement would be an integral part of the design. It might also eventually control resource use, although that would depend on the design and the extent to which the home were held accountable for total Medicare payments for its beneficiaries.

Concept 2: Bundled physician–hospital payments

Under bundled payment, Medicare would pay a single provider entity (composed of a hospital and its affiliated physicians) an amount intended to cover the costs of providing the full range of care needed over the hospitalization episode. With the bundle extending across providers, providers not only would be motivated to contain their own costs but also would have a financial incentive to choose new providers or collaborate with current partners to improve their collective performance. Providers involved in the episode could develop new ways to allocate this payment among themselves. Ideally, this flexibility gives providers a greater incentive to work together and to be mindful of the impact their service use has on the overall quality of care, the volume of services provided, and the cost of providing each service. In the early 1990s, Medicare conducted a successful demonstration of a combined physician–hospital payment for coronary artery bypass graft admissions, showing that costs per admission could be reduced without lowering quality.

In Chapter 4, we explore how the intent of bundling—holding providers accountable for care delivered over time and providing an incentive to work together—could be pursued through three concurrent policies:

- reporting to hospitals and physicians about their resource use around hospitalization episodes;
- reducing payments to hospitals with relatively high readmission rates for select conditions, coupled with shared accountability, or gainsharing, between hospitals and physicians; and
- a pilot program of bundled payments.

As we discuss in Chapter 3, hospitals and physicians have responded to the incentives in the current FFS payment systems by implementing various financial and organizational arrangements that enable, encourage, or reward volume growth. History suggests that it may be difficult to structure incentives to encourage physician–hospital clinical integration that controls resource use. It will be important to give financial incentives for physicians and hospitals to work together to improve the clinical quality of care (e.g., have lower readmission rates).

Anticipated effects on access, quality, and equity would depend on the design. Controlling resource use around the hospital stay might be feasible, but controlling changes in the number of episodes may be more difficult. Medicare may need to consider additional policies to control per capita admission rates.

Concept 3: Accountable care organizations

The goal of an ACO is to promote accountability for quality and resource use over an extended period of time for a population of patients. Under an ACO, physicians and other providers are encouraged to work together and improve care coordination. Over time, such organizations might control growth in the volume of services provided and improve the quality of their services. This concept could complement medical homes, which in some cases may be too small to support full accountability, and hospital–physician bundling, which creates no incentive to control the volume of initial admissions.

Some existing multispecialty group practices and integrated delivery systems (hospital and physician organizations) might already function as ACOs and could test the concept by volunteering to be accountable for a patient population and be rewarded on their performance. Performance could be measured against the group's baseline for resource use as is done in the physician group practice demonstration. For example, the ACO would receive FFS payments, some portion of which would be withheld and then returned if they met quality or cost targets. If both quality and cost targets were met, providers could receive the withhold and a share of the cost savings as a bonus. If they met neither quality nor cost targets, CMS could retain the withhold as a penalty. This shared savings approach differs from the capitated payment approach used in the Medicare Advantage (MA) program in that under shared savings the Medicare program retains its ability to set provider (e.g. hospital, physician) payment rates. This is important in markets with a dominant hospital or physician group that can dictate prices to MA plans. To foster the development of these organizations, payment incentives (both rewards and penalties) would need to be strong enough to counter the current incentives in the FFS program. With the correct incentives, ACOs might eventually improve health care quality and value while maintaining access to care.

An alternative approach to voluntary ACOs could be mandatory, virtual ACOs. This approach could be based on the extended hospital medical staff construct we described in our report on the sustainable growth rate last March (MedPAC 2007b). It drew on Elliot Fisher's work, which identifies through claims data a group of physicians that either practice in or treat patients who go to a particular hospital. The performance of that group of physicians can be assessed for the population of patients attributed to them. This concept might be used as a reporting mechanism. CMS could inform physicians what empirically defined virtual group they are part of and what that group's performance is relative to other groups.

Issues to be resolved

As these concepts and other payment system reforms are developed, policymakers will need to resolve several fundamental issues:

- How can incentives at the individual physician, group, or joint physician and hospital level be coordinated to obtain best value for the Medicare program? On the one hand, it may be desirable for groups of physicians and hospitals to be jointly responsible for a common set of process and outcomes measures. If they share responsibility for each measure, their incentives would be aligned to work together to improve performance, and the validity of the measure may be increased by the larger number of occurrences. On the other hand, some providers may be reluctant to be held

responsible for outcomes that are not completely in their control, and making a group rather than an individual the locus of responsibility may dilute the magnitude of individuals' financial incentives to improve their performance. In addition, the form of provider organization may vary by community, further complicating the coordination of measures and incentives at different levels.

- Can payment design accommodate small groups of providers in light of issues such as imperfect risk adjustment and acceptance of risk? Also, will measures of quality and resource use have sufficient statistical significance for small groups of patients?
- What responsibilities do beneficiaries have? Should cost sharing be designed to motivate patients to use certain providers? To what degree should patients be locked in to seeking care from a set of providers once they pick their provider? What information would be most useful to help beneficiaries make better choices and how can it be made available?

These issues will play a role in determining how far and how fast reform can progress. The process of reform should begin as soon as possible, even while certain issues are being resolved, because reform will take many years and Medicare's financial sustainability is deteriorating. The process of fundamental reform is evolutionary, and not knowing the final design should not deter us from beginning. ■

Endnotes

1 Although average life expectancy has increased in the United States, a recent study found: "From 1983 to 1999 life expectancy declined significantly in 11 counties for men (by 1.3 y) and in 180 U.S. counties for women (by 1.3 y)" (Ezzati et al. 2008).

2 In recent testimony to the Congress, Peter Orszag, Director of the Congressional Budget Office, stated:

> In the absence of significant changes in policy, rising costs for health care and the aging of the U.S. population will cause federal spending to grow rapidly. If federal revenues as a share of gross domestic product (GDP) remain at their current level, that rise in spending will eventually cause future budget deficits to become unsustainable. To prevent deficits from growing to levels that could impose substantial costs on the economy, revenues must rise as a share of GDP, or projected spending must fall—or some combination of the two outcomes must be achieved.
>
> For decades, spending on Medicare and Medicaid—the federal government's major health care programs—has been growing faster than the economy, as has health spending in the private sector. The rate at which health care costs grow relative to national income—rather than the aging of the population—will be the most important determinant of future federal spending. The Congressional Budget Office (CBO) projects that under current law, federal spending on Medicare and Medicaid measured as a share of GDP will rise from 4 percent today to 12 percent in 2050 and 19 percent in 2082—which, as a share of the economy, is roughly equivalent to the total amount that the federal government spends today. (Unless otherwise indicated, all years referred to in this testimony are calendar years.) The bulk of that projected increase in health spending reflects higher costs per beneficiary rather than an increase in the number of beneficiaries associated with an aging population (CBO 2007).

3 This chapter focuses on changes to Medicare FFS payment systems that would encourage delivery system reform. But the payment system for Medicare Advantage plans also needs reform, as we have previously reported (MedPAC 2007b). Many Medicare Advantage plans have not changed the way care is delivered and often function much like the Medicare FFS program. Paying Medicare Advantage plans appropriately would increase pressure on them to compete to find efficiencies in care delivery and improve quality.

4 "Moral hazard" is the patient's decision to purchase health care services that have less value to the patient than the full cost of the care. Patients may choose to purchase care that they value less than the care's cost when their insurer is partially or fully paying the cost of care. For a discussion of why some of the additional health care services purchased due to insurance reflect an improvement in social welfare and some do not, see Nyman (2004).

5 When complications arise, Medicare often pays more for the care than it would for the basic diagnosis related group without complications. Even if Medicare will not pay for a particular complication, often the payment system will recognize another complication and increase payment.

6 One way to obtain information for setting payment rates is through the market, when conditions allow. CMS is starting to use competitive bidding to set prices—for example, for durable medical equipment. Medicare is also using competitive bidding in the Medicare Advantage program and in Part D. Those programs show the importance of designing a bidding system that elicits competitive bids that provide the best value for the Medicare program. Where markets support competitive bidding (e.g., many providers, relatively uniform products), it could lead to more accurate rates and eventually better resource use if inaccurate prices are driving inappropriate use.

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CHAPTER 2

Promoting the use of primary care

RECOMMENDATIONS

2A The Congress should establish a budget-neutral payment adjustment for primary care services billed under the physician fee schedule and furnished by primary-care-focused practitioners. Primary-care-focused practitioners are those whose specialty designation is defined as primary care and/or those whose pattern of claims meets a minimum threshold of furnishing primary care services. The Secretary would use rulemaking to establish criteria for determining a primary-care-focused practitioner.

COMMISSIONER VOTES: YES 15 • NO 2 • NOT VOTING 0 • ABSENT 0

2B The Congress should initiate a medical home pilot project in Medicare. 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),
- conduct care management,
- use health information technology for active clinical decision support,
- have a formal quality improvement program,
- maintain 24-hour patient communication and rapid access,
- keep up-to-date records of beneficiaries' advance directives, and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

Medicare should provide medical homes with timely data on patient utilization. The pilot should require a physician pay-for-performance program. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

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

CHAPTER 2

Promoting the use of primary care

Chapter summary

Patient access to high-quality primary care is essential for a well-functioning health care delivery system. Research suggests that reducing reliance on specialty care may improve the efficiency and quality of health care delivery. Areas with higher rates of specialty care per person are associated with higher spending but not improved access, quality, health outcomes, or patient satisfaction (Fisher et al. 2003a, Fisher et al. 2003b, Kravet et al. 2008, Wennberg 2006). Moreover, states with more primary care physicians per capita have better health outcomes and higher scores on performance measures (Baicker and Chandra 2004, Starfield et al. 2005).

Despite these findings, primary care services—which rely heavily on cognitive activities such as patient evaluation and management (E&M)—are undervalued and they risk being underprovided relative to procedurally based services. Indeed, the share of U.S. medical school graduates entering primary care residency programs has declined over the last decade, and internal medicine residents are increasingly choosing to subspecialize rather than practice as generalists (Bodenheimer 2006). Also, the Commission found that although a small

In this chapter

share of beneficiaries reported looking for a new physician in 2007, those looking for a primary care physician were more likely to report problems finding one than those looking for a new specialist (MedPAC 2008).

Given signals that primary care is undervalued, the Commission has approached the problem in three ways. First, the Commission recommended improvements to the process for reviewing the relative value of physician services (MedPAC 2006). These recommendations sought to address concerns that cognitive services—mainly E&M services—were being devalued over time. Although the formal process for reviewing the service values has not changed, the physician work component of certain E&M codes increased substantially in 2007.

The second initiative is included in this chapter and concentrates on services furnished by practitioners whose practices focus mostly on primary care. The Commission recommends increasing Medicare Part B payments for primary care services furnished by such practitioners. This adjustment, administered in a budget-neutral manner, would help overcome the undervaluation of primary care services in the physician fee schedule.

Recommendation 2A

The Congress should establish a budget-neutral payment adjustment for primary care services billed under the physician fee schedule and furnished by primary-care-focused practitioners. Primary-care-focused practitioners are those whose specialty designation is defined as primary care and/or those whose pattern of claims meets a minimum threshold of furnishing primary care services. The Secretary would use rulemaking to establish criteria for determining a primary-care-focused practitioner.

COMMISSIONER VOTES:
YES 15 • NO 2 • NOT VOTING 0 • ABSENT 0

The services selected for the adjustment—a subset of E&M services within the statutory definition of primary care—would be office visits, home visits, and visits to patients in certain nonacute facility settings (skilled nursing, intermediate care, long-term care, nursing home, boarding home, domiciliary, and custodial care). The adjustment would help to promote the use of primary care. To ensure that the adjustment reaches the intended physicians and other practitioners who are focused on primary care, it will be important to determine practitioner eligibility. Accordingly, the Commission recommends that the Secretary use claims data to confirm that practitioners

are meeting a minimum threshold for the percentage of services they furnish that are primary care services.

The third initiative, also introduced in this chapter, is to establish a medical home pilot program in Medicare. A medical home serves as a central resource for a patient's ongoing care. Other purchasers and payers have begun programs that recognize the value of having specified clinicians accountable for effectively managing patient care (Baron and Cassel 2008). Through a pilot project, Medicare could test the effectiveness of a medical home program to support and encourage care coordination across settings and among providers for complex patients—those with multiple chronic conditions. This pilot would include monthly, per beneficiary payments to qualifying medical practices for infrastructure and activities that promote ongoing, comprehensive care management. Beneficiaries would not incur any additional cost sharing for the monthly fees. Qualifying medical homes could include primary care practices as well as specialty practices that focus on care for certain chronic conditions, such as diabetes. To be eligible for these monthly payments, medical homes would be required to meet several stringent criteria. In rural areas, the pilot could test the ability of medical homes to provide high-quality, efficient care with fewer structural requirements.

Recommendation 2B

The Congress should initiate a medical home pilot project in Medicare. 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),*
- *conduct care management,*
- *use health information technology for active clinical decision support,*
- *have a formal quality improvement program,*
- *maintain 24-hour patient communication and rapid access,*
- *keep up-to-date records of beneficiaries' advance directives, and*
- *maintain a written understanding with each beneficiary designating the provider as a medical home.*

Medicare should provide medical homes with timely data on patient utilization. The pilot should require a physician pay-for-performance program. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

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

Although medical homes should offer their patients guidance on selecting appropriate specialty services, participating beneficiaries would retain their ability to see specialists and other practitioners of their choice, as they would remain in fee-for-service Medicare. While the medical home pilot would stress the importance of patient–clinician communication regarding service use outside the medical home, Medicare should also provide medical homes with timely data on patients' Medicare-covered utilization outside the medical home, including services under Part A, Part B, and drugs under Part D. These data will assist medical homes in comprehensive care management.

A medical home pilot provides an excellent opportunity to test and implement physician pay for performance (P4P). Under the pilot project, the Commission envisions that the P4P incentives would allow for rewards and penalties based on performance in quality and efficiency. Efficiency measures should be calculated from spending on Part A, Part B, and Part D, and efficiency incentives could take the form of shared savings models similar to those under Medicare's ongoing physician group practice demonstration. Bonuses for efficiency should be available only to medical homes that have first met quality goals and that have a sufficient number of patients to permit reliable spending comparisons. Medical homes that are consistently unable to meet minimum quality requirements would become ineligible to continue participation.

The medical home pilot should be on a large enough scale to provide statistically reliable results to test the hypothesis that medical homes can improve the quality and efficiency of care for patients with multiple chronic conditions. However, the pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued entirely.

Finally, policymakers should also consider ways to use some of the Medicare subsidies for teaching hospitals to promote primary care. Such efforts in medical training and practice may improve our future supply of primary care clinicians and thus increase beneficiary access to them. The Commission will examine medical training issues in the future. ■

The value of primary care

Patient access to high-quality primary care is essential for a well-functioning health care delivery system. Research suggests that reducing reliance on specialty care may improve the efficiency and quality of health care delivery. Areas with higher rates of specialty care per person are associated with higher spending but not improved access to care, higher quality, better outcomes, or greater patient satisfaction (Fisher et al. 2003a, Fisher et al. 2003b, Kravet et al. 2008, Wennberg 2006). Moreover, research has found that states with more primary care physicians per capita have better health outcomes and higher scores on performance measures (Baicker and Chandra 2004, Starfield et al. 2005). Cross-national comparisons have demonstrated that countries with greater dependence on primary care have lower rates of premature deaths and deaths from treatable conditions, even after accounting for differences in demographics and gross domestic product (Starfield and Shi 2002).

Undervaluation of primary care in the physician fee schedule

Despite research that suggests a need to increase the use of primary care services over specialty services, primary care services—which rely heavily on cognitive activities such as patient evaluation and management (E&M)—are undervalued (Ginsburg and Berenson 2007, Maxwell et al. 2007, MedPAC 2006). Unlike other services, primary care services do not lend themselves to efficiency gains. Instead, they are composed largely of activities such as taking the patient's history; examining the patient; and engaging in medical decision making, counseling, and coordinating care. These activities require the clinician's time both with the patient and before and after seeing the patient. Many Medicare patients need longer visits because they have multiple chronic conditions and some have a compromised ability to communicate with their physician.

By contrast, efficiency can improve more easily for other types of services, such as procedures, with advances in technology, technique, and other factors. For example, research on open heart surgery showed that advances in techniques and technology allowed physicians to become more proficient in performing procedures, taking less time per procedure (Cromwell et al. 1990). Ideally, when such efficiency gains are achieved, the fee schedule's relative value units (RVUs) for the affected services should decline accordingly, while budget neutrality would raise the RVUs for the fee schedule's primary care services.

The Commission recommended that CMS's process for reviewing the relative values of physician services be improved (MedPAC 2006). The three five-year reviews completed so far—in 1997, 2002, and 2007—led to substantially more recommendations for increases than decreases in the relative values of services, even though many services are likely to become overvalued as time passes. The Commission recognized the valuable contribution made by the Relative Value Scale Update Committee, but we concluded that CMS relies too heavily on physician specialty societies, which tend to identify undervalued services without identifying overvalued ones. The Commission found that CMS also relies too heavily on the societies for supporting evidence. In any case, because of these problems with the review process, the two-step sequence described above—lower RVUs for overvalued services and higher RVUs for primary care—tends not to occur, giving rise to concerns that primary care services are undervalued.

Although the formal process for reviewing the service values has not changed, the work component of certain E&M codes—including those most frequently billed (e.g., the midlevel office visit for established patients)—increased substantially in 2007. Practice expense values have also increased for E&M codes through CMS's new methods for calculating direct and indirect practice expense relative values.

Another issue that exacerbates the devaluation of primary care services relative to other types of services has been the constraint on payment updates for physician services. To the extent that the sustainable growth rate limits growth in aggregate physician spending, differences in the rate of volume growth across services means that certain types of services—such as imaging—are capturing a larger portion of Medicare physician spending at the expense of other services.[1] The Commission has expressed concern about primary care services, which have been found to be capturing a smaller portion of Medicare physician spending even though the overall relative value of E&M services has increased (MedPAC 2006). An Urban Institute analysis of changes in the relative values assigned to physician services and how those changes interact with growth in the volume of services sheds light on this dynamic (Maxwell et al. 2007).

In consideration of the devaluation of primary care services, the Commission is concerned that these services risk being underprovided, as physicians view them as less valued and less profitable. Yet, primary care services and—

TABLE 2–1 **Nearly one-third of physicians who regularly bill Medicare specialize in primary care, 2006**

Physician specialty	Number of physicians	Percent of total physicians
Primary care	152,929	31%
All other	344,143	69
Total	497,072	100

Note: Primary care specialties include family medicine, internal medicine, geriatric medicine, and pediatric medicine. Counts include allopathic and osteopathic physicians who billed for at least 15 Medicare patients during the year. Specialty information is from physicians' self-designation.

Source: MedPAC analysis of Health Care Information System data, 2006.

perhaps more importantly—primary care clinicians, are critical to delivering more coordinated, high-quality care to the Medicare population. Therefore, the Commission has undertaken three initiatives to promote the services, practitioners, and activities relevant to primary care. The first initiative was the Commission's 2006 recommendation (mentioned previously) to improve the process for reviewing the relative value of physician services. The second and third initiatives for promoting the use of primary care are introduced in this chapter: fee schedule changes to increase the value of primary care services provided by health professionals who focus predominantly on primary care, and the establishment of a medical home pilot project in Medicare. Before discussing these two initiatives in more detail, we present some background information on primary care and access issues.

What is primary care and who provides it?

Primary care is comprehensive health care provided by personal clinicians who are responsible for the overall, ongoing health of their patients. Primary care is often considered first-contact care that treats an array of health care needs, including preventive, acute, and chronic care (Grumbach and Bodenheimer 2002). Primary care providers are responsible for making and managing appropriate patient referrals to specialists and other caregivers. Comprehensive primary care involves teamwork that can include physician and nonphysician providers.

Physicians who specialize in primary care are trained in family medicine, internal medicine, geriatric medicine, or pediatrics. Of the almost 500,000 physicians who regularly treat Medicare beneficiaries, 31 percent specialize in primary care (Table 2-1). Although osteopathic physicians make up only 8 percent of these primary care physicians, 46 percent of osteopaths specialize in primary care.[2] Osteopathic physicians are disproportionately more likely to be located in rural communities (Peters et al. 1999).

Nurse practitioners and physician assistants also provide primary care. Data on the number of nonphysician practitioners treating Medicare patients is compromised because they often do not bill Medicare directly; rather, supervising physicians frequently bill for their time.[3] A recent report from the Government Accountability Office finds that about 83,000 nurse practitioners and 23,000 physician assistants are in primary care practice, and their numbers have grown faster than those of primary care physicians (GAO 2008b). These figures, however, are not specific to the Medicare population.

The Institute of Medicine noted the multidimensional nature of primary care, particularly for people with special needs and disabilities (IOM 1996). Although practitioners in certain specialties often provide primary care to their patients (e.g., endocrinologists for diabetes patients), this chapter mainly focuses on the physicians and other providers who specifically train in and provide primary care.

Beneficiaries value having a usual source of health care

Survey research suggests that most Americans value having a primary care physician who is familiar with their medical problems (Grumbach et al. 1999, Schoen et al. 2007). Medicare beneficiaries are more likely than their (typically) younger counterparts to report having a usual source of care. A "usual" source of care becomes even more important when considering that beneficiaries with chronic conditions typically see multiple health professionals during the year (Pham et al. 2007). Thus, initiatives to promote and sustain primary care as a usual source of care directly support beneficiary preferences for having a personal physician.

Survey results from the Medicare Current Beneficiary Survey (MCBS) suggest that most beneficiaries may already consider themselves to have a central source for their ongoing care—that is, a version of a medical home. Specifically, 95 percent report having a particular medical person or clinic that they usually go to when they are sick or want medical advice (Table 2-2). Most beneficiaries (86 percent) report their usual source of care to be a doctor's clinic, office, or group. About one-third report that they have been going to their usual source of care for

TABLE 2–2

Most beneficiaries report having a usual and thorough source of care, 2005

Question	Response percentage
Is there a particular medical person or clinic you usually go to when you are sick or for advice about your health?	
Yes	95%
No	5
N/A	0
What kind of place do you usually go to when you are sick or for advice about your health?	
Doctor's clinic, office, group practice	86
Hospital emergency room	<1
Other	9
N/A	5
How long have you been seeing this doctor or going to this usual place?	
Less than 1 year	9
1–2.9 years	16
3–4.9 years	16
5–9.9 years	20
10 or more years	33
N/A	5
If you usually see a particular doctor, what is that doctor's specialty?	
Family medicine	19
General practice	37
Internal medicine	25
Cardiology	2
Other	7
N/A	8
Among those who reported NOT having a usual source of care (5%), reasons given (not mutually exclusive):	
Seldom get sick	65
Recently moved to area	12
Doctor no longer available	15
Like to go to different places	11
Places are too far away	8
Medical care is too expensive	16

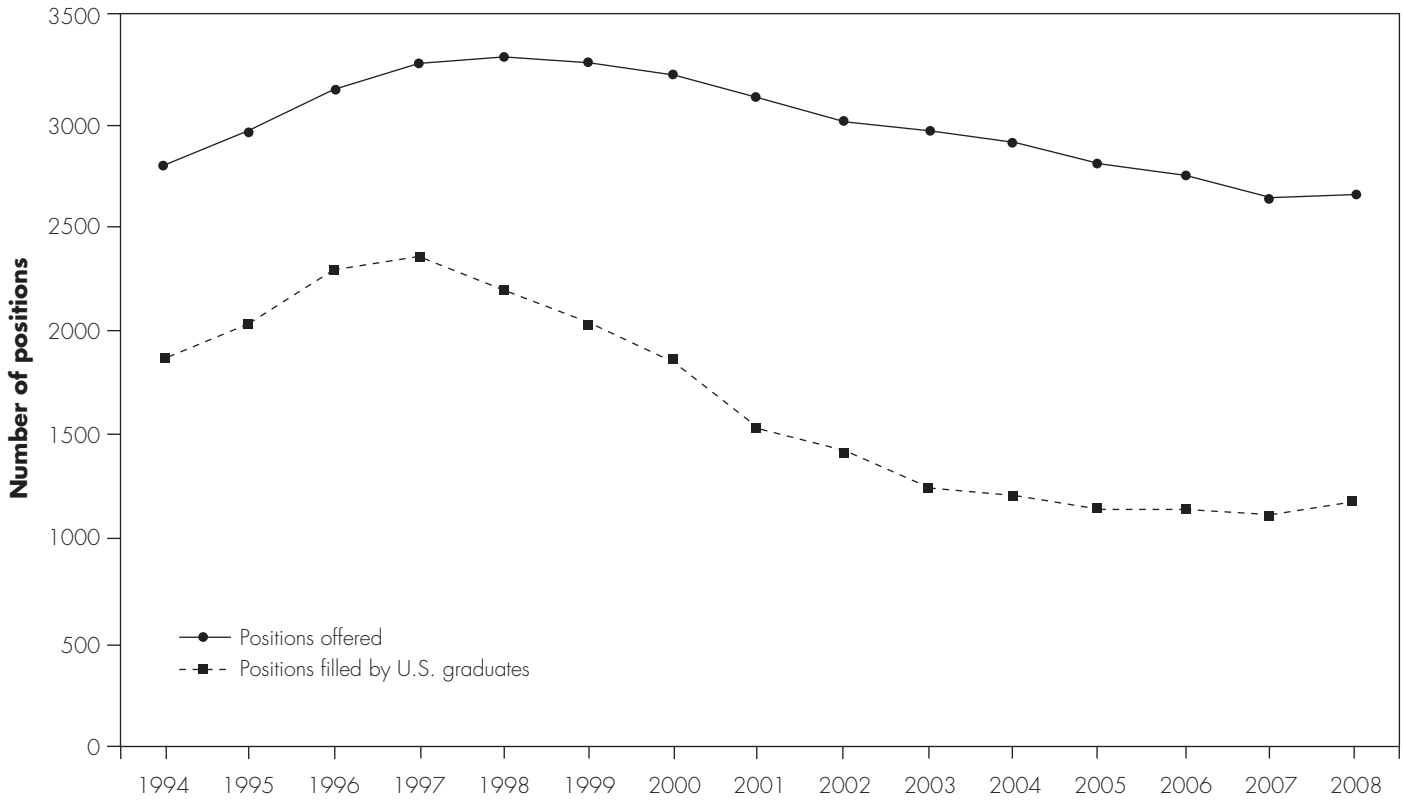
Question	Response percentage
Your doctor (or usual clinician) is very careful to check everything when examining you.	
Strongly agree or agree	91%
Strongly disagree or disagree	8
N/A	1
You often have health problems that should be discussed with your doctor (or usual clinician) but are not.	
Strongly agree or agree	9
Strongly disagree or disagree	89
N/A	2
Your doctor (or usual clinician) has a good understanding of your medical history.	
Strongly agree or agree	93
Strongly disagree or disagree	5
N/A	2
Your doctor (or usual clinician) often does not explain medical problems to you.	
Strongly agree or agree	10
Strongly disagree or disagree	89
N/A	1
Your doctor (or usual clinician) tells you all you want to know about your condition or treatment.	
Strongly agree or agree	91
Strongly disagree or disagree	8
N/A	1
Your doctor (or usual clinician) answers all your questions.	
Strongly agree or agree	95
Strongly disagree or disagree	4
N/A	1

Note: N/A (not applicable). Beneficiaries living in nursing facilities are excluded. Totals may not sum to 100 percent due to rounding and nonresponses.

Source: Medicare Current Beneficiary Survey Access to Care file, 2005.

FIGURE 2–1

Share of U.S. medical school graduates filling family medicine residency positions has declined over the last decade



Source: National Resident Matching Program (AAMC 2008).

10 years or more, and more than half report going for at least the past 5 years. Among those who report having a particular doctor at their usual place of care, 81 percent report that their doctor is trained in a primary care field, such as family medicine (19 percent), general practice (37 percent), or internal medicine (25 percent).[4]

Beneficiaries appear relatively satisfied with the care and attention they receive from their usual source of care. For example, 91 percent report that their doctor is careful to examine everything during their appointment. Only 9 percent of beneficiaries reported that they have health problems that should be discussed with their doctor but are not. Also, 93 percent reported that their doctor has a good understanding of their medical history. Small shares of beneficiaries indicate that the clinicians at their usual source of care do not explain their medical problems (10 percent) or do not answer all their questions (4 percent).

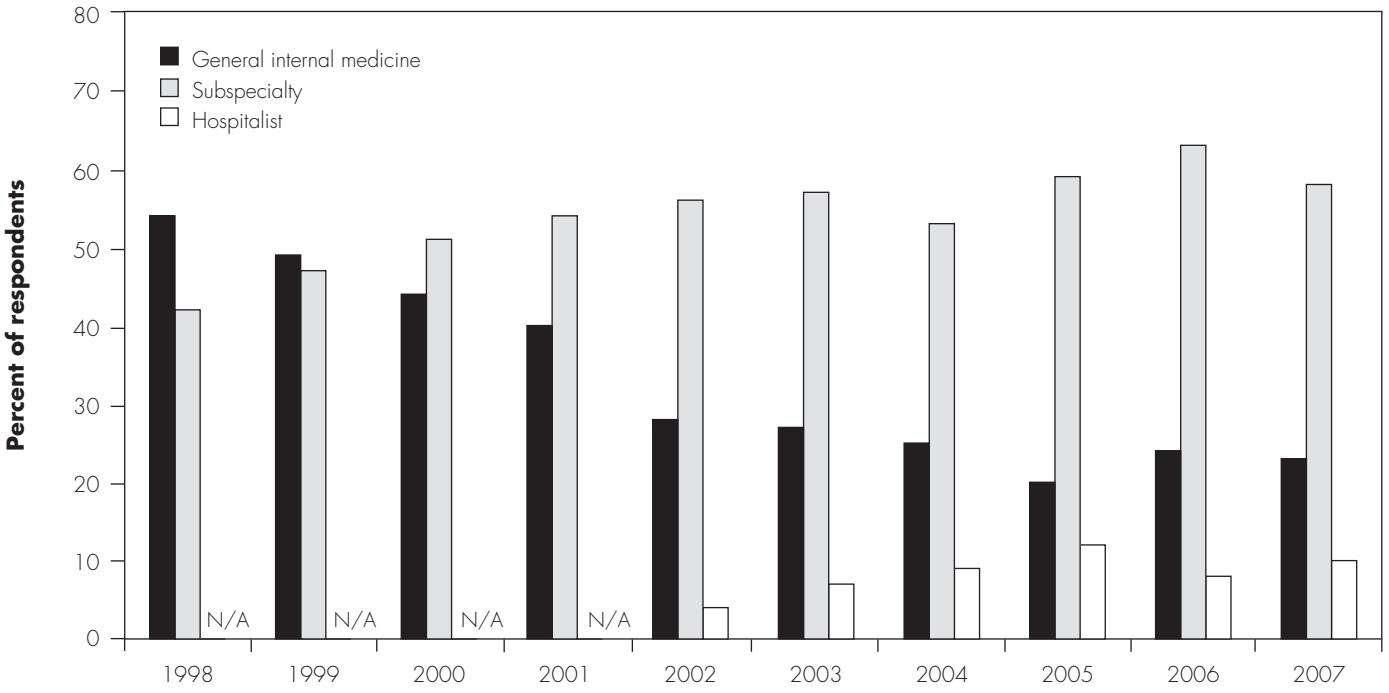
Among the small share of beneficiaries who reported not having a usual source of care (5 percent), the most common reason that they did not have a usual source of care was that they seldom get sick (65 percent). Other, less frequently cited reasons included medical costs, recently moving to the area, and their doctor no longer being available. A small share indicated that they preferred to seek medical care at different places rather than from a usual source. Because these results show that most beneficiaries strongly value having a usual source of care, signals that primary care is undervalued raise some concern about future access to primary care.

Access and medical training concerns

Although most beneficiaries report having a usual source of care, finding a new primary care physician

FIGURE 2–2

Proportion of third-year internal medical residents becoming subspecialists or hospitalists is 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.

appears more difficult than finding a new specialist (MedPAC 2008). In our 2007 beneficiary access survey, the Commission found that among the small share of beneficiaries looking for a new primary care physician, 30 percent reported some difficulties finding one. Specifically, 12 percent reported "small" problems and 17 percent reported "big" problems.

In addition to some access problems among those looking for a new primary care physician, another signal that primary care services may be undervalued relative to specialist services is the decline in the share of U.S. medical school graduates entering family practice and primary care residency training programs in the last decade (Figure 2-1). In recent years, international medical graduates have been filling this gap, but the trend may not adequately meet growing demand in future years.

Also, the proportion of third-year internal medical residents becoming generalists is declining because a growing share choose to subspecialize after residency or become hospitalists (Figure 2-2). Therefore, although the Government Accountability Office found that the number of physician residents in primary care training programs increased 6 percent over the last decade, it is important to understand that many of these residents do not remain in primary care practice (GAO 2008b).

The trend for medical students and residents to choose careers as specialists reflects a number of factors, including income prospects, lifestyle preferences (e.g., on-call schedules), student debt, and perceived prestige of specialists over generalists. Additionally, medical students may find family practice daunting because of perceived pressure to have vast knowledge about all health care problems. Policies to encourage medical training in primary care could improve primary care quality and access and thus promote beneficiary use of primary care services.

Medicare plays a large role in financing medical education and training. It provides two different payments to teaching hospitals: (1) graduate medical education (GME) payments toward the cost of resident and supervisory physician salaries, and (2) indirect medical education (IME) payments toward the higher cost of treating patients in a teaching hospital. These payments totaled about $8.6 billion dollars, or 2.3 percent of total Medicare program spending in 2006.

By statute, GME subsidies for individual teaching hospitals are based on a number of factors including a calculated number of allotted residency training positions. Although Medicare limits the amount of this subsidy, there is no limit on the number of residents a hospital may choose to employ. In general, Medicare places no specialty requirements when calculating the number of subsidized residency positions, nor does it require specific competencies in training curricula. Under certain circumstances, residents may train in ambulatory settings outside the hospital, but the hospital remains responsible for the residents' salaries and supervision costs.

Policymakers could consider ways to use some of these GME and IME subsidies toward promoting training in primary care. For example, a portion could be targeted specifically to support medical residency positions in primary care. Similarly, allocating shares toward nurse practitioners and physician assistants—key professionals in managing patients' chronic conditions—could be useful for promoting primary care services use. Further, a share of GME and IME subsidies could be expressly directed toward training all medical residents on the importance of primary care and interdisciplinary teams, quality measurement, and clinical uses for information technology (IT). Encouragement of geriatric training opportunities in nonhospital settings (e.g., nursing facilities) may also be useful. Medical education subsidies could also be used to help pay student loans for clinicians committed to primary care specialties. Primary care providers generally earn lower salaries than their more procedurally based counterparts (AMGA 2007, MGMA 2007, Modern Healthcare 2007). Therefore, student loan subsidies could somewhat offset incentives for medical students to select higher paid specialties to help pay off their medical school debts more easily.

Fee schedule adjustment for primary care

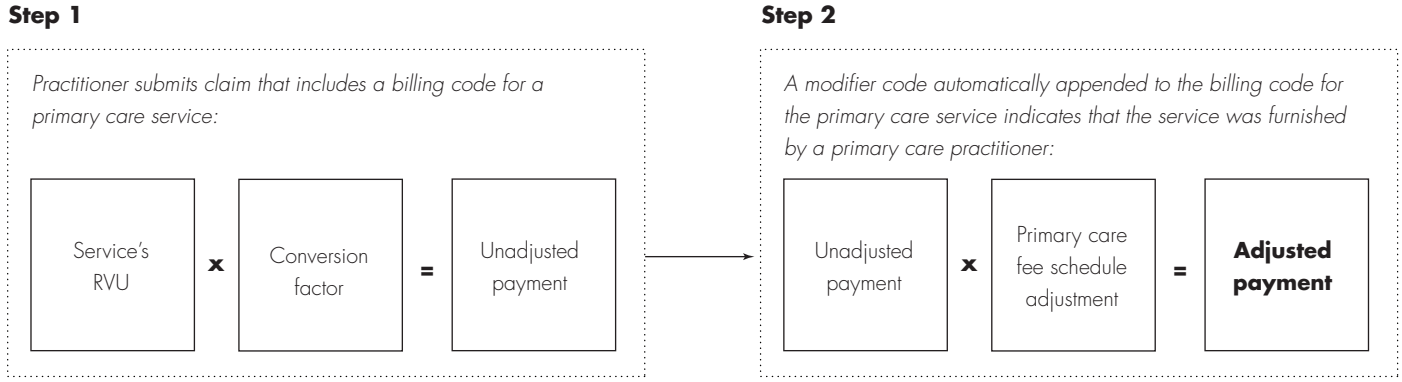
To promote use of primary care and redistribute payments toward services furnished by primary care providers, the Commission recommends that Medicare's payment system for physician services—the physician fee schedule—include an adjustment for primary care. The adjustment would raise payments for selected primary care services furnished by physicians, advanced practice nurses, and physician assistants with practices focused on primary care. Services we defined as primary care are a subset of E&M services: office and home visits and visits to patients in certain nonacute facility settings (skilled nursing, intermediate care, long-term care, nursing home, boarding home, domiciliary, and custodial care).[5]

For the adjustment to occur, Medicare would append information to claims for payment submitted by physicians, advanced practice nurses, and physician assistants. Specifically, Medicare's claims processing contractors would attach a special code—known as a modifier—to billing codes for primary care services furnished by qualifying practitioners. Under the physician fee schedule, modifiers signify payment adjustments; for example, modifiers specify whether a service is eligible for a bonus payment because it was furnished in a health professional shortage area or a physician scarcity area. The presence of a primary care modifier on the claim would trigger an adjustment that would bring about a higher payment (Figure 2-3).

The adjustment would target practitioners who focus on primary care services. The Commission's recommendation identifies two options for identifying such practitioners. The first option is to consider both a practitioner's specialty designation—geriatric medicine, family practice, internal medicine, and others—and whether he or she furnishes mostly primary care services instead of other services, such as procedures, imaging, and tests. As we discuss later, a practitioner's specialty is self-designated, and administrative changes would be needed to make a practitioner's specialty a reliable factor in determining eligibility for the adjustment.

The second option is to consider only whether the practitioner furnishes mostly primary care services. This option would not consider specialty designation. Instead, it would make the adjustment available to practitioners who

FIGURE 2–3 **Proposed payment adjustment for primary care could occur in two steps**



Note: RVU (relative value unit).

focus on primary care services even if they specialize in, for example, endocrinology or rheumatology.

To make the adjustment budget neutral, it would be funded by a reduction in the conversion factor for other services. Thus, the adjustment would lead to lower payment rates for services furnished by practitioners other than those receiving the adjustment. Even for practitioners receiving the adjustment, payment rates would go down for the services they furnish that are not office visits, home visits, or visits to patients in certain nonacute facility settings. Structured in this way, the adjustment would redistribute payments and reward primary care. It would also support investment in IT and other resources needed for the medical home programs discussed later in this chapter.

Physicians in specialties not focused on primary care have raised concerns about budget neutrality. However, there are three points to consider as they pertain to the Commission's recommendation. First, the recommendation does not mean that services subject to the reduction for budget neutrality should have lower RVUs. The five-year review would continue to address the RVUs for those services, as appropriate. Rather, the reduction for budget neutrality would occur through the fee schedule's conversion factor. Second, the Commission's position should not be viewed as a statement on the supply of practitioners furnishing services other than primary care. On the contrary, questions have been raised about the supply of generalist physicians outside of primary care, such as general surgeons (Fischer 2007). Instead, the Commission's position is that primary care is an overriding priority toward redesigning the health care delivery system in the long run. Third, the recommendation on the fee schedule adjustment is made in the context of other recommendations by the Commission for modest positive updates for physician services. For instance, the Commission has recommended an update for 2009 equal to the change in input prices for physician services less an adjustment for productivity, or about 1.1 percent (MedPAC 2008). By contrast, the preliminary estimate of the 2009 update under current law is −5.4 percent (see Appendix A, p. 243 of this report).

A rationale for the fee schedule adjustment is that primary care services appear to be undervalued in the fee schedule. In recommending improvements in the five-year review, the Commission expects that payments for primary care services and other E&M services will increase (MedPAC 2006). The fee schedule adjustment, however, is intended not just to increase payment for certain services but also to target the higher payments toward certain practitioners.

In addition to addressing concerns about the undervaluation of primary care, a fee schedule adjustment could augment other changes in policy that may help promote primary care. For instance, the Commission recommended that the Congress create an independent entity that would produce credible, empirically based information on comparative effectiveness—information that would help providers and patients make informed decisions about alternative services for diagnosing and

TABLE 2–3

Some practitioners derive much of their fee schedule payments from primary care services

Practitioner and specialty	Percent of allowed charges from primary care services
Physician	
Geriatric medicine	65.0%
Family medicine	62.5
Internal medicine	44.4
Pediatric medicine	36.5
Nurse practitioner	65.4
Physician assistant	34.8
All other	13.4

Note: Primary care services include office and home visits and visits to patients in certain nonacute facility settings (skilled nursing, intermediate care, long-term care, nursing home, boarding home, domiciliary, and custodial care). Analysis includes services billable under the physician fee schedule only.

Source: MedPAC analysis of 2006 claims data for 100 percent of Medicare beneficiaries.

treating common clinical conditions (MedPAC 2006). The Commission further discussed the option of allowing comparative effectiveness information to influence payment. For instance, a new set of budget-neutral RVUs that accounted for value as well as resource costs could be established in the fee schedule. To the extent primary care services are valued highly on their comparative effectiveness, they could garner higher payments through this policy change.

The fee schedule adjustment could have a meaningful impact on payments for the practitioners who receive it. Some practitioners derive a large share of their payments under the fee schedule from primary care services (Table 2-3). For instance, physicians with a specialty designation of geriatric medicine receive an average of 65.0 percent of their fee schedule payments from primary care services.

The fee schedule adjustment would also signal a major change in the purpose of the physician fee schedule. Currently, the fee schedule is intended only to account for differences in resource costs among services. By contrast, using the fee schedule as a vehicle for promoting primary care would be a very different role for the payment system. Instead of just accounting for current resource costs, a payment system that includes a fee schedule adjustment for primary care could look ahead to resources the nation needs to achieve a reformed delivery system.

RECOMMENDATION 2A

The Congress should establish a budget-neutral payment adjustment for primary care services billed under the physician fee schedule and furnished by primary-care-focused practitioners. Primary-care-focused practitioners are those whose specialty designation is defined as primary care and/or those whose pattern of claims meets a minimum threshold of furnishing primary care services. The Secretary would use rulemaking to establish criteria for determining a primary-care-focused practitioner.

RATIONALE 2A

A fee schedule adjustment for primary care would help overcome the undervaluation of primary care services. In addition, the adjustment could support investment in infrastructure—such as IT and staffing—between now and when medical home initiatives (discussed later in this chapter) are up and running. If commercial insurers, Medicaid programs, and other payers use Medicare's physician fee schedule as a basis for their payment rates, the fee schedule adjustment could promote primary care throughout the health care system.

IMPLICATIONS 2A

Spending

- As a budget-neutral policy, the fee schedule adjustment would not affect federal benefit spending relative to current law.

Beneficiary and provider

- For beneficiaries, the adjustment could improve access to primary care services.
- For physicians and other providers, the adjustment would have redistributive effects depending on the services they furnish.

The fee schedule adjustment raises certain issues. For one, it would require a decision about the level of the adjustment. Because there is no one formula or analytical approach to making the decision, judgment is required. In making that judgment, there are two precedents to consider. Currently, a 10 percent bonus is paid for services furnished in a health professional shortage area. There is also a 5 percent adjustment for services furnished in areas defined in the statute as physician scarcity areas.

For each of these policies, the Congress has already made a decision about the level of a fee schedule adjustment, albeit an adjustment with a purpose other than promoting primary care. In making a judgment about an adjustment for primary care, the Congress may wish to consider these precedents at least as a starting point for its deliberations.

Incentives are another issue. The adjustment is intended to give physicians and other practitioners an incentive to furnish primary care services. However, for beneficiaries without supplemental coverage, it could discourage use of primary care because their coinsurance is calculated as a percentage of allowed charges, and the fee schedule adjustment would raise allowed charges. Further work is necessary—perhaps in the design of the Medicare benefit package—to mitigate any mixed signals the fee schedule adjustment would send. We note also that the impact on beneficiary financial liability could be mitigated somewhat to the extent that primary care services are substituted for imaging, tests, and procedures.

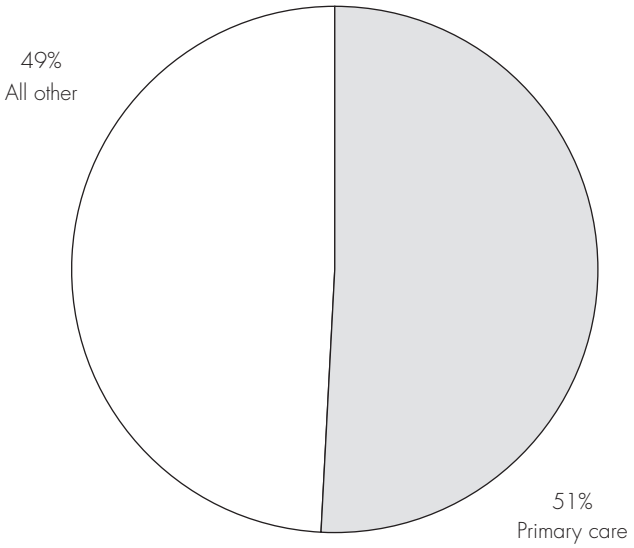
Other issues concern how the fee schedule adjustment would work administratively and its effects on payments to physicians and other practitioners. As we discuss below, the two options in the Commission's recommendation—specialty designation plus claims patterns versus claims patterns only—have different effects and require different administrative processes. In general, we find that considering specialty designation and claims patterns would result in a more tightly targeted adjustment and a relatively modest reduction in payments for other services to maintain budget neutrality, but that specialty designation is a problem administratively. On the other hand, the second option—an adjustment that relies on a review of a practitioner's claims pattern but not specialty designation—means that more physicians and a more diverse population of physicians would qualify for the adjustment and that the adjustment would be easier to administer. Nonetheless, this second option could require a larger reduction for budget neutrality or practitioners would have to meet a higher primary care services percentage threshold in order to qualify.

Targeting the adjustment with specialty designation and review of claims patterns

Targeting the fee schedule adjustment on the basis of specialty designation and a primary care services threshold would limit the adjustment to physicians with one of the designations often considered to be primary care: geriatric medicine, family practice, internal medicine, and pediatric medicine. The convention in Medicare is to also identify advanced practice nurses—such as nurse practitioners—and physician assistants as distinct specialties.

FIGURE 2–4

Primary care practitioners account for just over half of allowed charges for primary care services



Note: Primary care practitioners are physicians with a specialty designation of internal medicine, family medicine, geriatric medicine, or pediatric medicine; advanced practice nurses; and physician assistants. Allowed charges for primary services are allowed charges for office and home visits and visits to patients in certain nonacute facility settings (skilled nursing, intermediate care, long-term care, nursing home, boarding home, domiciliary, and custodial care).

Source: MedPAC analysis of 2006 claims data for 100 percent of Medicare beneficiaries.

Targeting the adjustment in this way would support a goal of rewarding generalists furnishing primary care. The primary care practitioners listed above account for 51 percent of allowed charges for primary care services (Figure 2-4). Specialists—such as cardiologists and orthopedic surgeons—and other practitioners bill for the remainder.

There are problems, however, with the use of physician specialty designation to decide who can receive the adjustment. One problem is that some physicians have mixed practices. For instance, a physician may have a designation of internal medicine while practicing as a cardiologist. Or the opposite may be true: A physician with a designation of cardiology may practice as a general internist. Either way, the specialty designation in these cases does not accurately characterize the nature of the

physician's practice and whether he or she is a primary care physician.

Another problem is that physician specialty is self-designated. That is, physicians declare a specialty when they apply to bill Medicare. Further, they can change their status when they add a billing location or for some other reason. One concern is that they may change their specialty in response to the availability of a fee schedule adjustment for primary care. Another concern is how to accommodate new physicians. They, too, would have an incentive to designate themselves as primary care physicians—as is the intention of the fee schedule adjustment. However, the incentive might prove strong enough to lead to specialty designations that are not consistent with how physicians are actually practicing.

Some problems with specialty designation could be addressed administratively. For instance, to counter the incentive for physicians to change their specialty to qualify for the fee schedule adjustment, the Secretary could consider limits on the frequency with which physicians can change their specialty designation. The Secretary could also evaluate board certification in a primary care specialty as an option. Certification takes time and effort to achieve and maintain, thereby indicating a commitment to primary care practice. Nonetheless, other steps may be necessary. As we discuss next, coupling consideration of specialty designation with review of claims patterns, as recommended by the Commission, could help mitigate the problem with self-designation of specialty and further identify primary-care-focused practitioners.

Review of claims patterns

In reviewing claims patterns for the fee schedule adjustment, the Secretary would establish a minimum threshold for the percentage of services furnished that are primary care services.[6] For example, the threshold could be that at least 65 percent of a practitioner's allowed charges must be for primary care services. A physician with one of the primary care specialty designations who meets the threshold would be deemed a primary care physician. The Secretary would then examine claims data—for example, over the past year—to confirm that the physician meets the threshold. Only those physicians at or above the threshold would receive the adjustment. The Secretary could institute such a procedure at the outset of implementing the fee schedule adjustment.

For new physicians, the Secretary could use a claim look-back as described above after each new physician's first year of submitting claims to Medicare. Such a review would ensure that the chosen specialty designation is a fair representation of the physician's practice and the services furnished.

Effects of a fee schedule adjustment based on specialty designation and review of claims patterns

To approximate the effects of a fee schedule adjustment based on specialty designation and review of claims patterns, we used Medicare claims data to model changes in allowed charges that would occur depending on the level of the adjustment and the threshold primary care practitioners would have to achieve to qualify for the adjustment. We used 2006 claims data for 100 percent of Medicare beneficiaries to obtain national estimates of the changes in allowed charges. Part of the analysis, however, required physician-specific estimates—aggregated to the level of specialty designation—of allowed charges for primary care services at or above the threshold. To obtain those estimates, we used 2004 claims data for 100 percent of Medicare beneficiaries in six metropolitan statistical areas: Boston, Massachusetts; Greenville–Spartanburg, South Carolina; Miami, Florida; Minneapolis–St. Paul, Minnesota; Orange County, California; and Phoenix, Arizona. These data may not be fully representative of the nation, and, to help overcome any lack of representativeness, the estimates for each specialty derived from them were weighted accordingly with weights derived from the 2006 national data. We note also that the analysis does not include changes in the fee schedule's RVUs that occurred subsequent to 2006, which means that effects of the fee schedule adjustment on allowed charges are somewhat overstated.[7]

In the analysis, we considered two levels for the adjustment: 10 percent and 5 percent. We then varied the threshold that practitioners would have to meet to qualify as primary care focused. The range chosen was 40 percent to 75 percent. For example, if the threshold was 40 percent, at least 40 percent of a practitioner's allowed charges would have to be for primary care services to qualify for the adjustment. To show impacts for services and practitioners not eligible to receive the adjustment, we applied a reduction for budget neutrality.

The results indicate the minimum net change in allowed charges for services furnished by primary care practitioners (Table 2-4). For a 10 percent fee schedule adjustment, the net increase would range from 3.4 percent to 7.4 percent, depending on the level of the qualifying

TABLE 2–4

Effects of a fee schedule adjustment based on specialty designation and review of claims patterns

Threshold percentage of primary care services provided in practitioner's Medicare practice	Percent of allowed charges (all practitioners) eligible for fee schedule adjustment	Minimum net change in primary care practitioners' total allowed charges for all services		Budget neutrality reduction applied to services not eligible for adjustment	
		10 percent adjustment	5 percent adjustment	10 percent adjustment	5 percent adjustment
40	9.5%	3.4%	1.7%	–1.0%	–0.5%
50	8.8	4.5	2.3	–1.0	–0.5
60	7.6	5.7	2.8	–0.8	–0.4
65	6.8	6.2	3.1	–0.7	–0.4
75	4.7	7.4	3.7	–0.5	–0.2

Note: Analysis includes services billable under the physician fee schedule only. Net change in total allowed charges includes a reduction for budget neutrality applied to services other than primary care services. Analysis does not include changes in the fee schedule's relative value units that occurred subsequent to 2006.

Source: MedPAC analysis of 2006 claims data for 100 percent of Medicare beneficiaries and—for estimates of practitioners meeting claims pattern threshold—2004 claims data for 100 percent of beneficiaries in six metropolitan statistical areas (Boston, MA; Greenville–Spartanburg, SC; Miami, FL; Minneapolis–St. Paul, MN; Orange County, CA; and Phoenix, AZ).

threshold for furnishing primary care services. For a 5 percent fee schedule adjustment, the increase charges would range from 1.7 percent to 3.7 percent.

These increases illustrate the fee schedule adjustment's effect on allowed charges as a net impact. That is, a practitioner qualifying for the adjustment would receive an increase in payments for primary care services but also a decrease in payments—when a reduction for budget neutrality is applied—for services other than primary care.

The effects of the adjustment for a given practitioner would vary depending on whether he or she met the primary care services threshold and depending on the mix of primary care and other services the practitioner furnishes. For instance, a practitioner with a practice composed entirely of primary care services would see all of his or her services eligible for the adjustment. In other words, for such a practitioner, the impact of a 10 percent adjustment would be an increase in allowed charges of 10 percent. By contrast, a practitioner furnishing fewer primary services would see a proportionally smaller impact of the fee schedule adjustment.

The reduction for budget neutrality would also vary. Specifically, the analysis shows the inverse relationship between the threshold and the reduction for budget neutrality: the higher the level of the threshold, the lower the necessary reduction for budget neutrality because fewer services qualify for the adjustment. For instance, with a 10 percent fee schedule adjustment and a 40 percent threshold, the estimated reduction for budget neutrality would equal −1.0 percent. By contrast, a 10 percent fee schedule adjustment with a 75 percent threshold would require a smaller reduction for budget neutrality: −0.5 percent. The reduction is smaller because fewer billings are affected by the adjustment when the threshold is higher.

Overall, modeling of this option for the fee schedule adjustment shows that the two components of such a policy—specialty designation and review of claims patterns—could complement each other. Considering specialty designation could help target the adjustment toward practitioners who are generalists. Review of claims patterns could help hold down the reduction necessary to make the adjustment budget neutral and help make the adjustment more focused on practitioners who concentrate on primary care.

Targeting the adjustment with review of claims patterns only

To simulate the effects of a fee schedule adjustment based on review of claims patterns only, we analyzed Medicare claims data in a manner similar to that described above. For this option, however, we assumed no requirements for a practitioner's specialty designation. Instead, any practitioner would be eligible for the adjustment if he or she met a threshold for furnishing primary care services.

TABLE 2–5 **Effects of a fee schedule adjustment based on review of claims patterns only**

Threshold percentage of primary care services provided in practitioner's Medicare practice	Percent of allowed charges (all practitioners) eligible for fee schedule adjustment	Minimum net change in qualifying practitioners' total allowed charges for all services		Budget neutrality reduction applied to services not eligible for adjustment	
		10 percent adjustment	5 percent adjustment	10 percent adjustment	5 percent adjustment
40	12.9%	3.1%	1.6%	–1.5%	–0.7%
50	11.1	4.4	2.2	–1.2	–0.6
60	9.1	5.6	2.8	–1.0	–0.5
65	8.0	6.2	3.1	–0.9	–0.4
75	5.5	7.4	3.7	–0.6	–0.3

Note: Analysis includes services billable under the physician fee schedule only. Net change in total allowed charges includes a reduction for budget neutrality applied to services other than primary care services. Analysis does not include changes in the fee schedule's relative value units that occurred subsequent to 2006.

Source: MedPAC analysis of 2006 claims data for 100 percent of Medicare beneficiaries and—for estimates of practitioners meeting claims pattern threshold—2004 claims data for 100 percent of beneficiaries in six metropolitan statistical areas (Boston, MA; Greenville–Spartanburg, SC; Miami, FL; Minneapolis–St. Paul, MN; Orange County, CA; and Phoenix, AZ).

We modeled effects of two levels for the adjustment: 10 percent and 5 percent. We allowed the primary care services threshold to range from 40 percent to 75 percent of allowed charges.

The analysis shows that an adjustment based on review of claims patterns only would have effects similar to those for an adjustment based on both specialty designation and claims patterns (Table 2-5). With an adjustment based on claims patterns only, the estimated reductions for budget neutrality are larger than they would be with the other type of adjustment, particularly at lower thresholds. For instance, with a threshold of 40 percent and a fee schedule adjustment of 10 percent, the estimated reduction for budget neutrality with claims patterns review only is −1.5 percent. With the same threshold and adjustment, estimated reduction for budget neutrality with both specialty designation and claims patterns review is −1.0 percent. With more practitioners capable of receiving the adjustment—practitioners in addition to primary care practitioners—the reduction for budget neutrality must be higher to offset the adjustment's effect on spending. The alternative is to set the primary care services threshold higher and maintain the reduction for budget neutrality at a given level.

To see why more practitioners would receive the fee schedule adjustment if it is based on claims patterns review but not specialty designation, consider two specialty designations: endocrinology and rheumatology. In 2006, 49.7 percent and 45.2 percent, respectively, of these specialties' allowed charges were for primary care services. As we saw earlier (Table 2-3, p. 34), other specialty designations had percentages that were much higher. For instance, the values were 65.0 percent for geriatric medicine and 65.4 percent for nurse practitioners. Nonetheless, even with lower average allowed charges for primary care services, enough practitioners with specialty designations other than those considered to be primary care would qualify for the adjustment—if it is based solely on claims pattern review—to make a difference in the distribution.

Otherwise, effects of the fee schedule adjustment are not markedly different. At lower threshold percentages, estimated changes in allowed charges are lower under an adjustment based solely on claims pattern review because of the larger reduction for budget neutrality applied to services other than primary care services. For instance, with a threshold of 40 percent and an adjustment of 10 percent, the net change in allowed charges for qualifying practitioners is 3.1 percent when the adjustment is based on claims pattern review only versus 3.4 percent when the adjustment is based on both specialty designation and claims pattern review. At higher thresholds, however, the effects of the two options for the adjustment are the same.

We make two observations about the option of a fee schedule adjustment based on review of claims patterns only.

- It would make the adjustment available to those physicians who are specialists to some extent but who also have concentrated their practices in primary care services. An example might be a physician who first achieved board certification in internal medicine, then went on to gain certification in cardiology, but continued to focus mostly on primary care.
- In turn, to make the fee schedule adjustment budget neutral, the required reduction in payments would need to be somewhat larger or the minimum threshold of primary care services would need to be somewhat higher, although the differences are small.

A medical home program in Medicare

Medical home initiatives, which highlight care coordination from within a medical practice, have the potential to add value to the Medicare program, particularly for patients with multiple chronic conditions. Unlike the current fee-for-service (FFS) payment system, which emphasizes treatment for acute conditions and face-to-face care, medical home programs encourage practitioners to coordinate their patients' care between visits and among providers. In improving care continuity and coordination, medical homes can enhance the role of primary care practice. As discussed earlier, efforts to promote the use of primary care services can increase our health system's quality and efficiency.

Other purchasers and payers have begun programs that recognize the value of having someone accountable for effectively managing patient care (Baron and Cassel 2008). In fact, several different models of medical homes exist, some of which are discussed in a later section of this chapter. Jointly, the American Academy of Family Physicians, the American College of Physicians, the American Academy of Pediatrics, and the American Osteopathic Association recently released key medical home principles (AAFP et al. 2007). Under the Tax Relief and Health Care Act of 2006 (TRHCA), CMS will begin a medical home demonstration project in January 2009.

A medical home serves as a central resource for a patient's ongoing care. In many medical home programs, patients can designate the office of a physician or medical group as their medical home. Typically, patients choose medical homes that include their primary care practitioner, but in some cases patients may choose specialty practices that manage their main chronic condition, such as endocrinology for patients with diabetes. A multispecialty group practice would be well suited to serve as a medical home because it could take full advantage of interactions and communications between primary care providers and other specialists within the same practice.

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 care delivery, particularly for patients with multiple conditions. A goal for medical homes is to improve patients' understanding of their conditions and medical advice and, in turn, reduce the use of high-cost settings such as emergency rooms and inpatient care. Ideally, through better care coordination, medical homes could also enhance communication among providers, thereby eliminating redundancy and improving quality.

In its June 2006 report, the Commission discussed the importance of care-coordination services—a major component of medical homes. Although the chapter did not explore medical homes per se, it examined many of the related activities and the organizational capabilities of entities that could serve as medical homes. Through literature reviews and interviews with a wide variety of experts and organizations involved in care-coordination programs, we found that two functions considered essential are: (1) a care manager (usually a nurse) to assist the patient in self-management and monitor patient progress; and (2) an information system to identify eligible patients, store and retrieve patient information, and share information with those who need it. Interviewees also noted that programs were more effective when integrated with the care the beneficiary receives from his or her physician. Further, most programs focus their efforts on beneficiaries at high levels of complexity, such as those with multiple chronic conditions or high users of health care services.

Care-coordination services appear to improve quality, but published research on cost savings is less clear. While most physician groups participating in Medicare's Physician Group Practice demonstration showed quality improvements, a smaller number achieved savings (GAO 2008a). Recent results from a CMS care-coordination pilot, Medicare Health Support (MHS), found that fees paid by CMS for care-coordination and disease

management services were not covered by reductions in Medicare spending in the program's first two years (CMS 2008a). However, a key difference between the MHS and a medical home program is that the MHS is operated by contractors—primarily private sector disease and care management service companies—that may act independently of the patients' physicians. In fact, the MHS evaluator found that only a small portion of physicians who treat the participating beneficiaries had formal relationships with the care-coordination contractors during the program's first year (RTI International 2007). In contrast, the Commission envisions a medical home model where the beneficiary's clinician would be the hub of care-coordination services for his or her Medicare patients.

The following section discusses functions that the Commission considers essential for a voluntary medical home program within Medicare. Some, but not all, of these capabilities are required in the Medicare demonstration project scheduled to start in January 2009.

Essential activities of a Medicare medical home

In addition to providing or coordinating appropriate preventive, maintenance, and acute health services, the Commission considers it essential for medical homes to provide the following activities:

- furnish primary care,
- conduct care management,
- use health IT for active clinical decision support,
- have a formal quality improvement (QI) program,
- maintain 24-hour patient communication and rapid access,
- keep up-to-date records of beneficiaries' advance directives, and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

Furnish primary care

Medical practices that provide primary care services—either exclusively or as part of their practice—would be eligible to participate in a Medicare medical home program. Thus, primary care, multispecialty, and geriatric medicine practices are natural candidates for medical home programs that manage beneficiaries' overall health care. Patients could choose a specialty practice as their medical home if that practice manages their main chronic condition—such as endocrinology for patients with diabetes or nephrology for patients with renal disease. However, like all practices participating in the medical home program, these practices would need to provide the full range of primary care services (preventive, maintenance, and acute care) to their medical home patients.

As part of its function to deliver primary care, a Medicare medical home would be responsible for monitoring its patients' medications. Medical homes should conduct periodic reviews of a patient's regular medications in addition to reviews immediately after an acute event, such as a hospitalization. These medication reviews should assess for medical necessity, dosage appropriateness, actual or potential adverse drug reactions or interactions, and missing medications (Hepler and Strand 1990). Ideally, these medication reviews would be coordinated with a pharmacist. Part D, the Medicare drug benefit, requires that participating insurers administer a medication therapy management program for at least their high-cost beneficiaries.[8] Medical homes also could coordinate with these drug plans to review patients' medication use. Additionally, Medicare should require drug plans to provide drug utilization data to their enrollees' medical homes, as discussed later in this chapter.

Conduct care management

Essential functions of medical homes include following up on patients and coordinating care among providers between appointments and health events. In particular, communication among practitioners during transitions out of the hospital should be a high priority (Coleman and Williams 2007). Care management also involves assessing patient adherence to treatment plans, conducting patient education on self-care, coordinating patient referrals for health and community services, and keeping track of results from tests and referral services through communication with other providers. Many of the services encompassing care management do not require the patient to be on site; instead, services such as conferring with other specialists on test results can be accomplished by telephone, electronic communications, or mail.

The function of care management requires an adequate ratio of clinical staff to patients. Physician offices with a relatively small patient panel, for example, may manage care with the help of only one nurse or nurse practitioner, but an office with a larger patient panel may require more

clinical staff to conduct appropriate care management. On the one hand, larger multispecialty practices may be better able to make initial investments (e.g., in staff and IT) to coordinate care; on the other hand, staff in smaller offices may be more familiar with their entire patient panel and may have developed successful, but perhaps less technical, mechanisms for monitoring patients.

Use health IT for active clinical decision support

Health IT has the potential to improve the quality, safety, and efficiency of health care (MedPAC 2006, MedPAC 2005, Shortell and Schmittdiel 2004). Medical homes should have the capability to use health IT to support their clinical decisions and functions. (The Commission does not consider health IT for the sole purpose of streamlining coding and billing processes to be clinically relevant.) Larger medical practices, such as multispecialty practices, are much more likely to have clinical health IT in place (Gillies et al. 2006, Hing et al. 2007).[9] However, smaller offices are increasingly adopting it in their practices. The medical home pilot should be careful to find a balance between ensuring that all medical homes participating in the pilot have important health IT functionality and not setting the bar so high that many primary care practices find it impossible to participate.

Below are several health IT functions medical homes could use to improve care. A number of these tools are components of electronic health systems described in an analysis by the Massachusetts General Hospital's Institute for Health Policy (Blumenthal 2008).

- Electronic medical records (EMRs) store and track patient demographic and clinical information such as diagnoses and treatments, prescribed medications, and clinical notes. EMRs help practices receive and organize patient encounters, referrals, test results, and follow-up.
- Patient registries keep track of patients by specified medical conditions or other characteristics and alert clinicians when a patient is due for an examination or test.
- E-prescribing facilitates beneficiary access to medications and physician records of patients' medication use.
- Clinical decision support tools at the point of service assist health professionals with conducting and ordering appropriate tests and procedures.
- A system for patients to access their personal health information in a timely manner promotes better patient–clinician communication.

Future technological innovation should make it increasingly possible for physicians in smaller practices to use IT. As with larger practices, smaller physician offices could use IT to connect to patients and other physicians as well as to facilitate effective clinical management. However, in less populated areas of the country medical practices are less likely to have health IT but may conduct more personalized care coordination—not only with the patients but also with other medical providers in the community. The medical home pilot could allot some funding for these medical homes to test their ability to provide high-quality, efficient care coordination with somewhat modified structural requirements.

Have a formal QI program

Medical homes should design and implement their own QI programs. This activity engages the practice in determining appropriate quality goals and measures. It requires data collection and analysis and, in return, provides medical homes with timely feedback on their ability to meet their own goals (Audet et al. 2005). It can also help guide medical homes in areas for improvement. Practices could develop their QI programs around several indicators, including outcome measures based on lab values, process measures based on services provided, patient satisfaction measures based on patient surveys, and efficiency measures based on spending and time expended.

The QI programs would be a requirement for participating medical homes. However, these programs would be internal and thus separate from a Medicare-sponsored pay-for-performance (P4P) program in a medical home pilot (discussed later in this chapter).

Maintain 24-hour patient communication and rapid access

Medical homes need to be accessible and promptly responsive to patient inquiries 24 hours a day. That is, during regular office hours, medical homes need to schedule timely appointments and have clinicians available to reply to patients' questions about their health care. Some medical practices have found secure e-mail communication an effective and efficient care management tool (Zhou et al. 2007). Further, patients with Internet access report interest in communicating with their doctors by e-mail (Cummings 2006). During nonregular office

hours, medical homes must have mechanisms in place for prompt clinician–patient contact to respond to patients' urgent and emergent needs. Accordingly, the clinician-based response is a key feature of this 24-hour-a-day criterion.

Keep up-to-date records of beneficiaries' advance directives

Medical homes are a natural place to keep signed copies of patients' advance directives—documents that convey patients' wishes and decisions about end-of-life care. Requiring medical homes to keep their patients' up-to-date advance directives strongly encourages patients and their personal physician to have a discussion to clarify patients' desires for health care in the last months of life. With this information, medical home physicians can monitor their patients' status and ensure that they receive the kind of end-of-life care they expressly want.

Medical home certification or accreditation in the future

With respect to the above criteria, CMS would need to determine a mechanism for verifying that medical homes are, in fact, furnishing these activities and meeting these criteria. P4P measures will help establish a way to encourage medical homes to provide high-quality care. If the pilot is successful, and thus is expanded nationwide, it may be useful for medical homes to undergo an accreditation or certification process conducted by an external accrediting body. Private insurers and employers are working to establish a process for assessing and identifying medical homes. These initiatives as well as Medicaid primary care case management are further discussed in the text box (pp. 44–45).

Our discussion focuses on medical homes in the context of Medicare FFS, but, in many cases, Medicare Advantage plans may develop or already be incorporating a medical home model in their plans. A certification or accreditation process that recognizes FFS medical homes may also be used for medical homes in Medicare Advantage.

Qualifying beneficiaries

Early medical home initiatives in Medicare should target beneficiaries with at least two chronic conditions. These individuals, who typically see multiple health professionals in various settings, have the most immediate care-coordination needs and account for the greatest share of Medicare spending, compared with their healthier counterparts (Anderson and Horvath 2002, Wolff et al. 2002). About 60 percent of the FFS Medicare population has two or more chronic conditions (CMS 2007). The most common conditions include heart disease, diabetes, arthritis, congestive heart failure, osteoporosis, depression, chronic obstructive pulmonary disease, and Alzheimer's and related disorders.

A medical home program that targets this beneficiary population will, in turn, target the physicians, nurse practitioners, and physician assistants who manage their care. As discussed earlier, clinicians in geriatric practice will be major candidates for medical home programs. Although increasing the eligibility pool to include all Medicare patients would encourage physicians and beneficiaries to establish relationships early in their Medicare enrollment, it is useful to focus the initial stage of the medical home program on a smaller, targeted population: those with multiple chronic conditions. In doing so, Medicare learns about the program's successes and challenges before opening up the program to a larger population.

Further work is needed to address particular beneficiary circumstances. For example, participation adjustments may be needed for beneficiaries in nursing homes, those in hospice care, and those who spend part of the year away from their medical home ("snowbirds"). Further consideration is also needed to select the chronic conditions that would qualify for medical home eligibility.

Other beneficiary responsibilities and rights

Participating beneficiaries would select a single medical home. The Commission recommends that beneficiaries sign a document—jointly with their main clinician—designating their selection and triggering Medicare's monthly fee to go to that medical home. The document would outline beneficiaries' responsibilities and rights in the medical home program and would encourage beneficiaries to consult with their medical home before or instead of seeking new specialists. Under these principles, the medical home serves as a resource to improve care continuity and help patients and families navigate through the health system to select optimal treatments and providers. Participating beneficiaries and medical homes would need to renew this understanding annually to ensure that each patient–clinician relationship was ongoing for each medical home. Medical homes would maintain this document.

Although medical homes should offer their patients guidance on selecting appropriate specialty services,

participating beneficiaries would retain their ability in FFS Medicare to see specialists and other health practitioners of their choice. This right would be outlined in the signed agreement described earlier.

When launching the medical home pilot to the beneficiary population, Medicare should engage in a public information campaign on the potential benefits of comprehensive primary care. These potential benefits include improvements in health and more judicious use of discretionary services. In fact, such public education efforts may be worthwhile regardless of the implementation of a medical home program. Because some people may have negative connotations associated with the term "home" in a medical context, Medicare might also explore alternative names for "medical home" that may appeal more to beneficiaries, such as a "designated medical practice."

Per beneficiary monthly payments to medical homes

In addition to receiving payments for the Medicare-covered fee schedule services they provide, qualifying medical homes would receive monthly payments for medical home infrastructure and care-coordination activities. Specifically, these monthly fees would be for medical home activities and expenses that exceed the pre- and post-visit time and expenses currently allocated in the physician fee schedule. Beneficiary cost sharing would not apply to these medical home monthly fees.

A number of implementation details regarding medical home payments need to be addressed. For example, an amount would need to be determined for the monthly fee. This amount must be sufficient to encourage participation and pay practices adequately for the desired activities but within the bounds of affordability for the Medicare program. Another consideration is whether the medical home fee would go to the practice or to the beneficiary's individual practitioner. Providing payments to the individual clinician encourages individual accountability. However, the concept of medical home is meant to promote comprehensive teamwork in health care delivery. Accordingly, directing payments to the practice (i.e., the medical group) rather than to individual physicians could foster this objective.

P4P component for quality and efficiency

In previous reports, the Commission has recommended that Medicare initiate P4P programs for physicians to encourage improvements in care quality and efficiency. A medical home pilot provides an excellent opportunity to implement and test physician P4P with payment incentives based on quality and efficiency. Under the pilot project, the Commission envisions that the P4P incentives allow for both rewards and penalties based on performance.

Improving care quality

Commercial insurers have focused quality incentives on primary care physicians, who make up the largest share of physician specialties experiencing P4P financial incentives (Cross 2007). A predominant reason for this focus is that the performance measures used in P4P programs often concentrate on primary care (e.g., flu shot rates). In 2006, the Commission surveyed physicians and found that larger practices, particularly multispecialty practices (which include a greater proportion of nonproceduralists than single-specialty practices), are more likely than smaller practices to take part in P4P programs from non-Medicare insurers (MedPAC 2007a).

In contrast to the Physician Quality Reporting Initiative, which pays physicians to report quality information, a P4P program would reward medical homes that met specified quality goals or that showed improvement toward those goals. P4P incentives would not be reward only; financial incentives would include both rewards and penalties. Thus, a high-performing medical home would receive the monthly fee plus a P4P bonus payment. Also, medical homes that did not attain specified goals or did not demonstrate improvement toward them would be penalized. Financial penalties could include either a portion of the medical home's monthly fee or a small percentage of the medical home's FFS billing. Additionally, medical homes that are consistently unable to meet minimum quality requirements would be ineligible to continue participation in the pilot.

Measures for determining medical home performance could largely rely on Medicare claims. Thus, providers would not experience an additional administrative burden when participating in the P4P component. As the Commission has stated, claims-based indicators can provide both process and outcome measures (MedPAC 2006). Process measures assess whether clinically indicated services were provided and include items such as eye exams for people with diabetes. Outcome measures assess resulting health status indicators and include items such as emergency room visits. Other measures could assess beneficiary experience. An existing survey instrument designed by the Consumer Assessment of Healthcare Providers and Systems for primary care

Medical home initiatives among private payers and Medicaid programs

Some private health insurance payers have announced they are planning or have recently implemented medical home pilot programs for their covered populations. Also, two major nonprofit accreditation organizations have launched medical home recognition and certification programs. Third, North Carolina and other state Medicaid programs have used primary care case management (PCCM) programs, which incorporate medical home concepts, for a number of years as part of their Medicaid managed care programs. These programs are explored briefly here.

Private health insurers' medical home programs

In August 2007, UnitedHealth Group, the American Academy of Family Physicians, the American Academy of Pediatrics, the American Osteopathic Association, and the American College of Physicians announced a medical home pilot program in Florida. The program will have approximately six selected primary care practices serving UnitedHealthcare commercially insured members. UnitedHealthcare states that it will support the participating practices with quality improvement and care management functions, including 24/7 nurse triage, identification of and outreach to plan members who may need clinical interventions, and educational tools and assistance to help patients manage their conditions.

In January 2008, two New York health insurers—Group Health and Health Insurance Plan of New York—announced they were launching a medical home program as a two-year pilot. Participants will be randomly assigned into a supported group and a comparison group, each consisting of 25 adult primary care physician practices. The total number of participants in the supported group is expected to include about 100 physicians and 20,000 patients. The University of Connecticut Health Center will conduct a formal program evaluation under a grant from the Commonwealth Fund.

Medical home recognition programs

Earlier this year, Bridges to Excellence (BTE) launched a medical home physician practice recognition program. BTE is a not-for-profit organization that develops programs to recognize and reward health care providers for selected goals. For the medical home recognition program, physicians assess their practices using a scoring tool to determine whether they meet specified performance standards, such as level of health information technology functionality and ability to identify and contact at-risk patients. This assessment is subject to independent, third-party verification. Practices may also use the scoring tools developed by the National Committee for Quality Assurance (NCQA) and described in the next paragraph. Once a physician practice has achieved BTE recognition, it is eligible to receive incentive payments from the health plans and purchasers that participate in BTE. These medical home payments would be made to the practice by a patient's health plan or employer and would be in addition to the payments made to the practice under regular contracted provider compensation arrangements.

(continued next page)

providers collects patient responses to questions on topics such as appointment wait times and follow-up communication for test results. Measures regarding care transitions (i.e., medical home communication with hospital clinical and discharge planning staff) would also be important to capture (Coleman and Williams 2007). Improvements in this area are key potential benefits of a medical home and can reduce hospital readmissions—an objective discussed in Chapter 4.

Promoting efficiency

In conjunction with quality incentives, a medical home pilot also offers an opportunity to examine ways to encourage medical practices to improve the efficiency of their patients' resource use. The Commission has recommended that Medicare begin confidentially informing physicians of their resource use and ultimately begin payment incentives that reward efficiency (MedPAC 2008).

Medical home initiatives among private payers and Medicaid programs (cont.)

NCQA announced a medical home recognition program earlier this year, called Physician Practice Connections–Primary Care Medical Home. According to NCQA, this model's standards emphasize the use of systematic, patient-centered, coordinated care management processes (NCQA 2008). Practices seeking recognition complete a web-based data collection tool and provide documentation to NCQA to validate their responses to it. It is not known how health plans will use the NCQA medical home designation, but they have used other NCQA recognition programs to designate providers in directories, to qualify providers for tiered provider networks, and as part of pay-for-performance programs.

North Carolina Medicaid medical home program

North Carolina's Medicaid program has had a medical home program for adults under age 65 and for children since 1991; according to the state's evaluations, it has achieved successful access, quality, and financial outcomes. The state is developing a pilot program to expand its medical home model to Medicaid recipients in the aged, blind, and disabled eligibility categories.

The program, called Community Care of North Carolina (CCNC), is a Medicaid PCCM program authorized by CMS. The North Carolina Department of Health and Human Services initiated the program in 1991 as a pilot in five counties in conjunction with the state's Office of Rural Health and Community Care. It became statewide in 1998. A key feature of the program is its use of physician-led community networks, which are private not-for-profit entities that contract with the state to provide many of the operational functions for the medical home program. Fourteen of these networks are operating currently, with each covering a different region of the state. Every primary care provider participating in CCNC joins his or her local community network. The responsibility for managing the care of the enrolled population falls to the community network, while management of resource use and quality of care for individual CCNC enrollees is the responsibility of each enrollee's designated primary care provider.

In addition to their fee-for-service payments, primary care providers participating in a community network are also paid a per member per month management fee. The network in which the primary care provider is enrolled also receives a management fee based on the number of Medicaid recipients enrolled with the network. The community networks develop and disseminate condition-specific initiatives designed to assist primary care providers in improving health outcomes for enrollees. Examples of these initiatives include disease management for asthma, congestive heart failure, and diabetes; reduction in emergency department use; and case management of high-risk and high-cost patients.

In addition to North Carolina, 9 other states had PCCM programs with at least 250,000 enrolled Medicaid recipients as of mid-2006 (the most recent date for which data are available), ranging from about 268,000 enrollees in Massachusetts to nearly 1 million in Texas. About 6.5 million total Medicaid beneficiaries were enrolled in PCCM programs in the United States in 2006 (CMS 2006). ■

In the first year, the pilot could measure patient resource use and confidentially share feedback on these results with the medical home. Medicare could also provide data feedback from the medical practice's previous year to help medical homes understand their practice pattern relative to that of their peers. In the second year, the pilot could begin assessing medical homes based on resource use. Because medical homes are designed to be central resources for managing enrollees' overall care, they are well suited for these measures and incentives.

The pilot might also explore different kinds of efficiency measures, such as type of service, care setting, or episode of care (MedPAC 2007b). Detailed reports that feed back information on all care that enrollees received, including from other providers, would greatly enhance the ability of medical homes to improve care coordination over

time. Nevertheless, CMS would have to evaluate the appropriateness of more detailed efficiency measures given the characteristics of physician practices that choose to participate, such as their number of enrollees, the number of conditions those enrollees had, and the extent to which their enrollees used services outside the medical home. The National Committee for Quality Assurance has begun measuring resource use among health plans for selected medical conditions.

Efficiency incentives could take the form of shared savings models similar to those under Medicare's ongoing physician group practice demonstration. Bonuses for efficiency should be available only to medical homes that have met quality goals and that have a sufficient number of patients to permit reliable spending comparisons. Although less individually targeted, another mechanism for encouraging efficiency would be to distribute a portion of any realized aggregate savings among all the medical home providers. In any case, measuring resource use across the entire medical home pilot is important to test the premise that medical home programs can improve care and promote more judicious use of discretionary services.

Notification of beneficiary service use outside the medical home

For comprehensive care management, medical homes need information on beneficiary service use outside the medical home. After referring patients to a specialist, medical homes should actively follow up on results, treatment, and recommendations. Moreover, medical homes should strongly encourage their patients to notify them of health care use outside the medical home. This objective can be addressed during the beneficiary enrollment and designation process.

In some cases, however, the medical home may not be aware of its patients' use of services outside the medical home. For example, patients may be admitted to the hospital for an acute event. Ideally, hospitals should notify patients' medical homes upon admission and discharge (as discussed in Chapter 4), but Medicare should also supply medical homes with timely data on patients' service use, which would provide the medical home with a backup method for keeping track of patients' health care utilization.

To this end, the Commission recommends that Medicare provide medical homes with a timely, periodic report that lists all the Medicare-covered services each of its medical home patients received in the previous month. Medicare's claims processors could compile these reports and send them to Medicare or to the medical home directly. The services to be included in the reports would include those in both Part A and Part B services. Medicare should also supply medical homes with patients' prescription drug use data under Part D. It may be more efficient to require contracted drug plans to provide this information to the medical homes directly. Similarly, Medicare should encourage all providers of Medicare-covered services to notify their patients' medical homes of their service use. Data on Medicaid service use would also be helpful for medical home providers who treat beneficiaries covered by Medicaid.

Recent efforts by Medicare to streamline FFS claims processing could facilitate this data-reporting activity. Specifically, Medicare is transitioning to single contractors (Medicare administrative contractors (MACs)) for processing both Part A and Part B claims. Using MACs rather than relying on separate entities for Part A (fiscal intermediaries) and Part B (carriers) should make FFS claims processing more efficient and can improve Medicare's ability to analyze beneficiary spending and utilization trends. MACs could assist in providing medical homes with data to help them understand their patients' service use. Under this premise, the medical home pilot could include—but not be limited to—areas where MACs are in place. Currently, three MACs have begun processing FFS claims in 14 states.[10] By 2010, the MAC program will be fully implemented, with 15 MACs responsible for all FFS claims processing.

Patient privacy concerns will need to be addressed before a MAC or Medicare can provide individual patient information to medical homes. Each participating beneficiary would need to sign a privacy agreement that allows Medicare to supply medical homes with information on his or her Medicare-covered utilization. This agreement could be a requirement for beneficiary participation in the medical home program. Additionally, medical homes would need to be held accountable for safeguarding patient information.

Advantages of a pilot project

The Commission considers the medical home concept a promising intervention for beneficiaries with multiple chronic conditions. Complex patients need care coordination and education—neither of which is currently fostered or rewarded by fee-for-service payment. Medical practices led by physicians, nurse practitioners, and physician assistants are a logical place to turn for these

services, particularly practices with strong nursing and other dedicated staff support, as well as information technology to assist in clinical monitoring. Medicare has invested considerable effort and money in programs to engage external third-party disease management companies and private health plans in coordinating care for such beneficiaries. Yet, the results from these efforts have been equivocal. The Commission believes it is now time to test patients' clinician-centered care coordination on a large-scale basis.

It is appropriate to test new policies before fully committing Medicare to them, but it is not without problems. It often takes three to five years to move from initial conception through implementation of the test to final evaluation, with legislation authorizing program-wide implementation adding another year or more. If the test is small scale, the cycle is longer because small numbers make it more difficult to attain statistically meaningful results. Thus, the test must run longer to help compensate.

A long test cycle is problematic when the costs of the current payment system, both in dollars and substandard care, are so large. It is imperative, then, that we seek ways to hasten the testing process. We see two opportunities to do so: first, to increase the scale of the project so we determine more quickly whether the intervention works (and can test more variations); second, to reduce the amount of time it takes to advance a successful intervention into program-wide implementation.

We are recommending that the medical home program take the form of a pilot project rather than a demonstration project in order to accelerate the testing of this promising concept. The Commission envisions a medical home pilot that would be about four times larger than the TRCHA medical home demonstration. (Some of the added resources would need to go to CMS to implement this complex project.) This scale would allow CMS to determine more quickly how the intervention affects quality and spending. We also recommend that the Congress establish, in advance, clear, measurable objectives for the project and authorize the Secretary of the Department of Health and Human Services to implement the program nationwide, without further legislative action, if those objectives are met.

The Commission recognizes that there are legitimate concerns about moving quickly to a large-scale pilot. First, the cost of a failed test is larger. More money would have been spent, and the constituency lobbying for continuation of the unsuccessful intervention would be more powerful. Second, the opportunity for a potentially sound intervention may be lost if the test is developed and implemented too hastily.

We acknowledge those risks, but going slower has its own. Given Medicare's pressing problems with cost and quality, especially for beneficiaries with multiple chronic illnesses, the status quo is itself extremely risky. After weighing one set of risks against the other, the Commission believes it is prudent to move as quickly as practicable to a large-scale pilot test of the medical home model.

Determining whether the pilot is successful: Efficiency and quality

Medicare should evaluate the medical home pilot using efficiency and quality measures to determine its overall success. These aggregate measures can be obtained largely through claims data. Measures for determining the success of the pilot could encompass:

- total spending and episode spending,
- outcome quality measures (e.g., rates of potentially avoidable hospitalizations and emergency room visits),
- process quality measures (e.g., rates of selected clinically necessary tests for a given condition), and
- structural measures (e.g., health IT functionality).

The pilot's success could be measured by aggregate changes from baseline in spending and quality over a specified time period. Alternatively, spending and quality assessments could be made relative to a comparison group. If the results do not meet predetermined thresholds for improvement, the pilot should be discontinued. However, if results show improvement, then the Secretary should begin implementing a medical home program in Medicare nationwide. To capture any savings and quality improvements that build over time, it would be important for the pilot to run for multiple years.

RECOMMENDATION 2B

The Congress should initiate a medical home pilot project in Medicare. 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),**
- **conduct care management,**

- **use health information technology for active clinical decision support,**
- **have a formal quality improvement program,**
- **maintain 24-hour patient communication and rapid access,**
- **keep up-to-date records of beneficiaries' advance directives, and**
- **maintain a written understanding with each beneficiary designating the provider as a medical home.**

Medicare should provide medical homes with timely data on patient utilization. The pilot should require a physician pay-for-performance program. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

RATIONALE 2B

The Commission considers the medical home concept a promising intervention to test, particularly for the treatment of beneficiaries with multiple chronic conditions. Medical home initiatives encourage improved care coordination and have the potential to add value to the Medicare program through efficiency and quality gains. Ideally, medical home programs can enhance communication among providers, thereby eliminating redundancy and improving quality. Medicare payments to medical homes would promote the important role of personal physicians, nurse practitioners, and physician assistants in delivering care to patients with multiple chronic conditions. The Commission recommends that medical homes meet several stringent criteria to be eligible to participate in the pilot. Additionally, the pilot should be on a large enough scale to provide statistically reliable results.

IMPLICATIONS 2B

Spending

- The pilot will require up-front costs, primarily in the form of monthly fees to medical homes and CMS resources. In general, the Commission envisions that the pilot would be about four times larger than the TRHCA medical home demonstration, which the Congressional Budget Office estimated to be about $100 million over three years. In the first year of the pilot, costs would be in the range of $50 million to $250 million. In a five-year window, costs would be in the range of $250 million to $750 million. Savings are not included in these estimates.

Beneficiary and provider

- Medical home initiatives will help sustain beneficiaries' relationship with their primary clinician because they will support ongoing, comprehensive care. With increased resources going to medical homes, this recommendation is also designed to enhance access to primary care and improve care coordination.
- Participating providers who specialize in primary care and in certain chronic conditions will receive additional Medicare resources for serving as patients' medical home and providing beneficiaries with comprehensive, ongoing care. ■

Endnotes

1 The sustainable growth rate determines the spending target for physician services. It is composed of growth rates for enrollment in Medicare fee-for-service, input prices for physician services, physician services spending due to changes in law and regulations, and—as an allowance for volume increases—real gross domestic product per capita.

2 Graduates of allopathic medical schools receive doctor of medicine (MD) degrees. Graduates of osteopathic medical schools receive doctor of osteopathic medicine (DO) degrees. Both are considered physicians.

3 When nonphysician practitioners bill Medicare directly for a physician service, they receive 85 percent of the Medicare physician fee schedule rate. Thus, medical practices have a financial incentive to consider the services of nonphysician practitioners as being under the supervision of physicians.

4 The MCBS uses different categorical variables than Medicare claims to describe physician specialty. We include "general practice" for reporting MCBS results, but not for our physician-designated claims analyses in the rest of the chapter.

5 To define primary care services, we started with the definition of primary care services in the Social Security Act (Sec. 1842(i)(4)) and then focused on a subset of E&M services within that definition. The definition in the statute includes three other categories of services typically furnished by specialists and not by primary care physicians and omitted from the discussion here. One is emergency department visits. Another is intermediate and comprehensive office visits for eye examinations and treatments. The third is monthly end-stage renal disease services.

6 In reviewing claims patterns, the Secretary could consider not just the services furnished but also the diagnoses of patients reported on claims and whether they are broad-based versus concentrated in a narrow range of conditions or otherwise characteristic of continuous and coordinated patient care. In the Commission's *Report to the Congress: Assessing Alternatives to the Sustainable Growth Rate System*, generalist physicians in specialties such as family medicine and internal medicine were reported to treat many types of episodes of care. By contrast, specialists—such as dermatologists and urologists—were reported to focus their practices on only a few different types of episodes (MedPAC 2007b).

7 The effects are overstated because of increases in RVUs for primary care services that have occurred since 2006. For instance, the RVUs for physician work went up for many primary care services as a result of the most recent five-year review. With those increases, it is likely that more physicians would have met the threshold for furnishing primary care services—at a given level of the threshold—in a year subsequent to CMS's use of those RVUs for payment in 2007. With more physicians meeting the threshold, the percent of allowed charges eligible for the fee schedule adjustment would go up, the reduction for budget neutrality would be larger, and the minimum net change in qualifying practitioners' allowed charges would go down.

8 Specifically, insurers must design a medication therapy management program for enrollees with annual spending at or above $4,000.

9 CMS is currently implementing a five-year Medicare demonstration project that will encourage small- to medium-sized primary care physician practices to use electronic health records (EHRs) to improve the quality of patient care. By the end of the second year of the demonstration, participating physician practices must be using an EHR to perform specific minimum core functionalities that include clinical documentation, ordering and recording lab tests, and recording prescriptions. CMS expects to announce the locations of 4 of the expected 12 sites for the EHR demonstration by the end of 2008, with the remaining 8 announced in 2009 (CMS 2008b).

10 The first MAC is processing claims in Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. The second MAC is processing claims in Colorado, New Mexico, Oklahoma, and Texas. The third MAC is processing claims in Iowa, Kansas, Missouri, and Nebraska.

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CHAPTER 3

Examining hospital–physician collaborative relationships

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Chapter summary

A fee-for-service (FFS) payment system, which pays for health care services for 80 percent of Medicare beneficiaries and most workers covered by employer-sponsored insurance, creates economic incentives for providers to increase the volume of medical services they furnish. By paying piecemeal for each service or set of services, a FFS payment system increases providers' revenues as long as they increase the number or intensity of the services they deliver. Many types of health care providers have responded to these incentives by forming financial and organizational relationships with one another that enable, encourage, or reward volume growth. The result is a health care industry designed to increase the volume and intensity of services for the vast majority of Medicare beneficiaries enrolled in the FFS program. This volume growth increases Medicare costs for beneficiaries and taxpayers, and there is no evidence of a correlation in the aggregate between greater volume of services per beneficiary and higher quality care or improved health outcomes.

In this chapter

This chapter focuses on the variety of collaborative relationships between hospitals and physicians—including joint ventures, hospital employment of physicians, and hospital recruiting of community physicians—that are becoming increasingly prominent in health care delivery systems across the country. Although collaborative arrangements between hospitals and physicians sometimes can be formed to achieve desirable program goals, such as improving the quality of inpatient care in response to pay-for-performance incentives or providing access to specialty services in hospital emergency departments serving underserved communities, this chapter focuses on how these relationships contribute to volume growth. By revealing how the drive to increase service volume becomes ingrained in the structures of the health care delivery system in response to current Medicare FFS payment policy, we underscore the need to reform the policies that contribute to this dynamic. ■

A fee-for-service (FFS) payment system, which pays for health care services for 80 percent of Medicare beneficiaries and most workers covered by employer-sponsored insurance, fuels economic incentives for providers to increase the volume of medical services they furnish.[1] By paying piecemeal for each service or set of services, a FFS payment system will increase providers' revenues as long as they increase the number of services delivered. In traditional economic markets, the volume of goods and services produced rises and falls primarily due to changes in consumer demand, but in a health care marketplace, the suppliers of services (i.e., providers) have a major influence on the amount and intensity of services they deliver to patients.

Many physicians and hospitals have responded to the incentives presented by FFS by implementing financial and organizational arrangements that enable, encourage, or reward volume growth. The result in most areas of the country is a health care delivery system designed to increase the volume and intensity of services for the vast majority of Medicare beneficiaries who are enrolled in the traditional FFS program. This volume growth increases Medicare costs for beneficiaries and taxpayers, but in the aggregate there appears to be no correlation between higher spending levels and higher quality of care or improved health outcomes; in fact, the opposite may be true (Baicker and Chandra 2004, CBO 2008, Fisher et al. 2003a, Fisher et al. 2003b, MedPAC 2003).

This chapter explores the collaborative financial and organizational arrangements that have arisen between hospitals and physicians over the past few years and examines how they may contribute to the observed growth in the volume of services provided to beneficiaries in FFS Medicare. The relationships between hospitals and physicians matter because they show how the drive to increase service volume under FFS payment becomes ingrained in the structure of the health care delivery system. Fundamental payment reforms are needed to drive the health care delivery system toward the Commission's goals of moderating volume growth, while increasing the quality and value of health care services delivered to Medicare beneficiaries and paid for by beneficiaries and taxpayers.

In reviewing relationships between hospitals and physicians, we and other researchers find growing competitive as well as collaborative dynamics at work (Berenson et al. 2006, Goldsmith 2006, MedPAC 2006). The two often are interrelated: The fear of competition has been a potent driver of collaboration in some health care markets across the country. For example, one of the most visible and controversial manifestations of competition between hospitals and physicians is the rapid growth in the number of physicians investing in stand-alone specialty hospitals, ambulatory surgical centers (ASCs), and diagnostic imaging facilities and diverting patients from community hospitals to these facilities. In the four years from 2002 to 2006, the number of physician-owned specialty hospitals grew 178 percent (from 46 to 128), and the number of Medicare-certified ASCs grew 31 percent (from 3,600 to 4,700). In response to this competitive pressure, hospitals in some communities have decided to collaborate with physicians by entering into joint ventures with certain types of specialists (e.g., cardiologists, orthopedic surgeons, and radiologists) to promote their own specialty service lines. The Commission and other researchers found that the increasing number of physician-owned specialty hospitals is fueling volume growth for certain types of procedures (MedPAC 2006, Mitchell 2007, Nallamothu et al. 2007).

Though not discussed further in this chapter, other work by the Commission has examined the implications of this recent growth in competitive relationships between hospitals and physicians, particularly the growth of physician-owned specialty hospitals, and how those competitive relationships contribute to volume growth (MedPAC 2006, MedPAC 2005b). The Commission will continue to analyze these issues in future work. We also have considered how the current complex system of laws that regulate relationships between hospitals and physicians may pose barriers to delivery system reforms (MedPAC 2007, MedPAC 2005b). We will continue to examine these issues as well.

Why hospital–physician collaborative relationships matter for payment policy

With their authority to make diagnosis and treatment decisions, physicians are the central actors in the health care delivery system. When they recommend services to patients, professional ethics and concern for their patients' best interests are powerful motivations. However, financial incentives also influence some physicians' decisions, particularly with regard to services that lack evidence-based guidelines (Wennberg et al. 2002).

By paying for each service performed, Medicare's traditional FFS payment system rewards providers for the volume of health care services they furnish rather than for the outcome of those services. For physician services, Medicare pays a separate fee for each of about 6,700 discrete services on its physician fee schedule. For most other types of services, payments are based on aggregated groups of discrete services (e.g., diagnosis related group payments for each inpatient hospital admission, resource utilization group payments for each skilled nursing facility admission, and home health resource group payments for each home health episode). With rare exceptions, Medicare payment policies do not limit the total number of services, admissions, or episodes of care that may be provided to an individual beneficiary.

Several analyses published over the past five years using data on care provided to Medicare FFS beneficiaries have found no systematic correlation between higher volume and higher quality of care, or between lower volume and lower quality of care. In 2003, the Commission analyzed the relationship between service use and quality and found that many states with low service use had relatively high quality and many states with high service use had low quality (MedPAC 2003). Elliott Fisher and colleagues found that states where Medicare spending is a third less than in higher cost areas had equal or better quality than more expensive areas (Fisher et al. 2003a, Fisher et al. 2003b). A separate study by Katherine Baicker and Amitabh Chandra concluded that "[s]tates that spend more per Medicare beneficiary are not states that provide higher quality care. In fact, additional spending is positively correlated with end-of-life care but negatively correlated with the use of effective care" (Baicker and Chandra 2004). A hospital-level analysis by Jack Wennberg and colleagues found that this phenomenon also appears to be true at the level of individual hospitals within a state (Wennberg et al. 2005). A recent analysis by the Congressional Budget Office compared adjusted Medicare spending levels by state with a composite quality of care indicator using Agency for Healthcare Research and Quality recommended care guidelines for three common medical conditions, and it concluded that "areas with higher Medicare spending tend to score substantially worse on [the] composite indicator" (CBO 2008). Lastly, two recent studies that looked at treatment patterns across areas for two specific conditions (heart attacks and colorectal cancer) found that patients who lived in high-cost regions were more likely to receive high-intensity treatments whether or not that may have been appropriate given the patient's other characteristics such as age, stage of disease, and presence of other illnesses (Chandra and Staiger 2007, Landrum et al. 2008). Taken together, these findings strongly suggest that if payment policy incentives focused on encouraging and rewarding providers for furnishing the appropriate mix of services, instead of more services, the overall cost of health care could be reduced without harming—and possibly improving—the overall quality of care patients receive.

Another reason for concern that incentives guiding the volume of care are misguided is grounded in providers' discomfort with the current arrangements. The growing entrepreneurial response of the medical establishment to financial incentives has prompted some providers to voice concerns about the effects of this trend on the medical profession. Arnold Relman, a long-standing leader in the medical community and former editor of the *New England Journal of Medicine*, recently observed that "almost all private, not-for-profit hospitals are now managed like businesses. They advertise and market their services and exert every effort to fill their beds with insured, paying patients." He found that doctors are succumbing to the same business incentives and noted that "health care has come to resemble a vast profit-oriented industry" (Relman 2007).

In a similar vein, a young physician recently stated in a *New York Times* essay that "overconsultation and overtesting have now become facts of the medical professions. The culture in practice is to grab patients and generate volume. 'Medicine has become like everything else,' a doctor told me recently. 'Everything moves because of money'" (Jauhar 2008). A 2005 report from an Arizona health policy organization found striking consensus among hospital and physician respondents that "the health industry was, in the words of one physician, in danger of 'losing its soul' and how there was more to this issue than just making more money and looking out after Number One…. Many [providers] wish to spend more time with patients and improving medical care" (Arizona Health Futures 2005).

Health services researchers have expressed concern about fragmentation in the delivery system, which stems from a medical culture that values autonomy and is reinforced by a FFS reimbursement system that pays providers individually, rather than collectively, for their work. This fragmentation has negative consequences for patient safety

by inhibiting the development of systems within hospitals and other health care delivery settings that emphasize and reward teamwork and shared accountability. Recognizing the interdependence of organizational culture in health care delivery and payment policy, the researchers note that eliminating barriers to patient safety in the current health care delivery system will be difficult without realigned financial incentives that increase the interdependence of health care provider organizations and increase the financial return on providing safe care (Shortell and Singer 2008).

In exploring the range of strategies hospitals and physicians are using to collaborate, it is important to acknowledge that some arrangements are more likely than others to influence volume and that the role of a given strategy may vary by community. For example, in communities experiencing rapid population growth or that are historically underserved, hospitals that are trying to attract more physicians may not be responding to FFS payment incentives to grow service volume as much as they are responding to community needs for improved access to care. Nevertheless, policymakers should be aware of the overall role of these strategies in producing more services and increasing costs for Medicare, its beneficiaries, and taxpayers.

What drives collaboration between hospitals and physicians?

Although the tenor of hospital and physician relationships since at least the 1990s has been increasingly tense or even hostile, hospitals and physicians still have compelling reasons for collaborating to exert more control over the volume of care and to share in the resulting increased revenues. The degree to which hospitals and physicians engage in collaboration or competition varies widely across local health care markets in the United States. The following section describes the different collaborative activities taking place.

Factors driving hospitals to collaborate with physicians

In this era that some researchers describe as one of "loose managed care," hospitals have at least four reasons to align with physicians. Alignment potentially improves a hospital's ability to compete for admissions, improve quality of care, control the cost of care, and gain leverage with health plans in rate negotiations (Casalino and Robinson 2003). The Commission's review of the literature and conference proceedings on recent industry trends, site visits, and discussions with industry representatives about alignment strategies indicates that all these factors are at play, but the drive for admissions and profits on outpatient services is particularly intense. Of particular interest is the competition among hospitals for relationships with physicians, who are essential to increasing admissions and outpatient referrals. As one hospital executive summarized this dynamic: "No physicians, no admissions, no hospital" (Casalino and Robinson 2003).

In securing their referral base through closer alignments with physicians, hospitals may be acting defensively—responding to the actions of others that threaten to undermine their sustainability. One motivation for hospitals to align with physicians is the concern that physicians will open a specialty hospital or ASC and redirect lucrative, if not all, referrals to the facility in which they have an ownership interest. Another concern is that a community's physicians will enter into a joint venture with other organizations to provide services such as imaging and cardiac catheterization, which has the effect of redirecting these high-margin services away from the hospital. Physicians' new-found leverage in the market stems from technological advances that make it possible to do more diagnostic and therapeutic services outside of the hospital and from Medicare payment policies that have created profitable service lines.

A hospital may also be concerned that if it does not align with physicians—that is, give them an opportunity for greater control and profit—another hospital in the community will.[2] Another possibility is that certain types of physicians will practice exclusively outside the hospital, refusing to take call at the hospital. Under either of these scenarios, a hospital could lose admissions and referrals to its own outpatient department and have a diminished capacity to meet patient needs or comply with regulatory requirements. The Center for Studying Health System Change recently found that hospitals in some large communities, including Miami and Phoenix, are experiencing emergency department (ED) coverage problems for many, particularly surgical, specialties. Because general acute care hospitals are obligated under the federal Emergency Medical Treatment and Active Labor Act to provide access to emergency care around the clock, the researchers found "[i]n the communities experiencing significant ED coverage problems, most

hospitals reluctantly have started paying physicians for ED call or have guaranteed payment for services rendered for those patients lacking health insurance, or both" (Berenson et al. 2006).

With or without the competitive threat from physician-owned specialty care facilities, a hospital may decide to partner with certain types of specialists as a business strategy to grow profitable specialty service lines such as cardiac care, orthopedic surgery, and advanced diagnostic imaging. Physicians can provide insight into what clinical services might experience future growth, bring in more admissions and referrals, help to reduce the hospital's costs per admission, and help to improve the hospital's quality of care in response to pay-for-performance programs.

Over time, these individual collaborative decisions may affect the composition of the physician workforce and supply of hospital resources in an area. Research by Baicker and Chandra suggests that the composition of the physician workforce in an area affects whether greater service volume, higher quality of care, or both will occur. Specifically, they found that states where more physicians are general practitioners tend to have higher quality care and lower per capita spending, and those where a larger share of the physician workforce is composed of specialists have higher per capita costs and lower quality (Baicker and Chandra 2004).

Over the last several years, Jack Wennberg, Elliott Fisher, and their colleagues have produced considerable evidence that concentrations of medical and surgical specialists combined with an abundant supply of hospital beds in a given geographic area are strongly associated with higher per capita health care costs (adjusted for patients' health status) and lower quality care for chronically ill Medicare beneficiaries (Fisher et al. 2003a, Fisher et al. 2003b, Wennberg and Cooper 1999, Wennberg et al. 2005, Wennberg et al. 2004). Similarly, other research found that supply of local hospital beds, rather than patient preferences, explained the differences in end-of-life care among patients (Pritchard et al. 1998).

Hospitals and physicians also have initiated collaborations in response to financial incentives or clinical imperatives to improve hospitals' quality of care. Medicare's use of pay-for-performance incentives in the Hospital Quality Improvement Demonstration has prompted hospitals to engage with physicians to improve the hospitals' performance results (Butcher 2007, Pham et al. 2006). Hospitals find that employing physicians in leadership positions to interact with community physicians improves physician compliance with hospital initiatives and priorities, such as implementing clinical guidelines. In addition, individual physicians have initiated effective quality improvement strategies for inpatient care and then worked with hospitals and payers to convince them of the economic and clinical rationales for investing in these innovations (Gawande 2007).

Factors driving physicians to collaborate with hospitals

Physicians are motivated to partner with hospitals for various reasons. First, partnering with hospitals has the potential to increase physicians' productivity, making it possible for them to do more in the same amount of time. For example, by working with the hospital to better manage the operating room schedule to reduce travel and preparation time, surgeons can do more surgeries faster. Second, some physicians are interested in pursuing opportunities for sources of income beyond their professional fees, and hospitals are in a position to offer them joint ventures on ancillary services, bonus payments for meeting certain quality objectives, hourly payment for attending medical staff meetings, joint ventures pertaining to real estate, and attractive bond offerings. Third, partnering with a hospital may give physicians better leverage in gaining entry to private insurers' provider networks and negotiating better payment rates with those insurers. In fact, such negotiations may compel physicians and hospitals to pursue clinical integration, the most interconnected form of hospital–physician collaboration.

Lifestyle preferences also may lead physicians who want greater scheduling flexibility and fewer administrative responsibilities into partnering with a hospital. Hospital employment offers a more predictable work schedule and a greater likelihood of part-time work. In addition, some physicians are increasingly eager to avoid the responsibilities of managing staff, billing insurers, and covering the costs of professional liability (malpractice) insurance.

Hospital and physician alignment strategies

The various alignment strategies hospitals and physicians use underscore the symbiotic relationship that exists between the two provider types. This section describes seven different alignment strategies in which hospitals:

- offer community physicians financial incentives to foster clinical integration,
- hire physicians as employees,
- employ hospitalists,
- recruit physicians to community practices within the hospital's market area,
- employ physician liaisons,
- enter into joint business ventures with physicians, and
- offer physicians participatory bond investment opportunities.

Fundamental to most of these business arrangements are the financial incentives embedded in FFS payment systems to increase the volume of health care services delivered. We could not measure the prevalence of each strategy with quantitative precision; instead, our analysis relied on provider site visits and publicly available industry statistics and reports. The implementation details of these strategies vary from market to market and they often are affected by the complex framework of laws, described in the text box (pp. 62–63), that regulate hospital–physician relationships.

Financial incentives to foster clinical integration between hospitals and community physicians

Some alignment strategies are designed to address the business challenge to hospitals posed by community physicians, who generally practice independently of the hospital and therefore have financial interests separate from the hospital. In recent years, hospitals have sought to bridge the two parties' separate financial incentives by integrating clinical practices. We examined the four most prominent clinical integration strategies in the health care marketplace today: comanagement arrangements, financial incentives associated with physicians' use of supplies and technology, information technology (IT) collaboration, and hospital payments to community physicians for their time spent providing services in the hospital.

Comanagement arrangements

Under comanagement arrangements, a hospital and physicians in the local community form a limited liability corporation (LLC), under which the LLC, funded by the hospital, pays the physician a salary for performing specific clinical tasks (e.g., quality improvement or medical technology evaluation), usually related to a specific service line (e.g., cardiology or orthopedics). The hospital also pays the physician a bonus for meeting certain objectives. According to consultants familiar with these arrangements, these objectives may be associated with improved patient safety; patient satisfaction results; and efficiency, standardization, and cost savings (Nathanson and Schmidt 2006). With bonuses tied to the achievement of quality and efficiency objectives, an opportunity exists under these arrangements to improve the value of health care dollars spent. Some comanagement arrangements are financed using a fixed amount of revenue. To ensure regulatory compliance, these arrangements tend to include the contracting of an outside valuation company to assess whether physicians are compensated at fair market value.

At the same time, an opportunity exists under comanagement arrangements to maximize revenues by increasing volume. For example, if physicians respond to a bonus by achieving shorter patient turnover time in the operating room, the hospital can increase the volume of patients it serves without necessarily increasing capital or staffing costs. Moreover, to the extent that a hospital's bonus system is tied directly to volume objectives, growth can be expected. At least one industry consultant indicated that increasing market share and meeting geographic growth targets are an acceptable basis for bonus awards (Eisenberg 2006). In this way, comanagement arrangements may encourage hospitals to attract and compensate high-volume physicians, cultivating a culture of performing more services without evidence that it will improve quality or health outcomes.

Financial incentives associated with use of supplies and technology

Under certain arrangements, a hospital will share with physicians any savings they achieve by increasing the efficient use of medical supplies and devices used in certain types of clinical procedures. An agreement between cardiologists and PinnacleHealth System regarding items used in a cardiac procedure is an illustrative case (Abelson 2005). The doctors and hospital agreed that, when possible, physicians would use a single artery-opening balloon in all stent-insertion procedures instead of using multiple balloons in each procedure. In so doing, the doctors would share in the savings. They would also share in the savings from using stents, pacemakers, and other cardiac devices that the hospital pays for at a negotiated volume discount. Regulators approved the arrangement because it offered adequate protections for the quality of care.

Laws that regulate hospital–physician relationships and their implications

Certain statutes governing relationships between hospitals and physicians are intended to protect consumers and payers from possible abuses. For example, hospitals might be inclined to reward physicians for referrals, which could result in the provision of unneeded care, higher Medicare spending, and unfair competition. Also, under Medicare's diagnosis related group payment system that pays hospitals a fixed rate per admission even if their costs exceed this rate, hospitals might be inclined to reward physicians for inappropriately limiting patient care to keep costs down. Accordingly, as hospitals and physicians forge relationships, they must navigate the statutes listed in Table 3-1.

The hospital industry has raised concerns that this legal structure is complex and lacks clarity, thereby stifling productive alignment between hospitals and physicians (AHA 2007a). Substantial gray areas exist in defining what is allowed and what is not. Providers may disagree on what incentives stretch the limits of the law or have different levels of tolerance for the risk of being in violation of applicable statutes. For example, can hospitals reward community physicians for increasing market share in a given geographic area, or would that practice violate the Stark law or the anti-kickback statute? Contrasting opinions exist within the industry on the legality of such strategies.

With respect to the alignment strategy traditionally called gainsharing (also referred to as shared accountability arrangements), the Commission recommended in 2005 that current law be reformed to permit arrangements that have the potential to encourage cooperation among providers in improving efficiency, reducing program costs, and enhancing quality (MedPAC 2005b). In a typical shared accountability arrangement, hospitals and physicians agree to share savings from reengineering clinical care in the hospital. Ideally, the legal framework within which these arrangements would operate could allow joint negotiating with manufacturers to obtain greater discounts on supplies and devices, more efficient scheduling of operating rooms, mutual compliance with

(continued next page)

TABLE 3–1 **Laws applicable to hospital–physician relationships**

Law	Description
Civil money penalty statute (Section 1128A of the Social Security Act)	Prohibits hospital payments to physicians to reduce or limit services to Medicare inpatients, regardless of the medical necessity of the services. A hospital would be in violation of this statute if, for example, it rewarded physicians for reducing the number of days in the intensive care unit or the drugs their patients use.
Federal anti-kickback statute (42 U.S.C. 1320a–7b)	Prohibits the offer, payment, or receipt of anything of value to induce the referral of patients for services paid for by federal health programs.
Ethics in Patient Referrals Act (the Stark law) (42 U.S.C. 1395nn)	Prohibits physicians from referring Medicare or Medicaid patients for certain services (e.g., imaging, hospital services, and physical therapy) to entities with which they have a financial relationship, unless the arrangement fits within an exception. Exceptions include certain compensation arrangements and surgical services provided by ambulatory surgical centers.
Antitrust laws (various federal and state statutes)	May apply to hospitals and physicians that are independent entities but that wish to jointly negotiate contracts with health insurance payers. Antitrust laws are enforced by the Federal Trade Commission, Department of Justice, state attorneys general, and—potentially—private litigants.

Laws that regulate hospital–physician relationships and their implications (cont.)

clinical protocols for improving efficiency and quality, and sharing bonuses earned for quality achievements.

Under current law, however, shared accountability arrangements are limited to a more narrow set of permissible activities. Efforts to promote these arrangements were largely stymied after the Office of Inspector General (OIG) issued a special advisory bulletin in 1999 stating that shared accountability arrangements (referred to by the OIG as gainsharing arrangements) are prohibited by the civil money penalty statute that prohibits hospitals from paying physicians to limit services to Medicare inpatients (OIG 1999). The OIG stated that, in addition to creating incentives for physicians to withhold or diminish care, these arrangements could induce physicians to refer patients to the hospital with which they have the most lucrative arrangement, a potential violation of the anti-kickback statute. OIG noted in its ruling that well-designed arrangements could result in better quality care at lower cost—for example, by encouraging physicians to substitute lower cost (but equally effective) supplies and devices and eliminate unnecessary ancillary services and inpatient days.[3]

In advisory opinions issued between January 2001 and January 2008, the OIG approved several narrowly defined shared accountability arrangements when they included several features that protected the quality of care and made it unlikely that physicians would be financially rewarded for referring patients to the hospital. However, these opinions apply only to the individual arrangements submitted for review by specific providers. Other providers wishing to receive OIG approval must design similarly narrow arrangements and then go through the lengthy advisory opinion process, which probably is a strong deterrent to forming the arrangements.

The Commission has encouraged the development of shared accountability arrangements in which hospitals and physicians collaborate to reduce costs and improve quality. These arrangements could counterbalance certain conflicting incentives inherent in separate payment systems for physicians and hospitals under fee-for-service Medicare. In its 2005 report to the Congress on physician-owned specialty hospitals, the Commission recommended that the Congress provide the Secretary of the Department of Health and Human Services (HHS) the authority to allow and regulate these arrangements (MedPAC 2005b). The recommendation called for the Secretary to develop rules that allow gainsharing arrangements as long as safeguards exist to ensure that cost-saving measures do not reduce quality and that payments to physicians are unlikely to influence their referrals.

Within HHS, CMS will be testing different types of shared accountability arrangements through two demonstration programs. In the Medicare Hospital Gainsharing Demonstration Program, authorized by the Deficit Reduction Act of 2005, CMS will allow hospitals to provide gainsharing payments to physicians that represent a share of the savings achieved by collaborative efforts to improve quality and reduce costs. The three-year project, involving as many as six hospitals, will evaluate short-term improvements in quality and efficiency that occur during, and up to 30 days after, the inpatient stay. By contrast, the broader Physician Hospital Collaboration Demonstration (authorized by Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) will examine the impact of shared accountability arrangements on longer term health outcomes (e.g., mortality and readmission rates) and use of services. This three-year project will focus on integrated delivery systems and physician groups. For both demonstration projects, CMS has issued solicitations but has not yet announced participants. ■

Although some hospitals have found the regulatory burden too great to pursue such arrangements, others have found ways around the restrictions. One hospital that we visited developed an approach it calls "virtual gainsharing": When physicians agreed to help the hospital negotiate lower rates with vendors for surgical implants and devices, the hospital invested a portion of the savings in infrastructure requested by physicians, such as new cardiac catheterization labs, operating rooms, and surgical equipment. Another hospital we visited has reached a similar agreement with physicians.

Virtual gainsharing arrangements may be attractive to hospitals because they can reduce supply costs and free up money to invest in profitable service lines, but the economic benefits to payers and patients are less clear. The Commission has recommended changes in the legal and regulatory structure for gainsharing arrangements that would allow the program and beneficiaries to share in any reduced costs produced by these efficiency gains. Perversely, the current legal framework may encourage hospitals and physicians to collaborate on reinvesting any savings from efficiency gains into new ventures, such as specialty service lines or medical equipment, that actually drive more volume and increase spending overall. In effect, operational and capital improvements that result in greater productivity also generate more procedures and higher spending, without evidence that more services are correlated with overall gains in quality or health outcomes.

Information technology

Hospitals can also facilitate alignment with community physicians by donating IT (including hardware, software, Internet connectivity, and training and support services) to physicians. The Congress enacted an exception to the regulations implementing the Stark law in October 2006 clarifying permission for this type of arrangement (AHA Center for Healthcare Governance 2007). In May 2007, the Internal Revenue Service (IRS) released a memo stating that IT-related financial assistance to physicians will not pose a threat to the tax-exempt status of a hospital donor (IRS 2007). There are several conditions in the IRS guidance: The technology must be used predominantly to create, maintain, transmit, or receive electronic health records (EHRs); have an e-prescribing capability; and be interoperable. Recipients of donated technology must also contribute at least 15 percent of the cost.

Many hospitals, particularly in competitive markets, are providing or planning to provide this technology to physicians. According to a recent survey of health care IT executives, an estimated 35 percent to 40 percent of hospitals are actively considering assisting physicians with EHRs or have already organized physician EHR programs (AHA Center for Healthcare Governance 2007).

A 2007 American Hospital Association analysis noted that hospitals and physicians have a variety of reasons to pursue alignment through IT (AHA Center for Healthcare Governance 2007). For both parties, there is the promise of improved quality and patient service. The availability of EHRs across care delivery sites eases and standardizes the process of populating a patient's health record with lab and imaging results and discharge notes. Clinical and administrative protocols and reminders can be built into the system. Administrative staff can query the patient database for overdue reminders, creating additional opportunities for patient education and engagement.

The benefits of EHRs in increasing physicians' efficiency in their own practices are considerable. They can increase practice revenue due to faster and better documented coding and claims submission processes. Physicians can more easily report on performance measures for quality-reporting incentive programs; more efficiently conduct patient outreach, which may increase service volume; and eventually deploy their office staff more efficiently (e.g., nursing staff can spend less time pulling patient charts and tracking down test results, effectively freeing them to see more patients).

The hospital also stands to gain from helping physicians finance their EHR systems and linking physicians' systems to the hospital. In addition to the potential quality gains, the hospital has a powerful tool to "bond physicians to the hospital." For example, an EHR strategy can be "an effective market defensive vehicle if the hospital is at risk of having referring physicians lured away by a competing hospital." In some highly competitive markets, there can be a "first-to-market" phenomenon, in which the hospital with the most attractive and cohesive community physician EHR initiative is more likely to lock in key physicians (AHA Center for Healthcare Governance 2007).

The Commission has noted that the adoption of clinical IT by providers has the potential to improve the quality, safety, and efficiency of health care, and we have recommended that Medicare quality incentive programs for physicians include measures of IT-supported functions (MedPAC 2005a). At the same time, the trend in the hospital industry to attract physicians to hospital market areas using IT improvements as an incentive may present a more complex picture of IT's potential benefits. To the extent hospital IT strategies help develop clinical integration with community physicians, volume is likely to increase in competitive hospital market areas.

Compensating community physicians for their time

Hospitals are increasingly paying community physicians to provide clinically related services at the hospital. Historically, physicians who belonged to a hospital's

medical staff spent some of their time covering the emergency room pro bono, tending to uninsured patients, and serving on hospital committees in exchange for enhancing a physician's reputation through association with the hospital. This reciprocal arrangement is no longer the default. As a physician group practice executive described: "Traditionally, physicians had a lot of loyalty to the hospital. They would actively go there to eat breakfast, for the camaraderie, etc. There is little loyalty now. Doctors don't take part in hospital governance unless they are forced to" (Berenson et al. 2006). Today, hospitals pay physicians to serve as medical directors for a service line, on either a part-time or a full-time basis. Time spent at hospital committee meetings may be compensated. Hospitals may also pay physicians Medicare rates or higher to care for uninsured patients.

Hospitals are also increasingly paying physicians for ED coverage (Johnson 2006, O'Malley et al. 2007). Most hospitals—73 percent in 2005, according to a 2006 survey of ED directors—find maintaining adequate call coverage a problem (ACEP 2006). In 2005, 36 percent of hospitals reported paying physicians for emergency room coverage, up from only 8 percent in 2004. Typically, hospitals pay $1,000 per day for ED coverage in scarce subspecialties such as neurosurgery, although one hospital reported it pays neurosurgeons $10,000 per week of ED coverage and 120 percent of Medicare payment rates for uninsured trauma patients (Berenson et al. 2006). Other hospitals have agreed to pay physicians' liability insurance in exchange for covering the emergency room (Berenson et al. 2006, O'Malley et al. 2007). Specialists in markets with physician shortages are most likely to be able to negotiate such arrangements. Hospitals, fearing the prospect of defections by specialist physicians to competitors or to meet their legal obligations under the federal Emergency Medical Treatment and Active Labor Act to provide access to emergency care around the clock, often believe they have no choice but to meet the physicians' demands. Hospitals' decisions to pay physicians for ED coverage may result in some increases in service volume, but in most cases this outcome is desirable from the perspective of ensuring rapid access to emergency care.

Hiring physicians as employees

Hospitals are increasingly hiring physicians as employees. According to a 2007 report from a large national physician recruitment firm, 43 percent of their physician search assignments in 2006–2007 were for placements in a hospital setting, compared with only 11 percent in 2003–2004 (Merritt, Hawkins & Associates 2007a).

A number of factors motivate hospitals to take this approach. Hiring physicians as employees can bypass regulatory concerns that complicate financial arrangements between hospitals and community physicians. For example, hospitals can offer payment incentives to employed physicians that otherwise might violate anti-kickback laws, without being subject to the same scrutiny that pertains to community physicians. From the physician's perspective, being employed by a hospital may provide benefits associated with career stability and lifestyle, such as more regular hours, administrative support systems, and the status of being associated with a well-regarded health system or hospital. From the hospital's perspective, by employing physicians it can avoid having to rely on the cooperation of community physicians in recruitment efforts (ECG 2005). Employing physicians can also improve the hospital's ability to persuade them to practice more cost-efficient medicine and reduce lengths of stay (LOSs) (ECG 2005). Employed physicians in charge of a department may also be more effective than a nonclinical administrator in communicating with community physicians.

Hiring may be complicated by perceptions held by community physicians, who may resent an arrangement that suggests favoritism by the hospital toward a particular group of community physicians or perceive hospital employment as a competitive threat to their livelihoods. In response, hospitals in some communities have chosen to employ all of the community's physicians. Other barriers to hospital employment of community physicians in California, Texas, Ohio, Colorado, Iowa, Illinois, New York, and New Jersey are laws banning the "corporate practice of medicine," which preclude hospitals from employing physicians to provide outpatient services.

The effect of employment on the volume of care delivered appears to vary. For example, one Midwestern health system provides an interesting example of an integrated delivery system (IDS) that rewards and encourages greater volume. The chief executive officer notes that the system's structure makes money and has withstood the test of time (18 years) as well as several IRS reviews. He notes that the health system's culture is oriented "to servicing physician practices." The text box (p. 66) provides further discussion.

Case study: A Midwestern integrated delivery system's experience employing physicians

A Midwestern integrated delivery system (IDS) with multiple hospitals, clinics, and post-acute care service facilities employs physicians under what it calls a "partnership model." The IDS pays its physician partners based on their individual production. Physicians receive a percentage of the revenue they generate (excluding technical fees) and the revenue generated by physician assistants and other nonphysician practitioners whom the physician supervises. At the beginning of the year, the physicians do not know what their income will be. They agree to receive a biweekly paycheck for a specified amount, which is reconciled quarterly based on a percentage of revenue from each payer generated by their services. For example, a physician may earn 54 percent of Medicare's payment amount for a given service, 54 percent of each private insurer's payment amount, and 54 percent of Medicaid's payment amount; the percentage may vary according to each physician's total revenue. The IDS retains the remainder of each payment as overhead and profit. The system also pays physicians a predetermined rate for any uncompensated care they provide. In effect, this payment system enables physicians to increase their total income by providing more services and thereby increasing the health system's revenue.

The base payment structure is supplemented by a performance incentive program under which physician partners can earn additional money for retirement if they meet certain goals, such as patient satisfaction, cost reduction, and quality improvement. According to the chief executive officer (CEO) and medical director, offering performance incentives motivates physicians, particularly given their competitive nature. An incentive system became necessary when the IDS's management officials realized that a production-oriented compensation system did not provide sufficient incentive for physicians to participate in hospital management, quality improvement, and cost containment initiatives.

Physician partners at the IDS have agreed to adjust the percentage of physicians' revenue so that primary care physicians receive a higher percentage than specialty physicians, in recognition of the fact that specialty services are paid higher rates and yet the specialists depend on the primary care physicians to refer patients to them. According to the IDS's CEO, the culture is not the same in a nearby state, where specialists do not think they need to sacrifice part of their income to primary care physicians.

The IDS manages the resources available to physicians in terms of technology (e.g., diagnostic imaging equipment), staffing, and information technology. As the IDS takes on these responsibilities, the physician has more time to see patients, generate volume, and increase income.

The IDS makes imaging and other equipment available to physicians as long as analysis shows that it will provide a return within three years. The IDS generates revenue for itself from facility fees for the use of hospital-owned technical equipment, such as MRI machines, and the physician partners benefit financially from the availability of the equipment to the extent it garners them additional volume. The CEO referred to this as a "win-win situation" for the IDS and its physician partners.

The IDS owns a range of other health care service providers, allowing the system to capture some of the profit associated with "downstream" services, such as home health care, physical therapy, durable medical equipment, and pharmacy, which the system's primary care practitioners prescribe for patients. The CEO estimates that for each dollar billed in the primary care physicians' offices the system generates an additional $9 in other health care revenues. ■

Some hospital systems use compensation models that differ from that used by the Midwestern IDS described in the text box. Some pay physicians an annual salary. Under a salary-based payment system, physicians tend to generate less volume than self-employed physicians and pay less attention to the costs of operating the practice (Casalino and Robinson 2003). One health system that we visited had traditionally paid its physicians an annual

salary and reportedly enjoyed the enhanced collegiality that being paid primarily on salary affords. For example, their colleagues tend to provide informal advice and consultations by telephone rather than requiring that they see the patient and bill for services. This system has recently blended physician salaries with a volume-based incentive payment structure. Because of the newness of this action, it was too soon to assess physicians' reactions. These physicians also have the opportunity to share in system profits on an annual basis.

Hospitals employing hospitalists

Hospitals are increasingly relying on hospitalists, generalist physicians who practice exclusively in the acute inpatient setting, to serve patients traditionally served by primary care and specialist physicians. In the last five years, the number of hospitalists in the United States has doubled. In 2003, the American Hospital Association reported 11,000 hospitalists working in its members' hospitals. Current estimates from the Society of Hospital Medicine suggest that there may be 24,000 hospitalists practicing in 2008, and some industry observers have projected that figure to grow to as much as 30,000 by 2010 (SHM 2007). Accordingly, hospitalists are serving a growing proportion of Medicare patients. In 2004, they were the attending physicians for 2.4 million Medicare beneficiaries or 20 percent of all Medicare discharges; by 2010, they are projected to be the attending physicians for 5.6 million beneficiaries or 43 percent of all Medicare discharges (SHM 2007). The text box (p. 68) describes how hospitals are employing hospitalists today.

The proliferation of hospitalists and hospitalist programs is widely considered a response by hospitals to the desires of primary care and specialist physicians who wish to spend more time seeing patients in their offices. Specifically, as technology has increased the number and complexity of services that can be performed in the outpatient setting, many primary care and specialty physicians have discovered that seeing their patients in the hospital may limit the amount of time they spend providing services in their offices. In addition, some researchers have posited that primary care physicians (PCPs) who spend less time in the hospital than others are less likely to have to treat uninsured patients (who may not be able to pay for treatment) and are less likely to encounter malpractice suits arising from hospital-based care (Pham et al. 2005). Thus, some hospitals may be employing more hospitalists as part of a strategy to improve their relationships with community physicians, who can generate patient referrals to the hospital. For their part, community physicians may welcome the addition of hospitalists to the local hospitals where they have admitting privileges, as that may increase both the amount of time community physicians have to see patients and the number of services they can perform.

Hospitals find that, aside from filling potential gaps in care created by the migration of PCPs out of the hospital, hospitalists offer other advantages, such as consolidating inpatient care into the hands of a few physicians, which may positively affect a hospital's cost management and quality improvement goals. Research to date on the cost and quality impacts of hospitalist programs indicates that they increase the efficiency of inpatient care, as measured by shorter average LOS and lower costs per stay, without decreasing the quality of care, as measured by mortality and readmission rates. The most recent analysis concluded that, compared with inpatients who were cared for by general internists, patients cared for by hospitalists had a modestly shorter average LOS (0.4 day shorter) and lower cost per stay ($268 less), with similar mortality and 14-day readmission rates (Lindenauer et al. 2007). The analysis also found that these trends generally persisted when patients of hospitalists were compared with patients of family physicians.

Other studies in the last 10 years have identified similar outcomes when comparing inpatients cared for by hospitalists with those cared for by other types of physicians. A 2007 study conducted in an academic teaching hospital over two years found that patients served by hospitalists were in the hospital approximately 0.9 day less than patients served by nonhospitalists (Southern et al. 2007). A 2005 study that isolated the impact of hospitalists on elderly patients admitted to the hospital for surgical repair of a hip fracture found that hospitalists' patients had a shorter time to surgery by six hours and a shorter LOS by three days compared with patients served by nonhospitalist physicians (Phy et al. 2005). Finally, a 2004 study conducted at an academic teaching hospital over one year found that patients served by hospitalists had a 1-day shorter LOS and significantly lower average costs per stay ($917) but higher average costs per day ($122) (Kaboli et al. 2004).

Evidence on the impact of hospitalist programs on overall Medicare spending is unclear. Under Medicare's inpatient prospective payment system, hospitalists' more efficient use of hospital resources during inpatient stays would

How are hospitals employing hospitalists today?

Hospitals employ hospitalists either directly or contractually. Most hospitalists are employed directly by hospitals or by hospitalist-specific physician group practices that contract with hospitals. In 2005, 34 percent of hospitalists were employed directly by a hospital, and 31 percent were employed by hospitalist-specific private practices, which includes hospitalist management companies (SHM 2007). An additional 20 percent were employed by a medical school or academic program and 16 percent were employed by a physician practice specializing in something other than hospital medicine. According to one industry expert, a growing proportion of hospitalists have been hired as contracted employees in recent years.

Some hospitals employ hospitalists as a part of a program that focuses on managing the clinical care of individual patients as they pass through the hospital's various clinical departments. These programs typically incorporate a variety of nonclinical efforts to assist facility administrators with improving hospital efficiency and commonly include nursing staff to assist hospitalists with patient care coordination. Some hospitals initiate and operate these programs internally. Others choose to outsource the implementation of these programs to hospitalist physician groups or companies that provide administrative services, such as hiring nursing support staff, establishing a hospitalist payment structure, and filing patient claims, along with contracting for a hospitalist group practice for the physician services. We spoke with a representative from one hospitalist company who noted that the cost of outsourcing the implementation of a hospitalist program can be prohibitive for smaller hospitals.

Hospitalists and hospitalist programs are more likely to exist at large, teaching, and urban hospitals and are less likely to exist at rural hospitals. Nationwide, 67 percent of hospitals with 200 or more beds, 63 percent of teaching programs, 57 percent of urban hospitals, and 17 percent of rural hospitals used hospitalists in 2006 (AHA 2007b). In addition, hospitalists are more common in certain geographic regions, such as on the East and West Coasts. For example, the presence of hospitalists is more pronounced in California than nationally. In California, 73 percent of large urban hospitals have hospitalist programs, compared with 32 percent of rural hospitals. ■

reduce hospital costs and increase the hospital's profit, but Medicare would not directly share in these savings in most cases. Many hospitalists have compensation arrangements that combine a base salary with volume-related bonuses, which may create incentives for them to increase the number of patients they see or services they provide. According to a 2005–2006 industry survey, 67 percent of hospitalists are compensated through a mix of salary and volume- and performance-based incentives, 5 percent are compensated based totally on a volume and performance basis, and 28 percent are salaried (SHM 2008). Hospitalists with volume-based compensation arrangements may indirectly benefit from increases in admissions ordered by hospital-affiliated community physicians and hospital ED physicians, but hospitalists cannot directly affect a hospital's admissions rate because they do not decide whether to admit patients. Hospitalist industry leaders suggest that programs rewarding hospitalists on the basis of volume may fail to produce efficiencies for the hospital and ultimately will be abandoned. They argue that programs that balance volume incentives with quality and patient satisfaction incentives tend to limit the daily number of patients a hospitalist sees and, in so doing, are more effective at improving quality and reducing LOS.

Some community physicians have speculated that the increased use of hospitalists could increase hospital readmissions because of communication breakdowns between shifting members of hospitalist staffs and a patient's PCP when a patient is discharged. These

observers contend that the resulting discontinuity of patient care across settings could result in lower quality care for patients and that information critical to patient care may be lost in the transition (Brewer 2008). However, the most recent published analysis found that 14-day readmission rates for patients cared for by hospitalists were similar to those for patients cared for by general internists or family physicians (Lindenauer et al. 2007). Hospitalist industry leaders believe that well-designed hospitalist programs have the potential to reduce readmissions by facilitating communication between the hospitalist and community physician when a patient is discharged from the hospital (SHM 2007). Cogent Healthcare, one of the country's largest hospitalist companies, and other firms require their hospitalists to write patient transfer notes for the patient's PCP and tie hospitalists' bonus payments to the performance of this task. Cogent's program also has access to clinical care coordinator nurses for patients entering and exiting the hospital, including telephone contact with every patient within 48 hours of discharge from the hospital to review discharge instructions and compliance with the care plan.

Hospitalists also may play an important role in hospitals' efforts to implement information technology and other process tools to improve patient safety and other inpatient quality-of-care measures. Unlike community physicians who admit patients to multiple hospitals, hospitalists can be "captive audiences for adoption of new information technology such as computerized physician order entry, because hospitalists practice in a single institution and their higher patient volume can help them learn new technology more quickly" (Pham et al. 2005). Thus, another reason hospitals are increasing the use of hospitalists may be an expectation that this investment will improve their performance in Medicare's and private payers' quality improvement incentive programs.

Hospital recruitment of physicians

Hospitals have a strong interest in ensuring that physicians practicing in the community refer patients to them. A lack of affiliated physicians can reduce the number of patients who go to a hospital. For example, if it takes PCPs months to schedule a gastroenterology consultation at a given hospital, they may start sending patients to specialists aligned with another hospital. Similarly, a hospital system's lack of PCPs may lead specialists to affiliate with a better organized system to generate referrals. In one example recounted in the *San Francisco Business Times*, a cardiology group changed its referral pattern from one hospital to another because it had lost faith in the former facility's ability to attract PCPs that could refer heart patients to the group. As an executive in the cardiology group put it, "I mean no disrespect to [the former hospital system], but they don't have a physician strategy" (ECG 2005).

Overall physician recruitment has increased over the past few years but the mix of physician specialties being recruited has shifted over time. In the mid-1990s, approximately 75 percent of the physician searches performed by a large national physician search firm were for primary care physicians, driven largely by the growth of managed care plans at that time. In the early- to mid-2000s, that proportion was reversed and about 75 percent of the firm's searchers were for surgical or diagnostic specialists. Most recently (in 2006–2007), family practice and internal medicine were the firm's two most requested physician search assignments (Merritt, Hawkins & Associates 2007a).

Even if the hospital is not at risk of alienating physicians by not having a "physician strategy," hospital executives may perceive that they are forgoing a potential revenue stream by not recruiting physicians with potentially high-volume and high-margin practices to their market area. For example, in a 2007 industry survey of hospital chief financial officers, the 119 survey respondents estimated that the average hospital inpatient and outpatient revenue generated per physician is about $2.7 million for each invasive cardiologist, $2.3 million for each orthopedic surgeon, $2.2 million for each noninvasive cardiologist, $2.1 million for each neurosurgeon, and just under $2.0 million for each internist and each general surgeon (Merritt, Hawkins & Associates 2007b). While somewhat lower in 2006–2007 compared with a few years ago due to recently increasing demand for primary care physicians, recruiting demand for specialist physicians remains strong, especially for radiologists, cardiologists, general surgeons, and orthopedic surgeons (Merritt, Hawkins & Associates 2007a).

Hospitals do not always have the support of existing community physicians for recruiting new ones. Physicians newly joining an existing practice are often money losers for the practice until they gain business. In addition, existing community physicians may think they compete for patients with new physicians—whether employed by a private practice or by the hospital. Accordingly, a

hospital must invest not only in attracting new physicians to the community but also in smoothing relationships with existing community physicians. Hospitals are unlikely to take on the costs and organizational challenges of hiring physicians unless the economic incentives presented by the payer environment make it increasingly worthwhile to do so.

Physician liaisons

Hospitals must develop a well-rounded integration strategy to ensure that community physicians use hospital services. To this end, hospitals pay particular attention to physicians' use of high-margin outpatient services by investing in "liaisons" or "sales teams," who visit community physicians with the primary goal of maintaining or increasing their use of hospital services.

Hospital industry experts report a spectrum of activities and roles these liaisons perform. The most limited role is a "check-in" model, which allows the hospital to apprise physicians of new or enhanced hospital capabilities and "present a friendly face." In a more ambitious model, liaisons have responsibility for helping physicians resolve technical problems that arise when they interact with a new hospital resource, such as a new information or communication technology that links the hospital and physicians. At the far end of the spectrum, liaisons are involved in physicians' or group practices' business development—for example, facilitating patient referrals and helping physicians build their practices by increasing potential patients' awareness of the physician's affiliation with the hospital. This "physician relations management" model, which industry consultants view as uncommon but growing, typically incorporates tracking a hospital's market share of admissions and referrals (Abrams and Morgan 2007).

At a 2006 conference on hospital–physician relationships, one hospital described how it stratifies the physician practices in its market area and deploys its 19-member sales team to target physicians whose volume of hospital-based outpatient services is below expected levels. Assuming the physician is in an area with projected need, the low volume could be due to a conservative practice style, a slow practice, or the physician's decision to refer some patients elsewhere. Team members are dispatched to "educate" targeted physicians and encourage them to increase service use or change referral patterns (Ghosn and Haas 2006).

Joint ventures

When confronted with the possibility of physicians investing in their own facilities, some hospitals have responded by establishing joint ventures with physicians. These arrangements include imaging centers, ASCs, cardiac catheterization labs, and even specialty hospitals. From the hospital's perspective, engaging in a joint venture allows it to reinforce physician loyalty and retain some of the revenue it otherwise might lose to a physician-owned entity. From the physicians' perspective, a joint venture allows them to take advantage of the hospital's capital, management ability, pool of patients, and potentially higher reimbursement rates (Berenson et al. 2006, Credit Suisse First Boston 2004). In some cases, a third party may partner with physicians and hospitals in developing a facility; the third party offers capital as well as development and management expertise. For example, United Surgical Partners International has developed many ASCs in conjunction with nonprofit hospital systems and physician groups. Generally, each party owns one-third of the ASC (Credit Suisse First Boston 2004).

Variations of joint ventures include agreements in which hospitals lease equipment to physician groups. For example, some hospitals establish imaging centers in a medical office building and lease the equipment and staff to physician practices in the building. These practices send their patients to the imaging center for studies such as MRI scans, bill the payer for the services, and pay the hospital a fee for use of the equipment and staff. The practices can profit from the difference between the reimbursement rate and the fee they pay the hospital. These arrangements, which can fit into an exception to the Stark law, may be more convenient for patients than traveling to the hospital and may help the hospital secure physician loyalty.

Another type of joint venture is an "under arrangements" model. In this model, a hospital contracts with a physician practice to furnish services such as diagnostic tests and outpatient surgery on behalf of the hospital's patients; the hospital bills Medicare and pays the practice a fee. Hospitals originally used this model to provide their patients with certain services that were not available at the hospital because they were needed infrequently and the hospital decided it was more cost effective to purchase them on an ad hoc, outpatient basis. According to CMS, "under arrangements" deals between referring physicians and hospitals have proliferated in recent years; anecdotal reports cite hospital and physician joint ventures that were created to provide imaging services to the hospital's

patients. Previously, the hospital provided these services directly (CMS 2007). The primary purpose of the arrangements described by CMS appears to be to allow physicians to profit from referring patients to the hospital, thereby providing a financial incentive for them to make such referrals, regardless of their clinical appropriateness. The arrangements may also allow physicians to share in Medicare's higher payment rates for services provided in hospital settings. For example, Medicare pays more for ambulatory surgical procedures under the hospital outpatient payment system than under the ASC payment system.

Joint ventures may have tax and physician self-referral legal implications (see text box, p. 62). If a joint venture involves a not-for-profit hospital and a for-profit physician group, the joint venture partnership must further the hospital's charitable purpose for the hospital to maintain its tax-exempt status. In these cases, the hospital must exercise sufficient control over the venture to ensure that it provides community benefits. Because of the legal risks involved in joint ventures and their belief that competing directly with physicians is not financially threatening, some hospitals have decided against participating in joint ventures (Berenson et al. 2006).

Participatory bonds: Paying physicians not to compete

Participatory bonds are another approach that hospitals may use to reward physicians for their loyalty. These instruments do not have the limitations inherent in rewarding physicians with investments in joint venture opportunities in ASCs or imaging centers—namely, that primary care physicians typically are excluded from specialty care joint venture opportunities and that joint venture income is taxable for physician owners.

Participatory bonds are tax-free bonds issued to physicians by nonprofit entities (e.g., a hospital, ASC, or imaging center). They often are sold to PCPs as well as specialists who admit to the hospital. Recently, physicians have been paid tax-exempt interest rates ranging from 9 percent to 12 percent, which is well above the market rate for other bonds issued by the same hospitals (typically about 5 percent). In exchange for the high rate of interest, physician investors must sign a noncompete agreement.

Hospitals tend to sell 60 percent of the bonds to nonphysician investors and 40 percent to referring physicians to qualify under the "60-40" safe harbor (42 CFR 1001.952). The 60-40 safe harbor provides protection against federal anti-kickback regulations, as long as 60 percent or more of an investment in an entity comes from individuals who do not have other dealings with the issuer of the bond (i.e., someone other than referring physicians or the hospital).

For a hospital to maintain its tax-exempt status, the IRS requires that the bonds have an interest rate in line with market rates. This requirement presents a potential quandary for hospitals, which need to assure the IRS that the interest rate on its bonds reflects market rates while convincing physician investors that the rate being offered is better than they could earn on alternative investments. To produce an effective interest rate of roughly 9 percent to 12 percent, these bonds often have features that in other situations typically necessitate the offer of a higher interest rate, such as being "callable" (meaning the hospital can pay them off at any time) and subordinate to other debt (meaning the participatory bonds are paid after the hospital's other debt holders if the hospital goes bankrupt). In addition, interest payments are deferred if the bond issuer (e.g., hospital) does not meet certain cash flow targets. Tying the timing of interest payments to hospital cash flows appears on the surface to be a way for doctors to "participate" in the hospital's cash flows, but even when the hospital does not meet cash flow targets in a given year, physicians will receive deferred interest payments when the bonds mature.

Although the call features and subordinate nature of the bonds allow hospitals to argue that the 9 percent to 12 percent rate paid is justified, investing physicians may consider it unlikely that the hospital will call the bonds (and upset the physicians) or go bankrupt. Given that their interest rate may be as much as twice that of other tax-free bonds issued by the hospital, participatory bonds are an attractive investment. In the limited number of cases of which we are aware, physician and nonphysician demand for the bonds has been strong. One question is whether the difference between the interest rate paid on participatory bonds (e.g., 10 percent) and the interest rate on other hospital debt (e.g., 5 percent) should be seen primarily as a tax-free payment to physicians for their noncompete agreements.

Conclusion

The common thread in most current hospital–physician collaboration strategies is that they enable, encourage, or reward volume growth. This is not a new or unusual

phenomenon—hospitals and physicians created distinct types of collaborative relationships in the 1990s (see text box) to respond to the predominant payment incentives in private health plans at that time. Some of the current types of collaborative relationships between hospitals and physicians have positive effects from the perspective of Medicare and its beneficiaries, such as collaborations that improve the quality of inpatient care in response to pay-for-performance incentives or provide access to specialty services in hospital EDs serving underserved communities. Nonetheless, most of the current collaborative relationships are rational responses to the FFS payment policy incentives presented by Medicare and many commercial health insurance payers, which reward providers with increased revenue as they increase the volume of services rather than rewarding increases in the quality or value of the care provided. Medicare's FFS payment system also rewards providers for improving their efficiency in delivering services, but under current law the Medicare program and its beneficiaries are, for the most part, not able to directly share in any savings generated by efficiency gains. To change these dynamics, it is incumbent upon Medicare to change the incentives inherent in current payment policy and clarify the legal framework governing hospital–physician collaborations to create incentives for providers to collaborate on improving the quality and value of care over time and across health care settings. ■

Recent experience illustrates the power of financial incentives to encourage hospital–physician collaboration

The observation that hospital–physician relationships will change in response to public and private payment policy incentives is not new. A key lesson from the 1990s is that providers' responses to financial incentives will result in structural changes in the health care delivery system.

Hospital–physician integration in the 1990s

In the 1990s, the rise of HMOs and the prospect of capitation eventually taking hold across the nation led doctors and hospitals to form physician–hospital organizations (PHOs) whose primary purpose was to allocate capitated payments. As an alternative to PHOs, hospitals were also purchasing physician practices in an effort to recruit physicians, ensure patient flows, and avoid having to negotiate every year with physicians in the PHO over how to divide patient revenues. Some integration strategies may have resulted in modest decreases in lengths of stay and lower inpatient Medicare costs (Mark et al. 1998, Stensland and Stinson 2002). But the dominant theme in the literature is that hospital–physician integration did not lead to major improvements in clinical integration in most markets (Bazzoli et al. 2004). According to Burns and Pauly (2002), "…the structures that were put in place to integrate different providers often failed to fundamentally alter the manner in which physicians practiced medicine and collaborated with other health care professionals. As a result, integrated structures rarely integrated the actual delivery of patient care."

Hospital–physician integration can be viewed as a continuum from almost no interaction between a patient's primary care physician and providers who care for the patient in the hospital to common ownership of the physician practice and hospital. Common ownership can take the form of one organization owning the hospital and employing physicians or physicians owning the hospital. Over the past 10 years, employment of physicians and physician ownership of hospitals have been on the rise, while looser forms of integration such as PHOs have been on the decline. We focus on the two most common types of financial integration: PHOs (loose financial integration) and the salary model (tight financial integration for employed physicians).

American Hospital Association data indicate that most hospitals have either a PHO, salary model, or some intermediate form of integration, but it is important to note that the integration often applies to only a subset of physicians (AHA 2008). Therefore, although many hospitals have some form of physician integration, numerous physicians in the community remain independent practitioners.

Physician–hospital organizations

Some PHOs were formed by hospitals and their medical staffs to provide joint contracting with managed care organizations (Morrisey et al. 1996). Roughly 75 percent of current PHOs are open to all members of the hospital medical staff, and roughly 25 percent of PHOs are "closed PHOs," meaning that membership is limited to physicians who meet certain criteria for quality or cost effectiveness (AHA 2007b). In addition to joint contracting, PHOs can also provide supporting activities such as utilization review and quality assurance, physician credentialing, and marketing; they may also jointly operate ancillary facilities (Snail and Robinson 1998). Because forming a PHO usually does not affect asset ownership, PHOs often lack permanence and may have minimal influence over physician practice styles. The lack of permanence is evident in the gradual decline in PHOs as indicated in Figure 3-1 (p. 74).

Figure 3-1 should be interpreted cautiously because there are many forms of PHOs. Some PHOs were formed in anticipation of capitation entering the market, and some of them were dissolved because capitation never materialized. Other PHOs were formed and signed contracts with insurers but dissolved after bitter arguments over how to divide payments. A large share of PHOs continue to contract with insurers. However, the Federal Trade Commission may be concerned that some of them may be primarily designed to negotiate higher prices (Casalino 2006). Lastly, few PHOs have had success in leading physicians and hospitals to work jointly toward improving clinical practices.

The question in the academic literature has been whether, on average, PHOs have lower costs or higher quality than in the average market with

(continued next page)

Recent experience illustrates the power of financial incentives to encourage hospital–physician collaboration (cont.)

independent physicians and hospitals. The findings are not encouraging. Two recent studies found that the average PHO either has no effect on quality or has at best a small positive effect on quality in the first few years after being formed (Cuellar and Gertler 2006, Madison 2004). The literature is mixed on the effect of PHOs on private sector pricing and costs of care; some studies find no effect, but others indicate PHOs may result in higher prices paid by private insurers and more Part B services purchased during the 90 days following Medicare admissions (Ciliberto and Dranove 2006, Cuellar and Gertler 2006, Federal Trade Commission and Department of Justice 2004, Madison 2004). PHOs that were formed to deal with private insurers may be based on an implicit agreement that physicians will help hospitals obtain patient volume and hospitals will use their market power to help physicians obtain higher payment rates. PHOs formed in reaction to Medicare policy might create a different dynamic between physicians and hospitals. Medicare is a price setter; therefore, PHOs would not be formed to gain market power over Medicare. With appropriate incentives, it is possible that a larger share of PHOs may focus instead on improving quality and efficiency for Medicare patients.

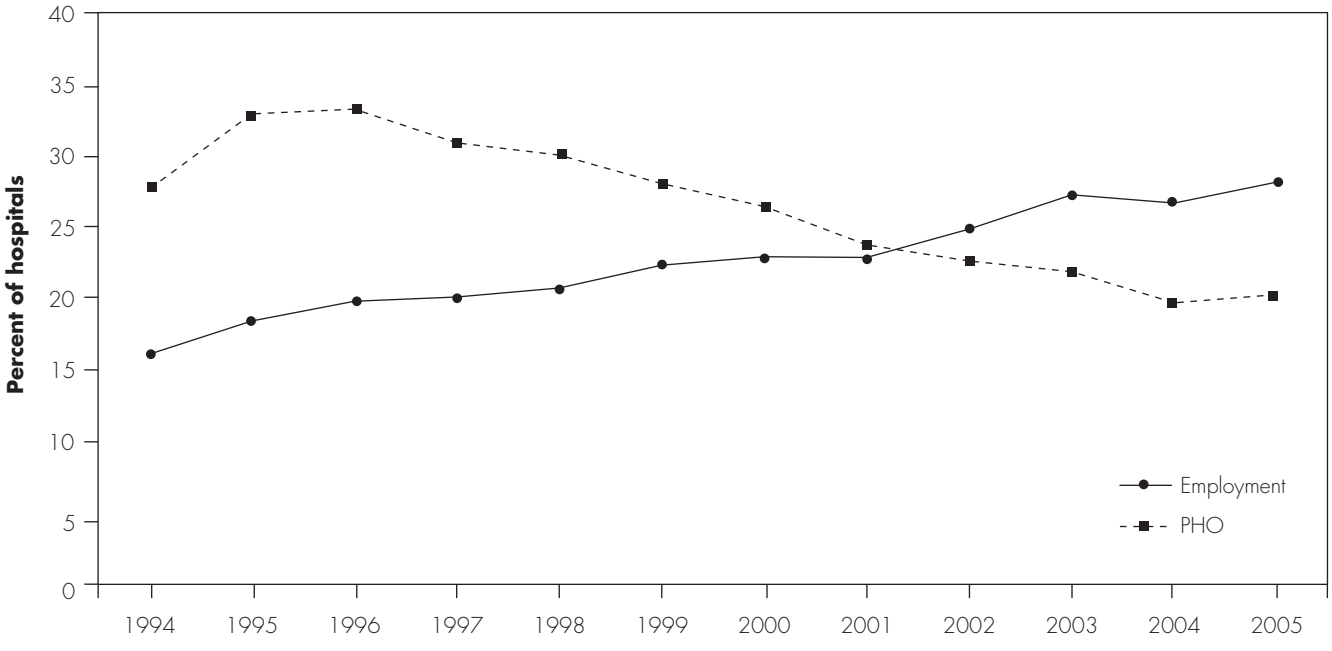
The salary model of hospital–physician integration

In the salary model, an integrated system or a hospital (often physician led) is formed to employ the affiliated physicians. The literature suggests that—on average—modest improvements in quality and efficiency appear to be more likely in the salary model and other strong models of integration than in loose PHOs (Cuellar

(continued next page)

FIGURE 3–1

Employment has surpassed PHOs as the most common model of hospital–physician integration



Note: PHO (physician–hospital organization).

Source: American Hospital Association. Hospital Statistics, various years.

Recent experience illustrates the power of financial incentives to encourage hospital–physician collaboration (cont.)

and Gertler 2006, Madison 2004, Mark et al. 1998, Stensland and Stinson 2002).

The salary model may be a more successful form of integration than PHOs because of its ability to unify management and influence physician behavior (Cave 1995). Hospitals employing physicians may be more assured of having physicians accept on-call coverage and not split their admissions with a rival hospital. From the physician's perspective, employment eliminates the risk of owning a private practice, reduces managerial headaches, and provides malpractice coverage from the hospital. Employment of physicians has continued to become more common through 2007 (AHA 2007b, Liebhaber and Grossman 2007).

As is the case with PHOs, there are a range of motivations for employing physicians. In some cases, a single entity has an integration strategy, owns hospitals, and employs most of the active medical staff. In other cases, physician employment is one of several strategies a hospital will use to recruit physicians to its active medical staff. In this case, recruitment—not clinical integration—may be the hospital's priority. A third motivation for employing physicians is a defensive acquisition; the goal is not integration but simply to prevent competitors from acquiring the admitting physicians' practices. For example, during the heat of the 1990s acquisition frenzy, Dr. Todd Sagan, head of practice acquisitions for Temple Hospital in Philadelphia, stated "most of the deals are being driven by a worry that if we don't do it, someone else will. The feeling is: 'I may suffer from doing acquisitions, but at least I'll stay in the game. If I don't do them, I may not survive'" (Anders 1997). Our site visits and the literature suggest that the losses on physician practices have diminished and the pressure to recruit specialty physicians, especially those who will take call, has increased. This situation may drive hospitals and integrated systems to continue to expand the salary model.

Why are hospitals and physicians increasingly choosing the salary model over a PHO?

From the hospital's perspective, PHOs are limited in their influence over physicians' on-call and referral decisions. Employing physicians overcomes these limitations. In addition, the PHO cannot be structured to take all contingencies into account in the initial PHO contract, providing the hospital little leverage to obtain physician cooperation when new issues arise. The literature also suggests that employed physicians tend to have slightly more loyalty to their hospital than those with looser forms of affiliation (Bazzoli et al. 2004). Employment also prevents hospitals from being at the mercy of referring physicians when negotiating the sharing of payments. Of course, not all hospitals will employ physicians. Some hospital executives may be reluctant to employ physicians because of the cost and a lack of tools to adequately manage and motivate physicians.

Physicians have personal preferences about whether they want to be entrepreneurs or employees. Some may enjoy entrepreneurial challenges and prefer to work in a small group. Others may prefer employment and the security it offers. In addition, physicians may see employment as a way to obtain lower cost malpractice coverage through their employer. Finally, some small physician groups may believe they can negotiate higher payments from plans if they are part of a larger organization (Casalino et al. 2004, Cuellar and Gertler 2006). The quest for higher private-payer payment rates and the rise of malpractice costs could be fueling the reduction in the share of physicians working in small group practices (Liebhaber and Grossman 2007).

Lessons learned from the 1990s

Although hospital–physician integration can be successful, there are some clear cautionary signs from the 1990s. In some cases, physicians and hospitals could not agree on how to share revenue, causing the collapse of the PHO. In other cases, the physician and hospital could agree on how to share revenue, but they did not clinically integrate—meaning they did not change the way they delivered care to the patient. Past experience suggests that financial integration and clinical integration are possible, but achieving these objectives will be a challenging and contentious process in many health care markets. ■

Endnotes

1 The percentage of workers with employer-sponsored health insurance enrolled in a traditional FFS indemnity insurance plan decreased from 27 percent in 1996 to 3 percent in 2007, but the share enrolled in a preferred provider organization plan, which is a form of FFS, increased from 28 percent to 57 percent in the same period. Enrollment in HMO plans, which tend to have the most capitated payment arrangements, decreased from 31 percent to 21 percent during this time (KFF/HRET 2007).

2 For example, as an administrator at the 100-bed Baptist Hospital Northeast said, "Our system has entered into these relationships [employing physicians] … largely as a defensive strategy because two of our major competitors in the Louisville-metro area have begun employing physicians. If your competitors are willing to employ physicians and they are soliciting the doctors in your network, overnight you could lose significant market share." (Johnson 2006).

3 Nevertheless, the OIG concluded that it lacked the statutory authority to require safeguards to ensure that cost-saving measures do not reduce quality.

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CHAPTER 4

A path to bundled payment around a hospitalization

RECOMMENDATIONS

4A The Congress should require the Secretary to confidentially report readmission rates and resource use around hospitalization episodes to hospitals and physicians. Beginning in the third year, providers' relative resource use should be publicly disclosed.

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

4B To encourage providers to collaborate and better coordinate care, the Congress should direct the Secretary to reduce payments to hospitals with relatively high readmission rates for select conditions and also allow shared accountability between physicians and hospitals. The Congress should also direct the Secretary to report within two years on the feasibility of broader approaches, such as virtual bundling, for encouraging efficiency around hospitalization episodes.

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

4C The Congress should require the Secretary to create a voluntary pilot program to test the feasibility of actual bundled payment for services around hospitalization episodes for select conditions. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

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

CHAPTER 4

A path to bundled payment around a hospitalization

Chapter summary

The fee-for-service payment system fails to encourage providers to cooperate with one another to improve coordination of beneficiaries' care and appropriately control the volume and cost of services delivered across an episode of care. This chapter explores changes in fee-for-service payment for care provided around a hospitalization to address these failures. It finds that bundling Medicare payment to cover all services associated with an episode of care has the potential to improve incentives for providers to deliver the right mix of services at the right time. The benefits of such a change in Medicare payment would likely not accrue to Medicare and its beneficiaries alone; given that Medicare is the single largest purchaser of health care, its payment reforms often influence other purchasers and insurers and spill over to other patients.

Under bundled payment, Medicare would pay a single provider entity (composed of a hospital and its affiliated physicians) an amount intended to cover the costs of providing the full range of care needed over a hospitalization episode. Although this approach holds great potential, the Commission recognizes the complexity associated with

In this chapter

bundling payment. Accordingly, the Commission offers an incremental approach, composed of three related policies.

First, the Commission recommends that the Secretary confidentially disclose to hospitals and physicians information about their service use around hospitalization episodes. This information would allow a given hospital and the physicians who practice in it to compare their risk-adjusted performance relative to other hospitals and physicians. In turn, they may consider ways to adjust their practice styles and coordinate care to reduce their service use. After two years of confidential disclosure to providers, the same information should be publicly available.

Recommendation 4A

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

The Congress should require the Secretary to confidentially report readmission rates and resource use around hospitalization episodes to hospitals and physicians. Beginning in the third year, providers' relative resource use should be publicly disclosed.

Because information disclosure alone is likely not sufficient to fully motivate and sustain change, the Commission also recommends changing payment to hold providers financially accountable for service use around a hospitalization episode. Specifically, it recommends that Medicare reduce payment to hospitals with relatively high risk-adjusted readmission rates for select conditions. The Commission recommends that this payment change be made in tandem with a previously recommended change in law to allow hospitals and physicians to share in the savings that result from reengineering inefficient care processes during the episode of care.

Recommendation 4B

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

To encourage providers to collaborate and better coordinate care, the Congress should direct the Secretary to reduce payments to hospitals with relatively high readmission rates for select conditions and also allow shared accountability between physicians and hospitals. The Congress should also direct the Secretary to report within two years on the feasibility of broader approaches, such as virtual bundling, for encouraging efficiency around hospitalization episodes.

Recognizing that readmissions account for only part of the variation in practice patterns around an admission, the Commission also recommends that the Secretary explore broader payment changes to encourage efficiency around hospitalization episodes for providers not accepting a bundled payment. Medicare should conduct a voluntary pilot program to test bundled payment for an episode of care extending past discharge for select conditions. Bundled payment raises a wide set of implementation issues. It requires that Medicare create a new payment rate for a bundle of services and that providers organize to deliver care efficiently and determine how they will share the payment. A pilot program allows CMS to identify and resolve the attendant design and implementation issues and gives providers who are ready the chance to start receiving the bundled payment. If the pilot succeeds in improving coordination of care and reducing costs, bundled payment for hospitalization episodes of care should become the dominant Medicare payment method for these services.

Recommendation 4C

The Congress should require the Secretary to create a voluntary pilot program to test the feasibility of actual bundled payment for services around hospitalization episodes for select conditions. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

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

The Commission is under no illusion that the path of policy change outlined here will be easy. Implementation will undoubtedly require more administrative resources for CMS. And, despite our best efforts to anticipate them, unforeseen consequences are likely to be encountered and policies will need to be adjusted. Nevertheless, the Commission believes the status quo is unacceptable. The current payment system is fueling many of the troublesome aspects of our health care system: Beneficiaries' care is often uncoordinated and health care costs are increasing to an extent that strains many beneficiaries' ability to pay their health care bills, the nation's ability to finance Medicare, and the ability of a large segment of the non-Medicare population to afford health insurance. ■

The fee-for-service (FFS) payment system fails to encourage providers to cooperate with one another to improve coordination of beneficiaries' care and appropriately control the volume and cost of services delivered across an episode of care. This chapter explores changes in FFS payment for care provided around a hospitalization to address these failures. The Commission finds that bundling Medicare payment to cover all services associated with an episode of care has the potential to improve incentives for providers to deliver the right mix of services at the right time.

Under bundled payment, Medicare would pay a single provider entity (composed of a hospital and its affiliated physicians) an amount intended to cover the costs of providing the full range of care needed over a hospitalization episode. Providers would not only be motivated to contain their own costs but also would have a financial incentive to partner with efficient providers or collaborate with current partners to improve their collective performance. Providers involved in an episode could develop ways to allocate payments among themselves. This flexibility should give providers a greater incentive to work together and be mindful of the impact their service use has on the overall quality of care, the volume of services provided, and the cost of providing each service.

With such significant change in incentives for an industry as complex as health care comes the possibility of unintended consequences and design challenges. The lack of "systemness" in health care suggests that hospitals and physicians may find it difficult to agree on how to effectively manage care and share the bundled payment (Berenson et al. 2006, Budetti et al. 2002). This chapter recommends incremental steps toward bundling payment over episodes of care around a hospitalization.

A first step is for Medicare to confidentially inform hospitals and physicians about their patterns of resource use around certain hospitalization episodes, including readmission rates. After two years, the information should also be disclosed to the public. If information is made public, providers may take it more seriously and beneficiaries may use it to inform their health care decisions.

Program-wide payment changes are also needed. The Commission recommends that payments be reduced for hospitals with high readmission rates for select high-volume, high-cost conditions. This change should encourage hospitals to dedicate resources to processes that can reduce readmission rates. Because the Commission recognizes that hospitals will need physician cooperation to reduce avoidable readmissions, it recommends that the Congress revise existing restrictions to allow hospitals to financially reward physicians for their focus in addressing this problem.

Concurrent with information dissemination and a change in readmissions payment policy, CMS should conduct a pilot program to test bundled payment. Bundling payment raises a range of implementation issues because under bundled payment the entity accepting the payment—rather than Medicare—has discretion in the amount it pays providers for care provided, whether to pay for services not now covered by Medicare, and how it rewards providers for reducing costs and improving quality. The advantage of this flexibility is that providers can decide the best way to structure service delivery and payment to achieve efficient, quality care. But these changes could also lead to some unintended consequences. A pilot program will allow CMS to consider policies to reduce the likelihood of unintended consequences and determine how Medicare can best share in the savings. It also gives entities that are ready the chance to start receiving the bundled payment. If the pilot succeeds in improving coordination of care and reducing costs, bundled payment for episodes of care should become the Medicare FFS payment method for these services.

This chapter first explores the problems with current FFS payment, how bundling payment across providers around a hospitalization episode can change their behavior and why focusing our attention on the window of time around an admission is so important. The second part of the chapter outlines the specific incremental steps the Commission believes will help realign financial incentives so that they reward providers for delivering the appropriate volume of services, coordinating beneficiaries' care, and improving efficiency across an episode of care.

The rationale for bundling payment

Ideally, payment systems should financially motivate hospitals and physicians to collaborate in identifying and implementing opportunities to limit the use of low-value services, coordinate beneficiaries' care, and work together to improve efficiency, particularly across an episode of

care. Bundling payment across an episode of care may be the best way to achieve these objectives in the context of a FFS system.

FFS rewards more care rather than the right mix

In FFS, Medicare generally pays a prospective amount for services delivered by each provider based on the expected costs of providing that service. For most providers, the unit of service is relatively narrow and encompasses only the services a provider furnishes. For example, most physicians are paid per visit, skilled nursing facilities are paid per day, and hospitals' outpatient departments and ambulatory surgical centers are paid per procedure and per test.

In some instances, Medicare bundles payment across services provided by a single provider type. For example, under the inpatient prospective payment system, hospitals are paid a single amount based on the patient's diagnosis to cover all hospital costs associated with the stay. (Physician services provided to beneficiaries during the stay are billed and paid separately under the physician fee schedule, even if the physician is employed by the hospital.) Surgeons are also paid a bundled fee called the global surgical fee. It covers the cost of all the surgeon's services around the surgery. The intent of these approaches is to break the link between payment and volume of services and, in so doing, induce greater efficiency. While these payment innovations may have improved providers' efficiency (e.g., shorter length of stay) during the episode of care, they pertain only to a single provider (e.g., the hospital) and therefore have a limited effect in reducing the aggregate volume of services paid for by Medicare.

FFS payment rewards volume because it pays for each service separately without regard to the mix or volume of services used in caring for patients. For example, Medicare pays hospitals the same for readmissions (some of which could be avoided) as for initial admissions. Similarly, Medicare pays most physicians for each service, without attention to the appropriateness of the mix of physician services. Because Medicare's payments do not promote coordination of and quality of care, more admissions (including readmissions) increase income for hospitals and more visits, procedures, and tests provide more income for most physicians.

Another confounding dynamic in FFS payment policy is that it often pays more generously for high-tech services than for low-tech services. Providers are, in turn, more inclined to deliver these high-tech, high-margin services, even if lower cost alternatives could achieve the same or better outcomes for patients. An account of the efforts of Seattle's Virginia Mason Medical Center (VMMC) to change its mix of services for certain conditions illustrates the financial trade-offs associated with providing more efficient care under FFS. In treating cardiac arrhythmias, VMMC realized that physicians often ordered more expensive stress tests using nuclear imaging scans instead of less expensive, less profitable, but equally effective, stress echocardiograms. By encouraging providers to use the less costly service, VMMC could reduce costs for a commercial insurer from $2,300 to $695 per episode, but this action would decrease its margin from $785 to $305. Similarly, because VMMC found that emergency department visits for insured patients are profitable (a margin of $180), it had little incentive to invest in reducing the number of them (Ginsburg et al. 2007). Hospitals for which readmissions are profitable have no financial motive to avert them (as discussed later).

In addition, legal restrictions often prevent hospitals from financially rewarding physicians for reducing hospital costs associated with Medicare patients.[1] Physicians clearly affect hospitals' costs in their treatment decisions (e.g., use of the intensive care unit (ICU)), the volume and mix of supplies they use (e.g., type of implantable device), and their decisions about when to discharge a patient. If they have some ability to share in the savings they can produce for hospitals, physicians might be more cost conscious.

The potential for improved efficiency is evidenced by the finding that areas with lower costs have comparatively good quality care. In fact, areas with higher Medicare spending tend to score substantially worse on a composite indicator of quality of care provided to Medicare beneficiaries (CBO 2008). A study on state-level spending variation found that, if spending per Medicare beneficiary increased by $1,000 in a state, there was an associated decrease in most measures of good medical practices, such as the share of heart attack patients who were given aspirin (Baiker and Chandra 2004). This research does not mean that any reduction in spending improves quality, however. The specific mix of services and the quality of those services matter.

The experience of industry leaders suggests a roadmap for improvement during hospitalization episodes. Motivated hospitals have found that—by working with physicians to revamp and standardize the care process—mortality

rates, complication rates, readmission rates, and costs have declined. For example:

- By having physicians and nurses complete a checklist of safety measures (e.g., whether the bed is propped up at the right angle, and whether ventilated patients are given antacids) during patients' ICU stays, Michigan hospitals reduced their infection rates by 66 percent within the first three months of the project. These declines have been sustained, saving about $75 million and 1,500 lives after 18 months of the initiative (Gawande 2007).
- Catholic Healthcare Partners created a program to improve care for its heart failure patients by promoting the consistent use of evidence-based guidelines. Aggregate all-cause heart failure readmissions within 30 days decreased from 22 percent in 2002 to consistently below 20 percent between 2004 and 2006. Performance on a composite of four Hospital Compare heart failure measures improved from 72 percent in 2003 to 95 percent in 2006. In addition, inpatient mortality for all patients with heart failure admitted over the same period declined 40 percent (Hostetter 2008).
- Intermountain Health System found that if, when discharging cardiovascular patients, physicians and nurses referred to a checklist of indications and contraindications for five medications known to prevent complications and save lives, appropriate use of the medications increased dramatically (Lappe et al. 2004).

Financial incentives in FFS are needed to motivate more providers to emulate these successes and increase efficiency.

Bundling payment around a hospitalization can change incentives

Paying a bundled fee for care provided during a hospitalization and immediately afterward means that instead of Medicare making a separate diagnosis related group (DRG) payment to the hospital and separate payment to the physician, skilled nursing facility, and outpatient department, Medicare would make one payment to a provider entity, which would allocate the funds among the providers delivering care during the covered episode. A bundled payment would create the possibility for the provider entity (likely organized around hospitals and physicians) to reward both desirable and undesirable behavior. However, the Commission believes that, through careful policy design, the risk for undesirable behavior can be minimized. CMS has had some experience addressing these types of issues in the course of demonstration programs and in aspects of the current FFS and Medicare Advantage programs.

Desirable responses

Providers would have the incentive to reduce unnecessary physician services during the hospitalization. Research suggests that there is an opportunity to reduce the number of inpatient physician visits without affecting the quality of care. Dartmouth researchers found that inpatient visits and inpatient specialist consultations were more than two times higher in the highest spending regions than in the lowest spending regions, with no discernible difference in the quality of care that patients received (Fisher et al. 2003a, Fisher et al. 2003b).

Second, hospitals could compensate physicians for using fewer resources during an inpatient stay. Accordingly, the hospitals' costs could be reduced, whether through shorter lengths of stay, less waiting time between surgeries in the operating room, less use of the ICU, or more judicious use of hospital supplies. For example, some cardiologists at the PinnacleHealth System hospital group in Pennsylvania who previously inflated an artery-opening balloon each time they inserted a stent into a patient's clogged arteries, agreed to try to use a single balloon throughout a procedure. That step, which the doctors say poses no additional risk to patients, saves at least a couple of hundred dollars per procedure (Abelson 2005).

In a third desired response—given a bundled payment covering a hospitalization and care provided for a specified time after discharge (e.g., 30 days)—providers would be encouraged to evaluate ways to reduce postdischarge costs such as readmissions and unnecessary post-acute care. Physicians have referred to time after discharge as "white space," reflecting the fact that providers are inconsistent in their attention to what happens to the patient at that point. Under this policy, for example, they should be motivated to increase the likelihood that patients recently discharged from the hospital have an office visit with their physician to avoid readmission. Providers should also evaluate the need for post-acute care and the best source for it.

Savings from preventing readmissions can be considerable. About 18 percent of Medicare hospital admissions result in readmissions within 30 days of discharge, accounting for $15 billion in spending. The Commission found that Medicare spends about $12 billion on potentially preventable readmissions, as defined by

one vendor's clinically based software (MedPAC 2007).[2] Obviously, the definition of potentially preventable involves some degree of clinical judgment and some of these cases may not be preventable.

The few studies that have been done of bundled payments suggest these desirable responses are attainable. One private sector pilot project looked at the impact of creating a medical episode-of-care payment for either knee or shoulder arthroscopic surgery that included a two-year warranty from the surgeon. As a result, total episodic costs were lower, the surgeon's and the hospital's margins had improved, and the number of "redos" and complications had decreased (Johnson and Becker 1994).

The Medicare Participating Heart Bypass Center demonstration of the 1990s found that bundled payment could increase providers' efficiency and reduce Medicare's costs. Most of the participating sites found that, under a bundled payment, hospitals and physicians reduced laboratory, pharmacy, and ICU spending. Spending on consulting physicians also decreased, as did spending for postdischarge care. Quality remained high (Cromwell et al. 1998). (See text box for a more detailed discussion.)

More recently, in 2006, the Geisinger Health System created a program that pays for coronary artery bypass graft surgery with a bundled payment covering all care for 30 days before and 90 days after an intervention, including related complications, readmissions, and follow-up care. The provider-driven pay-for-performance process that accompanied the change in payment method has been found to result in an increase in provider compliance with best practices and to positively influence 30-day clinical outcomes. Both length of stay and 30-day readmission rates declined. Incentive payments were available for physicians who adhered to best practices, but physicians were not at financial risk for the cost of complications in the 90-day postoperative window (Casale et al. 2007).

Undesirable responses

Providers could react to the incentives of a bundled payment in less desirable ways. In deciding how to share the bundled payment, the provider entity could choose to reward physicians who initiate more admissions, particularly those that are relatively generously reimbursed. This reaction would reinforce a culture that values volume growth. For example, providers may find that increasing the number of admissions creates a win-win situation for both hospitals and physicians under bundled payment. A higher volume could reduce the unit cost of each service by spreading fixed costs over a higher number of inpatient stays, thereby improving the margin on the bundle. This higher margin would leave a bigger pie for hospitals and physicians to share. Accordingly, physicians may be more inclined to admit a patient who could be treated on either an inpatient or an outpatient basis.[3]

A second concern is that, because there are disparities in the financial performance among hospitals, some hospitals will be more able to pay physicians higher rates than others. So, as they compete to attract physicians, some hospitals could be forced to redirect money needed for patient care (e.g., nursing) to physicians in order to offer attractive compensation arrangements.

Third, aligning economic incentives allows for the possibility that providers would seek to profit by furnishing inappropriately low levels of service (or "stinting"), which would compromise the quality of patient care. Similarly, providers could respond by "unbundling"—for example, by delaying some physician visits (e.g., a psychiatric consult) beyond the period that the bundled payment covered (e.g., the hospital stay). This type of stinting would increase Medicare spending, as Medicare would in essence pay twice for a service—once in its bundled payment amount and again when it is delivered outside the bundled period.

Fourth, to the extent that risk adjustment is imperfect and physicians find that payments for certain patients (e.g., frail, senile, nonadherent patients) are inadequate, physicians may avoid these patients. Also, physicians who care for these "low-margin" beneficiaries could find that hospitals are reluctant to grant them admitting privileges. This potential problem could be tempered by an outlier policy similar to the one in place for hospitals. Under this approach, providers would not be fully responsible for the costs of exceptionally high-cost patients.

A fifth possible response could be a change in how hospitals code patients' severity level for inpatient care. Currently, hospitals rely on physicians' notes on diagnoses in the medical record to determine how to code the severity of an admission. Because physicians' payment does not depend on their coding, they have no incentive to overstate the severity. Similarly, they have no incentive to be thorough, particularly in recording comorbidities, which can enable hospitals to bill for the level of payment that reflects the true severity of the patient. Under a bundled payment, however, physicians would have the

Medicare's experience with bundled payments under the cardiac bypass graft demonstration

Under a demonstration that ran from 1991 to 1996, Medicare paid a bundled rate for hospital and physician services around hospitalizations for cardiac bypass graft surgery. In this demonstration, the participating sites received a bundled rate for care surrounding admission for two diagnosis related groups.

Evaluation of the demonstration found that it generated considerable interest among providers, reduced the costs to Medicare and to most participants, and increased the quality of care. Given a bundled or global payment, each site under the demonstration created a pool of funds from which consulting physicians (e.g., pulmonologists, nephrologists, internists, and neurologists) were paid their regular Medicare allowable fees. Funds left over from the pool at the end of the year were awarded to the four specialists involved in bypass surgery who had control over the number of consulting physician services. Deficits from the pool were offset by lower payment amounts in the next period. In addition, two sites allowed physicians to share in hospital cost savings, creating further incentives to lower costs. One site awarded physicians one-quarter of any hospital cost savings that they personally generated, in addition to the originally negotiated payment. Another site awarded surgeons more operating room time and converted their nurse specialists and physician assistants in surgery into hospital employees because of the positive changes in surgeons' practice patterns (Cromwell et al. 1998).

Some sites also gained efficiencies by decreasing staff and introducing clinical nurse specialists to oversee each bypass patient's stay. This new position helped smooth transitions from service to service. Sites also substituted several less expensive or generic drugs for more costly ones; two hospitals saved $100,000 per year by doing this.

The demonstration was opposed by providers, who raised concerns about a government program designating some providers as higher quality than others and paying differently. These concerns contributed to the demise of a planned follow-up demonstration (Berenson and Harris 2002). ■

incentive to cooperate with hospitals on coding. To the extent this cooperation results in more accurate coding, rather than overstatements of severity, it may be desirable. However, it can increase Medicare spending. To offset this potential increase, CMS can make adjustments, just as it did when it anticipated coding behavior changes coinciding with DRG changes.

Why focus payment changes around a hospitalization episode?

There are several reasons to focus on changing payment incentives on hospitalization and postdischarge care. First, patients who have been hospitalized are more likely to receive care in different settings with different physicians supervising their care. This is particularly the case today, given the increasing prevalence of hospitalists, who care for patients only in an inpatient setting, leaving patients to obtain care from other physicians at discharge. Under these circumstances, joint accountability is particularly important.

Second, changing incentives around a hospitalization episode presents an opportunity to improve care delivery and reduce fragmentation at a time when patients are at greatest risk. Discharge from the hospital, in particular, is a critical and vulnerable care juncture for Medicare beneficiaries. Patients often experience the transition to home or post-acute care settings abruptly. Discharges may occur on weekends and involve clinicians who may not have an ongoing relationship with the patient, who may suddenly be expected to assume a self-management role in recovery with little support and preparation (Coleman and Berenson 2004). Patients and families may not realize how vulnerable patients are, particularly if the patient has not returned to his or her baseline physical or cognitive functional state in the interval between discharge and follow-up. Further, patients may not know which

provider to call with questions during that interval, as it is not always clear which provider is responsible for and informed about the patient's care (HMO Workgroup 2004).

Discharge is also a time when patients are more likely to be receptive to health care recommendations. The chances of long-term adherence to medication regimens are significantly higher when medications are provided at hospital discharge, and this difference is associated with decreased mortality rates (Lappe et al. 2004). Interventions at discharge may also be effective given the hospital-based resources and availability of the patient for consultation. Experts have noted that hospital-based interventions, such as improving discharge medications, could be more easily implemented, more effectively managed and measured, and more cost effective than other outpatient intervention strategies (Lappe et al. 2004).

Third, these beneficiaries tend to be among the most costly for Medicare. The most costly beneficiaries (i.e., in the top 20 percent) have an average of 1.7 admissions per year (CBO 2005). In the search for ways to target care coordination to those most in need, focusing providers' attention on these beneficiaries may be a highly cost-effective way to improve care coordination.

Fourth, focusing on the postdischarge period creates the opportunity to address some of the wide variation in spending across geographic areas and providers. For example, Medicare 30-day readmission rates range from 14 percent in the lowest decile of states to 22 percent in the highest decile (Commonwealth Fund 2006). The Commission's analysis also finds wide variation in service use during the postdischarge period (Table 4-1). For example, for patients with chronic obstructive pulmonary disease (COPD), hospitals with the most costly episodes for COPD patients spend about 65 percent more on readmissions than hospitals with average spending. These high-spending hospitals also pay about 78 percent more for post-acute care than hospitals with average spending. Because this analysis looks at Medicare spending only, it does not reflect differences in providers' costs or the potential for savings if variation in hospitals' costs were reduced. The Commission believes savings can be gained from inefficient hospitals reducing their costs; under a bundled payment approach, Medicare should share in those savings.

Fifth, focusing on care around a hospitalization engages the two most influential provider types (hospitals and physicians) in finding more efficient ways to deliver care, thereby fostering "systemness." Collectively engaging hospitals and physicians, rather than focusing on physicians and their "power of the pen" alone, has value. Hospitals have the managerial resources to restructure care, can play the role of convener to facilitate buy-in to best practices, and are geographically dispersed. Given these capabilities and their role in the marketplace, hospitals are positioned to promote change if incentives also apply to them.

An incremental approach to bundled payment

While the rationale for bundling payment is compelling, the previous section points to some of the thorny implementation issues. Because these issues are not easily resolved, the Commission concludes that an incremental approach is necessary to improve incentives without inviting large-scale unintended consequences. It should have three components: information disclosure, a change in payment for readmissions coupled with shared accountability, and a pilot program to test bundled payment.

These changes should apply to select conditions, at least initially, and should be pursued in conjunction with a separate pay-for-performance quality program, as the Commission has recommended in the past (MedPAC 2005a). Starting with select conditions is important, because providers can focus their efforts, increasing the likelihood that they will achieve early success. The lessons learned in caring for the selected conditions can then be applied to payment changes for other conditions. Conditions such as congestive heart failure and COPD appear to hold particular promise, given the success of pioneering providers in reducing costs (Naylor et al. 1999).

Implementing this incremental approach would require CMS to undertake a variety of new functions (e.g., measure and report resource use, adjust hospital payment for readmission rates, conduct a pilot program that may involve establishing facility-specific payment rates) and resolve a wide range of implementation issues (e.g., risk adjustment, outlier policies, selecting the conditions to be subject to the payment changes). Given the complexity and breadth of these demands on CMS, the Congress may wish to consider making a special appropriation to CMS,

TABLE 4–1

Average risk-adjusted spending for selected conditions during and 30 days after a hospital stay

Type of condition and service	Low-resource-use hospitals	Average	High-resource-use hospitals	High-resource-use hospital difference from average	
				Percent	Dollars
COPD					
Total episode	$6,372	$7,871	$9,748	23.8%	$1,877
Hospital	4,408	4,414	4,406	–0.2	–8
Physician	547	569	576	1.2	7
Readmission	671	1,543	2,550	65.3	1,007
Post-acute care	466	998	1,780	78.3	782
Other	280	347	436	25.6	89
CHF					
Total episode	$7,757	$9,278	$11,019	18.8	$1,741
Hospital	4,837	4,826	4,824	0.0	–2
Physician	612	647	650	0.5	3
Readmission	1,102	1,986	2,965	49.3	979
Post-acute care	842	1,378	2,041	48.1	663
Other	363	441	539	22.1	98
CABG with cardiac catheterization					
Total episode	$31,534	$33,421	$35,656	6.7	$2,235
Hospital	25,591	25,474	25,390	–0.3	–84
Physician	3,390	3,452	3,404	–1.4	–48
Readmission	947	1,887	2,911	54.3	1,024
Post-acute care	800	1,651	2,822	70.9	1,171
Other	806	957	1,129	18.0	172

Note: COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), CABG (coronary artery bypass graft). Spending for each service is risk adjusted to reflect differences in patient severity and reflects national standardized payment rates for Medicare, which exclude spending associated with specific missions (e.g., teaching) and geographic payment adjustments for differences in input prices. Spending does not reflect differences in the cost to the facility of providing services. Low-resource-use hospitals are in the bottom quartile of risk-adjusted episode spending and high-resource-use hospitals are in the top quartile of risk-adjusted episode spending (case weighted). Physician spending reflects physician care provided during the hospital stay. Readmission spending includes average spending for hospital care and physician care for the readmission. Other reflects outpatient care and physician care outside the hospital.

Source: MedPAC analysis of 5 percent sample of 2001–2003 Medicare claims files.

much as it did when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Reporting resource use to providers

CMS should first confidentially report provider resource use around select hospitalization episodes to hospitals and physicians. This feedback should be detailed so that providers can understand how their practice patterns differ from those of their peers and assess the opportunity for change. After two years the annual feedback should be available to the public.

Using resource use measurement results for provider education would give CMS experience using the measurement tool and allow the agency to explore the need for refinements. Providers could review the results and make changes to their practice as they deem appropriate and also help shape the measurement tool.

Providing feedback on resource use patterns to physicians alone has been shown to have a statistically significant, but small, downward effect on resource use (Balas et al. 1996, Schoenbaum and Murray 1992). Medicare's feedback on resource use could be more effective in reducing use than

previous experience in the private sector. As Medicare is the single largest purchaser of health care, its reports should command greater attention. In addition, because Medicare's reports would be based on more patients than private plan reports, they should have more statistical validity and acceptance from physicians. Nevertheless, disclosing their performance patterns to physicians alone is not likely to sufficiently motivate and sustain the magnitude of behavior change needed.

Publicly disclosing information on groups or individual providers can have a larger impact on changing behavior. For example, in New York, four years after information on hospital and physician risk-adjusted mortality rates became public, deaths from cardiac surgery fell 41 percent. However, patients did not appear to use the information to choose higher scoring providers (Chassin 2002). In one instance, releasing information to patients did influence their behavior. PacifiCare found that by releasing information on the quality of physician groups at the time of open enrollment, 30,000 enrollees chose the higher quality physician groups (MedPAC 2003).

RECOMMENDATION 4A

The Congress should require the Secretary to confidentially report readmission rates and resource use around hospitalization episodes to hospitals and physicians. Beginning in the third year, providers' relative resource use should be publicly disclosed.

RATIONALE 4A

Many providers may not be aware of the resources they use around a hospitalization. Once equipped with this information, they may consider ways to adjust their practice styles and coordinate care to reduce their resource use.

IMPLICATIONS 4A

Spending

- There are some administrative costs.
- Small savings could result from reduced utilization, but they are indeterminate.

Beneficiary and provider

- Beneficiaries would receive better coordination of care to the extent providers respond to this information by better managing care around a hospitalization.
- Because providers may respond by reducing the number of certain types of services, the growth in aggregate payments to some providers may slow over time.

Financial accountability for service use around hospitalization episodes: A focus on readmission rates

A program-wide change in financial incentives is needed to encourage providers to be aware of the collective impact of the actions of all the providers involved in care for a patient and to take greater responsibility for the coordination of care.

Reduce payment for high readmission rates

Currently, Medicare pays for all admissions based on the patient's diagnosis regardless of whether it is an initial stay or a readmission for the same or a related condition. As such, it does not reward hospital-based initiatives that can successfully avert many readmissions.

Many readmissions can be avoided by improving certain aspects of care. For example, by furnishing better, safer care during the hospital stay, providers can avoid complications that necessitate readmissions. Attending to patients' medication needs at discharge also makes a difference. Medication errors after discharge are not uncommon and contribute to readmissions. Improving communication with patients before and after discharge also reduces the need for readmission. Patients are often not adequately informed about self-care. Similarly, improving communication with other providers is important. Too often discharge summaries are not complete and are not available at the time of the first postdischarge physician visit (see MedPAC's June 2007 report to the Congress for a fuller discussion of this literature).

Spending on readmissions is considerable and accounts for much of the variation in spending for hospitalization episodes (Table 4-1, p. 93). Within 30 days of discharge, 17.6 percent of admissions are readmitted, accounting for $15 billion in Medicare spending in 2005. Not all these readmissions are avoidable, but some are.

A focus on readmissions can be viewed as a natural extension of the motivation behind recent Medicare payment changes that prohibit Medicare payment for "never events" and for the additional costs associated with patients acquiring preventable complications during a hospitalization. Never events are defined as "serious reportable" events by the National Quality Forum and include things such as leaving unintended objects in the patient as well as death or serious disability from falls, medication errors, and administration of incompatible blood during hospitalization. These payment changes

TABLE 4–2 **Potentially preventable 30-day readmission rates and spending for selected conditions**

Initial condition	Type of hospital admission	Number of potentially preventable 30-day readmissions (in thousands)	Percent readmitted within 30 days*	Average Medicare payment for readmissions	Total spending on potentially preventable readmissions (in millions)
Heart failure	Medical	139.2	19.1%	$6,490	$903
COPD	Medical	85.1	16.5	6,491	552
Pneumonia	Medical	86.4	13.3	6,681	577
AMI	Medical	30.5	18.7	6,540	199
CABG	Surgical	26.6	18.1	8,085	215
PTCA	Surgical	68.2	14.7	8,342	569
Other vascular	Surgical	30.0	18.6	10,061	302
Total for seven conditions		465.9			$3,318
Total for all DRGs		1,715.5			$12,008
Percent of total		27.2%			27.6%

Note: COPD (chronic obstructive pulmonary disease), AMI (acute myocardial infarction), CABG (coronary artery bypass graft), PTCA (percutaneous transluminal coronary angioplasty), DRG (diagnosis related group). Analysis is for readmissions within 30 days of discharge from the initial stay. Potentially preventable readmissions are identified using 3M software. Potentially preventable readmissions are readmissions that might be avoided with effective inpatient care, proper discharge planning, and follow-up care. Many potentially preventable readmissions will occur even under the best postdischarge care as a result of general disease progression. Potentially preventable readmissions, therefore, should not be viewed in isolation but should be used as a tool to compare hospitals with some normative standard of expected performance given a hospital's mix of patient conditions and patient severity.
*30-day readmission rates are calculated based on the set of cases that are potentially eligible for an initial readmission, thus they exclude readmissions and people that died in the hospital from the denominator.

Source: 3M analysis of 2005 Medicare discharge claims data.

reflect the sentiment that Medicare should not reward providers for delivering services that could have been avoided through the provision of better care.

The change in payment would mean that hospitals with high risk-adjusted rates of readmissions receive lower average per case payments. To do this, Medicare could first calculate each hospital's risk-adjusted readmission rate based on the prior year's performance and then select a benchmark rate (e.g., the average risk-adjusted readmission rate across all hospitals). For the next year, Medicare would reduce payment only for those hospitals with readmission rates above the benchmark rate.

It would be prudent to first focus on making this payment change for a limited number of conditions. DRGs with high volume and high rates of readmission are good candidates. By focusing on a subset of conditions, Medicare and providers can gain needed experience to refine measurement techniques and assess the value of expanding the policy to a broader set of DRGs. Good candidates for the starter set include congestive heart failure, COPD, and coronary artery bypass graft. In Table 4-2, we list those conditions as well as several others to illustrate a potential starter set.

Among the key measurement and payment issues are:

- What is the time period within which readmissions are defined? For the purposes of this discussion, we use 30-day readmission rates, but the interval could be longer (e.g., 60 days) or shorter (e.g., 15 days).
- Should all readmissions be counted in the selected time period or just the subset that are clinically determined to be potentially preventable? For the purposes of the analysis in Table 4-2, we explored identifying potentially preventable readmissions with software developed by 3M (see MedPAC 2007).[4] Potentially preventable readmissions are those that in many cases may be prevented with proven standards of care; however, not all of them can be avoided, even if hospitals follow best practices.

- What is the benchmark against which hospitals are measured? Should it be average readmission rates across all peers, or should it reflect a higher standard, such as the readmission rate of top performers, to raise expectations?
- Should readmissions be defined to include readmissions to a hospital other than the one that had the initial admission? The Commission believes the broader definition is appropriate. Thirty percent of readmissions are to hospitals other than the one with the initial admission; failing to hold hospitals accountable for these readmissions would limit the scope of the policy significantly and continue the current perverse incentives where providers operate in isolation.
- The policy involves risk adjusting for the patient's health status and severity of illness, but should it include additional adjustments for factors such as a high proportion of nonadherent patients or the mix of services available in the geographic area that might affect the likelihood of readmission?

Allow shared accountability

The Commission recognizes that hospitals need physician cooperation in making practice changes that lead to a lower readmission rate. Therefore, the Commission believes that hospitals that would like to financially reward physicians for helping to reduce readmission rates should be permitted to do so. Sharing in the financial rewards or cost savings associated with reengineering clinical care in the hospital is called gainsharing or, preferably, shared accountability. Allowing hospitals this flexibility in aligning incentives could, for example, help them make the goal of reducing unnecessary readmissions a joint one between hospitals and physicians. As discussed in a 2005 MedPAC report to the Congress, shared-accountability arrangements should be subject to safeguards to minimize the undesirable incentives potentially associated with these arrangements. For example, physicians who participate should not be rewarded for increasing referrals, stinting on care, or reducing quality (MedPAC 2005b).

The Commission recognizes that other providers, such as skilled nursing facilities and home health providers, can also be instrumental in avoiding readmissions. The Commission continues to explore ways to encourage these providers to avoid hospital readmissions, particularly with pay-for-performance programs that have readmission rates as a quality measure (MedPAC 2007). Including readmission rates as a pay-for-performance measure should also be considered, particularly for physicians who become a "medical home" (see Chapter 2). The recommended change in readmissions policy will create pressure for hospitals to develop relationships with high-quality post-acute care providers.

Explore virtual bundling and other broader payment changes

The Commission is interested in pursuing other, broader approaches to holding providers accountable for service use around hospitalization episodes. One approach it considered is virtual bundling. Under virtual bundling, providers would not receive a bundled payment; they would continue to receive separate payments from Medicare. However, payments to providers would be subject to the possibility of a reward or a penalty based on their relative aggregate spending for care delivered during a hospitalization episode. This change in financial incentives encourages providers to be aware of the collective impact of the actions of all providers involved in caring for a patient and to take greater responsibility for coordinating care (see text box, p. 98, for a discussion of the specific design of rewards and penalties).

Unlike a change in readmissions payment policy, virtual bundling holds providers accountable for all covered Part A and Part B services throughout the episode, rather than a single type of service. The advantage of this approach is that it does not encourage providers to inappropriately substitute one service for another. However, the Commission recognizes that virtual bundling may be complex to administer. For example, because providers have latitude in when they submit claims and each provider involved in an episode of care bills separately, it may be difficult for CMS to identify related claims in a timely way. Initially, the adjustments may not be appropriately applied, requiring later reconciliation and creating administrative complexity for providers. Moreover, a policy that requires withholding payment may create cash-flow problems for physicians, particularly those in small practices.

On balance, though, the idea of such an inclusive efficiency measure is appealing. For this reason, the Commission recommends that the Secretary explore the feasibility of virtual bundling and other approaches that may encourage greater efficiency around a hospitalization episode and report its findings to the Congress within two years.

RECOMMENDATION 4B

To encourage providers to collaborate and better coordinate care, the Congress should direct the Secretary to reduce payments to hospitals with relatively high readmission rates for select conditions and also allow shared accountability between physicians and hospitals. The Congress should also direct the Secretary to report within two years on the feasibility of broader approaches, such as virtual bundling, for encouraging efficiency around hospitalization episodes.

RATIONALE 4B

Reducing case payments when readmissions occur for hospitals with high readmission rates encourages providers to better tend to beneficiary needs during a vulnerable juncture in their care and to avoid complications during the initial stay. Research shows that specific hospital-based initiatives to improve communication with beneficiaries and their caregivers, coordinate care after discharge, and improve the quality of care during the initial admission can avert many readmissions. Allowing shared accountability, also known as gainsharing, permits hospitals to make reducing avoidable readmissions a goal of physicians as well. Other policies, such as virtual bundling, may offer promise as a broad efficiency measure but need further consideration.

IMPLICATIONS 4B

Spending

- There is a potential for savings, but the magnitude depends on the details of the policy.

Beneficiary and provider

- Coordination of beneficiaries' care could improve.
- Providers with high readmission rates would receive lower payments.

Pilot to test bundled payment

Bundled payment raises various implementation issues. It requires that Medicare create a new payment rate for a bundle of services and also allows providers discretion in how they will share the payment and what behavior they will reward. Accordingly, the Commission recommends that CMS conduct a pilot program in which providers opt to receive a bundled payment for all covered services under Part A and Part B associated with a hospitalization episode (e.g., the stay plus 30 days). The pilot should be conducted concurrent with the two steps discussed above—information disclosure and a change in payment associated with a high level of readmissions. The pilot should begin applying payment changes to only a selected set of medical conditions.

The objective of the demonstration should be to determine whether bundled payment across an episode of care can improve coordination of care, reduce the incentive for providers to furnish services of low value, improve providers' efficiency, and reduce Medicare spending while not otherwise adversely affecting the quality of care. Efficient providers should share in the savings from aligned incentives as well.

Extending the window of care to be paid for under the bundled payment beyond the stay reflects the Commission's commitment to improving incentives to coordinate care across sites, particularly at the time of discharge. Given both the wide variation and the magnitude of spending in the postdischarge period, significant efficiencies should be gained with the incentives included in the bundled-payment approach.

The Commission favors voluntary participation in the pilot because it recognizes that the health care delivery system is neither sufficiently nor uniformly organized in every community. Bundling payment across services in a hospitalization episode requires that Medicare pay a single provider entity (e.g., a hospital and its affiliated physicians), which would be responsible for paying individual providers for the care delivered during the episode. It is not clear whether in all communities providers would be able to agree to accept the bundled payment or would have the infrastructure to manage care and be accordingly rewarded through the bundled-payment provisions.

In choosing to recommend a pilot program as the vehicle to test bundled payment, the Commission seeks to balance the urgent need for a realignment of payment incentives with a healthy respect for the possibility that a well-intentioned policy change can result in unintended consequences. A pilot is more aggressive than a demonstration program in that it can be expanded nationally without the need for further legislation if it proves that the payment policy meets the stated objectives. Eliminating potential disruption and barriers to the expansion of bundled payment would be important in encouraging providers to participate in the pilot and invest in changing the culture, practice patterns, and infrastructure. If providers were concerned that the payment change would last only three years before being suspended pending legislative authorization, they might

How could virtual bundling be implemented?

To measure resource use for a hospitalization episode, policymakers need to select an episode duration that encompasses the time during the hospital stay and some time postdischarge. Next, CMS could measure resource use, which for our purposes is considered to be aggregate Medicare payments for all services across an episode covered by Part A and Part B and adjusted for the risk of the patient. Each episode of care would begin with a patient's admission to the hospital. For comparison purposes, the Medicare payments would need to be standardized so they do not reflect payment adjustments for wages and input prices or for special missions, such as medical education or caring for a high proportion of low-income beneficiaries.

CMS would then compare national hospital resource use performance over a previous year and identify relatively high- and low-spending hospital episode levels—perhaps benchmarked at the 75th and 25th percentiles of hospital performance, respectively. Performance relative to the high benchmark would determine eligibility for the penalty. Setting the benchmark significantly above average spending leaves some room for imprecision in risk adjustment, targeting only hospitals and physicians with resource use well above most of their peers.

At the beginning of the following year (and each year thereafter), providers would be informed of the spending benchmarks in advance. All inpatient hospital and inpatient physician services for the selected conditions would be subject to a withhold—that is, CMS would hold some portion of the payment amount in reserve.

Hospitals with relatively high episode spending on average, as determined either at the end of the year or semiannually, would not get their withhold back and thus would receive lower payments than under current policy. The withhold on services physicians provided in these hospitals would also not be returned. Hospitals and physicians would have withholds returned if, on average, episode spending is below the benchmark.

Hospitals with relatively low episode spending on average would receive their withhold and possibly bonus payments. The same would apply to the physicians billing for services in these hospitals. Applying a quality test to be eligible for bonus payments would be important to temper the financial incentive for providers to stint on needed care.

Under this approach to virtual bundling, whether a physician's payment for services provided in the hospital is penalized or rewarded depends on average episode spending across all the episodes assigned to the hospital. By calculating a hospital's average resource use per episode, CMS would give physicians and hospitals a strong incentive to implement administrative and treatment procedures that improve the performance of everyone practicing at that hospital. Ultimately, holding providers jointly accountable in this way should foster "systemness."

This concept of holding providers jointly accountable could be applied even more broadly than is outlined above. Ideally, under virtual bundling, the hospital and inpatient physicians would be held accountable—subject to penalties and rewards—as well as providers seeing the patient on an outpatient basis or in a post-acute setting within the 30 days after discharge. This would provide symmetric incentives for all involved in the episode to work together and be mindful of their collective performance. A concern is that the policy might adjust payments for providers who had no ability to influence the course of the episode (e.g., an allergist who sees a patient on the 28th day after discharge for a condition clinically unrelated to the one that initiated the episode). Once that issue is resolved, perhaps the incentives under virtual bundling should be expanded. Other policies, including skilled nursing facility pay for performance and physician resource use measurement—two initiatives the Commission previously recommended—should also be pursued to balance incentives (MedPAC 2007). ■

not be inclined to make the types of investments that are likely to be so critical to meeting program objectives and achieving financial success under this new payment method.

A pilot is less aggressive than fully implementing a national voluntary bundled payment policy. The Commission considered a national voluntary bundled payment approach but found several aspects of implementation particularly thorny, rendering the approach too risky. The policy challenges discussed below point to the rationale for why the Commission opted for a pilot rather than a national program and the spectrum of issues the pilot must address.

RECOMMENDATION 4C

The Congress should require the Secretary to create a voluntary pilot program to test the feasibility of actual bundled payment for services around hospitalization episodes for select conditions. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

RATIONALE 4C

A pilot would guide policy on a variety of design questions and allow some hospitals and their affiliated physicians to begin receiving bundled payments. It allows CMS to explore how savings could be shared between Medicare and providers and would help minimize the possibility of unintended consequences.

IMPLICATIONS 4C

Spending

- Spending implications are indeterminate, but the intent of the policy is to produce Medicare savings or, at a minimum, be budget neutral.

Beneficiary and provider

- Coordination of beneficiaries' care should improve.
- The pilot should align provider incentives, allowing them to share in savings resulting from greater efficiency.

Achieving Medicare savings

The Commission intends for bundled payments to achieve Medicare savings but has identified a number of challenges that must be addressed. First, making bundled payment voluntary has implications for how payment can be set to achieve savings, which raises concern about the administrative ease of the policy. Considering the payment alternatives can help to illustrate the challenge. For example, payment amounts for each bundle can be set at a national or regional average, similar to the way DRG rates were initially set. But under a voluntary option, if bundled payment rates were set at such an average, only those who would benefit (those with below-average spending across the episode) would likely participate. This dynamic would result in higher rather than lower Medicare spending.

An alternative way to set payment levels that is more likely to achieve savings is to calculate each provider's baseline spending amount and negotiate a discount from that rate. This approach was used in the heart bypass demonstration in the 1990s. However, CMS found that making this hospital-specific baseline calculation was administratively consuming. Accordingly, using this payment method, which may be necessary to achieve savings, requires that CMS start bundled payment in the context of a pilot, where it can limit the number of participants and select providers in different markets and with different integration models. Confining the policy approach in this way would allow CMS to manageably experiment with how best to streamline the calculation to minimize the administrative burden while ensuring it is fair and transparent to providers.

A related issue for CMS to address is how to determine the level of Medicare savings associated with aligned incentives. In the heart bypass demonstration, the base bundled payment rate was subject to a discount, the specific percentage of which varied by site. For the purposes of the pilot, savings could be achieved through a similar discount from the base rate, through lower future updates for inflation of the base rate, or through a combination of the two. The approach to securing savings could vary depending on the historical spending level of the providers. For example, those with exceptionally high costs could be subject to deeper discounts than other providers with relatively low episode costs. Another design option is to gradually increase provider-specific savings targets over time—so that, for example, a high-cost facility would face steady pressure to continually invest in ways to control its costs.

A second challenge to achieving savings is the potential for bundled payment to create an incentive for providers to produce more admissions. As discussed earlier, providers may recognize that increasing the number of admissions can create a win-win situation for the hospital

and physicians. In the short term, one approach that could dampen incentives to increase volume would be to regulate the financial arrangements between hospitals and physicians. For example, fair market value limits could be applied to physician payment rates. Another possibility would be to measure admission rates and adjust the bundled payment based on the providers' admission rate relative to a national average. Numerous technical issues would need to be resolved first to ensure fair measurement.

Addressing payment complexities

Whether the bundled payment base rate is set on a hospital-specific basis or on some type of average, other payment issues would need to be addressed. Among them are the following:

- How can CMS best adjust for a patient's relative risk (health status) over the course of a hospitalization episode? While risk adjustment for care during the stay has been well tested, Medicare has less experience in adjusting for differences in postdischarge costs—differences that can stem from variation in patient characteristics, their home environment, and the availability and mix of physicians and post-acute providers in the area.
- How can CMS identify outlier cases and make additional payments to cover the costs associated with exceptionally costly cases? Conversely, how can CMS make adjustments for exceptionally short hospitalization episodes, including those in which a patient dies during the hospitalization?
- How can CMS minimize the risk that hospitals receiving indirect medical education and disproportionate share funds could use them to create an unlevel playing field in the competition for physicians? Indirect medical education and disproportionate share funds could be diverted to attract and reward high-volume physicians caring for high-margin cases.
- How should CMS adjust its regular prospective payment system rates for services like home health care and hospital stays when a portion of the care was delivered in the bundled payment window? For example, home health services are usually paid in 60-day episodes. If Medicare paid for 30 days of care in the hospital bundle, it would need to recalibrate how it pays for home health beyond the end of the hospitalization episode.
- How should beneficiary cost sharing be addressed? With bundling, in which payment is unchanged by the number of visits, policymakers would need to reexamine how to calculate beneficiary coinsurance for visits to physicians and outpatient providers.[5] The interaction with supplemental coverage should also be considered, given that most beneficiaries have supplemental coverage for these cost-sharing requirements.
- Should prescription drug spending, covered under Part D of Medicare, ultimately also be included in the bundled payment?

Quality incentives

To address concerns about stinting, providers should be held accountable for quality. While the Commission recognizes that current quality measures are imperfect, CMS has gained experience measuring hospital quality and is continually exploring new measures and refinements to existing measures. In particular, the Commission encourages CMS to develop new measures that will promote coordination of care across settings, patient centeredness, longitudinal assessment, and shared provider accountability in addition to clinical quality.

In considering how providers receiving a bundled payment should be held accountable for quality, policymakers will need to consider the nature of the penalty for subpar levels of quality. For example, would Medicare publicly report the provider's performance, impose a payment penalty, or exclude the provider from the program?

The ability and willingness of providers to participate

Some providers might prefer receiving a bundled payment rather than the separate payments associated with the current payment system (and virtual bundling), but others may not. As discussed earlier, some—particularly those with a history of acrimony and distrust between hospitals and physicians—would not be able or willing to come together to accept and share the bundled payment, at least not initially. Providers might find that they were better off in the current or virtual bundling system. Determining the relative advantage of each system would depend not only on the payment rate a provider would receive but also on the provider's assessment of the impact of the bundled payment on costs.

Although bundling creates incentives for providers to reduce costs both during the hospitalization and afterward,

it also entails new administrative costs as well as some insurance risk. With respect to administrative costs, providers would need to negotiate contracts specifying how they would plan to share the bundle. This process could be extensive, as hospitals would need to contract with a wide range of physicians and post-acute care providers. The entity receiving the payment would then need to develop an administrative infrastructure to receive and pay bills—not only for its usual set of providers but also for others who might see the patient during the episode. This would likely be an entirely new administrative function for a hospital and could represent a significant financial investment.

Insurance risk refers to the ability of providers to manage the costs of care during the hospitalization episode so that they do not exceed payments. Part of the assessment providers make to manage this risk would concern whether they were responsible for costs clinically related to the initial admission or all costs. Some of the costs within the 30 days after discharge could be unrelated to the clinical circumstances of admission that initiated the hospitalization episode. Those costs might be more difficult to anticipate and manage and may dissuade some from participating. If this issue is perceived to be a significant barrier, some exceptions could be considered (e.g., providers would not be held accountable for costs associated with automobile accidents or other traumas after discharge). Geisinger Health System has pursued this type of approach in creating bundled payments for private sector payers.

Conclusion

The Commission is under no illusion that the path of policy change outlined here is easy. Despite our best efforts to anticipate them, unforeseen consequences are likely to be encountered and policies would need to be adjusted. Nevertheless, the Commission believes the status quo is unacceptable. The current payment system is fueling many of the worst aspects of our heath care system, leaving beneficiaries' care uncoordinated and increasing health care costs to an extent that strains beneficiaries' ability to pay Medicare premiums, the nation's ability to finance Medicare, and the ability of a large segment of the non-Medicare population to afford insurance.

The Commission has chosen a path that balances the need for change with an understanding that an industry as complex as health care cannot change quickly and that mistakes can carry serious, life-threatening consequences. Nevertheless, the Commission is motivated by a sense of urgency. The price we are paying is too great. ■

Endnotes

1 As discussed in Chapter 3, hospitals and physicians are finding ways to align incentives in a way that might induce physicians to help hospitals contain costs. Unfortunately, these alignment strategies appear to be aimed at increasing the volume of services performed rather than containing costs.

2 Many readmissions defined as potentially preventable would still occur even if best practices were followed. We cannot clearly identify with claims data what proportion of potentially preventable readmissions actually could be prevented if best practices were followed. Potentially preventable defines the subset of cases in which some reduction in readmissions is possible and savings could be achieved.

3 This increase in volume was not documented when the inpatient prospective payment system (case payments) for hospital stays was implemented. Because physicians, rather than hospitals, admit patients and the inpatient prospective payment system provided no incentive for them to admit more, the lack of volume growth may not be surprising. However, the dynamic could be different under a bundled payment policy because it aligns physicians' and hospitals' incentives.

4 3M's approach identifies readmissions that likely could have been prevented, such as readmissions for COPD after cardiac surgery, some of which may be avoided if COPD medications are appropriately adjusted at discharge. In determining potentially preventable readmissions, 3M excluded certain readmissions—including those related to trauma, cancer, and burns—and then combed through all permutations of diagnoses for an initial stay and for a readmission and evaluated the likelihood that a given readmission diagnosis was related to the first admission and, therefore, was potentially preventable.

5 Skilled nursing facility coinsurance does not begin until the 20th day of the stay, so it is not affected by a more modest bundling approach. Other services beneficiaries may use during the hospitalization episode are not currently subject to cost sharing, including home health, laboratory services, durable medical equipment, and readmissions

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CHAPTER 5

Producing comparative-effectiveness information

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Producing comparative-effectiveness information

Chapter summary

Comparative-effectiveness analysis evaluates the relative value of drugs, devices, diagnostic and surgical procedures, diagnostic tests, and medical services. By value, we mean the clinical effectiveness of a service compared with its alternatives. Comparative-effectiveness information has the potential to promote care of higher value and quality in the public and private sectors.

In our June 2007 report, the Commission concluded that there is not enough credible, empirically based information for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions. Many new services disseminate quickly into routine medical care with little or no basis for knowing whether they outperform existing treatments, and to what extent.

The Commission recommended that the Congress establish the capacity to produce and provide information about the comparative effectiveness of health care services (MedPAC 2007). Because the information can

In this chapter

benefit all users and is a public good, the Commission concluded that a federal role is necessary to produce the information and make it publicly available.

The Commission believes that the entity would:

- Be independent and have a secure and sufficient source of public and private funding;
- Produce objective information and operate under a transparent process;
- Seek input on agenda items from its constituents—patients, providers, payers, scientists, and researchers;
- Reexamine the comparative effectiveness of interventions over time;
- Disseminate information to its constituents; and
- Have no role in making or recommending coverage or payment decisions for payers.

The entity's primary mission would be to sponsor studies that compare the clinical effectiveness of a service with its alternatives. Although cost effectiveness is not a primary mission, the Commission does not rule it out. We emphasize that the entity would not have a role in how public and private payers use this information—that is, in coverage or payment decisions. Instead, it would disseminate the information to patients, providers, and payers who would then decide how to use it.

There are different ways to carry out a federal role. The Commission prefers a public–private option to reflect that all payers and patients would gain from comparative-effectiveness information; we also support an independent board of experts to oversee the development of an unbiased research agenda and ensure that the research is objective and methodologically rigorous. A federal role need not result in a large expansion of the government. We envision that the entity would contract most of the research to outside groups, including existing governmental agencies with experience conducting comparative-effectiveness research.

The goal of this chapter is to discuss three key issues that policymakers would need to consider when establishing a comparative-effectiveness entity: the design of the board, the placement of the comparative-effectiveness entity, and the entity's funding. This chapter considers the pros and cons of governance and funding options but does not recommend a specific approach.

In designing a board, a number of issues arise, including the ethics rules that should apply, the process of appointing members, the duration of their terms, and the board's composition and size. These issues affect the board's independence, objectivity, and stability. For example, establishing ethics rules would help ensure that board members are independent and objective, and appointing members to long and overlapping terms would help ensure the board's stability and independence.

The alternatives that we discussed to house a comparative-effectiveness entity vary in their closeness to the federal government and the private sector:

- A federally funded research and development center, which is a nonprofit private sector organization that is sponsored by an agency within the executive branch;
- An independent federal agency within the executive branch;
- An independent federal agency within the legislative branch; or
- A congressionally chartered nonprofit organization, which is a private sector organization established by the Congress.

Determining the entity's level of funding will be a key issue for policymakers to consider. Some researchers have proposed funding based on the nation's annual outlays for health care services, which would result in funds ranging from $1 billion to about $3 billion per year (Altman et al. 2003, Reinhardt 2004). The level of funding the entity requires will depend on the type of research it sponsors. Primary research (e.g., head-to-head clinical trials) is more costly to sponsor than secondary research (e.g., systematic reviews of existing literature).

The Commission supports funding from federal and private sources as the research findings will benefit all users—patients, providers, private health plans, and federal health programs. The Commission also supports a dedicated funding mechanism to help ensure the entity's independence and stability. Dedicated broadly based financing would reduce the likelihood of outside influence and would best ensure the entity's stability compared with financing from annual appropriations or funding on a per project basis. Even so, an entity that relies on such a mandatory funding source would be accountable to policymakers because the Congress always has the option to alter or end its funding.

The chapter concludes with a discussion of various ways CMS could use comparative-effectiveness information when the agency develops payment policies. A recent report by the Congressional Budget Office (CBO) noted that to reduce spending substantially under Medicare, CMS would probably need additional authority to consider the relative benefits and costs of services in a more extensive way when making payment and coverage decisions (CBO 2007). Under current policy and law, CMS generally covers any treatment that is "reasonable and necessary," regardless of its effectiveness or its cost relative to alternative approaches. ■

Background

For the past several decades, the United States has spent an expanding share of its resources on health care. In 1960, national health expenditures made up about 5 percent of gross domestic product. By 2005, that share had grown to 16 percent and CMS projects that by 2017 it will make up 20 percent (Keehan et al. 2008). Although many factors contributed to the growth in health care spending, the Congressional Budget Office (CBO) concluded that the largest single factor is the expanded capability of medicine brought about by technological advances over the past several decades (CBO 2008). Technological advances include the use of new treatments and existing treatments in a broader patient population. In the next decade, the pace of innovation in medical care is likely to accelerate (IOM 2008).

Even though substantial resources are devoted to health care in the United States, the value of services furnished to patients is often unknown. In some instances, medical innovations diffuse quickly into routine medical care with little or no basis for knowing whether or to what extent they outperform conventional care, which includes existing interventions and no intervention. The use of innovations with limited clinical evidence can sometimes lead to patients experiencing poorer outcomes than would have occurred under conventional care or to unanticipated adverse side effects. To draw lessons about the importance of evaluating the effectiveness of medical services, the text box (pp. 113–115) presents five brief case studies of services that widely diffused and were later shown to have limited clinical effectiveness compared with conventional care, harmful side effects, or both.

Increasing the value of health care spending requires knowledge about patient outcomes. Comparative effectiveness—a comparison of the outcomes of different treatments for the same condition—could help public and private payers alike get greater value from the health care resources they fund.

Last year, the Commission concluded that not enough credible, empirically based comparative-effectiveness information was available to patients, providers, and payers to make informed treatment decisions (MedPAC 2007). Comparative-effectiveness information is a public good because its benefits accrue to all users, not just to those who fund it. Because the information is a public good, private investment alone is suboptimal; a federal role is needed to ensure levels of investment that are more appropriate to society's returns on the knowledge. Consequently, in 2007, the Commission recommended that the Congress charge an independent entity to sponsor credible research on the comparative effectiveness of health care services and disseminate this information to patients, providers, and public and private payers (MedPAC 2007). Other organizations and policy analysts from disparate points of view, including American Health Insurance Plans, Gail Wilensky, and Uwe Reinhardt, have reached a similar conclusion (Table 5-1, p. 112).

To carry out a federal role, the Commission prefers a public–private option, reflecting the benefit of comparative-effectiveness information to the government, private payers, and patients. Specifically, to ensure the entity's independence and stability, the Commission supports:

- an independent board of experts to develop the research agenda and ensure that the research is objective and methodologically rigorous,
- an unbiased appointment process for board members and establishment of provisions to moderate conflicts of interest, and
- a dedicated public–private funding mechanism.

The entity's primary mission would be to sponsor studies that compare the clinical effectiveness of a service with its alternatives. This research would involve synthesizing existing effectiveness literature or sponsoring new analyses, such as head-to-head clinical trials. Although cost effectiveness is not a primary mission, the Commission does not rule it out. The entity would not have a role in how payers apply this information to coverage or payment decisions. Instead, it would make the information available for others—payers, providers, and patients—to decide how to use it. In the Commission's June 2007 report to the Congress, the chapter on producing comparative-effectiveness information discusses in greater depth the activities of a comparative-effectiveness entity (MedPAC 2007).

The entity would need to establish guidelines for studies that it conducts and that it contracts to public and private research groups. Work conducted by other U.S. and international groups could inform this process. It will not be necessary to reinvent mechanisms that are now working well. Consensus from the research community will be essential to establish the entity's credibility.

TABLE 5–1 **Review of governance and funding options other researchers have discussed**

Researcher	Summary of approach
IOM (2008)	Recommended that the Congress direct the Secretary of HHS to establish a single national clinical effectiveness assessment program with the authority and resources to set priorities for and sponsor systematic reviews of clinical effectiveness, and to develop methodological and reporting standards for conducting systematic reviews and developing clinical guidelines. Also recommended that the Secretary appoint a broadly representative Clinical Effectiveness Advisory Board to oversee the program.
AHIP (2007)	Recommended a new public–private organization to compare the clinical and cost effectiveness of new and existing drugs, devices, procedures, therapies, and other health care services and distribute this information in a useful format to patients and clinicians. The new entity should be funded through public sources supplemented with support from private sources through mechanisms that will provide stability and independence from political pressures.
CBO (2007)	Discussed following governance options: • expanding the role of an existing agency such as AHRQ or NIH; • creating or "spinning off " a new agency, either within HHS or as an independent body that is part of either the executive or the legislative branch; • augmenting an existing quasi-governmental organization such as IOM or the National Research Council; and • establishing a new public–private partnership, such as an FFRDC. Discussed the following funding options: regular appropriations, dedicated financing amounts from Medicare trust funds or set percentages of federal health outlays, direct contributions from or dedicated taxes on the health sector.
Commonwealth Fund (2007)	Recommended a quasi-governmental entity possessing legal characteristics of both the public and private sector, so that it could receive funding (and participation and support) from both.
Wilensky (2006)	Considered four options: (1) placing the entity in AHRQ, (2) placing the entity within HHS as a new or existing entity, (3) placing the entity in a quasi-governmental entity, and (4) placing the entity in the private sector. Concluded that placing the center within a quasi-governmental entity was the most attractive alternative and that an FFRDC associated with either AHRQ or a newly established board within HHS were options worth exploring.
AcademyHealth (2005)	Recommended establishing an entity either within or outside of AHRQ and reviewed four options: • AHRQ sponsors research, with guidance from an external board and panel of experts; • AHRQ establishes an FFRDC and receives guidance from an external board and panel; • The Congress creates a new quasi-governmental entity, with AHRQ remaining as currently structured; or • The Congress reconstructs AHRQ as a quasi-governmental agency, which would keep most of its existing functions and add comparative effectiveness to its research portfolio.
Kupersmith et al. (2005)	Recommended a public–private consortium to include federal agencies, payers, insurers, drug companies, device companies, patient advocacy and interest groups, professional societies, hospitals, academics, and health foundations. Under this proposal, new federal appropriations would fund the consortium, with the expectation that the private sector would also contribute.
Reinhardt (2004)	Endorsed the creation of nonprofit independent institutions to analyze the cost effectiveness of drugs. Concluded that housing the infrastructure in a federal agency with funds appropriated by the Congress would be too vulnerable to political influence. Proposed that the proceeds from a small surcharge (one-half percentage point or less) on the annual outlays on prescription drugs could establish permanent endowments for independent nonprofit organizations.

Note: IOM (Institute of Medicine), HHS (Department of Health and Human Services), AHIP (America's Health Insurance Plans), CBO (Congressional Budget Office), AHRQ (Agency for Healthcare Research and Quality), NIH (National Institutes of Health), FFRDC (federally funded research and development center).

Limited information on comparative effectiveness can lead to poor clinical decision making

Decisions about what treatments to use often depend on anecdotal evidence, conjecture, and the experience and judgment of individual medical providers. Sometimes poor decisions are made for lack of clinical evidence, leading patients to experience poor outcomes from unanticipated adverse side effects. The following five case studies underscore the importance of evaluating the effectiveness of a service compared with conventional care (which can include existing interventions or no intervention) before such service widely diffuses and leads to less effective care or harm.

Case 1: Bone marrow transplantation for breast cancer

High-dose chemotherapy with an autologous bone marrow transplant (HDC/ABMT) is a cancer procedure in which a patient receives high-dose chemotherapy followed by transplantation of the patient's own bone marrow or stem cells. Between 1990 and 1999, the use of HDC/ABMT grew rapidly among women with breast cancer despite little clinical evidence that showed its effectiveness compared with the standard of care—conventional chemotherapy (Mello and Brennan 2001). Rettig and colleagues (2007) summarized the factors associated with the growth of this procedure in the 1990s:

- The oncology establishment legitimated the procedure very early in the 1990s.
- Breast cancer patients often saw the treatment as their last best hope.
- Health insurers, reluctant to pay for investigational or experimental procedures, aided its rapid diffusion by provoking strong negative reactions to coverage denials, at least until litigation made that option unattractive.
- Federal and state government mandates required that HDC/ABMT be covered as a benefit without evidence of its effectiveness.
- The media promoted HDC/ABMT to patients and helped persuade legislators to mandate that insurers pay for the procedure.
- Financial incentives drove both for-profit and nonprofit providers to promote the use of the procedure.

Expanding clinical use of HDC/ABMT began in 1989. Demands on insurers for coverage increased during the 1990s, and breast cancer became the most common indication for such procedures. Insurers began to turn down coverage requests in the late 1980s, asserting that the procedure was still investigational (Rettig et al. 2007). Many women responded by seeking coverage of the procedure through the judicial system. Most cases were settled out of court to avoid the expense and publicity of a jury trial. Most health plans agreed

(continued next page)

The research the entity sponsors would need to examine comparative effectiveness in relevant patient populations and in different care settings. Because the health care delivery system might affect the usefulness of some services, the effectiveness of services provided under different delivery systems should be considered. (Issues related to improving the health care delivery system are discussed elsewhere in this report.)

With its focus on comparative effectiveness, the entity would have other responsibilities apart from conducting or sponsoring research. It could act as a clearinghouse of published comparative-effectiveness literature. For example, clinicians' day-to-day work would be simplified if there were a single source for published studies on comparative effectiveness and if the information were summarized in a helpful way to inform treatment decisions. In addition, the entity could sponsor conferences or scientific symposia on a host of issues surrounding the use of comparative-effectiveness analysis, including methodological questions.

Finally, the new entity would need to coordinate with existing public and private institutions conducting

Limited information on comparative effectiveness can lead to poor clinical decision making (cont.)

to cover HDC/ABMT by the mid-1990s because of litigation, political lobbying by patient advocacy groups, and government mandates.

In 1999, results from five randomized controlled clinical trials showed that HDC/ABMT did not result in better outcomes compared with conventional treatment. Women receiving HDC/ABMT did not survive longer or have a longer time to progression of disease than women who received conventional therapy (Stadtmauer et al. 2000). In addition, the incidence of nonfatal but serious side effects (myelosuppression, infection, diarrhea, and vomiting) was greater among women receiving HDC/ABMT than in women who received conventional therapy. Treatment-related mortality was virtually the same for women in both groups.

About 23,000 to 40,000 women received HDC/ABMT between 1989 and 2002 (Rettig et al. 2007). A precise assessment of the additional health care spending incurred for HDC/ABMT compared with conventional treatment is not available. Assuming a cost of $80,000 per transplant (Mello and Brennan 2001), between $1.8 billion and $3.2 billion was spent on a treatment that was ultimately found to offer no appreciable medical advantage compared with conventional care, which could have been provided for less than half the cost.

Case study 2: Hormone replacement therapy

Until 2002, hormone replacement therapy was the standard therapy for treating menopausal symptoms. Hormone replacement therapy diffused based on decades of observational evidence that suggested it was associated with cardiovascular benefits. By the end of the 1990s, almost half of all postmenopausal women were being treated with long-term hormone therapy (Hersh et al. 2004). Annual hormone therapy prescriptions increased from 58 million in 1995 to 91 million in 2001 (Hersh et al. 2004). Spending for hormone replacement therapy was substantial; for example, total sales were $1.2 billion in 2000 (Lundy and Levitt 2001).

The Women's Health Initiative—a large, multicenter study sponsored by the National Institutes of Health (NIH)—was the first randomized primary prevention trial of postmenopausal hormones (Fletcher and Colditz 2002).[1] Findings from the Women's Health Initiative showed that hormone therapy posed more health risks than benefits. Researchers found that women taking hormone therapy (estrogen and progestin) were at increased risk of heart disease, breast cancer, stroke, blood clots, and dementia.

The findings of the Women's Health Initiative were widely and rapidly disseminated through both scientific and medical communication channels. A year and a half after these results were first published, use of prescription hormone therapy declined by 43 percent (Majumdar et al. 2004).

Since 2002, additional studies have shed light on the effective use of hormone replacement therapy. For example, one recently published study reported that the increased risk of breast cancer remains after women stop taking the therapy (Heiss et al. 2008). Another recent study reported that postmenopausal women who take hormones have a lower risk of developing advanced age-related eye disease, especially if they took oral contraceptives in the past (NIH 2008b). Over time, more studies may be completed that refine the guidelines about the appropriate use of hormone replacement therapy.

Case study 3: Extracranial–intracranial arterial bypass surgery

Extracranial–intracranial (EC/IC) arterial bypass surgery, a procedure first performed in 1967, was rapidly adopted in the 1970s as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries. According to Wilson (2006), EC/IC diffused rapidly because it was easily explained to patients, it was not difficult for surgeons to learn how to do the procedure, and the potential population eligible for treatment was large.

(continued next page)

Limited information on comparative effectiveness can lead to poor clinical decision making (cont.)

In 1977, NIH initiated a randomized controlled clinical trial to test whether the procedure (connecting the superficial temporal artery to the middle cerebral artery) reduced stroke and stroke-related death compared with conventional medical care (EC/IC Bypass Study Group 1985).[2] This head-to-head clinical trial found no clinical benefit from the surgery; nonfatal and fatal stroke occurred more frequently and earlier in patients who had surgery.

After the release of the clinical trial results in 1985, Wilson (2006) reported that payers and patients rapidly abandoned the procedure. In 1991, Medicare withdrew coverage of the procedure as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries. The total number of Medicare beneficiaries undergoing EC/IC surgery before the program withdrew coverage is not known because the code used to identify the procedure also identifies other procedures. By 2005, fewer than 800 procedures were performed across all payers.

Case study 4: Rofecoxib

The Food and Drug Administration (FDA) approved rofecoxib, a cyclooxygenase–2 (COX–2) inhibitor, in May 1999 to relieve the symptoms of arthritis, acute pain, and painful menstrual cycles. It was later approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children. The manufacturer voluntarily withdrew the drug from the market in September 2004 because data from clinical trials showed an increased risk of serious cardiovascular events, such as heart attacks and strokes, with long-term use of the drug (FDA 2004). Researchers concluded that methodological limitations minimized the chance of finding cardiovascular side effects during the initial clinical trials (Psaty and Furberg 2005).[3]

Rofecoxib was one of the most widely used drugs ever to be withdrawn from the market. This medication's lower rate of gastrointestinal side effects compared with alterative therapies—nonsteroidal anti-inflammatory drugs or aspirin—led to its wide diffusion even though it offered similar degrees of pain relief (Solomon et al. 2005). In the year before withdrawal, spending for rofecoxib was estimated to be about $2.5 billion.

The liability associated with rofecoxib is substantial. In November 2007, the manufacturer set up a settlement fund of $4.85 billion to settle some 27,000 lawsuits of people claiming that they or family members had been injured or died after taking rofecoxib (Merck 2007).

Case study 5: "Fen-phen"

The FDA individually approved phentermine (in 1959) and fenfluramine (in 1973) as appetite suppressants for the treatment of obesity. Although the FDA never approved the use of the combination—referred to as "fen-phen"—many practitioners used the combination of the two products off label for the management of obesity. The combination's off-label use was related to the results from a small clinical trial, which suggested that patients who were prescribed both drugs together required lower doses of each agent and had fewer side effects than patients prescribed one of the drugs (Weintraub et al. 1984). The FDA approved dexfenfluramine, an antiobesity drug related to fenfluramine, in 1996.[4]

Use of these antiobesity agents diffused widely. Spending for fenfluramine and dexfenfluramine totaled $300 million in 1996. The Centers for Disease Control and Prevention estimated that between 1.2 million and 4.7 million persons were prescribed the drugs (CDC 1997).

In July 1997, Connolly and colleagues reported 24 cases of heart valve problems that could lead to severe heart and lung disease in women who were treated with the combination of fenfluramine and phentermine.[5] On the basis of these reports, the FDA asked the manufacturers to voluntarily withdraw their drugs; in September 1997, both drugs were no longer marketed in the United States.[6]

The liability associated with fenfluramine and dexfenfluramine is substantial. The company that marketed both fenfluramine and dexfenfluramine has set aside more than $21 billion to pay the claims from some 100,000 lawsuits (Hawthorne 2005). ■

comparative-effectiveness research. For example, the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), and private sector groups would likely continue to undertake comparative-effectiveness research, and some of their studies could overlap with the entity's agenda. Coordinating research efforts could help reduce duplication and variability in the quality of the work undertaken. The goal would be to prevent the lack of coordinated findings that exists today (IOM 2008). However, the entity would play the role of convener rather than that of "overseer." To that end, establishing a "users' group" or an advisory committee would enable public and private sector groups that sponsor comparative-effectiveness research to meet, discuss issues, and offer new ideas.

Ensuring that the entity operates under a transparent and objective process is important. Otherwise, the users (patients, providers, and payers) of comparative-effectiveness information may neither believe nor use the research to make decisions. A transparent and objective process will, over the long run, improve the quality of the published literature on effectiveness. As we discuss later, researchers have shown that the results of some studies sponsored by some manufacturers show the biases of the investigators and funding sources.

Conducting comparative-effectiveness studies is not the primary focus of any federal agency

No federal entity exists whose sole mission is to sponsor and disseminate information about services' comparative effectiveness. Although AHRQ supports research that compares the clinical effectiveness of alternative treatments, its primary mission is broader—to conduct and sponsor health services research, which encompasses studies ranging from patient safety to health system effects on economic and clinical outcomes.

Other federal agencies with broader missions also conduct comparative-effectiveness research. NIH is the largest sponsor of head-to-head clinical trials that compare alternative treatments. However, such research is spread over many of its 27 centers and institutes and is a small fraction of the total NIH research portfolio of medical and behavioral research (AcademyHealth 2005). In addition, the Veterans Health Administration devotes a portion of its clinical research to evaluating the comparative effectiveness of health care services.

Other developed countries, with varied health care delivery and financing systems, have already established central agencies to conduct comparative-effectiveness research. For example, the United Kingdom, a single-payer system, established the National Institute for Health and Clinical Excellence (NICE) in 1999 as a part of the National Health Service to analyze the comparative effectiveness of new and existing health care services. (We discuss the funding of NICE's comparative-effectiveness research effort on pp. 127–128.) Germany, a multipayer system, established the Institute for Quality and Economic Efficiency in Health Care (IQWiG) in 2004, which conducts scientific evaluations of the use, quality, and efficiency of health care services. The organizations established in the United Kingdom and Germany use different governance and funding approaches. For example, NICE is a part of the United Kingdom's National Health Service whereas IQWiG is a private foundation (IQWiG 2008).

The private sector does not systematically produce and disseminate objective comparative-effectiveness information

In some instances, manufacturers of drugs, biologics, and devices conduct comparative-effectiveness studies but some researchers have critiqued these studies and raised concerns that the efforts may not always be objective and available to the public. Researchers have shown that bias in industry-sponsored trials is common and often favors the sponsor's product (Peppercorn et al. 2007). Possible sources of bias in industry-sponsored trials include: the dose of the drug studied; the exclusion of patients who are elderly, disabled, or have multiple comorbidities from the study population; the statistics and methods used; and the interpretation, reporting, and wording of results. Researchers have reported a bias toward the publication of positive results (Turner et al. 2008). There are also instances in which manufacturers do not provide the Food and Drug Administration (FDA) with required postapproval data (FDA 2008a). A recent case study reported instances in which a manufacturer facilitated the publication of guest-authored and ghostwritten medical literature (Ross et al. 2008).

Pharmacy benefit managers, health plans, and other large providers (e.g., hospitals) consider a service's clinical effectiveness, cost, and cost effectiveness—particularly for their drug formularies—but do not necessarily make their evaluations public. These groups often focus on proprietary studies related to the health care practices of providers in their respective networks. Few private sector

groups systematically produce comparative-effectiveness information and make it available to the public. One exception is the Technology Evaluation Center established by Blue Cross Blue Shield Association, which relies on reviewing existing literature to compare the clinical effectiveness of alternative services and posts these studies on the Internet.

More comparative-effectiveness information could help support better decision making by patients and providers

There is little evidence whether or to what extent new health care services are equally effective or outperform existing treatments. The research that manufacturers conduct to obtain marketing approval from the FDA generally compares their product (a drug, biological, or medical device) with a placebo (inactive agent).[7] These studies rarely make direct comparisons of alternative treatments or products. For surgical procedures and for laboratory-developed diagnostic tests, less clinical information is available than for drugs, biologicals, and devices because the FDA does not review their safety and effectiveness. More comparative-effectiveness information would be available if, when seeking FDA approval, manufacturers sponsored head-to-head clinical trials comparing their product with its alternatives.

More information on comparative effectiveness could help ensure that future technologies and existing costly services are used only when they confer clinical benefits that are superior to those of other, less costly services. In addition, disseminating objective comparative-effectiveness research to patients, payers, and providers would help improve how society allocates its health care resources. A significant proportion of health care spending is for care that has not been shown to be effective and that may be harmful (Wennberg et al. 2002). Effectiveness research might also encourage the greater use of effective treatments that are currently underutilized.

More information on comparative effectiveness might also reduce the variation in the use of certain treatments. Currently, researchers have shown that the use of certain treatments varies widely throughout the country (Fisher et al. 2003). The geographic variation in use is greater when the medical community has not reached consensus about the course of treatment or when clinicians have some discretion in recommending, such as imaging procedures and back surgery.

TABLE 5–2 **Ten leading clinical issues that need more research as identified by CMS's Medicare Evidence Development & Coverage Advisory Committee**

Research topic
Appropriate use of erythropoiesis agents in cancer patients
Comparative effectiveness of treatment of carotid artery disease
Comparative effectiveness of treatment for ulcers: off-loading, debridement, biologics, revascularization
Treatment of atrial fibrillation
Appropriate use of hospice care
Benefits of cancer prognostic markets
Benefits of high-cost cancer drugs
New radiation treatments for cancer: IMRT, proton beam
Benefit of early aggressive treatment for diabetes
Comparative effectiveness of treatment of acute stroke: clot retrieval versus reperfusion drugs

Note: IMRT (intensity-modulated radiation therapy). In 2007, CMS's Medicare Evidence Development & Coverage Advisory Committee (MedCAC) created a list of more than 100 research issues and rated the importance of each topic on a scale of 1 (lowest priority) to 5 (highest priority). The highest ranked topics judged by MedCAC are listed above. Since this effort, federal agency officials have also developed a list of services that need more research.

Source: CMS 2008.

More comparative-effectiveness information may help close significant evidence gaps and improve clinical decision making. Uncertainty about clinical effectiveness applies to new and old services. In October 2007, CMS's advisory committee, the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), rank-ordered a list of research topics that could best fill evidentiary gaps for issues of critical importance to the Medicare program (Table 5-2). Since this effort, 50 scientists from federal agencies (Centers for Disease Control and Prevention, AHRQ, CMS, FDA, and NIH) participated in a workshop to revise and refine MedCAC's research questions. MedCAC reconvened in April 2008 to review and rank the research questions.

Filling in the knowledge gaps might lead to modest savings in national health care expenditures. CBO

estimated that expanding the federal role in sponsoring comparative-effectiveness research would reduce federal health care spending by $1.3 billion and total health care spending in the United States by $6 billion over a 10-year period (2008 through 2017) (CBO 2007, Orszag 2007).[8] CBO also estimated that, after considering the federal expenditures to establish a comparative-effectiveness entity, the net effect over 10 years would be to increase federal spending by $1.1 billion but decrease public and private spending by $3.6 billion (Orszag 2007).

Governance of a comparative-effectiveness entity

In our June 2007 report to the Congress, the Commission recommended that the Congress charge an independent entity to sponsor and disseminate comparative-effectiveness information. In this section, we consider the structure of a comparative-effectiveness entity. We explore the pros and cons of how to configure a board that would oversee the entity's research activities and where to place a comparative-effectiveness research function.

In evaluating governance and funding options, policymakers might consider whether (1) users will judge the research as being objective, credible, and produced with minimal or no conflict of interest and bias; (2) the entity is independent of various stakeholders and political pressures; and (3) the entity is stable. In our June 2007 report, the Commission emphasized the importance of independence and objectivity in structuring a comparative-effectiveness entity. The text box describes the experiences of three former Surgeons General, who testified before the Congress in 2007 about the lack of independence in speaking about certain public health topics. The text box (pp. 130–131) summarizes the experience of two defunct federal agencies—the congressional Office of Technology Assessment and the National Center for Health Care Technology—that conducted health technology assessments between 1978 and 1995.

Structuring a board of experts

The Commission believes that an independent board of experts should help develop the research agenda of a comparative-effectiveness entity and ensure that the research is objective and methodologically rigorous. The board of experts would have expertise in designing, conducting, and disseminating comparative-effectiveness research. In designing such an oversight group, a number of issues arise, including the participation of experts from the public and private sectors, the establishment of ethics rules, the appointment of experts to the board, and the role of advisory committees.

Tradeoffs between a board that is full time versus part time

One design issue is the level of involvement of experts from the public and private sectors. Board members could provide day-to-day oversight of the entity's activities—a full-time board. Alternatively, board members could provide periodic guidance to the entity's staff and director—a part-time board.

Certain tradeoffs exist with regard to requiring full-time or part-time service of board members. Compared with those providing part-time service, full-time board members could be more visible and better represent the interests of the comparative-effectiveness entity. Because full-time board members likely would not be permitted to engage in other business or employment, strong financial conflict-of-interest rules could be implemented. Compared with a part-time board, a full-time board would more likely incur higher costs due to expenses related to salaries and benefits. Examples of federal commissions with full-time advisory boards include the Securities and Exchange Commission, the Federal Reserve, and the Federal Trade Commission.[9]

Unlike a full-time board, individuals from both the public and private sectors could serve on a part-time board. For example, representatives from organizations conducting comparative-effectiveness research (e.g., AHRQ), public payers (e.g., the Veterans Health Administration), and private payers could be appointed to a part-time board. Part-time boards are typically larger than full-time boards. Between five and seven individuals typically serve on full-time boards, whereas some part-time boards are composed of more than 15 members. In addition, it might be more efficient to have a single officer (director) carry out the day-to-day activities of an entity rather than a board. For example, a board might not be able to make decisions as promptly as a single administrator or be able to reach consensus about delegating work (GAO 1992).

Under either approach, the role of the chair and the other members needs to be unambiguous to preclude disagreements between the chairperson and commissioners that could have an adverse effect on the agency's operations. For example, problems in administrative

Case study: Independence of Surgeons General from political influence

In 2007, three former Surgeons General testified before the House Committee on Oversight and Government Reform about their lack of independence from executive branch officials. The President appoints the Surgeon General with the consent of the Senate for a four-year term. The Surgeon General reports to the Assistant Secretary for Health within the Department of Health and Human Services.

The three Surgeons General who testified on facing political influence from administrations of both political parties are: Richard Carmona, MD, who served as Surgeon General between 2002 and 2006; David Satcher, MD, who served between 1998 and 2001; and C. Everett Koop, MD, who served between 1982 and 1989. These individuals reported that administration officials discouraged them from speaking about certain public health topics. They also noted the declining role of the office in dealing with key issues, such as public health preparedness.

The former Surgeons General suggested ways to help ensure the future independence of the office. Koop (2007) called for secure staffing and funding for the office to carry out its responsibilities effectively. Carmona (2007) noted that selection of Surgeons General should be depoliticized; future appointees should be selected from the ranks of career Public Health Service personnel "based on merit and without regard to political, ideological, or theological filters." ■

decision making occurred at the International Trade Commission (ITC), the Government Accountability Office (GAO) concluded, because the statute was not clear about the role of the chairperson and the commissioners (GAO 1992). The statute provided the chairperson with the authority to administer the agency but provided the commission the authority to approve the ITC's budget and to override any administrative decision made by the chairperson.

To ensure transparency, the board would need to meet on a regular basis and such meetings would need to be open to the public. In this way, stakeholders would have the ability to understand, follow, and engage in the process.

Establishing ethics rules

Ethics rules would be necessary to ensure that board members and the entity's staff avoid involvement in any real or apparent conflict of interest. The rules would address issues such as whether board members and staff could accept compensation from outside sources and what requirements would be needed for the regular reporting of their financial interests. Strong conflict-of-interest rules would be needed to preclude questions about the integrity of the research process and the scientific credibility and objectivity of the studies sponsored by the entity.

Recent high-profile cases have called attention to the possible effect of financial holdings, consultancies, research grants, and contracts on the decision-making process at NIH. Congressional and media concerns about conflicts of interest at NIH have included instances of senior scientists failing to disclose income from outside work, failing to get permission to consult with private sector groups, or performing work for private sector groups on government time (McNeil 2005). In response to these concerns, NIH has implemented broad restrictions on employees' outside activities and financial arrangements, including the holding of stock in biotechnology and pharmaceutical companies and the acceptance of prizes (NIH 2008a).

Strong standards of ethics are also important for individuals serving on scientific advisory committees to quell doubts about the impartiality of the committees. For example, observers have raised concerns about whether conflicts of interest have biased the recommendations made by the FDA's advisory committees, which are composed of outside experts and help the FDA reach decisions about the safety and efficacy of medications and medical devices. The FDA generally follows an advisory committee's recommendation but is not bound to do so (FDA 2008b).

In the past, members of FDA's drug advisory committees frequently had financial conflicts of interest but were still permitted to serve. In nearly three-quarters of drug advisory meetings held between 2001 and 2004, at least one advisory participant disclosed a financial conflict. However, few individuals with financial conflicts were recused from the committees (Lurie et al. 2006). In one instance in 2005, 10 of the 32 voting advisory members had financial associations with manufacturers of the drugs (COX–2 inhibitors) being considered at the meeting. The committee's vote favoring continued marketing of certain products would have changed if the 10 members with financial conflicts of interest had not voted (Steinbrook 2005). Lurie and colleagues (2006) reported that drug advisory committee members with conflicts of interest were 10 percent more likely to favor the drug being considered than members without reported conflicts.

The FDA Amendments Act of 2007 added new provisions regarding financial conflicts of interest of advisory committee members, including a requirement to review potential conflicts of interest for advisory committee appointments, public disclosure provisions, and an annual report requirement. Although the new law prohibits advisory committee members from participating in meetings if the member (or an immediate family member) has a financial interest that could be affected by the meeting outcome, it permits the agency to grant waivers to this prohibition if it is necessary to afford the advisory committee essential expertise. The legislation caps the number of waivers the FDA may issue in a given year.[10]

There is a tension between the cost and timeliness of administering an advisory committee and ensuring that it is composed of individuals with the necessary expertise without significant financial conflicts. Under contract to the FDA, the Eastern Research Group assessed the relationship between expertise and financial conflicts of interest of FDA advisory committee members. The contractor concluded that creating conflict-free FDA advisory panels could put an additional burden on the cost and the timeliness of advisory committee operations and that the agency might not always be able to match the specialized expertise of some existing advisory committees (Ackerley et al. 2007).

Finally, if formal stakeholder committees were established, they could not, as a practical matter, exclude individuals with financial conflicts of interest, as stakeholders, by definition, represent a particular interest. It would be important, however, to identify and make public any potential conflicts of interest to help ensure transparency.

Appointing individuals to the board

The process by which individuals are appointed to existing boards varies across public and quasi-public entities (e.g., congressionally chartered nonprofit entities). However, the process partly depends on where the entity is located (e.g., executive or legislative branch) and the function of the agency (e.g., carries out some type of function for the executive branch or advises the executive branch or advises the legislative branch).

The President appoints individuals to the boards of most independent federal agencies within the executive branch (GAO 1992). In addition, the President appoints members to the boards of some quasi-public entities because they support some function of an executive branch agency. For example, the President appoints the board to the Legal Services Corporation and the U.S. Institute of Peace. For some executive branch agencies and quasi-public entities, the Senate confirms the President's appointments. In addition, in many instances, the President selects the chair of the board.

Not all boards of executive branch entities are selected solely by the President. For example, the President and the Congress both appoint the advisory board members to the Commission on Civil Rights. The advisory board of the Reagan-Udall Foundation is selected by executive branch agencies, including the FDA, AHRQ, NIH, and the Centers for Disease Control and Prevention.

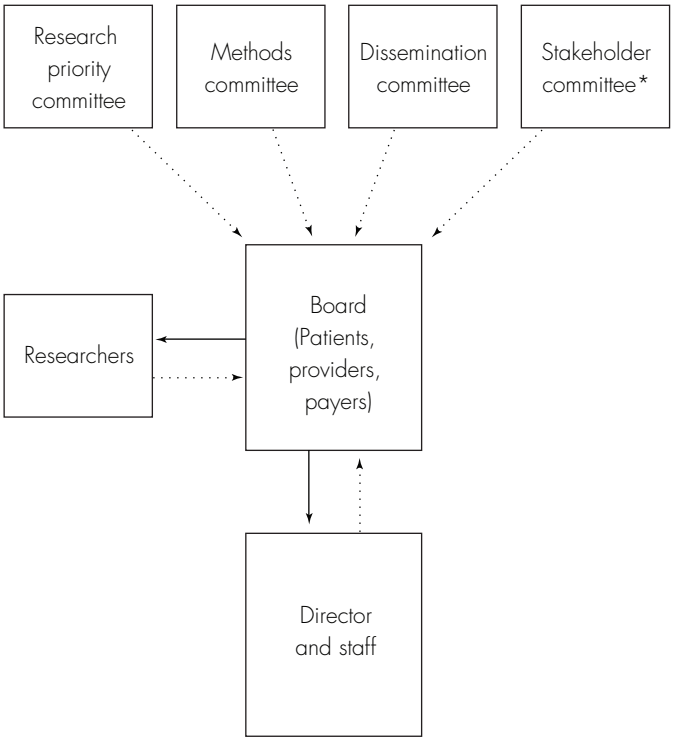
For independent agencies within the legislative branch, the Comptroller General of the United States at the GAO (a congressional agency) appoints members to one board (MedPAC), whereas Democratic and Republican leaders in the Senate and the House of Representatives appoint members to another board (the Stennis Center).

The process of selecting members to an entity's board also contributes to the general perception of the entity's objectivity. Having a neutral individual, such as the Comptroller General, select the board's chair and members could help ensure the board's objectivity and stability. It may be preferable to the presidential appointee process, which can bog down into lengthy delays when the President and the Senate, in its confirmation responsibilities, do not reach agreement. Vacancies on the board could have a negative effect on the entity's stability.

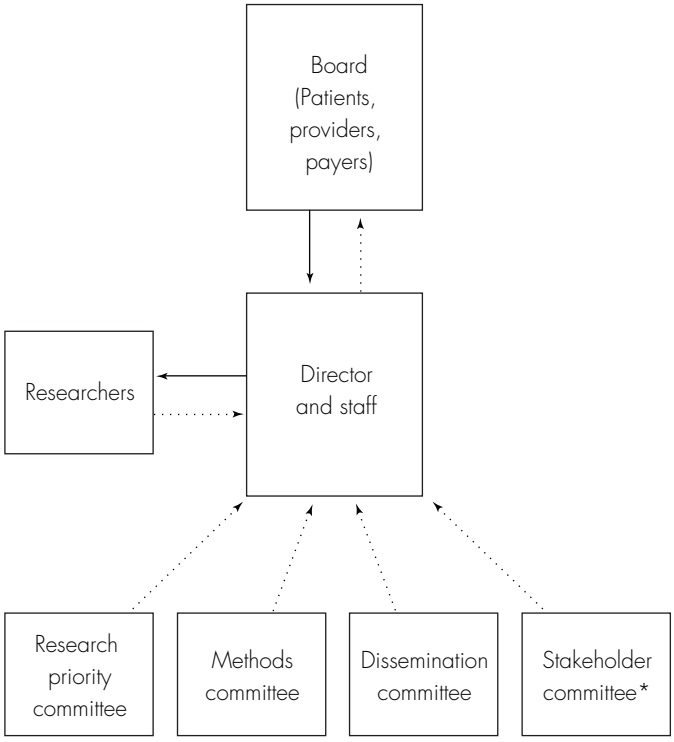
FIGURE 5–1

Two examples, using multiple consultative committees, for structuring a comparative-effectiveness entity

5-1A Committees provide input to the board



5-1B Committees provide input to director and staff



Note: The dashed line denotes input, while the solid line denotes direction.
*Composed of stakeholders such as manufacturers of health products and advocacy groups.

Longer term appointments would help ensure the independence of board members and the stability of the board. For example, members of the Federal Reserve's Board of Governors serve 14-year appointments. Staggering the terms of the board members (so that all the members' terms are not up at once) is a way to ensure the stability of the board.

Multiple advisory committees could allow for broad input from interested individuals

In addition to the board of experts, a regular process could be established to gain input from interested individuals. Multiple advisory committees could allow for broad input from individuals with specific technical expertise and individuals with interests in the entity's research agenda. These committees could provide input either to the board or to the staff and director.

As shown in Figure 5-1A, a full-time board could be advised by committees that individually have a single focus: for example, one focused on the research agenda, another on study methods, and another on communication strategies. The committee on study methods could advise the board about developing methodological guidelines for its studies and updating the guidelines to incorporate new and innovative study approaches. A board member with the pertinent expertise could act as chair and select the individual committee members. Alternatively, under a part-time board, multiple advisory committees could provide direct input to the director and staff (Figure 5-1B).

Neither the board of experts nor the staff would be bound by the information the advisory committees furnish. Advisory committee meetings held regularly throughout the year and open to the public would enhance the entity's

TABLE 5–3 **Options for structuring a comparative-effectiveness entity**

Type	Description	Examples
FFRDC: Nonprofit private organizations sponsored by an executive branch agency and administered by a private sector entity. Usually funded through contracts from the sponsoring executive branch agency.	According to current regulations, FFRDCs must meet a special long-term research need, which cannot be met as effectively by existing government or contractor resources (Code of Federal Regulations 2007).	National Cancer Institute at Frederick Center for Naval Analyses Lincoln Laboratory National Defense Research Institute Lawrence Livermore National Laboratory
Independent executive branch agency: Federal agencies in the executive branch, which are not under any cabinet department	Some agencies serve regulatory purposes while others are advisory.	Federal Reserve Federal Communications Commission International Trade Commission Securities and Exchange Commission
Independent legislative branch agency: Federal agencies in the legislative branch	Agencies generally advise the Congress.	Congressional Budget Office Congressional Research Service Government Accountability Office MedPAC Stennis Center for Public Service
Congressionally chartered nonprofit corporations: An entity chartered by the Congress in the private sector	Private entities that can accept and expend government and private funds on services that may be underprovided by the private market.	Legal Services Corporation U.S. Institute of Peace National Park Foundation American Institute in Taiwan

Note: FFRDC (federally funded research and development center).

transparency and ability to respond to constituents and stakeholders.

The use of advisory committees by federal entities is not uncommon. For example, several standing committees advise CMS—including MedCAC, the Practicing Physicians Advisory Council, and the Advisory Panel on Medicare Education—in areas such as physician services, coverage, beneficiary education, and management. Members include beneficiaries, physicians, pharmacists, providers of service, consumer and industry representatives, and other experts in the health care delivery field.

In addition, in the United Kingdom, NICE also employs multiple advisory committees. Multiple committees called "panels" select topics for study, review studies, and make recommendations.

Options for structuring a comparative-effectiveness entity

In this section, we compare governance approaches encompassing the full spectrum of public and private sector involvement: a federally funded research and development center (FFRDC), an independent federal agency within the executive branch, an independent federal agency within the legislative branch, and a

congressionally chartered nonprofit organization (Table 5-3).

We did not evaluate two other public–private options—government corporations and government-sponsored enterprises—because they are less relevant to the research objectives of a comparative-effectiveness entity. Government corporations, which are owned by the public sector, are generally created to serve a public function of a predominantly business nature with revenue potential, such as the Pension Benefit Guaranty Corporation (GAO 1996a).[11] Government-sponsored entities, such as the Federal Agricultural Mortgage Corporation (FarmerMac), are privately owned federally chartered financial institutions that have the implicit financial backing of the federal government (GAO 1996a, Kosar 2007).[12]

Creating an FFRDC sponsored by an existing Department of Health and Human Services agency

An FFRDC is a nonprofit private sector organization that is sponsored by a federal government agency and administered by an academic or a private sector entity. FFRDCs were established during World War II to meet specialized or unique research and development needs that could not be readily satisfied by government personnel or commercial contractors. Because there is a history of using such organizations for research purposes, it is a natural option to consider as the governance structure for an entity that sponsors comparative-effectiveness research.

Currently, 38 FFRDCs exist (NSF 2008). Most FFRDCs fall into the following categories: policy-focused study and analysis centers (e.g., the National Defense Research Institute operated by RAND Corporation for the Office of the Secretary of Defense), research and development laboratories (e.g., Lawrence Livermore National Laboratory operated by the University of California for the Department of Energy), and systems engineering and integration centers (e.g., the Aerospace Federally Funded Research and Development Center operated by the Aerospace Corporation for the Department of the Air Force) (IOM 2007). About two-thirds of all FFRDCs are associated with the Department of Defense or the Department of Energy. Many of the private organizations administering the 38 FFRDCs have established non-FFRDC divisions that perform research.

The sponsoring federal agency is responsible for the FFRDC's general oversight.[13] FFRDCs typically receive most of their funding from the sponsoring federal agency through a multiyear contract. FFRDCs are prohibited from competing for other government contracts. However, up to 30 percent of their funding may come from the private sector.

One advantage of FFRDCs is that they might provide a buffer against efforts by outside interests to reduce the sponsoring agency's funding because of disputed research findings (AcademyHealth 2005). An FFRDC sponsored by either AHRQ or NIH would provide a direct link to a federal agency that already carries out comparative-effectiveness research.

Flexibility would be another advantage of FFRDCs, which have no standard or required structure. FFRDCs can change staff on a project basis, hire staff for short durations, attract key researchers who would not wish to be employed by the federal government, and offer salaries that would be competitive with other private research organizations. This flexibility with staff could enhance the proposed entity's expertise, credibility, and visibility.

Some observers have suggested that FFRDCs might be too closely aligned to an executive branch department. Because the sponsoring federal agency is responsible for defining the FFRDC's scope of activities, some observers are concerned that FFRDCs may be susceptible to political influence. Wilensky (2006) questioned whether there is sufficient distance between the FFRDC and its sponsoring agency to ensure the FFRDC's objectivity.

Another issue concerns the stability of FFRDCs. The sponsoring federal agency decides whether to recompete the management and operating contract of its FFRDC.[14] On the one hand, periodically recompeting the contract of an FFRDC established to perform comparative-effectiveness analysis might be disruptive to the research process. On the other hand, recompeting the FFRDC's contract periodically might be healthy, encouraging a rotation of researchers into the environment. Periodic contract competition could enhance transparency and buy-in for the work and keep the organization from being locked into one methodology or from resisting reviewing past work.

Historically, most of the questions about FFRDCs' funding have focused on the sponsoring agency awarding contracts without competitive bidding (GAO 2003, Kosar 2007). The sponsoring federal agency may award the FFRDCs' new contracts or extend existing ones with FFRDCs noncompetitively in order to maintain an essential research and development capability (GAO 2002).

Some observers are concerned that an FFRDC's objectivity might be affected if it also conducts research for private sector (commercial) entities. Some observers are also concerned that the private sector entity that administers the FFRDC might benefit from its relationship with the FFRDC while conducting government and commercial research projects. A related concern is the extent to which an FFRDC can insulate its efforts from the private sector entity that administers it (Kosar 2007). Some of these issues might be dealt with by the statute that defines the FFRDC. For example, the statute could require that an organization operate only as an FFRDC comparative-effectiveness organization and not accept any private sector work.

Creating an independent agency within the executive branch

Independent executive branch agencies operate under general management laws of the federal government but typically do not report to a federal department or other federal agency. Many independent agencies exist, such as the Federal Reserve and the Securities and Exchange Commission.

These agencies are not subject to day-to-day executive branch supervision. A board or commission oversees the activities of some independent agencies. Many rely on a staff and a director to help manage the agency.

The responsibilities (regarding budget, personnel, and organizational decisions) of the chair, other board members, and the director vary across the independent agencies. GAO (1992) found that the strength of each chairman's administrative authority varied across 16 independent executive branch agencies.[15] Although statutes generally establish the overall roles and responsibilities of the chair and commission members, they allow for substantial interpretations and discretion (GAO 1992).

Because of their structural independence, these agencies are generally viewed as less vulnerable to political influences. Their independence is not absolute, however, as the members of the board are typically political appointees and most of these agencies are funded through congressional appropriations.

The Federal Reserve is identified as the most successful model of an independent executive branch agency. The Congress created the Federal Reserve as an independent agency to enable the central bank to carry out its responsibilities without excessive outside influence (Smale 2005). Although the Federal Reserve is required to report to the Congress on its activities, neither the president nor the Congress approves its decisions. The Federal Reserve consists of the Board of Governors and 12 private entities, federally chartered corporations known as Federal Reserve Banks (GAO 1996b). The seven-member Board of Governors represents the public sector and is appointed by the President and confirmed by the Senate for staggered 14-year terms. The Chairman and the Vice Chairman of the Federal Reserve Board are named by the President from among the members and are confirmed by the Senate. The Reserve Banks and the local citizens on their boards of directors represent the private sector. The Federal Reserve has been headed by a highly visible and well-respected professional, which helps minimize outside influence.

Most important to its independence is that the Federal Reserve does not receive any federal funding, so it is not subject to threats to cut off financial support. The Federal Reserve funds its activities with the interest earned from loans to banks and investments in government securities and from the revenue received from providing services to financial institutions (Federal Reserve Bank of Dallas 2008). This aspect makes the Federal Reserve more independent than most other independent federal agencies.

One drawback to the Federal Reserve as a model for a comparative-effectiveness entity is its lack of transparency. It has been criticized as being too secretive (Poole 2002). With respect to a comparative-effectiveness entity, the Congress would likely seek to achieve a better balance than exists with the Federal Reserve between ensuring independence for its operations and making the agency accountable for its actions (Smale 2005).[16]

In contrast, the Federal Communications Commission is an example of an independent executive branch agency that has not achieved as much autonomy as some had hoped. Hundt (2000) wrote that as Commissioner of the Federal Communications Commission, he coordinated the Commission's efforts with executive branch officials.

Creating an independent agency within the legislative branch

Like their counterparts in the executive branch, independent agencies within the legislative branch operate under general management laws of the federal government but typically are not subject to day-to-day oversight of their activities from policymakers or other agencies. There are 11 agencies that support the Congress including CBO,

the Congressional Research Service, GAO, MedPAC, and the Stennis Center for Public Service.

There are concerns that an agency within the legislative branch may be too close to policymakers and that it would not be sufficiently independent of political influences. On the other hand, some observers consider the work of some legislative branch agencies as being nonpartisan and objective. GAO notes that its mission is to provide objective, fact-based, nonpartisan, and nonideological analysis to policymakers. CBO's mandate is to provide objective, nonpartisan, and timely analyses to policymakers to aid in economic and budgetary decisions on the wide array of programs covered by the federal budget.

The structures of congressional agencies vary. Some agencies have a board or commission that oversees their activities. For example, the Commission and the Stennis Center for Public Service have an external board of experts overseeing a director and staff. Other congressional agencies, such as CBO and GAO, do not have a board overseeing their activities. Instead, they are headed by a single individual; CBO is headed by a director whereas GAO is headed by the Comptroller General of the United States. The Speaker of the House of Representatives and the President Pro Tempore of the Senate jointly appoint the CBO Director for a four-year term (with no limit on the number of terms). The President, with a slate of candidates the Congress proposes, appoints the Comptroller General to a 15-year term. Although CBO does not have a board overseeing its activities, it has established two advisory panels—the Panel of Economic Advisers and the Panel of Health Advisers—to review economic assumptions, methodologies, and projections and to advise on health research and cost estimates.

Creating congressionally chartered nonprofit corporations

Congressionally chartered nonprofit corporations include entities chartered by the Congress in the private sector. The legal and the organizational structures of these entities vary because the Congress stipulates the charter for each of them. For example, some government corporations:

- Rely on federal appropriations but are not associated with any federal agency. The Legal Services Corporation, established by a federal charter in 1974, relies on annual federal appropriations to sustain its mission of supporting legal assistance to low-income individuals involved in civil matters.
- Are associated with a federal agency and help carry out federal regulations but receive no federal funding. The two federally chartered nonprofit corporations associated with the Securities and Exchange Commission—the Securities Investor Protection Corporation and the Public Company Accounting Oversight Board—rely on funding from the private sector.[17]
- Are linked to a federal agency and perform functions the agency finds difficult to carry out but receive no federal funding. For example, the National Park Foundation administers gifts given to the National Park Service. It relies on private funding.

Like independent agencies we already discussed, some congressionally chartered nonprofit organizations are headed by some type of advisory board.

Some experts have looked at housing a comparative-effectiveness entity within the Institute of Medicine (IOM), which is a part of the National Academy of Sciences, a congressionally chartered nonprofit private corporation. The federal government created the National Academy of Sciences to be an adviser on scientific and technological matters. Neither the National Academy of Sciences nor its associated organizations—IOM and the National Academy of Engineering—receives direct federal appropriations for their work. Federally sponsored studies undertaken by the Academy are generally funded with appropriations made available to federal agencies. The National Academy of Sciences also receives funding from private sources. In 2006, about one-quarter of its total revenues ($228.5 million) were from nonfederal sources (National Academies 2006).

Wilensky (2006) explained that housing a comparative-effectiveness entity within IOM would provide for a trusted and independent intermediary to supervise the use of federal funds while making use of existing capacity in government for research contract management. IOM has generally been highly regarded by both industry and government. On the other hand, some of its meetings are closed to the public (e.g., when the study committee is discussing findings and recommendations of a report). In addition, Wilensky (2006) noted that there is some question about whether IOM can act in a timely way.

Accountability of congressionally chartered entities may be an issue because no single federal department within the executive or legislative branch is charged with overseeing their activities (Kosar 2007). There is

little regular oversight or supervision of government corporations by federal agencies. Kosar (2006) noted that individual corporations come under scrutiny from time to time by the Office of Management and Budget or by the Congress and that governmental oversight typically occurs once concerns are raised about the corporation's management, operations, efficiency, and fiscal practices.

Funding a comparative-effectiveness entity

In establishing a comparative-effectiveness entity, policymakers would need to develop sound budget estimates and design a financing scheme that would foster independence, transparency, and accountability. One way to think about funding is to use a bottom-up approach that assesses current comparative-effectiveness spending levels and estimates required expenditures based on the scope and research capabilities of the envisioned comparative-effectiveness entity. In this section, we present the budget experience for existing comparative-effectiveness organizations in the United States and the United Kingdom, which provides empirical information about the sizes of budgets for research programs that differ in scope. Alternatively, a top-down approach can be used to estimate an entity's funding. Some prominent health care economists have proposed such an approach by specifying a dollar amount or a percentage of current national health expenditures that could be used to fund comparative-effectiveness research. The functions the entity would carry out should inform its funding.

To finance a comparative-effectiveness entity, the Commission supports mandatory funding from a combination of public and private sources to create a comparative-effectiveness trust fund. Engaging both public and private funding sources would distribute the burden equitably, as the research findings would benefit all users—patients, providers, private health plans, and federal health programs. Dedicated funding would also reduce the likelihood of outside influence and would best ensure the entity's stability.

A bottom-up approach to estimate funding

In determining the funding levels necessary to establish a comparative-effectiveness entity, a look at the budgets of groups that currently conduct and sponsor comparative-effectiveness research is instructive. The Drug Effectiveness Review Project (DERP), the most narrowly focused of the existing comparative-effectiveness organizations we examined, is a collaboration of universities, organizations, and state governments to assess the effectiveness and safety of drugs within the same class. Since 2002, DERP has exclusively conducted retrospective research, with an average annual budget of $1.4 million (Gibson 2007). DERP makes its analyses publicly available on its website, but Consumer Reports Best Buy Drugs, a division of Consumers Union, translates DERP's research into reports designed to provide consumers and physicians with information to help guide prescription drug choices based on effectiveness, a drug's track record, safety, and price (Consumer Reports 2007). Consumer Reports Best Buy Drugs has operated since 2004 with a budget largely composed of a $3 million grant from the Engelberg Foundation and a $415,000 grant from NIH's National Library of Medicine.

AHRQ is the primary federal agency tasked with improving the quality, safety, efficiency, and effectiveness of health care. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that the agency conduct research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals. To fulfill this mandate, the agency began the Effective Health Care Program in 2005. In 2008, AHRQ's annual appropriation for the Effective Health Care Program doubled to $30 million (AHRQ 2008a). Research conducted under this effort includes: (1) sponsoring systematic literature reviews of the comparative effectiveness of health care services; (2) undertaking studies on comparative effectiveness using existing databases; and (3) translating comparative-effectiveness information for policymakers, providers, and consumers. To date, the program's Evidence-based Practice Centers have issued 14 comparative-effectiveness reviews. An additional eight reviews are in progress (AHRQ 2008b).

The Department of Veterans Affairs conducts comparative-effectiveness research as part of its Research and Development Program. One of the program's areas of focus is health services research. There are 15 Centers of Excellence, many of which focus on evidence-based medicine and comparative-effectiveness research. The fiscal year 2007 budget for the health services research area was $61 million, not all of which was used for comparative-effectiveness research (American Association for the Advancement of Science 2006).

NIH is the largest federal sponsor of prospective comparative-effectiveness research through head-to-head

TABLE 5–4 **National Institutes of Health comparative-effectiveness studies**

Study	Years	Funding (in millions)	Goal
Clinical Antipsychotic Trials of Intervention Effectiveness	N/A	$43	Compare the effectiveness, side effects, and cost effectiveness of older and newer antipsychotic medication to treat schizophrenia in real-world settings.
Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial	1993–2004	83	Tested whether the occurrence of heart attacks and strokes was lower for high-risk hypertensive patients treated with newer classes of drugs compared with long-established, inexpensive diuretics.
Sudden Cardiac Death in Heart Failure Trial	1997–2003	12	Tested whether an implantable cardiac defibrillator or an antiarrhythmic drug would better prevent sudden death in heart failure patients.
National Emphysema Treatment Trial	1997–2004	35	Tested the role, safety, and effectiveness of bilateral lung volume reduction surgery (LVRS) compared with standard medical care in the treatment of emphysema. A secondary objective was to develop criteria for identifying patients likely to benefit from LVRS.
Diabetes Prevention Program Clinical Trial	1994–2002	176	Tested effectiveness of two approaches to slowing development of type 2 diabetes in high-risk patients with impaired glucose tolerance.
Diabetes Control and Complication Trial	1982–1995	169	Tested whether sustained tight control of blood glucose could prevent or delay onset or progression of symptoms in type 1 diabetes.
Epidemiology of Diabetes Intervention and Complications	1966–ongoing	58	Tested whether sustained tight control of blood glucose could prevent or delay onset or progression of symptoms in type 1 diabetes.
Perinatal HIV Prevention Trial II	2000–2003	4	Compared effectiveness of adding the drug nevirapine to standard zidovudine therapy to lower risk of mother-to-child HIV transmission.
Medical Therapy for Prostatic Symptoms	1992–2002	57	Tested whether the combination of two drugs, doxazosin and finasteride, was more effective than either drug alone, in preventing progression of benign prostatic hyperplasia.
Total		**637**	

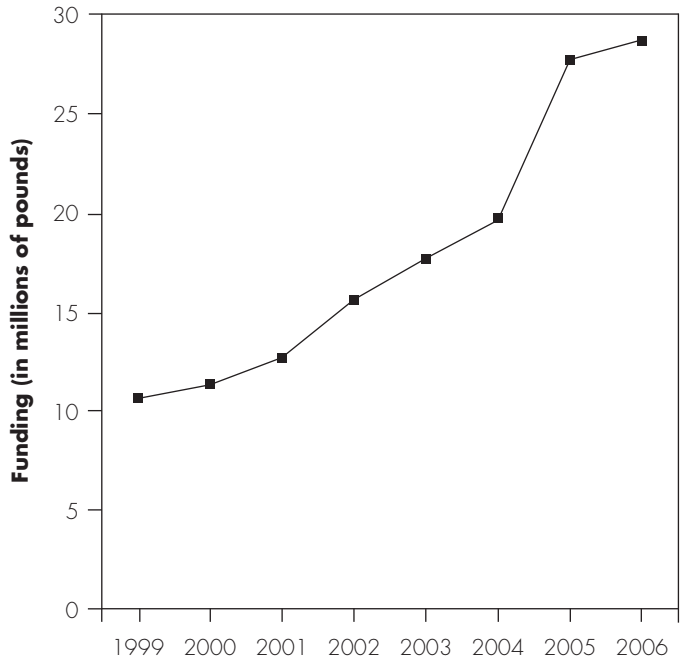
Note: N/A (not available).

Source: National Institutes of Health, Department of Health and Human Services. 2007. *Fact sheet: Research into what works best.* Bethesda, MD: NIH.

clinical trials. To date, NIH has conducted at least nine head-to-head clinical trials and spent more than $575 million since 1982 (Table 5-4). This amount accounts for a tiny fraction that NIH has received in government funding since that time. For example, in just one year (fiscal year 2007), NIH's federal budget allocation totaled $28.8 billion (Executive Office of the President of the United States 2008).

NICE issues guidance on the use of new and existing medicines, procedures, and treatments for specific diseases. As part of the United Kingdom's national health service, NICE was established in 1999 and funded at

FIGURE 5–2 NICE's annual budget



Note: NICE (National Institute for Health and Clinical Excellence).

Source: United Kingdom NICE annual reports, 2000–2007.

roughly £11 million. The budget has since grown to almost £29 million, or roughly $60 million in 2006 (Figure 5-2). NICE does not fund clinical trials or engage in primary data collection but instead issues recommendations based on analysis of existing research.

A top-down approach to estimate funding

Some prominent health care economists and researchers have proposed that spending targets—in nominal dollars and as a percentage of current national health expenditures—provide another means for setting a sound budget for comparative-effectiveness research. Reinhardt has suggested levying a 0.5 percent—or roughly $1 billion—surcharge on the nation's annual prescription drug expenditures to establish several independent pharmacoeconomic research institutes (KFF 2007, Reinhardt 2004).[18] Altman and colleagues suggested setting aside 5 percent to 10 percent—or roughly $1.4 billion to $2.8 billion—of the federal government's basic research funding levels for comparative-effectiveness research that would complement existing efforts (Altman et al. 2003, Executive Office of the President of the United States 2009).[19] Kupersmith and colleagues estimated that conducting 30 necessary new effectiveness studies would require an annual expenditure of $1 billion, or a doubling of the current investment (Kupersmith et al. 2005). The Commonwealth Fund (2007) has proposed a public–private partnership that would be funded with 0.05 percent of projected federal Medicare and Medicaid spending from general revenues and 0.05 percent of private insurance premiums, or $0.8 billion in 2008, $4.4 billion over 5 years, and $10.5 billion over 10 years. Wilensky has proposed a multibillion dollar comparative-effectiveness center, acknowledging that this funding level would not cover all the desired research but would require the entity to prioritize the topics for research (Wilensky 2006). Additionally, some private payers have estimated appropriate expenditures for a comparative-effectiveness entity. The Blue Cross Blue Shield Association recommends an annual budget not to exceed $375 million (BCBSA 2008).[20]

Mandatory public–private financing would provide a stable funding source

The Commission believes that mandatory financing from a combination of public and private sources would ensure maximum stability for a comparative-effectiveness entity. We examined two options for mandatory public–private financing to establish a comparative-effectiveness trust fund.

One option would be to designate a small percentage of the Medicare Part A trust fund and impose a levy on private sector organizations, such as private health plans and self-insured employers. This financing option has the benefit of mandating contributions from all payers—public and private. The impact of this new levy would likely fall on consumers. Additionally, with the fiscal pressures facing Medicare, increasing the burden on the Medicare Part A trust fund may not be the best long-term solution.

Alternatively, funding for a trust fund could come directly from general revenues. As a broadly based revenue source, a mandatory appropriation of general revenue funding would be one way for all payers—public and private—to contribute to a comparative-effectiveness entity. To ensure stability, policymakers could establish a funding reauthorization period similar to the State Children's Health Insurance Program's 10-year funding allocation. Alternatively, policymakers could establish a multiyear mandatory appropriation similar to the Health Care Fraud and Abuse Program (established by the Health Insurance

Portability and Accountability Act of 1996). Specifically, the statute appropriated money from the Medicare Part A Trust Fund to establish mandatory funding for health care fraud and abuse activities for fiscal year 1997 and automatically increased funding between 1998 and 2003. After 2003, the statute capped funding at the 2003 level but subsequent legislation has raised funding for some activities. Regardless of funding structure, periodic evaluation would be needed to ensure that efforts of the comparative-effectiveness entity are meeting the needs of its constituency.

A dedicated public–private funding mechanism would reduce the likelihood of undue influence, particularly for a start-up organization that has not established its own credibility or constituency. The text box (pp. 130–131) summarizes the experience of the Office of Technology Assessment and the National Center for Health Care Technology. Both of these entities, which received funding from annual appropriations, were ultimately defunded.

The Commission supports mandatory multiyear funding because it would be more stable than annual appropriations, which would require policymakers to consider annually the priority of such research compared with other programs. Such decisions could be subject to factors other than the priority of the research. For example, in 1995, funding of AHRQ (then known as the Agency for Healthcare Policy and Research) was severely threatened partly because of findings from a study the agency sponsored on back surgery. According to Gray and colleagues (2003), medical advocacy organizations disagreed with the findings of the research effort, asserting that the research was unsound and wasted taxpayer dollars, but AHRQ survived this threat to its appropriations because of efforts of many individuals and organizations on the agency's behalf.

Voluntary contributions from private groups—such as private plans, private payers, and manufacturers of drugs, biologics, and medical devices—could also be vulnerable to budget uncertainties. Private sponsors might decide to withhold or withdraw funding for subjective reasons, such as disagreeing with the entity's selection of a service for consideration. The influence of private groups that directly fund the research on a study's design and findings could be a concern. In addition, voluntary private contributions might be small because comparative-effectiveness research is a public good, and the benefits of such information accrue to all users, not just to those who pay for it.

Comparative-effectiveness information could help CMS make better policies

The Medicare program faces enormous challenges with financial sustainability. Policymakers will need to use a combination of approaches to address Medicare's long-term financing, including basing payment decisions on comparative-effectiveness information. Some researchers contend that CMS needs to base its payment decisions on more complete clinical evidence when dealing with costly new services (Redberg 2007). Investment in building a process for collecting information about the comparative effectiveness of health care services could lead to future use of this information in Medicare's payment policies.

In the past, CMS has faced obstacles in trying to use evidence about a service's clinical effectiveness in its payment policies. For example, after CMS set the payment rate for a new anti-anemia drug equal to the rate for an existing drug on the grounds that the products were functionally equivalent, the MMA prohibited the agency from using this standard in future cases involving payments to hospital outpatient departments. In another example, the MMA prohibited CMS from using AHRQ's research on comparative clinical effectiveness to withhold coverage of prescription drugs, although private drug plans administering the Part D benefit are not precluded from using such information in designing their formularies.

CMS has also faced obstacles in trying to consider a service's cost effectiveness or value in its coverage process. In 1989, CMS proposed considering cost effectiveness in its coverage decision-making process as a factor to determine whether a treatment was reasonable and necessary. The proposal generated opposition and was withdrawn. In 2000, the agency issued a notice of intent that outlined the criteria the agency would use when making national coverage decisions. The criteria considered whether the service provided added value to the program. Again because of strong opposition, CMS never issued a proposed regulation.

Under current policy and law, CMS generally covers any treatment that is "reasonable and necessary," regardless of its effectiveness or its cost relative to alternative treatments. CMS rarely uses clinical information to set payments. One exception is the use of a least costly alternative (LCA) for certain types of items, including durable medical equipment and drugs used to treat advanced prostate cancer. Using the LCA policy,

Former federal agencies sponsoring health technology assessments

The Office of Technology Assessment (OTA) was a nonpartisan congressional agency created in 1972 that used in-house researchers and outside experts to conduct independent analyses of complex scientific and technical issues. The agency conducted technology assessments in the areas of energy, transportation, and infrastructure; industry, telecommunications, and commerce; international security and space; education and human resources; environment; and health. In its 24 years, OTA published about 750 technology assessments, background reports, technical memos, case studies, and workshop proceedings.

A 13-member technology assessment board governed OTA's activities. As mandated by statute, the board consisted of six Senators, six Representatives (drawn equally from both parties), and OTA's Director. The board's Chairman and Vice Chairman alternated between the Senate and the House with each congressional session. The board made the final decision as to whether OTA could proceed with an assessment and reviewed all reports before their release. In addition to the board, the statute also established a 12-member technology assessment advisory council composed of 10 public members, the Comptroller General, and the Director of the Congressional Research Service. The council reviewed OTA's activities and made recommendations to the technology assessment board.

OTA's federal funding was not mandatory. Its authorizing legislation (the Technology Assessment Act of 1972) provided funding of $5 million for the first two years of its existence. Thereafter, the agency's funding underwent the annual authorization and appropriation process. OTA was disbanded in 1995 as part of budget reductions by the Congress (CRS 2007). Its appropriation was roughly $20 million in the year before its closure. Various reasons have

(continued next page)

Medicare's claims administration contractors do not pay for the added cost of a more expensive service if a clinically comparable service exists. In its January 2007 report to the Congress on payment for Part B drugs, the Commission supported using LCA policies but discussed the need for LCA to be applied in a clinically appropriate and consistent manner.

Because of the difficulties CMS has faced in using information about services' clinical effectiveness and value, the agency might need additional statutory authority to more effectively use such information to promote more effective care. CBO's recent report noted that to reduce spending substantially under Medicare, CMS would probably need additional authority to consider the relative benefits and costs of services when making coverage and payment decisions (CBO 2007). Under current law, Medicare does not have clear authority to take costs into account.

If changes in the statute were made, Medicare could use information about comparative effectiveness to promote the use of more effective care. Using comparative-effectiveness information in the coverage process may not be the area to begin to use this information. As we mentioned earlier, CMS faced opposition in using information about a service's cost effectiveness or value in the national coverage process. Rather, the agency could begin by using results of comparative-effectiveness studies to inform providers and patients about the value of services and to adopt payment policies that account for a service's value.

CMS could also use comparative-effectiveness information to prioritize Medicare's pay-for-performance measures and disease management initiatives or target screening programs. A pay-for-performance program could link providers' bonuses to the provision of services that are clinically effective and of high value. Because there are usually more potential measures than are practical to use, CMS could consider comparative-effectiveness information when choosing measures for pay-for-performance programs.

Former federal agencies sponsoring health technology assessments (cont.)

been put forth for OTA's demise. Eisenberg and Zarin (2002) contended that the medical profession and drug and device manufacturers advocated for eliminating the agency. Bimber (1996) argued that the agency was terminated because of changing priorities within the Congress. Others have said that the agency was defunded because its work was not timely and duplicated the work of other agencies (CRS 2007).

The National Center for Health Care Technology (NCHCT) was established in 1978 in the executive branch to serve as a focus for examining selected new and existing technologies, with the aim of assembling the best current evidence about their clinical effectiveness and cost and information on the social and ethical issues associated with their use. NCHCT's role included: providing information to state and local governments' health facilities planning agencies, advising the Health Care Financing Administration (now CMS) on which new technologies it should cover, prioritizing research on health technology assessment, and developing methodologies for health technology assessment. A National Council on Health Care Technology, composed of 18 members including scientific experts, technology industry representatives, clinicians, lawyers, ethicists, and members of the general public, was created to advise NCHCT. The agency's annual budget was about $4 million per year (Eisenberg and Zarin 2002).

NCHCT ceased operating after three years (in 1981). According to Perry and Thamer (1999), the medical device industry and several medical advocacy groups opposed NCHCT. Perry (1982) noted that the medical device industry objected to NCHCT's efforts to compile a list of emerging technologies, arguing that early assessments might stifle innovation and that assessments could be undertaken by existing federal entities. Eisenberg and Zarin (2002) also concluded that NCHCT survived for only three years because of lobbying by medical advocacy groups and the drug and medical device industries. ■

Researchers have suggested several ways for CMS to use comparative-effectiveness information in the payment process. This information could help CMS:

- create a tiered payment structure that pays providers more for those services that show more value to the program (or less for services that show less value),
- create a tiered cost-sharing structure that requires lower cost sharing for services that show more value to the program (or higher cost sharing for services that show less value), and
- avoid the additional cost of a more expensive service if evidence shows that it is clinically comparable to its alternatives (i.e., limit payment to the cost of the less expensive but comparably effective service).

Another option for using clinical effectiveness in Medicare's payment process is to require manufacturers to enter into a risk-sharing agreement, which links actual beneficiary outcomes to the payment of an item or service based on its comparative effectiveness. Manufacturers could rebate the Medicare program for items or services that did not meet expectations for effectiveness. In the United Kingdom, manufacturers are entering into such agreements with the National Health Service. For example, Johnson & Johnson proposed that the National Health Service pay for a cancer drug only for people who benefited from it (Pollack 2007).

In the United States, some private payers are beginning to enter into risk-sharing agreements with manufacturers of drugs, devices, and tests. For example, UnitedHealthcare is conducting a risk-sharing experiment for a genetic test that predicts the likelihood of breast cancer recurrence in women with newly diagnosed, early stage invasive breast cancer. Under the agreement, the manufacturer is held accountable for the cost of the test if it does not have the intended impact on actual medical practice (i.e., the provision of chemotherapy) (Culliton 2007). Another payer, Cigna, is trying to persuade the makers of cholesterol-lowering drugs to pay the medical expenses of patients who have heart attacks even though they have been taking their medication (Pollack 2007).

To improve its ability to make evidence-based coverage decisions, CMS in 2006 initiated an effort to gather information about some services' clinical effectiveness. The agency modified its national coverage process to require that providers collect clinical evidence for a service the agency might not have covered in the past because of insufficient data about its clinical value. CMS refers to this approach as coverage with evidence development. Currently, CMS requires the collection of additional clinical evidence (via medical registries or clinical trials) for five services.[21]

Additional clinical information is collected for few services. Most services do not go through Medicare's national coverage process. Rather, they are paid through the various fee schedules and prospective payment systems, which generally do not require the submission of clinical evidence, with few exceptions. CMS requires that dialysis providers report clinical information when submitting claims on behalf of dialysis patients.

Expanding the collection of information about a service's clinical effectiveness might in the long run have the potential to promote care that is more efficient and of higher quality. There may be more opportunities for the Medicare program to collect clinical information in the payment process, particularly for services with limited evidence on their effectiveness for Medicare beneficiaries. ■

Endnotes

1 Between 1993 and 1998, the Women's Health Initiative enrolled 161,809 postmenopausal women whose ages ranged from 50 to 79 years in a set of clinical trials on postmenopausal hormone use, low-fat dietary patterns, and calcium and vitamin D supplementation and an observational study at 40 centers in the United States (Writing Group for the Women's Health Initiative 2002).

2 The clinical trial randomly assigned 1,377 patients with atherosclerotic narrowing or obstruction of the internal carotid or middle cerebral arteries either to undergo the procedure or to receive conventional medical treatment (i.e., nonsurgical care). Patients were followed for an average of 56 months.

3 In the initial evaluations of the COX–2 inhibitors, the use of small, short-term trials, the exclusion of high-risk patients, and methodological issues (the lack of attention to cardiovascular side effects) all minimized the possibility of finding evidence of cardiovascular harm (Psaty and Furberg 2005).

4 Dexfenfluramine is the dex-isomer of fenfluramine.

5 The authors concluded that the appearance of clinically significant valvular heart disease (changes in the heart valves that cause leakiness and backflow of blood) in a population less than 50 years old is rare and that the association between the disease and the combination therapy is not likely to be due to chance.

6 The FDA did not request the withdrawal of phentermine, a stimulant that was thought to offset fenfluramine's side effects, drowsiness, and changes in mood.

7 For certain conditions, such as cancer and AIDS, clinical trials often compare the most accepted treatment with a new treatment. For devices, the FDA requires safety and effectiveness information only for high-risk devices, such as stents, that pose a significant risk of illness or injury to patients. (The FDA approves most devices for marketing in the United States based on their similarity to previously approved devices.)

8 CBO estimated the impact of Section 904 of the Children's Health and Medicare Protection Act of 2007 that would have established within AHRQ a center for comparative-effectiveness research.

9 The statute creating the Securities and Exchange Commission specifies that "no commissioner shall engage in any other business, vocation or employment than that of serving as commissioner" (Securities Exchange Act of 1934). The Federal Reserve Act states that "members of the Board shall be ineligible during the time they are in office and for two years thereafter to hold any office, position, or employment in any member bank" (Federal Reserve Act 1913). The five commissioners of the Federal Trade Commission are also not permitted to engage in any other business, vocation, or employment (15USC 41).

10 Specifically, the law requires the Secretary to determine the aggregate percentage of waivers provided in fiscal year 2007 and to decrease the number of waivers by 5 percent in each fiscal year between 2008 and 2012. In addition, the Secretary must disclose all waivers on FDA's website.

11 For example, the Pension Benefit Guaranty Corporation is a federal corporation created by the Employee Retirement Income Security Act of 1974. It protects the pensions of nearly 44 million American workers and retirees in private single-employer and multiemployer defined benefit pension plans. The Pension Benefit Guaranty Corporation receives no funds from general tax revenues. It collects premiums from contributing sponsors of covered pension plans.

12 For example, Farmer Mac provides financing for agricultural real estate and rural housing loans and liquidity to agricultural and rural housing lenders.

13 Federal management of FFRDCs is based primarily on two regulations—the Federal Acquisitions Regulation and the Office of Federal Procurement Policy Letter 84–1.

14 The Federal Acquisition Regulation, which implements federal law, requires that: there must be a written agreement of sponsorship between the government and the FFRDC; the sponsoring agency must justify its use of the FFRDC; before extending the contract, the agency must conduct a comprehensive review of the need for the FFRDC; and when the need for the FFRDC no longer exists, the agency may transfer sponsorship to another government agency or phase out the FFRDC.

15 These agencies are: the Commission on Civil Rights, Commodity Futures Trading Commission, Consumer Product Safety Commission, Equal Employment Opportunity Commission, Federal Communications Commission, Federal Elections Commission, Federal Energy Regulatory Commission, Federal Maritime Commission, Federal Mine Safety Health Review Commission, Federal Trade Commission, Interstate Commerce Commission, International Trade Commission, National Labor Relations Board, Nuclear Regulatory Commission, National Transportation Safety Board, and the Securities and Exchange Commission.

16 The Congress exercises oversight of the Federal Reserve in a variety of ways. GAO has the authority to audit the Board of Governors and the Reserve Banks and branches. According to the Congressional Research Service, such audits are limited, as GAO is prohibited from auditing monetary policy operations, foreign transactions, and the operations of the Federal Open Market Committee (CRS 2007). Congressional oversight on these matters is exercised through the requirement for reports and through semiannual monetary policy hearings.

17 The Securities Investor Protection Corporation ensures that securities held in brokerage firms are protected from losses caused by securities firms' failures. The Public Company Accounting Oversight Board oversees the audit of public companies that are subject to securities laws. The Securities Investor Protection Act of 1970 permits the Securities Investor Protection Corporation to impose assessments on its members—brokers or dealers of securities. The Sarbanes-Oxley Act of 2002 permits the Public Company Accounting Oversight Board to collect support fees from public companies.

18 The Kaiser Family Foundation reports that spending in the United States for prescription drugs was $200.7 billion in 2005.

19 The federal government's basic research budget was $27.7 billion in fiscal year 2007.

20 The budget for the comparative-effectiveness research sponsored by the Blue Cross Blue Shield Technology Evaluation Center is not available on its website.

21 Under its coverage with evidence development policy, CMS requires collection of clinical information for the following services: positron emission tomography (PET) for dementia; PET for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers; implantable cardioverter defibrillators; long-term treatment with oxygen; and PET for other types of cancer.

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CHAPTER 6

Public reporting of physicians' financial relationships

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Chapter summary

Physicians influence both the volume and the type of health care services Medicare beneficiaries receive. They recommend when patients should receive a specific drug or medical device or use a specific facility. Physicians are also involved in developing clinical protocols and researching new drugs and devices. Medicare and its beneficiaries depend on physicians, in carrying out these responsibilities, to act in the best interest of patients. However, physicians may have financial relationships with drug and device manufacturers and facilities that could compromise their independence and objectivity. Payers, plans, patients, and the general public are often not aware of these potential conflicts of interest. For example, physicians who serve on clinical guideline committees or publish research studies may have financial ties to pharmaceutical or device companies that are not fully disclosed.

According to physician surveys, state records, and legal cases, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (Campbell et al. 2007a, Department of Justice 2007, Ross et al. 2007). A physician survey conducted

In this chapter

in 2003 and 2004 found that more than three-quarters of physicians had received meals or drug samples from drug manufacturers in the preceding year and more than a quarter were paid for consulting, giving lectures, or enrolling patients in clinical trials (Campbell et al. 2007a). Manufacturers of medical devices, such as artificial joints and spinal implants, frequently pay physicians consulting fees and royalties to develop new products and subsidize their trips to attend conferences and training programs.

Although physician–industry relationships can lead to advances in medical technology and better patient care, they may also create conflicts between physicians' obligation to do what is best for their patients and the commercial interests of drug and device manufacturers. Physicians play an important role in developing drugs and devices by overseeing clinical trials, inventing products, and providing expert advice to manufacturers. Once a product is introduced, manufacturers' marketing efforts may lead to increased use of beneficial drugs. In addition, their training programs teach physicians how to safely use new devices. However, studies have shown that physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs, decreased prescribing of generic drugs, and physician requests to add drugs to a hospital formulary (Chren and Landefeld 1994, Wazana 2000). Research on human behavior suggests that providing gifts, food, and other favors creates a sense of indebtedness in recipients that may influence their decisions in subtle, unconscious ways (Dana and Lowenstein 2003, Katz et al. 2003).

Medicare should be concerned about the potential for bias because the program spent $48.6 billion on outpatient prescription drugs prescribed by physicians under Part D in 2007 and $10.1 billion on Part B drugs (which are primarily administered in physician offices) in 2005 (Boards of Trustees 2008, MedPAC 2007a). In addition, Medicare spends a significant amount on implantable medical devices.

Over the last decade, the federal government has initiated several criminal and civil cases against companies for allegedly giving physicians

inducements to prescribe their drugs or use their devices. In response to heightened scrutiny, industry associations, physician groups, and the Office of Inspector General developed ethical and legal guidelines for physician–industry relationships. However, some observers question whether the guidelines are sufficiently stringent and point out that compliance is not systematically measured and enforced (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). Several hospital systems and physician organizations have implemented stricter policies to limit conflicts of interest (e.g., Stanford University Medical Center, the Permanente Medical Group). In addition, some states have enacted laws requiring pharmaceutical companies to report their financial relationships with physicians. However, these laws do not apply to device manufacturers and the information collected often is not easily available to the public.

A federal law that would require drug and device companies to publicly report their financial ties to physicians could encourage physicians to reflect on the propriety of those relationships, perhaps discouraging inappropriate arrangements. A public reporting system also would help the media and researchers shed light on physician–industry relationships and explore potential conflicts of interest. Payers (including Medicare) and health plans could use this information to examine physicians' practice patterns. In addition, industry and physician associations could use public reporting to refine their ethical standards.

Many physicians also have financial relationships with hospitals and ambulatory surgical centers (ASCs). The number of physician-owned specialty hospitals more than doubled from 2002 to 2006 (CMS 2006, MedPAC 2005). The number of Medicare-certified ASCs—most of which have at least some physician ownership—grew by 31 percent from 2002 to 2006 (MGMA 2006, MedPAC 2007a). There has also been an increase in joint venture facilities owned by physicians and hospitals. Currently, it is difficult for payers, health plans, the media, and the general public to

obtain information about physicians' financial relationships with hospitals and ASCs. Although Medicare patients were recently granted the right to obtain ownership information from physician-owned hospitals when they are admitted to them, this information is not available to plans, payers, and others (CMS 2007b). Information on other physician–hospital relationships, such as joint ventures and equipment leases, is also not publicly available. CMS has proposed requiring ASCs to disclose physician ownership interests to patients, but payers and researchers would not have access to this information (CMS 2007a). If payers, plans, and reporters had access to basic data about certain financial relationships between physicians and hospitals (as well as physicians and ASCs), they could use the information to examine the influence of these relationships on referral patterns and the overall volume of services.

In this chapter, we explore options for collecting data on physicians' financial relationships with drug and device manufacturers, hospitals, and ASCs. We describe three key design questions for a potential federal law requiring drug and device companies to report their financial ties with physicians: How comprehensive should the reporting system be? What size and types of payments should be reported? How can the data be made readily accessible to the public? Next, we examine possible reporting requirements for hospitals and ASCs. Under the approaches we describe, the responsibility for public reporting would rest with pharmaceutical and device manufacturers, hospitals, and ASCs rather than with physicians. Even if a reporting system were implemented, individual physicians, manufacturers, and facilities would continue to be responsible for ensuring that their financial relationships are ethical and improve patient care. ■

Reporting physicians' financial relationships with drug and device manufacturers

According to physician surveys, state data, and legal cases, financial relationships between physicians and pharmaceutical and device manufacturers are pervasive (Campbell et al. 2007a, Department of Justice 2007, Ross et al. 2007). In 2005, pharmaceutical companies spent nearly $7 billion on physician detailing (visits from sales representatives to physicians) and provided free samples worth $18 billion (Donohue et al. 2007). Manufacturers of medical devices such as artificial knees, cardiac defibrillators, and spinal implants frequently pay physicians consulting fees and royalties to develop new products and subsidize their trips to attend conferences and training programs.

Although such relationships can lead to advances in medical technology and better patient care, they may also create conflicts between physicians' obligation to do what is best for their patients and the commercial interests of drug and device manufacturers. Studies have shown that physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs and decreased prescribing of generic drugs (Wazana 2000). More comprehensive information about physicians' financial relationships with drug and device manufacturers would help us better understand how they affect physician practice patterns.

Medicare should be concerned about the potential for bias because the program spent $48.6 billion on outpatient prescription drugs under Part D in 2007, about 11 percent of total benefits paid (Boards of Trustees 2008). In 2005, Medicare spent $10.1 billion on Part B drugs, which are primarily administered in physician offices (MedPAC 2007a). Medicare also spends a significant amount on implantable medical devices, but it is difficult to estimate the precise value because the cost of a device is usually included in the payment rate for the associated surgery.

In response to heightened legal and public scrutiny of physician–industry relationships, pharmaceutical and medical device associations, physician groups, and the Office of Inspector General (OIG) developed ethical and legal guidelines for these relationships. However, some observers question whether the guidelines are sufficiently stringent and point out that compliance is not systematically measured and enforced (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). Several hospital systems and medical groups have responded to such concerns by implementing strict policies to limit potential conflicts of interest. In addition, some states have enacted laws requiring drug companies to report their financial relationships with physicians. However, these laws do not apply to device manufacturers and the information collected is not easily available to the public.

This section explores the potential benefits and limitations of adopting a federal law requiring drug and device companies to publicly report their financial relationships with physicians. We also explore key design questions for such a system. A public reporting system could encourage physicians to reflect on the propriety of their relationships with the industry, perhaps discouraging inappropriate arrangements. It also would help the media and researchers shed light on physician–industry relationships, explore potential conflicts of interest, and examine whether manufacturers and physicians are complying with voluntary industry and professional guidelines. Payers (including Medicare) and health plans could use this information to examine physicians' practice patterns.

Relationships among drug and device companies, physicians, and other entities

According to a survey of physicians in six specialties conducted in 2003 and 2004, most physicians (94 percent) had some type of recent relationship with the drug industry (Campbell et al. 2007a). Within the previous year, more than three-quarters of the respondents received meals or drug samples from manufacturers; more than one-third were reimbursed by companies for costs related to attending professional meetings or continuing medical education (CME) events; and more than one-quarter were paid for consulting, giving lectures, or enrolling patients in clinical trials. Physicians also reported frequent meetings with industry sales representatives, averaging—for example—16 meetings per month for family practitioners, 9 meetings per month for cardiologists, and 2 meetings per month for anesthesiologists. In general, the industry's marketing efforts appear to focus on physicians who are in a position to influence the prescribing practices of others, such as those who develop clinical practice guidelines and train new physicians (Campbell et al. 2007a).

A recent study estimated that drug manufacturers spent nearly $7 billion in 2005 on physician detailing and more than $400 million for advertising in professional journals (Donohue et al. 2007). The amount spent on detailing

excludes gifts, meals, and events. Manufacturers also provided free drug samples with a retail value of more than $18 billion. Adjusting for inflation, spending in these areas increased by 246 percent between 1996 and 2005.

Researchers have found that physician interactions with pharmaceutical companies start during the formative years of medical school and residency and continue thereafter (Wazana 2000). Most residents report having interactions with pharmaceutical representatives and receiving gifts, samples, and meals from the industry (Wazana 2000). In a survey of residents at an internal medicine program, a significant majority of residents considered it appropriate to accept pharmaceutical industry promotions such as conference lunches, dinner lectures, and social outings (Steinman et al. 2001). Even many residents who considered it inappropriate to receive such promotions reported accepting them anyway. According to the Association of American Medical Colleges (AAMC), "medical schools … have become increasingly dependent on industry support of their core educational missions," in the form of gifts, meals, and travel expenses for students and residents; direct distribution of free drug samples to physicians; and paying faculty to participate in speakers' bureaus (AAMC 2008a). A recent newspaper article describes how some medical students feel pressure from their professors to attend dinners sponsored by drug manufacturers to promote their products (Emery 2007).

We are not aware of published studies that quantify the extent of relationships between medical device manufacturers and physicians. However, reports in the media and legal cases suggest that manufacturers often pay physicians consulting fees and royalties to develop new products, subsidize their trips to attend conferences, pay them to conduct postmarketing research, and sometimes offer them investment interests in their companies (Abelson 2006a, Abelson 2006b, Burton 2005, Zuckerman 2005). For example, according to a recent Department of Justice investigation of four orthopedic device companies, "surgeons who had agreements with the companies were typically paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips.…" (Department of Justice 2007). Investigators estimate that these manufacturers paid physician consultants more than $800 million under 6,500 consulting agreements from 2002 through 2006 (Demske 2008).

In addition to educational and marketing efforts directed at physicians, pharmaceutical and device companies also advertise directly to consumers. The text box discusses the growth and influence of direct-to-consumer advertising.

Both pharmaceutical and medical device manufacturers sponsor CME activities for physicians and other health professionals. Industry support for CME activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) quadrupled between 1998 and 2006, from $302 million to $1.2 billion, growing from one-third to one-half of total CME revenue (ACCME 2006). This funding goes to organizations that sponsor CME events, but physicians benefit through free or subsidized activities. Some observers have expressed concern that the dependence of CME on commercial support may lead to inappropriate industry influence over the topics, speakers, and content at educational events (Brennan et al. 2006, Hampton 2008, Steinbrook 2008).

The drug and device industry also plays a significant role in financing clinical research. A literature review concluded that financial relationships among manufacturers, scientific researchers, and academic institutions are widespread: About one-quarter of biomedical researchers at academic institutions receive funding from the industry, and approximately two-thirds of academic institutions hold equity in start-up ventures that sponsor research conducted by their faculty (Bekelman et al. 2003). Many collaborations between investigators and the industry have benefited patients by translating research discoveries into new drugs and devices, but in some cases these relationships may create conflicts of interest (AAMC 2008b). As a result, two national higher education and research organizations have recommended that universities and medical schools develop policies to address institutional conflicts of interest.[1] However, a recent survey found that only 38 percent of medical schools have adopted policies to deal with the institution's financial interests, although a higher proportion have issued policies to address the financial interests of medical school officials, such as members of institutional review boards (Ehringhaus et al. 2008).

Although physician relationships with drug and device manufacturers can lead to improved patient care, there may also be negative effects. Physicians play an important role in the development of new drugs and devices by overseeing clinical trials, inventing products, and providing expert advice to manufacturers (Abelson 2005, Campbell 2007b). Once a product is introduced, manufacturers' marketing efforts may lead to increased use of beneficial drugs (Powell 2007). In addition, device

Direct-to-consumer advertising

The pharmaceutical industry has rapidly increased its spending on direct-to-consumer (DTC) advertising in recent years, from $985 million in 1996 to $4.2 billion in 2005 (Donohue et al. 2007). This growth was driven in part by a change in Food and Drug Administration (FDA) policy that made it easier to advertise drugs on television (Wilkes et al. 2000). Although drug manufacturers spend more on physician detailing ($6.8 billion in 2005) than on DTC advertising ($4.2 billion), expenditures on consumer advertising are rising much faster (Donohue et al. 2007).

Although spending on DTC advertising by medical device manufacturers appears to have grown in recent years, it remains far less than such spending by drug companies. According to one estimate, device company expenditures on DTC advertising increased from almost nothing in 1996 to about $50 million in 2005 (Cutting Edge Information 2006). Several news articles have observed an increase in consumer advertising for devices such as stents, implantable cardioverter defibrillators (ICDs), artificial joints, and radioactive seeds (Feder 2007, Moylan 2007, Steinberg 2007). In 2007, for example, Medtronic—a manufacturer of ICDs—initiated a multimillion-dollar advertising campaign to raise awareness of sudden cardiac arrest (SCA) and the role of ICDs in preventing death from SCA (Medtronic 2007, Moylan 2007). Medtronic's effort—which involves print, television, and online advertising—encourages people who have had a heart attack or have been diagnosed with heart failure to visit a website where they can assess their risk for SCA (Medtronic 2007). Also in 2007, Cordis Corporation launched what is reportedly the first attempt to directly market a heart stent to consumers (Feder 2007).

Although DTC advertising for drugs can have positive effects by encouraging patients to talk to their physicians about undiagnosed conditions (e.g., high cholesterol, depression), it has also led to higher spending through increased use of the advertised drugs and other drugs used to treat the same condition (Donohue et al. 2007, GAO 2006).[2] DTC advertising appears to increase use by encouraging patients to ask their physicians for the advertised drugs. A recent survey found that DTC ads prompt nearly one-third of consumers to ask their physician about a drug; 44 percent of those who asked about an advertised pharmaceutical received a prescription for the drug, and 54 percent were prescribed a different drug (USA Today/Kaiser Family Foundation/Harvard School of Public Health 2008). There is evidence that DTC advertising may lead to greater use of underutilized drugs as well as higher use of an advertised drug when alternatives may be more appropriate (Donohue et al. 2007, GAO 2006). Because DTC advertising encourages patients to ask their physicians about new drugs, physicians and patients would benefit from having information that compares the effectiveness of new drugs with existing alternatives. The Commission has recommended that the Congress create an independent entity to produce and disseminate information about the comparative effectiveness of health care services (MedPAC 2007b).

DTC advertising has been criticized for stimulating demand for new drugs whose long-term safety has not been demonstrated (Donohue et al. 2007). Because some of the risks of new drugs are not known until they have been on the market for a period of time, the Institute of Medicine has recommended that the FDA restrict DTC advertising for new drugs during the first two years after approval (Committee on the Assessment of the U.S. Drug Safety System 2006). In addition, the American Medical Association has called for a temporary moratorium on advertising for newly approved drugs and devices to give physicians more time to understand their risks and benefits (AMA 2005). Some companies have voluntarily agreed to delay DTC ads for new drugs (Bristol-Myers Squibb 2005). ■

companies often provide important hands-on training to physicians in how to safely use new devices, which may involve paying physicians to conduct training programs and subsidizing their travel costs to attend programs at centralized locations (AdvaMed 2003).

Some of these relationships, however, may influence physicians' behavior in ways that undermine their independence and objectivity. According to several surveys, most physicians do not believe that accepting gifts and payments from drug manufacturers affects

their decision making (Gibbons et al. 1998, McKinney et al. 1990, Steinman et al. 2001). Two literature reviews suggest otherwise: Physician interactions with the pharmaceutical industry are associated with rapid prescribing of newer, more expensive drugs and decreased prescribing of generic drugs (Lexchin 1993, Wazana 2000).[3] Another study found that physicians who interacted with drug companies were much more likely than other physicians to request that drugs manufactured by those companies be added to a hospital formulary (Chren and Landefeld 1994). These interactions included meeting with sales representatives and accepting payments from manufacturers to speak at symposia or conduct research. Most of the drugs physicians wanted to add to the formulary represented little or no therapeutic advantage over drugs already on the formulary (Chren and Landefeld 1994). We are not aware of studies that examine the impact of relationships between physicians and device manufacturers on medical decisions. More comprehensive information about these financial ties would help researchers evaluate whether and to what extent they affect physician behavior.

Social science literature offers insights into how physician interactions with manufacturers may lead to bias. Providing gifts, food, and other favors creates a sense of indebtedness in recipients that tends to influence their behavior (Katz et al. 2003). Under the social rule of reciprocity, a gift recipient is expected to repay the giver, even if the value of the gift is small. According to the conventional understanding of conflicts of interest, people who are biased make a conscious decision to do something unethical to achieve personal gain. However, social science experiments show that, even when people try to be objective, "their judgments are subject to an unconscious and unintentional self-serving bias" (Dana and Lowenstein 2003).[4] This finding can be applied to conflicts of interest in medicine. For example, in a study of physicians who went on trips sponsored by a drug company to learn about two new drugs, most of them said that the subsidized travel would not affect their prescribing behavior (Orlowski and Wateska 1992). After the trips, however, use of the new drugs at their hospital increased much faster than use of the same drugs at comparable hospitals, which suggests that the physicians who went on the trips may have had an unintentional bias.

In addition, the Commission has previously expressed concern that clinical research funded by manufacturers is not always objective and publicly available (MedPAC 2007b). Research has found that industry-sponsored studies are significantly more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies (Als-Nielsen et al. 2003, Jørgensen et al. 2006). Bias in industry-sponsored drug trials is common and such bias often favors the sponsor's product (Bekelman et al. 2003, Heres et al. 2006, Peppercorn et al. 2007). Sources of bias include the dose of the drug studied, the exclusion of patients from the study population, and the statistics and research methods used. Industry sponsorship is associated with publication bias (publishing positive results more frequently than negative results) and withholding data (Bekelman et al. 2003). In a recent article, researchers found that a drug manufacturer withheld data from clinical trials showing that a drug being tested (rofecoxib) was associated with a higher risk of mortality (Psaty and Kronmal 2008). In a safety report to the Food and Drug Administration (FDA) in 2001, the company used a statistical technique that minimized the appearance of mortality risk from the drug. However, the sponsor had conducted a different, more comprehensive analysis, which revealed that rofecoxib was associated with a three-fold increase in mortality. These results were not submitted to FDA until 2003 and were not described in published articles about the drug (most of the articles' authors were employees of the manufacturer).

Moreover, some industry-sponsored research appears to serve promotional, rather than scientific, purposes. For example, the OIG has alleged that a device company paid several physicians $5,000 each to test five patients with a new spinal cord stimulation product (Demske 2008). According to the OIG, this program did not provide clinical value and the manufacturer's research department did not use the data collected through the program. Instead, the effort was allegedly used as a marketing tool to increase sales. Further, some Phase IV (post-FDA approval) studies of pharmaceuticals appear to be aimed at encouraging physicians to prescribe new drugs rather than to collect useful information (Angell 2005). Although many Phase IV studies serve legitimate purposes—to examine whether a new drug is safe and effective for additional uses or to ensure that a new product is safe for its approved uses—in some cases companies pay physicians to start patients on new drugs and answer questions that have very little clinical relevance, such as whether the physician is pleased or not pleased with the drug (Angell 2005).

Efforts to regulate physician–industry relationships

In the last several years, physician associations, drug and device organizations, individual companies, and the OIG have attempted to develop ethical and legal guidelines for interactions between physicians and industry. The primary factors motivating these efforts include:

- increased spending on prescription drugs and medical devices,
- growing awareness of the negative influence that some physician–industry relationships may have on patient care, and
- prosecutions of drug and device manufacturers under federal fraud and abuse laws (Chimonas and Rothman 2005, Department of Justice 2007, Studdert et al. 2004).

Although these guidelines attempt to set boundaries for ethical behavior and proscribe the most extreme practices, critics argue that the guidelines are too vague, are not stringent enough, and lack mechanisms to measure and ensure compliance (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Prescription Project 2007). In response, some health systems, physician organizations, and medical groups have adopted much stricter policies to limit potential conflicts of interest. In addition, some states have enacted laws requiring that drug companies report their financial relationships with physicians, and one state (Minnesota) has limited the size of gifts that can be given to physicians.

Prosecutions of drug and device manufacturers under fraud and abuse laws

In the late 1990s, the federal government began prosecuting some drug manufacturers for providing illegal inducements to physicians to use their products. Several of these cases led to convictions and very large settlements. In the case against TAP Pharmaceuticals, for example, the government alleged that the company induced urologists to prescribe Lupron (an injectable drug) by providing them with free samples and encouraging them to bill Medicare for the samples, employing physicians as consultants without requiring services in return, and awarding them educational grants with no strings attached (Studdert et al. 2004).[5] Prosecutors charged that these arrangements were intended to induce physicians to prescribe Lupron and were therefore illegal kickbacks. This case, which TAP settled for $875 million, led to several similar cases against other drug companies (Studdert et al. 2004).

Federal prosecutors have also charged several device manufacturers with violating fraud and abuse laws by providing inducements to physicians to use their products. In 2006, Medtronic agreed to pay $40 million to settle allegations that it had paid kickbacks to surgeons to use its spinal implants, which may have cost as much as $13,000 per surgery (Abelson 2006a, Abelson 2006b). The Department of Justice alleged that these kickbacks took the form of "sham consulting agreements, sham royalty agreements, and lavish trips to desirable locations" (Department of Justice 2006). According to a whistle-blower lawsuit against Medtronic, one physician received $700,000 in consulting fees in 2005 and another physician received $400,000 annually for eight days of consulting per year (Abelson 2006b). Recently, four large orthopedic device manufacturers paid the government a total of $311 million to settle cases alleging that they had paid surgeons thousands of dollars per year in consulting fees to induce use of their artificial hip and knee implants (Department of Justice 2007).[6] The investigation found that some payments to physicians were not related to physicians' actual work for the companies but instead were kickbacks designed to influence their decisions. According to an OIG official, for example, the companies sponsored consultant meetings at resort locations, covered the physicians' travel expenses, and paid them $5,000 per day, even though they attended meetings only a few hours each day (Demske 2008).

Under the settlement, the companies agreed to adopt corporate compliance procedures, including requiring physicians with whom they have a financial arrangement to disclose the arrangement to their patients and affiliated hospitals. The companies also agreed to post on their websites all payments made to physicians in 2007. However, the websites do not identify whether payments were for consulting, clinical studies, royalties, honoraria, or other purposes. The websites do not permit users to perform searches, and it is very difficult to print information from three of the websites. Despite these limitations, we were able to analyze data from the websites of two companies and found that they made payments to 311 physicians in 2007 (Biomet 2007, Smith & Nephew 2008). Across both companies, half the physicians received annual payments of more than $19,000. At least 53 individual physicians received total payments of $100,000 or more (roughly one-fifth of all physicians who received payments). Nine individual physicians received total payments of at least $1 million in 2007 (3 percent of the 311 physicians who received any payments).

Development of guidelines for physician–industry relationships

In response to heightened scrutiny of physician–industry interactions, manufacturer and physician groups have adopted or revised ethical codes of conduct. These codes are voluntary and compliance is not monitored. A representative of the Advanced Medical Technology Association (AdvaMed) recently stated that the association lacks the resources to enforce its code (Weiland 2008). In addition, antitrust laws may limit the ability of industry associations to enforce compliance with their codes.

The American Medical Association's (AMA's) code, which was developed in 1992 and updated in 1998, allows physicians to accept gifts (e.g., textbooks) as long as the gifts primarily benefit patients and are not of substantial value (AMA 1998). According to the code, physicians should not accept payments or subsidies from the industry to attend educational meetings or conferences, unless they are consultants or faculty. However, manufacturers may provide subsidies to conference sponsors, which can use the money to defray physicians' registration fees.

In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) adopted a new code of ethics that is similar to the AMA code and significantly stronger than the older guidelines it replaced (PhRMA 2002, Studdert et al. 2004). The PhRMA code states that manufacturers' relationships with physicians "are intended to benefit patients and to enhance the practice of medicine" and recognizes that physicians' decisions should be based "solely on each patient's medical needs" (PhRMA 2002). Therefore, "no grants, scholarships, subsidies, support, [or] consulting contracts … should be provided or offered to a health care professional in exchange for prescribing products."

In general, the PhRMA code attempts to limit the most egregious activities that previously led to legal problems and negative publicity. The code describes appropriate and inappropriate conduct in several important areas, such as gifts, support for CME activities, consulting arrangements, and sales presentations. Under the code, companies are permitted to provide gifts to physicians on an occasional basis if they are primarily for patients' benefit (e.g., an anatomical model) and are worth $100 or less. In addition, companies may give physicians items of minimal value that are associated with their practice, such as pens and notepads. Gifts that are not related to patient care, such as artwork or tickets to sporting events, are discouraged.

Manufacturers may provide support to third-party companies that organize CME conferences, but the CME organizers must control the selection of content, faculty, venue, and materials. Manufacturers are allowed to pay physicians reasonable compensation, travel, lodging, and meals for bona fide consulting relationships. A bona fide arrangement must involve a written contract that specifies the services to be provided. When physicians attend a sales presentation, manufacturers may offer occasional, modest meals in an appropriate venue, but not entertainment or recreational events. Spouses and guests should not be invited to these presentations.

AdvaMed, which includes many device manufacturers, adopted a code of ethics in 2003 (AdvaMed 2003). This code is quite similar to PhRMA's code. Companies are permitted to provide physicians modest meals, lodging, and hospitality in connection with legitimate training, education, and sales meetings. Companies may have bona fide consulting arrangements with physicians. Occasional, modest gifts are allowed, but "repeated gifts to the same person, each with a value below the $100 threshold, could violate the spirit of the Code" (AdvaMed 2005).

In 2002, the American College of Physicians (ACP) adopted a new ethical code, which states that: "Recent studies show that accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and … patient care" (Coyle 2002). Before accepting gifts, hospitality, and subsidies from manufacturers, the ACP code encourages physicians to ensure that their objectivity (or perceptions of their objectivity) will not be affected by asking themselves the following questions:

- What would my patients/the public/my colleagues think about this arrangement?
- How would I feel if the relationship were disclosed through the media?
- What is the purpose of the offer?

Although the ACP recognizes that even small gifts can affect clinical judgment, the code permits physicians to accept low-cost gifts of an educational or patient-care nature and modest hospitality connected with education. However, the code states that physicians should not accept commissions for articles that are ghostwritten by the industry and should not participate in postmarketing studies that are "thinly disguised promotional schemes" (Coyle

2002). In addition, they should disclose their industry ties to potential participants in clinical research studies.

The American Academy of Orthopaedic Surgeons (AAOS) recently adopted standards for physician–industry relationships that set limits on gifts, consulting agreements, and subsidies to attend CME and other educational events, and recommend disclosures to patients and institutions (AAOS 2007). For example, the standards require surgeons to disclose to patients any financial arrangement with a manufacturer that relates to their treatment, such as royalties, stock options, or consulting agreements. In addition, surgeons who influence the selection of products for an entity must disclose their relationships with the industry to the entity.

In 2003, the OIG issued guidance to help drug manufacturers identify practices that may lead to abuse and described ways to reduce the risk of violating the anti-kickback statute (OIG 2003). This law prohibits companies from making payments to induce or reward the referral of items or services reimbursed by federal health programs. According to OIG's guidance, when a manufacturer provides something of value to a physician, the company should examine whether it is providing a benefit to the physician with the intent to induce the use of its products. If a company identifies an arrangement that may be problematic, the company should ask several questions, such as:

- Does the arrangement have the potential to interfere with clinical decision making (e.g., is the payment based on referrals)?
- Does it have the potential to increase the risk of overutilization or inappropriate use?
- Does it raise patient safety or quality-of-care concerns?

The OIG encourages manufacturers to try to fit arrangements with physicians within a safe harbor; safe harbors are specific types of payment arrangements that protect entities against prosecution under the anti-kickback law. With regard to the funding of research and education, the guidance recommends that manufacturers separate their grant-making function from their sales and marketing function to reduce the risk that grants would be awarded to increase the use of a product. The guidance also recommends that industry funding of CME programs not involve control over the selection of content or faculty.

The OIG also warns against several practices that are highly suspect under the law, such as paying physicians as consultants for attending meetings and conferences and paying them for time spent listening to sales representatives. Although providing travel, meals, and gifts may potentially violate the anti-kickback statute, the guidance states that "compliance with the PhRMA code will substantially reduce the risk of fraud and abuse" but will not protect a company as a matter of law under the statute (OIG 2003).

The AAMC convened a task force to develop general principles for academic medical institutions to manage industry support of educational activities (AAMC 2008a). In forming the task force, the AAMC was motivated by concern about the increasing dependency of academic institutions on the industry for financing of education and evidence that such support can influence the objectivity of teaching, learning, and practice. The task force recently issued its final report (AAMC 2008a).

Concerns about effectiveness of guidelines

Although the development of ethical and legal guidelines has led to some positive changes in physician–industry relationships, critics point out that the guidelines lack mechanisms to measure and ensure compliance. There also is evidence that interactions prohibited by voluntary codes continue to occur (Blumenthal 2004, Brennan et al. 2006, Chimonas and Rothman 2005, Grande 2007, Prescription Project 2007, Sade 2007).

Drug companies appear to be ramping up their compliance efforts in response to the 2003 OIG guidance. Many manufacturers are developing official compliance policies, elevating the status of compliance officers, and transferring responsibility for CME and grant funding from sales and marketing staff to medical education or general business units (Chimonas and Rothman 2005, U.S. Senate 2007a). Spending for lavish gifts and entertainment has declined in favor of more resources for educational programs (Chimonas and Rothman 2005). Some physicians have lamented the end of the "golden era" when companies gave physicians tickets to sporting events and invited their spouses to industry-sponsored dinners (Chimonas et al. 2007).

Nevertheless, no mechanism exists to systematically monitor compliance with industry or OIG guidelines, as mentioned earlier (Chimonas and Rothman 2005). Companies are not required to report their financial relationships with physicians (with the exception of a

few states that mandate reporting, as described later). In fact, there is evidence that some noncompliant practices have continued. As noted earlier, the government has alleged that, from 2002 through 2006, four orthopedic implant manufacturers made payments to physicians that were kickbacks designed to influence their clinical decisions (Demske 2008). A physician survey conducted in late 2003 and early 2004 found that more than one-third of physicians had recently been reimbursed by the pharmaceutical industry for costs associated with professional meetings or CME events and 7 percent had recently received tickets from manufacturers to cultural or sporting events (Campbell et al. 2007a). According to an FDA official, some pharmaceutical manufacturers were still inviting physicians on cruises and to exotic resorts, free of charge (Harris 2005). The PhRMA code states that manufacturers should not pay physicians to attend CME or educational events, unless they are faculty or consultants, and discourages them from giving physicians tickets to sporting events (PhRMA 2002). Similarly, the AMA's position is that physicians should not accept subsidies from the industry to attend a CME conference or professional meeting or accept gifts unless they primarily benefit patients (AMA 1998).[7]

An investigation by the Senate Finance Committee found that industry sponsors improperly influence some CME activities (U.S. Senate 2007a). For example, a commercial sponsor was involved in selecting faculty and other activities and another sponsor influenced where and how many presentations were scheduled. According to standards set by the ACCME, PhRMA, AMA, and OIG, CME activities should be independent of commercial sponsors.

Some organizations have adopted stricter policies on relationships

According to some critics, the only way to ensure that physicians are not biased by their relationships with the industry is for physicians to not accept anything of value, even trivial items, from drug manufacturers (Blumenthal 2004). Groups that support this position include the American Medical Student Association and No Free Lunch, an organization of physicians who pledge to not accept gifts or hospitality from the drug industry (American Medical Student Association 2008, No Free Lunch 2008).

A group of physicians and researchers has proposed that academic medical centers (AMCs) adopt stricter policies to regulate conflicts of interest between physicians and industry (Brennan et al. 2006). Under this proposal, for example, physicians affiliated with AMCs would be unable to accept from manufacturers any gifts (regardless of value), free meals, or payments to attend meetings. The proposal would prohibit companies from directly providing drug samples to physicians; instead, manufacturers could provide vouchers to low-income patients. Physicians who have financial relationships with manufacturers would not be able to serve on hospital formulary committees. AMC faculty would be forbidden from serving on industry speakers' bureaus and from publishing articles that were ghostwritten by the industry. The proposal would allow legitimate consulting arrangements and research grants from the industry to AMCs as long as they were disclosed publicly on the Internet.

Elements of this proposal are reflected in policies adopted by several AMCs, health systems, and medical groups, and in a recent AAMC report (AAMC 2008a). For example:

- The University of Massachusetts Medical Center recently approved rules that prohibit its physicians from accepting gifts and meals from manufacturers, ban physicians from joining companies' speakers' bureaus, and prevent physicians who receive grants or consulting fees from companies from serving on hospital formulary committees (Kowalczyk 2007).
- Stanford University Medical Center bans industry sales representatives from patient care areas and prohibits its faculty from publishing articles that have been ghostwritten by the industry (Stanford University School of Medicine 2006).
- A health system in Minnesota limits sales representatives' access to its clinics and has purged its hospitals and clinics of all pens, notepads, and other promotional items received from drug companies (Karnowski 2008).
- The Permanente Medical Group prohibits physicians who have a financial interest in a manufacturer from being involved in purchasing decisions regarding that company's (or a competitor company's) products and forbids its physicians from accepting payments, gifts of any value, or travel expenses from the industry (Permanente Medical Group 2004).

State efforts to regulate relationships

Some states have designed laws to make physician–industry relationships more transparent and to place limits on those relationships. Four states and Washington, DC, have enacted laws requiring that drug manufacturers report to the

state any cash and in-kind payments made to physicians. Seventeen other states introduced similar bills last year, but none became law (Medicine & Health 2008). Minnesota bans drug companies from giving food and gifts worth more than $50 to physicians, which reportedly has led to a decline in visits by sales representatives to primary care physicians (Harris 2007).[8] Iowa and Massachusetts have considered a complete ban on all gifts from drug manufacturers to physicians (Ross et al. 2007). In addition, Washington, DC, prohibits drug manufacturers from offering gifts or remuneration to a member of a government formulary committee (District of Columbia 2008).

To date, four states (Minnesota, Vermont, Maine, and West Virginia) and Washington, DC, mandate reporting of pharmaceutical manufacturers' financial relationships with physicians, and California requires that manufacturers specify annual limits on the value of items provided to physicians.[9] Minnesota is the only state to make public the names of individual physicians who receive payments, but this information is not in a searchable electronic format. Vermont, Maine, and Washington, DC, require disclosure of payments over $25, whereas Minnesota and West Virginia require disclosure of payments over $100 (Table 6-1, p. 154).

All existing statutes require that the pharmaceutical manufacturer, not the health care provider, disclose payments. Most statutes mandate disclosure of the recipient's name, credentials, amount, form of payment (e.g., grant, donation, in-kind), and purpose of payment (e.g., honoraria, consulting, education). However, states vary considerably regarding disclosure of each provider's license number, address, and affiliated facility.

States also vary regarding which types of providers are included in a reporting mechanism. All states require that drug companies report payments and transfers of value to health care professionals, and two states and Washington, DC, also mandate reporting of payments to hospitals and nursing homes (Table 6-1). With regard to the types of payments that must be disclosed, all statutes exempt pharmaceutical samples intended to be free for patients, and most exempt payments related to clinical trials and other research (Table 6-1). Vermont's statute allows pharmaceutical manufacturers to broadly designate payments as "trade secrets."[10] As a result of this designation, the state withholds all information relating to these payments. In fiscal year 2006, 72 percent of manufacturers' payments to Vermont providers were designated "trade secrets" and withheld from public disclosure (Vermont Office of the Attorney General 2007).

Each state's statute varies in its supervisory agency and enforcement mechanisms. In Minnesota, the supervisory agency is the Board of Pharmacy, whereas the attorney general supervises disclosures in Vermont. Washington, DC, and Maine require manufacturers to pay an annual reporting fee. Fines for each violation or false submission range from $1,000 to $10,000, depending on the state. Three states (Vermont, Maine, West Virginia) and Washington, DC, compile an annual report of payments in aggregate (Lurie 2007). However, only Vermont makes this report available on the Internet. Minnesota does not publish an aggregate report, but scanned copies of each manufacturer's disclosure forms are available online (Minnesota Board of Pharmacy 2007). When Minnesota switches to electronic filing in fiscal year 2009, it may become the first state to post a searchable list of manufacturer payments to health care providers online (Wyckoff 2008).

In a recent article, researchers found that Minnesota's and Vermont's data are not complete and are difficult to analyze because payment categories are vaguely defined (Ross et al. 2007). This study found that, over 3 years, manufacturers made 6,238 payments exceeding $100 each to physicians in Minnesota, for a total of $22.4 million; the median payment was $1,000. Over 2 years, manufacturers reported providing 2,416 payments exceeding $100 each to health care providers in Vermont, for a total of $1.0 million; the median payment was $177. The authors reported several problems with data completeness, accessibility, and quality:

- Because Vermont aggregates its disclosures by pharmaceutical manufacturer, researchers had to negotiate with the Vermont Attorney General and submit a Freedom of Information Act request to obtain data at the individual physician level.
- To obtain access to some of the payments designated as "trade secrets" under Vermont's law, the authors had to sue 18 pharmaceutical manufacturers.
- Because of vague definitions of payment type and purpose, researchers had difficulty differentiating between payments for gifts and those for contracted services.
- In Vermont, the physicians' complete names were available for only 25 percent of the payments included in the state's annual report.

TABLE 6–1 **Disclosure requirements in state reporting programs**

Disclosure requirement	MN	DC	VT	ME	WV
Year of legislation	1993	2001	2003	2003	2004
Disclose payment amounts greater than	$100	$25	$25	$25	$100
Provide educational programs/materials	Yes	Yes	"any gift, fee, payment, subsidy or other economic benefit provided in connection with… marketing activities"	Yes	"gifts, grants, or payments of any kind" which are "provided directly or indirectly"
Provide food/entertainment/payments	N/A*	Yes		Yes	
Pay travel expenses	N/A*	Yes		Yes	
Pay honoraria/consulting fees	Yes	Yes		Yes	
Pay for clinical trials/research	Yes	No	No	No	No
Provide free samples for patients	No	No	No	No	No
Sponsor CME	Yes	Yes	Yes	Yes	No
Provide drug rebates/discounts	N/A*	Yes	No	Yes	No
Disclose payments made to	Practitioners	Health care professionals, plans, pharmacies, hospitals, nursing facilities, and clinics	Physicians, hospitals, nursing homes, pharmacists, anyone authorized to prescribe, dispense, or purchase prescription drugs	Health care professionals, plans, pharmacies, hospitals, nursing facilities, and clinics	Prescribers (physicians and other professionals)

Note: N/A (not applicable), CME (continuing medical education).
*These payments are banned under Minnesota law if in excess of $50.

Source: Lurie 2007, MedPAC analysis of state laws.

Should the federal government require public reporting of financial relationships between physicians and manufacturers?

Current public reporting laws on physician–industry financial relationships are limited to a few states and do not provide complete information that is easily accessible. Three bills were recently introduced in the Congress to create a national system in which drug and device manufacturers would be required to report all payments and gifts above $25 or $50 to physicians; this information would be publicly available in an online database (U.S. House 2008, U.S. House 2007, U.S. Senate 2007b). The following subsections examine the potential uses and limitations of a federal reporting system and identify key design issues for such a system.

Potential uses of data on physician–industry relationships

A national public reporting system could:

- encourage physicians to reflect on the propriety of physician–industry relationships, perhaps discouraging inappropriate arrangements;
- help the media and researchers shed light on physician–industry interactions, explore potential conflicts of interest, and examine whether manufacturers and physicians are complying with industry and professional guidelines;
- enable payers (including Medicare) and health plans to examine whether and to what extent industry ties influence physicians' practice patterns;

- allow hospitals to check whether physicians who recommend the purchase of specific devices and drugs have financial ties to the manufacturers;
- help manufacturers demonstrate their compliance with industry guidelines;
- assist industry and physician associations in refining their ethical standards; and
- highlight individual physicians, medical groups, and academic institutions that have decided to limit certain financial relationships with the industry.

Public reporting of payments from manufacturers to physicians might encourage physicians to critically examine their relationships with the industry. The ACP's code of ethics recommends that physicians ask themselves what their patients and colleagues would think about an arrangement with a manufacturer and how they would feel if the relationship were disclosed by the media (Coyle 2002). The possibility that colleagues, patients, and the general public might learn about their financial relationships with drug and device companies could give physicians an incentive to carefully consider these questions, perhaps discouraging arrangements that may compromise their objectivity.

Recent articles that used data from Minnesota's public reporting law and other sources to shed light on physician–industry interactions demonstrate how reporters and researchers could draw on national data to investigate potential conflicts of interest. These articles have explored the financial ties of physicians who serve on formulary and clinical guideline committees, lead clinical trials, and prescribe expensive new drugs. They have also evaluated manufacturers' compliance with industry guidelines.

According to a survey of physicians who helped write clinical guidelines, almost 60 percent of them had a financial relationship with companies whose drugs were considered in the guideline they authored (Choudhry et al. 2002). However, only 2 of the 44 guidelines studied in the article included a disclosure of the authors' financial arrangements with the drug industry. Only 7 percent of the authors with a financial relationship believed they were influenced by their relationship, but 19 percent of these physicians believed their coauthors' recommendations were influenced by such interactions. These potential conflicts of interest are significant because clinical guidelines influence the treatment recommendations of many physicians (Choudhry et al. 2002, Harris and Roberts 2007). Reporters used data from Minnesota's public reporting system to show that some physicians who coauthored clinical guidelines received significant funding from companies whose drugs were affected (Harris and Roberts 2007). For example, a physician who served on panels that developed guidelines for the use of hypertension and cholesterol drugs received more than $200,000 from a manufacturer of these drugs.

Physicians who serve on drug formulary committees for hospitals, health plans, and states influence which drugs are purchased or covered. Hospitals generally require that physicians who serve on such committees disclose their financial interests and in some cases prohibit physicians with financial interests from serving on these committees (American Society of Health-System Pharmacists 2000, Kowalczyk 2007). Some—but not all—state formulary committees have similar rules. Until recently, Minnesota's formulary committee, which recommends the drugs that should be covered by the state Medicaid plan, did not have a disclosure policy. Using data from Minnesota's disclosure records, a reporter found that a physician who served on the committee received more than $350,000 from companies whose drugs were considered by the panel (Lohn 2007).

When manufacturers apply for approval of a new drug or device, the FDA requires that they identify certain financial interests of researchers who performed clinical trials on the product (FDA 2001). According to a recent article, however, several researchers involved in a clinical trial of a new artificial spinal disk had invested in the product's manufacturer, yet this information may not have been disclosed to the FDA before the device was approved (Abelson 2008). The reporter obtained confidential data on the researchers' investment interests from a patient lawsuit. A public reporting system could make such information more easily available to the public.

A recent *New York Times* article used data from Minnesota on physician–industry relationships to examine psychiatrists' use of a new class of expensive drugs (atypical antipsychotics) for children covered by Medicaid (Harris et al. 2007). The use of these drugs for children has been controversial because of safety risks and scarce evidence that they are effective for children. The analysis found that psychiatrists who accepted significant payments (at least $5,000) from manufacturers of these drugs prescribed them to children much more frequently than psychiatrists who accepted less or no money.

Public information on physician–industry relationships could also be used to track compliance with voluntary

industry guidelines on interactions with physicians. For example, are companies providing only occasional gifts worth less than $100 to physicians? Do companies offer only modest meals and hospitality? Researchers using data from Minnesota's reporting law identified many payments to physicians that may have violated industry guidelines on modest gifts and meals (Ross et al. 2007).

A public reporting system would enable payers (including Medicare) and plans to examine whether physicians' practice patterns are affected by their financial relationships with manufacturers. For example, what factors—including financial ties to drug companies—influence which drugs physicians prescribe? Do patients treated by physicians with industry relationships have higher costs for an episode of care? Some plans in Minnesota have been using state information on physician–industry interactions to review physician prescribing behavior (Wyckoff 2008). Plans could also use this information to tier providers or make other network decisions.

Hospitals make important decisions about which drugs to include in their formularies and which devices to purchase. Physicians can request that a hospital add a pharmaceutical to its formulary or purchase an expensive new device, such as an artificial hip or cardiac stent. Surgeons have a great deal of discretion when deciding which implant to use in a patient. Although physicians are generally motivated by their patients' best interests when recommending a drug or device, financial incentives at times may play a role. Hospitals may be unaware if physicians have financial relationships with manufacturers and may have difficulty obtaining this information (Abelson 2005). A public reporting system would allow hospitals to check whether physicians who request that the hospital add a drug to its formulary or purchase an expensive device have financial ties to the manufacturer. Hospitals could use this information when deciding which drugs to include in a formulary and which devices to purchase, as well as when negotiating prices.

Potential limitations and costs of public reporting

When exploring a public reporting system, it is important to recognize potential limitations and costs:

- Information on financial relationships may not be useful to many patients.
- Mandatory reporting would not eliminate conflicts of interest.
- A federal reporting law may impose compliance costs on manufacturers (to report financial information) and some administrative costs on the government (to implement and enforce the law).

It is unclear whether information about physicians' financial ties to drug and device manufacturers would help patients make better medical decisions. Patients frequently lack medical expertise and usually trust their physicians and thus are unlikely to know how their physicians' financial interest could bias their advice or whether their physicians' recommendations are appropriate (Cain et al. 2005). If a patient's physician makes the disclosure, this may actually increase the patient's level of trust. For example, if a physician tells a patient that he or she is paid by a manufacturer to give speeches about a drug, the patient's trust may deepen because the physician has been honest. In addition, physician disclosure to patients may lead both parties to believe there is no longer a possibility for the disclosed relationship to bias physician decision making (Brennan et al. 2006, Cain et al. 2005). Disclosure may be more useful to those with medical expertise, such as providers, when they need to evaluate physicians' independence and objectivity.

Some observers have noted that, although public reporting would shed light on physician–industry interactions, it would not eliminate potential conflicts of interest (Prescription Project 2007). Physicians would still be able to accept gifts, research funding, consulting fees, meals, royalties, and other payments from manufacturers. However, public disclosure could discourage physicians from having relationships that violate professional guidelines. In addition, a public database could help payers and researchers examine the prevalence of different types of relationships and their impact on clinical decisions, which could inform future efforts to devise rules in this area.

Existing state laws require that manufacturers—not physicians—report information on physician relationships. PhRMA has expressed concern that a potential federal reporting law would impose a burden on manufacturers (Bloedorn 2007). The government agency that would implement a potential reporting law would require resources to develop rules, collect data, maintain an electronic database, and enforce the law. According to two states with public reporting laws (Minnesota and Vermont), the cost of collecting information from the industry and posting it on a website is minimal (Lunge 2008). However, these states do not have databases that are searchable electronically, which might increase costs.

We also lack data on costs incurred by states to monitor and enforce compliance with their reporting laws. One option for reducing the reporting costs of manufacturers and the administrative costs of the government is to require that manufacturers start by reporting higher value arrangements with physicians and then, over time, begin reporting smaller gifts and payments.

Key design questions for a federal reporting system

In this section, we examine three key design questions for a potential federal law requiring public reporting of physician–industry relationships:

- How comprehensive should the reporting system be?
- What size and types of payments should be reported?
- How can the data be made readily accessible to the public?

We also examine which agency should administer a potential public reporting law and whether a federal law should preempt existing state laws.

How comprehensive should the reporting system be?

Policymakers would need to determine which types of manufacturers should be subject to a public reporting law, which recipients of industry payments to include, and whether to allow companies to withhold information that they deem to be proprietary. Although state reporting laws apply only to drug manufacturers, a comprehensive federal law could also include manufacturers of biological products, medical devices, and medical supplies because these manufacturers often have extensive relationships with physicians and federal health programs spend a lot of money on these products. In addition, a comprehensive law could apply to small as well as large companies to achieve a level playing field.

An important question is whether payments made to entities other than physicians should be included in a public reporting law. Although including payments to other entities would increase transparency, it also would add complexity to a public reporting system. Manufacturers provide support for education and research to AMCs, so there may be a public interest in obtaining information on the nature and extent of financial relationships between companies and medical schools and teaching hospitals. In addition, industry support for CME organizations accredited by the ACCME amounted to $1.2 billion in 2006, half of their total income (ACCME 2006). This dependence on commercial support has led to concerns about inappropriate industry influence over CME activities and prompted a recent recommendation that CME funding should be disclosed through an online registry (Steinbrook 2008). Therefore, it may be important to include manufacturer payments to CME organizations in a public reporting system. Finally, medical societies and other organizations of health care professionals may receive grants and subsidies from drug and device companies for education and fellowships, which could also be included in a reporting law.

Eli Lilly, a pharmaceutical manufacturer, began voluntarily disclosing its educational grants and charitable contributions on its website in 2007 (Eli Lilly 2008). These disclosures include the name of the recipient, amount, and program title. Recipients include physician membership organizations, patient advocacy groups, academic institutions, and CME companies. Further, a dozen drug and device manufacturers recently announced that they intend to publicly disclose their medical education grants; some of these companies also plan to disclose payments to patient advocacy groups (Freking 2008).

Should manufacturers be required to report information they consider to be proprietary? On the one hand, companies may wish to shield details of their research, product development, education, and marketing programs from competitors. On the other hand, the public has a legitimate interest in learning about the industry's financial relationships with physicians. Vermont permits manufacturers to designate information as a "trade secret" that is not released to the public, but this policy resulted in 72 percent of payments being withheld from public disclosure in 2006 (Vermont Office of the Attorney General 2007). AdvaMed contends that, to protect proprietary information about a product under development from competitors, consulting arrangements with physicians should not be disclosed until a product is approved by the FDA (AdvaMed 2008).

What size and types of payments should be reported?

A public reporting system could collect detailed information on a wide variety of financial relationships between manufacturers, physicians, and possibly other entities. In designing a law, policymakers would need to set a dollar threshold for payments that must be reported and define which types of payments and what details must be reported.

State laws have different dollar thresholds for payments that must be reported, ranging from $25 to $100. Although

a low threshold would result in the collection of more information on small gifts and meals, this additional information should be weighed against the greater reporting burden on manufacturers.

Several types of payments or transfers of value could be included in a reporting requirement, ranging from smaller items to significant financial arrangements: free product samples intended for patients, gifts, food, entertainment, honoraria, payments or subsidies related to medical conferences, consulting fees, speakers' fees, funding for research, investment interests in a manufacturer, profit distributions, and product royalties. Most state reporting laws exclude payments for clinical trials and other research, although there is evidence that industry-sponsored research can be biased and some industry-sponsored studies appear to serve promotional, rather than scientific, purposes (Angell 2005, Bekelman et al. 2003, Demske 2008, Psaty and Kronmal 2008).

An important question is whether to require the reporting of free product samples intended for patients (the laws in four states and Washington, DC, exclude this category). On the one hand, because manufacturers frequently provide free samples to physicians, mandatory reporting of samples would increase both the complexity of a law and the compliance costs for companies. According to a physician survey, 78 percent of physicians received samples in the last year (Campbell et al. 2007a). PhRMA contends that free samples make it easier for patients to find the right drug and to start treatment sooner, and they help uninsured patients obtain medication (PhRMA 2008). According to beneficiary focus groups conducted by the Commission in 2007, some beneficiaries rely on free samples when they reach the coverage gap under Medicare Part D (Hargrave et al. 2008).

On the other hand, some researchers have pointed out that free samples enable sales representatives to gain access to physicians and lead physicians and patients to rely on branded drugs instead of cheaper generics that may be equally effective (Brennan et al. 2006). A recent study found that poor and uninsured individuals are less likely to receive free samples than wealthy and insured patients (Cutrona et al. 2008). Finally, researchers have estimated that the retail value of free samples provided by drug manufacturers equaled $18.4 billion in 2005, far more than the $6.8 billion spent by the industry on visits from sales representatives to physicians (Donohue et al. 2007). Including free samples in a reporting system would provide the public a more complete picture of industry promotional activities.

Regardless of which payment categories are included in a reporting system, it is important that they be clearly defined and standardized so that the information is consistently reported. Each payment made to each physician or entity could be itemized to allow researchers to examine the size and frequency of individual payments. In addition, manufacturers could be required to report the name and address of the physician or entity to whom a payment or transfer of value was made, the value of each payment, the type of payment (e.g., gift, meal, or consulting fee), and the date (or range of dates) of the payment. Companies could be allowed to report additional clarifying details about a payment (e.g., payment for training other physicians in the proper use of an implantable device). To keep the database up to date, policymakers could require that companies report information on a regular schedule, such as quarterly or annually.

How can the data be made readily accessible to the public? Making data easily available to the public is a significant issue, given the difficulties of accessing information collected under state laws (Ross et al. 2007). To further this goal, information on payments to physicians and other entities could be posted on the Internet in an electronic format that is easy to search and download. The website could allow users to search for and aggregate payments by type, amount, physician or entity, date, and manufacturer. Manufacturers could be required to report payment information electronically to facilitate the creation of a database.

Other issues Policymakers would need to decide which agency would be best suited to administer a reporting law. Although the FDA could be an option because it regulates products made by drug and device manufacturers, the agency currently faces severe resource constraints and growing demands (Subcommittee on Science and Technology 2007). Similarly, CMS could be an appropriate choice because Medicare and Medicaid are major purchasers of drugs and devices, but CMS also has funding and staffing constraints. As noted earlier, two states with public reporting laws spend very little to collect information from the industry and post it on a website, but the costs of monitoring and ensuring compliance are uncertain (Lunge 2008).

An important question is whether a potential federal reporting law should preempt existing or future state reporting laws. On the one hand, preemption would

reduce the compliance costs for manufacturers because they would need to comply with only one federal law rather than several state laws (AdvaMed 2008). A single source of information could also reduce confusion among users. On the other hand, preemption raises concerns about state autonomy. A potential compromise would be to allow state laws that require reporting of information not collected under a federal law. In other words, a federal law would constitute a minimum floor. For example, if a federal law excluded reporting of free samples, a state law could require such reporting. If this approach leads to multiple state laws, however, it would likely not reduce the industry's compliance costs.

Reporting physicians' financial relationships with hospitals and ambulatory surgical centers

The number of physician-owned specialty hospitals more than doubled from 2002 to 2006, from 46 to 128 (CMS 2006, MedPAC 2005). The number of Medicare-certified ambulatory surgical centers (ASCs)—most of which have at least some physician ownership—grew by 31 percent from 2002 to 2006, from 3,600 to 4,700 (ASC Coalition 2004, Medical Group Management Association 2006, MedPAC 2007a). There has also been an increase in joint venture facilities owned by physicians and hospitals, such as imaging centers, cardiac catheterization labs, and specialty hospitals (Chapter 3 in this report provides additional information on joint ventures). Although physician ownership of hospitals and ASCs may offer benefits to physicians and patients, there is evidence that the presence of physician-owned specialty hospitals is associated with a higher volume of surgeries in a market (MedPAC 2006, Nallamothu et al. 2007). In addition, a recent study suggests that physician ownership of ASCs may influence referral patterns (Gabel et al. 2008).

Currently, it is difficult for the general public to obtain information about physicians' financial relationships with hospitals and ASCs. CMS requires hospitals to disclose to patients whether they are owned by physicians and has proposed the same requirement for ASCs, which may help patients make informed decisions about their care. However, this information is not available to payers, plans, and researchers (Table 6-2, p. 160). Creating a searchable electronic database with information on physicians' financial relationships with hospitals and ASCs would help payers, plans, and researchers examine the influence of these relationships on referral patterns and the overall volume of services.

Physicians may also own health care facilities that provide physical therapy, radiation therapy, diagnostic imaging, clinical laboratory tests, and other ancillary services. Some might wonder whether these providers should also be required to publicly report their financial arrangements with physicians. However, the Stark law prohibits physicians from owning or investing in a facility to which they refer their Medicare or Medicaid patients for diagnostic tests or other ancillary services, with some exceptions.[11] According to one of those exceptions, physicians may provide these services to patients in their offices as long as the services are billed by the referring physician or the group practice and other conditions are met.[12] Therefore, CMS should know if a physician or group practice is providing ancillary services because the provider's billing number appears on the Medicare claim. In addition, patients may be aware that their physicians have a financial interest in ancillary services provided in their offices. Thus, it is probably not necessary to create a database that identifies physicians who own entities providing tests or other ancillary services.

Impact of physician ownership of hospitals and ASCs on volume and referrals

By giving physicians more control over their work environment, physician-owned hospitals and ASCs allow physicians to hire specialized staff, customize operating rooms for specific procedures, and schedule surgeries more efficiently (MedPAC 2005). Physician-owned facilities may also improve access and convenience for patients. However, the growth in the number of physician-owned facilities could also lead to a higher volume of services in a market through additional capacity and by creating financial incentives for physicians to refer patients for more procedures. First, if additional hospitals and ASCs increase overall capacity in a market, this may lead to greater use of supply-sensitive services, such as diagnostic tests and minor procedures. With supply-sensitive care, the capacity of the health care system drives the amount of services delivered. For example, a new cardiac hospital may be associated with an increased number of coronary angioplasties provided in a market. Second, physicians who invest in facilities have a financial incentive to refer patients for additional admissions or procedures, as long as those services are profitable.

With their authority to make decisions about diagnosis and treatment, physicians are the central actors in the health

TABLE 6–2 **Under current and proposed federal disclosure rules for hospitals and ambulatory surgical centers, information is limited and often not publicly available**

	Hospitals	ASCs
Current rules	• Report physicians who own 5 percent or more of hospital to CMS, but information not publicly available • Inform Medicare patients whether hospital is physician owned when they receive preadmission information or arrive for outpatient services	• Report physicians who own 5 percent or more of ASC to CMS, but information not publicly available • ASCs that comply with anti-kickback safe harbor must disclose physician ownership to patients
Recent CMS and IRS proposals	• A sample of hospitals would report to CMS physician ownership and other financial relationships (unclear if information would be publicly available) • Would require physicians with admitting privileges to disclose ownership in hospital to patients when they are referred to hospital • Nonprofit hospitals would report certain joint ventures with physicians on IRS Form 990, but not names of physician investors	• Would disclose physician financial interests in ASC, including ownership, to patients

Note: ASC (ambulatory surgical center), IRS (Internal Revenue Service). The general public does not have access to information on physician ownership disclosed to patients.

Source: CMS 2008a, CMS 2008b, CMS 2007a, CMS 2007b, IRS 2008, OIG 1999.

care delivery system. When they recommend services to patients, professional ethics and concern for their patients' best interest are powerful motivations. However, financial incentives may also influence some physicians' decisions, particularly with regard to services that lack evidence-based guidelines (Wennberg et al. 2002). For example, there is not much evidence in the medical literature on the appropriate indications for hospitalizations and use of diagnostic tests.

In MedPAC's 2006 specialty hospital study, we found that the opening of a physician-owned cardiac hospital resulted in additional cardiac surgeries in a market (MedPAC 2006). For the average heart hospital with a market share of 26 percent, total cardiac surgeries in the market were estimated to increase by 6 percent. A recent article confirmed these findings (Nallamothu et al. 2007). Likewise, another study examined physician-owned spine hospitals and found increases in spinal fusion after these facilities opened (Mitchell 2007). The Commission's research also found that physician-owned specialty hospitals generally treat less severe cases (expected to be relatively more profitable than average); concentrate on particular diagnosis related groups, some of which are relatively more profitable; and tend to have smaller shares of Medicaid patients than community hospitals (MedPAC 2005).

Although the relationship between physician investment in ASCs and the overall volume of surgical services has not been examined, evidence from a recent study indicates that physician ownership of ASCs may influence referral patterns (Gabel et al. 2008).[13] This article examined data from Pennsylvania and found that physicians who sent many patients to physician-owned ASCs were much more likely to refer their commercial/Blue Cross patients to a physician-owned ASC than their Medicaid patients; these physicians referred more than 90 percent of their commercial/Blue Cross and Medicare patients to a physician-owned ASC but only 55 percent of their Medicaid patients (Gabel et al. 2008). This finding raises a concern that physicians who invest in ASCs may refer more lucrative patients to their facilities and less lucrative patients to hospitals. This study has two main limitations, however:

- Physicians might have been more likely to refer their Medicaid patients to hospitals because Medicaid managed care plans might not cover surgeries in ASCs.

- Because the authors lacked public information on physicians who own or invest in ASCs, they used a proxy measure for ownership based on physicians who accounted for 50 percent of referrals to physician-owned ASCs.

With regard to the first limitation, physicians who sent many patients to non-physician-owned ASCs were also more likely to refer their commercial/Blue Cross patients than their Medicaid patients to an ASC, but the magnitude of this difference was smaller than that for physicians who referred patients to physician-owned ASCs.[14] This finding suggests that physician ownership of an ASC may have influenced referrals independent of Medicaid coverage policies. With regard to the second limitation, public information on physician ownership of ASCs would allow more robust research on whether and to what extent physician investment influences referral patterns and total volume in a market.

Reporting financial relationships between physicians and hospitals

Hospitals currently have to comply with two (or potentially three) CMS rules that require disclosure of physician–hospital relationships, but none of the required disclosures is comprehensive or available to the general public (Table 6-2).[15] Under one federal disclosure requirement, a hospital enrolling in Medicare must identify individuals—including physicians and their Medicare provider numbers—who own 5 percent or more of the hospital. Many investors in physician-owned specialty hospitals have less than a 5 percent interest and therefore would not be identified. The general public does not have access to this information, which is contained in the CMS database on provider ownership and enrollment in Medicare.

Under a second CMS requirement, a physician-owned hospital must inform its Medicare patients that the hospital is physician owned and that the patient can request a list of all physician owners of the facility (CMS 2007b). The hospital must notify patients of physician ownership when they receive their preadmission packet of information or arrive for outpatient services.[16] However, CMS does not receive this notification information.

Under a third reporting mechanism proposed by CMS, hospitals would be required to report physician ownership and details of other financial relationships with physicians to CMS, including the value of compensation arrangements and copies of agreements (CMS 2008a). However, this proposed data collection—called the Disclosure of Financial Relationships Report (DFRR)—would include a sample of only 500 hospitals, and it is not clear that any of the data would be available to other payers, plans, patients, or researchers.

In addition to Medicare's disclosure rules, 16 states require physicians who own a specialty hospital to disclose their ownership interest to patients they refer to the hospital (CMS 2006). Although one state (Texas) requires that physicians disclose ownership interests in a specialty hospital to the state, none of the state laws makes such information available to the general public.

To improve the transparency of physicians' financial relationships with hospitals, CMS could collect information on certain relationships from all hospitals and make the data publicly available on a searchable website that could be updated regularly. A database containing this information could include the hospital name and identification number, physician name and identification number, type of financial relationship, and, for physician owners, the ownership percentage. CMS would have to determine which relationships to include in a reporting requirement. The agency could begin by asking hospitals to report data on physician ownership, equipment and space leases, and joint ventures and later collect information on physician employment. To minimize the reporting burden on hospitals, CMS could exclude details of agreements between hospitals and physicians from the database. CMS could proceed with the DFRR on a sample basis to obtain more detailed data on physician–hospital relationships.

Payers and researchers could use information from a public database on physician–hospital relationships to examine whether different types of relationships influence patient referrals, resource use for an episode of care, or overall volume of services in a market. Patients could use such a database to learn about physician ownership before they select a physician and hospital. (Currently, they can request a list of physician owners only after they receive their preadmission packet of information for their scheduled admission or when they arrive for an outpatient service).

Reporting physician investments in ambulatory surgical centers

Most ASCs have at least some physician ownership, but there is no comprehensive public database that identifies all physicians who invest in ASCs.[17] As with hospitals,

ASCs must identify physicians and others with a 5 percent or more ownership interest when they enroll with Medicare (CMS 2008b) (Table 6-2, p. 160). However, this information is not publicly available, and physicians with smaller ownership interests are not reported to the agency. A requirement for physician ownership to be disclosed to patients applies to at least some—but not all—physician-owned ASCs, and CMS has proposed a new disclosure-to-patients rule that would apply to all ASCs. However, the current and proposed requirements have weaknesses that could be remedied by creating a public database.

Physician-owned ASCs that wish to comply with a safe harbor to the anti-kickback statute are required to meet a physician ownership disclosure requirement: Patients referred to the ASC by a physician investor must be fully informed of the physician's ownership interest in the ASC (OIG 1999).[18] However, it is unclear whether patients must be informed at the time of referral or when they arrive for surgery. This rule applies to physician-owned ASCs that comply with the anti-kickback safe harbor, but not all physician-owned ASCs are eligible for the safe harbor. For example, the safe harbor covers surgeon-owned, single-specialty, multispecialty, and hospital–physician ASCs that meet certain conditions, but not ASCs jointly owned by physicians and a corporate chain. In addition, this information is not reported to a federal agency or made available to the public.

As part of its proposal to update the ASC conditions of coverage, CMS has proposed requiring that ASCs disclose physician financial interests in the ASC (including ownership) to patients before their visit to the ASC (CMS 2007a).[19] However, this information would not be available to plans, payers, the media, researchers, and other members of the public. A number of states require physicians who own facilities (including ASCs) to disclose their ownership interests to patients they refer to the facility, but this information is not available to the general public.

Creating a public database on the CMS website that included the names of all physicians who invest in ASCs and their ownership percentage would help plans, payers, and researchers analyze whether and to what extent ASC ownership affects referral patterns and the number of procedures performed. This information could be part of a database on hospital–physician financial relationships.

Conclusion and future work

In this chapter, we described the financial relationships between drug and device manufacturers and physicians, academic institutions, and medical education organizations. Although these financial ties can lead to advances in medical technology, they may also create conflicts between physicians' obligation to do what is best for their patients and the commercial interests of manufacturers. If physicians' decisions are not fully objective and independent, this may lead to increased Medicare spending and suboptimal care for beneficiaries. Requiring manufacturers to publicly report information on their financial relationships with physicians could encourage physicians to reflect on the propriety of those relationships and perhaps discourage inappropriate arrangements. A public reporting system also would help payers, plans, researchers, and reporters shed light on physician–industry interactions and examine physicians' practice patterns. In future work, we plan to further explore key questions in designing such a system, such as which types of manufacturers to include, whether payments made to entities other than physicians should be reported, and which types of payments to include.

We also examined the rapid growth of physician-owned specialty hospitals and ASCs. Currently, it is difficult for the general public (other than patients) to obtain information about physicians' financial relationships with hospitals and ASCs. Information on other physician–hospital relationships, such as joint ventures and equipment leases, is also not publicly available. If payers, plans, and researchers had access to basic data about certain physician relationships with hospitals and ASCs, they could use this information to examine the influence of these arrangements on referral patterns and the overall volume of services. In the future, we intend to examine which types of relationships should be publicly reported. ■

Endnotes

1 These groups are the Association of American Universities and the Association of American Medical Colleges.

2 We are not aware of research that examines the effects of DTC advertising for medical devices on patients' requests for devices and use of devices.

3 Several factors other than marketing by drug manufacturers may also affect physicians' prescribing decisions, such as published literature, information from peers, CME activities, clinical guidelines, health plan formularies, and utilization management programs.

4 In one study, for example, individuals were assigned to the role of plaintiff or defendant in a lawsuit and asked to neutrally rate the importance of arguments favoring either side (Dana and Lowenstein 2003). Participants showed a strong tendency to favor the arguments of the side to which they had been assigned. This result demonstrates that it is difficult for people to be objective when they have a vested interest in reaching a conclusion.

5 Physicians who administer drugs to patients in their offices bill Medicare for the drugs under Part B.

6 A fifth orthopedic device company entered into a nonprosecution agreement with the government, under which it agreed to implement the same reforms as the other four companies but was not part of the financial settlement.

7 The PhRMA and AMA codes allow manufacturers to support CME and other educational activities indirectly through a third-party sponsor.

8 Minnesota's ban does not apply to manufacturer payments to physicians for educational programs, honoraria, and consulting fees.

9 California's statute mandates that each pharmaceutical manufacturer develop a comprehensive compliance program that specifies an annual dollar limit on gifts, promotional materials, and items or activities that the pharmaceutical company may provide to an individual medical or health care professional. These comprehensive compliance programs must conform to OIG guidelines and the PhRMA code (California Health and Safety Code 2004). Annual dollar limits set by pharmaceutical manufacturers range from $300 per health professional for McKesson to $3,000 per health professional for Novartis (McKesson 2005, Novartis 2008). Drug samples, financial support for CME, and consulting fees are exempt from the annual limit on payments.

10 Trade secrets are defined in 1 V.S.A. 317(b)(9) as "including, but not limited to, any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it" (Vermont Office of the Attorney General 2005).

11 The Stark law, also known as the Ethics in Patient Referrals Act, was enacted in two phases. Stark I covered financial relationships between physicians and clinical laboratories. Stark II covered relationships between physicians and entities that provide nine other services: diagnostic imaging, radiation therapy, physician and occupational therapy, durable medical equipment, parenteral and enteral nutrients, prosthetics and orthotics, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.

12 Ancillary services performed by a group practice in its office must also be performed or supervised by the referring physician or another physician in the group practice and done in the same building where the referring physician (or another physician in the group) provides patient care or in a "centralized building" used by the group for ancillary services.

13 A study by the Florida Health Care Cost Containment Board of physician-owned ASCs did not examine whether physician ownership influenced the overall volume of surgeries because the number of ASCs was relatively small (State of Florida 1991).

14 Top-referring physicians to non-physician-owned, for-profit ASCs sent 78 percent of their commercial/Blue Cross patients and 61 percent of their Medicaid patients to the ASC. The comparable numbers for physicians who referred many patients to physician-owned ASCs were 92 percent and 55 percent (Gabel et al. 2008).

15 In addition, beginning in 2009, the Internal Revenue Service plans to require that nonprofit hospitals report certain joint ventures with physicians on Form 990 (IRS 2008). However, the draft form does not require that hospitals report the names and provider numbers of physicians who invest in the joint venture.

16 In the proposed inpatient hospital rule for fiscal year 2009, CMS has proposed mandating that hospitals require physicians with admitting privileges to disclose their ownership or investment interests in the hospital to patients when they refer them to the hospital (CMS 2008a).

17 According to an industry survey conducted by the Federated Ambulatory Surgery Association in 2004, about 90 percent of ASCs have at least some physician ownership (ASC Coalition 2004). According to a survey conducted by the Medical Group Management Association, 64 percent of ASCs are owned by physicians, and 31 percent are owned by joint ventures, which may include physician ownership (MGMA 2006).

18 The anti-kickback statute prohibits health care providers from receiving or paying anything of value to influence the referral of services covered by federal health programs. The OIG has published safe harbor regulations that protect physicians who invest in ASCs from prosecution under the anti-kickback statute, if certain conditions are met.

19 The ASC conditions of coverage are the rules that ASCs must follow to participate in Medicare (CMS 2007a).

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CHAPTER 7

A revised prospective payment system for skilled nursing facilities

RECOMMENDATIONS

7A The Congress should require the Secretary to revise the skilled nursing facility prospective payment system by:

- adding a separate nontherapy ancillary component,
- replacing the therapy component with one that establishes payments based on predicted patient care needs, and
- adopting an outlier policy.

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

7B The Secretary should direct skilled nursing facilities to report more accurate diagnostic and service-use information by requiring that:

- claims include detailed diagnosis information and dates of service,
- services furnished since admission to the skilled nursing facility be recorded separately in the patient assessment, and
- skilled nursing facilities report their nursing costs in the Medicare cost reports.

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

CHAPTER 7

A revised prospective payment system for skilled nursing facilities

Chapter summary

The Commission, CMS, the Government Accountability Office, and health services researchers have identified two key problems with Medicare's prospective payment system (PPS) for skilled nursing facility (SNF) services. First, it does not adequately adjust payments to reflect the variation in facility costs for nontherapy ancillary (NTA) services such as intravenous (IV) medications, respiratory therapy, and drugs. Second, payments vary with the amount of therapy (e.g., therapeutic exercise and therapeutic activities) furnished, creating an incentive to furnish therapy services for financial rather than clinical reasons. In addition, the PPS does not include an outlier policy to defray the exceptionally high costs of some patients, which could make some providers reluctant to admit patients who are likely to be high cost.

The Commission contracted with the Urban Institute to develop an alternative PPS design to address these problems. Using patient and stay characteristics (e.g., the physical status of the patient and the duration of the stay) that best predicted costs per day, we designed a separate NTA payment component to add to the PPS and revised the

In this chapter

existing therapy payment component. We also developed an outlier policy based on exceptionally high ancillary costs per stay. To evaluate these changes, we assessed their accuracy in predicting NTA and therapy costs per day and their impact on facilities' payments. We considered whether the new design would create any inappropriate incentives, what would be required to implement the design, and what additional data would further improve payment accuracy and help monitor care quality.

Our findings provide strong evidence that a revised PPS design would better target payments to stays with high NTA costs, more accurately calibrate therapy payments to therapy costs, and afford some financial protection to SNFs that treat stays with exceptionally high ancillary costs compared with the existing PPS. Because the revised PPS would establish more accurate payments, SNFs would be much less likely to avoid patients whom hospital discharge planners reported having difficulty placing—those requiring IV antibiotics, expensive medications, and ventilator care. For these beneficiaries, access would improve. The chapter includes a recommendation to the Congress to revise the SNF PPS by adding a separate NTA payment component, replacing the therapy component with one that bases payments on predicted care needs, and adopting an outlier policy.

Recommendation 7A

The Congress should require the Secretary to revise the skilled nursing facility prospective payment system by:

- *adding a separate nontherapy ancillary component,*
- *replacing the therapy component with one that establishes payments based on predicted patient care needs, and*
- *adopting an outlier policy.*

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

We estimated the effects of a revised PPS on payments compared with current policy, and the results confirm that the targeting designs would be successful at raising payments for stays with high NTA costs. If implemented in a budget-neutral manner, aggregate payments would increase by 15 percent to more than 20 percent for facilities with the highest (top 10th percentile) NTA or ancillary costs per day, the highest shares (top

10th percentile) of patients in the extensive services case-mix groups (e.g., patients needing IV medications, tracheostomy care, or ventilator support), and the lowest shares (bottom 10th percentile) of patients in rehabilitation-only case-mix groups. Payments would also increase for facilities with the largest shares of patients in special care case-mix groups (e.g., those needing wound care). Payments would decline for facilities with the largest shares of rehabilitation-only patients and the smallest shares of patients in extensive services and special care case-mix groups.

Relative to the current PPS, we estimate that the revised design would increase aggregate payments to hospital-based SNFs and nonprofit SNFs and would reduce payments to freestanding SNFs and for-profit SNFs. There would be no shift in aggregate payments between rural and urban facilities. Not all facilities within a group would experience the same changes in payments, given the various mixes of patients and treatment patterns.

An outlier policy for exceptionally high ancillary costs would affect many SNFs but generally would have small effects on payments. Only a subset of facilities would receive higher ancillary payments as a result of the outlier policy, even though most SNFs would receive outlier payments, because base payments would be reduced so that total spending does not increase.

The revised PPS design would not require SNFs to collect any new data but, like any changes to a PPS, would require CMS to take several steps to implement. Payment accuracy is improved with the use of patient diagnosis information; however, because the quality of the information currently gathered by SNFs is poor, the best PPS designs use diagnosis information from the prior hospital stay. Requiring SNFs to report complete diagnosis information on their claims would facilitate CMS's implementation of the best alternative PPS designs. The best models also include whether IV medications were furnished to a patient. However, these data can include services provided during the prior hospital stay, so CMS would need to check that specific services appear to have been provided by the SNF. Revising the questions in the patient assessment tool would eliminate this

check but would require SNFs to change the services they record in the patient assessments.

One drawback common to prospectively set payments for a bundle of services is that facilities may be encouraged to furnish fewer services. Under the revised PPS design, facilities would have a financial incentive to furnish less therapy than may be clinically appropriate. CMS would need to monitor therapy provision and patient outcomes, underscoring the need to require SNFs to assess patients at discharge. A pay-for-performance program, as recommended by the Commission, that linked SNF payments to patient outcomes would help counter incentives to stint on services because poor beneficiary outcomes would result in lower payments. In addition, a low utilization payment adjustment that pays for therapy services on a cost basis for stays with therapy costs well below predicted levels may help discourage facilities from underproviding therapy services.

In developing these payment system changes, our work was hampered by inadequate information on patient diagnoses, the services furnished during the SNF stay, and nursing costs. Better data would further improve payment accuracy and enable the value of care to be assessed by linking payments, costs, service use, and patient outcomes. Our second recommendation directs CMS to require facilities to provide information on patient diagnoses, service use during the SNF stay, and nursing costs. ■

Recommendation 7B

The Secretary should direct skilled nursing facilities to report more accurate diagnostic and service-use information by requiring that:

- *claims include detailed diagnosis information and dates of service,*
- *services furnished since admission to the skilled nursing facility be recorded separately in the patient assessment, and*
- *skilled nursing facilities report their nursing costs in the Medicare cost reports.*

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

Medicare's skilled nursing facility (SNF) prospective payment system (PPS) is widely acknowledged to have two basic problems: It does not accurately pay for nontherapy ancillary services (NTA)—such as drugs, intravenous (IV) medications, and respiratory services—and it encourages facilities to provide therapy services (e.g., therapeutic exercise and therapeutic activities) for financial, not clinical, reasons (Abt Associates 2000, CMS 2000a, GAO 1999, Kramer et al. 1999, MedPAC 2007b, MedPAC 2005b, MedPAC 2002, MedPAC 2001, MedPAC 2000, White 2003, White et al. 2002). In its June 2007 report to the Congress, the Commission described CMS-funded research that examined ways to improve the PPS Medicare uses to pay SNFs (MedPAC 2007b). This work, conducted by the Urban Institute, examined ways to: separately pay for NTA services such as drugs, IV medications, and respiratory therapy; base payments for therapy services on predicted care needs, not service provision; and defray the costs of exceptionally expensive stays. We concluded that a revised PPS could set payments more accurately and afford SNFs some financial protection against exceptionally high-cost stays. If payments were more accurate, SNFs would have less incentive to avoid certain types of patients and access would improve for beneficiaries with high NTA care needs.

On the basis of these findings, we contracted with the Urban Institute to revise the PPS to include the following elements: a separate payment for NTA services, prospectively set payments for therapy services using patient and stay characteristics, and a budget-neutral outlier policy targeting exceptionally high-cost cases.

In this chapter, we examine alternative designs for the NTA and therapy payment components and an outlier policy, estimate the combined effect of a revised PPS design on facility payments using the best NTA and therapy component designs we tested, and discuss the need for additional data to improve payment accuracy.

How Medicare currently pays for SNF services

Medicare covers up to 100 days of SNF care when a beneficiary requires skilled nursing or rehabilitation services after a hospitalization of at least three days in the preceding month. The general goal of this care is recovery to the maximum level of functioning; three-quarters of SNF patients receive rehabilitation services (physical and occupational therapy and speech–language pathology services). Each year, about 3 percent of beneficiaries use SNF services; in 2007, Medicare spent more than $21 billion on these services. The most common conditions treated in a SNF (as determined by examining hospital discharge diagnoses) involve recovery from hip and knee joint replacement, heart failure and shock, pneumonia and pleurisy, broken hips, and strokes.

The SNF PPS design

SNFs receive a daily rate to cover nursing, ancillary, and capital costs (a more complete description of the PPS is found in *Medicare payment basics: Skilled nursing facility services payment system* (MedPAC 2007a)). The rate is adjusted for differences in case mix using the resource utilization group (RUG) classification system.[1] Patients are classified into a RUG based on the number and type of minutes of therapy used or expected to be used, the need for certain services (e.g., respiratory therapy and specialized feeding), certain clinical conditions (e.g., pneumonia and dehydration), the ability to perform activities of daily living (e.g., eating and toileting), and, in some cases, signs of depression.

Each daily payment has three components—a nursing component intended to reflect the intensity of nursing care and NTA services that patients are expected to require; a therapy component to reflect the physical and occupational therapy and speech–language pathology services provided or expected to be provided; and a component to cover room and board and other capital-related costs. The nursing and therapy components have separate base rates and case-mix weights to reflect their relative resource requirements; the other component is a fixed amount per day for all patients. In 2008, for patients in urban SNFs, the daily nursing base rate was $146.62, the therapy base rate was $110.44, and the other component was $74.83. For each day, the three components are summed. Therapy payments account for 16 percent to 60 percent of the daily payment depending on the case-mix group. There is no outlier policy to defray the costs of exceptionally costly stays.

The current PPS design incorporates features of prospectively set payments (for the nursing and other services components) and payments based on a fee schedule (for the therapy component). Facilities have a financial incentive to underfurnish nursing services because they will be paid the prospective rate regardless of the amount of service furnished. At the same time,

they have an incentive to furnish therapy services because therapy minutes are used to group patients into five tiers, with higher payments for each tier.

Problems with the SNF PPS design

Analysts have identified two basic problems with the existing SNF PPS. First, the RUG classification system does not adequately adjust payments to reflect the variation in providers' costs for NTA services. The system distributes payments for NTA services based on the expected amount of nursing care. Under this design, payments are the same for patients who require equivalent nursing care but different levels of NTA services such as expensive drugs and respiratory services. As a result, the relationship of the nursing case-mix weights to NTA costs is weak, with the weights accounting for only about 5 percent of the variation in NTA costs in 2003 (Urban Institute 2007). Although NTA costs make up a sizable share (16 percent on average) of total SNF costs, payments are not necessarily higher for patients who are expected to use these services (GAO 1999, White et al. 2002).

In addition, NTA costs vary across stays considerably more than nursing costs—18-fold compared with 2-fold (CMS 2006). Nursing payments vary but not enough to account for the range in NTA costs. Payments are too high for many beneficiaries and too low for those who need expensive NTA services. Hospital discharge planners and hospital administrators have reported problems placing patients who need IV antibiotics, expensive drugs, or ventilator care (Liu and Jones 2007, OIG 2006).

In an attempt to correct this shortcoming, in 2006 CMS added case-mix groups to the classification system for patients who qualify for both the rehabilitation and extensive services RUGs, which prior work found had higher NTA costs (Abt 2000).[2] The extensive services RUGs include patients who need IV medications, tracheostomy care, or ventilator support. CMS also increased the nursing case-mix weights by a uniform percentage for all RUGs, with the intent to improve the targeting of payments for NTA costs. However, the refinements remain insufficient, as payments continue to be tied to nursing time. In a comment letter to CMS on the proposed refinements, the Commission noted that the refinements were inadequate (MedPAC 2005a).

The second key problem with the current PPS is that payments increase with the amount of therapy delivered (or expected to be provided), creating a financial incentive to furnish therapy services. Over time, the number of beneficiaries receiving therapy and the amount they receive have increased.[3] CMS's refinements to the PPS in 2006 did not modify the financial incentive to provide therapy services. In 2006, rehabilitation days made up 86 percent of all Medicare days (up from 83 percent the year before) and the share of days in the highest rehabilitation RUGs (the ultra high and very high groups) grew 7 percentage points, accounting for 59 percent of the rehabilitation days (MedPAC 2008b). Given the growth in the provision of therapy services, we are concerned that current levels of therapy provision do not reflect only the care needs of patients.

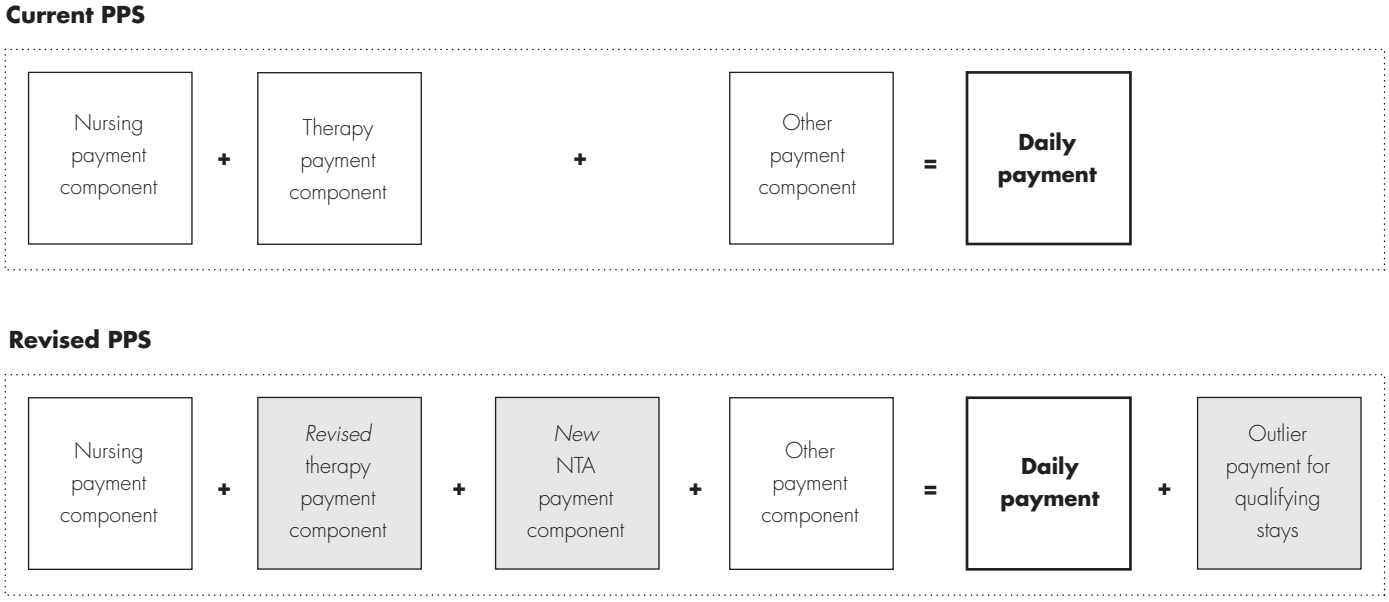
Another shortcoming of the SNF PPS is that it does not include an outlier policy to defray the costs of exceptionally costly cases. The goals of outlier policies are to minimize the financial risks for SNFs treating more costly patients, reduce potential access problems for costly patients, and help ensure that patients, once admitted, receive the care they need (Keeler et al. 1988). Outlier payments should not correct for systematic mismatches between payments and costs that result from limitations of a classification system, but they offer providers insurance protection against large losses. Outlier policies also help ensure access for beneficiaries whose care needs are likely to greatly exceed payments, particularly those who can be easily identified before SNF admission.

Designing a revised SNF PPS

The Commission considered three significant revisions to the SNF PPS (Figure 7-1). The first is to add a fourth payment component to the payment system that would target payments for NTA services. The second is to replace the existing therapy component with one that predicts care needs based on patient and stay characteristics. The third is to add a budget-neutral outlier policy.

The Urban Institute researchers constructed alternative designs for the NTA and therapy components that predicted per day costs for NTA and therapy services. They used the alternative designs that best predicted therapy and NTA costs to simulate payments under a revised PPS and then compared them with payments under current policy. The effect of a budget-neutral outlier policy targeting extraordinarily high ancillary costs on payments was also estimated.

FIGURE 7–1 **Comparison of current and revised skilled nursing facility PPS designs**



Note: PPS (prospective payment system), NTA (nontherapy ancillary).

Alternative designs for the NTA and therapy components

Our analysis compares different designs of the NTA and therapy components to estimate daily NTA and therapy costs. The researchers carefully evaluated the patient and stay characteristics, including those considered in previous work, to see how much each predictor contributed to explaining cost variation and to assess any inappropriate incentives that might result if the predictor were included in the payment component.[4] Most of the predictors were evaluated by a team of researchers headed by Dr. Andrew Kramer at the University of Colorado and were generally accepted as reasonable by a technical advisory panel (Urban Institute 2007).

The patient- and stay-level predictors include:

- the patient's age,
- the broad RUG category,[5]
- the patient's use of respiratory or IV medications in the SNF,
- the patient's physical and mental condition,
- the patient's ability to perform activities of daily living,
- information about the patient's diagnoses from the prior hospital stay,
- the patient's prior stay in a nursing home, and
- a length-of-stay proxy.[6]

Alternative designs vary in the predictors they include

The alternative designs for the NTA and therapy components vary in the predictors they include to estimate daily costs (see text box, pp. 180–181, on predicting NTA and therapy costs). Each alternative presents tradeoffs between its accuracy in predicting costs and other factors such as administrative simplicity.

Some of the NTA and therapy component designs include the full range of predictors—patient and stay characteristics from SNF claims, patient assessment information, an indicator that IV medications were furnished, and hospital diagnoses (Table 7-1 (p. 181) includes a list of predictors).[7] Because the quality of the SNF diagnosis coding is poor, the more accurate models

Predicting nontherapy ancillary and therapy costs per day

The alternative designs for the nontherapy ancillary (NTA) and therapy component are based on models that predict NTA and therapy costs per day. The Urban Institute researchers developed separate regression models to predict per day NTA and therapy costs using characteristics of the patient and the stay. The models use Poisson regression, which reflects the skewed distribution of costs per day. Many versions of NTA and therapy cost models were estimated using a random sample of 10 percent of stays and were evaluated using all stays from a random sample of 30 percent of facilities. The NTA and therapy models use very similar sets of predictors, but the coefficients (the direction and magnitude of a predictor's influence on costs) are generally different. For example, the impact of intravenous therapy as a predictor differed between NTA and therapy costs per day—increasing predicted NTA costs per day and decreasing predicted therapy costs per day. Using separate regression models allows the predictor to adjust NTA costs upward and therapy costs downward.

The alternative prospective payment system designs for the NTA and therapy components include patient and stay characteristics that help explain differences in the average NTA costs and therapy costs per day (Table 7-1). In the alternative component designs we

(continued next page)

also use diagnosis information from hospital claims.[8] The transfer of diagnostic information between the hospital and the SNF is essential for proper patient handoffs between settings but would take some work on the part of providers and CMS to administer. The provision of IV medications as a predictor recognizes the high cost for these services.

We also considered NTA and therapy component designs that would be simpler to implement and avoid the potential incentive to furnish unnecessary IV medications if the adjuster results in payments that are higher than a facility's costs. These designs exclude the hospital diagnoses and the predictor indicating that IV medications were furnished during the SNF stay.

The therapy component designs also differed in whether they included a predictor indicating whether the patient day was grouped into a rehabilitation RUG (i.e., the patient received at least 45 minutes of therapy per week). In designs with this predictor, payments would be higher for patients who were grouped into a rehabilitation RUG but, unlike the current PPS design, payments would not increase if more therapy were furnished. Instead, payments would increase as a function of patient and stay characteristics. For example, therapy payments would be higher for patients recovering from strokes or hip fractures than for cancer patients.

Selecting the best NTA and therapy designs

We used three criteria to evaluate the predictive ability of the alternative designs for the NTA and therapy components.

- Ability to explain cost differences across stays (the stay-level R-squared) and at the facility level (the facility-level R-squared).[9] Without accounting for a reasonably large share of the cost variation, a revised design would retain financial incentives for facilities to admit certain types of patients and avoid others.
- Effectiveness in predicting high-cost cases. An accurate model should be able to predict high-cost cases. We measure the share of stays in the top 10 percent of costs accurately predicted to be high cost.
- Proportionality between a facility's payments and its expected costs. For each component (NTA or therapy), a case-mix index (CMI) coefficient measures whether the relative expected costliness (of its NTA or therapy costs) of a facility's cases is proportional to the payments (the NTA or therapy payments). The CMI is calculated as the average predicted cost for the facility's cases divided by the average cost for all cases. Regression analysis was used to estimate the CMI coefficient, which measures the relationship between the actual average costs and the CMI used for

Predicting nontherapy ancillary and therapy costs per day (cont.)

tested, predictors were included if they contributed to the explanatory power of the model and were statistically significant in either the NTA or the therapy cost model.[10] Consistent with the prior work, some characteristics (e.g., keeping patients in bed or tube-feeding patients) were excluded because their inclusion in a payment component could create inappropriate incentives for providers to augment payments. ■

TABLE 7–1 **Patient and stay characteristics used to predict NTA and therapy costs**

Characteristic	Measure
Patient	
Age	Years
SNF care	
IV medication furnished	Yes/No
Respiratory care	Yes/No
IV medication and respiratory care	Yes/No
IV medication and respiratory condition in SNF stay	Yes/No
Physical and mental status	
Respiratory condition in SNF	Yes/No
No infection	Yes/No
Serious skin ulcer (stage 4)	Yes/No
Shortness of breath	Yes/No
Cognitive function	Cognitive Performance Scale score (6 levels)
Chewing problem (to help predict speech therapy)	Yes/No
Swallowing problem (to help predict speech therapy)	Yes/No
Surgical wounds	Yes/No
Ability to perform activities of daily living	
Locomotion on unit (ease in moving from patient's room to adjacent corridor on same floor)	5 levels
Assistance with eating	5 levels
Transfer to/from bed, chair, wheelchair, or standing position	5 levels
Hospital diagnoses	
Diagnoses	21 indicators
HIV	Yes/No
Solid organ transplant	Yes/No
Stay	
Broad RUG category	5 indicators
Prior nursing home stay	Yes/No
Length-of-stay proxy	Number of patient assessments

Note: NTA (nontherapy ancillary), SNF (skilled nursing facility), IV (intravenous), HIV (human immunodeficiency virus), RUG (resource utilization group). Broad RUG categories include rehabilitation, rehabilitation and extensive services, extensive services, special care, and clinically complex. Respiratory care indicates oxygen (linked to specific conditions), tracheostomy care, or ventilator care. Nursing homes are federally required to assess each patient's functional, mental, and behavioral status at set intervals throughout a patient stay using the Minimum Data Set. The number of patient assessments increases with a patient's length of stay.

Source: Analyses prepared for MedPAC by the Urban Institute, 2008.

Outlier policies vary considerably across prospective payment systems

Medicare's prospective payment system (PPS) outlier policies for other services vary considerably (Table 7-2). The pools range from 1 percent to 8 percent, with small pools used for services that have less risk associated with them, either because the unit of payment is small (e.g., an individual service in the outpatient hospital PPS) or because some of the risk of an exceptionally costly stay is tempered with a per diem payment (e.g., the psychiatric hospital PPS). In four of the PPSs, the loss amounts are a fixed dollar amount. In contrast, the outlier policy in the home health care PPS uses an amount that is a multiple of the episode payment; the outpatient PPS uses a combination of a fixed-loss amount and a multiple of the base rate. The loss-sharing amount is most frequently set at 80 percent. In the psychiatric hospital PPS, the loss-sharing amount declines after the median length of stay, from 80 percent to 60 percent, to reflect the declining costs per day with longer stays. ■

TABLE 7–2 **Existing Medicare PPS outlier policies provide models for a SNF outlier policy**

PPS, by setting	Service unit	Pool size	Fixed-loss amount	Loss-sharing ratio
Home health agency	Episode	5.0%	0.89 times the episode amount	80%
Inpatient rehabilitation facility	Discharge	3.0	$7,362	80
Psychiatric hospital	Day	2.0	$6,488	80% for days 1–9 60% for days 10+
Long-term care hospital	Discharge	8.0	$20,738	80
Hospital inpatient	Discharge	5.1	$22,640	80
Hospital outpatient	Individual service	1.0	1.75 times base rate and the cost must exceed the base rate by at least $1,575	50

Note: PPS (prospective payment system), SNF (skilled nursing facility).

Source: CMS 2008, CMS 2007a, CMS 2007b, CMS 2007c, CMS 2007d, CMS 2000b.

payments (the predicted costs).[11] A CMI coefficient of 1.0 indicates that a facility would be paid in proportion to its costs. There would be no gain from taking a more or less difficult case load because increased payments are offset by proportionate increases in costs. A coefficient greater than 1.0 indicates that a facility with a relatively costly case mix would tend to be underpaid, whereas a facility with a relatively inexpensive case mix would tend to be overpaid (Cotterill 1986, Pettengill and Vertrees 1982).[12] A CMI coefficient below 1.0 indicates that a facility with a relatively costly case mix would tend to be overpaid, while a facility with a less costly case mix would tend to be underpaid.

An outlier policy design

The PPS redesign includes the addition of an outlier policy to partially compensate providers that treat exceptionally costly patients. Consistent with other PPS outlier policies, payments would cover only a portion of the losses incurred in treating exceptionally costly cases so that a provider retains an incentive to be efficient (see text box). A provider must cover the difference between the PPS payment and the fixed loss associated with an exceptionally costly case. To discourage inappropriately extended stays, outlier payments cover only a portion of costs above the fixed-loss amount. The portion paid above the fixed-loss amount is often based on an estimate of the marginal costs. The outlier policy design needs to specify the share of payments to redistribute to high-cost cases (the target amount or "pool" size), the amount of

a provider's loss to qualify for an outlier payment (the fixed-loss amount), and the share of the costs that outlier payments will cover beyond the fixed loss (the loss-sharing ratio).[13]

Outlier policies are generally financed by lowering the base payments for all cases by a small amount so that total spending remains budget neutral. As such, outlier policies need to balance the protection they offer to SNFs with the lower payments SNFs would receive for all other cases.

We defined outlier cases comparing costs and payments on a per stay basis. The financial risk for a facility is determined by its losses over the stay, not on a given day. A similar rationale is used to define the psychiatric hospital outlier policy, a PPS with per day payments and a per stay outlier policy. Furthermore, because dates of service are not collected on SNF claims, the days when services were delivered (and the associated costs) cannot be determined.

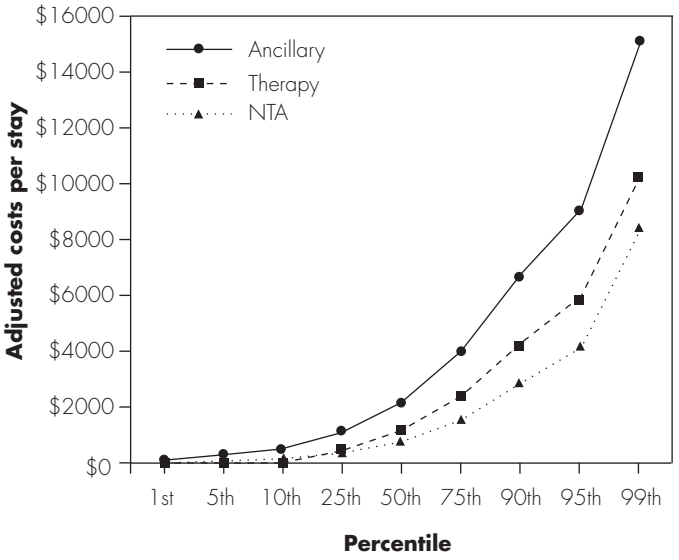
Although outlier policies typically consider total costs, we examined policies that would target ancillary (NTA and therapy) costs because they are highly variable and fluctuate due to differences among patients. Ancillary costs average 40 percent of total stay costs. Focusing on ancillary costs also avoids advantaging hospital-based facilities that would be more likely to qualify for outlier payments if total costs were used because hospital-based facilities have routine costs more than double those of freestanding facilities. Any higher costs incurred by hospital-based facilities that are attributable to their patient mixes would be reflected in these facilities' ancillary costs.

An outlier policy based on total ancillary (NTA plus therapy) costs can address the stays with exceptionally high therapy or NTA costs (or both). We considered an outlier policy targeting only exceptionally high NTA costs but found that some stays had exceptionally high therapy costs (Figure 7-2). The 99th percentile for NTA and therapy costs were both 10 times their medians. An outlier policy focused on NTA costs would benefit stays with exceptionally high NTA costs but would do nothing to defray the costs for stays with exceptionally high therapy costs. An outlier policy for exceptionally high ancillary costs allows stays with unusually high NTA or therapy costs (or both) to qualify for additional payments without advantaging stays with certain care needs over others.

We examined the distribution of ancillary losses per SNF stay under a revised PPS to determine the share of stays with exceptionally large losses. Just over 1 percent of stays incur losses of $5,000 or more per stay (Table 7-3, p. 184).

FIGURE 7–2

Exceptionally high NTA, ancillary, and therapy costs per stay are nearly 10 times higher than the median



Note: NTA (nontherapy ancillary). Exceptionally high-cost stays are at the 99th percentile in the distribution of per stay costs. Costs are adjusted for differences in labor costs.

Source: Analysis of 2003 skilled nursing facility claims, cost reports, and DataPro stays conducted for MedPAC by the Urban Institute, 2008.

A $3,000 fixed loss on ancillary services was used to assess the impact of an outlier policy on payments under a revised PPS design. This fixed loss requires SNFs to incur a loss on ancillary services roughly equal to the average ancillary cost per stay. We evaluated three other outlier policies—a $5,000 fixed-loss amount and two outlier pool sizes (2 percent and 3 percent). The 3 percent pool resulted in a pool that was sufficiently large that the fixed-loss amount ($1,442 per stay) did not appear to warrant an outlier policy. The fixed loss of $5,000 resulted in a pool that we considered too small, affecting only about 1 percent of stays. The 2 percent outlier pool had results fairly comparable to the $3,000 fixed-loss amount.

Evaluating the impact of a revised PPS

We considered several factors to evaluate a revised PPS design. First, we selected the alternative design of the NTA and therapy components that best predicted per day costs, as discussed above. Next, using the best designs for the NTA and therapy components and an ancillary outlier

TABLE 7–3 **Just over 1 percent of SNF stays incur ancillary losses of $5,000 or more**

	Ancillary loss per stay					
	Less than $1,000	$1,000–$2,500	$2,500–$5,000	$5,000–$10,000	$10,000–$25,000	More than $25,000
Percent of all stays	13.7%	4.7%	2.0%	0.8%	0.2%	<0.1%
Percent of stays with ancillary losses	64	22	9	4	1	<1

Note: SNF (skilled nursing facility). Ancillary losses are defined as per stay ancillary (nontherapy ancillary plus therapy) payments minus per stay ancillary costs.

Source: Analysis of 2003 skilled nursing facility claims, cost reports, and DataPro stays conducted for MedPAC by the Urban Institute, 2008.

policy, we compared payments under a revised PPS with payments under current policy (see text box describing how current and model payments were calculated). We examined the shifts in payments across different types of cases and SNFs as well as the distributions of the changes in payments.

We also considered the incentives a revised PPS would create, its data requirements, and the ease of implementation. One goal of the redesign was to avoid incentives that encourage the provision of services for financial reasons. Another goal was to avoid creating incentives for facilities to select the mix of cases they treat. A third goal was to minimize providers' data-reporting requirements. A final goal was to develop a revised PPS that CMS could readily implement.

A revised PPS design would make payments more accurate than current policy

Revising the current PPS design will improve the accuracy of payments and limit the incentives for SNFs to select certain types of cases over others and to furnish therapy services for financial reasons. Adding an NTA component to the PPS would substantially improve the payment system's ability to account for differences in NTA costs. Replacing the existing therapy component with one based on patient and stay characteristics (instead of service use) would account for differences in therapy cost as well as the current PPS. Both components would result in payments that are more proportional to costs, thereby lowering the incentive to select certain types of patients over others.

A revised PPS with an NTA component would make payments considerably more accurate than the current PPS

A new NTA component would substantially improve the accuracy of payment for NTA services relative to the current PPS (Table 7-4, p. 186). As a basis for comparison, we examined the ability of the current PPS to predict NTA costs. The current design explains only 5 percent of stay-level NTA costs per day. In addition, of the total high-cost stays (those in the top 10 percent of costs), only 25 percent were accurately predicted to be high cost. At the facility level, a larger share (but still low, 13 percent) of the variation in per day NTA costs was explained by the current PPS.

Moreover, the current PPS does not allocate NTA payments in proportion to the services' costs. The high CMI coefficient (2.34) indicates that facilities with a more costly than average NTA case mix were underpaid for the NTA services they provided, whereas facilities with a less costly than average NTA case mix were overpaid. These results are consistent with what hospital administrators have told us: Facilities have an incentive to avoid cases that require high levels of NTA services and patients who need these services are difficult to place (MedPAC 2007b).

A revised PPS using patient and stay characteristics to predict NTA costs shows dramatic improvement in payment accuracy. The alternative PPS design that uses hospital diagnoses and IV medication predictors was the most accurate design evaluated. At the stay level, the design accounts for 23 percent of the variance in NTA costs and properly identifies as high cost 45 percent of the high-cost cases. At the facility level, the design accounts for 31 percent of the NTA per day cost variation across

Estimating current and revised prospective payment system payments

Using 2003 Medicare claims and cost-report data, we calculated payments under current policy and compared them with payments that would be made under a revised prospective payment system (PPS) design. The revised PPS used the alternative designs for the nontherapy ancillary (NTA) and therapy components that best predicted daily NTA and therapy costs. The details of the per stay ancillary cost outlier policy are described below.

Payments under current policy: We calculated per day skilled nursing facility payments under current policy using 2003 base rates and adjusting payments for area wages. To reflect the current case-mix groups, we used the case-mix groups and relative weights from fiscal year 2006, the year the classification system was expanded from 44 to 53 resource utilization groups. Payments include the add-on payments for HIV cases.

Payments under revised PPS designs: We used the alternative NTA and therapy component designs that best predicted per day costs, which included the hospital diagnoses, the rehabilitation indicator, and the intravenous medication predictor. To estimate NTA and therapy payments, we calculated new payment weights for the NTA and therapy components and applied them to the 2003 base rates. To establish an NTA base rate, we allocated a portion of the 2003 nursing base rate to NTA services using information from CMS on the share of nursing payments attributable to NTA services (43.4 percent of the urban nursing base rate and 42.7 percent of the rural nursing base rate).[14] We made adjustments to ensure budget neutrality within each payment category (NTA and therapy). We calculated nursing payments in the revised PPS designs in the same manner as for current payments, except that we removed the estimated NTA costs from the nursing base rate.

Modeling outlier payments: We examined the effects of an outlier policy that includes the following features:

- Outlier payments are based on per stay losses on ancillary services (NTA and therapy services combined), where ancillary losses are defined as per stay ancillary payments minus per stay ancillary costs.
- Payments are made to facilities that incur a loss on a stay of more than $3,000 (wage adjusted) in ancillary services.
- Outlier payments cover 80 percent of the per stay ancillary costs above the fixed loss amount.[15]
- The outlier payment policy is budget neutral and financed by a 1.7 percent reduction in the base payment amounts for ancillary services for all facilities. ■

facilities. With a CMI coefficient of 1.14, payments would be substantially closer to costs than they are under the current PPS. Using this NTA component design, NTA payments would be distributed much more in line with facility costs—raising payments for facilities that disproportionately treat patients with high needs for NTA services and lowering them for facilities that do not. As a result, the design would reduce incentives to avoid such cases.

A PPS design that excluded the hospital diagnoses and IV medication predictors would also considerably improve the accuracy of payments for NTA services compared with current policy. This PPS design would substantially improve the prediction of NTA costs at the stay and facility levels and result in payments more proportional to facility costs. Because this design does not require information from the patient's preceding hospital stay, it would be easier to implement than a design that includes it. However, the design would lose the clinical advantage of having patients' hospital information available to SNF caregivers. Excluding the IV medication predictor avoids the financial incentive to furnish IV drugs if the predictor was inaccurate and raised payments higher than facility costs. Yet, because IV medications are expensive, excluding this predictor from the component's design will result in less accurate payments.

TABLE 7–4

A separate NTA component would substantially improve the PPS's ability to predict NTA costs

Evaluation criterion	Current PPS design	Revised PPS design: With hospital diagnoses and IV medication predictors	Revised PPS design: Without hospital diagnoses and IV medication predictors
Stay-level analysis			
Percent of variation in NTA costs explained	5%	23%	18%
Percent of high-cost cases accurately predicted	25	45	39
Facility-level analysis			
Percent of variation in NTA costs explained	13	31	27
NTA CMI coefficient	2.34	1.14	1.17

Note: NTA (nontherapy ancillary), PPS (prospective payment system), IV (intravenous), CMI (case-mix index). Percent of high-cost cases predicted is the share of cases in the top 10 percent of NTA costs accurately predicted to be high cost. A CMI coefficient of 1.0 indicates that facility payments are proportional to facility costs. The number of stays included in the analysis was 173,441; the number of facilities was 3,647.

Source: Analysis of 2003 skilled nursing facility claims, cost reports, and DataPro stays conducted for MedPAC by the Urban Institute, 2008.

Revised therapy component would be as accurate as current policy but would more closely calibrate payments to costs

A revised design for the therapy component would be essentially as accurate as the current PPS in predicting therapy costs but would calibrate payments more closely to therapy costs. With payments nearly proportional to costs, facilities would not have a financial incentive to adjust their mix of cases. In addition, the redesign would remove the financial incentive to furnish therapy services to boost payments.

Our analysis compared three alternative designs with the current PPS payment component (Table 7-5). The current PPS accounts for 36 percent of the stay-level variation in therapy costs and 38 percent of the facility-level variation. In addition, almost one-third of high-cost cases are accurately predicted. However, the current PPS does not pay facilities for providing therapy services in proportion to their costs (the CMI coefficient is 0.79). It overpays facilities with above-average therapy costs and underpays facilities with below-average therapy costs.

One revised PPS design includes all the patient and stay characteristics, the hospital diagnoses, and the IV medication predictor but does not include the indicator that the patient was grouped into a rehabilitation RUG. Its predictive abilities at the stay level (19 percent) and at the facility level (15 percent) are considerably lower than the current PPS. Like the current payment weights, this design would tend to overpay facilities with above-average therapy costs, although less so than current policy does. Although the design would remove the financial incentive to provide more therapy, it does not accurately account for therapy costs.

Including the rehabilitation indicator in the therapy component design dramatically improves the PPS's ability to pay for therapy costs appropriately. This design accounts for essentially the same share of therapy cost differences across patients as the current PPS (34 percent compared with 36 percent) and it correctly predicts high-cost cases somewhat less frequently (28 percent compared with 32 percent). However, this design would establish payments at the facility level that would be much more proportional to average facility therapy costs (the CMI is 1.05) compared with current policy. The near proportionality indicates little overpayment or underpayment at the facility level, affording facilities little financial incentive to adjust their mix of cases. Further, unlike the current PPS, there would be no financial incentive to furnish therapy beyond the amount required to be grouped into the lowest rehabilitation RUGs (45 minutes of therapy a week). As with any PPS that establishes payments for a bundle of services, there would be an incentive to underprovide services, which would need to be addressed (see discussion, pp. 191–192).

Exploring the performance of a design that would be simpler to implement, a third alternative design includes

TABLE 7–5

A redesigned therapy component can explain cost variation as well as or better than the current PPS

Evaluation criterion	Current PPS design	Revised PPS designs: With hospital diagnoses and IV medication predictors, but no rehabilitation indicator	Revised PPS designs: With hospital diagnoses and IV medication predictors and rehabilitation indicator	Revised PPS designs: With rehabilitation indicator, but no hospital diagnoses or IV medication predictors
Stay-level analysis				
Percent of variation in therapy costs explained	36%	19%	34%	33%
Percent of high-cost cases accurately predicted	32	25	28	26
Facility-level analysis				
Percent of variation in therapy costs explained	38	15	35	35
Therapy CMI coefficient	0.79	0.83	1.05	1.06

Note: PPS (prospective payment system), IV (intravenous), CMI (case-mix index). Percent of high-cost cases predicted is the share of cases in the top 10 percent of therapy costs accurately predicted to be high cost. A CMI coefficient of 1.0 indicates that facility payments are proportional to facility costs. The number of stays included in the analysis was 173,441; the number of facilities was 3,647.

Source: Analysis of 2003 skilled nursing facility claims, cost reports, and DataPro stays conducted for MedPAC by the Urban Institute, 2008.

the rehabilitation indicator but excludes the hospital and IV medication variables. This alternative maintains nearly all the explanatory power and near proportionality of the design that includes them. Because it does not include any of the hospital information, it would be easier to implement than designs that include this information. However, it would lose the clinical advantage of ensuring the transfer of this information to the SNF.

A revised PPS would redistribute PPS payments, with changes in payments inversely related to PPS margins

The revised PPS—with a new NTA payment component, a revised therapy payment component, and an outlier policy for stays with exceptionally high ancillary cost per stay—would redistribute payments across different types of cases and the facilities that treat them. In aggregate, payments would increase to SNFs treating large shares of patients with extensive service and special care needs and low shares of rehabilitation-only patients. Based on their mix of patients and treatment patterns, aggregate payments to hospital-based SNFs and nonprofit SNFs would increase considerably, and aggregate payments to freestanding SNFs and for-profit SNFs would decline slightly. Yet, because SNFs are not homogeneous, the effect on individual facilities would vary. Facilities with the highest PPS margins would have the largest reductions in payments; facilities with the lowest PPS margins would have the largest increases in payment. The redistributions would narrow the differences in financial performance across SNFs.

Revised PPS would redistribute payments

Using the NTA and therapy component designs that best predicted costs and a $3,000 fixed-loss outlier policy for ancillary costs per stay, we estimate that a revised PPS design would considerably redistribute Medicare payments.[16] Aggregate payments would be directed away from SNFs with high shares of rehabilitation-only patients and toward SNFs treating high shares of patients requiring extensive services (Table 7-6, p. 188). Aggregate payments to SNFs treating high shares of rehabilitation-only patients would decline 6 percent, whereas aggregate payments to SNFs treating low shares of these patients would increase considerably (17 percent). Likewise, aggregate payments to SNFs treating high shares of patients in extensive services RUGs (patients who received IV medications or suctioning or who received tracheostomy, ventilator, or respirator care) and patients in special care RUGs (patients treated for surgical wounds or skin ulcers or who received radiation therapy) would increase substantially (15 percent and 7 percent, respectively), and aggregate payments to

TABLE 7–6

Revisions to the PPS would increase aggregate payments to some SNF groups and decrease payments to others

SNF grouped by facility characteristic	Share of SNFs	Share of stays	Change in payments under revised PPS relative to current policy
Low share of rehabilitation-only patients	10%	13%	17%
High share of rehabilitation-only patients	10	8	–6
High share of extensive services patients	10	17	15
Low share of extensive services patients	10	6	–4
High share of special care patients	10	6	7
Low share of special care patients	10	7	–4
High NTA costs per day	10	15	23
Low NTA costs per day	10	7	–1
High ancillary costs per day	10	15	21
Low ancillary costs per day	10	7	1
Hospital based	11	19	20
Freestanding	89	81	–2
Nonprofit	27	32	7
For profit	68	64	–3
Government	5	4	7
Rural	32	21	0
Urban	68	79	0

Note: PPS (prospective payment system), SNF (skilled nursing facility), NTA (nontherapy ancillary). Revisions to the SNF PPS include a new NTA component, a revised therapy component, and an outlier policy for stays with exceptionally high ancillary costs. Share of stays is the percent of all Medicare stays treated by that type of facility. Low-share facilities are in the lowest 10th percentile share of cases; high-share facilities are in the top 10th percentile share of cases. Low and high ancillary costs per day (and low and high NTA costs per day) are defined as SNFs in the bottom and top 10th percentiles in ancillary costs (and NTA costs) per day. Rehabilitation-only includes patients grouped into rehabilitation resource utilization groups (RUGs) but excludes patients categorized into the rehabilitation plus extensive services RUGs. Extensive services patients include patients grouped into extensive services RUGs (e.g., patients who received IV medications in the past 14 days or suctioning, or patients who received tracheostomy, ventilator, or respirator care) or in a rehabilitation plus extensive services RUG. Special care patients include patients grouped into special care RUGs (e.g., patients treated for surgical wounds or skin ulcers or who received radiation therapy).

Source: Analysis of 2003 skilled nursing facility claims, cost reports, and DataPro stays conducted for MedPAC by the Urban Institute, 2008.

SNFs treating low shares of these patients would decline by 4 percent. Aggregate payments to SNFs with the highest NTA costs per day (top 10th percentile of NTA costs per day) would increase considerably (23 percent), whereas aggregate payments to those with the lowest NTA costs per day (bottom 10th percentile of costs per day) would decrease by 1 percent.

Under the revised PPS, the shifts in aggregate payments across facility types also reflect the mix of patients treated at different types of facilities and their patterns of providing therapy. A revised PPS would redistribute aggregate payments from freestanding SNFs and for-profit SNFs and to hospital-based SNFs and nonprofit SNFs. Aggregate payments to hospital-based facilities would increase 20 percent, and those to freestanding facilities would decline slightly (2 percent). By ownership, aggregate payments to nonprofits would increase moderately (7 percent) and aggregate payments to for profits would decline 3 percent. Aggregate payments to rural and urban facilities would not change.

Effect of a revised PPS would vary for individual facilities within each SNF group

Although a revised PPS would increase aggregate payments to some groups of SNFs and decrease aggregate payments to others, the effects on individual SNFs would vary depending on their patient mix and treatment patterns. For

TABLE 7–7

Under a revised PPS, changes in payments vary considerably across and within SNF groups

SNF grouped by facility characteristic	Payments lower by >10%	Payments lower by 5 to 10%	Payments lower by 1 to 5%	Percent change −1 to 1%	Payments higher by 1 to 5%	Payments higher by 5 to 10%	Payments higher by >10%
Low share of rehabilitation-only patients	1%	2%	8%	6%	16%	20%	47%
High share of rehabilitation-only patients	26	19	18	11	9	11	6
High share of extensive services patients	3	2	7	5	11	16	55
Low share of extensive services patients	18	20	17	10	12	11	12
High share of special care patients	2	7	14	10	24	21	21
Low share of special care patients	20	16	16	10	14	11	13
High NTA costs per day	1	2	4	2	5	10	76
Low NTA costs per day	13	16	17	12	22	12	8
High ancillary costs per day	6	3	6	3	6	8	68
Low ancillary costs per day	1	12	18	12	31	18	7
Hospital based	1	2	2	3	8	12	73
Freestanding	12	18	22	11	18	13	7
Nonprofit	6	9	13	10	17	16	29
For profit	13	19	23	10	17	10	7
Government	3	6	11	8	16	25	30
Rural	9	13	18	9	18	16	16
Urban	11	17	20	11	17	11	13

Note: PPS (prospective payment system), SNF (skilled nursing facility), NTA (nontherapy ancillary). Revisions to the SNF PPS include a new NTA component, a revised therapy component, and an outlier policy for stays with exceptionally high ancillary costs. Share of stays is the percent of all Medicare stays treated by that type of facility. Low-share facilities are in the lowest 10th percentile share of cases; high-share facilities are in the top 10th percentile share of cases. Low and high ancillary costs (and NTA costs) per day are defined as SNFs in the bottom and top 10th percentiles in ancillary costs (and NTA costs) per day. Rehabilitation-only includes patients grouped into rehabilitation resource utilization groups (RUGs) but excludes patients categorized into the rehabilitation plus extensive services RUGs. Extensive services patients include patients grouped into extensive services RUGs (e.g., patients who received IV medications in the past 14 days or suctioning or patients who received tracheostomy, ventilator, or respirator care) or in a rehabilitation plus extensive services RUG. Special care patients include patients grouped into special care RUGs (e.g., patients treated for surgical wounds or skin ulcers or who received radiation therapy). Rows may not sum to 100 percent due to rounding.

Source: Analysis of 2003 SNF claims and cost reports conducted for MedPAC by the Urban Institute, 2008.

example, the vast majority (83 percent) of SNFs with low shares of rehabilitation-only patients would experience payment increases, whereas payments to a small share (11 percent) of these SNFs would decline (Table 7-7). Similarly, most SNFs treating high shares of patients in the extensive services and special care RUGs would experience payment increases but payments would decline for some of these facilities. Payments would decline for over half of SNFs treating low shares of patients in extensive service and special care RUGs, yet modest shares of these facilities would see large payment increases (at least 10 percent). Payments would increase by at least 10 percent to more than three-quarters of SNFs with high NTA costs per day, yet 1 percent of these SNFs would experience payment declines of a similar magnitude.

Similar differences in payment changes would be seen across SNFs by facility type and ownership. Almost three-quarters of hospital-based SNFs would experience fairly sizable increases in payments (at least 10 percent), and payments to just 1 percent of these SNFs would decline by at least 10 percent. More than one-half of freestanding SNFs would see their payments decline, but payments would increase for more than one-third of them and some (7 percent) would experience fairly large increases (at least 10 percent). Nonprofit and for-profit SNFs would experience similar disparities in changes in payments. Most nonprofit SNFs (62 percent) would see their payment increase by at least 1 percent, many with payment increases of at least 10 percent. However, payments to

TABLE 7–8

Under a revised PPS, changes in payments would be inversely related to actual SNF Medicare margin

SNF margin	Payments lower by >10%	Payments lower by 1 to 10%	Percent change –1 to 1%	Payments higher by 1 to 10%	Payments higher by >10%
Positive margin					
More than 10%	83%	66%	54%	50%	13%
5 to 10%	9	11	10	12	5
0 to 5%	2	7	10	9	4
Negative margin					
0 to –5 %	3	5	9	8	4
–5 to –10%	2	3	3	5	3
Less than –10%	2	6	14	16	70
Total	100	100	100	100	100

Note: PPS (prospective payment system), SNF (skilled nursing facility). Revisions to the SNF PPS include a new nontherapy ancillary component, a revised therapy component, and an outlier policy for stays with exceptionally high ancillary costs. Margins were calculated for 2003, the same year of the simulated nontherapy ancillary and therapy components. Columns may not add to 100 percent due to rounding.

Source: MedPAC analysis of changes in payments simulated by the Urban Institute and 2003 Medicare margins. Analysis includes 3,335 of the 3,647 facilities (91 percent) that were in both data sets.

more than one-quarter of nonprofit SNFs would decline at least 1 percent; for some (6 percent), the decline would be sizable (at least 10 percent). Most for-profit SNFs would experience payment declines, but payments for some (7 percent) would increase at least 10 percent. A larger share of rural facilities would see their payments increase (50 percent) compared with urban facilities (41 percent) under the revised PPS.

Many SNFs would receive small outlier payments

Under a $3,000 fixed-loss outlier policy, outlier payments would be made for a small share of stays that would be broadly distributed across many SNFs, reflecting the random nature of extraordinary costs. Specifically, 2.6 percent of stays distributed over 60 percent of SNFs would qualify for an outlier payment.[17] A slightly larger share of hospital-based SNFs (69 percent) would receive outlier payments compared with freestanding facilities (61 percent).

Yet, only a subset of SNFs (20 percent of freestanding facilities and 28 percent of hospital-based facilities) would, on net, benefit from the outlier policy after their base ancillary payments were lowered to fund the outlier pool. In contrast, most facilities would not recoup the amounts they pay into the outlier pool. The outlier policy would afford a small share of facilities (7 percent) a moderate increase (more than 5 percent) in the ancillary payments. A larger proportion of nonprofit SNFs and hospital-based facilities than other types of SNFs would receive outlier payments of this magnitude.

Payment increases and declines are inversely related to Medicare margins

To gauge the financial impact that changes in payments would have on facilities, we examined the SNF margins of the facilities that would experience the largest changes in payments. Under a revised SNF PPS, most SNFs that would experience the largest changes in payments had the highest and lowest Medicare margins in 2003 (Table 7-8). The vast majority of the SNFs (83 percent) that would experience large declines in payments had margins of at least 10 percent in 2003. Conversely, 70 percent of SNFs that would receive the largest payment increases had the lowest Medicare margins (less than –10 percent) in 2003. Of the facilities that would experience large increases in payments and that had high Medicare margins, most were freestanding and for profit but some (11 percent) were hospital based and one-quarter were nonprofit.

Under a revised PPS, differences in Medicare margins across SNF groups would narrow. Aggregate margins

would change the most for hospital-based SNFs, but most of them would continue to have negative margins. Because the redesigns change only ancillary payments, the very high routine and overhead costs of many hospital-based facilities would continue to affect their financial performance. Aggregate margins for freestanding facilities and for-profit facilities would decline slightly.

Our analyses indicate that, compared with the current system, a revised PPS would more accurately pay for NTA and therapy services and offer SNFs protection against extraordinarily high-cost cases. Because payments would be more accurate, SNFs would have little financial incentive to select certain types of patients and access would improve for beneficiaries who require expensive NTA services. In view of our findings, we recommend that the Congress require the Secretary of Health and Human Services to revise the SNF PPS by adding an NTA component, replacing the existing therapy component with one that bases payments on care needs, and adopting an outlier policy.

RECOMMENDATION 7A

The Congress should require the Secretary to revise the skilled nursing facility prospective payment system by:

- **adding a separate nontherapy ancillary component,**
- **replacing the therapy component with one that establishes payments based on predicted patient care needs, and**
- **adopting an outlier policy.**

RATIONALE 7A

The current PPS design does not accurately pay for patients with high NTA care needs, encourages providers to furnish therapy services for monetary gain, and does not offer financial protection for SNFs against extraordinarily high-cost cases. As a result, SNFs favor certain types of cases over others, which can impair access for some patients.

Our work indicates that a separate NTA component can be designed that substantially improves payment accuracy for these services. A therapy payment component can be designed that predicts therapy costs as well as current policy but bases its payments on the care needs of the patient and not therapy provision. An outlier policy targeting high ancillary costs protects SNFs against extraordinary losses without paying for facility differences that may be unrelated to patients.

IMPLICATIONS 7A

Spending

- This recommendation would not affect federal program spending relative to current law. The changes would be implemented to be budget neutral.

Beneficiary and provider

- This recommendation is expected to improve access for beneficiaries with high-cost care needs.
- The revised PPS will improve the accuracy of payments for individual stays. Payments will increase for some providers and decrease for others depending on their mix of patients and treatment patterns.

Implementing a revised PPS

A revised PPS as described in this chapter—which includes an NTA payment component, bases therapy payments on predicted therapy care needs for each patient, and includes an outlier policy—would improve payment accuracy but impose changes on providers and CMS. The revised therapy component would create an incentive to stint on therapy care rather than overprovide services. CMS could temper this incentive in two ways: by adopting a pay-for-performance policy to encourage optimal patient outcomes and by paying for therapy services on the basis of costs for stays with therapy costs considerably below average. The PPS revisions would not require facilities to gather any new data but would require them to obtain diagnostic information from the referring hospital. CMS would need to make several changes to its current operations, similar to those it makes when implementing or revising a PPS.

Preventing undesirable SNF responses to a revised PPS

Certain features of the revised PPS that would improve the accuracy of payments may also create opportunities for SNFs to change their practices in ways that will not necessarily benefit patients. Most notably, under the revised PPS design, SNFs would be paid for the predicted amount of therapy care a patient needs, even if they provide fewer services. Like any prospectively determined payment, the redesign creates a financial incentive for SNFs to underfurnish services—in this case, therapy services. CMS could lower the risk of stinting on therapy services in two ways. First, Medicare could tie a portion of its payments to quality measures. This year,

the Commission recommended that Medicare implement pay for performance for SNFs and noted that changes in a patient's functional status would be a good indicator to include in the measure set (MedPAC 2008b). For measures to accurately reflect the care furnished to short-stay patients, SNFs must be required to assess patient outcomes at admission and discharge, which the Commission has repeatedly recommended (MedPAC 2008b, MedPAC 2006, MedPAC 2005b).

A second way to lower the risk of underproviding services is to pay for therapy on a cost basis for stays with unusually low therapy costs. The PPS for home health care has a low utilization payment adjustment (LUPA) whereby home health agencies are paid on a per visit basis when a 60-day episode (its unit of payment) includes fewer than 5 visits.[18] A LUPA policy for SNFs could pay facilities for therapy services on a cost basis when a stay's therapy costs were well below the predicted costs. Similar to the outlier policy, CMS would identify unusually low therapy costs over the course of a stay, not on a per day basis, as therapy may not be provided as predicted on a given day for reasons that would not constitute stinting.

The redesigned PPS does not alter the prospectively set payments for the nursing and other services components. Facilities will continue to have a financial incentive to keep these components' costs below their payments. As with any PPS for a bundled service, this can result in facilities underproviding nursing services. A pay-for-performance program that uses outcome measures that are sensitive to the amount of nursing provided to patients should, if enough dollars are at stake, discourage providers from stinting on these services. The two measures the Commission has recommended for pay for performance—rates of community discharge and rehospitalization—are sensitive to nurse staffing levels.

The indicator for IV medications would improve payment accuracy but, if inaccurate, could create a financial incentive for SNFs to furnish unnecessary IV medications if the payment adjuster raises payments too high relative to costs. As long as the payment adjuster is accurate, the financial incentives to select certain patients or to furnish specific services will be minimized. Although excluding the predictor from the PPS design would eliminate the potentially inappropriate incentive, payments are likely to be less accurate without it, which would also create incentives for SNFs to selectively admit patients.

It is critical that CMS monitor provider behavior to assess whether there are mismatches between costs and payments for the stay and patient predictors included in the NTA and therapy component designs. It is important for CMS to periodically recalibrate the weights associated with each predictor so that payments continue to accurately reflect treatment costs and practice patterns.

Proposed PPS revisions do not require additional data collection

The proposed PPS revisions do not require providers to gather any new information (Table 7-9). The information is either currently collected by SNFs or hospitals or is calculated by CMS.

The SNF care variables (whether patients received IV medications or respiratory care) and diagnosis information from the prior hospital stay would require additional work by CMS and SNFs to implement. To "confirm" that the services were furnished in the SNF (and not during the prior hospital stay), information about the use of IV medications and respiratory care requires a match between the patient assessment and a SNF claim.[19] Modifications to the Minimum Data Set (MDS) would eliminate the need for this step. Although transferring diagnostic information from the hospital to the SNF adds an administrative task for both settings, communicating this information is key to quality patient transitions and should occur for every patient. CMS has the diagnostic information from hospital claims, but there could be timing problems between when CMS receives and adjudicates a hospital claim and when a SNF submits a bill for a stay.

The transfer of information between SNFs and hospitals highlights the need for information technology industry wide. CMS is conducting a demonstration to test a uniform patient assessment instrument that gathers and transmits this information from the hospital to post-acute settings, but its results are not expected until at least 2011. The use of hospital diagnoses underscores the need for SNF claims to include accurate diagnosis codes (see p. 194).

Changes required of CMS and providers

A revised PPS would require CMS to make several changes to its current operations, consistent with those it makes when implementing or revising any PPS. The NTA and therapy payment component designs would require CMS to:

- recalculate the nursing base rate after removing NTA costs from the rate, establish an NTA component, and modify how total payments are calculated (summing four components instead of three);

- revise the therapy rate calculation;
- modify the cost report;
- merge diagnosis information from the patient's preceding hospital stay (until SNF claims include more accurate information); and
- notify and educate providers about the PPS revisions.

Introducing an outlier policy would also add steps to determining facility payments, consistent with methods used to calculate outlier payments in the psychiatric hospital PPS. Outlier cases would need to be identified by calculating per stay ancillary costs (by summing the ancillary charges for a stay and converting the charges to costs using each facility's ratio of charges to costs) and comparing the costs with the fixed-loss amount adjusted by each facility's area wage index. Because outlier status cannot be determined until after the stay is complete, outlier payments could be made only at the end of the SNF stay.

A LUPA policy for therapy services would require CMS to compare the predicted therapy costs of a stay (from the therapy payment component) with the stay's actual therapy costs (calculated from the steps to determine a case's outlier status). CMS would need to define a threshold ratio of actual-to-predicted costs, below which stays would be paid on a cost basis for the therapy services they furnished. For example, if a stay's actual therapy costs were 20 percent of the predicted costs, the therapy payment would be based on the stay's actual costs. As with the outlier policy, CMS would need to determine LUPA payments at the end of the stay.

The revised PPS would require CMS to educate providers about the NTA and the revised therapy components and the LUPA and outlier policies. If the MDS were modified to identify the SNF-provided services, facilities would have to train their assessors on how the assessment tool's questions had changed. SNFs would need to ensure that they had mechanisms in place to receive diagnosis information from hospitals about incoming patients.

Transitional policies can ease major changes to a payment system. In the case of a revised SNF PPS, if a transition period is used, it should be short (less than three years), during which time CMS would pay facilities based on a blend of "old" and "new" systems. A short transition period would hasten the ability of the PPS to pay SNFs appropriately. Most SNFs that would experience large payment reductions had high Medicare margins, whereas most SNFs whose payments would increase by more than 10 percent had negative margins.

We appreciate the competing demands on CMS's time and its limited resources to implement the required changes. However, we believe the work required to make the changes is outweighed by having a PPS that would establish more accurate payments and offer facilities some financial protection from exceptionally costly stays. Because payments would more closely track provider costs, the revisions would enhance access for patients with high care needs and eliminate the incentives of the current system to avoid these patients.

TABLE 7–9

Revised PPS designs use currently available data

Predictor	Data collection effort
Activities of daily living Physical and mental status MDS assessment indicator Patient had a prior nursing home stay	Collected by the MDS
Intravenous medication use in SNF Respiratory care in SNF	Collected by the MDS and SNF claims; requires CMS to confirm that services were furnished during the SNF stay (and not during the preceding hospital stay). Modifications to MDS would eliminate this step.
Broad RUG category Rehabilitation indicator	Collected by the MDS. Calculated by CMS; no additional effort.
Diagnostic information from prior hospital stay	Collected by hospitals; requires hospitals to transfer information to the SNF and CMS to merge hospital and SNF information.

Note: PPS (prospective payment system), MDS (Minimum Data Set), SNF (skilled nursing facility), RUG (resource utilization group).

Source: MedPAC analysis of data elements required by PPS redesigns modeled by the Urban Institute.

Better data would enhance PPS payment accuracy and evaluation

Additional information that is currently not available about SNF care would enhance the accuracy of payments and the ability to evaluate the value of the care furnished. Three improvements are discussed here: obtaining accurate SNF diagnostic information, recording the services furnished since admission to the SNF (and the date of service), and gathering nursing cost information.

Accurate SNF diagnostic information

The Commission previously noted that accurate information about patient diagnoses and comorbidities would facilitate categorizing patients into case-mix groups with similar care needs (MedPAC 2007b). More complete information would also help adjust for differences in patient mix across facilities when comparing costs, payments, and outcomes. Freestanding SNFs often do not code secondary diagnoses, whereas hospital-based facilities frequently use a general rehabilitation diagnosis code that does not convey sufficiently specific information about the patient (Urban Institute 2007). SNF claims have fields for recording specific diagnosis codes but the data are not required for payment.

Concurrent with the adoption of payment components that use diagnosis information to establish payments, diagnosis fields on SNF claims should become required fields. SNFs should use the full five-digit International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) codes to describe the principal diagnosis and comorbidities of each patient stay. If CMS instructed its claims contractors to reject claims without this information, providers would quickly comply with the requirement.[20] As this information becomes available on SNF claims, the predictive models used by the NTA and therapy components could use these data. Under the revised PPS, SNFs would have a financial incentive to include diagnosis codes on their claims. Therefore, CMS will need to monitor changes in case mix as recorded on the SNF claims and assess the portion that reflects real changes in the complexity of cases treated.

Services furnished by SNFs

CMS also needs better information about the services furnished during a patient's SNF stay so that payments are accurate. The existing MDS patient assessment tool requires SNFs to report on NTA services provided during a look-back period of 14 days that, for a patient's first assessment (on or about day 5 of the stay), can include services provided during the preceding hospitalization. In comparing NTA service information from the patient assessment and SNF claims, researchers found that almost half the stays indicated the patient's use of IV medication but few SNF claims had charges for the services. The researchers concluded that the services were either furnished during the prior hospital stay or were low-cost services that facilities did not consistently report (Urban Institute 2007).

Although a July 2007 version of the revised MDS distinguished services furnished in the past five days from those provided since admission to the SNF, a more recent draft version of the revised MDS did not retain this distinction. Instead, the January 2008 draft version reverted to the existing requirement for SNFs to report services furnished during the past 14 days. This look-back period will continue to preclude distinguishing between services furnished since admission to the SNF and those furnished during the prior hospital stay. In a comment letter to CMS, the Commission urged the agency to fix this problem in the revised MDS (MedPAC 2008a).

Better information about when services were provided would also help predict daily costs more accurately and could be used to assess the value of services. SNFs typically bill for services on a monthly basis and claims include the numbers of units furnished but not the dates of service. To estimate daily costs, per stay costs are averaged over the number of days in the stay, even though higher costs could be incurred early in the stay. For patients whose care needs change throughout a stay, it is difficult to accurately apportion patient costs to each day. In addition, dates of service would allow costs to be linked to patient assessment information.

Nursing costs

Accurate nursing cost information is key to measuring cost differences in care needs across patients. CMS gathers staff times on individual patients that are used to establish the nursing component relative weights. These studies are expensive to administer and therefore are undertaken only periodically with a sample of facilities. Since the PPS was implemented in 1998, CMS has collected these data only once and the study's results are not expected until later this year. CMS will need to carefully examine the representativeness of the study's stays and facilities before it uses the information to update the payment weights for Medicare payments.

CMS needs facility-level nursing cost information so that it can evaluate the relationships among case mix, costs,

quality, and staffing. Many Medicaid cost reports require this information. In 2004, the Commission recommended that the Secretary require SNFs to report nursing costs separately from routine costs in the SNF Medicare cost report (MedPAC 2004). It would be useful to have this information categorized by type of nurse (registered nurse, licensed practical nurse, and nurse aide), which most facilities' payroll systems can report.

In addition to better facility-level cost data, CMS needs a relatively easy way to estimate the nursing costs of individual patients. Using administrative data would allow CMS to routinely recalibrate the nursing weights used to establish payments, thereby keeping Medicare's payments accurate. One idea to explore is for nursing homes to use an expanded set of service codes to bill for nursing services. Different daily service codes and charges could reflect different levels of nursing services. For example, facilities could use separate billing codes to reflect daily nursing services provided to long-stay patients, post-acute patients, and patients with special care needs (e.g., being weaned from a ventilator or having wound dressings changed). With different levels of nursing care reflected in a patient's claim, charges (which could be converted to costs) could be used to establish the relative weights associated with each case-mix group. CMS uses charges to update the relative weights in other PPSs.

To improve the accuracy of the payment system, CMS needs better data about the patients treated in SNFs and the services furnished to them. SNF claims need to include diagnostic information and the dates when services were furnished to patients. The MDS needs to distinguish services furnished by the SNF from those provided during the prior hospitalization. Because nursing care is a key component of the services a patient receives, facilities need to report their nursing costs separately from routine costs in their Medicare cost reports.

RECOMMENDATION 7B

The Secretary should direct skilled nursing facilities to report more accurate diagnostic and service-use information by requiring that:

- **claims include detailed diagnosis information and dates of service,**
- **services furnished since admission to the skilled nursing facility be recorded separately in the patient assessment, and**
- **skilled nursing facilities report their nursing costs in the Medicare cost reports.**

RATIONALE 7B

Establishing accurate payment rates and understanding differences across patients and SNFs requires better clinical and service-use information. These data would also allow the value of SNF care to be assessed. The data could be used to improve risk-adjustment methods so that payments could be accurately predicted and compared across SNFs and patients.

IMPLICATIONS 7B

Spending

- This recommendation would not affect federal program spending relative to current law.

Beneficiary and provider

- This recommendation would not directly affect beneficiaries but could improve access if the data resulted in more accurate payments.
- Providers would incur modest expenses to report the data included in this recommendation. Most facilities' payroll systems can report payroll expenses by nursing category and many states' Medicaid cost reports require providers to report nursing costs. SNFs would have to train patient assessors on changes to the questions in the revised MDS. SNFs would have to learn to use the ICD–9–CM coding scheme to accurately report the active medical conditions of their patients. More accurate diagnosis coding could increase payments to some providers and decrease payments to others.

CMS would need to make several changes to gather the additional data items. The Medicare cost report would need to be revised to include nursing cost information. Revised MDS forms and manuals would need to be produced and providers made aware of the changes. The July 2007 version of the MDS includes revised questions that ask about services furnished by the SNF. The SNF claims do not need to be modified; there is already space on them for diagnosis codes, service codes, and dates of service. ■

Endnotes

1 Urban and rural SNFs have separate base rates, which are adjusted for differences in labor costs.

2 Under the original case-mix groups, patients requiring both therapy and extensive services were grouped into rehabilitation RUGs because the classification system is hierarchical and the payments associated with rehabilitation RUGs were higher than those associated with extensive services RUGs.

3 Under the current PPS, some facilities appear to furnish just enough therapy services to classify patients into the highest possible case-mix group. A comparison of the minutes of therapy patients received and the minimum number of minutes required to be classified into a case-mix group found that patients often receive the minimum amount of therapy to qualify for a payment group. Some patients do not receive even the minimum because an estimate of the minutes a patient will receive can be used to qualify them for certain case-mix groups (GAO 2002). CMS reported that in 2003 fewer patients received the minimum qualifying minutes than when the PPS was implemented, but the pattern persists (CMS 2006).

4 Variables in the New Profiles and the RUG–58 + service index models were evaluated (MedPAC 2007b, Urban Institute 2007).

5 Broad RUG categories include rehabilitation, rehabilitation and extensive services, extensive services, special care, and clinically complex.

6 The number of assessments conducted on a patient was used as a proxy for length of stay. Nursing homes are federally required to assess each patient's functional, mental, and behavioral status at set intervals throughout a patient stay using the Minimum Data Set. The number of assessments conducted on a patient increases with the length of the stay.

7 We used patient assessment variables from the Minimum Data Set 2.0. When this assessment tool is updated, the design will be revised to include measures from the most current version. Key factors—such as a patient's physical and mental status, ability to perform activities of daily living, and certain service use—are likely to continue to be important in explaining cost differences across patients. We do not expect such substitutions to significantly change our conclusions.

8 Freestanding SNFs use the International Classification of Diseases, Ninth Revision, codes much less frequently than hospital-based SNFs. As a result, measuring case mix using SNF claims would "shortchange" freestanding SNFs. In addition, hospital-based SNFs regularly use very general rehabilitation diagnosis codes that do not include much information.

9 The accuracy of each design was evaluated by comparing its estimated per day costs with the actual costs per day. Actual costs were calculated by converting charges on SNF claims (using 2003 data) to costs using cost-to-charge ratios (CCRs) derived from each facility's Medicare cost report. For each facility, separate CCRs were calculated for drugs, respiratory therapy, rehabilitation therapy, and other NTA services when data were available. When data were missing, the CCR for the next higher level of service aggregation was used. For example, the CCR for total NTA services was used if data were not available to calculate a CCR for drugs.

10 Certain variables (HIV or organ transplant diagnosis from the hospital stay) were kept in the models even though they describe few cases. However, excluding them would decrease the model's ability to predict resource use for those patients and the facilities that treat them. Many variables were examined but dropped because they did not contribute significantly to the explanatory power of the models. Dropped variables included: the activity of daily living measuring a patient's ability to transfer to and from bed, chair, and standing position; the share of SNF stays with prior hospital stays with high severity of illness (scores of 3 or 4); high drug charges in the prior hospital stay; radiology charges in the prior hospital stay; speech–language pathology charges in the prior hospital stay; rehabilitation therapy charges in the prior hospital stay; and a composite measure for activities of daily living (the Barthel index score).

11 We distinguish between the CMI coefficient of the payment system design and the CMI for a given facility.

12 A coefficient greater than 1.0 is sometimes referred to as CMI compression, whereas a CMI less than 1.0 is known as CMI decompression.

13 The three elements—fixed loss amount, pool size, and loss ratio—are interrelated. For a given loss ratio, a large pool size means that cases with smaller losses will qualify for an outlier payment. A fixed loss amount determines the pool size by identifying the cases that qualify. When the pool size has been set, the loss-sharing ratio affects the fixed loss amount because the upper limit on outlier spending has been capped. Setting the share of costs paid above the threshold amount and the upper limit on outlier spending will determine the fixed loss amount.

14 To keep the share of the daily rate that is adjusted for differences in wages the same as existing policy, we adjusted the NTA, therapy, and nursing base payments for differences in area wages using the 2003 labor-related share. Drugs and supplies are not included in the share of costs that is adjusted for differences in wages.

15 Although consistent with outlier policies of other PPSs, the 80 percent loss-sharing ratio may be high. Our analysis of the outlier policy parameters for inpatient hospitals found that 80 percent was likely to overstate marginal costs. For a discussion of the Commission's analysis of inpatient hospital marginal costs, see http://www.medpac.gov/transcripts/1003-04medpac.final.pdf. To more accurately reflect the lower daily costs of longer stays, another refinement to consider is a loss-sharing ratio that declines after the median length of stay. The psychiatric hospital PPS outlier policy includes two loss-sharing ratios that vary according to day of stay.

16 The best predictive NTA and therapy designs include the patient and stay characteristics listed in Table 7-1, the diagnostic information from the preceding hospitalization, a broad RUG indicator, and whether the patient received IV medications.

17 The shares of cases and facilities that would receive an outlier payment are very similar to the shares that would receive one if an outlier policy were included with current policy.

18 The PPSs for long-term care and rehabilitation hospitals establish separate payments for unusually short stays. The acute inpatient PPS reduces payments when patients have short stays and are transferred to another hospital covered by the acute hospital PPS or, for stays grouped into 182 case-mix groups, are discharged to a post-acute care setting.

19 The researchers at the Urban Institute previously found that the MDS variable alone was an unreliable indicator of NTA services in the SNF. This is because the MDS questions about NTA use refer to services patients received in the past 14 days. Depending on when the assessment is conducted, this "look-back period" can include services provided at the hospital. This step would not be needed if the MDS were modified to gather information about NTA services provided during the SNF stay. In addition, the match appears to indicate high NTA use. Patients with both a claim and indication in the MDS for the service had above-average NTA costs.

20 When CMS needed revenue codes from outpatient therapy providers to operationalize the therapy caps, its contractors rejected claims without revenue codes; within a year, most claims contained this information.

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CHAPTER 8

Evaluating Medicare's hospice benefit

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Chapter summary

Medicare's hospice benefit, which provides palliative care and support services for terminally ill patients and their families, has grown considerably since its inception in 1983. CMS estimates that Medicare spending under the hospice benefit exceeded $10 billion in fiscal year (FY) 2007, more than the program spends on inpatient rehabilitation hospitals, critical access hospitals, long-term care hospitals, psychiatric hospitals, comprehensive outpatient rehabilitation facilities, or ambulatory surgical centers. Medicare spending for hospice is expected to more than double in the next 10 years (OACT 2008) and will account for roughly 2.3 percent of overall Medicare spending in FY 2009.

Spending growth has been driven by increased numbers of beneficiaries using hospice and longer hospice stays for those who elect the benefit. In 2005, roughly 40 percent of Medicare decedents used hospice, compared with only 27.3 percent in 2000. Between 2004 and 2005, the number of beneficiaries using hospice increased by 10 percent, hospice spending per user increased by nearly 8 percent, and overall spending on hospice grew by nearly 20 percent (CMS 2007a). By contrast, total

In this chapter

Medicare enrollment increased by about 2.5 percent, per capita spending increased about 7.1 percent, and total spending grew by 8.9 percent over this period.

Because of the per diem–based structure of Medicare's hospice payment system, increased spending per beneficiary has been driven largely by increases in the average length of stay in hospice. Part of this increase reflects changes in the mix of patients electing hospice. At the outset of the hospice benefit, most patients who elected hospice had terminal diagnoses such as cancer and other relatively acute conditions for which a reasonably certain prognosis of death within six months could be established. Now, cancer patients are a minority (although still a substantial percentage) of hospice enrollees. Patients with diagnoses such as Alzheimer's disease, nonspecific debility, and congestive heart failure, who typically have longer stays, make up the majority of Medicare's hospice patients. However, change in patient mix does not entirely explain the increases in hospice length of stay we observe.

Concomitant with the change in patient mix, a small but growing number of hospices are exceeding an aggregate per beneficiary limit on Medicare payments, the more prominent of two so-called "hospice caps." The caps were implemented at the beginning of the benefit to ensure that hospice care would be less costly than curative treatments for terminal conditions, and that hospice would not become a de facto long-term care benefit. Some have expressed concerns that large cap assessments would force hospices to close, affecting beneficiary access to hospice care.

We found that hospices with payments exceeding the cap differed from those with payments remaining below the cap, generally having a higher percentage of patients with terminal diagnoses associated with longer hospice stays, such as dementia and congestive heart failure, than hospices that did not exceed the cap. However, patient mix alone did not explain why hospices exceeded the cap. Across all diagnoses, the average length of stay for above-cap hospices exceeded that for below-cap hospices by 23 percent

to 122 percent. These findings suggest, among other issues, the presence of financial incentives in Medicare's hospice payment system to provide long stays that may lead some hospices to exceed the cap. These incentives may work to undermine one of the fundamental premises underlying the establishment of the hospice benefit, that in addition to offering beneficiaries a choice in their end-of-life care consistent with their wishes to avoid intensive medical interventions, the hospice benefit would result in lower Medicare spending relative to conventional end-of-life care. Additionally, certain market issues may affect whether hospice programs are at greater risk of exceeding the cap. Analyses of hospice length of stay on a market-by-market basis may shed additional light on this question.

In comparing Medicare's payments with hospices' costs, we found that payments were generally adequate in the aggregate but that hospices' financial performance under Medicare varied considerably. The aggregate Medicare margin for all hospices was 3.4 percent in 2005. Hospices that exceeded the cap had among the highest Medicare margins (before the return of overpayments), as longer stays under this payment system led to higher margins. Because of the lack of data on services provided to patients with specific diagnoses, we could not determine the adequacy of Medicare payments relative to the cost of hospice care on a condition-specific basis, nor could we determine conclusively whether the payment system encourages or discourages the admission of certain patients to hospice on the basis of their profitability.

Hospice care has changed significantly in the 25 years since Medicare implemented the hospice benefit, with the most significant changes occurring in the last seven years. Hospice was a niche benefit at first, but in 2007 nearly 40 percent of Medicare decedents had used the hospice benefit. CMS encouraged use of hospice for clinically appropriate patients on multiple occasions since 2000. The profile of the beneficiary population electing hospice has changed considerably, as has the profile of hospice providers. Most hospice providers in 1983 were nonprofits affiliated with

religious or community organizations. Now, for-profit hospices make up a majority of providers and constitute the vast majority of the new entrants into the Medicare program since 2000.

During this time of major change, Medicare's payment system for hospice care has changed relatively little. Payments have been updated over time, but otherwise the basic structure is much as it was in 1983, with per diem reimbursements for four types of care, and few reporting requirements to assist in refining or evaluating the benefit. As a result, changes in the provision of hospice care have exposed weaknesses in the Medicare payment system and adverse incentives that may unduly influence some hospices to provide care in a manner not warranted by patients' clinical needs. CMS has begun efforts to improve the availability of data that could inform payment system improvements and is developing measures to assess the quality of end-of-life care that could be relevant to improvements in the Medicare hospice payment system. Substantially more data will be needed—data that historically have been uniquely lacking in hospice—to address these concerns and modernize Medicare's payment system for hospice. ■

Medicare's hospice benefit

Medicare began offering a hospice benefit in 1983, pursuant to the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). The benefit covers palliative and support services for terminally ill beneficiaries who have a life expectancy of six months or less if the terminal disease follows its normal course. Two physicians, typically the patient's doctor and a hospice physician, must certify the prognosis for a patient to be eligible to elect hospice. Covered services include:

- nursing care provided by or under the supervision of a registered nurse;
- medical social services provided by a social worker under the direction of a physician;
- physicians' services;
- counseling services provided to the patient and family members or other persons caring for the patient at home;
- short-term inpatient care (including respite care) provided in a participating hospice inpatient unit or a participating hospital or skilled nursing facility;
- medical appliances and supplies;
- drugs and biologicals related to the individual's terminal illness;
- home health aide services and homemaker services;
- certain physical therapy, occupational therapy, and speech–language pathology services for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills;
- any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions; and
- bereavement services available for the patient's family for up to a year after the patient's death.

Beneficiaries must "elect" the Medicare hospice benefit; in so doing, they agree to forgo Medicare coverage for curative treatment for the terminal illness. Medicare continues to cover items and services unrelated to the terminal illness. A written plan of care must be established and maintained by the attending physician, the medical director, or the physician designee and by an interdisciplinary group for each person admitted to a hospice program, according to Medicare's current conditions of participation.[1] In addition to the physician, the interdisciplinary group consists of a registered nurse, social worker, and pastoral or other type of counselor. Hospices are also required to use volunteers to provide services equal to at least 5 percent of total paid patient care time. The plan of care must assess the patient's needs, identify services to be provided (including management of discomfort and symptom relief), and describe the scope and frequency of services needed to meet the patient's and family's needs.

Beneficiaries elect hospice for defined benefit periods. These periods have changed over time in significant ways. When first established under TEFRA, the Medicare hospice benefit incorporated a fairly tight benefit period structure. A beneficiary could elect hospice for a 90-day coverage period, followed by (if necessary) a second 90-day period, and a subsequent 30-day period. Beyond this total 210-day period, Medicare's coverage ceased. The Medicare Catastrophic Coverage Repeal Act of 1989 and the Balanced Budget Act of 1997 eased this limit. Under the current policy, the first hospice benefit period is 90 days. If the patient's terminal illness continues to engender the likelihood of death within 6 months, the patient can be recertified for another 90 days. After the second 90-day period, the patient can be recertified for an unlimited number of 60-day periods, as long as he or she remains eligible. Beneficiaries can switch from one hospice to another once during a hospice election period and can disenroll from hospice at any time.

The relaxation of the initial limits on the length of time a beneficiary could enroll in hospice has created a tension with one of the key coverage criteria for use of the benefit—the prognosis of likely death due to a terminal condition within six months. The criterion of impending death still governs eligibility for a Medicare beneficiary's admission to hospice; once admitted, however, beyond the episodic need for recertification by the patient's physician and the hospice director, there is no limit on the duration of time a beneficiary can receive hospice care. Average length of enrollment in hospice has been increasing since the coverage period was expanded in 1997 (MedPAC 2006, OIG 1997).

Medicare payment for hospice

The Medicare program pays a daily rate to hospice providers for each day a beneficiary is enrolled in

TABLE 8–1

Medicare pays for four categories of hospice care

Category	Description	Base payment rate, FY 2008	Labor share, FY 2008	Share of days, FY 2005
Routine home care (RHC)	Home care provided on a typical day	$135 per day	69%	94.9%
Continuous home care (CHC)	Home care provided during periods of patient crisis	$32.86 per hour	69	2.8
Inpatient respite care (IRC)	Inpatient care for a short period to provide respite for primary caregiver	$140 per day	54	0.2
General inpatient care (GIC)	Inpatient care to treat symptoms that cannot be managed in another setting	$601 per day	64	2.2

Note: FY (fiscal year). Payment for CHC is an hourly rate for care delivered during periods of crisis if care is provided in the home for 8 or more hours within a 24-hour period beginning at midnight. A nurse must deliver half of the hours of this care to qualify for CHC-level payment. The minimum daily payment rate at the CHC level is $263 per day (8 hours at $32.86 per hour); maximum daily payment at the CHC level is $789 per day (24 hours at $32.86 per hour). Shares of days may not sum to 100 percent due to rounding.

Source: Base payment rates and labor shares are from CMS Manual System Pub. 100–04 Medicare Claims Processing, Transmittal 1280, "Update to the Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice Pricer for FY 2008." Data on share of days are from CMS's analysis of 100 percent hospice standard analytical files from CMS for fiscal year 2005.

hospice. The hospice assumes all financial risk for costs and services associated with care related to the patient's terminal illness. The hospice provider receives payment for every day a patient is enrolled, regardless of whether the hospice provided a visit to the patient each day. This payment design encompasses the costs a hospice incurs for on-call services, care planning, drugs, medical equipment and supplies related to the patient's terminal condition, patient transportation between hospice care sites, and other less frequently used services. Payments are made according to a fee schedule that has base payment amounts for four categories of care: routine home care, continuous home care, inpatient respite care, and general inpatient care. The payment rates have been increased for inflation and on occasion have been adjusted via specific legislative provisions, but the payment methodology and the base rates for hospice care have not been updated since initiation of the benefit.

The four payment categories are distinguished by the location and intensity of the services provided. The base payment rates are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index (Table 8-1).[2] A hospice is paid the routine home care rate for each day the patient is enrolled in hospice, unless the hospice provides continuous home care, inpatient respite care, or general inpatient care. Routine home care accounts for the vast majority of hospice care days.

Beneficiary cost sharing for hospice services is minimal. Hospices may charge a 5 percent coinsurance (not to exceed $5) for each drug furnished outside the inpatient setting. For inpatient respite care, beneficiaries are liable for 5 percent of Medicare's respite care payment per day, not to exceed the Part A inpatient deductible, which was $992 per benefit period in 2007.

Medicare hospice payment limits ("caps")

The Medicare hospice benefit was designed to give beneficiaries a choice in their end-of-life care, allowing them to forgo intensive conventional treatment (often in inpatient settings), and die with dignity at home and with family according to their personal preferences. The inclusion of the Medicare hospice benefit in TEFRA was based in large part on the premise that the new benefit would be a less costly alternative to conventional end-of-life care (GAO 2004, Hoyer 2007).[3] To achieve this outcome, when the Congress established the hospice benefit it included two limitations on payments to hospices, or "caps."

The most visible cap limits the average annual payment per beneficiary a hospice can receive from the program. This cap was implemented at the outset of the hospice benefit to ensure that Medicare payments did not exceed the cost of curative care for patients at the end of life. If a hospice's total payments divided by its total number of beneficiaries exceed the cap amount, it must repay

the excess to the program.[4] This cap is not applied individually to the payments received for each beneficiary but to the average of payments across all patients admitted to the hospice in the cap year. Medicare updates the payment cap amount by the medical expenditure category of the consumer price index for urban consumers but does not adjust it for geographic differences in cost. As a result, an agency serving a lower wage area can provide more days of care per beneficiary before reaching the cap than an agency serving a higher wage area.[5]

Because the per beneficiary payment cap is averaged across all of a hospice's patients, a hospice can stay below the cap by admitting the types of patients whose expected lengths of stay will enable the hospice's per patient payments to remain below the limit. Hospices are likely to exceed the cap when a disproportionately large share of their patients have longer stays that result in payments above the cap, or when a smaller share of their patients have very long stays that affect their aggregate average. The number of hospices exceeding the average annual payment cap has historically been low. The Government Accountability Office found that, between 1999 and 2002, fewer than 2 percent of hospices reached the cap (GAO 2004).

With rapid growth in Medicare hospice spending in recent years, this hospice cap is the only significant fiscal constraint on the growth of program expenditures for hospice (Hoyer 2007). This stricture has been called into question as more hospice providers have exceeded the Medicare payment limit since 2004.

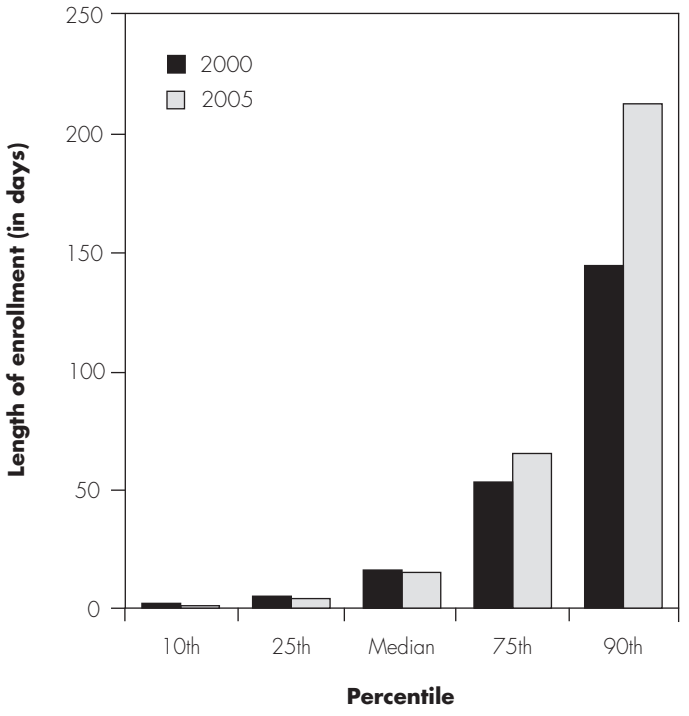
Cost of hospice relative to curative care at end of life

Research studies on the effects of hospice enrollment on Medicare spending have shown that beneficiaries who elect hospice incur less Medicare spending in the last two months of life than comparable beneficiaries who do not, but also that Medicare spending for beneficiaries is higher for hospice enrollees in the earlier months before death than it is for nonenrollees.[6] In essence, hospice's net reduction in Medicare spending decreases the longer the patient is enrolled, and beneficiaries with very long hospice stays may incur higher Medicare spending than those who do not elect hospice. Despite methodologic and conceptual difficulties intrinsic to assessing the effect of hospice use on Medicare spending at the end of life, several points of agreement have emerged:

- In the last month of life, Medicare spending is less for patients who use hospice than for patients who opt for conventional curative treatment.
- The spending differential occurs through the substitution of less costly hospice care for more costly hospital inpatient care.
- Medicare spending may be less for hospice patients than for comparable nonhospice patients in the fourth through second months before death, but patient-specific or other factors may affect the cost relationship in these months.
- Total Medicare spending for patients enrolled in hospice is higher than for patients not enrolled in each month beginning as early as the third month before death but definitively so by the sixth or seventh month before death.
- The hospice spending differential is not uniform across all terminal diseases.[7]
- Hospice use is more likely to result in lower Medicare spending for patients with shorter stays in hospice and for patients with conditions that typically require inpatient care at the end of life (e.g., cancer); hospice use results in higher spending relative to conventional end-of-life care for patients with long hospice stays or patients whose terminal diseases would normally incur lower levels of inpatient care (e.g., Alzheimer's disease).
- For the last year of life, there are no significant differences in Medicare spending for decedents who enrolled in hospice and those who did not.

Hospice can result in lower Medicare spending relative to conventional treatment at the end of life, but most of this reduction occurs through the reduced use of Part A services in the last month or two of life; hospice care in earlier months before death incrementally increases spending. Thus, from a fiscal perspective, the Medicare program has an incentive to ensure that the timing of the hospice admission reflects optimal use of the benefit. Although opinions based on existing studies vary about the specific point when hospice admission should occur, the six-month presumptive eligibility period appears to represent a reasonable upper bound. Should the program desire greater reductions in spending, eligibility could be

FIGURE 8–1 **Long hospice stays are getting longer, while short stays persist**



Note: Data are for decedent beneficiaries in both fee-for-service Medicare and Medicare Advantage.

Source: MedPAC analysis of 2007 100 percent Medicare Beneficiary Database file from CMS.

established at a shorter period of time, although reducing the benefit period may exclude beneficiaries from hospice because of difficulties in predicting death for certain illnesses (see Kinzbrunner 1998).

The per beneficiary payment cap serves as an external brake on hospice spending. For the period ending October 31, 2004, the cap limited hospice payments to an average of $18,963.47 per beneficiary (CMS 2007c). By contrast, spending per beneficiary in the last year of life for all Medicare services was $22,107 (KFF 2007). The hospice cap, designed to cover six months of hospice care, appears to be sufficient, on average, to cover 85 percent of the cost of curative care during the last year of life. (In practice, the way the cap is applied with respect to patients whose hospice use spans a cap year changes this relationship somewhat.) Increasing the cap amount, as some have suggested, would work against the financial interests of the Medicare program by moving the hospice benefit farther from the original congressional expectation that the benefit result in lower Medicare spending relative to conventional end-of-life care.

Trends in hospice utilization

In recent years, Medicare spending for hospice care has increased dramatically, and the CMS Office of the Actuary projects continued robust growth. Spending reached $10 billion in fiscal year (FY) 2007 and is expected to more than double over the next 10 years (OACT 2008). This spending increase is driven by greater numbers of beneficiaries electing hospice as well as longer hospice stays.

Hospice length of stay continues to increase

Most hospice users have hospice care episodes of less than six months, but the number of long hospice episodes is increasing. Between 2000 and 2005, the length of hospice episodes decreased slightly for patients with stays below the median, whereas the length of stays above the median substantially increased. In 2005, beneficiaries in hospice at the 90th percentile for length of stay had stays of 212 days, an increase of nearly 50 percent from 2000 (Figure 8-1).

CMS reports that, between 1998 and 2000, the national average length of stay for hospice patients was unchanged at 48 days; between 2000 and 2005, it increased by 40 percent to 67 days (CMS 2007a).[8] Similar trends occurred regarding growth in the percentage of patients who used hospice beyond the initial six-month benefit period. The National Hospice and Palliative Care Organization (NHPCO) documented an increase in the number of patients who received hospice care from their member organizations and who died after more than six months in hospice (NHPCO 2005). Between 2001 and 2004, the percentage of these hospice patients grew from 5.7 percent to 9.2 percent. The Commission currently estimates that, in 2000, more than 14 percent of beneficiaries who used hospice had election periods exceeding 180 days; by 2005, that share had grown to nearly 21 percent.[9]

Longer hospice stays consistent with growth in noncancer diagnoses

The length of a patient's enrollment in hospice is closely correlated with the patient's terminal diagnosis (Campbell et al. 2004, MedPAC 2006, Nicosia et al. 2006). From 2000 to 2005, CMS reported that the average number of hospice days per patient increased by an average annual

TABLE 8–2

Average length of hospice stays has steadily increased for selected high-volume diagnoses

Diagnosis	Average hospice days per patient						Percent change, 2000–2005	Average annual percent change, 2000–2005
	2000	2001	2002	2003	2004	2005		
Alzheimer's disease	66	73	84	93	96	99	50.0%	8.4%
Senile dementia	57*	64*	69	78	84	85	49.1	8.3
Debility–not otherwise specified	51	56	59	65	70	73	43.1	7.4
Adult failure to thrive	32*	50*	63	70	76	78	143.8	19.5
Total – All diagnoses	48	51	57	63	65	67	39.6	6.9

Note: *Did not emerge into the top 10 diagnosis codes until 2002.

Source: CMS, "Medicare Hospice Data - 1998–2005." http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/downloads/HospiceData1998-2005.pdf. Accessed September 2007.

rate of 8.4 percent for patients with Alzheimer's disease, 8.3 percent for patients with senile dementia, 7.4 percent for patients with nonspecific debility, and nearly 20 percent for patients diagnosed with adult failure to thrive (Table 8-2). The CMS-reported average annual change in length of stay for hospice patients for the top 10 diagnoses over this period was just under 7 percent. These trends suggest that not only are the lengths of stay for patients with cerebral degenerative diseases and other nonspecific diagnoses higher than those for patients with more acute terminal diseases such as cancer but also that the lengths of stay for these patients are growing somewhat faster than for other patients.

The Commission also examined length of stay by patient diagnosis (Table 8-3, p. 212). In general, a relatively small number of disease categories account for all admissions to hospice. In 2005, cancer (both lung and other types) accounted for 36 percent of hospice admissions, heart failure and other circulatory diseases represented almost 20 percent of admissions, and Alzheimer's disease and other cerebroneurological disorders accounted for about 17 percent of admissions. Patients with Alzheimer's disease or senile dementia had longer stays than patients with cancer or cerebrovascular disease. Further, episodes of greater than 180 days typically represented a larger share of overall stays for these diagnoses than did stays for more acute diagnoses. About 25 percent of patients admitted to hospice with dementia had stays of more than 180 days, compared with just over 7 percent of patients with lung cancer.

The full import of these differences in utilization patterns is unclear. Given the greater difficulty in predicting death for diagnoses such as Alzheimer's disease (Lynn and Adamson 2003, Lynn et al. 1997), it is not surprising that the average length of stay is greater for these patients than for other hospice patients. However, we do not yet fully understand why the average length of stay is growing faster for these patients than for those with other diagnoses.

Characteristics of hospices exceeding the payment cap

We posited that differences in patient mix may help explain differences in length of stay and thus illuminate why some hospices exceed the cap while others do not. We wanted to assess whether this hypothesis had merit, or whether other factors—either specific to hospices that exceed the cap or to characteristics of their markets—could explain these patterns.

In 2006, MedPAC examined data from the four regional home health intermediaries (RHHIs), the contractors that process and pay Medicare hospice claims. We found that an increasing number of hospices exceeded the aggregate annual per beneficiary cap and hospices served by a single intermediary accounted for nearly all of the increase (MedPAC 2006).[10] (The 20 percent inpatient cap is rarely reached, according to data from the RHHIs.)

TABLE 8–3 **Average days per hospice patient, by disease category, all diagnoses, 2005**

Disease category	Number of patients	Days per patient: Mean	Median	90th percentile	Percent of cases >180 days	Diagnosis share of total cases
Cancer (except lung cancer)	198,920	46	20	123	8.7%	25.6%
Circulatory diseases (except heart failure)	82,853	55	12	178	17.7	11.3
Lung cancer	81,474	44	19	115	7.4	10.4
Heart failure	61,194	63	21	186	18.7	8.4
Nonspecific debility	54,101	68	25	193	19.0	7.4
Alzheimer's and related diseases	42,756	86	35	252	29.3	6.2
Chronic airway obstruction, NEC	42,291	70	25	213	22.6	5.9
Unspecific symptoms/signs	39,337	69	26	197	19.6	5.4
Dementia	30,966	75	27	223	24.9	4.4
Organic psychoses	24,189	74	27	223	23.8	3.4
Genitourinary diseases	23,697	22	6	59	3.9	3.0
Nervous system diseases (except Alzheimer's)	19,175	81	35	236	26.2	2.7
Respiratory diseases	18,744	43	8	135	11.6	2.4
Other	14,740	46	12	141	12.8	1.9
Digestive diseases	11,932	37	11	105	8.2	1.5

Note: NEC (not elsewhere classifiable).

Source: MedPAC analysis of 2005 100 percent hospice standard analytical file from CMS.

The differences in shares of hospices reaching the cap across the four RHHIs raised the question of whether providers exceeding the cap were concentrated in certain regions or whether all the RHHIs consistently applied either hospice admissions guidance or the cap calculation payment methodology. Our analysis suggests that differences in the cap calculation methodology did not cause this pattern. Instead, provider characteristics, patient diagnoses, and market conditions were more closely correlated with the likelihood of a provider exceeding the cap. Ownership was a major factor; for-profit hospices are much more likely to exceed the cap than nonprofit hospices. Treating a disproportionate share of patients with diagnoses associated with longer lengths of stay, and market conditions, were also important factors.

The Commission used hospice-level data aggregated from hospice cost reports, CMS's Provider of Services records, and claims for 2002 through 2005 to create a model for calculating the cap on a hospice-specific basis. A summary of our results appears in Table 8-4.[11] The number of hospices exceeding the cap, although having grown steadily between 2002 and 2005, remained relatively small, with just under 8 percent of hospice providers exceeding the cap in 2005. Medicare payments over the cap attributable to these hospices represented 2 percent of total hospice payments in 2005, suggesting that they are smaller providers in terms of their Medicare patient load and revenues.

Table 8-5 lists the types and percentages of hospices that exceeded the cap for 2002 through 2005. Ownership status appeared to be a key factor in those hospices exceeding the cap; more than 84 percent of hospices that exceeded the cap in any year were for-profit entities. This pattern held regardless of whether the hospice was freestanding or provider based (most for-profit hospices are freestanding). In all years, 90 percent or more of the hospices that exceeded the cap were freestanding facilities.

Hospices exceeding the aggregate per beneficiary payment cap were more likely to have smaller patient loads than hospices that remained below the cap. Between 2002 and 2005, hospices with payments exceeding the cap had about half the patient loads as those that stayed below the cap. A lower patient count suggests that these hospices

TABLE 8–4 **Share of hospices that exceeded Medicare's annual payment cap has steadily grown**

	2002	2003	2004	2005
Number of hospices				
All	2,286	2,401	2,580	2,809
Above cap	60	98	150	220
Percent of hospices above cap	2.6%	4.1%	5.8%	7.8%
Total spending (in millions)	$4,517	$5,682	$6,897	$8,155
Payments above the cap				
Subject to recovery (in millions)	$28.2	$65.1	$112.3	$166.0
As a percent of overall Medicare hospice spending	0.6%	1.2%	1.6%	2.0%

Note: The cap year is defined as the period beginning November 1 and ending October 31 of the following year.

Source: MedPAC analysis of 100 percent hospice standard analytical file (claims) data, 2002–2005; Medicare hospice cost reports, 2001–2005; CMS Provider of Services file data, 2002–2005; and CMS Providing Data Quickly file.

had a smaller base across which to distribute the effects of patients with longer stays, putting them at greater risk of exceeding their payment limit. Freestanding hospices exceeding the cap had average lengths of stay significantly longer than below-cap hospices.[12] In 2003, the average length of stay for freestanding hospices that exceeded the cap was about 46 percent higher than that for hospices under the cap. By 2005, average length of stay for above-cap hospices was more than double that for below-cap hospices.

We also found that a hospice's case mix influenced whether it exceeded or remained under the cap but did not explain it entirely (Table 8-6, p. 214). For example, in 2005, cancers, which typically incur relatively shorter hospice lengths of stay, made up a greater share of cases

TABLE 8–5 **Most hospices with payments exceeding Medicare's annual cap are freestanding for-profit agencies**

	Percent of hospices							
	2002		2003		2004		2005	
Category	Above cap	All	Above cap	All	Above cap	All	Above cap	All
All	100%	2.6%	100%	4.1%	100%	5.8%	100%	7.8%
Urban	55.0	1.4	54.1	2.2	59.3	3.4	60.5	4.7
Rural	45.0	1.2	45.9	1.9	40.7	2.4	39.5	3.1
Nonprofit	13.3	0.3	12.2	0.5	13.3	0.8	8.6	0.7
For profit	85.0	2.2	84.7	3.5	85.3	5.0	89.1	7.0
Government	N/A	N/A	2.0	0.1	0.7	0.0	0.9	0.1
Other	1.7	0.0	1.0	0.0	0.7	0.0	1.4	0.1
Freestanding	93.3	2.4	91.8	3.7	92.0	5.3	92.3	7.2
Provider based	6.7	0.2	8.2	0.3	8.0	0.5	7.7	0.6

Note: N/A (not applicable). Percentages may not add to 100 due to rounding.

Source: MedPAC analysis of Medicare hospice cost report, claims, and Provider of Services data from CMS.

TABLE 8–6

Above-cap hospices had longer stays than below-cap hospices for every disease category, 2005

	Hospices below cap			Hospices above cap			Difference in ALOS, hospices above cap versus below cap
Disease category	Number of cases	Percent of total cases	ALOS (in days)	Number of cases	Percent of total cases	ALOS (in days)	
Cancer (except lung cancer)	194,089	27.2%	46	4,831	14.5%	68	49%
Lung cancer	79,560	11.2	44	1,914	5.8	54	23
Circulatory (except heart failure)	77,653	10.9	51	5,200	15.7	114	122
Heart failure	57,010	8.0	58	4,184	12.6	121	107
Debility, NOS	51,616	7.2	65	2,485	7.5	116	77
Chronic airway obstruction, NOS	39,796	5.6	67	2,495	7.5	119	76
Alzheimer's and similar disease	39,572	5.5	82	3,184	9.6	130	58
Unspecific symptoms/signs	36,770	5.2	66	2,567	7.7	107	62
Dementia	28,830	4.0	71	2,136	6.4	119	67
Genitourinary diseases	23,118	3.2	21	579	1.7	37	75
Organic psychoses	22,907	3.2	72	1,282	3.9	116	62
Respiratory diseases	18,300	2.6	42	444	1.3	90	116
Nervous system (except Alzheimer's)	18,179	2.5	78	996	3.0	134	73
Other	14,168	2.0	44	572	1.7	104	138
Digestive diseases	11,576	1.6	37	356	1.1	64	75
Total	713,144	100.0	54	33,225	100.0	105	93

Note: ALOS (average length of stay), NOS (not otherwise specified). Totals may not sum due to rounding.

Source: MedPAC analysis of 2005 100 percent hospice standard analytical file from CMS.

(38.4 percent) in hospices that did not exceed the cap than in hospices that exceeded it (20.3 percent). Conversely, diseases with typically long hospice stays made up a larger share of patient volume at above-cap hospices than in those whose payments remained below the cap. Alzheimer's disease, dementia, organic psychoses, and other neurological diseases, which typically have long lengths of stay relative to other conditions, made up almost 23 percent of cases at above-cap hospices in 2005, compared with only about 15 percent in below-cap providers. This pattern held true even with respect to the one non-neurological long-stay diagnosis shown—nonspecific chronic airway obstruction—which made up almost 8 percent of cases at hospices that exceeded the cap but fewer than 6 percent of cases at below-cap hospices.

Case mix alone did not explain a hospice's relationship to the cap. We found that hospices that exceeded the cap had longer lengths of stay than their below-cap counterparts for every disease category. Stays in hospices that exceeded the cap ranged from almost 23 percent longer for lung cancer to about 122 percent longer for circulatory diseases other than heart failure.[13] Even among diagnoses associated with longer stays, the average stay for above-cap hospice patients was much longer than that for the diagnosis across all hospices. In 2005, stays in below-cap hospices for patients with diagnoses associated with long stays were only 45 percent to 81 percent of those for similar patients in above-cap hospices. Ninety-three percent of hospice patients with Alzheimer's disease received care from hospices that did not exceed the cap in 2005.

In sum, above-cap hospices were more likely to be for-profit, freestanding facilities and to have smaller patient loads than below-cap hospices. They treated a larger share of patients with Alzheimer's disease and other neurological conditions than hospices that did not exceed the cap. Most importantly, hospice providers exceeding the cap exhibited significantly longer lengths of stay than

TABLE 8–7

In selected markets, share of cancer diagnoses is lower and average length of stay for cancer patients is higher in above-cap hospices, 2005

	Share of cancer diagnoses			Average length of stay for cancer patients (in days)		
Geographic area	**Hospices below cap**	**Hospices above cap**	**Percent difference**	**Hospices below cap**	**Hospices above cap**	**Percent difference**
Rural areas						
Mississippi	39.2%	21.0%	–46%	54.2	78.7	45.3%
Alabama	34.3	17.9	–48	55.8	77.8	39.5
Oklahoma	32.0	22.5	–30	54.1	71.0	31.3
North Carolina	42.2	25.4	–40	52.8	80.5	52.5
Arizona	37.8	26.8	–29	42.2	56.1	33.0
MSAs						
Phoenix, AZ	33.2	15.0	–55	46.9	51.8	10.4
Oklahoma City, OK	30.1	20.8	–31	55.4	60.5	9.1
Tulsa, OK	31.3	17.2	–45	55.9	54.8	–2.1
Los Angeles, CA	41.2	27.2	–34	41.6	56.6	35.9
San Diego, CA	36.5	20.6	–44	48.5	50.6	4.2

Note: MSA (metropolitan statistical area).

Source: MedPAC analysis of 2005 100 percent hospice standard analytical file from CMS.

hospices remaining under the cap, even when controlling for patient mix.

Some hospice providers who have been affected by the cap assert that their patient mix reflects that of the communities where they operate—in other words, that their communities include disproportionate numbers of patients with terminal conditions likely to generate longer stays in hospice. They argue that, to the extent that patient mix includes a disproportionate number of patients with terminal diagnoses with typically long stays, the hospice cap unfairly penalizes them for serving patients in their community. To test this claim, we analyzed case mix (using share of cancer diagnoses as a proxy) and length of stay for the five urban areas and the five statewide rural areas with the largest numbers of hospices exceeding the cap (Table 8-7).

Two clear patterns emerge from this analysis. First, in each of the 10 areas, patients with a diagnosis of cancer represented a smaller share of patients in hospices exceeding the cap than those remaining under the cap. The share of cases represented by cancer in above-cap hospices was about 40 percent less than the share of cancer diagnoses in below-cap hospices. Second, in 9 of the 10 areas we studied, stays for cancer patients were longer at above-cap hospices than for those at below-cap hospices. These two patterns illustrate that admission patterns for hospices that exceed the cap do not necessarily mirror the mortality profile of their area. These hospices have consistently longer hospice stays—even in the case of patients with diagnoses that would be expected to have relatively short hospice stays.

We do not fully understand why lengths of stay are longer in some hospices, causing them to exceed Medicare's payment limit, whereas others in the same market do not. Hospices in the same market are generally served by a single Medicare fiscal intermediary and thus are subject to the same admissions guidance and cap calculation methodology, negating the hypothesis that variability in these factors among intermediaries would explain this phenomenon. Other market forces may drive hospices to incur long lengths of stay, such as whether a hospice is a new entrant in a market or an established provider. The number of Medicare beneficiaries per hospice provider in a given market may also be a factor. Other drivers of long lengths of stay could include a desire for patients to have the benefit of hospice care for a longer period at the end of life and a provider response to the profit incentives implicit

TABLE 8–8

Growth in Medicare-participating hospices suggests beneficiary access to care is growing

	2000	2002	2004	2005	2006	2007	Average annual percent change, 2000–2007
Total	2,240	2,310	2,662	2,887	3,069	3,253	5.5%
Nonprofit	1,193	1,167	1,175	1,189	1,192	1,205	0.1
For profit	725	822	1,148	1,330	1,496	1,660	12.6
Government/other	322	321	339	368	381	388	2.7
Voluntarily closed providers	74	41	41	40	42	41	N/A
New providers	88	111	249	266	222	226	14.4

Note: N/A (not applicable).

Source: CMS Providing Data Quickly query, https://pdq.cms.hhs.gov, accessed February 25, 2008.

in a per diem payment system. But regardless of the cause, the fact remains that above-cap hospices' patients have consistently longer hospice stays than below-cap hospices' patients for all conditions—even in the case of patients with diagnoses that would be expected to have relatively short hospice stays.

Effects of the cap on access to hospice care

It has been asserted that the growing number of hospice providers exceeding the cap affects Medicare beneficiaries' access to hospice care. Some hospice providers have indicated that the cap may force many hospices to go out of business or to deny or defer access to eligible noncancer patients (NAHA 2006). We evaluated access in terms of the number of hospice providers (both nationally and by state) and the number of patients using hospice (including various demographic strata) and found no evidence to suggest that the growing number of providers exceeding the Medicare limit on payments has affected patients' access to hospice care.

Supply of providers

We examined the supply of hospices, including new providers and those that discontinued participation in the program, to assess whether the caps were affecting the number of hospices available to Medicare beneficiaries (Table 8-8). Given the lag in the time it takes the RHHIs to calculate the cap, the effects of hospices exceeding the cap in 2004 and later years would not necessarily have shown up in 2005 data, but any effects of the earlier years' application of the cap should be reflected in the later years' data.

Between 2005 and 2007, the overall number of hospices grew by more than 360 providers, or nearly 13 percent. Over this time, the number of nonprofit hospices remained relatively flat, growing by about 1 percent, and the number of for-profit providers—the ones disproportionately affected by the cap—grew by nearly 25 percent (not shown in Table 8-8). In the aggregate, the supply of providers does not appear to have been adversely affected during the most recent period of growth in the number of providers reaching the cap.

The number of hospices that voluntarily stopped participating in Medicare has remained constant at about 40 providers annually since 2002. Our data do not distinguish between closures and mergers, so it is possible that some of these entities merged during this time and continue to provide end-of-life care to Medicare beneficiaries. Nor do these data allow us to attribute causality of closures to the effects of the hospice cap.[14] Additionally, the number of new hospices participating in Medicare continues to increase, well exceeding the number of hospices exiting the market. In 2007, more than five times as many new hospices began participating in Medicare as left the program.

With respect to the supply of providers, we examined growth in the number of hospices by state over time. The results varied, with some states experiencing extremely robust growth in the number of hospices (e.g., Alaska and Utah, with an average annual growth of more than 20 percent between 2000 and 2006), whereas other states experienced either no growth (Hawaii, Kentucky, Maryland, North Dakota, plus the District of Columbia) or very slight declines in the number of hospice providers (West Virginia, New York, and South Dakota). The three states with the highest share of hospices reaching the cap in 2005 (Alabama, Mississippi, and Oklahoma) were among the 10 states with the highest rates of growth in the number of hospices between 2000 and 2006, with average annual increases in the number of providers ranging from about 11 percent to almost 17 percent during this time.[15] Each of these three states had more than twice as many hospices as New York and Florida, states that have much larger numbers of Medicare beneficiaries, and that also have certificate-of-need criteria governing the establishment of hospices. Further analysis may be needed to fully understand the myriad relationships between growth in the number of hospices, variation in length of stay by state or within states, the number of hospices reaching the cap in any given state, and state certificate-of-need laws.

Recognizing that raw counts of hospices per state are not the best measure of access, given that a hospice's capacity may vary, we also measured the number of hospices per 10,000 beneficiaries and the number of Medicare hospice users as a percentage of total Medicare decedents. Of the 10 states with the highest hospice access (as measured by hospice use as a percent of total decedents), five also had among the highest rates of growth in the number of hospices between 2000 and 2005. Five of the 10 also had the highest access as measured by hospices per capita, and 6 had among the highest rate of hospices exceeding the cap (Table 8-9). Colorado and Florida had relatively high access to hospice in terms of hospice users per decedent, but relatively few hospices per Medicare beneficiary. (Access in Utah and Arizona, as measured by hospice users per decedent, was at a level generally recognized by the industry as the highest practical level of hospice utilization.)

TABLE 8–9 **Cap does not appear to be affecting hospice access, 2005**

State	Hospices per 10,000 beneficiaries	Percent of hospices above the cap	Medicare hospice users as a share of decedents
Utah	2.4	21.2%	70.2%
Arizona	0.7	20.0	67.6
Oklahoma	2.9	28.3	60.0
Colorado	0.9	0.0	57.4
Florida	0.1	4.9	57.3
Alabama	1.5	41.7	56.5
New Mexico	1.6	17.9	56.3
Oregon	1.0	2.1	53.2
Mississippi	2.3	36.0	51.5
Kansas	1.3	6.1	50.8

Source: CMS Providing Data Quickly query, https://pdq.cms.hhs.gov, accessed October 18, 2007; MedPAC analysis of 100 percent Medicare hospice standard analytical file from CMS; and Medicare hospice cost reports from CMS.

Volume of services

Growth in the volume of hospice services is another indicator that access to hospice care, in the aggregate, has not declined in recent years. The number of unique beneficiaries using hospice increased by an average annual rate of 10 percent between FY 1995 and 2005, reaching nearly 870,000 beneficiaries in FY 2005 (Figure 8-2, p. 218). Our analysis indicates additional growth to more than 913,000 beneficiaries in calendar year 2006. This increase—just above 7 percent—is lower than the prior fiscal year trends reported by CMS (an average annual increase of roughly 11 percent over the last five fiscal years) but substantially exceeds the increase in Medicare enrollment (2 percent to 3 percent) over this period.[16]

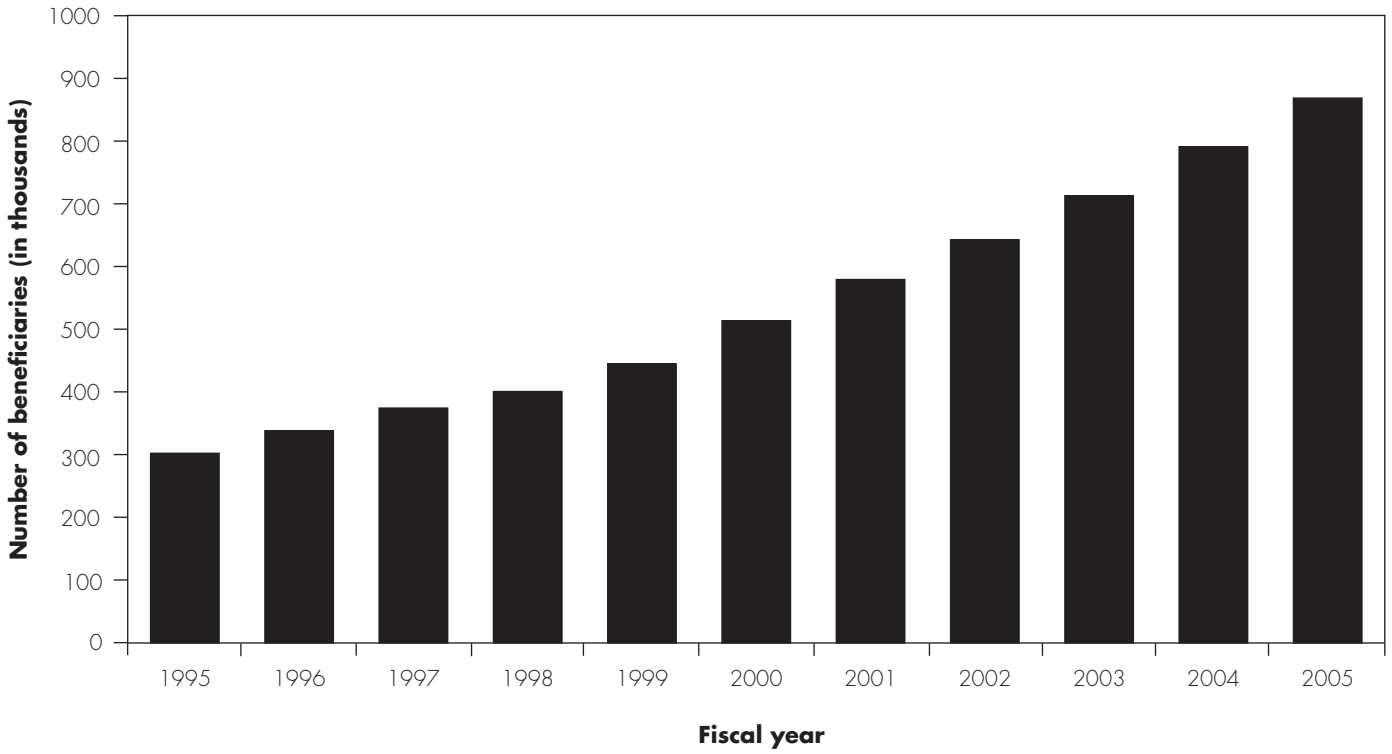
Growth in hospice use was more rapid for patients with Alzheimer's disease and other generalized cerebroneurological disorders associated with long hospice stays than for other terminal diseases such as cancer and congestive heart failure. This growth suggests that the cap has had no discernible effect on hospices' willingness to provide care for these patients; on the contrary, there appear to be financial incentives in Medicare's hospice payment system that make such patients attractive, despite the potential adverse effects of exceeding the cap.

Hospice use trends by demographic groups

Between 2000 and 2005, growth in hospice use occurred not only in the aggregate but also for all but one

FIGURE 8–2

Growth in hospice use tripled in recent years



Source: CMS 2007. http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/downloads/FY05update_hospice_expenditures_and_units_of_care.pdf

demographic group of Medicare decedents.[17] We analyzed changes in the percent of Medicare decedents who had used hospice between 2000 and 2005 by sex, race, age, and Medicare eligibility.

In 2000, about 23 percent of Medicare decedents died while covered by hospice, with this share increasing to about 34 percent in 2005. Between 2000 and 2005, hospice use by Medicare beneficiaries increased by 50 percent, compared with a 7 percent increase in Medicare enrollment in the period. Among the highlights of our findings, of Medicare beneficiaries who died while covered by hospice:

- Growth in hospice use was higher for females than for males.
- Hospice use by white and black beneficiaries increased faster than for beneficiaries of Hispanic and Asian heritage.
- Hospice use by Native American Medicare beneficiaries doubled between 2000 and 2005.
- Hospice use grew fastest for the oldest Medicare beneficiaries, aged 85 and older; this group now has the highest rate of hospice use of any Medicare age group.

Across all measures, hospice use by Medicare decedents who had been enrolled in managed care plans was higher than those in fee-for-service, but the gap narrowed between 2000 and 2005, with growth rates for fee-for-service hospice use higher than those for managed care. The utilization increase across all beneficiary groups suggests that access to hospice care was not affected by the cap during this time.

Incentives in Medicare's hospice payment system

Our assessment of hospice margins suggests that, in the aggregate, Medicare payments to hospices are sufficient, an assessment shared even by some hospices subject to the cap (Armstrong 2006). Aggregate margins partially reflect providers' ability to manage a mix of patients, some of whom incur costs greater than the reimbursement and some of whom have care that costs less. However, these aggregates also reflect considerable underlying variation in a number of aspects, including ownership type, provider affiliation, and geography. These margins reflect differences in the provision of hospice care across the country, which may not be related to the specific clinical needs of hospice patients (Iwashyna et al. 2002).

Some evidence suggests that the cost of hospice care does not vary by patient diagnosis (MedPAC 2006, Nicosia et al. 2006). However, it is worth questioning this premise, given the relationships between diagnosis and length of stay, and corresponding clues about the variation in types of services used by hospice patients either by length of episode (Cheung et al. 2001) or by terminal disease (Mor and Birnbaum 1983). If per patient resource use varies, either over time or by patient diagnosis, Medicare's payment system, which does not account for differences in patient diagnosis or in costs by diagnosis relative to nonhospice care, will pay too much for some patients and too little for others. This is likely to create financial incentives for hospice providers that are not related to and may even be in conflict with hospice patients' needs. Data do not exist to assess the accuracy of Medicare hospice payments at the level of specific diagnoses, but we can evaluate payment accuracy in the aggregate and identify related payment incentives.

Incentives under Medicare's hospice payment system

The Commission's previous analyses of visit-level data from a large national for-profit hospice chain suggested that hospice episodes are more resource intensive at the beginning and at the end of episodes (MedPAC 2006, Nicosia et al. 2006). These findings on cost trends across hospice episodes, consistent with those of other health services researchers (Carney et al. 1989, Fitch and Pyenson 2003, Huskamp et al. 2001), suggest that Medicare's hospice payment system "might now create incentives for providers to lower their average daily costs by seeking patients with longer lengths of stay" (Nicosia et al. 2006). In 2001, actuaries from Milliman USA demonstrated that longer stays were more profitable. Analyzing data from 1998 and 1999, a period when average hospice length of stay was decreasing, hospices incurred pronounced deficits under Medicare for stays of less than 21 days (Cheung et al. 2001). Beyond 21 days, the magnitude of deficits declined, and the stays became profitable. Virnig and colleagues (2004) pointed to declining lengths of stay as a source of "financial difficulties" for small rural hospices, implying that longer stays were more profitable, based on utilization data from 1998 and 1999.

In their filings with the Securities and Exchange Commission (SEC), publicly traded for-profit hospice chains also generally acknowledge the nonlinear cost function of resource use within hospice episodes. VistaCare notes that "our profitability is largely dependent on our ability to manage costs of providing services and to maintain a patient base with a sufficiently long length of stay to attain profitability," and that "cost pressures resulting from shorter patient lengths of stay … could negatively impact our profitability" (HCSM 2004). Similarly, Odyssey HealthCare acknowledged in their 2004 annual SEC filing that "length of stay impacts our direct hospice care expenses as a percentage of net patient service revenue because, if lengths of stay decline, direct hospice care expenses, which are often highest during the earliest and latter days of care for a patient, are spread against fewer days of care" (Odyssey HealthCare 2004). Odyssey HealthCare's average length of stay increased from 79 days in 2004 to 86 days in 2006, with no apparent change in the mix of patients it treated (Odyssey HealthCare 2007).

The most explicit analysis of the relationship between hospice profitability and length of stay is the study by Lindrooth and Weisbrod published in 2007. They hypothesized that this relationship could be observed in the differences in patient selection between for-profit and nonprofit hospices (Lindrooth and Weisbrod 2007). They found that patients at for-profit hospices were more likely to be enrolled in managed care and had fewer surgical procedures before admission to hospice than patients at nonprofit religious hospices. The mix of patients in the two groups of hospices differed significantly beyond what would have been expected due to random variation. Nonprofit religious hospices had a larger share of patients with cancer diagnoses (generally short-stay patients)

TABLE 8–10 **Hospice Medicare margins, 2001–2005**

Category	Percent of hospices, 2005	2001	2002	2003	2004	2005
All	100%	1.0%	3.1%	4.5%	3.2%	3.4%
Urban	64	1.4	3.6	4.9	3.6	3.4
Rural	36	–1.8	0.1	2.5	0.0	3.3
Nonprofit	48	–4.4	–3.7	–2.9	–3.6	–2.8
For profit	43	12.0	14.6	15.9	12.4	11.8
Government*	7	–16.4	–17.9	–26.0	–11.9	–16.2
Freestanding	59	5.6	6.8	9.0	6.7	6.3
Provider based	41	–10.5	–7.6	–8.9	–7.5	–5.6
Percent of hospices						
Below the cap	91	N/A	2.1	3.3	1.8	1.5
Above the cap (including overpayments)	9	N/A	30.1	23.0	17.4	18.9
Above the cap (net of overpayments)	9	N/A	13.3	2.1	–4.6	–2.9
Patient volume (quintile)						
1	20	–12.6	–6.7	–1.4	–1.0	–0.2
2	20	–4.5	–1.4	–3.1	0.5	5.0
3	20	–0.4	3.4	3.8	2.6	3.0
4	20	–1.8	3.3	2.9	3.1	5.5
5	20	3.0	3.8	6.1	3.7	2.8
Length of stay (decile)						
1	10	–4.1	–6.6	–2.3	–9.9	–6.7
2	10	–1.1	–3.1	–1.6	–2.0	–4.6
3	10	1.0	–1.6	4.1	–2.1	–1.4
4	10	1.0	3.0	6.8	0.8	2.5
5	10	2.5	1.8	8.4	9.2	8.2
6	10	8.7	9.9	6.7	9.8	7.1
7	10	8.8	12.0	14.7	13.0	11.0
8	10	8.9	16.4	14.5	13.4	12.0
9	10	14.8	15.5	17.3	11.7	18.4
10	10	29.9	26.1	25.0	21.6	14.4

Note: N/A (not applicable). Percentages by ownership do not sum to 100 because "other" ownership types are excluded from this table.
*Government-owned providers operate in a different context from other providers, so their margins are not necessarily comparable. Margins for all categories include cap overpayments, except where specifically indicated; subtracting overpayments would reduce reported margins, especially for for-profit hospices.

Source: MedPAC analysis of Medicare hospice cost reports, 100 percent hospice claims standard analytical file, and Medicare Provider of Services data from CMS.

than for-profit hospices, whereas for-profit hospices had much larger shares of long-stay patients. Lindrooth and Weisbrod linked the utilization patterns to hospice profitability, stating that noncancer diagnoses "have the longest expected lengths of stay, and therefore, the greatest profitability" (Lindrooth and Weisbrod 2007). They asserted that the differences in patient mix are directly attributable to affirmative practices on the part of for-profit hospices, such as selective admissions based on identifiable patient characteristics. Although their argument is compelling and makes logical inferences (i.e., for-profit hospices will engage in the most profitable practices), they did not confirm their assertion through an analysis of hospice margins.

Evidence of hospice profitability under Medicare

A limited number of health services research and government studies have estimated hospices' historical margins that range from as low as 2 percent to as high as 52 percent (GAO 2004, Kidder 1998, McCue and Thompson 2005). Financial analysts have estimated margins for the three largest publicly traded hospice firms (Vitas, Odyssey, and VistaCare) that ranged from 6 percent to nearly 15 percent in 2006 (Wharton 2006).

Additional indicators of hospice profitability can be found in the Securities and Exchange Commission (SEC) filings of publicly traded hospices. Among these are Vitas (a subsidiary of Chemed), Odyssey HealthCare, VistaCare, Manor Care, and Beverly Enterprises.[18] Whereas these margin estimates reflect revenues and costs for all patients (not just Medicare), Medicare accounts for the largest share of hospice revenue, exceeding 90 percent. In its most recent annual filing with the SEC (Chemed 2007), Vitas reported a pretax profit margin of about 7 percent for calendar year 2006. VistaCare reported operating losses of 5 percent in FY 2006, and 3 percent in 2007, partly on the basis of costs attributable to a corporate restructuring and other factors, including ongoing cap liability (VistaCare 2007). VistaCare has reduced its cap exposure each year since 2004, and it estimates a further reduction in 2007. The third major for-profit hospice chain, Odyssey HealthCare, reported pretax operating margins of 7.8 percent for calendar year 2006, down slightly from 8.8 percent in 2005. As part of a management strategy that includes an aggressive acquisition program, Odyssey HealthCare has an open offer to acquire all outstanding shares of VistaCare. Like VistaCare, Odyssey HealthCare has begun to reduce its exposure to cap overpayments, which peaked in 2006 at just over $14 million as estimated by the company, up from just under $8 million in 2005. Analysts now estimate that Odyssey HealthCare may generate margins of 11 percent to 12 percent over the next several years (Deutsche Bank Equity Research 2008). ■

Because Medicare's payment system makes a fixed payment for each day of care regardless of its position in the course of an episode, a financial incentive exists for hospice providers to enroll patients who are likely to have longer stays. To an extent, this relationship is implicit in the growth in for-profit hospices since 2000, a period of time when length of stay also increased. Partially counterbalancing this incentive, the Medicare aggregate per beneficiary payment cap provides a strong inducement for providers to be judicious in their admissions and admit patients who meet the presumptive eligibility requirements.[19]

Hospice providers' payments and costs

To date, there has been no systematic evaluation of hospice providers' payments and costs, although some evidence exists to suggest that hospices have generally performed well financially under Medicare (see text box). Given the absence of comprehensive data on hospice margins, we developed our own estimates of Medicare hospice margins using Medicare claims and cost report data for the period 2001 to 2005. Overall, hospices' Medicare margins have ranged from about 1 percent to 4.5 percent since 2001 and were 3.4 percent in 2005 (Table 8-10). These totals, however, mask pronounced differences in margins by hospice provider type.

Between 2001 and 2005, freestanding hospices had Medicare margins ranging between about 6 percent and 9 percent, in the aggregate, with a margin of 6.3 percent in 2005. In contrast, provider-based hospices' margins were negative over the period of analysis, ranging from –10.5 percent in 2001 to –5.6 percent in 2005.

As might be expected, for-profit hospice providers in general had significantly higher margins than nonprofits. For-profit hospice margins ranged from 12 percent to about 16 percent between 2001 and 2004, dropping slightly to 11.8 percent in 2005. Over the same period, nonprofit hospice providers' margins were between –2.9 percent and –4.4 percent, ending at –2.8 percent in 2005.[20]

We also examined margins as a function of hospice geography. The relationship between urban and rural hospice Medicare margins has varied over the five years

TABLE 8–11

Some above-cap hospices are profitable only because of overpayments, but a large share are profitable net of overpayments

Category	2002	2003	2004	2005
Margin (including overpayments)	30.1%	23.0%	17.4%	18.9%
25th percentile	9.7	11.6	3.9	4.7
Median	29.4	23.6	16.3	17.4
75th percentile	39.4	35.4	29.8	28.0
Mean payment-to-cost ratio				
With overpayments	1.40	1.34	1.26	1.25
Without overpayments	1.14	1.07	0.99	0.95

Source: MedPAC analysis of Medicare hospice cost reports, 100 percent hospice claims standard analytical file, and Medicare Provider of Services file data from CMS.

we examined. Margins for urban facilities were generally positive. Urban hospices' margins are roughly 2.5 to 3.5 percentage points higher than those for rural hospices, although this differential narrowed to only 0.14 percentage point in 2005.

Patient volume seemed to have a general, but not linear, effect on hospices' Medicare margins. In each year, hospices in the lowest quintile of patient volume had negative margins, and hospices in the highest quintile had positive margins. In this regard, the patterns (but not the absolute values) we observe for hospice margins are not dissimilar from those exhibited by freestanding home health agencies, where lower volume providers have somewhat lower margins than higher volume agencies (MedPAC 2007). In general, neither hospice nor home health agencies have large capital infrastructures, unlike institutional providers for which it is financially beneficial to distribute costs over as many patients, visits, or discharges as possible (roughly 20 percent of hospice providers own and operate inpatient or residential facilities, however). As a result, variation in hospice margins as a function of the number of patients may be less pronounced than might be the case with institutional providers.

We also calculated Medicare hospice margins as a function of whether hospices exceed the aggregate per beneficiary payment limit. As a group, hospices that exceeded the cap had the highest Medicare margins of any category of hospices, from just over 30 percent in 2002 falling to nearly 19 percent in 2005 (Table 8-11). Margins at the 25th percentile of the distribution were nearly 4.7 percent in 2005, whereas hospices at or above the 75th percentile had margins of 28 percent or higher.

These margins include the overpayments that hospices must return to the Medicare program. To assess the impact of returning the overpayments on above-cap hospices' profitability, we calculated payment-to-cost ratios for above-cap hospices with and without the excess payment amounts. We found that excluding the overpayments had a major impact on profitability. In 2004 and 2005, excluding overpayments resulted in a shift of payment-to-cost ratios from 1.25 to below 1.0, indicative of a negative margin.

Length of stay in hospice was by far the dominant driver of whether a hospice exceeded the cap. Hospices that exceeded the cap had longer lengths of stay than below-cap hospices, and for-profit hospices had lengths of stay that were 45 percent longer than those of nonprofit providers. Given the relationship between long length of stay and profitability under Medicare's payment system for hospice, it is not surprising that hospices that exceed the cap have high Medicare margins before they return the overpayments.

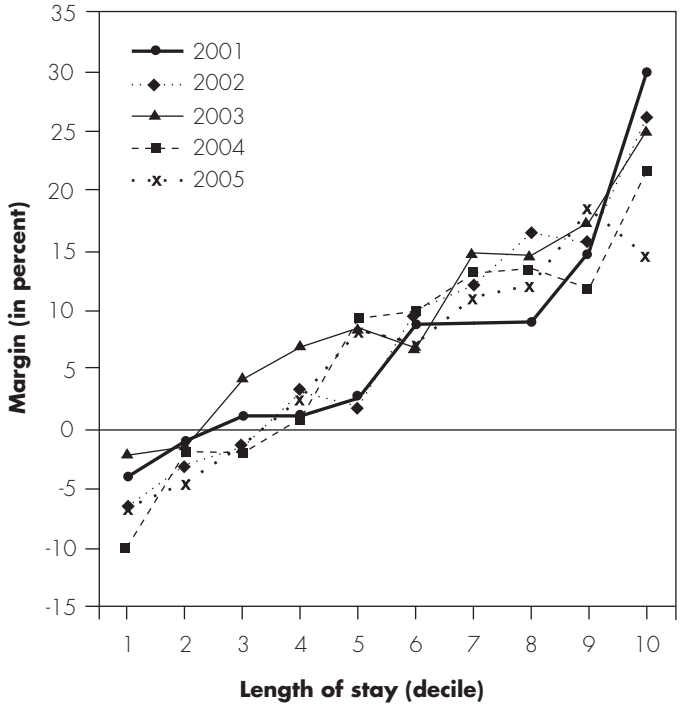
We evaluated the relationship between margins and hospice length of stay directly. To do this, for each year from 2001 to 2005, we categorized the freestanding hospices in our database into length-of-stay deciles, using length of stay as reported on their cost reports.[21] In each year, hospices in the lowest length-of-stay deciles had the smallest margins, and hospices in the highest deciles had the highest margins (Figure 8-3). This relationship was nearly, but not quite, linear—that is, the longer the length

of stay, the greater the Medicare margin. An exception to this trend occurred in 2005, when hospices in the highest length-of-stay decile exhibited lower margins than those in the preceding decile. As noted earlier, the cap, by serving to check length of stay, may thus limit hospices' profitability. For example, large hospice chains indicate that, when their hospices exceed the cap in one year, they take actions to reduce their exposure in later years.

Growth in the number of hospice patients with long stays is partly a consequence of more service to noncancer patients such as those with a diagnosis of Alzheimer's disease, a population that historically has been underrepresented in hospice compared with patients diagnosed with cancer. However, the provision of hospice care may also be driven partly by Medicare's payment system, under which longer hospice episodes are more profitable. This profit incentive may operate in direct conflict with Medicare's interest in ensuring that the hospice benefit provide a less costly alternative to traditional end-of-life care.

FIGURE 8–3

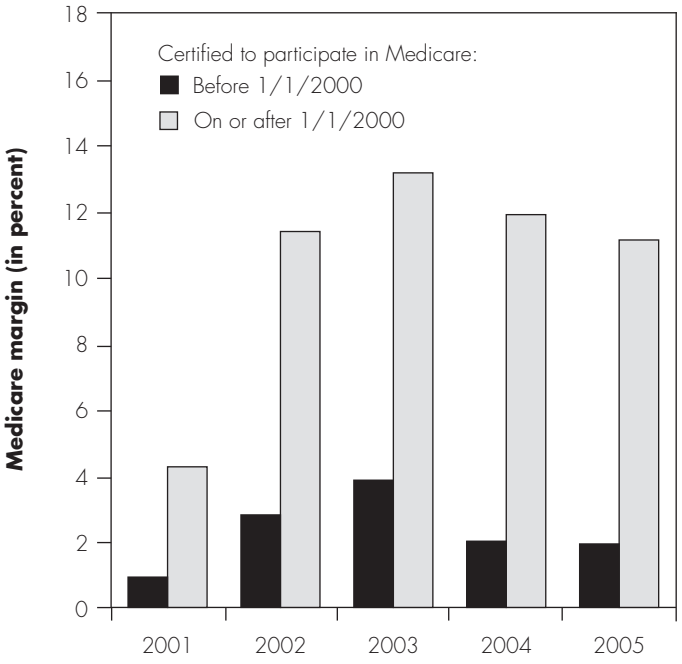
Hospice Medicare margins increase with length of stay



Source: MedPAC analysis of Medicare hospice cost reports, 100 percent hospice claims standard analytical file, and Medicare Provider of Services data from CMS.

FIGURE 8–4

Hospice Medicare margins are larger for new hospices



Source: MedPAC analysis of Medicare hospice cost reports, 100 percent hospice claims standard analytical file, and Medicare Provider of Services data from CMS.

Some in the hospice community have contended that length of stay may be correlated with the length of time a hospice has participated in the Medicare program. They argue that more established hospices in a market have developed relationships with physicians and referral sources in their market that permit them to identify and admit patients whose diagnoses are likely to incur shorter lengths of stay (e.g., cancer). As a result, new entrants in a market would be left with longer stay patients (e.g., patients with dementia, Alzheimer's disease, and other nonspecific diagnoses), who are ostensibly less desirable from the hospices' perspective because they can push hospices closer to the cap. Thus, the argument goes, the cap discourages hospices from admitting noncancer patients and penalizes the hospices that admit them (NAHA 2006).

We found that hospices that began participating in Medicare in 2000 or later had consistently and substantially higher margins than those participating in Medicare before 2000 (Figure 8-4). These margins

include those for above-cap hospices before the return of overpayments to Medicare.

The higher margins observed for the newer hospice entrants is consistent with the growth in the number of for-profit hospices, which tend to enroll larger shares of long-stay patients—those who appear to be more profitable under Medicare's payment system, despite the cap on aggregate annual Medicare payments.

These margins may not provide a full picture of hospices' financial status. Nonprofit hospices derive revenues from philanthropic donations, which are an integral part of their operations and mission; these revenues are not consistently reported on Medicare cost reports. Such revenues may help offset the generally negative margins we observe for nonprofit hospice providers. Additionally, as is the case with hospital-based skilled nursing facilities, which tend to have high negative Medicare margins, hospitals may find it desirable to operate hospices, even in light of negative hospice margins. Harrison and colleagues (2005) found that hospitals that operated hospice programs had higher return on assets and higher hospital occupancy rates, as well as shorter lengths of stay, than hospitals without hospices. We will continue to evaluate these data to assess the full impact of Medicare payments on the hospice industry as we work toward developing specific policy proposals to address deficiencies in Medicare's hospice payment system.

For-profit hospices have lower costs per day than nonprofits

We examined hospice costs to gain insights on the differential margins between hospices as a function of ownership or provider affiliation. Much of the difference in margins stems from the fact that for-profit hospices have lower unadjusted costs per patient day than do nonprofit hospices. Similarly, provider-based hospices' unadjusted costs were higher than those of freestanding hospices. We do not have information on the reason for differences in costs per day among hospice providers. For-profit hospices' costs per day may be lower than those of nonprofit hospices because they are more efficient, because they provide a different mix of services, or because they provide fewer services over the course of a hospice episode of care. Because hospices are not yet required to report information on the number, type, and duration of visits and services they provide, data do not exist to fully answer such questions.

Medicare has insufficient information on the hospice care it purchases

The rapid growth in Medicare spending for hospice care—exceeding $10 billion in 2007—has brought a greater degree of scrutiny to the benefit. Yet, beyond counts of beneficiaries, the number of hospice episodes, and the number of days of service under each of the four types identified for purposes of Medicare payment, the program has virtually no information on the hospice care it purchases, in terms of either the specific services provided or the quality of care obtained. CMS will begin requiring hospices to report some of this information on their claims beginning in July 2008 and is in the early stages of developing quality measures for hospice.

Information on services paid for under hospice

Under the Medicare hospice payment system, hospices bill Medicare for days of service at the appropriate level of care for as long as a patient is under their care. Medicare pays these daily rates regardless of whether a hospice provides a visit on a given day, although some items and services may be provided beyond the scope of a single visit. Medicare historically has not required that hospices report detailed information on the types of visits provided. The Commission and others have highlighted the need for CMS to collect data on the number, frequency, and duration of hospice visits and information on who provides these visits (MedPAC 2006, see also GAO 2004).[22]

Beginning July 1, 2008, CMS will require hospices to report the number of visits furnished by nurses, home health aides, social workers, physicians, and nurse practitioners (when they serve as the hospice enrollee's attending physician) (CMS 2007b). Hospices were supposed to have been able to submit this information voluntarily beginning January 1, 2008, but software problems have prevented claims from being accepted into the system, and these problems will not be resolved until early in the summer of 2008.

The hospice community has criticized the CMS data collection effort. The industry's chief concern relates to the required content; specifically, they note that these visit types do not reflect the full spectrum of personnel who provide hospice care and that, by not requiring hospices to report time increments for visits, there is no way to differentiate a 2-hour nursing visit from one lasting only 15 minutes. Additionally, hospices are concerned about

the requirement that visits be counted for care provided in inpatient facilities under contract with the hospice, indicating that it is almost impossible to report how many times a hospital staff member enters the patient's room and performs a "medically necessary" activity. The industry has also expressed concerns about the CMS timeline for requiring this new level of reporting. The organizations representing the hospice community have volunteered to assist CMS in defining and collecting more comprehensive data on hospice visits. CMS has responded that the new requirement is only a first step in collecting data, with the first round intended to minimize hospices' reporting burden, and that additional phases of data collection are planned. Even given the resolution of concerns surrounding the initial effort, information from this requirement will likely not be available until mid-2009 at the earliest.

Few studies on the composition of hospice episodes exist in the health services research literature. Miller and colleagues (2003) evaluated visit-level data from a large national hospice chain to assess whether the provision of care differed for patients in nursing homes. They found no significant difference in provision of visits according to patients' residence but noted that patients with short stays were more likely to have a visit intensity (i.e., visits per unit of time) above the sample median, whereas patients with long stays (more than 181 days) were likely to have a visit intensity below the median.

Analysis of visit data from a large, for-profit national hospice chain

In the absence of systematic data on hospice utilization, we consulted other sources. In 2005 and 2006, the Commission contracted with RAND Health to analyze visit-level data from a large national for-profit chain. The analysis found that, although some diseases required more visits than others, overall patient diagnosis was a generally poor predictor of service use (MedPAC 2006, Nicosia et al. 2006).

In the fall of 2007, the same hospice chain provided the Commission with additional visit-level information, reflecting their experience with more than 250,000 Medicare patients at 44 hospices in 17 states between 2002 and 2007, or roughly 5 percent of all Medicare beneficiaries who received hospice care during those years. Most of their patients were in Florida, Texas, and California. The data include a patient's visit-level variables, such as visit discipline type, visit location, and visit start and end times, which we aggregated to construct individual hospice episodes. This analysis illustrates the benefits the federal government and others may derive from visit-level hospice data and the extent to which the data might be used to make informed improvements to Medicare's hospice program.

Consistent with trend data from broader analyses of Medicare's hospice program, data for this large chain indicate that its Medicare patient mix has shifted over time to include a greater share of patients with noncancer diagnoses. With this change in patient mix, average length of stay for Medicare patients served by this chain increased between 2002 and 2007 from 44 days to more than 83 days. The increase was largely driven by particular types of noncancer patients. From 2002 to 2007, the average length of stay increased from approximately 60 days to 138 days (130 percent) for neurological patients, from 66 days to 113 days (71 percent) for patients with nonspecific debility, and from 38 days to 73 days (92 percent) for all other noncancer patients.[23] By contrast, the average length of stay for cancer patients increased during this time from approximately 38 days to 46 days (21 percent).

Visit frequency data from the chain in our analysis showed that, from 2001 to 2007, patients had an average of 1.1 visits per day in the first 5 days of their hospice episode and 1.6 visits per day in the last 5 days, but they had 0.82 visit per day across their entire episode. This result is consistent with previously reported findings that hospices' costs are higher at the beginning and end of episodes and lower in the interim period. Medicare's per diem–based payments do not reflect this nonlinear trend in visits but instead provide a steady revenue stream over the course of an episode, independent of the number of visits patients receive each day. Thus, a hospice can increase its profit by increasing the number of more profitable interim days of an episode relative to the number of less profitable days.

The content of patient episodes, such as the average number of visits patients receive per week and the types of staff providing those visits, also affects profitability. In our analysis of the hospice chain's patients, both of these metrics generally correlated with the patient's terminal diagnosis. Patients with diagnoses associated with longer hospice stays, such as neurological patients, had less intensive treatment regimens than shorter stay patients (Table 8-12, p. 226).

From 2002 to 2007, the number of visits cancer patients received per week remained relatively constant at approximately 6.1 visits per week, but the number of

TABLE 8–12

At one large for-profit chain, the number of visits per week declined for Medicare patients with most disease types

Disease category	2002	2007	Percent change
Cancer	6.1	6.2	1.0%
Neurological	5.8	5.5	–5.5
Nonspecific debility	5.5	5.3	–2.8
Cardiovascular	6.0	5.2	–12.5
All other diseases	6.2	5.6	–10.0

Source: MedPAC analysis of data from a large national chain hospice provider.

visits per week noncancer patients received declined. For example, during this period, the average number of visits per week for neurological patients declined slightly from an average of 5.8 visits per week to 5.5 visits per week. Average visits per week for patients with nonspecific debility also declined slightly from 5.5 to 5.3. Declines in visits per week were most pronounced for patients with all other noncancer diagnoses, from about 6.1 visits to 5.4 visits, a decline of 13 percent. These declines in average visits per week are consistent with our other findings suggesting that long-stay patients may be more profitable for hospice agencies. Declines in visit intensity also may result from the ability of hospices to stabilize patients' needs and required interventions over time.

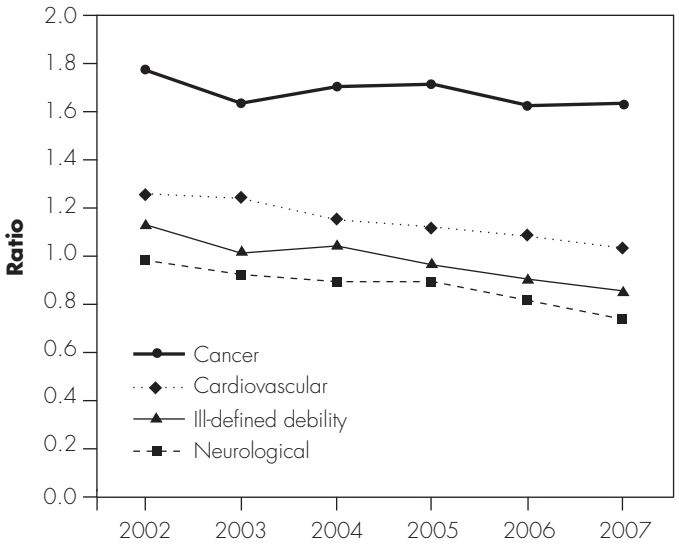
The use of less expensive home health aide services over more expensive registered nurse (RN) or licensed practical nurse (LPN) services, where clinically appropriate, may also explain why longer episodes in hospice are more profitable. Our analysis of the hospice chain's data for 2002–2007 showed that the ratio of visits conducted by RNs and LPNs to visits conducted by home health aides remained relatively constant for cancer patients but declined for neurological, nonspecific debility, and cardiovascular patients (Figure 8-5).

These data initially appear to suggest that hospice patients with noncancer diagnoses receive a lower level of care than patients admitted to hospice with cancer. To some extent that is true, as evidenced by the way the practitioner mix varies according to diagnosis. But it is also true that these data are confounded by the relationship between diagnosis and length of stay. We have documented that hospice episodes are more costly at the beginning and end of the episode because of the intensity of services provided at those times—that is, hospices provide more visits right after the patient is admitted to hospice and in the time shortly before death. Intervening periods are characterized by fewer visits per time period. As a result, shorter episodes will reflect a larger number of visits per week, whereas longer episodes will appear to have fewer visits per week. Given that some diagnoses typically have shorter lengths of stay than others, diagnoses such as cancer will appear to have higher visit intensity than diagnoses such as nonspecific debility.

Controlling for episode length, our analysis of the hospice chain's data showed a remarkable consistency in the number of visits per week its hospices provide. In all years of data analyzed, we found that shorter episodes had uniformly higher visit intensity regardless of diagnosis, as measured by visits per week, and that longer episodes had uniformly lower intensity. In 2007, the hospice chain's Medicare beneficiaries with cancer and neurological diagnoses with episodes of 30 or fewer days received an average of 12.3 and 13.1 visits per week, respectively (Figure 8-6). In the same year, cancer and neurological

FIGURE 8–5

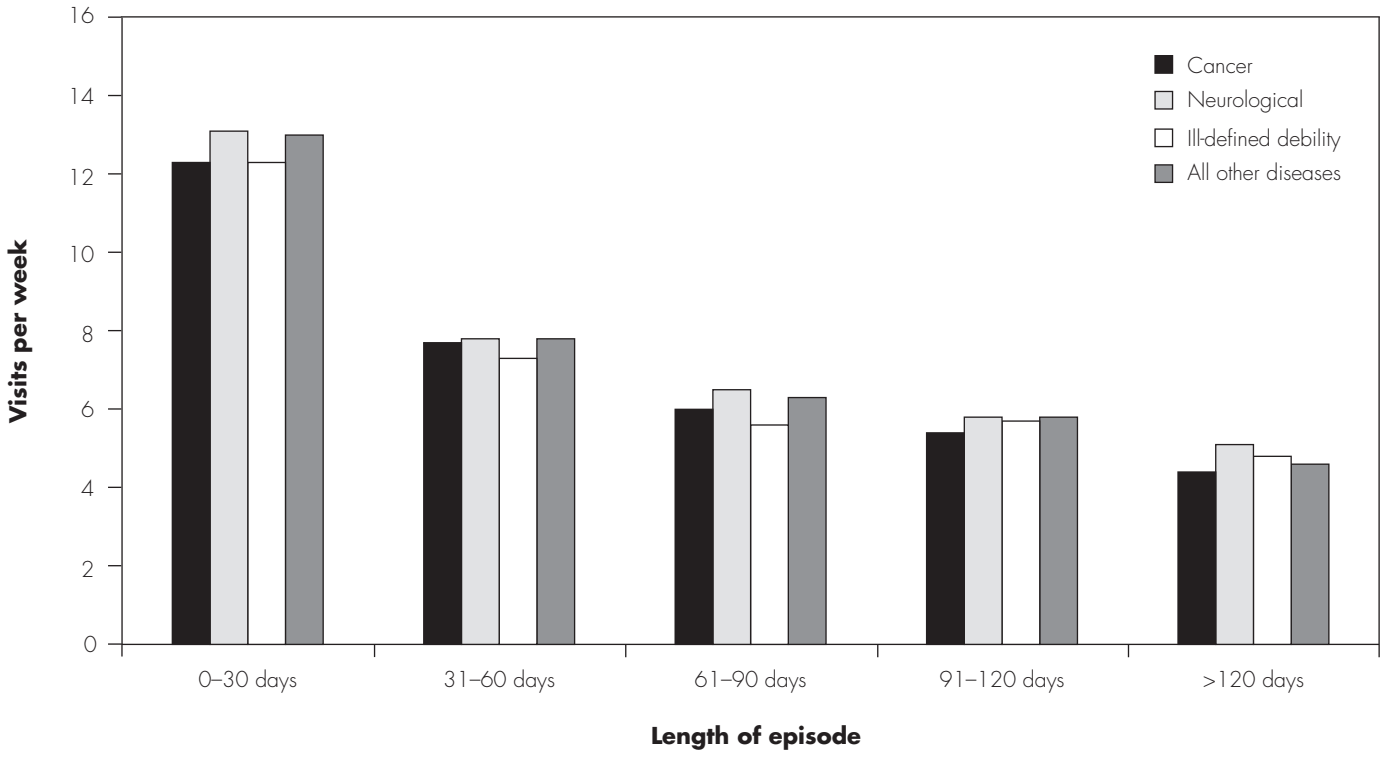
Change in ratio of LPN and RN visits to home health aide visits during Medicare hospice episodes, by disease type



Note: LPN (licensed practical nurse), RN (registered nurse).

Source: MedPAC analysis of data from a large national chain hospice provider.

FIGURE 8–6 **Shorter stays have higher visit intensity; longer stays have lower visit intensity, 2007**



Source: MedPAC analysis of data from a large national chain hospice provider.

patients with episodes of 121 or more days had 4.4 and 5.1 visits per week, respectively.[24] Patients with very short episodes had higher visit intensity than longer stay patients, regardless of patient diagnosis. This analysis further illuminates our previous findings that the beginning and end of hospice episodes are more costly because of the more intensive provision of services at these times. It also empirically demonstrates, for this national hospice chain at least, why longer episodes are more profitable than shorter ones.

Although these patterns may not be representative of all hospices nationwide, they are consistent with our understanding of hospice care based on anecdotes or qualitative descriptions from hospice providers and their trade associations and may represent a good basis of comparison for the initial data CMS will collect via hospice claims effective in the summer of 2008.

Measuring and reporting quality of hospice care

CMS does not currently require hospices to report information on the quality of care they provide. Numerous studies have indicated that hospice improves the quality of remaining life for patients who elect hospice (Kane et al. 1984, Miller et al. 2003). But developing standardized empirical quality measures that can be used for program administration—either to compare provider performance or to adjust payments under future pay-for-performance programs—presents unique challenges. The set of hospice characteristics that are correlated with quality is not clear-cut, and structural, process, and outcomes measures are scarce. Measures that rely on patient (or family) perceptions of care are more common, but establishing the validity of those characteristics may be difficult because of their subjective nature.

Whereas identifying appropriate quality indicators and developing corresponding measurement protocols are difficult in any health care setting, assessing the quality of hospice care presents unique challenges. Some measures of patients' experience with hospice care exist, although patients' ability to directly assess the quality of care during the course of the episode may vary considerably, if they can do it at all (e.g., dementia patients may not be able to accurately or objectively respond to written or verbal questions). Given that the median length of stay in hospice is roughly two weeks, many patients with other diagnoses nearing the end of life may not be able to assess their experience with hospice care. Measuring satisfaction with care directly from the hospice patient presents challenges that are unique among patient populations. Therefore, some assessment of the quality of hospice care can be ascertained only through other means—either by virtue of a hospice's staffing and other provider characteristics or by assessments of care obtained from the hospice patient's survivors (who are also the beneficiaries of some of the hospice's activities during the course of an episode of hospice care).

Hospice-level quality indicators

In 1997, the Institute of Medicine (IOM) identified a number of elements that it considered intrinsic to health care systems (including hospices) engaged in providing care at the end of life (IOM 1997). These include providing or arranging for:

- symptom prevention and relief;
- attention to emotional and spiritual needs and goals;
- care for the patient and family as a unit;
- sensitive communication, goal setting, and advance planning;
- interdisciplinary care; and
- services appropriate to the various settings and ways in which people die.

IOM did not identify the tools needed to measure the extent to which these activities and capacities could be achieved. Instead, it listed structural and process "dimensions" of quality of care for dying patients that could be used as administratively based quality measures (e.g., staffing, fiscal controls, and the establishment of prognoses and care plans). In 2004, the Agency for Healthcare Research and Quality sponsored an intensive literature review on end-of-life care (including hospices) that focused on relevant patient, family, and provider factors as well as processes and interventions that could be used to identify components of high-quality care (Lorenz et al. 2004).[25] This review identified the following factors as influencing end-of-life care outcomes:

- pain and symptom management
- support for families and other caregivers
- continuity and coordination of care
- advance care planning and respect for patients' wishes

Hospices can vary considerably in their ability to provide even these essential services. In 2007, Carlson and colleagues reported their assessment of the performance of hospices from 1992 to 2000 in providing core services (as defined in the applicable sections of the U.S. Code of Federal Regulations governing the Medicare hospice benefit) using data from the discharge questionnaire of the National Home and Hospice Care Survey administered by the National Center for Health Statistics (Carlson et al. 2007).[26]

Carlson and her colleagues defined five essential categories of care (nursing care, physician care, medication management, psychosocial care (counseling and spiritual care), and caregiver support), based on the National Consensus Project's eight domains of high-quality care.[27] They found that in 2000, only 14 percent of hospices (accounting for 22 percent of the sample's patients) provided care in all five categories; 12 percent of hospices provided care in only one category. These percentages represented an increase in hospices' provision of service by category from 1992. The provision of services did not vary by whether the hospice was urban or rural.

Analyzing the provision of services from the patients' (rather than the hospices') perspective, Carlson and colleagues again noted considerable variation. Table 8-13 shows that between 1992 and 2000, the percentage of patients using skilled nursing services declined slightly (from 95 percent to 92 percent), whereas the percentage of patients using homemaker services increased by more than 62 percent. The percentage of hospice patients receiving physician services and medication management increased, and the percentage of patients receiving counseling declined over this time, as did the provision of respite care.

Carlson and colleagues could not definitively ascertain the reasons for variation in service provision but suggested that variation in the provision of nonhospice palliative care may have played a role—that is, patients may have access to palliative care services outside of the hospice benefit. The study did not assess whether all patients needed or had been offered all these services but simply whether they had been provided. The fact that such variation exists, in terms of both the distribution of hospices' provision of core services and the percentage of patients receiving core services in a given category, suggests that additional data collection is necessary (e.g., hospice patients' use of drugs, medical equipment, emergency services, and services unrelated to their terminal conditions) and that CMS survey and certification efforts may be necessary to ensure that hospices are providing the essential categories of care enumerated in Medicare's applicable conditions for participation.

TABLE 8–13

Variation exists in patients' use of hospice services

Service category	1992	2000	Percent change
Homemaker/household services	8%	13%	62.5%
Medication management	39	59	51.3
Physician services	24	30	25.0
Skilled nursing	95	92	–3.2
Counseling	36	31	–13.9
Respite care	11	7	–36.4
Spiritual care	N/A	59	N/A

Note: N/A (not available).

Source: Adapted from Carlson et al. 2007.

Patient and family assessments of hospice quality

In addition to hospice-level factors associated with care quality, patient and family assessments can suggest the presence or absence of quality in the hospice care a patient receives. One of the most prominent of such assessments is the Family Evaluation of Hospice Care (FEHC), a survey developed and fielded by NHPCO, with major analytic and substantive input from researchers at Brown University (Connor et al. 2005, Connor et al. 2004). The FEHC surveys recipients on how well the hospice attended to family support and information needs and how well the hospice assisted in coordinating care. It also solicits information on the family's perception of how well the hospice met the patient's needs for pain management, assistance with respiratory difficulty, and emotional support. The survey is mailed to the family of the deceased hospice patient or other designee, generally one to three months after the patient's death. Respondents are asked to return the survey to the hospice or its contractor, which submits the data to NHPCO. Then NHPCO compiles the survey responses for each responding hospice, calculates state and national totals, and provides each hospice with a detailed summary of its scores and how its scores compare with those of other hospices in the state and nationwide. Since 1999, NHPCO has worked to refine the survey instrument, improve the quality of data reporting, and improve the survey response rate. In October 2006 the National Quality Forum endorsed national voluntary consensus standards related to the quality of care for symptom management and end-of-life care for patients with cancer. The National Quality Forum standards included nine performance measures for accountability, internal quality improvement, and/or surveillance. Among the endorsed measures was NHPCO's FEHC, which was the only measure designated as an accountability measure. One of the NHPCO End Result Outcome Measures, the Comfortable Dying Measure, was also selected as a quality improvement measure.

In the fall of 2007, the National Association for Homecare and Hospice (NAHC) developed an abbreviated version of a family satisfaction survey as well as a patient survey. Each is a single page, and each asks the survey respondent to rate the hospice's performance by agreeing or disagreeing with statements characterizing how well the hospice met the patient's pain and symptom management and other needs, its communications with the patient and the family, and the hospice staff's personal interactions with the patient. Participating hospices provide the surveys to the patient (two weeks after admission) or the family (two months after the patient's death); respondents return the surveys directly to NAHC, which compiles the data and reports hospice-specific results to each participating hospice. (The NAHC survey effort is in its early stages, and there are no aggregate results to report at this time. Therefore, much of the following discussion deals with the FEHC survey, but many of the conceptual issues pertain to both surveys.)

NHPCO's efforts to improve the FEHC and NAHC's efforts to develop a shorter family survey (as well as a patient survey) represent potentially useful tools for

hospices to identify areas for improvement within their operations. The FEHC and the NAHC family survey can provide useful feedback to individual participating hospices by identifying specific areas where they can improve the quality of care they provide. For example, most hospices participating in the FEHC in 2004 performed well in managing their patients' pain and shortness of breath and in providing emotional support. There was variation in other measures, however; 29 percent of respondents overall indicated that hospices had "opportunity for improvement" in communicating information about the patient's condition to their families. At the 75th percentile of hospices, more than one-third of patients expressed such concerns (Connor et al. 2005).

However, there are limitations to the potential use of these types of surveys by the Medicare program in assessing the quality of hospice care. First, the surveys are voluntary, and although the organizations encourage their members to participate in the survey effort, members are not required to do so. In 2008, one-half of NHPCO's members participated, representing roughly one-third of all hospices nationwide (Connor 2008). Hospices that are not NHPCO members (and thus not represented in the FEHC) are more likely to be smaller and to be for-profit hospices or to have membership in another hospice association. Hospices that are not association members may be less likely to adhere to the association's principles and guidelines governing hospice care. In addition to potential bias related to association membership, hospices that participate in the surveys may consider themselves high-quality providers and look to the surveys to validate these perceptions, a self-selection that could introduce additional bias into the results. In addition to a potentially skewed distribution of participating hospices, family response rate—currently 46 percent—may also skew the results in that we do not know how nonrespondents characterized their satisfaction with the care the hospice patient received. NHPCO believes that participation in the survey may increase if CMS's proposed revisions to the hospice care amendments (conditions of participation) (CMS 2005) are finalized, given that hospices could use FEHC participation and subsequent responsive action as evidence of a quality assessment and performance improvement program required by the proposed rule.

Second, the FEHC and the NAHC family survey measure hospice care through the perceptions of family members or persons otherwise closely related to the hospice patient. Many questions rely almost exclusively on the perceptions of these respondents, whose answers on behalf of the patient may not necessarily reflect the patient's actual experience, particularly if the patient was unable to communicate well. For example, the FEHC asks respondents questions about whether the patient's pain medication was the right amount or more or less than the patient wanted and whether the hospice team always, usually, sometimes, or never treated the patient with respect.[28] The NAHC's Patient Satisfaction Survey, currently in the early stages of implementation, may provide information to fill this gap in the future. NHPCO, in conjunction with researchers at Brown University and the University of Massachusetts, is also in the early stages of developing and testing a patient evaluation-of-care tool. However, measuring hospice patient satisfaction is a uniquely difficult endeavor. In developing the patient perception-of-care survey instrument, researchers working with NHPCO estimate that only 20 percent to 25 percent of patients would be able to respond to a survey administered 14 days after admission.

Other questions are aimed at assessing how well the hospice performed in meeting the family's needs (e.g., "how often did the hospice team keep you informed about the patient's condition?" and "did the hospice team explain the plan of care to you in a way that you could understand?"). Given the lack of quantifiable specific outcomes under the hospice benefit and that much of the hospice benefit consists of emotional, spiritual, and psychological supports, family perceptions may be appropriate indicators of the quality of hospice care.

A third limitation of hospice performance assessments by nonprofessionals is the tendency for respondents to give positive ratings; thus, such assessments may not adequately differentiate performance among hospices. One goal of the FEHC was to develop questions that would differentiate among hospices' performance in the various domains of care, something that NHPCO's initial attempt at a survey instrument did not adequately do. However, despite refinements to the survey in light of field experience over the last several years, it is unclear whether the current iteration of the survey has improved the ability to differentiate hospice performance among its various measures. For example, results from the 2005 FEHC suggest that well over 90 percent of survey respondents rated their family member's care as "excellent" or "very good" (Rhodes et al. 2007). (Somewhat better differentiation occurs when these two categories are disaggregated (Connor 2008).) The FEHC also reports composite scores for each hospice provider, assessing

overall satisfaction with care. In 2004, the average composite satisfaction score was 47.1 (of a possible score of 50), with a median of 47.6, and an interquartile range of 46.7 to 48.2 (Connor et al. 2005). These scores may reflect the nature of family members' perceptions—that they greatly appreciate almost any hospice involvement at the end of the patient's life.

CMS measures of hospice quality

CMS does not currently require hospices to collect or report information on the quality of care they provide. In part, the absence of such a requirement reflects the fact that hospice quality measures remain under development and that, to a large extent, assessments can be subject to interpretation and bias. As part of the revisions to the hospice conditions of participation CMS proposed in 2005, hospices would be required to engage in quality assessment and performance improvement projects linked to improving palliative outcomes and end-of-life support services (CMS 2005). Hospices would be required to collect performance data on measurable quality indicators and demonstrate that they continuously monitor these data and use them on an ongoing basis to improve the quality of their care. In its proposed rule, CMS does not require that hospices use any specific or particular process or measures but suggests that participation in NHPCO's surveys (e.g., the FEHC) would satisfy this requirement. CMS does not propose public reporting of any data obtained through the hospice's quality assessment and performance improvement projects.

In 2006, CMS implemented a project with the Carolinas Center for Medical Excellence (CCME), Medicare's quality improvement organization for North and South Carolina, to identify quality measures for end-of-life care and collect and analyze the instruments available to gather data on those measures. The CCME submitted the first deliverables of the project (known by its acronym PEACE) to CMS in February 2008. Some of these measures are generally comparable to measures NHPCO uses in its FEHC survey. The PEACE instrument contains similar measures for assessing and treating dyspnea and other clinical symptoms—as well as measures of psychological, social, and spiritual aspects of care—all generally expressed as a percentage of the hospices' total patients. The PEACE measures aim to better quantify quality data by assessing the percentage of patients whose care met certain process benchmarks or received certain services within a specified period of time. For example, the PEACE instrument measures the percentage of patients who were screened for pain on admission, the percentage of patients affirming pain who had a clinical assessment within one day, and—of those—the percentage whose pain was mitigated within 48 hours. These data would be obtained through a variety of sources, including the hospice's existing administrative data, through after-death family surveys, and through patient chart reviews (CCME 2008). CMS is reviewing CCME's deliverables; the National Quality Forum will also review the measures before they are publicly disseminated.

Public reporting of hospice quality data

In recent years, the American Hospice Foundation has been developing a hospice "report card" that would provide a vehicle for public reporting of quality and other data to allow members of the public to compare hospices' performance in terms of quality. The hospice report card would use many of the measures included in NHPCO's FEHC, such as mitigation of pain, mitigation of shortness of breath, and patient and family satisfaction indicators. It would also report administrative data, such as visits per week and staffing ratios, and include graphic displays that compare hospices in the same market and the average performance on these quality measures for all hospices in a state.

Other potential measures using administrative data

In the absence of good outcomes measures, some members of the hospice community have indicated that certain administrative measures, such as service intensity (measured by visits per week) and staffing ratios, could serve as gross indicators of quality that could differentiate performance among hospices. Outcomes measures or direct measures of quality of care are generally preferable, but, given the limitations of such measures in the hospice setting, such administrative measures may have a place in assessing hospice quality.

Some hospices have suggested that a measure of nursing costs per patient day may help differentiate hospices in the level of care they provide. The American Hospice Foundation uses nursing visits per week as one measure of quality in its "hospice report card" currently under development.

In our analysis of hospices' nursing cost data, we found that nursing costs were consistent by provider type, did not vary by patient load, and were correlated with a hospice's profitability. Specifically, in the four years we examined, nonprofit hospices had higher nursing costs per day than

TABLE 8–14 **Higher margin hospices have lower nursing costs per day, 2005**

Category	Nursing costs per day
All	$53.67
Urban	54.54
Rural	48.95
Nonprofit	55.80
For profit	50.23
Government	77.57
Other	63.37
Freestanding	49.84
Provider based	66.13
Home health based	56.72
Hospital based	75.41
Patient volume (quintile)	
1	54.00
2	50.24
3	52.90
4	52.08
5	54.76
Margin (decile)	
1	101.31
2	71.55
3	56.96
4	54.48
5	53.09
6	53.52
7	50.96
8	49.49
9	42.94
10	33.34

Source: MedPAC analysis of Medicare hospice cost reports, 100 percent hospice claims standard analytical file, and Medicare Provider of Services data from CMS.

did for-profit hospices, and provider-based hospices had higher nursing costs than freestanding providers (Table 8-14).

In addition, we found that nursing costs did not vary significantly with patient load. That is, nursing costs per day for the 20 percent of hospices with the fewest patients are generally comparable to nursing costs per day for hospices with the greatest number of patients. This pattern suggests a relatively constant relationship of nursing costs to patient loads; a hospice's nursing costs rise as its census increases.

In contrast, we found that hospices' nursing costs varied as a function of their profitability under Medicare. Hospices in the highest margin decile had nursing costs per day that were roughly only one-third of the nursing costs per day of hospices in the lowest margin decile.

Four factors could independently or in combination explain the progressively lower nursing costs with each margin decile category:

- ***Provider efficiency.*** More profitable providers could be serving their patient base with lower levels of nursing care than their less profitable (and less efficient) counterparts.
- ***Patient mix.*** A provider might have a large share of long-stay hospice patients (e.g., those with neurodegenerative diseases or nonspecific debility) who use a smaller percentage of skilled nursing services than do patients with diagnoses associated with shorter stays.
- ***Provider type.*** Provider-based hospices have higher overall costs per day than do freestanding facilities, in part due to the allocation of costs from the parent provider, but other factors likely play a role as well.
- ***Differences in skilled nursing visits per day.*** A hospice provider can achieve lower nursing costs per day by using more home health aides and fewer nurses and by providing fewer nursing visits per week to its patients.

Measures of staffing or other administrative measures would need further evaluation to fully test their validity as indicators of hospice quality.

Conclusion and implications for next steps

Medicare's hospice benefit is unique in its provision of a package of services tailored to patients at the end of life and their families. It provides clinical and personal support services for patients at the end of life beyond what Medicare covers through its traditional benefit package, allowing a dignified death at home and with family for those who choose to do so. In exchange for this benefit, hospice enrollees explicitly forgo Medicare coverage of

curative treatment for their terminal conditions. In making this choice, beneficiaries avoid the costs of hospitalizations and other intensive medical interventions at the end of life. It is important that the hospice benefit, and Medicare's reimbursement system for hospice care, be as well aligned as possible with the costs to an efficient hospice of providing care to meet these patients' needs.

The population using hospice has changed since the inception of the hospice benefit, and now patients with terminal diagnoses other than cancer choose to avail themselves of this benefit. Such an expansion to appropriate patients is desirable from a number of perspectives. However, our current work suggests that the hospice payment system provides an incentive for hospices to seek patients likely to have long hospice episodes, which are more profitable than short episodes. We have seen that longer hospice stays are more costly for the Medicare program than traditional curative end-of-life care, and thus the incentive in the payment system that financially rewards hospices for longer stays runs counter to the fiscal interests of Medicare overall, operating in direct conflict with Medicare's interest in ensuring that the hospice benefit provide a less costly alternative to traditional end-of-life care. The hospice cap serves as a check on additional Medicare expenditures for hospice care, but a relatively generous one, given that the cap amount in 2004 was roughly equivalent to 85 percent of the cost of a full year of end-of-life care in that year. The hospice payment system should be changed to minimize incentives that make some patients more profitable than others, so that access is equal for all Medicare beneficiaries who wish to use the benefit.

The aggregate per beneficiary payment limit should be reevaluated and updated to reflect the current provision of end-of-life care through hospice, but only as part of a larger restructuring of the hospice payment system. Any revisions to the cap should be made in a manner consistent with changing the incentives in the payment system to ensure the most appropriate use of hospice care at the end of life. Additionally, fiscal and program management controls should be strengthened where they currently exist, and new ones should be implemented where they do not, for purposes of increasing the fiscal integrity of the benefit and for general programmatic management.

The cap has raised questions about the guidance that CMS, Medicare intermediaries, and hospice associations provide to individual hospices regarding the identification of patients near the end of life who are appropriate for admission to hospice. Hospices reaching the cap assert that they are admitting patients in conformity with the guidance applicable to them. However, striking differences in the lengths of stay between hospices that exceed the cap and those that do not persist across virtually all diagnoses and disease categories. Neither above-cap nor below-cap hospices are able to explain this phenomenon, and administrative data do not contain sufficient information to permit an assessment of patient characteristics that may shed light on it. These differences suggest that the guidance for some terminal conditions may not adequately identify the stage in the progression of the disease when hospice admission is appropriate. This, coupled with the financial incentives to admit patients with the potential for long stays, could help explain these patterns.

Little accountability exists in the hospice payment system in terms of requirements to document services provided as a condition for reimbursement. Hospice is the only Medicare provider payment system under which providers do not have to report the services they furnish on their claims. Providers have had to report only the number of days of patient care broken down by the four hospice care categories. They have not been required to report information on the resources used, the content or duration of services provided, or the outcomes of these services. The recent CMS change request will require hospices to report a limited amount of information that will begin to fill this gap, but this new information will not fully meet the program's data needs. For example, in the first iteration of the data collection, CMS will collect information on the number of nursing visits but not their duration or type, nor will the agency collect information on all practitioners involved in hospice care. Nevertheless, the new requirement represents a first step in ensuring the flow of information that will be vital to refining and monitoring the hospice benefit in the future.

Because of the lack of data on services provided to patients with specific diagnoses, it is difficult to determine the adequacy of Medicare payments relative to the cost of hospice care on a condition-specific basis. We have little information on how the cost of hospice care varies by the patient's admitting diagnosis, so we do not know if the payment system inappropriately discourages or encourages different kinds of admissions based on the relationship of Medicare payments to patient costs. The only publicly available measure that correlates resource use by diagnosis is length of stay. We know that longer stays are more profitable, based in part on the differential visit intensity during the course of an episode. We also

know that profitability is highest for providers with low nursing costs, but we do not have information on how these costs are distributed among these hospices' patients with different diagnoses.

Lastly, we note that standardized data on the quality of hospice care that could be used for program oversight and evaluation are virtually nonexistent. The hospice community surveys patients and their families to compile information on the quality of care hospices provide, but due to the subjective nature of such protocols and concerns about their ability to differentiate among hospice providers' performance, they are not immediately useful for program administration purposes. Process or operational measures (e.g., staffing ratios or visit intensity) either have not been evaluated or data do not exist to establish baselines as they pertain to quality of care. CMS will likely require hospices to engage in quality improvement projects as part of new conditions for participation scheduled to be promulgated in May 2008. However, a considerable period of time will elapse before data on the quality of care, resulting from such projects or from administrative or other systematic data, will be available for purposes of comparing quality among hospice providers or to institute quality-based payment incentives in Medicare's hospice payment system. ■

Endnotes

1 New conditions of participation for hospices were published in a proposed rule on May 27, 2005 (CMS 2005). The current conditions of participation went into effect in 1983 and were last amended in 1990.

2 The wage index is determined by the location where the services are provided, not by the location of the hospice provider. The hospice wage-index values are the prefloor, prereclassification hospital wage index values subject to a budget-neutrality adjustment or wage-index floor (an amount 15 percent greater than the raw wage index calculated for areas with a wage index of less than 0.80). Budget neutrality is defined as estimated aggregate payments to hospice providers that would have been made if the 1983 wage-index values remained in effect. CMS recommended eliminating the budget-neutrality adjustment in a proposed rule published May 1, 2008 (CMS 2008).

3 This premise came from a Congressional Budget Office analysis in the early 1980s that suggested that hospice would reduce Medicare spending for care at the end of life by substituting less costly home care for expensive inpatient hospital treatments (Bayer and Feldman 1982, Freudenheim 1986, Miller and Mike 1995, UPI 1982) as well as from the anticipated results of the Medicare National Hospice Study, conducted from 1978 to 1981. Reduced spending was to be enforced via a limit on the amount Medicare would pay hospices under the benefit that took the form of the "hospice cap." Draft legislation (H.R. 5180, S. 1958) initially set the cap at 75 percent of the average Medicare cost of treating a cancer patient in the last six months of life, but, by the time the legislation passed in August 1981 (P.L. 92-248, 96 STAT. 324), the cap had been reduced to 40 percent (Bayer and Feldman 1982). On imposing the cap in 1983, however, it was discovered that, although the Health Care Financing Administration (the agency that is now CMS) had implemented the statutory language establishing the benefit correctly, that language was based on an erroneous congressional interpretation of the Congressional Budget Office scoring of the draft legislation. The cap was legislatively set at $6,500 in June 1983 (Dole 1983). It is updated for inflation annually.

4 The average annual payment cap is calculated for the period November 1 through October 31 each year. For the year ending October 31, 2005, the cap amount was $19,776; for the period ending October 31, 2007, the cap was $21,410. Beneficiaries are counted in a given year if they have filed an election to receive hospice care from the hospice during the period beginning on September 28 before the beginning of the cap period and ending on September 27 before the end of the cap period. If a beneficiary receives hospice care from more than one hospice during the year, each hospice counts the fraction that represents the portion of a patient's total hospice stay spent in that hospice.

5 The second cap limits the share of inpatient care days (either inpatient respite care or general inpatient care) an agency may provide to 20 percent of its total patient care days each year. This cap was intended to prevent hospice care from becoming a predominantly inpatient benefit and to preserve the delivery of hospice care in the patient's home (Gage et al. 2000). If an agency exceeds the 20 percent inpatient cap, Medicare pays the routine home care rate for the days above the threshold. Hospices rarely exceed the 20 percent inpatient limit on total patient care days.

6 Studies consulted in developing this summary information include Brooks (1989), Brooks and Smyth-Staruch (1984), Campbell and colleagues (2004), Cheung and colleagues (2001), Emanuel and Emanuel (1994), Emanuel and colleagues (2002), Gage and colleagues (2000), Greer and Mor (1986), Hannan and O'Donnel (1984), Hughes and colleagues (1992), Kane and colleagues (1984), Kidder (1998, 1992), Miller and colleagues (2004), Miller and Mike (1995), Mor and Birnbaum (1983), Mor and Kidder (1985), Pyenson and colleagues (2004), Spector and Mor (1984), and Taylor and colleagues (2007).

7 Similarly, the cost differential may vary by patient age. This is especially important to keep in mind, as the rate of hospice enrollment by age group is fastest among the oldest segment of the Medicare population—historically, those who incur the lowest spending at the end of life regardless of hospice.

8 In the early 1990s, the Department of Health and Human Services Office of Inspector General, the Health Care Financing Administration (now CMS), and the Administration on Aging had implemented Operation Restore Trust (ORT), which was a concerted effort to combat waste, fraud, and abuse in the Medicare program. Hospices were specifically targeted for ORT focus, given a long list of potentially fraudulent practices identified by the Office of Inspector General that some hospices may have engaged in to maximize Medicare reimbursement. ORT's activities may have contributed to the reduced length of stay observed in this period by making physicians more wary of referring all but the most clear-cut terminal cases to hospice.

9 This figure is not precisely comparable to the preceding NHPCO percentages. The NHPCO figures reflect a subset of hospices rather than all Medicare-participating hospices. In addition, the Commission's figure includes decedents as well as hospice users who did not die in 2005.

10 One Medicare hospice intermediary, Palmetto GBA, accounted for more than 80 percent of hospices reaching the cap in 2005, raising speculation that this intermediary may have been anomalous with respect to its admissions guidance or its cap calculation methodology (MedPAC 2006). However, discussions with all the RHHIs have indicated that there is no general inconsistency in admissions guidance, and, with the exception of how each intermediary handles patients who transfer from one hospice to another during the course of their end-of-life care, all RHHIs use the same methodology for counting patients for the purpose of calculating the cap.

11 These aggregate numbers do not precisely match the previously published figures we received from the RHHIs. This could be due to a number of methodologic factors. The trends are consistent between the two sources.

12 Length of stay is reported on cost reports only for freestanding facilities.

13 The length of stay for "all other diseases" was about 138 percent greater in above-cap hospices than it was for hospices that did not reach the cap, but given the heterogeneous content of this category, it is difficult to impute more than a general significance to this fact.

14 We focused on voluntary closures rather than involuntary terminations under the assumption that involuntary terminations could be definitively ascribed to factors other than a hospice reaching the cap; CMS does not terminate participation for exceeding the cap.

15 In terms of the number of hospices per capita, Oklahoma ranked highest in 2005, with 2.86 hospices per 10,000 Medicare beneficiaries (145 hospices and 506,000 beneficiaries). By contrast, Maine, at the midpoint of the distribution, had 0.87 hospice per 10,000 beneficiaries, and Florida had the smallest number of hospices per 10,000 beneficiaries with 41 hospices serving more than 2.8 million beneficiaries in 2005, a ratio of 0.14 hospice provider per 10,000 beneficiaries.

16 Over the last 10 fiscal years, annual increases in hospice use have ranged from 7.0 percent to 15.4 percent (CMS 2007a).

17 The rate of hospice use by beneficiaries with end-stage renal disease enrolled in managed care declined between 2000 and 2005.

18 Hospice care is one of several health care lines of business that Beverly Enterprises operates. Aseracare, its hospice unit, operates 52 hospice and home health locations, which accounted for only $65.6 million of Beverly's $2 billion in revenues in 2004. The company's financial statements do not permit the calculation of margins by business line. Similarly, hospice makes up a relatively small share of Manor Care's operations, and information necessary to calculate its hospice-specific margin is not available.

19 Although increasing length of stay may be a strategy to maximize the profitability of Medicare hospice episodes, the strategy is not without risks. In addition to the heightened risk of cap exposure as length of stay increases (with the corresponding obligation to return excess payments to the Medicare program), increasing length of stay may also attract the attention of regulatory and enforcement agencies. In April 2005, the Department of Health and Human Services Office of Inspector General issued civil subpoenas to Vitas alleging inappropriate billings for its Medicare and Medicaid hospice patients (Chemed 2007). Vitas had been investigated previously on the basis of similar allegations under the auspices of Operation Restore Trust; that investigation concluded without adverse findings against Vitas. The Department of Justice investigated Odyssey HealthCare on the basis of suspected admission of patients who did not meet the presumptive eligibility requirement. In 2006, Odyssey HealthCare settled the Justice Department complaint, paying a $13 million fine, without admitting wrongdoing (Odyssey HealthCare 2007).

20 Government providers' margins were negative in all years between 2001 and 2005, but their underlying cost report data exhibit irregularities and atypical values that lead us to question the reliability of these margins.

21 Cost reports for provider-based hospices do not include this variable.

22 For the most part, data on hospice visits are limited to those collected under the auspices of the National Hospice Study, the three-year demonstration (1978–1981) that laid the groundwork for the Medicare hospice benefit. Even at that time, differences in service utilization by patient diagnosis were evident: "Based upon the billing data received from demonstration hospices, noncancer patients appear to use almost twice as many hours of home health, homemaker, and nursing services during their stay in hospices" as do cancer patients (Mor and Birnbaum 1983).

23 Data from this provider for the first two months of 2008 suggest that average length of stay for patients with noncancer diagnoses may have begun to level off somewhat.

24 Although the number of visits per week increased for many of the length-of-stay and disease categories we examined, visit intensity declined overall during this period, as illustrated in Figure 8-5. This is because longer stays (with lower visit intensity) increased as a percentage of this chain provider's total stays.

25 The Agency for Healthcare Research and Quality analysis also identified patient satisfaction as an indicator of the effectiveness of provision of care at the end of life.

26 Core services are defined under Subpart D of the conditions of participation codified at 42 CFR 80–88 as nursing services, medical social services, physician services, and counseling services (bereavement, dietary, and spiritual).

27 These domains are: structure and processes of care; physical aspects of care; psychological and psychiatric aspects of care; social aspects of care; spiritual, religious, and existential aspects of care; cultural aspects of care; care of the imminently dying patient; and ethical and legal aspects of care.

28 Even questions aimed at the hospice patient that are more amenable to quantification, such as mitigation of pain (measured on a numeric scale) within 48 hours, are subject to individual patient perceptions.

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APPENDIX A

Review of CMS's preliminary estimate of the physician update for 2009

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Review of CMS's preliminary estimate of the physician update for 2009

In CMS's annual letter to the Commission on the payment update for physician services, the agency's preliminary estimate of the 2009 update is –5.4 percent (Rich 2008). A negative update in 2009 would be in addition to a 10.6 percent decrease to occur on July 1, 2008, at the end of a temporary six-month bonus that was included in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA).

These reductions are required under the sustainable growth rate (SGR) formula, which is defined in statute as the policy for updating Medicare's payment rates for physician services. The formula has a spending target for physician services, and spending has exceeded the target in recent years. CMS estimates that the accumulated deficit between spending and the target will reach $57.8 billion by the end of 2008.

As the deficit has grown, the formula has been calling for payment reductions. Meanwhile, the Congress has overridden the formula. According to CMS's estimates, the formula is now calling for a payment adjustment of –26.5 percent. With a payment adjustment this large, the accuracy of CMS's estimates becomes less important than it would be otherwise. Although the formula may show an adjustment of –26.5 percent, the statute also includes a limit on how large the reduction can be in any one year. The limit is –7.0 percent. Because the calculated adjustment exceeds the limit by such a wide margin, it is very unlikely that there are any inaccuracies in CMS's estimates sufficient to make the adjustment anything other than –7.0 percent.

In turn, the update is unlikely to differ much from the –5.4 percent that CMS has calculated. Arithmetically, the estimate of –5.4 percent is a function of expected inflation in input prices of 1.7 percent and the update adjustment of –7.0 percent. The inflation estimate is the only factor in the calculation with any meaningful likelihood of changing, and it may change somewhat between now and November when CMS publishes the update that would actually occur.

It is in this context that the Commission fulfills its requirement to review CMS's estimate of the 2009 update for physician services. In examining the technical details involved in estimating the update under the SGR formula (in accordance with current law), we find that CMS used estimates in calculating the update that are consistent with recent trends.[1]

Before presenting these findings, we note that, in communicating the update estimate to the Commission, CMS states that it is engaged in a number of activities that would link payments to the value of care provided and transform Medicare from a passive payer for services into an active purchaser of high-quality care. The Commission concurs with CMS that Medicare should initiate strategies to improve the program's value. CMS's estimate comes at a time when Medicare and other purchasers of health care face enormous challenges (MedPAC 2008). Health care

TABLE A–1 **Preliminary estimate of the sustainable growth rate, 2009**

Factor	Percent
2009 change in:	
Input prices for physician services*	2.1%
Real GDP per capita	1.8
Fee-for-service enrollment	–0.2
Change due to law or regulation	–2.9
Sustainable growth rate	0.7

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 costs includes inflation measures for services furnished by a physician or in a physician's office. It is adjusted for productivity growth.

Source: Rich 2008.

costs are growing faster than the economy and incomes, and quality frequently falls short of patients' needs. Unexplained variations in the use and quality of care in the current system suggest that opportunities exist for reducing waste and improving quality.

In presenting this review of CMS's update estimate, we remind readers that previously the Commission discussed flaws in the SGR formula (MedPAC 2007). As mandated by the Congress, the Commission examined alternative approaches to the SGR system, many of which included frameworks with expenditure targets. In the end, Commissioners disagreed on the utility of expenditure targets. On the one hand, they neither reward physicians who restrain volume growth nor penalize those who prescribe unnecessary services. Ideally, Medicare's physician payment system should include incentives for physicians to provide better quality of care, to coordinate care (across settings and medical conditions), and to use resources judiciously. On the other hand, it may be better to think of an expenditure target as a tool for altering the behavior of policymakers than as a tool for improving how providers deliver services. That is, an expenditure target first alerts policymakers that spending is rising more rapidly than anticipated and then makes it more difficult for them to increase payment rates. Despite the disagreement, the Commission is united in its belief that a major investment should be made in Medicare's capability to develop, implement, and refine payment systems to reward quality and efficient use of resources while improving payment equity. Examples of such reforms include establishing pay-for-performance programs for quality, improving payment accuracy, measuring physician resource use, and bundling payments to reduce overutilization. Nonetheless, it is understood that the underlying incentives in current fee-for-service (FFS) payment systems and the structure of the delivery system will make significant gains in value difficult to realize.

Prefacing our review of CMS's estimate, we first summarize certain provisions in the MMSEA. An awareness of these provisions helps with interpreting next year's update. We also review the steps in the update calculation.

How the MMSEA affects 2008 and 2009 updates for physician services

The MMSEA included several provisions that affect physician payments in 2008 and 2009. To avert a cut in the fee schedule's conversion factor that would have been effective January 1, 2008, under the SGR, it provided for a temporary 0.5 percent increase in the fee schedule conversion factor for the first six months of 2008. If this change had not been enacted, the 2008 update would have been –10.1 percent.[2]

For payments after the first six months of 2008, the MMSEA requires that the conversion factor be calculated as if the temporary increase had never been applied. Thus, the conversion factor is scheduled to decline by a total of 10.6 percent on July 1, 2008. The reduction would remove the temporary 0.5 percent increase, and it would implement the 10.1 percent decrease that would have occurred in the absence of the MMSEA.

The MMSEA also extended two payment policies that were scheduled to expire at the end of 2007: the floor on the geographic practice cost index (GPCI) for physician work and a 5 percent bonus payment to physicians practicing in designated physician scarcity areas. Both extensions are effective through the first six months of 2008.

The Congressional Budget Office (CBO) scored these MMSEA provisions—the temporary 0.5 percent increase and the extensions of the GPCI floor and the scarcity area bonus—as an increase in Medicare spending totaling $3.1 billion in fiscal year 2008. To help pay for this

increase, the MMSEA eliminated almost all of a $1.35 billion Physician Assistance and Quality Initiative Fund. This fund was created under the Tax Relief and Health Care Act of 2006 (TRHCA) for physician payment and quality improvement initiatives. Use of the fund to help pay for the temporary increase was consistent with the Commission's position on how to apply it.[3]

The MMSEA did not eliminate a current quality improvement initiative, the Physician Quality Reporting Initiative (PQRI), however. It was extended for another year—through 2009—but with a different funding source. Instead of the fund created under TRHCA, PQRI payments to physicians are now funded directly from the Part B Trust Fund without the $1.35 billion cap on total spending that was imposed under TRHCA. The payments remain equal to 1.5 percent of a physician's total allowed charges.

One last MMSEA provision is relevant to physician updates. The MMSEA established a fund of nearly $5 billion for future physician updates. We anticipate that future legislation will define when and how to apply this new funding.

TABLE A–2 **Preliminary estimate of the physician update, 2009**

Factor	Percent
***Excluding* MMSEA bonus**	
2008 update per SGR formula	–10.1%
2009 update factors per SGR formula:	
MEI	1.7
Update adjustment factor	–7.0
2009 update per SGR formula	**–5.4**
***Including* MMSEA bonus**	
2008 updates	
January–June	0.5
July–December	–10.6
2009 update	**–5.4**

Note: MMSEA (Medicare, Medicaid, and SCHIP Extension Act of 2007), SGR (sustainable growth rate), MEI (Medicare Economic Index). Percentages are converted to ratios and multiplied, not added, to produce the update. The MEI—an estimate of the change in input prices (inflation) for physician services—includes a productivity adjustment. Payment changes are changes from the previous period. Estimates shown are preliminary.

Source: Rich 2008.

Calculating the update

Calculating the physician update is a two-step process. CMS first estimates the target growth rate—the SGR—and then computes the update. For the first step, the SGR is the target growth rate in spending for physician fees and is a function of projected changes in:

- productivity-adjusted input prices for physician fees—an allowance for inflation,[4]
- real gross domestic product (GDP) per capita—an allowance for growth in the volume of services,[5]
- enrollment in 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 2009 is 0.7 percent (Table A-1).

For the second step, CMS calculates the update, which is a function of:[6]

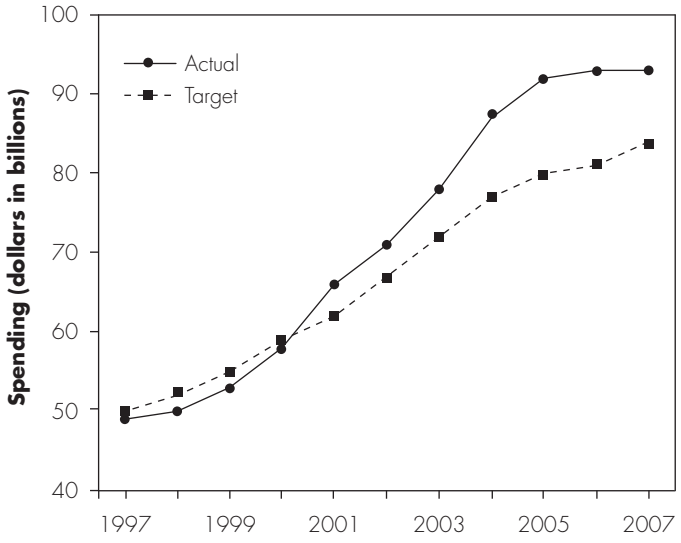
- the change in productivity-adjusted input prices for physician services, as measured by the Medicare Economic Index (MEI); and
- an update adjustment factor (UAF) that increases or decreases the update as needed to align actual spending, cumulated over time, with target spending determined by the SGR.

The estimate of the change in input prices for use in the 2009 update is 1.7 percent (Table A-2).[7] The part of the update calculation that has the larger effect, however, is the UAF, which CMS estimates at –7.0 percent, which is the maximum negative adjustment permitted under current law. Combining this adjustment with the estimated change in input prices results in an update of –5.4 percent. (Note that this calculation of the estimate converts percentages to ratios, which are multiplied rather than summed to produce the update.)

The UAF is negative because actual spending for physician services started to exceed the target in 2001 (Figure A-1, p. 246). As the deficit has grown, the formula has called for payment reductions, but the Congress has

FIGURE A–1

Since 2001, actual spending for physician services has exceeded target



Note: Estimates shown are preliminary.

Source: Office of the Actuary 2008.

overridden the formula. According to CMS's estimates, the UAF would now be –26.5 percent in the absence of the statutory limit. Thus, CMS's update estimate (–5.4 percent) is unlikely to change by a substantial amount because a UAF of –26.5 percent is well beyond the limit (–7.0 percent). For this reason, the Commission anticipates that no alteration in the factors of CMS's estimates would be large enough to bring the UAF within the limit. Even so, we review the factors that CMS considers in its update estimate, beginning with the change in input prices.

Reviewing CMS's estimate

Measured by the MEI, CMS's estimate of the change in input prices is within the range during the last 15 years—though it is at the low end of the range.[8] It is low primarily because input prices for physician services have grown at a relatively low rate recently and because productivity has grown. According to the Bureau of Labor Statistics, the measure of productivity growth in the MEI has trended higher in recent years (BLS 2007).

After adjusting for population growth, the change in real GDP per capita of 1.8 percent equals the 10-year moving average of real GDP estimates from the Bureau of Economic Analysis (BEA 2008).

The change in FFS enrollment is a little less certain. CMS assumes a decrease of 0.2 percent for 2009. This figure differs by 1.6 percentage points from CBO's enrollment projection, which is a decrease in FFS enrollment of 1.8 percent for (fiscal year) 2009 (CBO 2008). Because CMS and CBO project similar total Medicare enrollment, the difference is primarily due to difficulties projecting shifts in enrollment from Medicare FFS to Medicare Advantage (MA). For 2009, CMS projects an MA increase of 8 percent, but CBO projects an increase of 15.4 percent. CMS may be better able to project any such shift when MA plans submit bids and identify market areas in June 2008. CMS can then revise the enrollment projection, if necessary, before the update becomes final in November 2008. Even then, CMS will have limited information on changes in enrollment in 2008, but the agency will have another two years to revise the enrollment estimate if better data become available, just as the agency does with changes in spending due to law and regulation.

CMS's estimate also allows for anticipated changes in payments due to law and regulation. A change in current law that might increase total payments, such as benefit expansion under Part B, would allow CMS to estimate a proportional increase (positive impact) to the SGR. In contrast, a change that requires a payment decrease, such as the expiration of a payment bonus, would call for a proportional decrease (negative impact) in CMS's estimate of the SGR.

For the 2009 SGR, CMS anticipates that some statutory and regulatory changes will increase physician spending. However, on net, CMS expects changes in law and regulation to reduce spending by 2.9 percent. This SGR factor is negative because three provisions in the MMSEA—the temporary conversion factor bonus, the floor on the work GPCI, and the physician scarcity bonus—are raising fees in 2008, albeit only for the first six months of the year. The effect of these provisions is to raise fees in 2008—on average—relative to 2009.[9]

Despite an overall reduction in spending due to law and regulation, CMS projects that certain legislative provisions will increase spending in 2009. For instance, in compliance with the MMSEA, PQRI bonus payments will continue in 2009. Although the bonuses will remain at 1.5 percent of allowed charges, CMS sees two reasons for higher spending on the bonuses in 2009 than in 2008.

First, the bonuses paid in 2009 will be for a full year instead of six months of allowed charges, which was the case with the bonuses paid in 2008. Second, CMS expects a greater proportion of physicians to receive the bonuses in 2009 than in 2008.

As was the case with the SGR for 2008, CMS also expects an increase in spending in 2009 due to a change in the effects of a provision in the Deficit Reduction Act of 2005 (DRA). Specifically, for certain imaging services, the DRA requires that Medicare pay the lesser of hospital outpatient department rates or physician fee schedule rates. Because hospital outpatient prospective payment system (OPPS) services will receive a positive update in 2009 while physician fee schedule services are projected to receive a negative update, CMS estimates that total spending will increase. That is, for some imaging services currently subject to the DRA limits, OPPS rates will rise to a level that exceeds the applicable fee schedule rates, thus reducing savings that had previously occurred because of the limits. (Note that, for the 2007 SGR estimate, CMS projected initial savings from the DRA legislation from those items that moved to the OPPS payment level.)

The remaining issue in calculating the update for 2009 concerns CMS's estimates of actual spending in 2007 and 2008. Data on actual spending are nearly complete through the first three quarters of 2007 but are less complete for the last quarter of that year. Therefore, the estimate of actual spending in 2007 may change somewhat before CMS issues a final rule on the update in November 2008. Of course, the uncertainty that accompanies the estimates of actual spending for 2008 is greater than for 2007 because CMS currently has very little information on actual spending in 2008.

Summary

Regardless of what happens with the various estimates that determine the physician update, it is unlikely that any change will overcome an update adjustment factor of –26.5 percent. Therefore, we anticipate that CMS will revise the update calculations this fall, in preparation for implementing the 2009 update on January 1, and that, barring any overriding statutory provisions, the calculations will show the maximum reduction the statute permits: the change in productivity-adjusted input prices (as measured by the MEI) minus 7.0 percentage points, or –5.4 percent. ■

Endnotes

1 Note that our purpose in reviewing CMS's estimate is not to assess the adequacy of the update, but rather to evaluate the technical details involved in estimating the update under current law. For further information on the Commission's analysis of payment adequacy for physician services, see our March 2008 report (MedPAC 2008).

2 A 2008 update of −10.1 percent would have been the combination of a negative update calculated with the SGR formula for that year and a negative update for 2007 that would have occurred in the absence of the Tax Relief and Health Care Act of 2006.

3 In addition to the fund, the other budgetary resources necessary for the 0.5 percent increase represent an increase in Part B spending.

4 For calculating the SGR, physician fees include fees for services commonly performed by a physician or in a physician's office. In addition to physician fee schedule services, these fees include diagnostic laboratory tests and most of the drugs covered under Medicare Part B.

5 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.

6 For the update, physician services include only those services in the physician fee schedule.

7 In its March 2008 report to the Congress, the Commission used a CMS forecast of change in the MEI in 2009 that equaled 2.6 percent. This forecast was not adjusted for productivity growth. If we compare the forecast in the Commission's report with the MEI increase of 1.7 percent in CMS's preliminary estimate of the update for 2009, one reason for the difference is that the increase with the preliminary estimate is adjusted for productivity growth. That is, the 1.7 percentage point increase includes an adjustment for productivity growth of 1.4 percentage points. The other reason the MEI numbers differ is that the increase of 1.7 percent is not a forecast for 2009. Instead, it is an estimate of historical change—in this case, from 2007 to 2008.

8 Since 1992, the MEI has ranged from 1.7 percent to 3.2 percent.

9 Earlier conversion factor overrides explicitly did not require a change in law and regulation for purposes of the SGR calculation. By contrast, the conversion factor bonuses in the TRHCA and the MMSEA allowed a change in law and regulation to be a factor in CMS's update calculation.

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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: Direction for delivery system reform

No recommendations

Chapter 2: Promoting the use of primary care

2A The Congress should establish a budget-neutral payment adjustment for primary care services billed under the physician fee schedule and furnished by primary-care-focused practitioners. Primary-care-focused practitioners are those whose specialty designation is defined as primary care and/or those whose pattern of claims meets a minimum threshold of furnishing primary care services. The Secretary would use rulemaking to establish criteria for determining a primary-care-focused practitioner.

Yes: *Behroozi, Bertko, Castellanos, Crosson, Dean, DeParle, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Stuart, Wolter*
No: *Borman, Scanlon*

2B The Congress should initiate a medical home pilot project in Medicare. 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),
- conduct care management,
- use health information technology for active clinical decision support,
- have a formal quality improvement program,
- maintain 24-hour patient communication and rapid access,

- keep up-to-date records of beneficiaries' advance directives, and
- maintain a written understanding with each beneficiary designating the provider as a medical home.

Medicare should provide medical homes with timely data on patient utilization. The pilot should require a physician pay-for-performance program. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

Yes: *Behroozi, Bertko, Borman, Castellanos, Crosson, Dean, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*
Absent: *DeParle*

Chapter 3: Examining hospital–physician collaborative relationships

No recommendations

Chapter 4: A path to bundled payment around a hospitalization

4A The Congress should require the Secretary to confidentially report readmission rates and resource use around hospitalization episodes to hospitals and physicians. Beginning in the third year, providers' relative resource use should be publicly disclosed.

Yes: *Behroozi, Bertko, Borman, Castellanos, Crosson, Dean, DeParle, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*

4B To encourage providers to collaborate and better coordinate care, the Congress should direct the Secretary to reduce payments to hospitals with relatively high readmission rates for select conditions and also allow shared accountability between physicians and hospitals. The Congress should also direct the Secretary to report within two years on the feasibility of broader approaches, such as virtual bundling, for encouraging efficiency around hospitalization episodes.

Yes: *Behroozi, Bertko, Borman, Castellanos, Crosson, Dean, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*
Absent: *DeParle*

4C The Congress should require the Secretary to create a voluntary pilot program to test the feasibility of actual bundled payment for services around hospitalization episodes for select conditions. The pilot must have clear and explicit thresholds for determining whether it can be expanded into the full Medicare program or should be discontinued.

Yes: *Behroozi, Bertko, Borman, Castellanos, Crosson, Dean, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*
Absent: *DeParle*

Chapter 5: Producing comparative-effectiveness information

No recommendations

Chapter 6: Public reporting of physicians' financial relationships

No recommendations

Chapter 7: A revised prospective payment system for skilled nursing facilities

7A The Congress should require the Secretary to revise the skilled nursing facility prospective payment system by:

- adding a separate nontherapy ancillary component,
- replacing the therapy component with one that establishes payments based on predicted patient care needs, and
- adopting an outlier policy.

Yes: *Behroozi, Bertko, Borman, Castellanos, Dean, DeParle, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*
Absent: *Crosson*

7B The Secretary should direct skilled nursing facilities to report more accurate diagnostic and service-use information by requiring that:

- claims include detailed diagnosis information and dates of service,
- services furnished since admission to the skilled nursing facility be recorded separately in the patient assessment, and
- skilled nursing facilities report their nursing costs in the Medicare cost reports.

Yes: *Behroozi, Bertko, Borman, Castellanos, Dean, DeParle, Durenberger, Ebeler, Hackbarth, Hansen, Kane, Milstein, Reischauer, Scanlon, Stuart, Wolter*
Absent: *Crosson*

Chapter 8: Evaluating Medicare's hospice benefit

No recommendations

Appendix A: Review of CMS's preliminary estimate of the physician update for 2009

No recommendations

Acronyms

Acronyms

AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
AAOS	American Academy of Orthopaedic Surgeons
ACCME	Accreditation Council for Continuing Medical Education
ACEP	American College of Emergency Physicians
ACO	accountable care organization
ACP	American College of Physicians
AdvaMed	Advanced Medical Technology Association
AHA	American Hospital Association
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
ALOS	average length of stay
AMA	American Medical Association
AMC	academic medical center
AMGA	American Medical Group Association
AMI	acute myocardial infarction
ASC	ambulatory surgical center
ASHP	American Society of Health-System Pharmacists
BCBSA	Blue Cross Blue Shield Association
BEA	Bureau of Economic Analysis
BLS	Bureau of Labor Statistics
BTE	Bridges to Excellence
CABG	coronary artery bypass graft
CBO	Congressional Budget Office
CCME	Carolinas Center for Medical Excellence
CCNC	Community Care of North Carolina
CCR	cost-to-charge ratio
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CFR	Code of Federal Regulations
CHC	continuous home care
CHF	congestive heart failure
CME	continuing medical education
CMI	case-mix index
CMP	civil money penalty
CMS	Centers for Medicare & Medicaid Services
COPD	chronic obstructive pulmonary disease
COX–2	cyclooxygenase–2
CRS	Congressional Research Service
DERP	Drug Effectiveness Review Project
DFRR	Disclosure of Financial Relationships Report
DO	doctor of osteopathic medicine
DRA	Deficit Reduction Act
DRG	diagnosis related group
DTC	direct-to-consumer [advertising]
E&M	evaluation and management
EC/IC	extracranial–intracranial
ED	emergency department
EHR	electronic health record
EMR	electronic medical record
FDA	Food and Drug Administration
FEHC	Family Evaluation of Hospice Care
FFRDC	federally funded research and development center
FFS	fee-for-service
FY	fiscal year
GAO	Government Accountability Office
GDP	gross domestic product
GIC	general inpatient care
GME	graduate medical education
GPCI	geographic practice cost index
HCFA	Health Care Financing Administration
HDC/ABMT	high-dose chemotherapy with an autologous bone marrow transplant
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HMO	health maintenance organization
HRET	Health Research and Educational Trust
ICD	implantable cardioverter defibrillator
ICD–9–CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICU	intensive care unit
IDS	integrated delivery system
IME	indirect medical education
IMRT	intensity-modulated radiation therapy
IOM	Institute of Medicine
IQWiG	Institute for Quality and Economic Efficiency in Health Care (Germany)
IRC	inpatient respite care
IRS	Internal Revenue Service
IT	information technology
ITC	International Trade Commission
IV	intravenous
KFF	Kaiser Family Foundation

LCA	least costly alternative
LLC	limited liability corporation
LOS	length of stay
LPN	licensed practical nurse
LUPA	low utilization payment adjustment
LVRS	lung volume reduction surgery
MA	Medicare Advantage
MAC	Medicare administrative contractor
MCBS	Medicare Current Beneficiary Survey
MD	doctor of medicine
MDS	Minimum Data Set
MedCAC	Medicare Evidence Development & Coverage Advisory Committee
MedPAC	Medicare Payment Advisory Commission
MEI	Medicare Economic Index
MGMA	Medical Group Management Association
MHS	Medicare Health Support
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007
MRI	magnetic resonance imaging
MSA	metropolitan statistical area
N/A	not applicable
N/A	not available
NAHA	National Alliance for Hospice Access
NAHC	National Association for Homecare and Hospice
NBGH	National Business Group on Health
NCHCT	National Center for Health Care Technology
NCQA	National Committee for Quality Assurance
NEC	not elsewhere classifiable
NHPCO	National Hospice and Palliative Care Organization
NICE	National Institute for Health and Clinical Excellence (United Kingdom)
NIH	National Institutes of Health
NOS	not otherwise specified
NTA	nontherapy ancillary
OACT	Office of the Actuary
OIG	Office of Inspector General
OPPS	outpatient prospective payment system
ORT	Operation Restore Trust
OTA	Office of Technology Assessment
P4P	pay for performance
PACE	Program of All-Inclusive Care for the Elderly
PBGH	Pacific Business Group on Health
PCCM	primary care case management
PCP	primary care physician
PET	positron emission tomography
PHO	physician–hospital organization
PhRMA	Pharmaceutical Research and Manufacturers of America
PPS	prospective payment system
PQRI	Physician Quality Reporting Initiative
PTCA	percutaneous transluminal coronary angioplasty
QI	quality improvement
RHC	routine home care
RHHI	regional home health intermediary
RN	registered nurse
RUC	Relative Value Scale Update Committee
RUG	resource utilization group
RVU	relative value unit
SCA	sudden cardiac arrest
SEC	Securities and Exchange Commission
SGR	sustainable growth rate
SHM	Society of Hospital Medicine
SNF	skilled nursing facility
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982
TRHCA	Tax Relief and Health Care Act of 2006
UAF	update adjustment factor
U.S.	United States
VMMC	Virginia Mason Medical Center

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Robert D. Reischauer, Ph.D., vice chairman
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Washington, DC

Term expires April 2008

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Commissioners' biographies

Mitra Behroozi, J.D., is the executive director of 1199SEIU Benefit and Pension Funds. Ms. Behroozi oversees eight major benefit and pension funds for health care workers. Collectively, the funds are among the largest in the nation. Previously, Ms. Behroozi was a partner with Levy, Ratner & Behroozi, PC, representing New York City unions in collective bargaining negotiations and proceedings. While at the law firm, she also served as union counsel to Taft-Hartley benefit and pension funds. Ms. Behroozi has a law degree from New York University and an undergraduate degree in sociology from Brown University.

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., is a professor of surgery and vice-chair for surgical education at the University of Mississippi Medical Center. She is a member of the American College of Surgeons' General Surgery Coding & Reimbursement Committee and is on the board of directors of the American Board of Surgery. Dr. Borman was a member of the executive committee and vice-chair of the American Medical Association's Current Procedural Terminology editorial panel. Dr. Borman frequently works with the Centers for Medicare & Medicaid Services on issues related to physician payment. She also has served in various positions at the American Association of Endocrine Surgeons, the Association for Academic Surgery, the Association of Program Directors in Surgery, and the Association for Surgical Education. Dr. Borman earned her medical degree from Tulane University. Her undergraduate degree in chemistry is from the Georgia Institute of Technology.

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.

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, for 28 years. 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.

Nancy-Ann DeParle, J.D., is managing director of CCMP Capital Advisors, LLC, and adjunct professor of health care systems at the Wharton School of the University of Pennsylvania. From 1997 to 2000, she served as administrator of the Health Care Financing Administration (HCFA), which is now the Centers for Medicare & Medicaid Services. Before joining HCFA, Ms. DeParle was associate director for health and personnel at the White House Office of Management and Budget. From 1987 to 1989 she served as the Tennessee Commissioner of Human Services. She has also worked as a lawyer in private practice in Nashville, TN, and Washington, DC. She is a trustee of the Robert Wood Johnson Foundation and a board member of Cerner Corporation, CareMore Health Plan, Noble Environmental, DaVita, and Boston Scientific. Ms. DeParle received a B.A. degree from the University of Tennessee; B.A. and M.A. degrees from Oxford University, where she was a Rhodes Scholar; and a J.D. degree from Harvard Law School.

David F. Durenberger, J.D., is president of Policy Insight, LLC; senior health policy fellow at the University of St. Thomas in Minneapolis, MN; and chairman of the National Institute of Health Policy. He is also president of the Medical Technology Leadership Forum, a member of the Kaiser Foundation Commission on Medicaid and the Uninsured, the Board of the National Committee for Quality Assurance, and the National Commission for Quality Long Term Care. From 1978 to 1995, he served as the senior U.S. Senator from Minnesota, as a member of the Senate Finance Committee, and chairman of its health subcommittee. He was a member of the Senate Environment Committee; Government Affairs Committee; and the committee now known as the Health, Education, Labor, and Pensions Committee. He chaired the Senate Select Committee on Intelligence. Senator Durenberger is a graduate of St. John's University, received his J.D. degree from the University of Minnesota, and served as an officer in the U.S. Army.

Jack C. Ebeler, M.P.A., is a consultant in health care policy, focusing on federal policy and the changing health care marketplace. Previously, he served as president and CEO of the Alliance of Community Health Plans. Prior to that, Mr. Ebeler was senior vice president and director of the health care group at the Robert Wood Johnson Foundation, where he focused on the uninsured, health care quality, and chronic care issues. Mr. Ebeler served as deputy assistant secretary for planning and evaluation for health and as acting assistant secretary for planning and evaluation at the U.S. Department of Health and Human Services. Over the years, he has also held positions in the health care industry and on Capitol Hill. Mr. Ebeler serves on the health care services boards of the Institute of Medicine and Inova Health System in Virginia. He is also on the boards of directors of Families USA and the National Academy of Social Insurance. Mr. Ebeler holds an M.P.A. from the John F. Kennedy School of Government at Harvard University and his undergraduate degree is from Dickinson College.

Glenn M. Hackbarth, J.D., 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. From 1981 to 1988, he held positions at the U.S. Department of Health and Human Services, including deputy administrator of the Health Care Financing Administration. He currently serves on the Board of the National Committee for Quality Assurance and is a member of The Commonwealth Fund's Commission on a High Performance Health System. He is also secretary/treasurer of the Foundation of the American Board of Internal Medicine. Mr. Hackbarth received his B.A. from Pennsylvania State University and his M.A. and J.D. from Duke University.

Jennie Chin Hansen, R.N., M.S.N., F.A.A.N., of San Francisco, is president-elect of AARP; a senior fellow at University of California's Center for the Health Professions; and a part-time nursing faculty member at San Francisco State University. Ms. Hansen was executive director of On Lok Senior Health Services, the prototype for the Program of All-Inclusive Care for the Elderly (PACE), which integrates Medicare and Medicaid finances and service delivery and was signed into federal legislation as a provider type in the Balanced Budget Act of 1997. She has practiced and taught nursing in both urban and rural settings. She currently serves in leadership roles with the National Academy of Social Insurance, Lumetra (California's Quality Improvement Organization), and the Robert Wood Johnson Executive Nurse Fellows Program. Ms. Hansen consults with other foundations on leadership development and independent reviews. She also serves as

a board member on AARP Services—AARP's commercial entity—and as a Fellow in the American Academy of Nursing. Ms. Hansen received her B.S. 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 health care 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 the Urban Medical Group, a nonprofit physician group practice providing care to frail elderly in institutional and home settings, and PatientFlow Technology. 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.

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. Dr. Milstein's work and publications focus on private and public sector health care purchasing strategy, clinical performance measurement, and the psychology of clinical performance improvement. 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. In 2005, he was selected for the highest annual award of the National Business Group on Health (NBGH) for nationally recognized innovation and implementation success in health care cost reduction and quality gain. In 2006, he was elected to the Institute of Medicine. 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.

Robert D. Reischauer, Ph.D., is vice chairman of the Commission and president of The Urban Institute. Previously, he was a senior fellow with the Brookings Institution, and from 1989 to 1995 he was the director of the Congressional Budget Office. Dr. Reischauer currently serves on the boards of the Academy of Political Sciences, the Center on Budget and Policy Priorities, and the Committee for a Responsible Federal Budget. He also is a member of the Institute of Medicine, the National Academy of Public Administration, and Harvard Corporation. Dr. Reischauer received his A.B. degree from Harvard College and his M.I.A. and Ph.D. from Columbia University.

William J. Scanlon, Ph.D., is a senior policy advisor with Health Policy R&D. He is a consultant to the National Health Policy Forum and is a research professor with the Institute for Health Care Research and Policy at Georgetown University. 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. Government Accountability Office. Previously, he was co-director of the Center for Health Policy Studies and an associate professor in the Department of Family Medicine at Georgetown University and was a principal research associate in health policy at the Urban Institute. Dr. Scanlon has a Ph.D. in economics from the University of Wisconsin-Madison.

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.

Nicholas Wolter, M.D., is a pulmonary and critical care physician who serves as chief executive officer for Billings Clinic in Billings, MT. Billings Clinic is a regional, not-for-profit medical foundation consisting of a multispecialty group practice, a tertiary hospital, critical access hospital affiliates, a health maintenance organization, a research division, and a long-term care facility serving a vast rural area in the northern Rockies. Dr. Wolter began his Billings Clinic practice in 1982 and served as medical director of the hospital's intensive care unit from 1987 to 1993. He began his leadership role with the successful merger of the clinic and hospital in 1993. Dr. Wolter is a diplomate of the American Board of Internal Medicine and serves on the boards of many regional and national health care organizations. He has a B.A. degree from Carleton College, an M.A. degree from the University of Michigan, and an M.D. degree from the University of Michigan Medical School.

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