JUNE 2009

REPORT TO THE CONGRESS

Improving Incentives in the Medicare Program

MEDPAC Medicare Payment Advisory Commission

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

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

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

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

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

June 15, 2009

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

Dear Mr. Vice President:

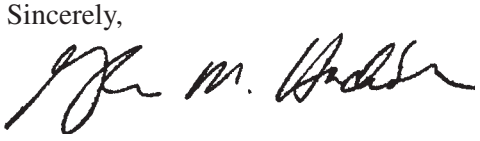
I am pleased to submit the Medicare Payment Advisory Commission's June 2009 *Report to the Congress: Improving Incentives in the Medicare Program*. This report fulfills the Commission's legislative mandate to examine issues affecting the Medicare program and to make specific recommendations to the Congress.

Medicare's payment systems do not embody incentives for providers to produce appropriate, high-quality care at an efficient price. Rather, incentives induce providers to provide more care, without encouraging coordination or rewarding quality. 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 Medicare's role in graduate medical education and offers future directions;
- examines ways accountable care organizations could affect the growth in service volume;
- lays out principles for reporting resource use to physicians so they can actively and collaboratively participate in appropriately constraining service volume;
- provides new information on the role of self-referral in imaging use and the effect of imaging use on Medicare cost growth;
- explores ideas to ensure that pricing for follow-on biologics produces value for Medicare;
- examines restructuring Medicare's benefit design to provide beneficiaries with better incentives and protections;
- analyzes various aspects of Medicare Advantage payment, fulfilling a requirement mandated by Section 169 of the Medicare Improvements for Patients and Providers Act of 2008; and
- discusses care management for beneficiaries with chronic conditions, as required by Section 150 of the Medicare Improvements for Patients and Providers Act of 2008.

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.

Enclosure

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June 15, 2009

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Speaker of the House
U.S. House of Representatives
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Room H-232
Washington, DC 20515

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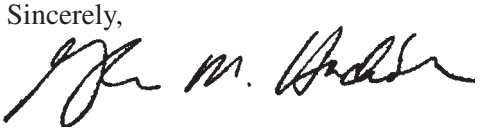

Glenn M. Hackbarth, J.D.

Enclosure

Acknowledgments

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

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

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Executive summary

Recent studies show that the U.S. health care system is not buying enough recommended care and is buying too much unnecessary care, much of it at very high prices, resulting in a system that costs significantly more per capita than in any other country. These facts strongly indicate that our health care system is not delivering value for its stakeholders. As a major payer, the Medicare program shares in these problems.

For decades, researchers 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., likely driven by a geographic area's supply of specialists and technology), differ greatly from one region to another. The higher rates of use are often not associated with better outcomes or quality and instead suggest inefficiencies. One recent analysis shows that, at the state level, 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 spending is highly correlated with both preventable hospitalizations and hospitalizations for ambulatory-care-sensitive conditions. These findings point to inefficient spending patterns that result in poor value for our health care dollars. At the same time, they point to opportunities for improvement.

If current spending and utilization trends continue, the Medicare program is fiscally unsustainable. The share of the nation's gross domestic product committed to Medicare is projected to grow to unprecedented levels, squeezing other priorities in the federal budget. In addition, expenditures from the Hospital Insurance (HI) trust fund, which funds inpatient stays and other post-acute care, exceeded its annual income from taxes in 2008. In their most recent report, the Medicare trustees project that the assets of the HI trust fund will be exhausted in 2017. Rapid growth in Medicare spending has implications for beneficiaries as well as taxpayers. Between 2000 and 2007, Medicare beneficiaries faced average annual increases in the Part B premium of nearly 9.8 percent. Monthly Social Security benefits grew by about 4 percent annually over the same period.

Costs are high and increasing at an unsustainable rate in part because the health care delivery system we see today is not a true system: Care coordination is rare, specialist care is favored over primary care, and quality of care is often poor. Part of the problem is that Medicare's fee-for-service (FFS) payment systems reward more care—and more complex care—without regard to the quality or value of that care. In addition, Medicare's payment systems create separate payment "silos" (e.g., inpatient hospitals, physicians, post-acute care providers) and do not encourage coordination among providers within a silo or across silos. Medicare must address those limitations—creating new payment methods that reward higher quality, promote efficient use of limited resources, and encourage effective integration of care.

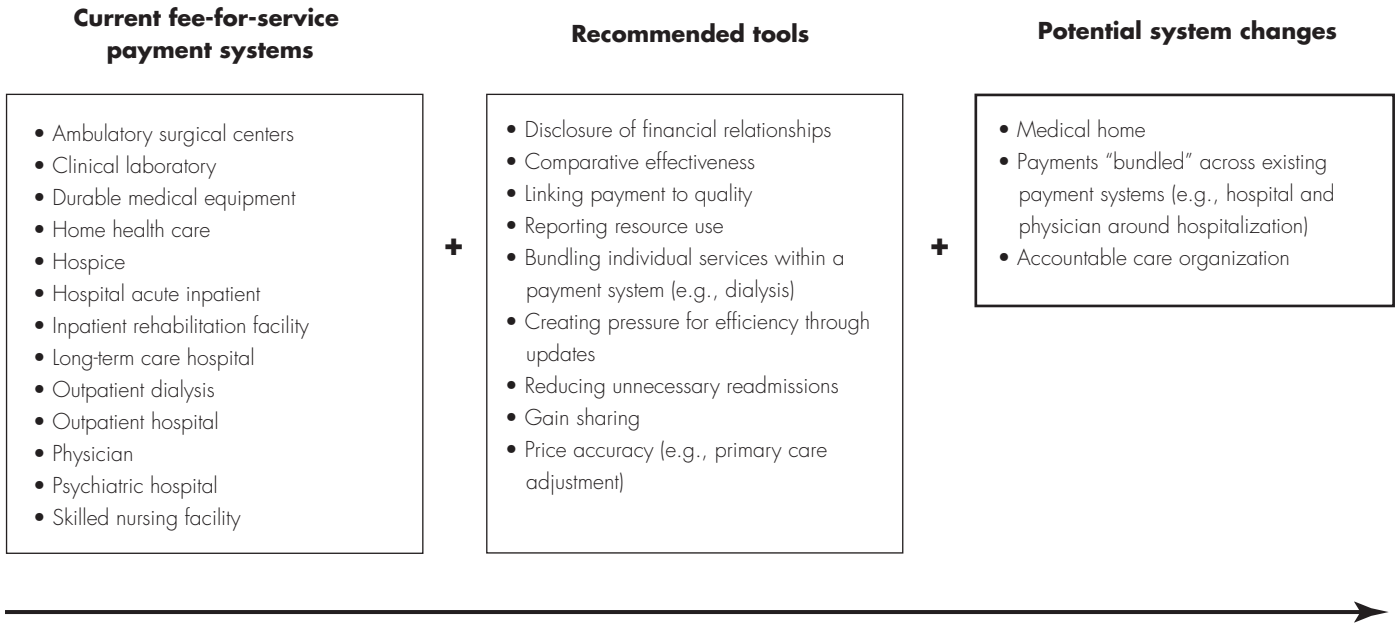
In previous reports, the Commission has recommended that Medicare adopt tools for increasing efficiency and improving quality within the current Medicare payment systems, including: encouraging the use of comparative-effectiveness information, linking payment to quality (pay for performance), measuring resource use and providing feedback, and improving payment accuracy within Medicare payment systems. However, the structure of the current FFS payment systems and the current payment silos limit the benefit of these tools.

To increase value for beneficiaries and taxpayers, the Medicare program must overcome the limitations of its current payment systems. A reformed 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 they use to provide it. Our current view on this evolution is illustrated in Figure ES-1. 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 pay for performance and resource measurement to improve quality and efficiency.

In this report, the Commission discusses a number of issues and challenges for Medicare payment and delivery system reform. The issues range broadly but focus on how incentives in the current Medicare payment systems could be changed to reward value not volume.

We discuss paths to promote delivery system reform. First, we examine how medical education could be structured to better support the future needs of the Medicare program

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



for physicians trained in multidisciplinary teamwork and other skills aligned with the objectives of delivery system reform. We further develop the concept of accountable care organizations and how they could promote care coordination and delivery system organization and thereby higher quality and lower cost growth. We explore applying physician resource use measurement and how it might slow the rate of cost growth. We also examine two issues mandated in recent law: improving the care management of beneficiaries with chronic conditions, which will be essential for Medicare sustainability going forward, and using payment reforms to the Medicare Advantage program to encourage efficient, high-quality plans that would introduce innovative delivery systems into Medicare.

In addition we look ahead at the long-run challenge of controlling growth in spending for biologics, consider how to improve the benefit design of traditional Medicare to make cost sharing a tool for increasing value, and provide information on the extent to which self-referral increases spending on imaging.

Medicare ensures that the elderly and disabled have good access to high-quality medically necessary care. In doing so, the program also must 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.

Medical education in the United States: Supporting long-term delivery system reforms

Medicare is the largest financial supporter of graduate medical education, spending an estimated $9 billion in 2008. Despite this spending, a number of reports and articles have expressed concern that our health professionals are not learning certain skills necessary to work optimally in delivery systems that provide the kinds of care that will best serve the public's needs. Reforming medical education will be a key component to transforming the nation's health care delivery system from one that historically has focused on care for acute illness to one that values patient-centered care, quality improvement, and resource conservation. Our medical schools and residency training programs need to emphasize a set of skills and knowledge that will

equip students and residents to practice and lead under reformed payment incentives.

Although medical education encompasses a variety of professionals, in Chapter 1 we focus on physicians. In a study of internal medicine residency programs, we found that formal curricula are not well aligned with objectives of delivery system reform. Although most programs provide at least some training in selected topics essential for delivery reform (e.g., care coordination across settings), overall, their curricula fall far short of the instruction recommended by the Institute of Medicine and other experts.

Of particular concern is the relative lack of formal training and experience in multidisciplinary teamwork, cost awareness in clinical decision making, comprehensive health information technology, and patient care in ambulatory settings. Residency experience in nonhospital and community-based settings is important because most of the medical conditions that practicing physicians confront should be managed in nonhospital settings. However, inherent financial incentives and Medicare regulations strongly encourage teaching hospitals to confine their residents' learning experiences to within the hospital.

Future Commission work on medical education policy issues may include exploring ways to link delivery system reforms to medical education incentives and structuring medical education subsidies to produce the optimal balance of generalists and specialists. Another issue to examine is enlisting all payers to contribute explicitly to medical education.

Accountable care organizations

In Chapter 2, we define an accountable care organization (ACO) as a set of providers held responsible for the quality and cost of health care for a population of Medicare beneficiaries. An ACO could consist of primary care physicians, specialists, and at least one hospital. It could be formed from an integrated delivery system, a physician–hospital organization, or an academic medical center. If the ACO achieves both quality and cost targets, its members receive a bonus. If it fails to meet both quality and cost targets, its members could face lower Medicare payments. Ideally, these financial incentives would lead the ACO to judiciously constrain the use of health care services and capacity in contrast to the incentive in FFS payment systems to always increase the volume of services.

Chapter 2 provides an overview of the ACO model. For ACOs to successfully improve quality while constraining cost growth:

- Spending targets for an ACO should be set in advance. Targets could be based on the ACO's past experience plus a single national allowance for spending growth per capita. Alternatively, the allowance could be set as a function of prior utilization trends, with low-service-use areas receiving a higher allowance, and high-use areas receiving a lower allowance (which would provide a greater incentive to control utilization).
- ACOs would have to be fairly large (at least 5,000 patients) to make it possible to distinguish actual improvement from random variation.
- ACOs would need a formal organization and structure that allows them to make joint decisions, because savings would primarily result from the joint incentive to change overall practice patterns and eventually constrain capacity.
- Private insurers may have to provide ACO-type incentives, because a large share of the patients in a practice would need to be in an ACO to overcome FFS incentives to expand capacity and volume.

We discuss two variations on the ACO model, one in which providers volunteer to form an ACO and one in which participation is mandatory. In a voluntary, bonus-only ACO model, ACOs receive bonuses for meeting cost and quality targets. FFS rates will likely have to be constrained for Medicare to fund those bonuses at a sufficient level to change provider behavior without increasing its overall spending because of random variation. Under a mandatory, bonus-and-withhold model, bonuses could be funded by shared savings and by penalizing providers who fail to meet cost and quality targets.

Physician resource use measurement

In 2005, the Commission recommended that Medicare measure physician resource use and share the results with physicians in a confidential manner to address variation in physician practice patterns and Medicare's unsustainable rate of spending growth. The Congress enacted the Commission's recommendation in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and CMS has begun a phased implementation of the program.

The Commission has proposed several policy principles to guide Medicare's physician resource use measurement program. These principles include adopting a methodology for measuring resource use that is transparent to all physicians under observation, ensuring that physicians are able to actively modify their behavior on the basis of the feedback provided, risk adjusting clinical data to ensure fair comparisons among physicians, and obtaining ongoing feedback from the physician community on CMS's measurement methods and other aspects of the program.

In Chapter 3 we examine several technical aspects of measuring physician resource use. We find a high degree of stability in physicians' efficiency scores over time, suggesting that the episode grouper software identifies outlier physicians consistently across years. We also find that various methods for attributing episodes to physicians have both advantages and drawbacks, suggesting that CMS may want to consider more than one attribution method when its physician resource use measurement program is fully implemented.

Impact of physician self-referral on use of imaging services within an episode

The Commission recognizes that there has been rapid technological progress in diagnostic imaging over the past several years, which has enabled physicians to diagnose and treat illness with greater speed and precision. Between 2002 and 2007, the volume per beneficiary of imaging services paid under the physician fee schedule grew nearly twice as fast as all physician services. Although the rate of growth slowed in 2007, there are reasons to be concerned that some of the increased use in recent years may not be appropriate, which contributes to Medicare's growing financial burden on taxpayers and beneficiaries. First, the Government Accountability Office found an almost eightfold variation in per beneficiary spending on in-office imaging services across the states. Second, there is evidence that costly imaging services are mispriced under the physician fee schedule, thereby creating financial incentives to provide more imaging. Rapid growth in imaging may also be driven by technological innovation, defensive medicine, inconsistent adherence to clinical guidelines, an increase in imaging performed in physician offices, and other factors.

Although increased in-office imaging may improve access and convenience for patients, it might also lead to higher volume through additional capacity and financial incentives for physicians to refer patients for more tests. Several studies have found that physicians who furnish imaging services in their offices refer patients for more tests than other physicians. In Chapter 4, we expand upon earlier research by analyzing whether physician self-referral is related to higher use of imaging by type of clinical episode. We find that:

- A higher proportion of episodes with a self-referring physician received at least one imaging service than episodes with no self-referring physician.
- Episodes with a self-referring physician have higher ratios of observed-to-expected imaging spending than episodes with no self-referring physician (the ratios control for variations in beneficiaries' clinical condition and disease severity, market area, and physician specialty).

We also investigated whether greater use of imaging within an episode is associated with higher or lower total episode spending. Although in specific cases an imaging study may substitute for other services, our findings suggest that greater use of imaging (and specific types of imaging) is associated with greater overall resource use during an episode, adjusting for type of episode, patient severity, and other factors.

Medicare payment systems and follow-on biologics

Medicare spending on biologics—drug products derived from living organisms—was about $13 billion in 2007. The top six biologics account for 43 percent of spending on separately billed drugs in Medicare Part B. Biologics account for a relatively small—but rapidly growing—share of Part D spending. Currently, the Food and Drug Administration (FDA) does not have an approval process for follow-on versions of most biologics, and the price of these products has not fallen over time. The Congressional Budget Office estimates that an expedited approval process for follow-on biologics (FOBs) could save the federal government $9 billion to $12 billion over the next 10 years. Much of that savings would accrue to Medicare.

Medicare spending on biologics is substantial and is expected to grow significantly. Therefore, the establishment of a process to approve FOBs has important implications for Medicare. In Chapter 5, we summarize key issues that are being discussed as policymakers and stakeholders consider the potential establishment of a regulatory pathway for FOBs. FDA would have jurisdiction over approval of FOBs. However, as a large payer for biologics, Medicare has a strong incentive to ensure that it gets value for the money it spends on these products.

Establishment of a regulatory approval process for FOBs is necessary to provide more competition among biologics and generate cost savings. The amount of savings would also depend in part on how biologics are treated under the Medicare payment systems. In Chapter 5, we discuss coding and payment strategies that could be pursued to ensure that Medicare Part B realizes the maximum benefit from competition between FOBs and innovator biologics. The Part D benefit would also need to be restructured to take advantage of the potential savings offered by FOBs. While Medicare Part D should achieve savings on FOBs for older biologics, the current benefit structure is likely to limit savings for newer products.

An approval process for FOBs can create the opportunity for competition among manufacturers of biologics and, combined with payment system changes, will lead to savings for Medicare. However, given the magnitude and growth of spending for drugs, policymakers may want to look at other ways for Medicare to achieve savings. To help improve the value of Medicare spending, we discuss three pricing strategies:

- *Reference pricing:* Set a drug's payment rate no higher than that for currently available treatments unless evidence shows that the drug improves beneficiaries' outcomes.
- *Payment for results:* Link a drug's payment to beneficiaries' outcomes through risk-sharing agreements with manufacturers.
- *Bundling:* Create payment bundles for groups of clinically associated products and service.

Improving traditional Medicare's benefit design

FFS Medicare does not protect beneficiaries against catastrophic levels of out-of-pocket spending. Medicare's significant cost-sharing requirements and its lack of catastrophic protection have been important catalysts behind the widespread use of supplemental coverage. Yet coverage that fills in most or all of Medicare's cost sharing can lead to higher use of services and Medicare spending, and its prevalence prevents Medicare from being able to use cost sharing as a policy tool. Chapter 6 explores these issues.

We find that Medicare spending for beneficiaries with supplemental insurance tends to be higher than for those without such coverage. We also find that beneficiary spending for premiums and cost sharing varies as a function of supplemental coverage. Beneficiaries with high health care costs and no supplemental coverage generally spend a larger share of their incomes on health care than those with supplemental coverage.

In the future, cost sharing could be used as a tool to complement various policy goals such as: improving financial protection for Medicare beneficiaries and distributing cost-sharing liability more equitably among individuals with differing levels of health care costs, encouraging use of high-value services and discouraging use of low-value ones, and reinforcing payment system reforms that seek better value for health care expenditures. An additional goal may be to improve Medicare's financial sustainability. Steps toward each of the goals would be more effective if Medicare's deductibles and coinsurance were changed at the same time that the role of supplemental coverage were redefined.

Medicare Improvements for Patients and Providers Act of 2008 Medicare Advantage payment report

The Commission supports private plans in the Medicare program and the innovative delivery systems and care management techniques they potentially can bring to beneficiaries. But plans will innovate only if Medicare Advantage (MA) payment benchmark rates encourage them to do so; currently, benchmarks are set higher than FFS spending. Paying more than FFS is unfair to taxpayers and beneficiaries not enrolled in MA plans who subsidize those payments. We estimate that in 2009 Medicare is paying about $12 billion more for the beneficiaries enrolled in MA plans than it would have spent if they were in FFS Medicare and that the Part B premium is increased by about $3.00 a month for all beneficiaries, whether or not they are enrolled in an MA plan. Encouraging efficient plans is a key step. Plans that can provide the basic Medicare benefit more efficiently than FFS Medicare can by definition provide extra benefits yet be financially neutral to FFS Medicare. They can then compete with each other on quality and benefits and provide meaningful choices for beneficiaries.

Section 169 of MIPPA requires a Commission study and report on the MA payment system and alternatives to it. Our findings are presented in Chapter 7. We analyze four options for setting MA payment benchmarks administratively—all financially neutral to FFS Medicare in the first year. We also report a modification to those options that differentiates payment for extra benefits between higher and lower use areas. This modification would help balance extra benefits among areas and

thus help mitigate some of the concerns about equity under the new options. Another alternative is setting benchmarks through a competitive bidding process. We present the fundamental decisions that would have to be made when designing a competitive bidding system and outline some possible ways that plans might respond. To further improve quality, we also discuss how plans could be paid for higher quality through the transition to new benchmarks.

Finally, we address two technical points in response to the mandate. First, we find that, for the most part, CMS's estimates of county-level spending in traditional FFS Medicare are reasonably accurate and plan payments include the appropriate level of administrative costs. However, further work remains on determining the effect of beneficiaries' use of Department of Defense facilities on county-level FFS spending estimates (CMS has not found a material effect from use of Department of Veterans Affairs facilities). To increase the reliability of FFS estimates, the size of the payment areas used in the MA program should be increased as the Commission has previously recommended. Second, we find that MA plan costs to deliver Part A and Part B benefits (as reflected in plan bids) and county-level per capita spending under FFS Medicare are highly correlated.

Improving Medicare chronic care demonstration programs: Section 150 of the Medicare Improvements for Patients and Providers Act of 2008 report

There is a need for better ways to manage care for beneficiaries with multiple chronic conditions. A recent analysis by the Congressional Budget Office estimated that in 2001 the costliest 25 percent of Medicare beneficiaries accounted for 85 percent of total Medicare spending and that more than 75 percent of these high-cost beneficiaries had one or more of seven major chronic conditions. Section 150 of MIPPA directs the Commission to study the results of two of the largest Medicare chronic care coordination demonstration and pilot programs and advise the Congress on the feasibility of establishing a "Medicare chronic care practice research network" as another approach to testing new models of care coordination for beneficiaries with multiple chronic conditions. Our findings are presented in Chapter 8.

The Congress and CMS have initiated a number of demonstration and pilot programs to test different approaches to improve care coordination for Medicare beneficiaries. Results suggest that some of these programs may have modest effects on the quality of care and mixed impacts on Medicare costs, with most programs increasing Medicare costs overall.

We have reviewed a specific proposal from a group of 12 organizations called the Medicare Chronic Care Practice Research Network (MCCPRN). The network would be financed by Medicare and its purpose would be to develop, implement, and evaluate the effects of evidence-based chronic care interventions. On the basis of our review, the Commission has several concerns about the submitted proposal, including the following:

- The initial group of network sites would not be competitively selected through a transparent public process, which could set an undesirable precedent for future proposals.
- The fees paid to network sites for their care coordination interventions would not be at risk for Medicare costs (or savings) attributable to the network's interventions.
- The role of CMS in selecting research projects and administering the network may not be prominent enough to ensure accountability for the Medicare funds spent on the network's activities.
- The proposed network could duplicate some of the existing financial and administrative resources the Agency for Healthcare Research and Quality currently devotes to its two practice– and delivery-system–based research networks.

While the Commission has concerns about the specific MCCPRN proposal, we very much share the concerns the proposal is trying to address. We must act expeditiously to find innovative ways to change the misaligned cost and quality incentives in the health care delivery system that result in high costs of treating beneficiaries with chronic medical conditions, with little emphasis on coordination of care that could lead to improved outcomes. The results of our review also suggest larger issues with the structure and funding of research and development in Medicare. Funding levels for Medicare research activities are low relative to the overall size of the program, CMS often has externally imposed constraints on redirecting research funding as program needs and priorities shift, and administrative process requirements are time-consuming. Medicare needs to be able to conduct demonstrations and implementation

in a rapid cycle to make fundamental payment system reforms. CMS will need the resources to do so.

Review of CMS's preliminary estimate of the physician update for 2010

In CMS's annual letter to the Commission on the update for physician services, the agency's preliminary estimate of the 2010 update is a reduction of 21.5 percent. In Appendix A, we provide our required technical review of CMS's estimate.

The reduction is a combination of three factors. The first factor is the Medicare Economic Index, which CMS is estimating to be 1.0 percent. That estimate could change slightly. The second factor is the expiration of temporary bonuses enacted over several years; this factor will not change. (The bonuses were overrides of negative payment updates for 2007, 2008, and 2009 under the sustainable growth rate formula.) The third factor is the update adjustment of –7.0 percent for 2010, which is very unlikely to change. The combination of the three factors is thus unlikely to differ substantially from CMS's preliminary estimate of –21.5 percent. ■

CHAPTER 1

Medical education in the United States: Supporting long-term delivery system reforms

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Chapter summary

Spending an estimated $9 billion in 2008, Medicare is the largest financial supporter of graduate medical education. Averaging almost $100,000 per resident per year, Medicare subsidizes education and training for about 90,000 residents in more than 1,100 hospitals through direct and indirect payments for graduate medical education. To some extent, this federal support signals the societal value the Congress places on educating and training our physicians. Despite this spending, however, a number of reports and articles have expressed concern that our health professionals are not gaining certain skills they need to provide the kinds of care that will best serve the public's needs.

Reforming medical education will be a key component in transforming the nation's health care delivery system from one that historically has focused on care for acute illness—at the expense of chronic condition management, coordination of care across settings, and disease prevention—to one that values patient-centered care, quality improvement, and resource conservation. Our medical schools and residency programs need to emphasize a set of skills and knowledge

In this chapter

that will equip students and residents to practice and lead in reformed delivery systems that work under restructured payment incentives.

In considering ways to reform both health care delivery and medical education and training in the United States, this chapter offers an initial focus on physicians. Specifically, it reviews the multifaceted process of becoming a practicing physician, including the organizations involved in accreditation and certification; the costs and benefits for hospitals and physicians involved in teaching and supervising residents; internal medicine residency programs' curricula as they relate to health delivery system reforms; and the financial disincentives and regulatory issues that discourage residency rotations in nonhospital settings.

Residency programs' curricula are not well aligned with objectives of delivery system reform—To learn about how selected curricula are presented in residency programs, we contracted with RAND researchers to conduct a series of semistructured interviews with directors from 26 internal medicine residency programs. This study found that, although most programs provide at least some formal instruction in selected topics essential for delivery reform (e.g., care coordination across settings), overall their curricula fall far short of instruction recommended by the Institute of Medicine and other experts (Cordasco et al. 2009). Of particular concern is the relative lack of formal instruction and experience in multidisciplinary teamwork, cost awareness in clinical decision making, comprehensive health information technology, and patient care in ambulatory settings. Reform-related topics that were reported to be covered more consistently in residency programs are evidence-based medicine and communicating with patients about end-of-life care. As may be expected, researchers found large variations in the extent of and approach to teaching, and program directors reported multiple factors that facilitate or impede their ability to instruct in topics related to delivery system reform. Faculty expertise in selected topics, such as quality measurement, can strongly influence residents' skills and experience.

Financial incentives and regulatory issues discourage nonhospital residency experience—Residency programs are largely based in teaching hospitals. These hospitals face financial and regulatory incentives to keep residents in the hospital for their education and training rather than encourage them to rotate to nonhospital settings. Consequently, residents spend most of their time involved in caring for acutely ill hospital inpatients. This hospital-based experience provides residents with important skills for treating serious illnesses, but it must be balanced with sufficient education and training in nonhospital and community-based settings. Devoting too much resident time in the hospital setting can be problematic, as most of the medical conditions that practicing physicians confront are, and should be, managed in nonhospital settings (e.g., physician offices, nursing facilities, and patient homes). The development of skills in these nonhospital settings is important for patient health, patient comfort, and health care spending.

While accreditation organizations specifically require ambulatory experience for many specialties, Medicare places no requirements on residency programs. Many programs satisfy their accreditation requirements for ambulatory care through residency rotations in hospital outpatient departments, rather than nonhospital settings. The reluctance of teaching hospitals to have residents rotate outside the hospital can be attributed to historical patterns of medical education, regulatory issues, and financial incentives. For example, under current statute and regulations, in certain circumstances, when residents rotate to nonhospital settings, teaching hospitals may lose some of the funding they could otherwise receive through Medicare's graduate medical education payments. Hospitals face an even greater financial incentive to keep residents within the hospital to retain the clinical labor that residents provide.

Future issues for exploration—Future Commission work will stem not only from the findings of work presented in this chapter but also from exploring other issues and questions on the topic of medical education in the United States. Thus, in addition to analyzing specific ways to encourage more

residency experience in nonhospital settings, further analysis will focus on three main areas:

- *Linking delivery system reforms to medical education incentives*—The Commission recognizes that residents and other health care professionals will best learn the skills needed to provide high-quality, efficient care when medical education occurs in settings where such care is actually performed. Thus, the Commission will explore policies that might link medical education incentives with delivery system reforms.

- *Structuring medical education subsidies to produce the professionals we need*—Among physicians, nurses, and physician assistants, medical education incentives could be helpful in achieving the optimal balance of generalists and specialists to help reform our health care delivery system. The Commission will examine possible ways to address this issue as well as ways to increase the diversity of medical school enrollment.

- *Enlisting other payers to contribute explicitly to medical education*—Considering the shared societal benefits of high-quality medical education for patients of all ages, the Commission will analyze options that expand contributions from other health care payers for medical education. This analysis also could explore potential mechanisms for distributing collected funds equitably and efficiently across settings and programs. ■

Spending an estimated $9 billion in 2008, Medicare is the largest financial supporter of graduate medical education. Averaging almost $100,000 per resident per year, Medicare subsidizes education and training for about 90,000 residents in more than 1,100 hospitals through direct and indirect payments for graduate medical education. To some extent, this federal support signals the societal value the Congress places on educating and training physicians. Despite this spending, however, a number of reports and articles have expressed concern that our health professionals are not gaining certain skills they need to perform the kinds of care that will best serve the public's needs (Blue Ridge Academic Health Group 2003, Blumenthal 2002, COGME 2007, Holmboe et al. 2005, IOM 2008, IOM 2003, Ludmerer and Johns 2005, Meyers et al. 2007, Mullan 2009, Weinberger et al. 2006).

Reforming medical education will be a key component in transforming the nation's health care delivery system from one that historically has focused on care for acute illness—at the expense of chronic condition management, coordination of care across settings, and disease prevention—to one that values patient-centered care, quality improvement, and resource conservation. Our medical schools and residency programs need to emphasize a set of skills and knowledge that will equip students and residents to practice and lead in reformed delivery systems that work under restructured payment incentives.

In considering ways to reform both health care delivery and medical education and training in the United States, this chapter offers an initial focus on physicians. In addition to background information on physician education, we examine the federal funding policies that bias medical education heavily toward acute hospital care.

Process of becoming a physician and continuing practice

The process of becoming a practicing physician is multifaceted. It starts with undergraduate preparation, followed by four years of medical school, a minimum of three years of graduate medical education in a specialty, and potentially further instruction in a subspecialty. Physicians must also obtain a medical license in order to practice independently. After completing a residency program, physicians may—and most do—seek specialty board certification. Throughout their years of practice, physicians maintain their medical license through continuing medical education (CME). They also maintain their board certification by fulfilling a comprehensive, multifaceted mix of requirements over a set period of time (Figure 1-1, p. 8).

Undergraduate preparation

The journey to becoming a physician begins at the undergraduate level, where students must fulfill basic premed coursework requirements (biology, chemistry, mathematics, physics, and English), while maintaining a well-rounded undergraduate experience that includes coursework in humanities and social sciences. Medical schools also look favorably on applicants who volunteer at local hospitals and clinics (AAMC 2009). The average student applies for admission to 13 allopathic medical schools. For the 2007–2008 academic year, more than 42,000 people applied for a little more than 18,000 first-year positions (AAMC 2008a).[1] Almost all medical schools require students to take the Medical College Admission Test, which is a standardized, multiple-choice examination designed to assess students' problem-solving ability, critical thinking, writing skills, and knowledge of science concepts and principles prerequisite to the study of medicine.

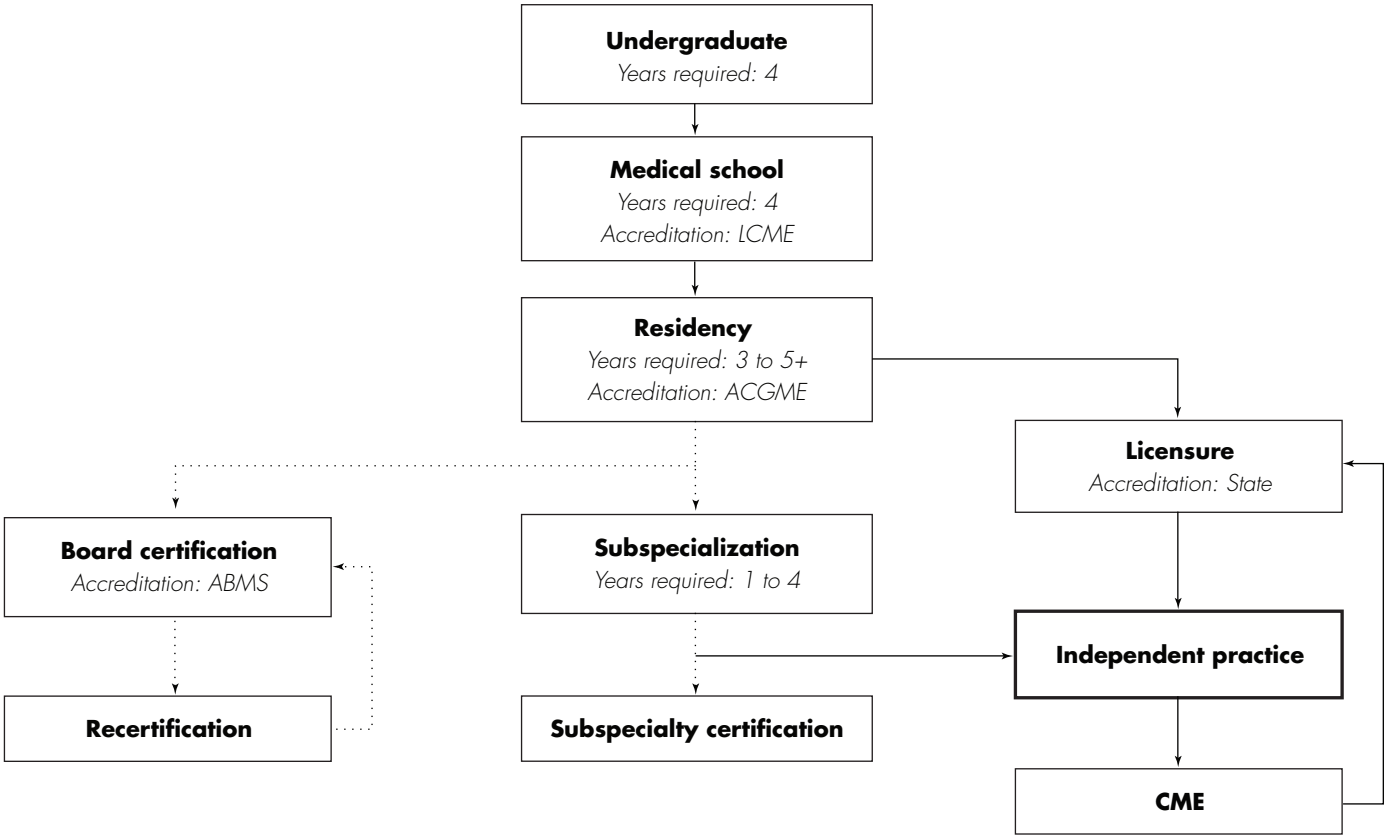
Medical school

Medical school usually lasts four years. Each medical school differs in how it organizes its program. In general, during the first two years, students study the sciences basic to medicine: anatomy, biochemistry, physiology, microbiology, pathology, pharmacology, and behavioral sciences. In addition, they are introduced to basic interviewing and examination techniques. In the third year, students start clinical clerkships, where they gain clinical experience in hospitals and other settings. These third-year clerkships are usually in internal medicine, family medicine, pediatrics, obstetrics and gynecology, general surgery, and psychiatry. In the fourth year clinical rotations continue, although students often focus on specific subfields.

During the fourth year of medical school, students decide on the specialty they want to pursue and participate in the National Residency Matching Program (NRMP), a matching service that uses a computer algorithm to match applicants to programs according to the preferences of the medical students and residency programs.[2] Through the NRMP, students can choose from 26 core specialties. Virtually all medical students participate in the match to be assigned to a residency program. Only after the match is complete can students who are not successfully matched

FIGURE 1–1

The process of becoming a physician and continuing practice



Note: LCME (Liaison Committee on Medical Education), ACGME (Accreditation Council for Graduate Medical Education), ABMS (American Board of Medical Specialties), CME (continuing medical education). Solid flow lines indicate required paths. Dotted flow lines indicate optional paths. Most physicians seek board certification. Physicians may seek subspecialization after completion of their residency.

attempt to pursue slots left unfilled by the matching process. A match between an applicant and a program is considered a binding commitment.[3]

Diversity in medical education

Medical students tend to come from relatively affluent families. In 2005, 55 percent of students came from families in the top quintile of family income; only about 5 percent came from families in the lowest quintile (Figure 1-2) (AAMC 2008b). This trend has been fairly consistent for the past 20 years. Given the association of college graduation with family income, some skewing can be expected in medical school enrollment toward higher income families; nevertheless, the U.S. medical school enrollment figures show an overwhelming lack of economic diversity among students and subsequently among practicing physicians entering the profession.

The racial and ethnic composition of medical school enrollees also is not representative of the population at large (Table 1-1). For instance, for the 2007–2008 academic year, African Americans account for 12.3 percent of the U.S. population, but just 6.3 percent of allopathic and 3.5 percent of osteopathic medical school matriculants (first-year enrollees). Similarly, Hispanics account for 15.1 percent of the U.S. population but just 7.9 percent of allopathic and 3.6 percent of osteopathic medical school matriculants. Asian Americans, on the other hand, make up 4.4 percent of the U.S. population but account for 19.8 percent of allopathic and 17.1 percent of osteopathic medical school matriculants. As in the general

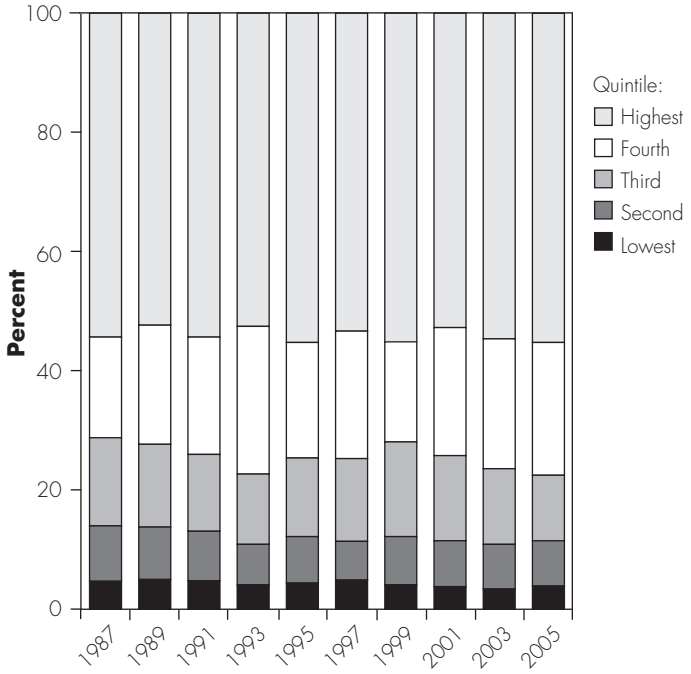
population, whites make up the largest share of students entering medical school.

Table 1-1 also shows that the demographic composition of medical school enrollment roughly parallels the proportion of applications medical schools receive. This suggests that factors such as financial and educational barriers affect students' decisions to apply to medical school and ultimately shape the demographics of the physician workforce. Although college graduation is one factor influencing minority enrollment, the proportion of African Americans and Hispanics in medical school has not increased much over the past decade, despite substantial increases in the number of African Americans and Hispanic students graduating from four-year colleges, including increases relative to whites in the number graduating with majors in biological and biomedical sciences (Grumbach and Mendoza 2008). This growth presents an opportunity for developing strategies to increase diversity in medical school enrollment.

There are a number of benefits to having an ethnically diverse physician workforce, and the Commission is concerned about this issue. Research has shown that a racially and ethnically diverse health care workforce is associated with better access to and quality of care for disadvantaged populations, greater patient choice

FIGURE 1–2

Parent household income of entering medical students in U.S. medical schools, by quintiles, 1987–2005



Source: Association of American Medical Colleges 2008.

TABLE 1–1

Racial and ethnic composition of medical school applicants and matriculants for the 2007–2008 academic year

		Medical school			
		Allopathic		Osteopathic	
Race/ethnicity	U.S. population	Applicants	Matriculants	Applicants	Matriculants
White	66.0%	56.4%	58.9%	59.4%	69.6%
Hispanic	15.1	7.3	7.9	6.4	3.6
Black or African American	12.3	7.2	6.3	5.9	3.5
Asian	4.4	19.6	19.8	19.5	17.1
Native American/Alaskan native	0.9	0.3	0.3	0.6	0.8
Native Hawaiian/Pacific Islander	0.1	0.3	0.2	0.1	*
Other/unknown	1.2	9.0	6.5	8.2	5.4

Note: For the applicants and matriculants groups the "other/unknown" category includes foreign students who are not U.S. residents, individuals with more than one race, and individuals that did not provide their race. Totals may not sum to 100 percent due to rounding.
* Native Hawaiian and Pacific Islander included with Asian.

Source: Association of American Medical Colleges data warehouse applicant matriculant file as of October 10, 2008; American Association of Colleges of Osteopathic Medicine 2009 applicant and first-year enrollment data; and U.S. Census annual estimates of the population by sex, race, and Hispanic origin for the United States: April 1, 2000 to July 1, 2007.

and satisfaction, and better educational experiences for students in health professions (HRSA 2006, IOM 2004a, Komaromy et al. 1996, Mertz and Grumbach 2001, Moy and Bartman 1995). Greater diversity in the health professions would likely lead to improved public health by increasing access to care for underserved populations and by increasing opportunities for minority patients to see practitioners with whom they share a common race, ethnicity, or language. Race, ethnicity, and language concordance, which are associated with better patient–practitioner relationships and communication, may increase patients' likelihood of receiving and accepting appropriate medical care (HRSA 2006). From an educational standpoint, an ethnically diverse student body has been associated with better performance across all ethnicities on intellectual and civic development (IOM 2004a). As the nation becomes increasingly diverse, a business case can also be made for a health care workforce that is culturally and linguistically diverse and attuned to the population being served (Grumbach and Mendoza 2008).

Medical school students also appear to come disproportionately from urban areas, but research on this correlation is limited (Fordyce et al. 2007). Factors associated with lower rates of medical school enrollment among students from rural areas include lower income and less proximity to medical schools. Research suggests that medical students born in rural areas are more likely to select primary care specialties and to practice in rural areas (Brooks et al. 2002, Phillips et al. 2009). Therefore, geographic diversity among medical school students is important for maintaining access to care across the United States. In general, osteopathic medical schools enroll a proportionately higher share of rural students compared with allopathic medical schools (Peters et al. 1999).

Many decades ago women represented less than a quarter of U.S. medical school enrollees, but they now account for about half of all enrollees.

Student debt

Although medical students are significantly more likely to come from higher income families, many graduate from medical school with sizable student debt from tuition and fees. Only 13 percent of medical students graduate without any educational debt. In 2008, the average student reported a debt load of $154,600, which is 11 percent higher than for the previous year. Today's graduates commit about 9 percent to 12 percent of their after-tax income for educational debt service (Steinbrook 2008). More than a quarter of graduates with indebtedness carried a debt of more than $200,000 (AAMC 2008c). Medical school students with higher debt are more likely to participate in loan repayment programs for underserved communities, such as the National Health Service Corps (Phillips et al. 2009). However, overall rates of U.S. medical school graduates practicing in these communities have fallen, particularly for primary care.

Graduate medical education

After completing medical school, graduates enter the residency programs to which they are assigned through the NRMP. During residency, residents gain more practical experience in a specific field of medicine. Most residency programs are sponsored by teaching hospitals or medical schools. Teaching hospitals are hospitals that participate in graduate medical education; a large proportion of residents' education takes place in inpatient and outpatient departments of teaching hospitals.

The length of time of residencies varies by specialty: from three years for the primary care specialties of family medicine, internal medicine, and pediatrics to five or more years for general surgery and other surgical specialties. Some specialties require a preliminary year of residency in internal medicine or general surgery before entering (e.g., dermatology, urology). When physicians graduate from a residency program, they are eligible to take their specialty board certification examinations. After completing a residency program, however, many new physicians subspecialize with additional fellowship years (e.g., cardiology, hand surgery), stretching the total length of education and training an additional one to four years, depending on the subspecialty.

Roughly one-quarter of all residents are graduates of medical schools located outside the United States and Canada. These international medical graduates (IMGs) must also be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) before entering an approved residency. The ECFMG assesses the readiness of IMGs to enter residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). A higher proportion of IMGs enter primary care residencies than other specialties (Salsberg et al. 2008).

Physician licensure

States maintain their own rules for physicians' licensure. Licensure occurs through each state's medical licensing board and involves, among other requirements, passing the three-step United States Medical Licensing Examination

(USMLE). The first two exams take place during medical school, and the third takes place during the first year of residency. To be licensed to practice independently, physicians must also complete a minimum number of years in an approved residency program, which varies by state and is typically one to two years. In most states and under most circumstances, physicians who graduate from an accredited medical school outside the United States or Canada or complete graduate medical education overseas are required to complete an ACGME-approved program before being licensed to practice medicine.

After they have completed their residencies and are licensed to practice, physicians maintain their competencies and licenses and learn about new and developing areas in medicine and their specialty by pursuing CME. Physicians may receive CME credits by attending approved lectures or conferences; reviewing certain publications; or using online programs, audio, video, or other electronic media designed to provide CME credits. All but five states require a minimum number of CME credits to maintain state licensure.[4] The number of CME credits required varies across jurisdictions; on average, states require 30 credit hours per year, with 11 states requiring as many as 50.[5] Some states mandate specific types of CME. California, for instance, requires all general internists and family physicians, for whom at least 20 percent of their patient population is 65 or older, to receive at least 20 percent of their CME hours in geriatric medicine or the care of older patients. Other states have requirements on HIV/AIDS care, risk management, and end-of-life palliative care (AMA 2008). In general, physicians are not required to get CME credits in areas related to their practice nor are they required to demonstrate to the state licensing boards what they have learned from CME activities (FSMB 2009).

Specialty certification

After completing a residency, most physicians become board certified in their specialty. Specialty certification is voluntary and not required for state licensure. Many health plans and hospitals, however, require certification for inclusion in networks and hospital privileges. Specialty certification occurs through the medical specialty board for each specialty. To become eligible for board certification in a specialty, a physician must complete an approved residency in that specialty and have an institutional or valid license to practice medicine. A physician who meets these basic admission standards will be evaluated by a specialty board using written and oral examinations. Because specialties differ so widely, the criteria that inform these tests are quite different (ABMS 2009).

Most specialty boards require physicians to pass recertifying exams and meet other requirements to maintain their certification, also referred to as maintenance of certification (MOC). These other requirements include a minimum amount of CME relevant to their specialty and evidence of participation in practice-based assessment.[6] The time cycle for recertification is 6 to 10 years depending on the specialty. Some physicians, however, are grandfathered out of MOC requirements depending on their specialty and year of initial certification.

Accreditation and certification organizations

All education components along the path to becoming a practicing physician involve accreditation or licensure. Allopathic and osteopathic medical schools have their own accrediting organizations—the Liaison Committee on Medical Education (LCME) and the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation, respectively. In 2007, 129 accredited medical schools enrolled 17,759 first-year students (AAMC 2008a); 25 accredited osteopathic schools enrolled 4,528 first-year students (AACOM 2009). Accreditation standards for these schools cover a wide range of requirements, including clerkship setting requirements, education curricula, and educational resources.

Residency programs may be accredited by the ACGME or the AOA, or they may be dually accredited. In the 2007–2008 academic year, there were a total of 8,589 ACGME-approved residency programs, with 106,012 residents and fellows—an increase of 7.9 percent from the 2002–2003 academic year. The number of first-year residents totaled 23,759, an increase of 8.7 percent from five years earlier. International medical graduates accounted for 28.6 percent of first-year enrollment (Brotherton and Etzel 2008). In the 2007–2008 academic year, there were 223 AOA-approved internships and 718 AOA-approved residency programs with 4,934 osteopathic residents (Freeman and Lischka 2009).

Completing an accredited residency program is important for a number of reasons. All states, for example, require completion of a minimum number of years of an accredited residency before being granted a license to practice independently. Medicare also requires residency

programs to be accredited to receive medical education funds from Medicare.[7] Finally, physicians must complete an accredited residency program to be eligible for board certification in a specialty. The text box (pp. 14–15) describes the process ACGME uses for residency program accreditation.

Although medical school, graduate medical education, and specialty certification are governed by separate accrediting agencies, many of their appointees come from some of the same pool of medical organizations (Table 1-2). For example, the American Medical Association and the Association of American Medical Colleges appoint members to the bodies that accredit medical schools (LCME) and residency programs (ACGME). Specialty groups are represented in the residency review committees (RRCs), which also govern specialty certification decisions for physicians. Some of the specialty boards have worked closely with the ACGME and RRCs in developing some of the changes that have taken place in the accreditation process. The groups represented in these accrediting agencies are also closely involved in providing undergraduate, graduate, and continuing medical education, including teaching hospitals and physician educators.

The interrelatedness of these organizations creates both benefits and concerns. Overlaps of the governance of these organizations for multiple purposes can help ensure some consistency and logical flow across the different points of the medical education continuum. However, the interrelatedness of accrediting bodies and their potential incentives for maintaining the status quo raise some concerns about reforming medical education policies. Several experts and researchers have discussed the possible role of an independent board in making decisions about allocating funding for medical education (COGME 2007, IOM 2003, Pew Center for Health Professions 1998, Whitcomb 2007). Another option is to increase the share of public members participating in the governance of these accrediting and certifying organizations.

Medicare's subsidies for graduate medical education

Since its inception, Medicare has subsidized much of graduate medical education in the United States. When the Congress created Medicare in 1965, it recognized the societal benefits of medical education and specified that the Medicare program support its share of medical education costs, until the community determined other means.

> Educational activities enhance the quality of care in an institution, and it is intended, until the community undertakes to bear such education costs in some other way, that a part of the net cost of such activities (including stipends of trainees, as well as compensation of teachers and other costs) should be considered as an element in the cost of patient care, to be borne to an appropriate extent by the hospital insurance program (U.S. House 1965, U.S. Senate 1965).

Currently, Medicare's subsidy is provided through both direct and indirect payments to teaching hospitals. In total, Medicare's payments for graduate medical education account for about $9 billion annually—an average of almost $100,000 per resident.

Payments toward direct and indirect costs

Direct graduate medical education (GME) payments are designed to fund the teaching aspects of residency programs—resident salaries and benefits, supervisory physician salaries, and administrative overhead expenses. Direct GME payments are based on a hospital-specific per resident payment amount for which Medicare pays its share. These payments, which go to teaching hospitals, totaled $2.9 billion in 2007. See the text box (pp. 16–17) for more details on Medicare's direct GME payment.

Medicare also provides a small amount of education funding to hospitals to support direct costs of hospital-based education and training programs for nursing and various allied health professions.[8] In future work, the Commission may examine ways to provide more support for nursing education, as nurses are key professionals in delivering coordinated patient care.

The indirect medical education (IME) adjustment is a percentage increase (or "add-on") to the inpatient prospective payment system rate that varies with the intensity of hospitals' residency programs. The IME adjustment was developed to account for the higher costs of patient care associated with care in teaching hospitals, such as unmeasured patient severity, residents "learning by doing," and greater use of emerging technologies. Because Medicare's IME payments are tied to Medicare inpatients, teaching hospitals in communities with smaller shares of Medicare beneficiaries receive proportionately lower total IME payments per resident.

TABLE 1–2 **Multiple accrediting organizations are involved in physician education and practice**

	Type of certification/accreditation				
	Medical school	**Graduate medical education**	**Specialty certification**	**State licensure**	**Continuing medical education**
Accrediting organization	LCME	ACGME	ABMS	State medical boards	ACCME
Purpose	Accreditation of medical schools.	Accreditation of GME programs and institutions sponsoring GME programs.	Assist member boards in developing standards for certification of physicians in a given specialty.	License physicians, investigate complaints, and discipline physicians who violate the law.	Sets standards and accredits organizations and institutions that offer CME.
Governance	*17 members:* • 6 AAMC • 6 AMA • 2 students • 2 public • 1 CACMS	*25 members:* • 4 AAMC • 4 AHA • 4 AMA • 4 ABMS • 4 CMSS • 3 residents • 2 public • 1 government observer	*27 members:* • 1 from each specialty board • 3 public	Volunteer physicians and members of the public, in most cases, appointed by the governor. Total of *57* state medical boards.	*17 members:* • 3 AAMC • 3 ABMS • 3 AHA • 3 AMA • 1 AHME • 3 CMSS • 1 FSMB
Related organizations	**ECFMG** Certifies eligibility of graduates of non-LCME accredited medical schools. *Members from:* • AAMC • ABMS • AHME • AMA • FSMB • NMA	**RRCs** Develop specialty-specific guidelines for accreditation. 24 separate RRCs for each major specialty. *Members from:* • AMA • Specialty boards • Specialty societies	**Specialty boards** Develop guidelines for certification and recertification. 24 separate boards for each major specialty. *Members:* Physicians distinguished in teaching, research, or patient care	**FSMB** Cosponsors USMLE exam. Verifies physician credentials and maintains data bank on disciplinary actions. *Members from:* *57* state medical boards	**State medical societies** Approve state-specific CME *Members:* Individual physicians in a state.

Note: LCME (Liaison Committee on Medical Education), ACGME (Accreditation Council for Graduate Medical Education), ABMS (American Board of Medical Specialties), ACCME (Accreditation Council for Continuing Medical Education), GME (graduate medical education), CME (continuing medical education), AAMC (Association of American Medical Colleges), AMA (American Medical Association), CACMS (Committee on the Accreditation of Canadian Medical Schools), AHA (American Hospital Association), CMSS (Council of Medical Specialty Societies), AHME (Association for Hospital Medical Education), FSMB (Federation of State Medical Boards of the U.S., Inc.), ECFMG (Educational Commission on Foreign Medical Graduates), NMA (National Medical Association), RRC (residency review committee), USMLE (United States Medical Licensing Examination).

Source: MedPAC analysis of information from each of the accrediting organization's public websites.

When an IME adjustment was developed for Medicare's inpatient prospective payment system in 1983, it was set at double the empirical relationship between teaching intensity and costs per case, based on analysis estimating that teaching hospitals would not perform well financially under the new prospective payment system (Lave 1985). With the doubled adjustment, however, teaching hospitals performed much better than other hospitals. Despite some reductions in the IME adjustment over time, the Commission's analysis has shown that the current IME adjustment of 5.5 percent is set at more than twice the estimated relationship between teaching intensity and costs per cases (MedPAC 2007). In 2007, IME payments totaled $6.0 billion. The text box (pp. 16–17) provides additional details on Medicare's IME adjustment.

Summary of the Accreditation Council for Graduate Medical Education residency program accreditation process

The Accreditation Council for Graduate Medical Education (ACGME) accredits individual residency programs and the institution sponsoring the programs. The work of reviewing the programs and making accreditation decisions is carried out by 27 residency review committees (RRCs), 1 for each major specialty and 1 for transitional year programs. An institutional review committee accredits the institutions that sponsor residency programs. RRC members are volunteer physicians appointed by the appropriate medical specialty organization, medical specialty board, and the American Medical Association Council on Medical Education.

ACGME field staff representatives conduct one-day site visits to programs once every two to five years, depending on the strength of the program. They visit about one-third of the programs in a given year. The field staff representatives produce reports on the programs they visit based on lengthy interviews with program directors, faculty, and residents as well as a review of supporting documents. The RRCs, which on average meet three times a year, review the site visitors' reports along with data provided by the programs. The RRC members then vote on the appropriate accreditation action to take for each program on the agenda for that meeting.

Program requirements

To meet accreditation standards, programs must fulfill the requirements set up by the RRCs for the individual specialties. The ACGME has established a set of common program requirements or general competencies that all programs are required to integrate into their curriculum: patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice. (The text box on pp. 20–21 describes these subject areas.)

The movement to a competency-based system of accreditation is part of the Outcome Project, a long-term initiative that started in 1999, by which the ACGME is increasing emphasis on educational outcome assessment in the accreditation process. The shift in emphasis to outcome assessment is reflected in requirements for programs to:

- identify learning objectives related to the ACGME general competencies,

(continued next page)

The sum of Medicare's graduate medical education payments can be divided into three components, as illustrated in Figure 1-3. Two components reflect empirical costs discussed earlier: the cost of operating residency programs and the higher costs of patient care associated with educating and training residents. The third component is the extra IME payment that remains because the IME add-on is set at a percentage more than twice what can be empirically justified. In past reports, the Commission has recommended that part of the extra payment for IME be used to support a pay-for-performance program for all hospitals. The other two components—the direct GME and the empirically based portion of the IME payment—could be affected by policies that target funding to the type of settings and educational programs that best meet our health care needs.

Number of residents that Medicare supports

In 2006, Medicare provided direct GME support to hospitals for about 89,600 full-time equivalent (FTE) residents and fellows.[9] On average, hospitals received more than $70,000 in IME payments and $30,000 in direct GME payments for each FTE resident eligible for Medicare funding. Regulations for counting eligible FTEs for direct GME and IME payments are complex and vary, so the numbers Medicare supports through direct GME and IME payments differ. For the IME payment adjustment, Medicare supported 79,800 FTE residents in inpatient prospective payment system hospitals. For each teaching hospital, Medicare limits the number of residency positions it supports through a hospital-specific cap on medical education subsidies. However, hospitals may hire

Summary of the Accreditation Council for Graduate Medical Education residency program accreditation process (cont.)

- use increasingly more dependable (i.e., objective) methods of assessing residents' attainment of these competency-based objectives, and
- use outcome data to facilitate continuous improvement of both resident and residency program performance (ACGME 2008).

The Outcome Project is now in its third phase, which began in 2006, with full integration of the competencies and their assessment with learning and clinical care. The fourth phase, which will begin in 2011, will be an expansion of the competencies and their assessments to develop models of excellence, by identifying benchmark programs and adopting generalizable information about emerging models of excellence (ACGME 2008). The ACGME is also moving toward an evaluation system for programs that would be annual rather than every five years (Nasca 2008).

Before the Outcome Project, graduate medical education accreditation was based on a "minimal threshold model," by which programs were judged according to how they complied with minimum standards established by the RRCs and the ACGME. In the Outcome Project's competency-based model, programs are asked to show how residents have achieved competency-based educational objectives and, in turn, how programs use information drawn from evaluation of those objectives to improve the educational experience of the residents (ACGME 2008). ■

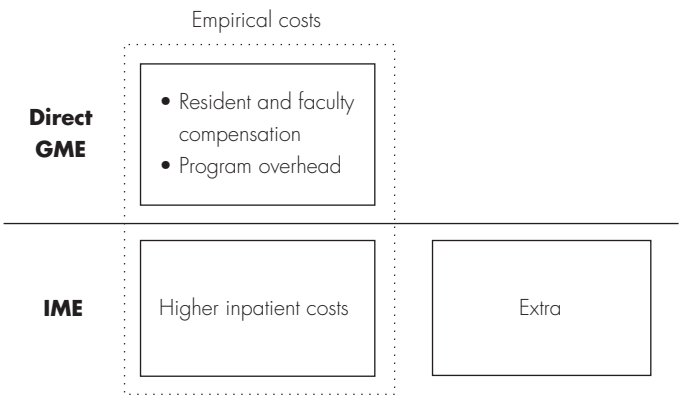
additional residents; in 2006, hospitals had more than 8,000 FTE residents for whom they did not have Medicare funding because the hospitals had exceeded their Medicare cap.[10] Preliminary research using cost report data suggests that hospitals that exceed Medicare's cap have a smaller proportion of residents in primary care specialties than hospitals that do not exceed the cap.

Non-Medicare funding sources for graduate medical education

The aggregate spending from all payers for graduate medical education is not well known (Wynn et al. 2006). Although Medicare is the largest single contributor to graduate medical education, other funding sources exist, mostly through federal and state programs. For example, state Medicaid programs contribute more than $3 billion annually to graduate medical education financing. In addition, the Department of Veterans Affairs (VA) supports more than 9,000 resident FTEs and allows more than 30,000 residents and fellows to rotate through its hospitals each year. The Department of Defense supports the education and training of about 3,000 residents. The Children's Hospital Medical Education Program administered by the Health Resources and Services Administration (HRSA) provides $300 million to support direct and indirect GME costs. Some Title VII grants administered by HRSA are also used to support residency programs in primary care and geriatrics, but funding for these programs is relatively low and has been reduced in recent years.

Teaching hospitals may also receive resources from their medical school affiliations, research grants, endowments, and foundation grants. Some private insurers contribute to

FIGURE 1–3 **Current Medicare subsidies for graduate medical education**



Note: GME (graduate medical education), IME (indirect medical education). "Extra" refers to the aggregate amount of IME payments that exceed empirically calculated IME costs.

Medicare payments for direct graduate medical education (GME) and indirect medical education (IME)

Direct GME payments

Direct GME payments are based on hospital-specific per resident costs in a base period, updated each year for inflation by the consumer price index for all urban consumers (CPI-U). A hospital's payment is the product of three factors:

- the hospital's updated per resident payment amount;
- a weighted count of full-time equivalent residents supported by the facility; and
- the hospital's Medicare patient share, based on the ratio of Medicare patient days to total patient days in the acute inpatient setting.

Medicare direct GME payments totaled about $2.9 billion in 2007. Medicare makes direct GME payments to short-stay acute care hospitals as well as other types of hospitals supported by the Medicare program (cancer, children's, long-term care, psychiatric, and rehabilitation hospitals).

Hospitals' per resident payment amounts are based on their total per resident costs in 1984 updated for inflation. A floor rate was set at 85 percent of a locality-adjusted national average under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, which also eliminated annual CPI-U increases in the rates from 2001 through 2013 if a hospital's per resident amount is 140 percent or more of the locality-adjusted national average. The per resident payment amounts also depend on the residents' specialties. Payments are about 6 percent higher for residents in primary care specialties (family practice, general internal medicine, general pediatrics, and obstetrics and gynecology) and some selected specialties (geriatrics and public health and preventive medicine) than for other specialties. There is no differential in payments by specialty for hospitals that established residency programs after 1995 or for hospitals that are at the floor rate.

The weighted count of residents used in the payment formula is based on a three-year rolling average. The resident counts for most hospitals are also capped at their 1996 levels because of concern that the payment formulas were providing a strong incentive for hospitals to increase the number of residents in their programs.[11] Residents in their initial residency period—the minimum period required for board certification in the first specialty program entered after medical school, up to a maximum of five years—are given a weight of 1.0. Residents who pursue a second specialty or a subspecialty or who spend longer in their initial residency period are given a weight of 0.5.

(continued next page)

supporting graduate medical education indirectly through higher patient care payments provided to teaching-affiliated health care providers. A small number of states require private insurers to contribute explicitly to graduate medical education. However, in most states private insurers generally do not make specific payments to providers for direct or indirect medical education costs.

Medicare payments to teaching physicians for services when supervising residents

When supervising residents, teaching physicians are permitted to bill Medicare for Part B services that their residents perform. Residents may not bill for these services.[12] For payment, Medicare requires that the supervising physician be physically present during the critical or key portion of the service being provided or actually perform this portion of the service. In addition, the supervising physician must supply more than his or her signature in the clinical documentation for the service. Specifically, the supervising physician must document who provided what portions of the service and that the supervisor was present during the critical or key portion of the service and participated in management of the patient. These regulations apply to services provided under Medicare's physician fee schedule in hospital and nonhospital settings. In certain circumstances, Medicare relaxes the supervision requirements for primary care

Medicare payments for direct graduate medical education (GME) and indirect medical education (IME) (cont.)

A hospital's Medicare patient share is the proportion of its Medicare acute care inpatient days to its total acute care inpatient days. The formula for direct GME payments for Medicare Advantage patients is the same, but the Medicare patient share is based on Medicare Advantage patient days to total days.

IME payments

The IME adjustment is a percentage add-on to a hospital's inpatient prospective payment system payments that varies with the intensity of the hospital's residency programs. The IME adjustment is currently set so that operating payments increase approximately 5.5 percent for each 10 percent increment in resident intensity, measured by the ratio of residents to hospital beds.[13] Because IME payments are an adjustment to base payment rates, a hospital's IME payments are tied to its volume and mix of Medicare cases as well as its number of residents. As is the case with direct GME payments, the number of residents included in the resident-to-bed ratio is also capped. Medicare IME payments totaled $6.0 billion in 2007.

While the IME adjustment is intended in part to pay for the indirect costs of running a teaching program, the current IME adjustment of 5.5 percent substantially exceeds the estimated relationship between teaching intensity and costs per case. The Commission's analysis has shown that Medicare inpatient costs per case (operating and capital costs combined) increase about 2.2 percent for every 10 percent increase in the ratio of residents to hospital beds (MedPAC 2007). The current IME adjustment is thus set at more than twice what can be empirically justified, directing more than $3 billion in extra payments to teaching hospitals above the effect that educating and supervising residents and fellows has on the cost of caring for Medicare patients. These funds are currently provided to teaching hospitals without any restriction on how they are used; teaching hospitals report that they use this extra payment amount for mission-driven activities, such as trauma-center care. To encourage quality improvement, the Commission believes some of these funds should be made available to all hospitals that provide high-quality care. The Commission therefore recommended in its 2007, 2008, and 2009 March reports that the IME adjustment be reduced from 5.5 percent to 4.5 percent per 10 percent increment in the resident-to-bed ratio and that the funds obtained from reducing the IME adjustment be used to help finance quality-incentive payments. ■

services but increases the requirements for surgical, high-risk, or other complex procedures.

In the middle to late 1990s the Department of Health and Human Services' Office of Inspector General undertook a series of audits of physician services at teaching hospitals. These were called the Payment for Academic Teaching Hospitals (PATH) audits. Since they took place, CMS and teaching hospitals have increased their focus on ensuring compliance with the supervision rules.

Economic costs and benefits of participating in teaching activities

To varying degrees, participation in graduate medical education provides both costs and benefits to hospitals and physicians. With respect to direct costs, teaching hospitals incur the expenses associated with operating a residency program, including salary and benefit costs of residents, faculty supervisory costs, and program overhead expenses. Other types of costs include facility infrastructure expenses, such as maintaining an extensive medical library for residents to conduct clinical research, providing office space for supervisory faculty, providing on-call rooms for residents, and adopting expensive technologies. Teaching hospitals also experience added indirect costs such as higher costs of patient care from residents learning by doing, from ordering more services (e.g., diagnostic tests and imaging), and from taking longer to perform procedures.

Alternatively, teaching hospitals benefit in many ways from having residents, and overall the number of residents in

accredited programs has increased 30 percent during the last two decades (Salsberg et al. 2008). Benefits to teaching hospitals include, for example, Medicare and Medicaid payments to hospitals toward the direct and indirect costs of residency programs described earlier. Moreover, Medicare's indirect payments are currently set so hospitals receive payments that are more than double the indirect costs. Hospitals also benefit by having residents available for on-call coverage and to assist in providing patient care. In many cases, resident wages are lower than those of other health professionals who could perform these duties, thus affording hospitals some gains in staffing costs (Rich et al. 2002). Teaching hospitals and affiliated physicians also benefit from the prestige associated with being involved in physician education and training. The last two factors—greater physician staffing and prestige—can lead to higher patient volumes, as patients and community physicians favor these facilities. With prestige may also come the ability to garner higher prices in negotiations from private payers to help cover these institutions' higher costs for patient care.

Similarly, physicians experience costs and benefits from their participation in medical education. Depending on the resident's skill level, a supervising physician's productivity may fall because of the extra time needed for activities such as teaching and reviewing clinical documentation with residents. Recent actions regarding medical education—such as rules restricting residents' duty hours to 80 per week and the PATH audits—may have decreased residents' and supervisory physician's output, but research on this topic is limited. One study on surgery showed that surgical operations take longer with resident involvement (Babineau et al. 2004). Another study of residents in an internal medicine practice showed small productivity losses from participating in residency instruction, more so for first-year residents (Johnson et al. 2008).[14] Other supervisory costs include the time involved in negotiating agreements and maintaining paperwork on individual residents. Some practices also incur costs from expanding office space to accommodate residents in their office.

Experienced physicians can also benefit from participation in residency supervision and education. Many are paid by the teaching hospital for their role in educational, supervisory, and administrative activities. Even when physicians volunteer their time, they may receive a faculty appointment, which adds prestige to their practice and may also allow access to other benefits from the educational sponsor, such as medical library privileges. Faculty appointments may help increase practice volume and total patient revenues. In addition, being involved in medical education allows physicians to keep up with the latest medical research and provides an opportunity to recruit future practice partners. Residents may also help with on-call coverage in physician practices as well as patient preparation and triage—thereby increasing the practice's productivity.

Given the complexities of calculating the costs and benefits of participating in GME, it is difficult to discern whether it is, on net, profitable for providers. Hospitals' and physicians' decision to participate in GME activities may also be driven by their mission focus, such as education and research.

Medical education should support needed delivery system reform

Our health care delivery system is not a true system: care coordination across providers is not routine, fragmented specialist care is often favored over primary care, quality of care is too often poor, and costs are high and increasing at an unsustainable rate. In congressional testimony and in our reports to the Congress, the Commission calls for payment system reforms and other tools to moderate spending while increasing value. To this end, the Commission has recommended the following changes aimed at encouraging physicians to increase care coordination and assume greater accountability for quality and resource use:

- medical home pilot programs for beneficiaries with multiple chronic conditions,
- efforts to measure physicians' use of health care resources and provide feedback results,
- financial disincentives for certain hospital readmissions,
- pilot program for bundled payments for all services provided in a hospitalization episode,
- linking providers' payment to quality, and
- encouraging the use of comparative-effectiveness information and public reporting.

Such reforms in payment policies need to be accompanied by reforms in medical education. This pairing is important to ensure that students and residents learn the skills they need to provide care and leadership in new delivery models under restructured payment and incentives.

These skills include quality measurement and practice improvement, care coordination, multidisciplinary teamwork, cost awareness, and interpersonal skills. Research on internal medicine residency programs (discussed later in this chapter) found several gaps in formal instruction on many of these skills.

Residency experiences are designed to prepare physicians for clinical practices. Thus, exposure to skills such as care coordination during residencies is critical to improving the quality and efficiency of our nation's health care. Recognizing shortcomings, the specialties of internal medicine, family medicine, surgery, and pediatrics have embarked on major redesigns of their residency programs to improve the way residents prepare for practice in their specialty (Whitcomb 2008). Further, recent ACGME requirements in residency program curricula (described in text box, pp. 20–21) also seek to address some of these concerns.

Yet, Medicare—with an enormous financial stake in health care and graduate medical education—has never specifically linked any of its direct GME or IME subsidies to promoting or fostering important goals in medical education. Medicare should consider ways to ensure that residents and other health care professionals obtain the skills they need to provide efficient, coordinated, high-quality care.

Study suggests that curricula in many internal medicine residency programs fall short in topics associated with delivery system reform

A Commission-sponsored study, conducted by RAND researchers, found that, although most internal medicine residency programs provide at least some instruction and experience in topics associated with quality and efficiency improvements, their curricula fall short of recommendations from the Institute of Medicine (IOM) and other experts (Cordasco et al. 2009).[15] This study consisted of semistructured interviews with 26 directors from a representative sample of internal medicine residency programs. It examined several specific formal and experiential curricular activities within the following broad topics:

- practice-based learning, focusing on measuring care quality and improving medical practice;
- system-based practice, focusing on care coordination, multidisciplinary teamwork, cost awareness, and patient safety;
- interpersonal communication, focusing on communication with other providers, patients, and family and on patient education;
- health information technology, including electronic medical records and computer order entry; and
- care settings, focusing on experiences in nonhospital settings.

Of particular concern from the interview findings is the lack of formal instruction and experience in: multidisciplinary teamwork, cost awareness in clinical decision making, comprehensive health information technology, and patient care in ambulatory settings. Formal instruction involves structured and organized educational experiences. Topics that residency program directors reported to be covered with more consistency through formal instruction are evidence-based medicine and communicating with patients about end-of-life care. In all areas, particularly interpersonal communication, directors reported that more experiential learning—with faculty modeling, mentoring, and informal feedback—is the predominant form of instruction. As may be expected, researchers found large variation in the extent of and approach to teaching these topics, and program directors reported multiple factors that facilitated or impeded their ability to instruct residents in them.

The project consisted of 26 hour-long telephone interviews with program directors from a representative, random sample of internal medicine programs.[16] A board-certified internal medicine physician, familiar with residency education, conducted all interviews. Given available resources, we were unable to expand the scope of this project to include other types of residency programs, such as family medicine and surgical programs. It is likely that findings would differ among specialties.

Practice-based learning: Measuring care quality and improving medical practice

The IOM states that physicians must be able to assess the quality of care they provide and implement changes in their practice for improvement. This process is often referred to as practice-based learning and calls for physicians to obtain skills in two aspects: the methodology of quality measurement and the use of tools for implementing practice or system changes where quality is deficient (Ogrine et al. 2003). Systematic data collection and the use of chronic disease registries provide educational and experiential opportunities for obtaining experience in quality measurement. The American Board

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

Approved by the ACGME Board February 13, 2007

ACGME competencies

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

Patient care

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

Medical knowledge

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

Practice-based learning and improvement

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

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

Interpersonal and communication skills

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

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

(continued next page)

of Internal Medicine offers a web-based learning module on collecting patient data and implementing practice changes. Experience with tools such as evidence-based medicine and clinical decision aids are geared toward improving practice and systems.

The RAND researchers found that, while many residency programs provide some exposure to quality assurance and system change, only a small share require residents to complete their own systematic data collection, analysis, and resulting system change (Table 1-3, p. 22). Fewer than half the programs (11 of 26 programs) have lectures or computer-based training on quality assurance, but more (18 programs) require that residents work on quality assessment at the hospital. Fewer than a third (seven programs) have established curricula in which residents collect and analyze data on their own patients. The same share of programs introduces residents to chronic disease registries and provides lectures or computer-based training on implementing system change. Fewer still (four programs) have residents work directly on projects to implement system changes.

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

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

Professionalism

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

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

Systems-based practice

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

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

Source: ACGME

Among the programs in the study that seem to devote more resident time to quality measurement and practice improvement, one includes requiring these activities throughout an ambulatory rotation that spans several months. In some programs, a hospital's quality management department co-leads efforts in these curricula.

Overall, program directors reported that their residents' instruction in evidence-based medicine is stronger. The most frequent instruction methods in this topic are formal sessions on how to search and conduct literature reviews and journal article discussions. Half the programs provide residents with faculty mentoring or assistance from an epidemiologist or statistician for literature analysis. Most program directors reported that evidence-based medicine is also taught informally through daily interactions with faculty in the course of patient care. While most programs reported teaching their residents to use clinical prediction rules (e.g., pneumonia severity index), only a little more than one-third (nine programs) have information technology to support these tools in clinical practice. In some cases, however, residents have the technology on their personal hand-held computers.

TABLE 1–3

Residency instruction in measuring quality and improving medical practice

Topic/activity	Number of programs (of 26) that include topic in curricula
QA and improvement	
Have lectures/computer-based training in QA	11
Hospital administration collects, analyzes, and presents data to residents on quality measures	9
Each resident works on quality assessment	18
Residents collect or are provided data on own patients	7
Use chronic disease registries	7
Have lectures/computer-based training in system change implementation	7
Each resident does project implementing system change	4
EBM	
Formal session—searching literature	18
Journal club/EBM conference	26
Lectures on critiquing literature	13
EBM assignments	8
Clinical decision aids	
Use order sets or critical pathways	18
Formal lectures on clinical prediction tools	6
IT supports clinical prediction tools	9

Note: QA (quality assurance), EBM (evidence-based medicine), IT (information technology). Table presents presence but not intensity level of the activity.

Source: Cordasco et al. 2009.

System-based practice: Care coordination, cost awareness, and patient safety

Individual physicians work within a complex arrangement of health care delivery in the United States. This complexity has led to fragmentation in care along the continuum of health care services (within a hospitalization, at hospital discharge, and in outpatient care). Moreover, discontinuity has likely contributed to the increase in hospitalizations that researchers have found are related to exacerbations or complications of chronic conditions (Wolff et al. 2002). To counter this trend and the unsustainable growth in health care spending, experts have introduced system-based practice, which calls for a better understanding of the components and costs of health care delivery to improve coordination, spending, and safety (Berwick 1996). Under this concept, physicians—regardless of their practice setting—must be able to coordinate plans of care, work with multidisciplinary professionals, and utilize systems ensuring patient safety (Shortell et al. 2000).

RAND researchers found that formal instruction on many aspects of system-based practice is limited or nonexistent, particularly in the outpatient setting (Table 1-4). For the inpatient setting, program directors stated that coordinating provider handoffs of patients has recently become an area of increased attention in residency programs. Many programs (14 programs) have specific instruction in handoffs and some (6 programs) have supervision in "sign-out" procedures to communicate inpatient status during the residents' shift changes. For coordinating care across hospital discharge, the experience is less formalized, with fewer than half (11 programs) having formal instruction on this activity. Among those that do, case managers often lead the instruction. One program reported that residents rotate through a special "discharge team" that takes the lead on care coordination and patient education on the day of discharge. Compared with the inpatient setting, formal care coordination instruction for the outpatient setting is even less common. Fewer than one-third (eight programs) reported that their residents receive specific instruction or attend conferences on care coordination in the outpatient setting.

Similarly, formal experience working in multidisciplinary teams (often composed of physicians, nurses, social workers, nutritionists, and pharmacists) is more common in the inpatient setting than in the outpatient setting. Of the 19 programs with formal inpatient multidisciplinary team experience, most are on subspecialty rotations; only 4 programs include formal multidisciplinary teamwork during the general medicine service rotation. Fewer than one-third (eight programs) reported formal multidisciplinary experience in the outpatient setting, but directors from these programs often noted that residents may engage in semiformal or informal multidisciplinary teamwork or have multidisciplinary staff available for consultation.

Only about one-quarter (six programs) have formal methods for teaching about absolute and relative costs of diagnostic tests, treatments, and medications. Most program directors indicated that they rely on informal instruction for this topic. Among those that have formal

instruction, directors mentioned topics such as hospital service costs, billing, and coding. Programs are similarly unlikely to instruct residents about patients' share of medical charges. Among those that do, the focus is typically during ambulatory experiences, such as in a clinic that uses sliding-scale policies. Directors did not mention having formal instruction about overall spending on health care in their residency programs, but the study did not ask about it specifically.[17]

All programs include some formal instruction in patient safety issues (e.g., preventing falls, proper patient identification). However, only about one-quarter (six programs) teach basic safety design principles, as recommended by the IOM. These principles include methods such as standardization of practices and analysis of the root causes of safety problems. Some (four programs) require residents to be involved in safety-related projects that examine causes of adverse or "near miss" events within the hospital.

Interpersonal communication

The quality of communication between patients and their physicians is important, as aspects of care such as adherence to treatment regimens and satisfaction with care plans can influence patients' health outcomes (Lorig et al. 2001, Stewart et al. 2000). Thus, to maximize health care effectiveness, it is essential for physicians to communicate collaboratively with patients and their families as well as with other health professionals to determine appropriate diagnostic and treatment regimens. Instruction in this area should teach new physicians how to communicate with patients and families in ways that are adaptable to patient age, culture, health literacy, and health status. Communication skills are particularly important when treating patients with chronic illnesses because self-management of chronic diseases relies on patients' and caregivers' clear understanding of symptoms and treatment. Previous Commission work has highlighted the importance of physician communication with patients about end-of-life treatment choices and decisions (MedPAC 2008).

The RAND researchers in this study found that, although only a little more than half the programs (15 programs) cover communication skills between health care providers, more, but not all (22 programs), include formal instruction on how to communicate clearly with patients about diagnoses and treatment plans (Table 1-5, p. 24). Looking specifically at forms of patient–physician communication, we see that communication activities that include more patient engagement are less frequently included in formal residency instruction. For example, half the programs (13 programs) instruct residents on how to conduct shared decision making, only 10 formally instruct residents on how to counsel patients on regimen adherence and behavior change, and fewer than one-third (8 programs) ensure resident experience with the techniques of patient education, such as those used for the management of chronic disease (e.g., diabetes education classes).

TABLE 1–4

Residency instruction in care coordination, cost awareness, and safety

Topic/activity	Number of programs (of 26) that include topic in curricula
Coordination of care	
Formal instruction in inpatient provider hand-offs	14
Faculty/chief resident supervise sign-outs	6
IT support (computer-based tool) for sign-outs	10
Formal instruction in hospital discharge coordination	11
IT supports hospital discharge	14
Formal instruction in outpatient coordination	8
IT supports outpatient coordination	11
Multidisciplinary teams	
Formal inpatient teams	19
Formal teams on general medical inpatient service	4
Formal outpatient teams	8
Awareness of absolute and relative costs	
Lectures on costs/cost-effectiveness	6
Lectures on patient share of costs	6
Patient safety issues/methods	
Formal instruction in patient safety issues	26
Formal instruction on safety design principles	6
Patient safety project	4

Note: IT (information technology). Table identifies presence but not intensity level of the activity. Programs without formal multidisciplinary training may have semiformal or informal experiences.

Source: Cordasco et al. 2009.

TABLE 1–5

Residency instruction in interpersonal communication

Topic/activity	Number of programs (of 26) that include topic in curricula
Communication skills with health care providers	15
Communicating clearly with patients about diagnosis and treatment plan	22
Engaging patients in shared decision making	13
Patient education techniques	8
Counseling in adherence/ behavior change	10
Cultural competency	24
Using interpreters	7
Health literacy	13
End-of-life communications	22
Holding family meetings on end-of-life issues	7

Note: Table identifies presence of formal training sessions about the topic but not intensity level of the communication activity. Programs without formal sessions may rely on informal instruction during patient care experiences.

Source: Cordasco et al. 2009.

With respect to instruction on communication with special populations or in special situations, most residency programs (24 programs) indicated that they have formal sessions on cultural competency, but only a little more than a quarter (7 programs) specifically teach skills for working with an interpreter. Half (13 programs) provide instruction on adapting communication based on patients' health literacy. In most programs (22 programs), directors reported that residents receive formal instruction on how to communicate end-of-life issues, such as advance directives, with patients and caregivers. Only seven programs formally instruct residents on how to hold family meetings to discuss end-of-life issues.

Use of health information technology

The use of information technology (IT) is a critical component of improving the quality, safety, and efficiency of health care delivery (MedPAC 2005). To make such improvements, physicians must become adept with the tools of infomatics, such as electronic medical records, computer order entry, electronic sources of medical care information and guidelines, and IT-supported clinical decision-making aids (Gorman et al. 2000, IOM 2003).

In recent legislation, the Congress included substantial financial incentives (totaling up to almost $37 billion from Medicare and Medicaid over the next 10 years) for hospitals and physicians to adopt health IT. To qualify for these incentive payments, providers must prove that their health IT is certified and that it is put to "meaningful use." Through the federal rule-making process, the Secretary of Health and Human Services will define the certification process and the term "meaningful use." To maximize federal (Medicare and Medicaid) investment in these IT incentives, it will be essential to ensure that participating hospitals and physicians commit to using the technology for improving the quality, efficiency, and safety of care. The Commission has recommended that performance incentives be based on the results gained through IT use, rather than simply the possession of health IT. Other key features for the success of health IT will be interoperability and standardization. Interoperability will facilitate the transfer of data and other communications across providers and settings. Standardization among technologies will allow professionals to know how to use health IT when they switch between settings. Even if health IT is standardized and interoperable, health care providers will still need to redesign some elements of their practice to take full advantage of this important technology.

In our study, the RAND researchers found that, although all interviewed programs provide residents with some exposure to electronic medical records (EMRs), in most programs, the EMRs are not comprehensive and lack one or more important components, such as the ability to enter orders or patient progress notes (Table 1-6). Only 1 of the 26 programs uses a comprehensive EMR in both inpatient and outpatient settings (not shown). Because the VA hospitals and clinics are equipped with comprehensive EMRs, residents who rotate through VA facilities gain some experience with high-functioning EMRs. Five programs reported that none of their residents' outpatient experiences includes the use of EMRs. The remaining programs include either comprehensive or partial EMR experience in the outpatient setting. As shown previously in Table 1-3, residency experience in using health IT to support other clinical functions (e.g., decision support and outpatient coordination) is limited.

Residency experience in nonhospital settings

Hospital inpatient experience is an important component of residency education to gain exposure to acute, serious

TABLE 1–6

Residency exposure to information technology

Setting and IT capability	Number of programs (of 26) that include IT capability in curricula
Inpatient	
Comprehensive EMR	4
Partial EMR	22
Computer order entry	11
Outpatient	
Comprehensive EMR	7
Partial EMR	14
Computer order entry	8

Note: IT (information technology), EMR (electronic medical record). Table identifies the presence but not the intensity level of the instruction in IT-related activities. Programs without formal sessions may rely on informal instruction during patient care experiences.

Source: Cordasco et al. 2009.

illnesses, but it is equally essential for residents to have adequate experience in nonhospital settings. As has been documented over decades, most health care is provided in settings other than acute care hospitals (Green et al. 2001, White et al. 1961). Therefore, residents should receive sufficient education and training in nonhospital settings. Also, to coordinate care for patients across settings, residents need exposure to and experience in a variety of health care settings (COGME 1999, IOM 2003).

The RAND researchers found that the share of residents' time working in community-based medicine or in ambulatory settings with patients in managed care is extremely limited, even though most programs (21 programs) include at least some community clinic or private practice experiences in their residency. For most of these programs, directors reported that nonhospital experiences account for only a small amount of physicians' total residencies. About half the programs require residents to perform home visits and many require a rotation in which the residents provide care in a nursing home or rehabilitation unit (Table 1-7). Many directors reported that their residents have some experience with ambulatory patient populations in managed care, but in several of them, managed care patients were only a small share of the residents' caseloads. No directors reported that their residents have experience in a medical practice designated as a "medical home" by insurers or accrediting organizations; however, several directors indicated that their clinics are either working toward achieving this designation or have many of the features of one.

Teaching hospitals face considerable financial incentives and regulatory barriers that discourage them from rotating residents to nonhospital settings. We discuss these issues, as well as the impacts of residents' limited nonhospital experience, in a later section of this chapter.

Factors affecting programs' instruction in selected topics

During their interviews, residency program directors reported to the RAND researchers that multiple factors affect their ability to instruct in selected topics on practice-based learning, system-based practice, and interpersonal communication. These factors include IT infrastructure, faculty expertise and time, institutional support, the program's setting, residents' baseline characteristics, and relative lack of research-based evidence on the best methods for instructing residents on these skills.

The presence or absence of IT was the factor cited most often that either facilitated or impeded instruction in topics essential for delivery system reform. Directors stated that a comprehensive EMR system at residency sites was not only key for helping residents gain competence in using EMRs but was also helpful in teaching other skills. For example, EMRs provide data sources for quality improvement projects, tools for reinforcing the

TABLE 1–7

Residency experience in selected nonhospital settings

Setting	Number of programs (of 26) that include at least some experience in nonhospital setting
Community clinic or private practice	21
Home visits	14
Nursing homes or rehabilitation centers	21
Ambulatory care, managed care patients	20
Palliative care/hospice*	18

Note: Table presents ever/never experience in the setting but does not present information on the total time in the setting.
*Training in palliative care and hospice can occur in the hospital or nonhospital setting.

Source: Cordasco et al. 2009.

use of clinical decision support, methods to coordinate patient care between inpatient and outpatient settings, links to patient education materials, and, in some cases, comparative-effectiveness and cost information. We discussed opportunities and challenges related to health IT investments in a previous section of this chapter.

In the interviews, residency program directors stated that the levels of faculty expertise and institutional support (i.e., support from the sponsoring hospital) were key determinants of the quality and quantity of teaching in topics associated with delivery system reform. Directors often attributed the success of a given curriculum to a "faculty champion" who spearheaded its development and implementation. Alternatively, where curricula were lacking, directors cited weaker faculty members, among other contributing factors. They also noted that the attending physicians' clinical productivity requirements for the hospital can sometimes supersede the educational needs of the residency program. Competing with the hospital for the residents' time was frequently cited as a major barrier to teaching on topics relevant to delivery system reform, such as care coordination across settings. In contrast, programs with stronger institutional support for the residency programs—such as the availability of comprehensive health IT—appeared to have more ability to instruct on the topics we examined. Overall, directors viewed program accreditation requirements as being crucial for obtaining institutional support for their curriculum needs.

In discussion about facilitators and barriers, directors again raised the issue of care settings, indicating that opportunities and barriers may rest in the environment of the sponsoring hospital and community. For example, some programs serve a diverse patient population, but others do not. Some programs rely on rotations in community-based clinics that provide more experience with ambulatory care for lower income individuals, but placement in this type of setting was relatively rare.

Program directors also cited the level of residents' incoming knowledge from medical school as a factor in program strength. Directors generally indicated that physicians entered their residency with little experience in quality improvement methods but relatively stronger experience in evidence-based medicine skills. The variation in residents' skill levels in interpersonal communication was also cited as a major factor, particularly for international medical graduates. Directors also noted that residents' general lack of interest in these topics is a barrier, particularly because they are not a focus on board certification exams.

Finally, program directors reported a dearth of proven educational methods or tools available for teaching residents competencies in topics such as care coordination. Directors noted that it is difficult to determine the appropriate mix of formal and informal instruction methods because tools for evaluating their effectiveness are limited.

Study limitations

This study presents a snapshot of the current activities and methods that internal medicine residency programs are using to instruct in topics important for reforming the U.S. health care delivery system. It does not provide a comprehensive analysis of each topic's educational methods because each topic could be the subject of its own study. Note that the absence or presence of teaching in a specific area is only a crude measure and does not represent curriculum quality, intensity, or effectiveness. Although our sample included only 26 of 381 (7 percent) internal medicine programs, the sampling frame was designed to produce a representative sample of internal medicine programs. In other specialties, it is likely that results would differ.

Financial incentives and regulatory barriers discourage nonhospital residency rotations

In keeping with historical patterns of graduate medical education, residency programs are largely based in inpatient, acute care teaching hospitals. Although this setting provides residents with important and crucial experience diagnosing and treating a variety of seriously ill patients, it is equally important for most residents to have adequate experience in nonhospital settings for a number of reasons.

First, as changes in health care have evolved, most of the medical conditions that practicing physicians confront are, and should be, managed in nonhospital settings, such as offices, nursing facilities, and patient homes. Thus, residents' education and training should include settings that will give them sufficient experience diagnosing and treating common medical problems and chronic conditions. Some research has found, for example, that

internal medicine residents reported that they did not perform many common ambulatory procedures frequently enough (if at all) during their residencies and were, thus, not confident in performing them (Wickstrom et al. 2000). In other studies, family medicine residents were more likely to report feeling prepared for treating outpatients, whereas internal medicine residents were more likely to report feeling prepared to treat inpatients (Wiest et al. 2002). It is important for residents to be prepared to practice independently in nonhospital and outpatient settings because the complexity of patients and their care in these settings has grown.

Second, to understand how to coordinate care for patients across settings, residents need exposure to and experience in a variety of health care settings (COGME 2007, IOM 2004b). Third, improving residents' comfort level with care in these settings not only positively influences residents' skills in community-based care but could also increase their desire to practice community-based care—an essential component of a delivery system designed to prevent patients from being unnecessarily hospitalized. Taken together, these three reasons strongly suggest that enhancing residents' skills in nonhospital settings is important for patient health, patient comfort, and health care spending.

Currently, the relatively large share of residency time spent in hospital settings can be attributed to historical patterns of medical education, financial incentives, and regulatory issues. These factors encourage teaching hospitals to keep residents in the hospital and discourage hospitals from developing nonhospital rotations for their residents. We focus on the regulatory issues and the financial incentives in this section of the chapter.

Residents provide clinical labor in hospitals

For hospitals, residents provide valuable clinical services, particularly on-call duties that may include writing timely prescription orders and conducting patient admissions. Hiring or contracting other physicians, physician assistants, or nurse practitioners to provide these activities and services is more expensive for the hospital because hospitals must pay them higher wages (Rich et al. 2002). Moreover, Medicare does not subsidize the salaries and fringe benefits paid to these other health professionals, as it does for residents.

This labor cost incentive has been a longstanding constraint on hospitals' willingness to reduce residents' time in the inpatient setting, cited by many experts including the Commonwealth Fund Task Force on Academic Health Centers, the IOM Committee on the Roles of Academic Health Centers in the 21st Century, the Council on Graduate Medical Education, and the Blue Ridge Academic Health Group (Ludmerer and Johns 2005). Recent reductions in the limits on residents' total duty hours have intensified this incentive because hospitals have fewer hours per resident available.[18]

TABLE 1–8

Medicare supports didactic (nonpatient care) instruction in the hospital setting only

Site of residency instruction	Payment to teaching hospital	
	Direct GME	IME
Teaching hospital	All approved educational activities: • Patient care activities • Didactic instruction (e.g., interdisciplinary grand rounds) • Research	Patient care activities
Nonhospital setting*	Patient care activities	Patient care activities

Note: GME (graduate medical education), IME (indirect medical education). *Teaching hospitals must have a written agreement or other documents in place demonstrating that they are incurring the costs of residents' salary and benefits and all or substantially all of the nonhospital setting's supervisory activities.

Source: Adapted from Association of American Medical Colleges 2008d.

Medicare supports didactic (nonpatient care) instruction in the hospital setting only

Medicare's support for graduate medical education draws some distinctions regarding both the type of instructional experience and the setting (Table 1-8).

- IME payments are limited to activities that are specific to individual patient care. Thus, IME payments do not cover residents' time spent on research and didactic activities (e.g., a meeting or a lecture) that are unrelated to the care of residents' specific patients—regardless of the setting. Teaching hospitals can continue to receive IME payments for residents performing patient care activities in nonhospital settings.

- Direct GME can cover time related to residents' research and didactic (nonpatient care) learning experiences, but only when these experiences take place within the teaching hospital. Therefore, didactic activities that take place in nonhospital settings (e.g., meetings on overall practice management in physician offices) do not qualify for Medicare's direct GME payments.

Under these regulations, therefore, for each resident who rotates to a nonhospital setting, the teaching hospital effectively loses the resident's direct GME payment proportional to the time the resident spends in didactic (nonpatient care) activities. The teaching hospital also would not qualify for IME payments for these didactic activities, but that is true regardless of the setting.

To enforce this policy, teaching hospitals must track and characterize all their residents' hours as either patient care or otherwise at various sites and submit the information to Medicare in a log, which may be audited. The ACGME also requires this information to review completion of specialty requirements.

Additional Medicare statute and regulations require that teaching hospitals incur "all or substantially all" of the costs borne by nonhospital settings for teaching residents, including the cost of supervision. Thus, teaching hospitals must incur the costs of research and supervised didactic (nonpatient care) activities that occur in nonhospital settings. However, teaching hospitals do not receive direct GME payments for these non-patient-care activities when they occur outside the hospital. Consequently, under Medicare regulations, teaching hospitals must pay for the cost of research and didactic activities performed in nonhospital settings, when they are expressly excluded from Medicare's medical education subsidy.

Medicare regulates specific provisions of hospital–nonhospital residency arrangements

If teaching hospitals do not show Medicare that they are incurring all or substantially all of the nonhospitals' costs related to resident teaching and supervision, they forgo direct GME and IME payments proportional to the time residents spend outside the hospital. Although some in nonhospital settings may welcome this compensation for their time, others would prefer to volunteer their time and are not willing to complete the paperwork that teaching hospitals need to comply with Medicare regulations. This paperwork includes a written agreement stating that the teaching hospital will incur the costs of the residents' salaries and fringe benefits in addition to the portion of the teaching physicians' salaries and fringe benefits attributable to resident instruction and supervision.[19] To fulfill these regulations, CMS would also accept written documentation proving such payments were made, in lieu of a formal written agreement.

Calculating the cost of this supervisory activity can be complex, and physician organizations, such as the American Association of Family Physicians, report that although CMS has taken some steps to reduce this paperwork burden, it is still cumbersome and many supervising physicians would prefer to volunteer their time.[20] Attending physicians enjoy mentoring new physicians, view it as a professional responsibility, and may often gain stature by being listed as "adjunct faculty" at the affiliated teaching institution. In addition, depending on the skills of the resident, nonhospital sites may gain in productivity with residents' patient care activities.

Without these written agreements or other documentation on the hospital's responsibility to incur all or substantially all of the costs of a resident's training in a nonhospital site, the teaching hospital effectively loses Medicare's graduate medical education payments for that resident's time in the nonhospital setting. With some exceptions, nonhospital settings are not permitted to receive direct GME and IME payments directly from Medicare.[21] Some have called for graduate medical education funding to go directly to more types of nonhospital entities responsible for providing the medical instruction and resident learning experiences (AAFP 2009, Mullan 2009, Rich et al. 2002).

As stated earlier, teaching hospitals that meet the regulations for claiming nonhospital resident time not only receive direct GME but also continue to receive IME payments for the time residents rotate in nonhospital settings, provided they are performing patient care (Table 1-7, p. 25). This allowance was instituted in the Balanced Budget Act of 1997 to ameliorate the financial disincentives for teaching hospitals to rotate residents into nonhospital settings to gain community-based experiences. However, other, perhaps greater, financial incentives—such as retaining the (often lower cost) clinical labor that residents provide—continue to override this objective.

Impacts of hospital focus on residency experience

Inpatient hospital experience provides residents with important exposure to serious illnesses, but it must be balanced with sufficient experience in nonhospital and community-based settings. For most specialties, learning how to successfully manage a patient's medical conditions outside the hospital is important for patient health, patient comfort, and Medicare spending. Yet, inherent financial incentives and payment regulations discourage teaching hospitals from establishing strong offsite affiliations and, in limiting residents' experiences, may ultimately affect residents' specialty and setting choice for their future medical practice. The Commission has raised concerns about the decline in the number of U.S. medical school graduates selecting primary care and geriatrics, and the growth in the number of internal medicine physicians deciding to subspecialize or become hospitalists. These trends likely contribute to a reduction in the number of physicians who continue to treat their patients when they enter nursing homes (Levy et al. 2005).

While accreditation organizations require at least some education and training in ambulatory care settings for many specialties, Medicare's subsidies for graduate medical education place no requirements on nonhospital experience. In the case of internal medicine, for example, ACGME requires that at least one-third of internal medicine residents' time must be in ambulatory sites. In many cases, residency programs fulfill this ambulatory requirement by rotating the residents to the teaching hospitals' own outpatient departments, clinics, and physician offices. These ambulatory rotations, which occur in hospital-owned facilities, do not place hospitals' graduate medical education payments at risk. However, the teaching hospitals' loss of residency time and labor remains a factor, potentially prompting the ambulatory care requirements instituted by accrediting organizations and specialty boards.

Work for future exploration

Medical education plays a key role in shaping new physicians' attitudes and skills with respect to health care delivery reforms. Accordingly, the Commission looks forward to more detailed discussions about possible reforms to the medical education process. In addition to further examination of ways to encourage more educational experience in nonhospital settings, we will focus our future analysis on three main areas, as outlined below.

Linking medical education incentives with delivery system reforms

Linking Medicare's medical education subsidies to specific delivery system reforms could improve residents' education and training. This strategy is based on the premise that residents and other health professionals will be more likely to learn "best practices" when they are learning within a delivery system that is integrated, coordinated, high quality, and focused on the efficient provision of care. Medical education incentives could include, for example, higher subsidies to entities with infrastructure that facilitates high-quality efficient care, such as integrated care and communication among providers across different types of health care settings. The main objective in linking medical education subsidies to delivery system reforms would be to shift more payments to the hospitals and residency programs that emphasize superior quality and judicious resource use and away from those structured more heavily on long-established, volume-based incentives.

Another focus could be on selected payment reforms that concentrate on managing the quality and efficiency of care across providers and settings. For example, hospitals and physician offices that accept bundled payments for all Part A and Part B services in a given episode of care could receive higher medical education subsidies. Curricula that specialize in delivery system reforms, such as care-coordination techniques and cost awareness, could also be recognized. Also, because faculty expertise is an influential factor in residency program curricula, efforts to encourage programs and institutions to educate existing core faculty—as well as recruit other faculty with selected expertise in such topics as quality measurement and improvement—could be effective. Other curricular incentives could include basic instruction in geriatric care across all specialties. The Commission recognizes, however, that resident education and interest are strongly influenced by the content and format of board certification exams.

Structuring medical education subsidies to produce the professionals we need

The Commission will also examine ways for medical education subsidies to help generate a balance of advanced health care professionals that efficiently meets the needs of Medicare patients and the U.S. population at large. Among physicians, nurses, and physician assistants, it

is important to achieve the right share of generalists and subspecialists. Although the exact balance may evolve over time, the Commission is particularly concerned about access to health professionals who provide primary care, such as those focusing on family, internal, geriatric, and pediatric medicine. These professionals and other generalists, such as general surgeons, are essential for a well-functioning health care delivery system. Thus, if medical education subsidies were to more strongly favor programs that educate and train generalists, then teaching institutions (e.g., teaching hospitals) may be more inclined to invest in these programs. Nevertheless, the influence of reimbursement differentials for primary care and procedural services and widely known income disparities between these specialties present a major hurdle for recruiting residents into generalist specialties.

We will also explore other ways to recruit health professionals, including physicians, nurse practicioners, and physician assistants, who can most effectively help reform our health care delivery system. For example, loan forgiveness policies may help to attract students from diverse economic, ethnic, and geographic backgrounds. Increased support for advanced nursing education and training programs could focus attention on these key team members for improving the coordination of care. Considering Medicare's subsidy of approximately $100,000 per resident per year, Medicare could require practicing physicians to conduct some minimal public service in exchange for this support. For example, they could be required to provide occasional on-call services at hospitals or in other settings after their residency. Such a requirement would necessitate long-term contractual agreements from the resident, and some contend that this process could be complicated and that physicians should not be expected to donate their time simply because the government made some investments on their behalf. Having an adequate panel of local physicians on call is a crucial component of the nation's access to health care, yet, in recent years, fewer physicians are agreeing to take call (CHCF 2005).

Enlisting other payers to contribute explicitly to medical education

Currently Medicare, Medicaid, and other federal programs are the largest funders of graduate medical education. Although a small number of states require private insurers to contribute toward this endeavor, most do not. Some private insurers report that they support graduate medical education indirectly through higher patient care payments to teaching-affiliated health care providers. Considering the shared, societal benefits of high-quality medical education, the Commission will analyze options for all insurers to contribute explicitly to the costs of educating our nation's medical professionals.

With additional sources of funding for medical education, several researchers have discussed the role of an independent board in making decisions about allocating medical education subsidies (COGME 2007, IOM 1997, Pew Center for Health Professions 1998, Whitcomb 2007). A goal for such a board would be to ensure the equitable and efficient distribution of funds to appropriate entities that provide medical education and training across all ages. For graduate medical education, these entities could include teaching hospitals, nonhospital settings, and even residency programs. Goals guiding the distribution of these funds could stem from the objectives described previously, such as delivery system reforms and adjusting the balance of health care professionals to ensure adequate access to primary care. ■

Endnotes

1 There were also 11,742 applicants for 4,389 positions in osteopathic medical schools in 2008. As there is some overlap between the applicant pools, the total number of unique applicants to allopathic and osteopathic medical schools combined cannot be determined.

2 Osteopathic residency programs have their own match structured in a similar fashion to the NRMP match.

3 The binding commitment is for one year. Residents can choose to change programs after the first year of training, if they find a program willing to accept them.

4 Colorado, Indiana, New York, South Dakota, and Vermont have no minimum CME requirements.

5 Illinois, Kansas, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, North Carolina, Ohio, Pennsylvania, and Washington require an average of 50 credit hours.

6 The American Board of Medical Specialties on March 16, 2009, adopted a new set of standards for the MOC program that the individual specialty boards will incorporate into their MOC programs from 2010 to 2012. These new standards include self-assessment requirements, evidence of participation in practice-based assessment and quality improvement, patient safety assessment, and evaluation of communication assessment skills.

7 In addition to the allopathic and osteopathic accreditation, dental and podiatry programs accredited by their respective accrediting bodies also qualify.

8 This support totals about $300 million and is limited to programs sponsored by the hospital, mostly diploma programs, which have been replaced by associate and baccalaureate programs sponsored by community colleges and universities, which are ineligible for Medicare support, even though some training may take place in the hospital. Title VII, administered through the Health Resources and Services Administration, also provides funding for nurse education.

9 Approximately 19,000 of these residents were counted as half an FTE for direct GME payments because the trainees were in either a subspecialty fellowship—having completed their initial residency—or training beyond the minimum required for initial board certification in a specialty.

10 With the total Medicare-supported residents and the 8,000 additional residents, in 2006 there were about 97,800 FTE residents training in Medicare-supported hospitals (91,800 in short-stay acute care hospitals). A little more than 7,000 residents were in non-inpatient prospective payment system hospitals (e.g., cancer hospitals, children's hospitals).

11 Exceptions may apply for new programs established in rural hospitals, hospitals that had no residents in the base period, and urban hospitals with a new separately accredited rural training track.

12 Provided they are fully licensed, residents may bill Medicare for (moonlighting) services they provide that are not considered part of their residency training experience.

13 There is also an IME adjustment that is made to capital payment rates that is based on a different formula. Capital IME payments, which totaled about $360 million in 2007, are scheduled to be eliminated by the Secretary in 2010. The inpatient rehabilitation facility prospective payment system (PPS), long-term care hospital PPS, and psychiatric hospital PPS also include an IME adjustment based on their own payment formulas.

14 The study showed that physician productivity, as measured by relative value unit output, declined when residents were present in an internal medicine practice. Relative value unit output per hour declined by 0.8 when physicians were working with first- and second-year residents and by 0.5 when working with third-year residents.

15 See, for example, Blue Ridge Academic Health Group 2003, Blumenthal 2002, COGME 2007, Holmboe et al. 2005, IOM 2008, IOM 2003, Ludmerer and Johns 2005, Meyers et al. 2007, Mullan 2009, Weinberger et al. 2006.

16 In comparison with the universe of U.S. internal medicine residency programs, the RAND researchers found that the randomly selected sample was representative on the following characteristics: number of residents, type of hospital (university, community, municipal), geographic region, and type of program accreditation (allopathic, osteopathic). Programs that had *both* allopathic and osteopathic accreditation were slightly oversampled.

17 In preliminary research on medical school curriculum, we found that fewer than 10 percent of medical school programs include instruction on health care costs and spending as a requirement or objective in the curriculum.

18 Beginning July 2003, the ACGME limited residents' duty hours to an 80-hour work week, averaged over 4 weeks. In December 2008, the IOM recommended further specifications on the need for a 5-hour sleep period.

19 The hospital must incur at least 90 percent of the total of all the nonhospitals' associated training costs. CMS does not consider resident salaries and fringe benefits to equal "all or substantially all of the costs of the training program in the nonhospital setting." Prior to 1998, Medicare accepted resident salaries and fringe benefits as meeting this requirement in full.

20 Effective July 1, 2007, in determining the teaching physician supervisory cost, hospitals may also use national average salary data in place of actual teaching physician salary information and may also use a proxy percentage representing the amount of time the teaching physician spends supervising the residents.

21 The exceptions are Federally Qualified Health Centers, Rural Health Clinics, and Medicare+Choice organizations. These entities became eligible to receive direct GME and IME from Medicare through the Balanced Budget Act of 1997.

References

Accreditation Council for Graduate Medical Education. 2008. *Educating physicians for the 21st century.* Chicago: ACGME. http://www.acgme.org/Outcome/.

American Academy of Family Physicians. 2009. *Transforming graduate medical education.* Policy document. Washington, DC: AAFP. http://www.aafp.org/online/etc/medialib/aafp_org/documents/policy/fed/background/gme031009.Par.0001.File.tmp/TransformingGME031009.pdf.

American Association of Colleges of Osteopathic Medicine. 2009. *2009 annual statistical report on osteopathic medical education.* Chevy Chase, MD: AACOM.

American Board of Medical Specialties. 2009. *How a physician becomes board certified.* Evanston, IL: ABMS. http://www.abms.org/Who_We_Help/Consumers/process.aspx.

American Medical Association. 2008. *State medical licensure requirements and statistics, 2008*. Chicago: AMA.

Association of American Medical Colleges. 2009. *Getting into medical school.* Washington, DC: AAMC. http://www.aamc.org/students/considering/gettingin.htm.

Association of American Medical Colleges. 2008a. *Data warehouse: Applicant and matriculant file as of 10/10/2008.* Washington, DC: AAMC. http://www.aamc.org/data/facts.

Association of American Medical Colleges. 2008b. *Diversity of U.S. medical students by parental income*. Analysis in brief, vol. 8, no. 1. Washington, DC: AAMC.

Association of American Medical Colleges. 2008c. *Medical student education: Costs, debt, and loan repayment facts.* Washington, DC: AAMC.

Association of American Medical Colleges. 2008d. Medicare DGME and IME payments: Counting resident time in didactic and research activities. Presentation to MedPAC staff.

Babineau, T. J., J. Becker, G. Gibbons, et al. 2004. The cost of operative training for surgical residents. *Archives of Surgery* 139, no. 4: 366–369.

Berwick, D. M. 1996. A primer on leading the improvement of systems. *British Medical Journal* 312: 619–22.

Blue Ridge Academic Health Group. 2003. *Reforming medical education: Urgent priority for the academic health center in the new century*. Report 7. Athens, GA: Emory University.

Blumenthal, D. 2002. *Training tomorrow's doctors: The medical education mission of academic health centers*. New York: Commonwealth Fund.

Blumenthal, D., J. Gokhale, E. Campbell, J. Weissman. 2001. Preparedness for clinical practice. *Journal of the American Medical Association* 286, no. 9: 1027–1034.

Brooks, R. G., M. Walsh, R. E. Mardon, et al. 2002. The roles of nature and nurture in the recruitment and retention of primary care physicians in rural areas: A review of the literature. *Academic Medicine* 77: 790–798.

Brotherton, S. E., and S. I. Etzel. 2008. Graduate medical education, 2007–2008. *Journal of the American Medical Association* 300, no. 10 (September 10): 1228–1243.

California HealthCare Foundation. 2005. *On-call physicians at California emergency departments: Problems and potential solutions.* Issue brief. Oakland: CHCF.

Cordasco, K., M. Horta, N. Lurie, et al. 2009. *How are residency programs preparing our 21st century internists? A review of internal medicine residency programs' teaching on selected topics*. Santa Monica, CA: RAND Corporation. Contractor report prepared for MedPAC.

Council on Graduate Medical Education. 2007. *COGME 19th report: Enhancing flexibility in graduate medical education.* Washington, DC: COGME.

Council on Graduate Medical Education. 1999. *COGME 13th report: Physician education for a changing health care environment.* Washington, DC: COGME.

Federation of State Medical Boards. 2009. *Maintenance of licensure, frequently asked questions.* Dallas, TX: FSMB. http://www.fsmb.org/m_mol_faqs.html.

Fordyce, M., F. Chen, M. Doescher, L. Hart. 2007. *2005 Physician supply and distribution in rural areas of the United States.* University of Washington Rural Health Research Center. Report 116. Prepared for The Federal Office of Rural Health Policy, Health Resources and Services Administration, Department of Health and Human Services.

Freeman, E., and T. Lischka. 2009. Osteopathic graduate medical education. *Journal of the American Osteopathic Association* 109, no. 3: 135–145.

Gorman, P. J., A. H. Meier, C. Rawn, et al. 2000. The future of medical education is no longer blood and guts, it is bites and bytes. *American Journal of Surgery* 180, no. 5: 353–356.

Green, L. A., G. E. Fryer, B. P. Yawn, et al. 2001. The ecology of medical care revisited. *New England Journal of Medicine* 344, no. 26 (June 28): 2021–2025.

Grumbach, K., and R. Mendoza, 2008. Disparities in human resources: Addressing the lack of diversity in the health professions. *Health Affairs* 27, no. 2: 413–422.

Health Resources and Services Administration. 2006. *The rationale for diversity in the health professions: A review of the evidence*. Rockville, MD: HRSA. October. ftp://ftp.hrsa.gov/bhpr/workforce/diversity.pdf.

Holmboe, E. S., J. L. Bowen, M. Green, et al. 2005. Reforming internal medicine residency training. *Journal of General Internal Medicine* 20, no. 12: 1165–1172.

Institute of Medicine. 2008. *Retooling for an aging America: Building the health care workforce.* Washington, DC: National Academy Press.

Institute of Medicine. 2004a. *In the nation's compelling interest: Ensuring diversity in the health care workforce.* Washington, DC: National Academy Press.

Institute of Medicine. 2004b. *Academic health centers: Leading change in the 21st century*. Washington, DC: National Academy Press.

Institute of Medicine. 2003. *Health professions education: A bridge to quality*. Washington, DC: National Academy Press.

Institute of Medicine. 1997. *On implementing a national graduate medical education trust fund*. Washington, DC: National Academy Press.

Johnson, T., M. Shah, J. Rechner, et al. 2008. Evaluating the effect of resident involvement on physician productivity in an academic general internal medicine practice. *Academic Medicine* 83, no. 7 (July): 670–674.

Komaromy, M., K. Grumbach, M. Drake, et al. 1996. The role of black and Hispanic physicians in providing health care for underserved populations. *New England Journal of Medicine* 334, no. 20: 1305–1310.

Lave, Judith R. 1985. *The Medicare adjustment for the indirect cost of medical education: Historical developments and current status.* Washington, DC: AAMC.

Levy, C., A. Epstein, L. Landry, et al. 2005. *Literature review and synthesis of physician practices in nursing homes*. Denver: University of Colorado, Health Sciences Center. Report prepared under contract to ASPE/HHA.

Lorig, K. R., D. S. Sobel, P. L. Ritter, et al. 2001. Effect of a self-management program on patients with chronic disease. *Effective Clinical Practice* 4: 256–262.

Ludmerer, K., and M. Johns. 2005. Reforming graduate medical education. *Journal of the American Medical Association* 294, no. 9: 1083–1087.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

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

Mertz, E. A., and K. Grumbach. 2001. Identifying communities with low dentist supply in California. *Journal of Public Health Dentistry* 61, no. 3: 172–177.

Meyers, F., S. Weinberger, J. Fitzgibbons, et al. 2007. Redesigning residency training in internal medicine: The consensus report of the alliance for academic internal medicine education redesign task force. *Academic Medicine* 82: 1211–1219.

Moy, E., and B. A. Bartman. 1995. Physician race and care of minority and medically indigent patients. *Journal of the American Medical Association* 273, no. 19: 1515–1520.

Mullan, F. 2009. Workforce issues in health care reform: Assessing the present and preparing for the future. Testimony before the Senate Finance Committee. March 12.

Nasca, Thomas. 2008. Statement at MedPAC meeting. October 2.

Ogrine, G., L. A. Headrick, S. Mutha, et al. 2003. A framework for teaching medical students and residents about practice based learning and improvement, synthesized from a literature review. *Academic Medicine* 78, no. 7: 748–756.

Peters, A., N. Clark-Chiarelli, and S. Block. 1999. Comparison of osteopathic and allopathic medical schools' support for primary care. *Journal of General Internal Medicine* 14, no. 12: 730–739.

Pew Center for Health Professions. 1998. *Beyond the Balanced Budget Act of 1997: Strengthening federal GME policy.* San Francisco: Pew Center for Health Professions. Executive summary of the full report.

Phillips, R., M. Dodoo, S. Petterson, et al. 2009. *Specialty and geographic distribution of the physician workforce: What influences medical student and resident choices?* Washington, DC: The Robert Graham Center. Prepared with support from the Josiah Macy, Jr., Foundation.

Rich, E. C., M. Liebow, M. Srinivasan, et al. 2002. Medicare financing of graduate medical education: Intractable problems, elusive solutions. *Journal of General Internal Medicine* 12: 283–292.

Salsberg, E., P. H. Rockey, K. L. Rivers, et al. 2008. US residency training before and after the 1997 Balanced Budget Act. *Journal of the American Medical Association* 300, no. 10: 1174–1180.

Shortell, S. M., R. R. Gillies, and D. A. Anderson. 2000. *Remaking health care in America*. 2nd ed. San Francisco: Jossey-Bass.

Steinbrook, R. 2008. Medical student debt—is there a limit? *New England Journal of Medicine* 359: 2629–2632.

Stewart, M., L. Meredith, J. B. Brown, et al. 2000. The influence of older patient–physician communication on health and health-related outcomes. *Clinics in Geriatric Medicine* 16, no. 1: 25–36.

U.S. House. 1965. 89th Cong., 1st sess. 32, H.R. 213.

U.S. Senate. 1965. 89th Cong., 1st sess. 36, S.R. 404, pt. 1.

Weinberger, S. E., L. G. Smith, V. U. Collier, et al. 2006. Redesigning training for internal medicine. *Annals of Internal Medicine* 144: 927–932.

Whitcomb, Michael E. 2008. Statement at MedPAC meeting. October 2.

Whitcomb, Michael E. 2007. Medical education reform: Is it time for a modern Flexner report? *Academic Medicine* 82, no. 1 (January): 1–2.

White, K. L., F. Williams, and B. G. Greenberg. 1961. The ecology of medical care. *New England Journal of Medicine* 265 (November 2): 885–892.

Wickstrom, G., M. Kolar, C. Keyserling, et al. 2000. Confidence of graduating internal medicine residents to perform ambulatory procedures. *Journal of General Internal Medicine* 15: 361–365.

Wiest, F., T. Ferris, M. Gokhale, et al. 2002. Preparedness of internal medicine and family practice residents for treating common conditions. *Journal of the American Medical Association* 288: 2609–2614.

Wolff, J. L., B. Starfield, and G. Anderson. 2002. Prevalence, expenditures and complications of multiple chronic conditions in the elderly. *Archives of Internal Medicine* 162: 2269–2276.

Wynn, B., C. Guarino, L. Morse, et al. 2006. *Alternative ways of financing graduate medical education*. RAND working paper. Santa Monica, CA: RAND Corporation. May.

CHAPTER 2

Accountable care organizations

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Chapter summary

As part of a broader discussion of options for reforming Medicare's health care delivery system, the Commission and others have introduced the concept of holding a set of providers responsible for the health care of a population of Medicare beneficiaries (CBO 2008, Fisher et al. 2009a, MedPAC 2008). We refer to this set of providers as an accountable care organization (ACO).

In our model, the ACO would consist of primary care physicians, specialists, and at least one hospital. It could be formed from an integrated delivery system, a physician–hospital organization, or an academic medical center. The defining characteristic of ACOs is that a set of physicians and hospitals accept joint responsibility for the quality of care and the cost of care received by the ACO's panel of patients. The goal is to create an incentive for providers in the ACO to constrain volume growth while improving the quality of care. If the ACO achieves both quality and cost targets, its members receive a bonus. If it fails to meet both quality and cost targets, its members could face lower

In this chapter

Medicare payments. These financial incentives may lead to slower growth in Medicare spending.

This chapter provides an overview of two variations on the ACO model—one in which providers volunteer to form an ACO and one in which participation is mandatory. To induce physicians and hospitals to volunteer to form an ACO, Medicare would have to provide the physicians with a significant upside reward and very little (if any) downside penalty. For that reason, the voluntary ACO model we discuss is a bonus-only design. The current Physician Group Practice (PGP) demonstration provides an example of how a bonus-only voluntary ACO design might work. The demonstration has achieved quality objectives, but whether the demonstration has actually generated savings for the Medicare program is debatable. Generating savings may require larger incentives to constrain capacity and volume growth.

Implementation of a voluntary, bonus-only model would require bonuses large enough to offset the current incentive in the fee-for-service (FFS) payment system to increase volume. To fund bonuses of this magnitude, FFS rate increases would have to be constrained. By constraining FFS Medicare payment rates to fund larger ACO bonuses, Medicare would create an environment in which providers would want to form ACOs and would be rewarded when they constrained volume growth and improved the quality of care.

A mandatory model could have both bonuses for good performance and penalties for poor performance. In this model, shared savings and the penalties could fund the bonuses.

On the basis of our work developing an ACO model, we arrive at the following conclusions:

- ACOs would have to be fairly large (at least 5,000 patients) to make it possible to distinguish actual improvement from random variation on a reasonably consistent basis.

- Each ACO should have a spending target set in advance. One approach is to set the ACO's spending target based on its past experience plus a national allowance for spending growth per capita (e.g., a fixed dollar amount of $500). This proposal differs from some others in that the growth allowance is not affected by the ACO's historical level of spending. Over time using a single national growth allowance could compress regional variation in spending per capita. An alternative approach is to set a lower allowance in high-service-use areas and a higher allowance in low-service-use areas. This alternative would place greater pressure to constrain volume on areas with historically high utilization.
- Savings would result primarily from ACOs' incentive to change overall practice patterns and eventually constrain capacity. Therefore, successful ACOs will need to have a formal organization and structure that allows them to make joint decisions on capacity.
- To overcome incentives in FFS payment systems to expand capacity and volume, a large share of the patients in a physician's practice would need to be in an ACO. To achieve this critical mass, private insurers may have to join Medicare in providing ACO-type incentives to constrain capacity.
- In a voluntary, bonus-only ACO model, some providers will receive bonuses for "shared savings" stemming from favorable random variation rather than from the ACO's efforts to reduce spending growth. Currently, in the absence of ACOs, Medicare keeps all the "savings" from favorable random variation. Unless Medicare's share of true savings from ACOs' efforts to reduce spending exceeds the cost of bonuses paid due to random variation, Medicare spending will not be reduced. In part for this reason, under a voluntary, bonus-only model, FFS Medicare payment rates will likely have to be constrained.

- Under a mandatory, bonus-and-penalty model, the bonuses could be funded by the combination of true shared savings and a penalty assessed on poor performers. Under this model, ACOs with high cost and low quality scores would lose their withhold and in effect receive lower Medicare payment rates.

ACOs should be viewed as just one tool that can be used to induce change in the health care delivery system. The ACO's role is to create a set of incentives strong enough to overcome the incentives in the FFS system to drive up volume without improving quality. The degree to which ACOs will succeed in counterbalancing the current incentive for volume growth is uncertain. However, there is no uncertainty in the need to create a new set of incentives. The current unrestrained FFS payment system has created a rate of volume growth that is unsustainable. ■

As part of a broader discussion of options for reforming Medicare's health care delivery system, the Commission and others have introduced the concept of holding a set of fee-for-service (FFS) providers responsible for the health care of a population of Medicare beneficiaries (CBO 2008, Fisher et al. 2009a, MedPAC 2008). We refer to this set of providers as an accountable care organization (ACO).

In this chapter we first outline why Medicare may want ACOs. Next, we discuss two potential models: a voluntary, bonus-only model and a mandatory model with bonuses and withholds. We then outline some challenges and design issues common to both models. We conclude by discussing how ACOs relate to other Commission policy initiatives.

Why Medicare may want accountable care organizations

The current trajectory of Medicare spending is unsustainable. By definition, something unsustainable cannot continue. The question is: What mechanisms should Medicare use to change the spending trajectory? The establishment of ACOs could provide Medicare with an additional mechanism to help achieve sustainability in concert with other reforms.

ACOs will create a system of incentives that tie provider payments to quality and resource use. The objectives are to improve the quality of care, enhance the sustainability of the Medicare program, and reduce the regional variation in care by lowering the use of unnecessary services in high-use areas. The system of incentives in an ACO system should encourage cooperation among physicians and hospitals and could be structured to give providers in high-use areas a strong incentive to constrain capacity growth and reduce the volume of unnecessary care. For example, ACOs could provide health care systems that are currently operating at full capacity an incentive to improve outpatient care and reduce unnecessary hospital admissions rather than spend their capital on expanding hospital capacity.

Under our ACO concept, a group of physicians teamed with a hospital would have joint responsibility for the quality and cost of care provided to a large Medicare patient population.[1] By making providers jointly responsible for quality and cost metrics, ACOs would be expected to improve the coordination of care and reduce duplication of services. Because ACOs would take responsibility for resource use, Medicare could constrain health care spending by using a system of bonuses and, in some cases, withholds. This system would be designed to counterbalance the incentives under FFS payment to increase volume.

Constraining Medicare spending growth will always be difficult. Slower growth in Medicare spending means slower growth in provider revenue. However, reduced revenue growth does not have to mean reduced net income. Providers could compensate for slower revenue growth by restraining their costs (e.g., not purchasing an MRI machine) and by sharing in the savings from reductions in Medicare spending. By giving physicians and hospitals a way to increase their income through ACO-wide quality improvement and reducing unnecessary services, the Medicare system would gain a way to constrain spending other than through the blunt instrument of lowering FFS updates. We look at two models to accomplish this goal: a voluntary, bonus-only model and a mandatory, bonus-and-withhold model.

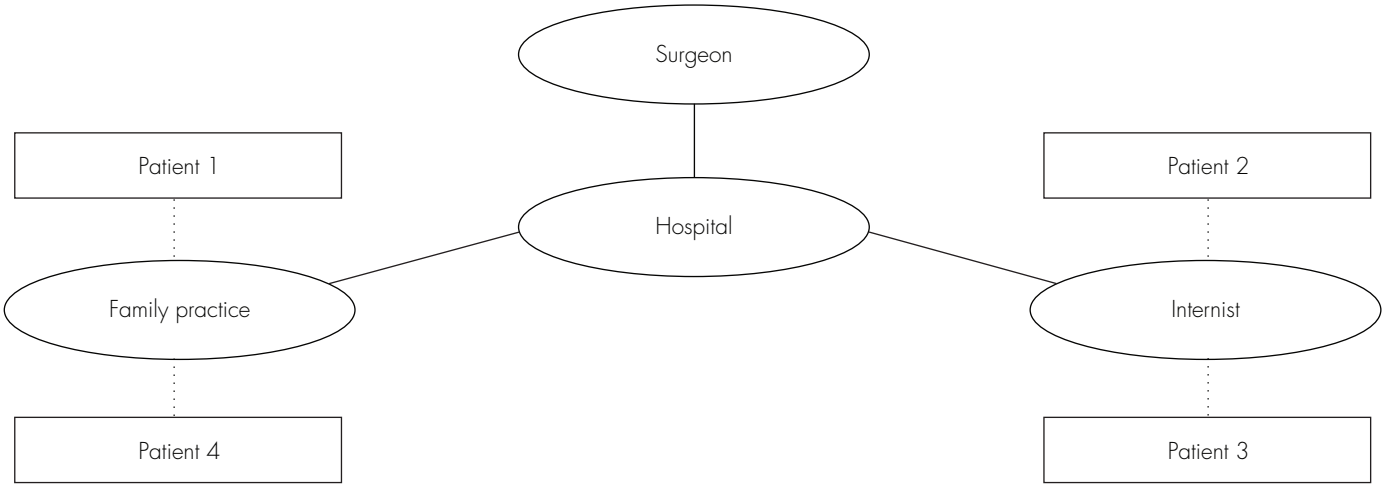
A voluntary, bonus-only ACO

We define an ACO as a combination of a hospital, primary care physicians, and specialists. The ACO should be able to provide primary care as well as basic medical and surgical inpatient care. Potential ACOs include: integrated delivery systems, physician–hospital organizations, a hospital plus multispecialty groups, and a hospital teamed with independent practices. While ACO models proposed by others have some differences (they may omit the hospital), in all ACO models the providers in the ACO are held accountable for total Medicare spending and quality of care for a defined patient population while continuing to be paid on a FFS basis.

In a voluntary ACO model, Medicare would inform all physicians and hospitals of their current relationships based on Medicare claims data. Physicians and a hospital could then organize and choose to be considered by Medicare as an ACO. Medicare would assign patients to the ACO based on the primary care physician who provided the plurality of the patient's office visits (Figure 2-1, p. 44). Primary care physicians would volunteer to associate with a hospital and other physicians who they believe could most improve the value of the care their patients receive. The physicians and hospital would then

FIGURE 2–1

Assignment of patients to an ACO via primary care providers



Note: ACO (accountable care organization).

be eligible for bonuses based on their ACO's performance, and their incentives would be aligned. Hospitals and physicians that were already part of an integrated delivery system or a physician–hospital organization would find it easier to become ACOs. Other hospitals would have to join with multispecialty groups or independent practices. Medicare would not prejudge which structure works best.

In Figure 2-1 we illustrate the assignment of four patients to an ACO. The two primary care physicians, the surgeon, and the hospital have agreed to form an ACO. By doing so, they agree to be held responsible for the quality of care and all the Medicare spending for the ACO's patients. The patients can see any physician they choose. However, if they mainly use primary care physicians in the ACO, then they will be assigned to that ACO. (The patients may have to be assigned by the affiliation of the specialists they see if they have not seen a primary care physician in recent years.) Using a similar system, Elliot Fisher and colleagues found that patients' assignment to an ACO was relatively stable; in the year following assignment, 83 percent of patients continued to see physicians affiliated with the same ACO (Fisher et al. 2009a).

Providers in voluntary ACOs would continue to be paid standard FFS Medicare payment rates.[2] Bonuses would depend on meeting both spending and quality targets, which would be set as discussed later.

Setting spending targets for ACOs

In setting ACOs' spending targets, Medicare would need to address geographic variation in spending per beneficiary. Use of Medicare services is substantially higher in some regions of the country than in others. To allow providers in all regions (high- and low-use areas) to potentially benefit from the ACO model, the financial incentives would need to be based on changes in spending rather than on levels of spending. However, in measuring changes in spending, low-resource-use ACOs could be disadvantaged, as they would have fewer opportunities for efficiency gains.

To address this concern, every ACO could have an allowance for spending growth per capita that is adjusted for area wage rates—but not for regional differences in utilization. A fixed allowance (e.g., $500 per capita) would represent a larger percentage change in annual spending in low-spending areas than in high-spending areas. For example (assuming that quality targets are met), an ACO with per capita spending of $7,000 and a spending growth allowance of $500 would receive bonuses if spending growth were below 7 percent ($500/$7,000). In contrast, an ACO that was spending $10,000 per patient would have to bring spending growth to below 5 percent ($500/$10,000) to obtain a bonus. Adjustments could be made for area wages, patient severity, and other

TABLE 2–1

Potential method for setting ACO-specific Medicare spending targets

	National average	Spending targets for ACOs with different base spending levels		
		Low-use ACO	Average ACO	High-use ACO
Base spending per capita	$10,000	$7,000	$10,000	$12,000
Dollar allowance for spending growth	500	500	500	500
Target spending	10,500	7,500	10,500	12,500
Percent increase	5.0%	7.1%	5.0%	4.2%

Note: ACO (accountable care organization). For purposes of illustration, the example's input costs and average risk scores for the beneficiaries in the ACOs are assumed to be the national average of 1.0. A $500 spending allowance is used purely for illustrative purposes.

factors outside the ACO's control, but no adjustment for regional differences in utilization would affect the fixed dollar allowance (Table 2-1). For purposes of illustration, the example's input costs and average risk scores for the beneficiaries in the ACOs are assumed to be the national average of 1.

The purpose of the low-use ACO having a higher percentage increase than the national average is to reward the ACO for its historically low resource use. The fixed dollar allowance puts the high-use ACO under greater pressure to meet its target through efficiency gains. Reductions at the high-use ACO should be possible given the ACO's high starting level of resource use. An alternative approach, which places even greater pressure on high-utilization areas to constrain volume, is to set a lower dollar allowance in high-service-use areas and a higher dollar allowance in low-service-use areas.

The Congress would retain control over the growth allowance, just as it now controls updates to prospective payment rates. The allowance could be adjusted based on the need to constrain Medicare spending. Lowering the spending growth allowance could be seen as an alternative to the more blunt approach of cutting payment rates.

Setting quality targets for ACOs

Medicare would also give ACOs a financial incentive to maintain or improve the quality of care provided to beneficiaries for whom they are responsible. While initial sets of quality metrics may be primarily process measures with a limited set of outcomes, quality metrics could eventually include mortality, hospital admissions that could have been avoided through better ambulatory care, readmissions, patient satisfaction, additional clinical outcomes, and improvements in functionality. The quality targets could be aggregated into a weighted quality score. The ACO bonus structure could require that both quality and spending targets be met to achieve bonuses. These targets would be used in the voluntary, bonus-only ACO model described previously and the mandatory, bonus-and-withhold ACO model we describe next.

A mandatory, bonus-and-withhold ACO

In a mandatory model, CMS would assign physicians and patients to a hospital, and that set of providers would define the ACO. On the basis of Medicare claims, all physicians would be assigned to an ACO according to which hospital the physician primarily worked in or which hospital the plurality of the physician's patients used if the physician did not do any inpatient work (the extended hospital medical staff model) (Fisher et al. 2009a). CMS would also assign each patient to the primary care physician who provided the plurality of the patient's office visits. Because the physician would be linked to an ACO, the patients assigned to the physician would be linked to the ACO as well. The providers in the mandatory ACO might not have any contractual or other relationship and may be unaware of their status until Medicare informs them. In a sense, they would be a virtual ACO—a construct, not an actual entity. Nonetheless, they would be subject to bonuses and penalties based on their joint performance as an ACO.

FIGURE 2–2

Potential bonus and penalty criteria for mandatory ACOs

Resource use over three years	Quality over three years: Meets target in all three years	Quality over three years: Mixed performance on target	Quality over three years: Fails target in all three years
Meets target in all three years	Return withhold and share of savings (bonus)	Return withhold	Withhold not returned (penalty)
Mixed performance on target	Return withhold	Return withhold	Withhold not returned (penalty)
Fails target in all three years	Return withhold	Return half withhold	Withhold not returned (penalty)

Note: ACO (accountable care organization).

Providers in mandatory ACOs would continue to receive FFS payments, subject to a withhold. Providers in the ACO would get their withhold back and receive a bonus only if they met quality and resource use targets. (These targets would be set in the same manner as described above for the voluntary, bonus-only ACO.) Figure 2-2 shows the conditions for receiving bonuses and withholds. If an ACO consistently (for three straight years in this design) met its quality and resource use targets, it would recover the withhold and receive a share of Medicare savings as a bonus. If its results were mixed for both quality and resource use over those three years, the withhold would be returned. If the ACO failed to meet its quality target all three years, the withhold would not be returned, which would be a penalty.

An example of how the incentive to maintain quality and restrain resource use may work is shown in Table 2-2. Essentially, ACOs with higher quality and lower growth in resource use would be paid more than those with lower quality and higher growth in resource use. In the Table 2-2 example, the net Medicare payment differs by only $200 per capita, but the difference in practice income would be

TABLE 2–2

Illustrative example of ACO withholds and bonuses

Quality of care	ACO base spending in 2011	Target spending in 2012	Actual 2012 FFS billing	Withhold (10 percent)	Bonus of 80 percent share of savings	Net Medicare payment
Good	$7,000	$7,500	$7,000	$700 (returned)	$400	$7,400
Poor	7,000	7,500	8,000	$800 (not returned)	0	$7,200

Note: ACO (accountable care organization), FFS (fee-for-service). Spending is per capita.

TABLE 2–3 **A comparison of two types of accountable care organizations**

	Voluntary	Mandatory
Organization characteristics	Physicians and hospitals choose to form ACO and be held jointly responsible for the quality of care and the level of spending on their Medicare patients.	All physicians and hospitals are assigned to virtual ACOs and held jointly responsible for the quality of care and the level of spending on their Medicare patients.
	Model is dependent on physicians and hospitals agreeing to form PHOs.	Physicians and hospitals are assigned to virtual ACOs.
	Model requires waiting for PHOs to form.	Implementation could encourage PHOs to form.
	Physicians and hospitals agree on how to share revenues, or the government mandates a bonus structure.	Medicare administers a system of withholds and bonuses.
	ACOs have capability to make joint decisions. Unorganized providers would remain outside the system.	Some ACOs have structures that allow joint decision making. Unorganized providers face financial incentives to develop structures for joint decision making.
Incentives	Only those that expect to gain from bonuses would be likely to join.	Everyone is subject to withholds and bonuses.
	Bonuses are given to top performers, while poor performers face no penalties (or they will not join).	Bonuses are given to top performers and penalties are applied to performers with low quality and high costs.
	Difficult patients could be dropped or transferred to non-ACO providers.	ACOs could drop patients, but another ACO would continue to be responsible for cost and quality.
Implications	Providers face no risk.	Providers face some risk.
	Medicare continues to depend on restraining FFS payment rates to make the system sustainable.	ACO incentives provide Medicare a strong lever—possibly instead of restraining FFS rates—to induce sustainability.
	ACO bonuses would be funded with shared savings and by restraining FFS rates. This would result in relatively lower FFS rates than under a mandatory system given any set level of Medicare spending.	ACO bonuses would be funded by shared savings and penalties for providers with poor quality and high costs.
	There could be an increase in the ACOs' market power engendering antitrust issues.	There could be an increase in the ACOs' market power engendering antitrust issues.

Note: ACO (accountable care organization), PHO (physician–hospital organization), FFS (fee-for-service).

much greater. The practice with consistently poor quality delivers more services for less payment than the practice with good quality. Presumably, the poor-quality ACO has incurred higher costs in providing the higher volume of services than the good-quality ACO. Therefore, the income of the poor-quality ACO (lower revenue – greater cost) is much less.

The spending growth allowance could be set based on consideration of both the national projected rate of spending growth and the need to restrain the level of spending growth.

Comparing the voluntary and mandatory ACO models

The characteristics and implications of the two ACO options are summarized in Table 2-3.

On the one hand, voluntary ACOs have to be organized before they can volunteer; thus, a voluntary model could take some time to get going and may never incorporate all hospitals and physicians. On the other hand, mandatory ACOs would include everyone but they would not

necessarily be organized and could have difficulty reaching joint decisions. ACOs under this model would have a strong incentive to organize if they wished to be successful. Under either model, Medicare could decide how bonuses would be shared among the participants in the ACO. For example, to avoid conflict over how to divide bonuses, Medicare could give all providers a fixed percentage add-on to their FFS payments. The add-on percentage would be set so the aggregate of bonuses paid by Medicare to providers in the ACO would equal the ACO's share of savings.

The incentives would differ in the two models. Most proposals for voluntary ACOs have bonus-only incentive structures without penalties for poor performance; otherwise, few would be likely to volunteer. But for the very reason that voluntary ACOs might be more appealing—no downside risk—they may be less effective in achieving savings and changing inappropriate clinical practices. Some providers may form ACOs without any real structure for joint decision making and simply hope that their costs will be below target due to random variation or existing regional practice patterns. The incentives for the mandatory model can be stronger (e.g., include a withhold) because those ACOs do not have any choice; they are automatically included.

The implications of the two designs are very different. Remember that one motivation for talking about ACOs is to find a way to slow the growth in Medicare spending. The governing equation is:

Medicare spending = price × volume

This equation means there is a trade-off between the two. Price, or volume, or both have to be constrained to constrain spending.

Under the voluntary model, there are weaker incentives to control volume because the program has to have weak or no penalties to attract volunteers—and even then, not all hospitals and physicians will join. Without strong incentives to restrain volume, there would need to be stronger restraint on FFS Medicare payment rates to reach a sustainable level of Medicare spending.

On the other hand, mandatory ACOs—because their incentives would include withholds—have stronger incentives to control volume. Penalties could be stronger and all hospitals and physicians are included, so incentives for volume control apply to everyone. As a result, there could be softer restraint on FFS Medicare payment rates in the mandatory model.

Reducing the growth of Medicare spending will involve either weak ACO incentives and relatively lower FFS Medicare payment rates or stronger ACO incentives and relatively higher FFS rates. Given a choice, if controlling volume means eliminating unnecessary care, that would be preferable to harsh constraints on FFS rates for all providers without regard to their efficiency or quality. Research on geographic variation suggests that the volume of supply-sensitive services could be lowered in high-use regions without harming the quality of care Medicare beneficiaries receive.

The Physician Group Practice (PGP) demonstration, as described in the text box, is one example of how a voluntary ACO program could be designed. It has achieved quality objectives, but there are questions as to whether the demonstration has generated savings for the Medicare program. Two limitations on the PGP incentives cited by PGP participants are that the PGP demonstration covered only a fraction of their patients and the initial demonstration period was only three years. (This period has been extended.) These considerations limit the participants' willingness to permanently change practice patterns and restrain capacity growth.

Common design issues for voluntary and mandatory ACOs

All ACOs would be required to have a panel of primary care physicians, specialists, and at least one hospital. In this section we address:

- how large an ACO's population of patients would need to be to distinguish actual improvement in ACO performance from random variation,
- what implications ACO size would have for the effectiveness of individual and joint incentives,
- why successful ACOs would need the ability to make joint decisions, and
- conditions that are necessary for ACOs to reduce overall Medicare spending.

ACOs must include a large number of physicians to reduce volatility

Per beneficiary spending is expected to vary across ACOs for two reasons. One reason is that random variation exists due to differences in patients' health not captured

The Physician Group Practice demonstration

The Physician Group Practice (PGP) demonstration is one example of how a voluntary accountable care organization (ACO) program could be designed. The groups in the PGP demonstration are large, averaging 500 doctors and 22,000 beneficiaries. They also tend to be tightly managed groups that have the ability to take joint actions to change care protocols, improve quality metrics, and constrain capacity growth. Through the first two years of the program, the quality metrics have improved for all practices in the PGP demonstration. Many PGP sites improved in all four areas of care they monitor: diabetes, congestive heart failure, coronary artery disease, and preventive care (CMS 2008).

In contrast to the clear improvements in quality, it is questionable whether the PGP demonstration has saved money. While 4 of 10 PGP sites had low enough growth in risk-adjusted cost to qualify for bonuses, the finding of lower growth in cost depended on the accuracy of the risk adjuster.[3] After 2 years, 5 of the 10 PGP sites had unadjusted cost growth that was materially higher than their comparison groups, 4 had roughly equal cost growth, and only 1 had lower cost growth (RTI 2008). At 9 of the 10 PGP sites, patient risk scores grew faster than at the comparison sites, accounting for the difference between the unadjusted and risk-adjusted cost growth. There are three possible explanations for the relative increase in risk scores at PGP sites. One possibility is that, after the PGP sites joined the demonstration, they attracted a greater share of the regions' very sick patients than previously. A second, unlikely, reason is that PGP sites did less to keep their patients healthy than the comparison sites. A third, perhaps more plausible, reason is that the increase in risk scores was due to better detection and coding of illness at the PGP sites.

PGP sites have an incentive to improve the completeness of their coding, and as patients visit physician offices for their preventive care—such as blood pressure screenings, foot exams, pneumonia vaccinations, cholesterol screening, colorectal screening, and mammography—physicians have the opportunity to detect and code additional conditions. When these screenings are increased, quality scores improve, but risk scores may also increase. Because the increased risk scores of patients at the PGP sites may be due to improved detection and coding of acute and chronic conditions, the evidence that the PGP demonstration has reduced the costs of care during its first two years is not definitive. CMS is aware of how rising risk scores could influence results and plans to limit how much changes in risk scores can alter spending targets for the fifth year of the CMS demonstration (Pilotte 2009). ■

by risk adjustment. The second reason is that differences are expected to exist among ACOs in improvements they make in practice patterns and capacity in response to incentives in the ACO payment structure. A successful ACO policy would enable physicians who improve their practice patterns and restrain capacity to have an effect on resource use that is large enough to be distinguished from random variation. Bonuses based on shared savings would then reflect actual earned changes in performance—and not just random variation.

Random variation is substantial

To evaluate how much random variation there is in overall Medicare spending for pools of Medicare beneficiaries, we examined data on extended hospital medical staffs (EHMSs) that were compiled by researchers at Dartmouth. Under the EHMS model, each hospital is assigned an extended medical staff and a Medicare beneficiary population based on Medicare claims.[4] Our objective was to see how much random variation existed in spending for patients treated by an EHMS from one year to the next. We found that even for EHMSs with 5,000 beneficiaries (which usually include more than 50 physicians) spending growth varied often from 5 percent above the national average growth rate one year to 5 percent below the national average the next. Even using a three-year moving average, we found that year-to-year spending for more than 15 percent of ACOs differed by more than 2 percent, presumably due to random variation.[5] The spending data we used were not risk adjusted.[6]

TABLE 2–4

Illustrative example of how ACOs would not have a material effect on a surgeon's financial incentive to conduct surgery

	Incentive to perform an additional surgery
Assumed payment for the surgery	$1,000
Minus assumed value of surgeon's time, practice expense, other costs	–$600
Direct profit per physician	**$400**
Effect of the action on the ACO bonus per physician	
Cost of the surgery to Medicare (physician and hospital)	$5,000
Divided by number of physicians in the ACO	÷ 50
Multiplied by the probability of the practice meeting a bonus threshold	× 50%
Multiplied by the share of savings given to practices meeting threshold	× 80%
Expected reduction in bonus per physician	**$40**
Net incentive for surgery	**$360**

Note: ACO (accountable care organization). We assume that whether or not the practice will get a bonus is not known at the time of the decision and is assumed to be 50 percent by the decision maker. Also, we assume a design in which the physician practice would receive 80 percent of any shared savings, but other percentages for both numbers would yield similar results.

Measuring cost over three years could reduce random variation

While spending typically oscillates between a rise in one year and a drop in another, EHMSs rarely stay below average spending growth for three years in a row due to random variation. Therefore, one way to significantly reduce the effect of random variation on bonus payments is to give bonuses only to ACOs that meet quality and spending targets every year for three years and assess penalties only on ACOs that fail to meet quality or bonus targets for three straight years. Each ACO would be evaluated annually to see if it is eligible for a bonus. The bonus would be a rolling average of its past three years' share of savings. From 2002 to 2004, only 5 percent of EHMSs had spending growth that was 2 percent above or 2 percent below the national average for three straight years. In the future, if ACOs have strong incentives to constrain costs, we would expect a larger share of providers to consistently have spending growth lower than the national trend. Any consistent change in spending growth that we observe after instituting ACO incentives is likely to be due to the effect of the incentives and not to random variation in costs.

One objective of an ACO is to promote care coordination and a shift to interventions that create long-term benefits for the patient. Ideally, to achieve this objective, an ACO policy would be designed to encourage physicians to maintain a relationship with their patients and make clinical decisions aimed at improving the patient's short-term and long-term health. Under such a policy, a physician's bonus could be based on shared savings over a three-year period. For example, the bonuses a physician received in 2010, 2011, and 2012 would in part depend on the Medicare spending in those years for the patients assigned to that physician in 2010. The physician would be responsible for the patients assigned in 2010, even if the patients switched physicians (although not if the patient moved to a different market area). This arrangement would have several benefits, including:

- an incentive to maintain long-term relationships,
- an incentive to invest in health care interventions with long-run benefits,
- a reduced incentive to drop difficult patients, and
- a smoothing out of random variations in the ACOs' per capita Medicare expenditures.

Large ACOs have small financial incentives for individual actions

If Medicare policy required ACOs to have 5,000 or more patients to limit random variation, any financial incentives in these large ACOs would be split among at least 50 physicians. The result is that individual physicians would

TABLE 2–5

Illustrative example of ACOs' effects on capacity decisions

	Individual action: A physician in a 50-person practice orders an MRI	Capacity decision: A 50-physician practice leases an MRI machine
Payment per MRI (all payers)	$500	$500
Practice revenue from the action	$500	$500,000[a]
Minus practice marginal cost	–$200	–$450,000[b]
Profit	$300	$50,000
Divided by number of physicians in the ACO	÷ 50	÷ 50
Profit per physician	**$6**	**$1,000**
Effect of the action on the ACO bonus per physician		
Change in Medicare spending for ACO's patient population	$500	$250,000 annually[c]
Divided by number of physicians in the ACO	÷ 50	÷ 50
Multiplied by the probability of the practice meeting a bonus threshold	× 50%	× 50%
Multiplied by the share of savings given to practices meeting threshold	× 80%	× 80%
Expected reduction in bonus per physician	**$4**	**$2,000**
Net incentive per physician	**$2**	**–$1,000**

Note: ACO (accountable care organization). We assume that whether or not the practice will get a bonus is not known at the time of the decision and is assumed to be 50 percent by the decision maker. Also, we assume a design in which the physician practice would receive 80 percent of any shared savings, but other percentages for both numbers would yield similar results.
a. Assumes 1,000 MRIs per year.
b. Includes lease and operating costs.
c. For illustrative purposes, assume a 50-physician practice would bill Medicare for 500 more MRI scans per year and bill private insurers for 500 scans for every additional MRI machine leased by the practice. Laurence Baker has estimated that the number of Medicare MRI scans increases by 733 for every additional MRI machine installed (Baker 2008). Therefore, an increase of 500 scans may be viewed as conservative.

have very little direct financial incentives to restrain volume because they would receive 100 percent of the revenue from increases in their patients' volume but only 2 percent (1/50th) of the ACO bonus from restraints in their patients' volume. This is a standard "tragedy of the commons" problem. Consider, for example, an ACO's interventional cardiologist who has a choice of performing a nonemergent surgical procedure (insertion of a stent) or treating stable angina medically (Weintraub et al. 2008). In the illustrative example in Table 2-4, the financial incentive to perform the surgery would be $400—the interventional cardiologist's assumed direct profit on the surgery, net of opportunity costs. The surgery would also result in a reduction in the ACO's expected bonus. However, because the bonus reduction would be spread across the ACO's 50 physicians, the surgeon's loss would be only $40, much less than the direct incentive to perform the surgery. Hence, the financial incentive in large ACOs for physicians to change their individual decisions affecting a single patient would be small.

Large ACOs have large financial incentives for joint actions

The ACO bonus structure is designed to affect group practices' joint decisions, such as those involving purchasing equipment or recruiting specialists. In a second illustrative example, we examine how the ACO bonus structure could reduce a practice's incentive to purchase or lease an MRI machine. Table 2-5 shows that for a physician in a group that owns an MRI machine, ordering an MRI for one patient results in a profit of $6 for the physician, which is not fully offset by the reduction in the expected ACO bonus of $4. For a physician in this group, a $2 incentive exists for ordering an MRI. In other words, once a practice has sunk the fixed costs into a machine or a service, it is very difficult to counterbalance the financial incentive to use that machine as much as possible. However, it may be possible through the ACO bonus structure to reduce a practice's incentive to purchase or lease an MRI machine. In the second column in Table 2-5, we look at the decision to lease an MRI machine for

the practice. In this case, the direct profit to the physician for leasing an MRI machine would be $1,000, but it would be more than offset by the expected reduction in the ACO bonus of $2,000 per physician. Hence, the physicians in the ACO would have an incentive to not lease the additional machine in this example. Creating this type of financial incentive for physicians to constrain capacity could generate shared savings for physicians and for the Medicare program and thus bend downward long-term trends in spending growth.

ACOs would also create incentives to improve coordination of care and management of chronic diseases. By maintaining the health of beneficiaries the ACO could prevent unnecessary admissions and relieve the need to build new capacity. Unlike the current FFS system, providers in an ACO would receive a financial reward for working together to maintain health and reduce the level of medical services needed.

If all payers adopted an ACO model, the potential for it to constrain capacity growth could be maximized. The state of Vermont is currently attempting to test this type of incentive system for both public and private payers. Without private payer involvement, the risk is that physicians' incentives to increase capacity for their privately insured patients would more than offset any incentives that the Medicare ACO provided to constrain capacity.

Shared savings stem more from joint than from individual decisions

One lesson from our illustrative examples is that the formation of ACOs should not be assumed to change an individual physician's behavior directly. The financial incentives would have to change joint practice-level decisions to be effective. Joint practice-level decisions that could be influenced by an ACO incentive include care protocols, equipment purchases, recruitment strategies, and incentive structures offered to physicians (e.g., do not tie physician income to increased revenue generation). For an ACO to have joint decision making, there would be a need for some type of formal organizational structure. For voluntary ACOs, such a structure would mean that individual physicians would have to give up some autonomy and make clinical practice and technology acquisition decisions jointly. An investment would likely need to be made in better data and collection systems to inform those decisions. For mandatory ACOs, a joint decision-making structure would need to be preceded by efforts to educate providers about how their compensation depended on their ACO's collective results. For both voluntary and mandatory models, formal contracts, decision systems, and data systems would be critical to the ACO and its constituent providers' success.

Given the random variation in costs for small providers, we expect ACOs would need to have more than 50 physicians and more than 5,000 patients. In some cases, a large group practice would serve 5,000 or more patients. However, in small communities several practices across a region would need to band together to form an ACO organization to reach the 5,000-patient threshold.[7] It would be possible for ACOs to encompass large geographic areas or to encompass nonproximate areas. For example, hospitals that form a system and their associated physicians may all want to be considered part of the same ACO. In a state with only a few hospital systems, there could be just a few ACOs in the entire state. Agreements would have to be reached with most of the providers associated with those hospitals, whether or not there were existing contractual relationships, for the ACOs to be able to make joint decisions.

Under what conditions will an ACO policy reduce Medicare spending?

One goal of the ACO model is to create an incentive for providers to reduce their rate of spending growth by restraining capacity and improving care protocols. These behavioral changes will generate a certain amount of savings. Medicare would pay providers bonuses equal to their share of the savings: 80 percent of the savings in our examples.

Spending may also change due to random variation. For an ACO with a small number of patients, it will be difficult to determine whether a reduction in spending trends is due to active efforts on the physicians' part or to random fluctuation in their patients' health. In a bonus-only model, an ACO policy will reduce Medicare spending only if Medicare's share of savings from behavioral changes is larger than the bonuses Medicare pays due to random variation. From a budgetary standpoint, volume constraint is the benefit of ACOs, and payments for random variation are the cost.

Currently, when a group of patients' use of services declines below national trends due to random variation, Medicare spends less—resulting in savings. For example, if a group of providers' payments were $1 million below

the expected level due to random variation, then Medicare would save $1 million. However, under the ACO model, if random variation drives down spending for an ACO's patients (a low-illness year), then the ACO and Medicare will share those savings. For example, a $1 million random reduction in spending in an ACO shared-savings model could result in Medicare paying providers 80 percent of shared savings ($800,000) purely for random variation.[8] That $800,000 is the cost of the ACO model to Medicare. Because of the asymmetry of incentives in a bonus-only model, Medicare would not receive any offsetting revenues from penalties for random increases in an ACO's costs. The necessary condition for a bonus-only ACO policy to result in reduced Medicare expenditures can be stated as follows:

> Savings from behavioral change × (1 – ACO share of savings) > bonuses paid due to random variation

To increase the odds that an ACO policy saves Medicare money, the ACO needs to be designed to maximize the odds of positive behavioral changes and minimize the amount of bonuses paid for random variation. Several actions can be taken. First, random variation can be reduced by increasing the size of the pool of patients in the ACO. Second, performance can be calculated over multiple years to smooth out random variations. A third option is to reduce the share of the bonuses going to ACOs. However, reducing bonuses may not increase Medicare savings because reduced bonuses also may diminish the incentive for behavioral change.

One option that will almost certainly increase the odds that the program generates savings is to fund the bonus via a reduction in the update of FFS Medicare payment rates. This strategy would create immediate savings and could result in offering providers a larger share of savings (bigger bonuses), which would increase the odds of providers choosing to restrain capacity and volume growth.

How much uncertainty is there in projections of savings?

Work by researchers at Dartmouth has shown that there are large regional variations in Medicare costs and cost growth (Fisher et al. 2009b). Because high costs do not appear to be correlated with better quality, there is room for improvement in efficiency; that is, costs could be reduced without harming quality. While it is easy to conceptualize savings, it has historically been difficult to achieve them.

Research has shown that when an integrated delivery system is paid capitation it can reduce hospital admissions and the overall costs of care (Baker et al. 2000, Newhouse 1994). However, these examples often represent situations in which the incentive to restrain costs is strong (i.e., capitation) and a large share of a practice's patients are under this incentive.

Attempts to reduce costs with more modest incentives via paying for improved preventive care, care coordination, and disease management have had mixed results at best. They may improve care, but a reduction in overall government expenditures appears to be a difficult objective to achieve (see Chapter 8 in this report) (Cohen et al. 2008, Damberg et al. 2009, Russell 2009). While the literature often finds that the interventions improve health and are worth the additional cost, they nevertheless find that these interventions cannot be counted on to reduce health care spending. Several hypotheses for why spending constraint goals were rarely met have been cited, such as the small size of bonuses, the small share of a practice's patients affected by the programs, the lack of active involvement of physicians, and a lack of clear spending targets. Even the PGP demonstration, which has active physician involvement, has not definitively shown savings in its first two years (see text box, p. 49).

Any projections of savings from the formation of ACOs are subject to a high degree of uncertainty. Given the uncertainty surrounding the savings from ACOs, the ACO should be viewed as one of a series of initiatives that could improve the efficiency of health care delivery.

How would ACOs relate to other MedPAC policy initiatives?

MedPAC made several policy recommendations last year that could intersect with the ACO model, including recommendations on medical homes, bundling, readmissions, and informing physicians about resource use. The ACO concept is consistent and in some cases complementary with these initiatives. It is possible for CMS to explore several of these options through pilots or demonstrations and ultimately design payments around a subset of the various options.

Medical homes as ACO building blocks

In our June 2008 report, the Commission recommended a pilot project to test the concept of "medical homes" (MedPAC 2008). In our vision, a medical home is a medical practice that is paid a fixed monthly fee in addition to FFS payments. It is expected to furnish primary care, conduct care management, have a formal quality improvement program, have 24-hour patient access, maintain advance directives, and maintain a written understanding with each beneficiary that it is the patient's medical home.

Given the large number of solo and small primary care practices in the United States, many medical homes would have far fewer than 5,000 Medicare patients, so annual Medicare spending per patient would vary widely. The effect of random variation on spending would be too large to be offset by savings achieved through more efficient clinical practices. Hence, paying bonuses based on changes in spending growth would be difficult for medical homes. However, because average spending per Medicare patient becomes more stable as the number of patients increases, an ACO formed around a set of multiple medical homes could effectively earn a bonus or absorb a penalty based on resource use. (Resource use would include any per member per month medical home payment.) The state of Vermont plans to test this type of ACO—patients are assigned to medical homes and sets of medical homes are coupled with a hospital to become an ACO. The primary care physician receives one payment for serving as a patient's medical home and shares in the ACO's bonus or penalty, depending on the collective quality and spending results achieved by the entire ACO.

Bundling

In our June 2008 report, the Commission recommended a pilot to test the feasibility of bundling physician and hospital payments associated with a hospitalization episode (MedPAC 2008). The intent of bundling is to align provider incentives around a costly episode of care to encourage greater coordination of care and reduce the use of low-value services. One potential difficulty with a bundling proposal is that physicians will have a new incentive to increase low-severity admissions. They would profit because the payment amount they received would cover a patient with average resource needs, whereas the low-severity patient they admitted would require low time commitments from the physician. The incentive to keep marginal cases out of the hospital would decrease. In contrast, the ACO creates an incentive to reduce unnecessary admissions. Therefore, the ACO may be seen as a necessary counterweight to the effect that bundling would have on the number of admissions.

Readmissions

ACO incentives complement the incentive in the Commission's readmission policy recommended in June 2008 (MedPAC 2008). The readmission recommendation creates a penalty for hospitals (but not physicians) with high readmission rates. Under the ACO model, physicians as well as hospitals are rewarded if a reduction in readmission rates leads to lower annual spending per beneficiary. By aligning physician and hospital incentives to reduce readmissions, the ACO policy coupled with a readmission policy could have a larger effect than either policy on its own.

Resource use reporting

In 2005 and 2008, the Commission also made a recommendation for CMS to inform physicians of their resource use over time (MedPAC 2008, MedPAC 2005). A crucial first step in any ACO model would be for CMS to inform the physicians and the hospital of what claims data say about their historical relationships with other providers, their patient population, and Medicare payments and quality measures for that population. Under a voluntary model, hospitals and physicians could use this information to decide if they wanted to volunteer to be considered an ACO. Under the mandatory model, in which CMS assigns physicians to a hospital and patients to physicians, the physicians would be made aware of whom they were associated with and the ACO's cost and quality levels relative to targets. Physicians might then change their referral patterns or affiliations.

Some maintain that simply informing physicians of where they stand in relation to other physicians and their affiliated hospitals could have a salutary effect. If informed that their assigned ACO was providing poor-quality care, the physicians might want to change the ACO they were affiliated with or take initiatives to improve the care provided by the ACO to which they were assigned. However, others may argue that the effects of information alone may be transitory and will not result in large permanent changes in practice patterns.

How do ACOs fit along the continuum from FFS to Medicare Advantage plans?

FFS Medicare has an inherent incentive to increase the volume of service provided to each patient and represents

TABLE 2–6

The continuum of incentives to control volume

	Type of payment system			
Characteristics	**FFS**	**Voluntary ACO (bonus only)**	**Mandatory ACO (bonus and withholds)**	**MA plan**
Incentive to constrain cost	Rewards increases in volume	Limited rewards tied to cost and quality	Limited rewards and penalties tied to cost and quality	Plans are rewarded for lower volumes
Patient choice	Patients free to choose physicians	Patients free to choose physicians	Patients free to choose physicians	Plans can constrain choice
Physician control over referrals	Limited influence	Limited influence	Limited influence	Plans can control referrals
Insurance functions	None	None	None	Negotiates rates Processes and pays claims
Provider risk	No financial risk for providers	No financial risk for providers	Limited financial risk for providers	Full insurance risk
Medicare funding	Standard FFS	Bonuses funded by shared savings and restraining FFS rates	Bonuses funded by shared savings and withholds	Based on administratively set benchmarks and the plan "bid"

Note: FFS (fee-for-service), ACO (accountable care organization), MA (Medicare Advantage).

one end of the payment spectrum. Medicare Advantage (MA) plans are fully capitated, have a strong incentive to constrain volume, and represent the other end of the spectrum. ACOs lie in the middle of the spectrum. ACOs still receive FFS payments per unit of service but would face a separate system of incentives to improve quality and constrain volume, potentially resulting in lower overall Medicare spending. ACOs differ from MA plans in that ACOs would not take substantial actuarial (or insurance) risk and would not be burdened by the insurance functions of negotiating rates and paying claims.

Because ACOs would still be paid on a FFS basis, the financial risk of very sick (costly) beneficiaries would not be borne solely by the ACO. In the bonus-only model, Medicare takes on all the risk; in the model with withholds, the provider's risk is limited to the loss of a withhold. The distribution of payment models along the spectrum of incentives to constrain volume is shown in Table 2-6.

As Table 2-6 illustrates, ACOs would be able to incorporate some incentives to restrain volume without constraining patients' choice of physician. They also would be easier for providers to operate because the providers in an ACO would not have to negotiate prices or pay claims.

ACOs' relationship with private insurers

The main mechanism for ACOs to achieve savings is through constraining capacity. The incentive to constrain capacity will hinge on whether physicians face similar incentives from private payers. If private payers continue to pay on a FFS basis without the carrots and sticks of an ACO to lower resource use, Medicare may not have sufficient market power to offset the inducements afforded by the private sector's unencumbered FFS payments. Therefore, the ACOs should be structured so that private insurers find it attractive to set up bonuses based on ACO resource use.

The ACO bonus structure would create incentives for building systems, and systems would come with enhanced

market power. One danger is that physician groups consolidate into larger entities and use this negotiating power to increase prices charged to private insurers. There would need to be some protections for the privately insured patients when their insurers negotiate with large, dominant integrated providers.

Conclusions

ACOs could create incentives for improving quality and constraining costs, but they will not be a simple solution to Medicare's quality and budgetary problems. Providers in a successful ACO will need a mechanism to jointly decide on care protocols and capacity building. They will also need to develop a degree of coordination and systems thinking that is currently lacking in many health care markets. We are concerned that this level of joint decision making may be difficult to achieve in a mandatory model in which providers are placed together without having agreed on a system of common governance.

ACOs' incentives are tied to quality and spending targets. The spending targets will have to be based, at least in part, on a given ACO's spending history. On the one hand, if targets were based purely on national averages, there would be few participants from high-cost areas, and Medicare spending would have a substantial likelihood of increasing for participants in other areas. On the other hand, using an ACO's historic spending alone would raise questions of equity. One approach to balance these concerns is to set an ACO's spending target equal to the sum of the ACO's historical spending and an allowance for spending growth. Medicare could set a single national growth allowance, or Medicare could set lower allowances in high-service-use areas and higher allowances in low-service-use areas. This approach could allay the equity concerns to some extent and eventually compress regional variation in spending per capita.

The PGP demonstration has shown that ACO-type incentives can lead to improved quality scores, but it has also illustrated the difficulty of restraining Medicare cost growth. However, the success of ACOs over time could be greater than early PGP results might indicate. If incentives to constrain volume growth were implemented by more payers and offered nationally, innovations that reduced the cost of care might be more actively developed. So far, because providers do not have a strong incentive to control volume growth, there is no market for innovations that do so. ACOs could supply the stimulus for such innovations.

ACOs' odds of success could also be improved by giving providers clear spending targets, increasing the share of patients subject to the incentive (e.g., by involving private payers), and increasing the size of the incentives for meeting targets (by restraining FFS rates and putting some of the savings toward bonuses). The latter step will especially be needed in a system of voluntary, bonus-only ACOs both to ensure Medicare savings in light of random variation and to create bonuses large enough to induce significant change.

One of the ACOs' primary mechanisms for restraining spending growth could be limiting the growth in the supply of specialists and expensive capacity. Research shows that supply-sensitive services (e.g., those services that are correlated to the supply of specialists and health system capacity) account for much of the difference between high- and low-spending areas of the country (Dartmouth 2009). If ACOs can limit the growth in capacity and reduce unnecessary services, they might be able to create efficiency gains, which could be shared by providers and the Medicare program. ACOs that prove they can generate bonuses for physicians through efficiency gains and high-quality care for patients will attract physicians and increase their market share. However, ACOs would have to be evaluated over the long term, because capacity changes will not happen overnight. Given the track record of various interventions, we need to project the success of future interventions with an acknowledgment of uncertainty and with a certain amount of humility.

For Medicare to become sustainable, the delivery system has to change. ACOs could prove to be an important catalyst for delivery system reform by creating incentives for increased organization and joint decision making. However, several issues must be resolved in creating an initial set of incentives that are strong enough to overcome the existing incentives in the FFS system to drive up volume. Long-term sustainability may require refining ACOs' incentives as they evolve. ■

Endnotes

1 In the past, we have considered ACOs without a hospital as an option. We include hospitals in the ACO definition here for three reasons. First, care coordination will require hospitals and physicians to work together. Second, we think joint decisions will be important for ACOs' success, and hospitals may have the convening power to bring parties together. Third, a significant amount of anticipated savings would be expected to come from reducing preventable hospital admissions and reducing readmissions. Hospitals will face these revenue losses and will want to share in the savings. Otherwise, they might raise strong objections to any ACO program.

2 Under a system of voluntary ACOs, it would be imprudent for Medicare to set higher base FFS Medicare payment rates for providers in ACOs than for other providers, as the higher rates would encourage providers to join an ACO, even if they were not committed to improving the efficiency of care.

3 To qualify for bonuses, PGP sites had to have risk-adjusted cost growth that was more than 2 percent lower than the comparison group.

4 Physicians with inpatient work are assigned to the hospital where they do the most inpatient work. Physicians without inpatient work are assigned to the hospital where most of their patients are admitted. Patients are assigned to physicians according to which physician provides the plurality of their primary care visits.

5 The amount of variation might diminish over time as ACOs were held accountable for their population's Medicare spending. Current patterns reflect today's FFS system; no population is assigned, no measurement is made, and there is no accountability.

6 The risk adjustment is not expected to significantly reduce volatility because we are examining changes in average cost per beneficiary from one year to the next in the same ACO. Because the pool of patients is not expected to change significantly, we do not expect significant shifts in risk scores that could explain significant shifts in costs. In contrast, if we based penalties and rewards on cross-sectional comparisons of ACOs, risk adjustment would be more important.

7 According to the Dartmouth data analysis, 4,658 single hospital EHMSs could be defined, of which 1,736 would have an assigned patient population of 5,000 or more and could meet our definition of ACOs. Those large ACOs would account for about 78 percent of Medicare beneficiaries (Dartmouth 2009). The number of large ACOs and the share of Medicare beneficiaries in ACOs could increase if the physicians and hospitals in several small communities banded together to become "system ACOs."

8 In our examples, we assume providers retain 80 percent of shared savings, while others have suggested a 50 percent shared-savings model. Providing a larger share of the savings to physicians and hospitals increases the magnitude of the incentive to change capacity and care protocols.

References

Baker, L. 2008. Expanded use of imaging technology and the challenge of measuring value. *Health Affairs* 27, no. 6: 1467–1478.

Baker, L., J. Cantor, S. Long, et al. 2000. HMO market penetration and costs of employer-sponsored health plans. *Health Affairs* 19, no. 5: 121–128.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. *Medicare physicians group practice demonstration: Physicians groups continue to improve quality and generate savings under Medicare physician pay for performance demonstration*. Baltimore: CMS. August.

Cohen, J., P. Neumann, and M. Wienstein. 2008. Does preventive care save money? Health economics and the presidential candidates. *New England Journal of Medicine* 358, no. 7: 661–663.

Congressional Budget Office. 2008. *Key issues in analyzing major health insurance proposals*. Washington, DC: CBO. http://www.cbo.gov/ftpdocs/99xx/doc9924/12-18-KeyIssues.pdf.

Damberg, C., K. Raube, S. Teleki, et al. 2009. Taking stock of pay-for-performance: A candid assessment from the front lines. *Health Affairs* 28, no. 2: 517–525.

Dartmouth Atlas of Health Care. 2009. *Supply sensitive care*. Lebanon, NH: Dartmouth Center for the Evaluative Clinical Sciences. http://www.dartmouthatlas.org/topics/supply_sensitive.pdf.

Fisher, E., M. McClellan, J. Bertko, et al. 2009a. Fostering accountable health care: Moving forward in Medicare. *Health Affairs* 28, no. 2: w219–w231. Published online January 27.

Fisher, E., J. Bynum, and J. Skinner. 2009b. Slowing the growth of health care costs—lessons from regional variation. *New England Journal of Medicine* 360: 849–852.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system*. Washington, DC: MedPAC.

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

Newhouse, J. 1994. *Free for all? Lessons from the RAND health insurance experiment*. Cambridge, MA: Harvard University Press.

Pilotte, J. 2009. E-mail message to author, February 27.

RTI. 2008. *Physician Group Practice demonstration selected results from performance year two*. Research Triangle Park, NC: RTI.

Russell, L. 2009. Preventing chronic disease: An important investment, but don't count on savings. *Health Affairs* 28, no. 1: 42–45.

Weintraub, W. S., J. A. Spertus, P. Kolm, et al. 2008. Effect of PCI on quality of life in patients with stable coronary disease. *New England Journal of Medicine* 359: 677–687.

CHAPTER 3

Physician resource use measurement

CHAPTER 3

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Chapter summary

Measuring physician resource use and confidentially sharing the results with physicians is one option that might help to address variation in physician practice patterns and Medicare's unsustainable rate of spending growth. In 2005, the Commission recommended that Medicare measure physician resource use and share the analysis results with physicians in a confidential manner. Through the Medicare Improvements for Patients and Providers Act of 2008, the Congress enacted the Commission's recommendation, and CMS has begun a phased implementation of the program, making this an opportune time to detail how the Commission envisions that Medicare's physician resource use measurement program should work.

The Commission has proposed several policy principles to guide Medicare's physician resource use measurement program. These principles include, among others, adopting a methodology for measuring resource use that is transparent to all physicians under observation, ensuring that physicians are able to actively modify their behavior on the basis of the feedback provided, risk adjusting clinical

In this chapter

data to ensure fair comparisons among physicians, and obtaining ongoing feedback from the physician community on CMS's measurement methods and other aspects of the program.

The Commission has also continued to assess its own physician resource use analyses, specifically examining the stability of results over time and studying alternative ways to attribute utilization and costs to physicians. Analyses conducted by the Commission found a high degree of stability in physicians' efficiency scores over time, suggesting that the episode grouper software identifies outlier physicians consistently across years. Our analyses also found that various methods for attributing episodes to physicians have advantages and drawbacks, suggesting that CMS may want to consider more than one attribution method when its physician resource use measurement program is fully implemented. ■

Background

Measuring physician resource use and confidentially sharing the results with physicians is one option that might help to address variation in physician practice patterns and Medicare's unsustainable rate of spending growth. In its March 2005 report, the Commission recommended that Medicare measure physician resource use and share the analysis with physicians in a confidential manner (MedPAC 2005). The Congress enacted this recommendation in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (§131), which requires the Secretary of Health and Human Services to establish a physician feedback program using claims data to provide confidential feedback reports to physicians that measure the resources used to provide care to Medicare beneficiaries. Medicare has already begun work referred to as the Physician Resource Use Measurement and Reporting Program to comply with the MIPPA mandate and to test several characteristics of the program.

Measuring physician resource use is one option to help to address variation in practice patterns and Medicare spending growth

Slowing the increase in Medicare spending is urgent. Medicare's rising costs threaten to place a significant burden on taxpayers. Even the current level of spending may be considered unaffordable as it crowds out other budget priorities and strains financing sources (e.g., the Part A trust fund is now projected to be insolvent in less than 10 years) (Boards of Trustees 2009). Expenditure levels and growth also directly affect beneficiary out-of-pocket costs through higher Part B and supplemental insurance premiums as well as higher cost sharing.

Currently, the government's budgetary mechanism to address rising growth in Medicare expenditures for physician services calls for significant cuts to physician fees. It uses a spending target system, called the sustainable growth rate (SGR) system. The SGR system is designed to offset—through physician fee reductions—spending that exceeds established targets. As designed, the SGR system is inequitable in that all physicians are subject to the consequences (fee cuts) of excess spending that stem from excessive use of resources by only some physicians. In recent years, the Congress has intervened to avoid the fee cuts resulting from aggregate spending on physician services consistently exceeding targets. There is concern that over the long run, sustained payment reductions, such as those called for by the SGR system, could threaten beneficiary access to services.

While seeking to remedy the SGR problem and make Medicare more sustainable, policymakers have become increasingly interested in examining variation in the use of resources by physicians. Research shows that Medicare spending per beneficiary varies widely across regions of the country, that more variation exists in physicians' practice patterns than can be explained by differences in patients' health status alone, and that areas with more spending do not have better quality outcomes. One study shows dramatic differences in Medicare expenditures among physicians within the same geographic area as well as across areas (GAO 2007). Such variation suggests that an opportunity exists to reduce and redistribute spending to achieve greater efficiency—that is, to get better value—without sacrificing quality. If the physician community were able to glean new insights from analyses comparing physicians' resource use, innovations that improved efficiency—in terms of both quality of outcomes and quantity of resources used—could result.

Measuring physician resource use and confidentially sharing the results with physicians is one option—among several the Commission has discussed—that might help to address Medicare's unsustainable rate of spending growth. In contrast to the inequity of the SGR system, the major advantage of this option is that it would encourage individual accountability among physicians by showing them how their practice patterns affect their patients' total resource use.

Physicians are unique among providers in terms of their ability to drive total resource use. Physicians determine the services they deliver to their patients and influence the care other providers deliver. Under Medicare payment policies, physicians generally receive a separate payment for each individual service they provide.[1] Thus, Medicare spending increases as the volume or intensity of services physicians provide and prescribe increases. In contrast, Medicare pays most other providers a fixed amount for a bundle of services, such as an inpatient hospital stay or a 60-day spell of home health services. This is not to say that bundled payments solve all problems; the Commission has suggested ways to improve payment systems for many types of providers, including those with bundled payments. However, physicians are at one end of the spectrum in terms of fee for individual services, which, as a payment system, presents unique problems.

Providing confidential feedback could alert physicians to inefficient practice patterns they may not be aware of, spurring them to examine and change their practice styles. Providing such feedback directly to physicians has been shown to have a statistically significant, if small, downward effect on resource use (Balas et al. 1996, Schoenbaum and Murray 1992). Because Medicare is the largest single purchaser of health care, its feedback on resource use measurement is likely to be more successful than previous experience in the private sector. The potential success of Medicare's program will depend in part on a significant investment of resources—in terms of dollars and administrative flexibility. In addition, because Medicare's reports would be based on more patients than reports produced by private plans, they may have greater validity and acceptance from physicians.

MIPPA mandate to establish physician feedback program includes program design flexibility

MIPPA (§131) requires the Secretary of Health and Human Services to establish a physician feedback program using claims data to provide confidential feedback reports to physicians measuring the resources used to provide care to Medicare beneficiaries (MIPPA 2008).

It grants the Secretary broad flexibility in designing the program. The Secretary may choose to use data from other sources in addition to claims, provide feedback to individuals and physician groups, and include feedback on both utilization and quality of care. The mandate also permits measuring resources on a per episode basis, a per capita basis, or both. The Secretary may adjust data used for the feedback reports for beneficiaries' health status and other characteristics.

MIPPA also grants the Secretary flexibility to focus the physician feedback program on:

- specialties that account for a significant share of Medicare spending,
- physicians who treat high-cost or high-volume (or both) conditions,
- physicians who use a larger amount of resources than other physicians,
- physicians practicing in certain geographic areas, and
- physicians who treat no fewer than an established minimum number of beneficiaries.

MIPPA required that the Secretary implement the program by January 1, 2009, and conduct education and outreach activities for physicians as part of the feedback program. MIPPA requires the Government Accountability Office to evaluate the physician feedback program by March 1, 2011.

Medicare has begun the physician feedback program

Medicare has begun to test ways to measure physician resource use, distinguish among practice patterns, and share results confidentially with physicians. The work, referred to as the Physician Resource Use Measurement and Reporting Program, complies with the MIPPA physician feedback mandate and will evolve based on experience gained in phases (CMS 2008a). Phase I of the Physician Resource Use Measurement and Reporting Program uses per capita and per episode measurement based on two commercially available software packages (the same ones we have used in our analysis: Symmetry Episode Treatment Groups® (ETGs®), developed by Ingenix, Inc., and the Medical Episode Grouper® (MEG®), by Thomson Reuters) to analyze Medicare claims, produce alternative resource use reports (RURs) for several acute and chronic conditions, provide confidential feedback to selected physicians, and conduct one-on-one interviews with a sample of physicians who receive feedback. The text box provides more detail on episode groupers.

Phase I of CMS's Physician Resource Use Measurement and Reporting Program focuses on four acute conditions (community-acquired pneumonia, urinary tract infection, hip fracture, and cholecystitis) and four chronic conditions (congestive heart failure, chronic obstructive pulmonary disease, prostate cancer, and coronary artery disease with acute myocardial infarction) (CMS 2008b). For these conditions, the program compares physicians with their specific specialty peers and with more general, aggregated peer groups. The program relies on physician-designated specialty, but physicians can have multiple specialties and may treat different conditions, especially across geographic areas. In our own analyses, we discovered—by working backward from a condition rather than by physician-designated specialty—that conditions were largely treated by a few expected specialties but sometimes were treated by unexpected specialties. These rates differed by condition, but instances occurred for which a not insignificant share of physicians treating a condition were of an unexpected specialty (e.g., orthopedic surgeons treating acute myocardial infarction). CMS's program similarly works backward from a condition to create peer groups that cross specialty designations but tend to treat

Episode groupers

Episode groupers are software packages that use clinical logic to assign claims to clinically distinct episodes of care—a series of clinically related health care services over a defined time period, such as all claims related to a patient's diabetes condition. Episode groupers use all types of health care claims: inpatient admissions, physician visits, other outpatient services, and prescription drugs. They risk adjust by controlling for patients' comorbid conditions and other characteristics as well as the severity levels of each condition, allowing episode groupers to make more like-to-like comparisons by comparing similar episode–comorbidity–severity combinations rather than comparing all beneficiaries.

A physician's resource use for selected episodes of care can be compared with the average resource use for similar episodes by peers. This episode-focused comparison may provide more detailed and thus more actionable information than analyses that look at all types of care provided in a physician's practice. For example, a physician might treat certain patients or conditions in a more resource-intensive manner than others, but when all the physician's patients are combined in an analysis of per capita spending, the physician's use of resources appears to be average. An episode grouper has the potential to identify differences in physicians' practice patterns as well as to examine physicians' treatment of certain patients or conditions relative to their peers (e.g., excessive use of advanced imaging). ■

similar conditions. CMS's program is also designed to test multiple geographic areas for comparison (national, state, and hospital service area).

Phase I of CMS's program tests three risk-adjustment approaches. All three approaches use age, sex, and episode severity. The second approach adds beneficiary overall health status (using hierarchical condition category (HCC) scores). The third approach is similar to the second but adds local area characteristics (county physician supply, average income, and racial and ethnic demographics).

Phase I of the program tests six approaches to attribute episodes to physicians:

- Identify the physician billing most evaluation and management (E&M) visits (plurality).
- Identify the physician billing most E&M visits and accounting for at least a minimum share of total episode costs (plurality-minimum).
- Identify the physician billing most "established patient" E&M visits for chronic conditions only (plurality-established).[2]
- Attribute the entire cost of an episode to each physician billing for any E&M visit or procedure in the episode (multiple-even).
- Attribute the episode cost to each physician in proportion to billed E&M visits in the episode (multiple-proportional).
- Attribute the entire episode cost to the physician billing for the episode's first E&M visit for acute episodes only (first contact).

(See attribution discussion on p. 70.)

Phase I also tests several comparison approaches. In principle, to measure physicians' efficiency, a physician's resource use for a given episode must be compared with an expected value, often determined by the average resource use of comparable physicians. Under one approach, the program tests using a mean and a median for the expected resource use comparison. As a variant of that approach, the program also explores the right (high cost) and left (low cost) sides of the physician efficiency distribution. CMS is exploring how cut points for defining cost-inefficient and cost-efficient physicians can be set in multiple ways—e.g., two standard deviations from the mean or top or bottom decile.

To gather physician input, CMS distributed RURs to a sample of about 250 physicians in the 12 sites used for the Community Tracking Survey, plus the Baltimore–Washington, DC, area.[3] CMS's contractor to evaluate the physician feedback program, Mathematica Policy

Research, Inc., conducted one-on-one interviews with samples of physicians who received feedback. Physicians were asked their opinions of the alternative RURs and methodologies, especially risk adjustment, attribution, benchmarks, per capita measures, composite measures, details about type of cost or service, and RUR layout.

Informed by the results of phase I of the program, CMS will implement phase II, which may expand the evaluation of physician feedback by including additional specialties, conditions, and geographic areas and including feedback on quality measures.

Significant investment is needed for Medicare's physician feedback program to evolve from testing various features with a limited number of physicians to a large, widespread program measuring resource use and giving feedback to many physicians. Developing and implementing transparent Medicare-specific measurement methodology, gathering physician input, focusing on outreach and education, and conducting many other resource-intensive activities will shortly be necessary to give the feedback program a chance to achieve its goals. Shortchanging any of these activities risks the viability of the entire physician feedback program. Calling on Medicare to become a value-based purchaser through activities like physician feedback will require a much larger investment in CMS—in terms of both dollars and administrative flexibility.

Medicare's physician resource use measurement program should follow several policy principles

Given what has recently occurred—we recommended, MIPPA enacted, and CMS has begun a program to implement physician resource use measurement and feedback—it is an opportune time for us to outline how we envision that Medicare's physician resource use measurement program should work. The measurement and feedback program has the greatest chance of achieving the goals of promoting efficiency and discouraging inefficiency if it follows key policy principles, such as adopting a transparent measurement methodology, reaching out to the physician community for input, focusing on education and outreach, and improving the program over time.

Anticipation of Medicare's physician resource use measurement program has led to calls to expand the program from confidential feedback to other activities, such as public reporting, payment adjustments, and aligning efforts with private payers. These kinds of activities would be transformative steps toward Medicare becoming a value-based purchaser. However, the Commission is concerned that expanding beyond confidential feedback too rapidly could lead to a flawed physician resource use measurement program and that even the appearance of moving too rapidly could undermine physician and beneficiary confidence in the program. The Commission has recommended that Medicare design physician resource use measurement so as to be prepared for any eventual public reporting and payment adjustments. First, Medicare and the physician community will need time to learn from the experience of confidential feedback. In the meantime, Medicare is gaining related experience through public reporting of physicians participating in the Physician Quality Reporting Initiative, paying physicians based on quality reporting, and sharing claims data with other entities through the Generating Medicare Performance Results Project and Chartered Value Exchanges (Milgate 2008). Together, these experiences should inform decisions about the future direction for the physician resource use measurement program.

Adopt measurement methodology that is transparent

Before Medicare finalizes the confidential physician feedback program, it should make publicly available an explanation of its measurement methodology and a description of the data sources used. Currently, CMS's Physician Resource Use Measurement and Reporting Program relies on commercially available episode grouper software packages, which allows the agency to evaluate the software packages' features that can be included in a Medicare-specific, open source software package. However, the Commission has never expected the Medicare program to purchase off-the-shelf software with proprietary, black-box methodology; CMS does not normally pursue such a strategy. It usually contracts with vendors to develop tailored programs, such as is done for the Medicare severity–diagnosis related groups used in the inpatient hospital payment system. Similarly, the episode grouper CMS finally decides on for its physician resource use measurement program should use a Medicare-specific, transparent method. (Existing episode grouper methodology has become more transparent. In March 2009, Ingenix, Inc., released its ETG measurement methodology for public review and comment (Ingenix

2009).) The program CMS selects could be provided by one of the existing episode grouper software companies, tailored to suit Medicare's needs. Existing episode grouper software has been used by private payers. Since Medicare was not a customer until recently, the software was not developed with the program's unique characteristics in mind. Therefore, existing software may need to be modified to suit the Medicare program.

Adopt measurement refinements as program evolves

Medicare should not wait until the measurement methodology is perfected to implement the physician feedback program. Since the proposed resource use measurement program relies on confidential feedback to educate physicians, it should begin as soon as possible with as many measures as are ready. Measures can be refined and new ones added over time.

Ideally, changes in physicians' year-to-year resource use measurement results should be due to changes in their practice patterns alone rather than to changes in measurement methods. However, this program will be a new endeavor for Medicare. It is unrealistic to expect the measurement methodology used in the first year to remain unchanged in future years. One way to help deal with these changes is to pilot test any future refinement by including new measures, highlighted as such, in detailed feedback for a year or two before including them in overall scores.

Ensure that feedback is actionable

Feedback should include detailed breakouts—such as by type of service, provider, and condition—in addition to overall scores in such a way that it is clear to physicians which aspects of their practice patterns they should act on (Figure 3-1, p. 68). (This sample feedback form has not been used in any feedback programs and is provided for illustrative purposes. Other feedback forms, including the one used by the Medicare program, differ from this one.) For example, some physicians treat diabetic patients in a more resource-intensive manner or use more intensive imaging services than their peers. Providing detailed information in addition to aggregate measures makes physician feedback more actionable by identifying differences in practice patterns that influence physicians' overall feedback results.

Medicare will need to balance the value of providing physicians with detailed information about total resource use with beneficiaries' right to privacy. Detailed information about services provided by other physicians and other types of providers would greatly enhance physicians' ability to evaluate their practice and referral patterns. Without this type of information, it is unreasonable to expect physicians to significantly improve care coordination and chronic disease management and achieve many similar policy goals. However, sharing information on care not directly provided by that physician—even providing a list of other physicians caring for a patient—can easily run afoul of beneficiary (and other physician) privacy rights. Perhaps a way for the Medicare program to balance these two competing goals is to ensure that sufficient information is provided to physicians to make them aware of their relative performance and to strive to provide as much additional information as possible to support care coordination. In other words, information about resource use can be aggregated in a way that physicians can see that they are more or less efficient than their peers without disclosing information about specific services provided to individual patients or by individual providers. For physician feedback to also support care coordination, the Medicare program should strive to include more detailed information, especially the names of other providers involved in the physician's episodes. This information would not reveal the average efficiency scores of other physicians, but it would allow physicians to act on feedback by discussing treatment patterns with their colleagues. The ability to call other physicians to discuss the treatment of patients is at the heart of care coordination.

We want to be clear that the feedback will not answer all questions about how to improve practice patterns for greater efficiency. The success or failure of the feedback program will depend on Medicare's ability to forge a collaborative partnership with physicians and on the physician community's willingness to embrace thoughtful examination of their practice patterns. Physicians will have to come together in professional societies and other organizations to learn from feedback and discuss how best to improve efficiency and then act on these decisions.

Risk adjust data to ensure appropriate comparisons

MIPPA gives the Secretary discretion to adjust data used for the feedback reports for beneficiaries' health status and other characteristics. The program must make such adjustments to measure resource use as accurately as possible.[4] Risk adjustment can help to indicate when resources are overprovided to healthy patients as well as when resources are underprovided to patients in greater need.

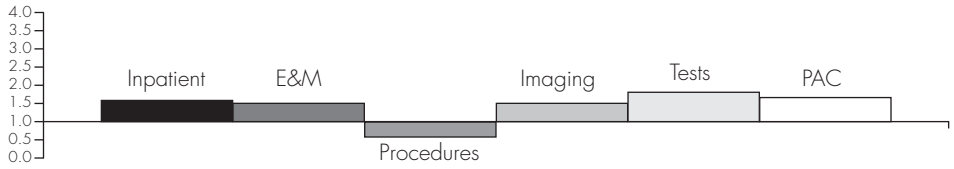
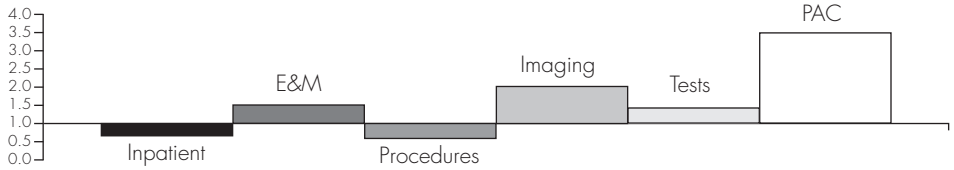
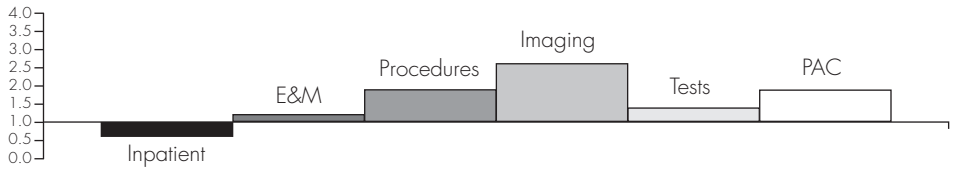
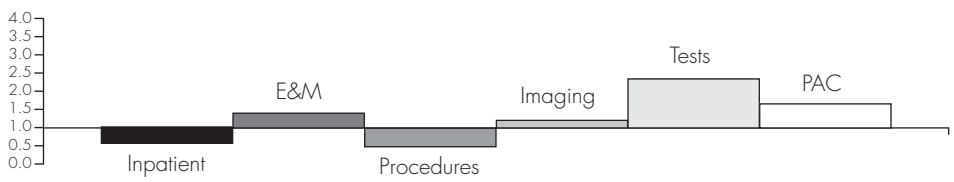
FIGURE 3–1

Example of the first page of a physician feedback form

Summary of patterns of care

	John Smith, MD	**Peers' average**
Name:		
Peer group:	Cardiology	Cardiology
Total spending:	$XXX,XXX	$YYY,YYY
Number of patients:	XX	YY
Cost per patient:	$X,XXX	$Y,YYY
Number of episodes:	XX	YY
Cost per episode:	$X,XXX	$Y,YYY
Episodes per patient:	X	Y
Average patient health status:	X.XX	Y.YY

Summary of top 10 episodes by total cost

Episode	Number of episodes	Your cost per episode	Peers' cost per episode	Your cost index
Total (all episodes)	**XX**	**$X,XXX**	**$Y,YYY**	**1.2**
Your type of service cost index relative to peers'				
Hypertension	XX	$X,XXX	$Y,YYY	1.3
Your type of service cost index relative to peers'				
Coronary artery disease	XX	$X,XXX	$Y,YYY	1.0
Your type of service cost index relative to peers'				
Arrhythmias	XX	$X,XXX	$Y,YYY	0.8
Your type of service cost index relative to peers'				

Note: E&M (evaluation and management), PAC (post-acute care).

Existing episode grouper software packages do risk adjust for disease stages, patients' comorbid conditions, and other characteristics. The methods are somewhat similar to those included in the CMS–HCC risk-adjustment method used by Medicare to adjust Medicare Advantage plans' payments for the health status of their enrollees. An appropriate risk-adjustment method, such as CMS–HCC, should be used for beneficiary-level measures of resource use, such as per capita utilization.

We have conducted our analysis by comparing physicians only with others in the same specialty and the same metropolitan statistical area (MSA) (see text box, p. 71). This is a conservative methodology, in that it is less likely to find differences among physicians' efficiency than comparing against national averages. It also helps to offset one of the limitations of risk adjustment based on diagnoses: Individuals who receive more health services are likely to have more (and more serious) diagnoses coded than individuals who receive fewer health services, even when factors other than health, such as the supply of specialists, influence the amount of health services.

Some researchers have suggested comparing across specialties or geographic areas. If Medicare were to do so, it would be critical that the program not adjust away any spending differences that Medicare should be concerned about, such as spending differences correlated with differences in the supply of specialists. In other words, risk adjustment is designed to help match spending to patients. One expects patients who are old and sick to cost more than those who are young and healthy. Physicians should not be held accountable for these resulting spending differences; therefore, we try to risk adjust for these differences. However, patients' costs are influenced by other factors, such as the types of physicians they visit and where they live. Physicians should be held accountable for spending driven by some of these factors, and therefore one should measure these spending differences and not risk adjust for them.

Use multiple measures of resource use to produce more meaningful results

The physician feedback program should have the flexibility to measure physician resource use on both a per episode and a per capita basis (Figure 3-1). Both methods analyze claims data to better understand physicians' practice patterns. Episode-based methods group claims into clinically distinct episodes of care and then compare resource use for similar episodes. Per capita–based methods analyze total resource use for each patient or each beneficiary in an area. Together these measures more fully capture the relevant characteristics of physicians' practice patterns by revealing physicians' resources used in an episode and the number of episodes per patient. Relying on either measure alone could mask differences between physicians and even allow gaming such as generating more episodes to appear more efficient on a per episode basis. Additional measures—such as rate of prescribing generic drugs and use of basic versus advanced imaging—should also be included when warranted to produce a more complete picture of resource use. As a practical matter, however, the program cannot wait for implementation until all these measures are ready. Instead, the program should begin with as many appropriate measures as it reasonably can and transition to implementation of the full measurement set. The program should be flexible enough to weight or even exclude measures where appropriate.

Obtain physician input on resource use measurement program

The program will need to balance Medicare's need to make methodology decisions necessary to begin implementation with physicians' right to be fairly measured. In seeking this balance, the program will need—and has already begun—to obtain physician input. First, CMS's Physician Resource Use Measurement and Reporting Program obtains physician input through one-on-one interviews with select physicians who receive feedback under the program. Second, the Medicare program will need to continue to obtain physician input over time. To this end, the agency will need to consult with physicians and may want to consider working with formal physician advisory boards and through informal interactions with physician organizations and individual physicians. Third, CMS should include, as part of the physician proposed rule published each year, a description of planned changes to the resource measurement program's methodology, feedback process, or other issues. Finally, once Medicare implements confidential feedback, as long as it seeks physicians' reactions, it will essentially operate a continuous physician comment period.

Provide feedback to nonoutlier as well as outlier physicians

In principle, the feedback component of the resource use measurement program is intended to change the behavior of physicians. Some suggest providing feedback only to physicians whose clinical practices fall outside the norm (outliers), creating system inefficiency, adversely affecting quality, or both. In this case, feedback would

TABLE 3–1

Physicians' 2002 efficiency scores are highly correlated with their 2003 scores, using either multilevel or Monte Carlo models

MSA	Multilevel	Monte Carlo
Boston, MA	0.90	0.87
Greenville, SC	0.91	0.89
Miami, FL	0.88	0.86
Minneapolis, MN	0.86	0.84
Orange County, CA	0.89	0.84
Phoenix, AZ	0.90	0.88
Total	0.89	0.87

Note: MSA (metropolitan statistical area). Physicians with fewer than 20 episodes were excluded from the analysis. Correlation coefficients measure how the ranks of items in two different lists compare. A perfect correlation of 1.00 means that the items are at exactly the same rank in both lists. A coefficient of 0 means that there is no relationship between the rank of items on the two lists.

Source: MedPAC analysis of 100 percent sample of 2001–2004 Medicare claims using the Thomson Reuters Medical Episode Grouper®.

be provided only to physicians whose resource use exceeded a certain threshold, physicians who treated higher cost or more common conditions, or other subsets of physicians. Focusing on such outliers would be more feasible administratively and less costly, while offering the opportunity for some positive impact by altering the practice patterns of the most inefficient physicians.

Alternatively, advantages exist to providing feedback to most Medicare physicians. Giving detailed feedback to physicians across the entire efficiency distribution would allow even nonoutliers to recognize any of their own inefficient practices—such as ordering duplicative tests or overusing advanced imaging—and to work toward improving them. As a practical matter, however, the program could not be expected to provide feedback to all physicians who treat Medicare beneficiaries. Instead, the program is designed to measure and compare physicians' resource use with their peers' use only if they provide enough of a beneficiary's care to be considered responsible for the beneficiary or a given episode of care and if they treat enough beneficiaries and episodes to warrant comparison.

Measure and provide feedback to both individual physicians and group practices

The physician feedback program should use individual physicians as the basic building block of resource use measurement methodology but be capable of aggregating these measures in multiple ways—such as by physician group practice or by accountable care entities—for confidential feedback. This capacity will allow the program maximum flexibility in applying the measurement results in multiple ways to tailor feedback reports to best suit physicians' preferences. It also will allow the program to measure the nearly 40 percent of physicians who continue to work as solo practitioners (Hing and Burt 2008).

Focus on education and outreach

MIPPA requires that Medicare conduct education and outreach activities as part of the physician feedback program. Merely mailing physicians a feedback report is not enough. At a minimum, physicians need to be able to contact someone for answers to their questions. We learned through site visits that education and outreach are often neglected aspects of physician resource use measurement programs and that this oversight impairs these programs' chances of success. Given CMS's limited resources and numerous responsibilities, these new efforts will be challenging. CMS could partner with other entities, including physician organizations and specialty societies, to support physicians in interpreting feedback reports and using them to improve practice patterns. Another possible approach is to redirect the Quality Improvement Organizations' scopes of work to these efforts.

Other issues important to physician resource use measurement include stability of results over time and attribution methods

In our ongoing physician resource measurement analyses of using Medicare claims and episode grouper software, we most recently explored the stability of results over time and the trade-offs among different methods for deciding which physicians to hold responsible for a beneficiary's episode of care. The strong correlations in physicians' efficiency scores over time suggest that those scores are generally stable over time. The existence of advantages and drawbacks of various attribution methods means that CMS may need to consider using more than one attribution method in its fully implemented physician resource use measurement program.

Statistical methodology

The analysis to evaluate the year-to-year stability of physicians' efficiency scores was conducted by Thomson Reuters using the firm's Medical Episode Grouper® (Thomson Reuters 2009b). We used two statistical models to compare physicians' observed resource use with their peers' (expected) resource use. The two models build on the simple observed-to-expected ratios that are generally used. (Peers are defined as physicians in the same specialty in the same metropolitan statistical area (MSA).) In each case, the observed resource use is the same; what differs is the measure of expected resource use. Both the multilevel regression and the Monte Carlo randomization models calculate expected resource use taking into account case-mix variation. As in any calculation of a threshold, it is up to the judgment of the analyst to decide what threshold defines an outlier. To be conservative, we chose to set relatively high thresholds for identifying outlier physicians.

We used Medicare claims for beneficiaries living in six MSAs: Boston, MA; Greenville, SC; Miami, FL; Minneapolis, MN; Orange County, CA; and Phoenix, AZ. We standardized payments by excluding variation in resource costs due to geographic differences in input costs or policy considerations (e.g., teaching hospital payments). For this analysis, we wanted resources spent on, for example, a hospital admission for stroke to be comparable across geographic areas and facility types. Removing the effects of payment policies allowed us to conclude that underlying differences in clinical resource use were due to differences in practice patterns. ■

Physicians' efficiency scores are stable over time

To determine the stability of physician efficiency scores developed from our resource use analyses, we compared physicians' efficiency scores (measures of relative resource use) over two points in time—2002 and 2003 (Thomson Reuters 2009b). Correlations between 2002 and 2003 efficiency scores, weighted by each physician's average number of episodes per year, are shown in Table 3-1. The correlations were high, indicating good year-to-year stability in the efficiency scores using two statistical methods—one based on a multilevel model and the other based on a Monte Carlo model (see text box on statistical methodology). Physicians with high efficiency scores in 2002 tended to have high scores in 2003 and vice versa.

In addition to comparing all physicians' efficiency scores year to year, we further analyzed physicians whose efficiency scores qualified them as outliers in 2002. A physician was considered an outlier in 2002 if the physician's observed score differed statistically from his or her risk-adjusted expected score at the 0.0001 significance level. Further, that physician would be considered an outlier in both 2002 and 2003 if the physician's 2003 observed score also differed from his or her risk-adjusted score at the 0.05 level of statistical significance. Setting the threshold in this way gives us great confidence that we are not identifying false-positive outliers—that is, physicians whose practice styles appear unusually high because of random fluctuation. Using this definition, we found that of the 611 outliers in 2002, 572 (94 percent) were also outliers in 2003. The 6 percent of physicians who were labeled outliers in 2002 but not in 2003 may have been "false positives." Alternatively, it is possible that these physicians were truly outliers in 2002 and truly not outliers in 2003. One would expect some natural variation in physicians' efficiency from year to year.

Trade-offs between using single and multiple attribution

One of the main goals of grouping claims into episodes is to attribute the care provided during those episodes to particular physicians and ultimately to quantify how efficient their use of resources was for their patients. In the private sector, some plans—such as HMOs that use gatekeepers—formally assign patients to a primary care physician, so attribution is relatively straightforward. However, in other plan types and in the Medicare fee-for-service program, patients have the freedom to see any physician. This structure makes attribution less straightforward. In these cases, users of episode grouper software rely on patterns in claims data to attribute episodes to physicians.

TABLE 3–2

The number of physicians, the number of physicians who submitted any claim for at least 20 episodes, and the mean number of episodes per physician varied by MSA

	Total physicians		Physicians who submitted any claim for at least 20 episodes					
			2002			2003		
MSA	2002	2003	Number	Percent	Mean episodes per physician	Number	Percent	Mean episodes per physician
Boston, MA	16,495	17,191	11,111	67%	314	11,615	68%	337
Greenville, SC	2,715	2,948	2,137	79	623	2,254	76	613
Miami, FL	6,331	6,654	4,787	76	409	4,969	75	417
Minneapolis, MN	10,015	10,565	7,098	70	271	7,486	71	268
Orange County, CA	6,570	6,835	4,450	68	343	4,715	69	347
Phoenix, AZ	8,338	8,946	5,950	71	328	6,411	72	338
Total	50,464	53,139	35,533	70	343	37,450	70	352

Note: MSA (metropolitan statistical area). The 20-episode minimum was selected for illustrative purposes only.

Source: MedPAC analysis of 100 percent sample of 2001–2004 Medicare claims using the Thomson Reuters Medical Episode Grouper®.

A key question about how to attribute episodes to physicians is whether to use single attribution (holding a single physician responsible for the care provided) or multiple attribution (holding more than one physician responsible for the care provided). Single attribution is designed to identify the "decision maker," perhaps the primary care physician, and hold this individual responsible for all care rendered. Multiple attribution acknowledges that the decision maker, if there is one, has incomplete control over treatment by specialists and other physicians, even if the decision maker referred the patient to those other physicians.

For our analysis to date we have used a single attribution method with a 35 percent threshold of E&M dollars; that is, if a physician was responsible for at least 35 percent of the E&M dollars in a given episode, we attributed that episode, and all its costs, to that physician. Policymakers should not interpret our use of a 35 percent threshold of E&M dollars as a recommendation. In fact, attribution methods and their policy implications warrant further discussion.

Results of attribution analysis

There are significant trade-offs between attribution methods, so we wanted to examine whether a quantitative analysis yielded a clearly preferable method. To explore attribution methods, we compared resource measurement results using multiple attribution with those using single attribution. Table 3-2 shows—for each of the 6 MSAs examined in 2002 and 2003—the total number of physicians, the number of physicians who submitted any claim for at least 20 episodes (the required minimum for a physician to be included in the analysis), and the average number of episodes per physician (Thomson Reuters 2009a). (Researchers who use episode groupers generally agree that it is statistically invalid and unfair to calculate efficiency scores for physicians with too few episodes. We selected 20 episodes as a minimum for illustrative purposes; this selection should not be viewed as a policy recommendation.) The number of physicians who submitted any claim for at least 20 episodes was generally greater than the number of physicians who were attributed responsibility for episodes, which varied by attribution method. Within each MSA, the three sets of numbers were similar for the two years, whereas the three sets of numbers varied substantially by MSA. For example, the total number of physicians in each MSA ranged from fewer than 3,000 in Greenville to more than 16,000 in Boston.

We examined four methods of attributing episodes to physicians, based on a combination of the following variables: episodes associated with a single physician, episodes associated with multiple physicians, physician expenditures identified for E&M services (E&M dollars), and physician expenditures identified for all Medicare-

covered services (total dollars).[5] The four attribution methods are depicted in Figure 3-2. All four methods calculate ratios of observed-to-expected (O/E) resource use, using an average of episode-level O/E ratios, which we found to be preferable to calculating O/E ratios using ratios of average dollars.[6]

We compared results for each of the attribution methods. Both the choice of using single versus multiple attribution and using E&M versus total dollars affected the share of physicians to whom at least 20 episodes are attributed. As one would expect, the number of physicians who are attributed at least 20 episodes differed by attribution method, with multiple attribution methods resulting in more physicians meeting this threshold than single attribution methods (Table 3-3). Similarly, attribution methods based on total dollars resulted in more physicians meeting the 20-episode threshold than those based on E&M dollars, but this difference (total versus E&M) was smaller than the difference between multiple and single attribution methods.

TABLE 3–3

Multiple attribution based on total dollars produced the greatest number of physicians meeting the 20-episode minimum requirement for inclusion in our measurement analysis

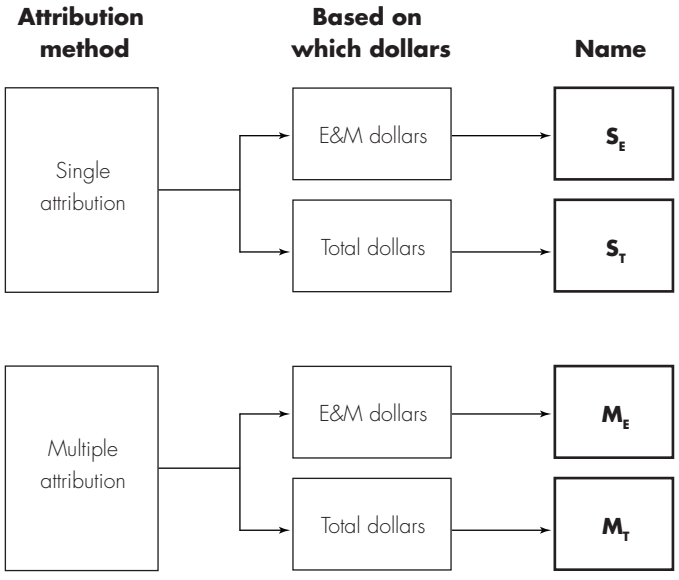
Attribution method	Name	Percentage of physicians attributed at least 20 episodes
Multiple attribution		
Based on total dollars	M_T	70.4%
Based on E&M dollars	M_E	55.6
Single attribution		
Based on total dollars	S_T	53.9
Based on E&M dollars	S_E	48.0

Note: E&M (evaluation and management). The 20-episode minimum was selected for illustrative purposes only.

Source: MedPAC analysis of 100 percent sample of 2001–2004 Medicare claims using the Thomson Reuters Medical Episode Grouper®.

FIGURE 3–2

Four methods for attributing episodes to physicians



Note: E&M (evaluation and management). Single attribution methods result in a weight of 1 for the physician attributed responsibility for the episode and 0 for all other physicians involved with the episode.

We were also interested in the effect different attribution methods had on physicians' O/E ratios. The correlations among the four attribution methods are shown in Table 3-4 (p. 74). These correlations are based on physicians to whom at least 20 episodes were attributed under both methods being compared, and the physicians were weighted by the average number of episodes in both methods. For example, if a physician had 20 episodes attributed using the multiple attribution based on E&M dollars (M_E attribution method) and 30 episodes using the single attribution based on E&M dollars (S_E attribution method), that physician would have been included in the calculation of the correlation between M_E and S_E with a weight of 25. Only the correlations for 2003 are shown; there was little difference between the 2002 correlations and the 2003 correlations.

Single attribution and multiple attribution indices give very similar results based on E&M dollars (0.97); the correlation is similarly high for indices based on total dollars (0.95). The correlations are somewhat lower—between 0.86 and 0.91—when comparing S_E and M_E indices with indices based on total dollars (S_T and M_T). Therefore, the attribution method selected does not significantly affect physicians' O/E ratios. Physicians who appear to be efficient (or inefficient) under one attribution

TABLE 3–4

Number of physicians being compared and correlations among attribution methods, 2003

Attribution method	M_E	M_T	S_E	S_T
M_E		29,563	25,529	25,690
M_T	0.91		25,529	25,690
S_E	0.97	0.87		25,690
S_T	0.86	0.95	0.87	

Note: M_E (multiple attribution based on evaluation and management (E&M) dollars), M_T (multiple attribution based on total dollars), S_E (single attribution based on E&M dollars), and S_T (single attribution based on total dollars). Correlation coefficients measure how the ranks of items in two different lists compare. A perfect correlation of 1.00 means that the items are at exactly the same rank in both lists. A coefficient of 0 means that there is no relationship between the rank of items on the two lists. Correlations among attribution methods are shown below the diagonal line. The numbers of physicians attributed at least 20 episodes under both methods being compared are shown above the diagonal line. The 20-episode minimum was selected for illustrative purposes only.

Source: MedPAC analysis of 100 percent sample of 2001–2004 Medicare claims using the Thomson Reuters Medical Episode Grouper®.

method generally appear to be efficient (or inefficient) under other attribution methods.

Finally, we compare the year-to-year stability in physicians' O/E ratios for the various attribution methods. The year-to-year correlations, shown in Table 3-5, tend to be fairly high for all of the attribution methods. The lowest correlation was 87 percent for the S_E attribution method and the highest correlation was 91 percent for the S_T and M_T methods. The lack of significant effect of attribution method on the year-to-year stability of physicians' O/E ratios also appears to rule out stability as a factor to use in deciding which attribution method would be optimal.

The lack of clear differentiation among attribution methods based on our statistical analysis means that there is no single "right" answer to the question of how to attribute episodes to physicians. Therefore, the choice among attribution methods probably comes down to a qualitative decision based on the policy goals of the program. For example, if Medicare would like physicians to focus more on the effects of their referrals, they might select a single attribution method. Alternatively, if Medicare wanted to trigger conversations among physicians caring for the same patient, the program might select a multiple attribution method. The final program may have reason and room for more than one attribution method.

Conclusion

The Commission has recommended that Medicare develop a physician resource use measurement program and confidential feedback program; this program was enacted by MIPPA and is being implemented by CMS. The

TABLE 3–5

Year-to-year correlations of physicians' observed-to-expected ratios are high for all four attribution methods

Attribution method	Name	Correlation in physicians' observed-to-expected ratios, 2002–2003
Multiple attribution		
Based on E&M dollars	M_E	0.89
Based on total dollars	M_T	0.91
Single attribution		
Based on E&M dollars*	S_E	0.87
Based on total dollars**	S_T	0.91

Note: E&M (evaluation and management). Correlation coefficients measure how the ranks of items in two different lists compare. A perfect correlation of 1.00 means that the items are at exactly the same rank in both lists. A coefficient of 0 means that there is no relationship between the rank of items on the two lists. Correlations are based on physicians with at least 20 attributed episodes in both years, and each physician was weighted for his or her average number of episodes per year. The 20-episode minimum was selected for illustrative purposes only.
* For single attribution, the physician with the most E&M dollars is given a weight of 1 for the episode and all other physicians are given a weight of 0.
** For single attribution, the physician with the most total dollars is given a weight of 1 for the episode and all other physicians are given a weight of 0.

Source: MedPAC analysis of 100 percent sample of 2001–2004 Medicare claims using the Thomson Reuters Medical Episode Grouper®.

program should begin with the best methodology possible, but it should not be delayed until all methodologic questions are addressed. The measures should be added to and refined as Medicare gains experience. As Medicare and physicians learn from confidential feedback and related activities, this experience should inform decisions about the future direction for the program, such as the possibility of adding public reporting and aligning activities with private payers.

Physicians' efficiency scores are generally stable over time. Attribution is one of the methodology questions that should continue to be explored. The choice between single and multiple attribution cannot be made based on statistical results alone. Therefore, the choice may hinge on other policy considerations, such as how best to spur discussion among physicians about their individual contributions to overall resource use. ■

Endnotes

1 There are exceptions—for example, the global surgical bundle pays for physician services before, during, and after operations.

2 E&M visits are separated into those for new patients and those for established patients.

3 The 12 sites used for the Community Tracking Survey are Boston, MA; Cleveland, OH; Greenville, SC; Indianapolis, IN; Lansing, MI; Little Rock, AR; Miami, FL; Northern New Jersey; Orange County, CA; Phoenix, AZ; Seattle, WA; and Syracuse, NY.

4 No risk-adjustment method predicts all costs. There is truly random variation that cannot be predicted at the individual level (e.g., being struck by a bus). Nor should a risk-adjustment method be expected to adjust away all cost differences. There is variation that should be examined by researchers and policymakers (e.g., geographic differences in utilization identified in the Dartmouth Atlas (Wennberg et al. 2008)). Both per capita and per episode methods for risk adjustment have improved over time and will continue to improve in their ability to appropriately account for cost variation. The Commission regularly analyzes potential refinements to risk adjustment. It is important that CMS use the best risk-adjustment methods available and implement refinements over time.

5 We examined eight attribution methods and include the four best here. For information on the other four methods, see the multiple attribution report (Thomson Reuters 2009a).

6 To calculate a ratio of averages for a given physician, one would calculate the mean of his or her observed payments and then divide this value by the mean of corresponding expected payments. Mathematically, the result differs from calculating an average of episode-level ratios by calculating an O/E ratio for each individual episode and then taking a mean.

References

Balas, E., S. Borch, G. Brown, et al. 1996. Effect of physician profiling on utilization: Meta-analysis of randomized clinical trials. *Journal of Internal Medicine* 11, no. 10: 584–590.

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2009. *2009 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.* Washington, DC: Boards of Trustees.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008a. Medicare program; payment policies under the physician fee schedule and other revisions to Part B for CY 2009; e-prescribing exemption for computer-generated facsimile transmissions; and payment for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Final rule. *Federal Register* 73, no. 224 (November 19): 69775–69824.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008b. VBP initiatives: Physician resource use. Baltimore: CMS. http://www.acc.org/advocacy/advoc_issues/MDI_conf_2008/CMS_PRU%20ACC%202008-10-30_CMS.ppt.

Government Accountability Office. 2007. *Medicare: Focus on physician practice patterns can lead to greater program efficiency.* GAO–07–307. Washington, DC: GAO.

Hing, E, and C. W. Burt. 2008. Characteristics of office-based physicians and their practices: United States, 2005–2006. *Vital and Health Statistics* 13, no. 166. http://www.cdc.gov/nchs/data/series/sr_13/sr13_166.pdf.

Ingenix. 2009. Ingenix makes market-leading Episode Treatment Groups® methodology available for public review. March 10. http://www.ingenix.com/News/Article/92/.

Medicare Improvements for Patients and Providers Act, Pub. L. No. 110–275, 122 Stat. 2494. 2008. Codified at 42 U.S.C. 1305 note § 131.

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

Milgate, K. 2008. *Use of Medicare information to improve health care delivery*. Baltimore: CMS. http://www.ftc.gov/bc/workshops/hcbio/docs/hcq/kmilgate.pdf.

Schoenbaum, S., and K. Murray. 1992. *Impact of profiles on Medicare practice*. Conference on profiling no. 92–2. Physician Payment Review Commission, paper no. 4: 72–102.

Thomson Reuters. 2009a. *Multiple attribution of episodes for physician profiling in Medicare*. New York: Thomson Reuters.

Thomson Reuters. 2009b. *The use of an episode grouper for physician profiling in Medicare.* New York: Thomson Reuters.

Wennberg, J., E. Fisher, D. Goodman, and J. Skinner. 2008. *Dartmouth atlas of health care 2008: Tracking the care of patients with severe chronic illness.* http://www.dartmouthatlas.org/atlases/2008_Chronic_Care_Atlas.pdf.

CHAPTER 4

Impact of physician self-referral on use of imaging services within an episode

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Impact of physician self-referral on use of imaging services within an episode

Chapter summary

There has been rapid technological progress in diagnostic imaging over the past several years, which has enabled physicians to diagnose and treat illness with greater speed and precision. Between 2002 and 2007, the volume per beneficiary of imaging services paid under Medicare's physician fee schedule grew nearly twice as fast as all physician services. Although the rate of growth slowed between 2006 and 2007, there are reasons to be concerned that some of the increased use in recent years may not be appropriate, which contributes to Medicare's growing financial burden on taxpayers and beneficiaries. First, the Government Accountability Office found an almost eightfold variation in per beneficiary spending on in-office imaging services across the states. Second, there is evidence that costly imaging services are mispriced under the physician fee schedule, thereby creating financial incentives to provide more imaging. Rapid growth in imaging may also be driven by technological innovation, defensive medicine, inconsistent adherence to clinical guidelines, an increase in imaging performed in physician offices, and other factors.

In this chapter

Although the rise of in-office imaging may improve access and convenience for patients, it might also lead to higher volume through additional capacity and financial incentives for physicians to refer patients for more tests. Several studies have found that physicians who furnish imaging services in their offices refer patients for more tests than other physicians. However, only two studies controlled for differences in patients' clinical conditions and only one examined whether physicians were referring patients to other members of their practices for imaging.

Given the limitations of prior research, we investigated whether physician self-referral is related to higher use of imaging, adjusting for differences in patients' clinical conditions and severity of illness, physician specialty, and market area. We used Medicare claims data to identify whether physicians referred patients to their practices for several types of imaging services, including computed tomography (CT), MRI, nuclear medicine, echocardiography, and standard imaging. In addition, we used Symmetry Episode Treatment Groups® (ETGs®) to classify beneficiaries by type of episode and patient severity; using ETGs allowed us to compare the observed imaging cost of a given episode with the average imaging cost of similar episodes (expected cost).

Our descriptive analyses of 2005 data revealed two key findings. First, a higher proportion of episodes with a self-referring physician received at least one imaging service than episodes with no self-referring physician. These differences were statistically significant for all but 1 of the 22 ETG-imaging types we examined. Second, episodes with a self-referring physician have higher ratios of observed-to-expected imaging spending than episodes with no self-referring physician. The ratios control for variations in beneficiaries' clinical condition and disease severity, market area, and physician specialty. The differences between the ratios ranged from 5 percent to 104 percent, depending on the ETG and type of imaging. These differences were statistically significant for all ETG-imaging types. Across all the ETGs and

imaging types we analyzed, the mean difference between the ratios was 68 percent.

We also used ETGs to investigate whether greater use of imaging within an episode is associated with higher or lower total episode spending. Some studies have found that the use of imaging in specific clinical circumstances saves money by preventing expensive interventions and hospital admissions or by reducing hospital length of stay. On the other hand, results from imaging may initiate a cascade of diagnostic tests and interventions, thereby increasing total episode costs. For each of the 13 ETGs we analyzed with 2005 data, we found that the ratio of observed-to-expected imaging spending was positively correlated with the ratio of observed-to-expected total episode spending. Although in specific cases an imaging study may substitute for other services, our finding suggests that greater use of imaging is associated with greater overall resource use for the types of episodes we examined, adjusting for patient severity and other factors. In addition, for the types of episodes we studied, greater use of specific types of imaging (e.g., nuclear medicine for ischemic heart disease) is associated with higher overall resource use during an episode. We also found that higher imaging use was positively correlated with higher procedure use, indicating that, on average, more spending on imaging is associated with slightly more spending on procedures during an episode.

In future work, we plan to analyze multiple years of data. We will use multivariate analyses to estimate the relative impact of various factors on the use of imaging during an episode, such as the self-referral status and specialty of physicians involved in the episode, the beneficiary's geographic location, and the number of physicians involved in the episode. Further, we will examine whether physicians order more imaging per episode after their practices begin performing in-office imaging and whether measures of appropriate imaging use can be linked to our data on self-referring physicians. In addition, we intend to explore policies to encourage more

prudent use of imaging services. One such option is to encourage greater adherence by physicians to appropriateness criteria developed by specialty societies; another option is to increase the size of the unit of payment in the physician fee schedule to include bundles of services that physicians often furnish together or during the same episode of care. ■

Background

The Commission recognizes that there has been rapid technological progress in diagnostic imaging over the past several years, which has enabled physicians to diagnose and treat illness with greater speed and precision. Between 2002 and 2007, the volume of imaging services paid under Medicare's physician fee schedule grew by 44 percent per fee-for-service (FFS) beneficiary, compared with 23 percent volume growth per beneficiary for all physician services (MedPAC 2009). Although the rate of growth slowed to 3.8 percent between 2006 and 2007 (compared with 2.9 percent growth for all physician services), there are reasons to be concerned that some of the increased use in recent years may not be appropriate. First, the Government Accountability Office (GAO) found an almost eightfold variation in per beneficiary spending on in-office imaging services across the states in 2006 (GAO 2008). According to GAO, the magnitude of this variation suggests that these differences are more likely related to variation in physician practice patterns than patients' health status. Second, there is evidence that costly imaging services are mispriced under the physician fee schedule, thereby creating financial incentives to provide more imaging (MedPAC 2009).

Increased use of imaging contributes to Medicare's growing financial burden on taxpayers and beneficiaries. In addition, certain types of imaging expose beneficiaries to ionizing radiation, which is associated with an increased risk of developing cancer. A recent report estimates that the U.S. population's per capita dose of radiation from medical imaging increased almost 600 percent from the early 1980s to 2006 (National Council on Radiation Protection and Measurements 2009). This increase was due mostly to higher use of computed tomography (CT) and nuclear medicine studies. Although an individual's risk of developing cancer from a single test is small, these risks are being applied to a growing number of patients.

Many factors appear to be driving imaging use, including:

- technological innovation and new clinical applications for imaging,
- incentives in Medicare's FFS payment systems,
- defensive medicine,
- consumer demand for diagnostic tests,
- lack of research on the impact of imaging on clinical decision making and patient outcomes,
- inconsistent adherence to clinical guidelines, and
- physician ownership of imaging equipment and opportunities to earn ancillary revenue (Douglas 2006, Douglas et al. 2006, GAO 2008, Gibbons et al. 2008, Hadley et al. 2006, Hendel 2009, Iglehart 2009, MedPAC 2009, MedPAC 2005a, NCQA 2006).

Recent research points to an expansion of in-office imaging as many physicians purchase machines for their offices. The Stark self-referral law contains an exception that allows group practices to provide imaging services to patients in their offices (see text box, p. 86). According to a survey sponsored by the Commission in 2006, almost 20 percent of physicians reported that they had expanded their use of in-office imaging in the past year (MedPAC 2007a). GAO found that physician offices accounted for 64 percent of imaging spending under the physician fee schedule in 2006, compared with 58 percent in 2000 (GAO 2008). Physicians in several specialties that provide in-office imaging—other than radiology—have obtained an increasing share of their Medicare revenue from imaging; for example, between 2000 and 2006, the share of cardiologists' revenue related to in-office imaging grew from 23 percent to 36 percent (GAO 2008).

Although the rise in physician ownership of imaging equipment may improve access and convenience for patients, it may also lead to higher volume through additional capacity and financial incentives for physicians to refer patients for more tests. Proponents claim that in-office imaging improves quality of care and patient convenience (Casalino 2008, Kouri et al. 2002). According to one study, patients are more likely to receive imaging on the same day as their office visit for seven clinical conditions if their physician self-refers for imaging services (Gazelle et al. 2007). However, the rate of same-day imaging for patients of self-referring physicians ranged from 11.5 percent (nuclear medicine studies for patients with cardiac or coronary disease) to 91.5 percent (radiography for knee pain), indicating that many imaging studies are scheduled in advance. The ability to provide tests on the day of an office visit may enable physicians to develop treatment plans more quickly. Supporters of in-office imaging also contend that physicians can better supervise the quality of imaging performed in their office.

The Stark law allows physician practices to provide in-office imaging

The Ethics in Patient Referrals Act, also known as the Stark law, prohibits physicians from referring Medicare or Medicaid patients for "designated health services" (DHS)—such as imaging, hospital services, radiation therapy, home health, and physical therapy—to entities with which they have a financial relationship, unless the relationship fits within an exception. For example, physicians are prohibited from referring patients to an imaging center or clinical lab that they own. However, a provision in the law—called the in-office ancillary exception—allows group practices to provide most DHS, including imaging, in their own offices (42 CFR § 411.355). When the law was enacted, this exception was expected to apply mostly to in-office laboratory tests or X-rays, recognizing that a need often exists for a quick turnaround time on crucial tests (Congressional Record 1989). However, the exception protects all imaging services, as long as they are provided and billed under certain conditions.[1]

The in-office ancillary exception prohibits group practices from compensating their physicians in a manner that directly or indirectly reflects their referrals for imaging or other DHS (42 CFR § 411.352) (Johnson and Walker Keegan 2006). However, the Stark rules allow practices to allocate profits from imaging to physicians in the practice using certain indirect methods, such as on a per capita basis or based on the practice's distribution of revenue from non-DHS services. In addition, practices may create separate pools of profits from imaging and other DHS services for separate subgroups of physicians, as long as each subgroup has five or more physicians. Physician subgroups may be based on specialty, practice location, level of referrals for ancillary services, or other factors (Johnson and Walker Keegan 2006). The pool of profits may be distributed to each physician in the subgroup on a per capita basis or by another indirect method.

In addition to practices providing imaging services in their own offices, arrangements exist in which a physician practice leases a block of time from an imaging provider or agrees to pay the provider a per service (per click) fee to use its equipment. The practice then refers its patients to the imaging provider for imaging studies and bills the insurer for the services, profiting from the difference between the insurer's payment rate and the fee paid by the practice to the imaging provider. According to data from a California health plan, more than 60 percent of the physicians who billed the insurer for MRI or CT scans engaged in such arrangements (Mitchell 2007). These arrangements may comply with the Stark law's in-office ancillary exception if certain conditions are met—for example, if the provider that performs the imaging study is located in the same building where the referring physician furnishes non-DHS services (42 CFR § 411.355).[2] Under a new CMS rule, however, imaging providers that are enrolled in Medicare as independent diagnostic testing facilities (IDTFs) may not lease their operations to or share testing equipment with other organizations (42 CFR § 410.33). Although this rule prohibits leasing arrangements between group practices and IDTFs, group practices may still engage in block of time or per click leases with other practices. ■

On the other hand, physician acquisition of imaging equipment could lead to greater overall capacity, and evidence suggests that additional machines in a market are associated with higher volume. A recent article estimated that each additional MRI scanner in a market is associated with 733 additional MRI studies among Medicare beneficiaries, and each additional CT machine is associated with 2,224 additional CT scans (Baker et al. 2008). The study also estimated that, between 1995 and 2004, the number of MRI scanners in the United States more than doubled and the number of CT scanners increased by more than 50 percent.

Physicians who purchase machines for their offices have a financial incentive to refer patients for additional services, as long as those services are profitable. Although physicians are usually motivated by professional ethics and concern for their patients' best interests, physician ownership could influence the clinical judgment of some physicians, particularly when there is not strong evidence to guide their decisions. Some physicians have noted the

TABLE 4–1 **Methodologies of selected studies of physician self-referral and use of imaging**

	Hillman et al. 1992	GAO 1994	Gazelle et al. 2007	MedPAC analysis
Physician is defined as self-referring if…	Same physician orders and performs at least one imaging study	More than 50 percent of studies ordered by physician are performed by his/her practice	All imaging ordered by physician is interpreted by himself/herself or providers in the same specialty	More than 50 percent of studies ordered by physician are performed by his/her practice
Unit of analysis	Percent of episodes with imaging, charges per episode	Number of tests ordered per 1,000 office visits	Percent of episodes with imaging	Percent of episodes with imaging, ratio of observed-to-expected imaging spending per episode
Data source	United Mine Workers' claims,1988–1989	Medicare claims from Florida, 1989–1991	Claims from large national health plan, 1999–2003	Medicare claims from six markets, 2005 (100 percent)
Adjustment for clinical episode?	Yes (10 types of episodes)	No	Yes (6 types of episodes)	Yes (13 types of episodes)
Adjustment for patient severity within episode?	No	No	Adjustment for patient's age and number of comorbidities	Adjustment for comorbidities, complications, treatment, and patient severity*
Adjustment for physician specialty?	Yes	Yes	No	Yes*

Note: GAO (Government Accountability Office).
*The analysis of the ratios of observed-to-expected imaging spending adjusted for these factors; the analysis of the percent of episodes with imaging did not.

Source: GAO 1994, Gazelle et al. 2007, Hillman et al. 1992.

paucity of research on the impact of imaging on physician decision making and patient outcomes (Douglas et al. 2006, Redberg and Walsh 2008).

Several studies have found that physicians who own imaging facilities or furnish imaging services in their offices refer patients for more imaging than other physicians (see text box, pp. 88–89). The studies did not ascertain whether the additional services improved quality of care or outcomes. Only two of the studies grouped patients by clinical condition and only one examined whether physicians were referring patients to other members of their practices for imaging (Table 4-1).

Given the limitations of prior research, we investigated whether physician self-referral for imaging services is related to higher use of imaging, adjusting for differences in patients' clinical conditions and severity of illness, physician specialty, and market area. We used Medicare claims data to identify whether physicians referred patients to their practices for imaging services, and we used Symmetry Episode Treatment Groups® (ETGs®), an Ingenix, Inc., product, to classify beneficiaries by condition and illness severity. As in previous studies, we did not evaluate whether more imaging led to improved outcomes. Table 4-1 compares the methodology used for our study with that of other studies.

We also used ETGs to investigate whether greater use of imaging within an episode is associated with higher or lower total episode spending. Some studies have found that the use of imaging in specific clinical circumstances saves money by preventing expensive interventions and hospital admissions or by reducing hospital length of stay (Rao et al. 1998, Ross et al. 2007, Wardlaw et al. 2004). On the other hand, results from imaging studies may initiate a cascade of diagnostic tests and interventions, thereby increasing total episode costs (Deyo 2002).

Literature on the relationship between physician self-referral and imaging use

Several studies have found that physician investment in imaging facilities or equipment is associated with higher volume (Baker 2008, GAO 1994, Gazelle et al. 2007, Hillman et al. 1992, Hillman et al. 1990, Kouri et al. 2002, Litt et al. 2005). A study by the Government Accountability Office (GAO) found that physicians in Florida who were investors in diagnostic imaging centers referred their Medicare patients more frequently for MRI, computed tomography (CT), nuclear medicine, and ultrasound studies than nonowners (GAO 1994). Some of the differences were dramatic: Imaging center owners ordered twice as many MRI scans and 29 percent more CT scans for their patients than nonowners. GAO also found that physicians who were members of practices that performed in-office imaging ordered studies more frequently than physicians who referred patients to outside facilities. For example, physicians with MRI machines in their offices ordered about three times as many MRI scans per 1,000 office visits as other physicians. Cardiologists who performed echocardiography in their offices ordered 2.6 times as many echocardiograms as other cardiologists. The GAO report adjusted for physician specialty but did not control for the health status of patients treated by each physician or address whether the additional services were appropriate.

A study by Hillman and colleagues examined the use of imaging for patients with 10 common clinical episodes (e.g., chest pain, congestive heart failure, and knee pain) (Hillman et al. 1992). This analysis, which was based on claims for primarily elderly patients covered by the United Mine Workers of America Health and Retirement Funds, found that physicians who performed imaging services in their offices were more likely to use imaging than physicians who referred their patients to a radiologist for imaging. Depending on the type of episode, self-referring physicians were 1.7 to 7.7 times more likely to order at least one imaging study during an episode than other physicians. The results were similar when the researchers adjusted for physician specialty. The study also found that self-referring physicians had higher mean imaging charges per episode than non-self-referring physicians.[3] Although the authors controlled for type of clinical condition, they did not adjust for patients' comorbidities or complications within a condition. The study did not attempt to determine whether the additional tests ordered by self-referring physicians were inappropriate.

(continued next page)

Is physician self-referral associated with additional use of imaging in an episode?

Following earlier studies examining the effect of physician self-referral on the use of imaging services, we analyzed whether physician self-referral might affect the use of imaging within an episode of care. Our methodology allowed us to compare the observed cost of a given episode with the average cost of similar types of episodes in the same market area (the expected cost). Two key results emerged: (1) compared with episodes with no self-referring physician, a higher proportion of episodes with a self-referring physician received at least one imaging service, and (2) episodes with a self-referring physician had higher-than-expected spending on imaging, while episodes with no self-referring physician had lower-than-expected spending on imaging.

Defining self-referring physicians

To identify whether physicians self-referred for different imaging modalities, we used 100 percent of Medicare claims from 2005 for beneficiaries in six markets (Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN; and Phoenix, AZ). These markets, which are located in different parts of the United States and have different levels of per capita Medicare spending, have been used in prior Commission research

Literature on the relationship between physician self-referral and imaging use (cont.)

Likewise, a more recent study found that self-referring physicians used imaging more frequently than physicians who referred patients to radiologists (Gazelle et al. 2007). This study, which used data from a large national health plan, examined patients in six clinical episodes based on Symmetry Episode Treatment Groups® (ETGs®).[4] Physicians were classified as self-referring if they referred patients to themselves or to other physicians in the same specialty for imaging services (physicians in the same specialty could represent partners in the same practice). The study found that patients of self-referring physicians were 10 percent to 130 percent more likely to receive an imaging study during the episode than patients of radiologist-referring physicians, depending on the ETG. Similarly, when the researchers adjusted for each patient's age and number of comorbidities, most of the ETGs demonstrated higher use of imaging by self-referring physicians.[5] A weakness of the study is that physicians in the same specialty may not be members of the same practice, in which case the referring physician probably would not benefit financially from the referral.[6]

In a study presented at a public Commission meeting, Laurence Baker found that patients of neurologists and orthopedic surgeons who owned MRI machines were more likely to receive an MRI scan within seven days of an office visit than patients of neurologists and orthopedic surgeons who did not own MRI machines (Baker 2008). For example, 14.5 percent of patients who saw a neurologist who owned a machine received an MRI scan within seven days of their visit, compared with 9.3 percent of patients who saw other neurologists. This analysis used Medicare claims data from 1999 through 2005. Baker also used a regression model to examine the impact of acquiring an MRI machine on a physician's likelihood of ordering MRI studies, controlling for physician and patient characteristics. Acquiring an MRI scanner led to a 22 percent increase in the probability of ordering MRI scans by orthopedic surgeons and a 28 percent increase in the probability of ordering MRI scans by neurologists.

A study of California workers' compensation cases concluded that self-referring physicians were more likely than other physicians to order medically inappropriate MRI scans (Swedlow et al. 1992). The researchers, who examined about 500 MRI scans, found that 38 percent of the scans ordered by physicians with an ownership interest in an MRI facility were determined to be inappropriate during a precertification review. By contrast, 28 percent of the scans ordered by physicians without such an ownership interest were found to be inappropriate. ■

(MedPAC 2007b, MedPAC 2006). We examined seven different types of imaging, or modalities: CT (head), CT (other), MRI (brain), MRI (other), nuclear medicine, echocardiography, and standard imaging. Although we explored various definitions of a self-referring physician, our primary definition is one who refers more than 50 percent of the imaging studies that he or she orders to his or her practice.[7] For one of our analyses, we tested a less restrictive definition based on whether a physician refers at least 1 percent of the imaging services that he or she orders to his or her practice. We examined physicians' referral patterns for each imaging modality to determine modality-specific self-referral categories.

Consistent with previous Commission work, we assume that physicians who share the same tax number are in the same practice (MedPAC 2007b). However, a physician affiliated with multiple practices may bill under multiple tax numbers. In these cases, we have assigned physicians the tax number that appears on the plurality of their Medicare claims.

Because our definition of self-referral is based on Medicare claims data, which do not indicate where a test was performed, we are unable to determine whether the imaging study was performed in the practice's office or by another provider with whom the practice has a leasing arrangement. According to an analysis of data from a California insurer, more than 60 percent of the physicians

who billed the insurer for MRI or CT scans did not own the equipment; rather, they leased time from an imaging provider or paid the provider a set fee to perform the scan (Mitchell 2007). As described in the text box on p. 86, such arrangements may be structured to comply with the in-office ancillary exception to the Stark law.

Regardless of whether the study is performed on equipment owned by the practice or through a leasing arrangement with another provider, we assume that most physicians who refer patients to their practice for imaging services benefit indirectly from their referrals, as long as they are profitable for the practice. As described in the text box on p. 86, the Stark self-referral rules allow a group practice to use indirect methods to allocate profits from imaging to physicians in the practice, such as on a per capita basis or based on the distribution of nonancillary revenue. However, the rules allow a practice to allocate profits from imaging to a subset of five or more physicians, meaning that some physicians in the practice may not receive profits from imaging. In addition, the Stark law prohibits physicians who have a direct employment relationship with a hospital from being compensated based on their imaging referrals to the hospital, either directly or indirectly (Johnson and Walker Keegan 2006). Because we do not have data on the compensation methods of individual practices, we are not able to fully distinguish between physicians who benefit financially from referrals and those who do not. Therefore, our analysis may include some physicians who refer patients to their practices for imaging services but do not receive a share of the imaging profits. Including these physicians in the self-referral category reduces the likelihood of finding a significant difference between self-referring and non-self-referring physicians.

Although we can tell if a physician's practice bills Medicare for performing imaging studies, we are unable to detect other financial relationships that might influence physician referrals. For example, if a physician invests in a hospital, we would not know about his or her financial interest in the hospital's imaging equipment. Thus, our comparison group of non-self-referring physicians may include some who have a financial interest in imaging, which might bias our study toward finding no difference between self-referring and non-self-referring physicians.

Grouping claims into episodes and selecting episodes for analysis

Medicare claims from 2005 for beneficiaries in the six markets were grouped by Ingenix into clinical episodes using the ETGs episode grouper (version 7.0). The Commission has used ETGs and other groupers in prior work, and Chapter 3 in this report describes additional work using episode groupers (MedPAC 2007b, MedPAC 2006). Episode groupers are software packages that use clinical logic to assign claims to distinct episodes of care—a series of clinically related health care services over a defined time period, such as all claims related to a patient's diabetes. Episode groupers use all types of health care claims: inpatient admissions, physician visits, other outpatient services, and prescription drugs.[8] The ETGs software groups claims into episodes based on the patient's underlying condition, complications, comorbidities, treatment, and severity level.[9] In March 2009, Ingenix released its ETGs grouper methodology for public review and comment (Ingenix 2009).

For our analysis, we selected 13 ETGs that represent a broad range of conditions and imaging modalities and are treated by a variety of specialties (Table 4-2). For 10 of the ETGs, imaging accounted for at least 10 percent of overall resource use, on average. For each ETG, we selected one or two modalities that accounted for the largest share of imaging dollars within the episode type, for a total of 22 ETG-imaging categories.

Assigning physicians to episodes and categorizing episodes

We assigned physicians to an episode of care if they provided an evaluation and management (E&M) office visit that was part of the episode.[10] Almost two-thirds of the episodes (across all 13 ETGs) had only one physician who provided an office visit; one-quarter had two physicians and 11 percent had three or more. If an episode had multiple office visits provided by different physicians, each physician would be assigned to the episode. We used this method because each of the physicians who provided an office visit during the episode could have decided to order an imaging test.

Next, we divided all the episodes within an ETG into three categories:

- episodes in which at least one physician who met our primary definition of self-referral (more than 50 percent of the imaging studies ordered by the physician were performed by his or her practice) provided an E&M office visit;
- episodes in which no physician who met our primary definition of self-referral provided an office visit,

TABLE 4–2 **Type of episodes selected for analysis**

Type of episode (ETG®)	Primary imaging modalities	Primary specialties	Share of total dollars spent on imaging (all modalities), 2005
Cerebral vascular accident	MRI: brain, CT: head	Internal medicine, neurology, family practice	10.2%
Spinal trauma	MRI: other	Internal medicine, orthopedic surgery, family practice	6.0
Migraine headache	MRI: brain	Neurology, family practice, internal medicine	21.1
Ischemic heart disease	Echocardiography, nuclear medicine	Cardiology, internal medicine, family practice	9.8
Congestive heart failure	Echocardiography, nuclear medicine	Internal medicine, cardiology, family practice	3.8
Valvular disorder	Echocardiography, nuclear medicine	Cardiology, internal medicine, family practice	22.5
Malignant neoplasm of pulmonary system	CT: other	Internal medicine, hematology/ oncology, pulmonary disease	15.4
Kidney stones	CT: other	Urology, internal medicine, family practice	16.0
Joint degeneration, localized—back	Standard imaging, MRI: other	Internal medicine, family practice, orthopedic surgery	14.8
Joint degeneration, localized—neck	Standard imaging, MRI: other	Internal medicine, family practice, orthopedic surgery	15.7
Joint derangement—knee and lower leg	Standard imaging, MRI: other	Orthopedic surgery, family practice, internal medicine	16.4
Bursitis and tendonitis—shoulder	Standard imaging, MRI: other	Orthopedic surgery, internal medicine, family practice	13.8
Other minor orthopedic disorders—back	Standard imaging, MRI: other	Internal medicine, family practice	17.6

Note: ETG® (Symmetry Episode Treatment Groups®, an Ingenix, Inc., product), CT (computed tomography). Primary specialties are the specialties that account for at least 10 percent of the evaluation and management office visits for an ETG®.

Source: MedPAC analysis of 100 percent Medicare claims data from six markets (Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN; and Phoenix, AZ) using ETGs® version 7.0.

but at least one physician with a lower level of self-referral (referring between 1 percent and 50 percent of the imaging studies he or she ordered to his or her practice) furnished an office visit; and

- episodes in which no physician who met either definition of self-referral provided an E&M office visit.

To compare physicians with strong self-referral patterns with non-self-referring physicians, we dropped episodes in the middle category from our analyses. However, our risk-adjusted analysis (described below) tests the sensitivity of combining the first two categories into a single self-referral category.

Research suggests that radiologists can influence the ordering of imaging by making recommendations for

follow-up studies in their reports to the ordering physician (Lee et al. 2007).[11] Non-self-referring physicians are more likely to refer patients to radiologists for imaging studies; hence, any influence of radiologists on follow-up testing would be present in the comparison group of episodes with no self-referring physician (Gazelle et al. 2007, Hillman et al. 1992).

Methodology for basic and risk-adjusted analyses

We used the episode data to perform a basic descriptive analysis—with no adjustments for patient severity within the episode, geographic market, or physician specialty—and a risk-adjusted analysis that controlled for these factors. In the basic analysis, we calculated the proportion of episodes with and without a self-referring physician that received at least one imaging service for each ETG and modality (e.g., ischemic heart disease and nuclear medicine). This analysis included 493,000 episodes from 2005 across all 13 ETGs. On the basis of prior research, we expected to find that a higher proportion of episodes with a self-referring physician received an imaging study than episodes with no self-referring physician.

In our risk-adjusted analysis, we calculated the ratio of observed-to-expected spending for specific imaging modalities (e.g., CT (head)) for each ETG. The observed value equals the amount of spending for a particular episode. The expected value is based on average spending for episodes within a fairly narrow category: the same ETG (which varies depending on whether there are complications, comorbidities, or specific treatments), patient severity level, geographic market, and the specialty of the physician responsible for at least 35 percent of the E&M payments.[12] Thus, a ratio describes the costliness of an episode relative to similar episodes and patients. Imaging spending includes payments made by Medicare under the physician fee schedule and the hospital outpatient prospective payment system. The payment amounts for each claim within an episode have been standardized to remove the effects of geographic payment adjustments. The payments have been normalized to a base year (2001) because some of Medicare's payment systems are updated on a fiscal year, rather than a calendar year, basis. Thus, payment rates may change within a calendar year. Normalizing payments to a base year also facilitates comparisons across multiple years, which we plan to do in future work.

As part of our risk-adjusted analysis, we identified episodes that had a claim for an imaging interpretation (the professional component) but lacked an associated technical component claim for performing the imaging study. Such episodes might have had an imaging service provided during an inpatient stay, in which case there would be no technical component claim because Medicare's inpatient payment rate includes any facility services provided during the admission. Alternatively, the technical component claim associated with the professional component claim might have had a different diagnosis code, procedure code, or beneficiary identification number, in which case it could have been grouped with a different episode. In either case, the amount of imaging spending for the episode would be lower than for an episode in which a technical component claim is present. To avoid the possibility that such episodes (about 5 percent of the total) could bias our results, we did not include them in our ratio calculations.[13]

For the episodes in each self-referral category, we computed the mean ratio of observed-to-expected spending on imaging. This analysis included 443,000 episodes from 2005 across all 13 ETGs. On the basis of prior research, our hypothesis was that episodes linked to self-referring physicians would have higher ratios of observed-to-expected spending on imaging.

Results of analyses

We first present results from our basic analysis, which show that a greater proportion of episodes with a self-referring physician received at least one imaging service than episodes with no self-referring physician (Table 4-3). The magnitude of the variation ranges from 2 to 23 percentage points. In all but one case (malignant neoplasm of the pulmonary system and CT (other)), the differences are statistically significant using a univariate logistic regression. Although this analysis controls for the type of episode and imaging modality, it does not adjust for severity of illness within the episode, physician specialty, or the market area; our risk-adjusted analysis controls for these factors.

The results in Table 4-3 are comparable to previous research demonstrating that self-referring physicians are more likely to order imaging. The study by Gazelle and colleagues found that the proportion of episodes with self-referring physicians that received at least one imaging study was 1.5 to 14.0 percentage points higher than

TABLE 4–3

Episodes with a self-referring physician are more likely to receive at least one imaging service, 2005

ETG® and type of imaging	Percent of episodes with imaging				Number of episodes	
	Episodes with self-referring physician	Episodes with no self-referring physician	Percentage point difference	Ratio	With self-referring physician	With no self-referring physician
Cerebral vascular accident—MRI: brain	37%	25%	12	1.5	1,774	43,822
Cerebral vascular accident—CT: head	36	29	7	1.3	1,483	43,892
Spinal trauma—MRI: other	37	22	15	1.7	505	6,570
Migraine headache—MRI: brain	14	8	6	1.5	311	7,393
Ischemic heart disease—nuclear medicine	38	19	19	2.0	72,361	94,956
Ischemic heart disease—echocardiography	50	27	23	1.8	74,397	69,284
Congestive heart failure—nuclear medicine	12	7	5	1.7	12,299	32,169
Congestive heart failure—echocardiography	36	26	10	1.4	13,561	25,422
Valvular disorder— nuclear medicine	16	8	8	2.1	10,123	12,323
Valvular disorder—echocardiography	67	46	21	1.5	11,451	8,397
Malignant neoplasm of pulmonary system—CT: other	75	73	2	1.0	459	5,807
Kidney stones—CT: other	58	50	8	1.2	718	7,919
Joint degeneration, localized, back—MRI: other	40	27	13	1.5	9,268	86,915
Joint degeneration, localized, back—standard imaging	60	38	22	1.6	39,913	39,880
Joint degeneration, localized, neck—MRI: other	35	22	13	1.6	2,608	29,521
Joint degeneration, localized, neck—standard imaging	58	35	23	1.6	13,315	13,400
Joint derangement, knee and lower leg—MRI: other	61	53	8	1.1	1,299	6,769
Joint derangement, knee and lower leg—standard imaging	72	58	15	1.3	5,513	1,820
Bursitis and tendonitis, shoulder—MRI: other	26	14	12	1.9	1,683	11,969
Bursitis and tendonitis, shoulder—standard imaging	59	38	21	1.6	7,645	4,033
Other minor orthopedic disorders, back—MRI: other	14	6	8	2.3	705	12,372
Other minor orthopedic disorders, back—standard imaging	38	24	14	1.6	3,546	6,525

Note: ETG® (Symmetry Episode Treatment Groups®, an Ingenix, Inc., product), CT (computed tomography). Episodes with imaging have at least one physician fee schedule or hospital outpatient department claim for a given type of imaging service. For each type of imaging, a self-referring physician is one who referred more than 50 percent of the imaging services he or she ordered during the year to his or her practice. Physicians were assigned to an episode if they provided an evaluation and management office visit during the episode. Except for malignant neoplasm of the pulmonary system, the difference between episodes with a self-referring physician and episodes with no self-referring physician is statistically significant ($p < 0.05$) using a univariate logistic regression for all comparisons. Percentage point differences reflect the effects of rounding.

Source: MedPAC analysis of 100 percent Medicare claims data from six markets (Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN; and Phoenix, AZ) using ETGs® version 7.0.

episodes with radiologist-referring physicians, depending on the ETG (Gazelle et al. 2007). Depending on the clinical condition, Hillman and colleagues found that the proportion of episodes with self-referring physicians that received at least one imaging study was 6 to 47 percentage points higher than episodes without self-referring physicians (Hillman et al. 1992).

For our risk-adjusted analysis, we compared imaging spending for episodes with and without a self-referring physician by computing the mean ratio of observed-to-expected spending on imaging for each ETG and modality. The expected spending level for each episode varies by its ETG, modality, patient severity level, geographic market, and physician specialty.

As shown in Table 4-4 (p. 94), episodes with a self-referring physician have a higher mean ratio of observed-to-expected spending for an imaging modality than episodes with no self-referring physician. The differences

TABLE 4–4

Episodes with a self-referring physician have higher ratios of observed-to-expected imaging spending, by ETG® and type of imaging, 2005

	Mean ratio of observed-to-expected imaging spending			Number of episodes	
ETG® and type of imaging	Episodes with self-referring physician	Episodes with no self-referring physician	Percent difference	With self-referring physician	With no self-referring physician
Cerebral vascular accident—MRI: brain	1.39	0.96	45%	1,470	31,606
Cerebral vascular accident—CT: head	1.49	0.97	55	1,142	29,553
Spinal trauma—MRI: other	1.43	0.94	53	393	3,111
Migraine headache—MRI: brain	1.76	0.95	85	267	4,383
Ischemic heart disease—nuclear medicine	1.37	0.69	100	69,225	89,462
Ischemic heart disease—echocardiography	1.35	0.69	96	67,808	60,414
Congestive heart failure—nuclear medicine	1.54	0.75	104	11,137	28,543
Congestive heart failure—echocardiography	1.44	0.74	96	11,335	20,104
Valvular disorder—nuclear medicine	1.31	0.72	83	9,504	10,911
Valvular disorder—echocardiography	1.15	0.81	42	10,804	7,081
Malignant neoplasm of pulmonary system—CT: other	1.12	0.97	15	392	3,306
Kidney stones—CT: other	1.32	0.95	39	633	4,747
Joint degeneration, localized, back—MRI: other	1.18	0.96	23	8,980	82,720
Joint degeneration, localized, back—standard imaging	1.20	0.82	47	38,260	36,687
Joint degeneration, localized, neck—MRI: other	1.27	0.95	34	2,481	27,140
Joint degeneration, localized, neck—standard imaging	1.20	0.81	49	12,461	12,170
Joint derangement, knee and lower leg—MRI: other	1.03	0.98	5	1,251	6,322
Joint derangement, knee and lower leg—standard imaging	1.02	0.96	6	5,312	1,625
Bursitis and tendonitis, shoulder—MRI: other	1.20	0.93	29	1,616	11,268
Bursitis and tendonitis, shoulder—standard imaging	1.10	0.90	22	7,352	3,642
Other minor orthopedic disorders, back—MRI: other	1.52	0.95	59	690	11,673
Other minor orthopedic disorders, back—standard imaging	1.14	0.93	23	3,443	5,931

Note: ETG® (Symmetry Episode Treatment Groups®, an Ingenix, Inc., product), CT (computed tomography). This analysis excludes episodes in which there is a claim for interpreting an imaging study but no claim for performing an imaging study; in these episodes, either the imaging study was provided during an inpatient stay or the claim for performing the study is missing from the episode. The expected value in the ratio equals average spending for episodes within the same ETG®, patient severity level, geographic market, and physician specialty. Thus, the ratios describe the costliness of an episode relative to similar types of episodes. The spending amounts have been standardized to remove the effects of geographic payment adjustments. For each type of imaging, a self-referring physician is one who referred more than 50 percent of the imaging services he or she ordered during the year to his or her practice. Physicians were assigned to an episode if they provided an evaluation and management office visit during the episode. The difference between episodes with a self-referring physician and episodes with no self-referring physician is statistically significant ($p < 0.05$) for all comparisons using a Wilcoxon rank order test. The statistical testing does not adjust for the clustering of episodes for the same patient or same physician.

Source: MedPAC analysis of 100 percent Medicare claims data from six markets (Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN; and Phoenix, AZ) using ETGs® version 7.0.

between the ratios range from 5 percent to 104 percent, depending on the ETG and type of imaging. Across all the ETGs and imaging types, the mean difference between the ratios was 68 percent (weighted by the number of episodes in each ETG and imaging type). In all the comparisons, the differences are statistically significant using a Wilcoxon rank order test. The analysis includes episodes with and without spending on the imaging modality being examined.

Our results indicate that episodes with a self-referring physician are associated with greater imaging spending than episodes with no self-referring physician, controlling for differences in patient severity level, geographic market,

and physician specialty. For example, the mean spending ratio for nuclear medicine for ischemic heart disease was twice as high for episodes with a self-referring physician as for episodes with no self-referring physician. Although prior studies have not compared ratios of observed-to-expected spending on imaging for episodes with and without self-referring physicians, our results are consistent with previous research showing that self-referring physicians are more likely than other physicians to order imaging (see text box on pp. 88–89).

We tested a less restrictive definition of self-referral based on whether a physician's practice performed at least 1 percent of the imaging services ordered by that physician during the year. Similar to the results described above, episodes with a self-referring physician (based on the less restrictive definition) had ratios of observed-to-expected spending on imaging that were between 5 percent and 100 percent higher than episodes with no self-referring physician (the differences for all comparisons are statistically significant using a Wilcoxon rank order test). Across all the ETGs and imaging types, the mean difference between the ratios using the less restrictive definition of self-referral was 57 percent, compared with a 68 percent difference when using the more stringent definition of self-referral. As we would expect, the spending gap between episodes with and without a self-referring physician becomes smaller when we include physicians with weaker self-referral patterns in the self-referring group.

Do episodes with more imaging have higher or lower total spending?

We used the same 13 ETGs that we included in our self-referral analysis to investigate whether greater use of imaging is associated with higher or lower total spending in an episode. Some studies have found that the use of imaging in specific clinical circumstances saves money by preventing expensive interventions and hospital admissions or reducing hospital length of stay. For example, the use of CT scans for suspected appendicitis has been reported to prevent unnecessary appendectomies and hospital admissions and to result in net savings (Rao et al. 1998). A study from the United Kingdom estimated that the costs of immediately performing CT scans on patients with acute stroke are offset by savings in reduced length of stay (Wardlaw et al. 2004). Another study found that patients with transient ischemic attack who received a diagnostic protocol that involved more imaging tests had shorter lengths of stay and lower hospital costs than patients in the control group (Ross et al. 2007). On the other hand, results from imaging studies may initiate a cascade of diagnostic tests and interventions, thereby increasing total episode costs. In some cases, incidental findings or false-positive results from imaging tests can lead to follow-up testing and surgical interventions with uncertain benefits for patients (Deyo 2002). For example, CT scans sometimes reveal benign adrenal tumors that are followed up with multiple blood tests and repeat imaging.

As with our analysis of physician self-referral, we calculated ratios of observed-to-expected spending for each episode. The expected value is based on average spending for episodes within the same ETG, patient severity level, geographic market, and physician specialty. We calculated the correlation coefficient for the ratio of observed-to-expected imaging spending and the ratio of observed-to-expected total spending for the episodes in an ETG (the unit of observation was an individual episode). If higher-than-expected use of imaging is associated with lower-than-expected use of all services, we would find a negative correlation. If higher-than-expected use of imaging is associated with higher-than-expected use of all services, we would find a positive correlation. This analysis included 509,000 episodes from 2005 across all 13 ETGs.

For each ETG, observed-to-expected imaging use was positively correlated with observed-to-expected total resource use, suggesting that more imaging is associated with greater overall resource use during the episode (Table 4-5, p. 96). The correlations are different from 0 at a statistically significant level. In addition, we found that greater use of imaging within specific modalities (e.g., nuclear medicine or echocardiography for ischemic heart disease) is associated with higher overall resource use during an episode. The ratio of observed-to-expected imaging use was also positively correlated with the ratio of observed-to-expected procedure use, indicating that, on average, more spending on imaging is associated with slightly higher spending on procedures during an episode (Table 4-5, p. 96). For four of the five ETGs with substantial inpatient spending, there was a slightly positive correlation between the ratio of observed-to-expected imaging use and the ratio of observed-to-expected inpatient hospital use.[14]

These findings support the hypothesis that, on average, higher spending on imaging within an episode is

TABLE 4–5

Greater use of imaging is correlated with higher total resource use and higher use of procedures within an episode, 2005

ETG®	Correlation coefficient: Imaging and total resource use	Correlation coefficient: Imaging and procedure use	Number of episodes used in correlation of imaging and total resource use
Cerebral vascular accident	0.25	0.06	47,938
Spinal trauma	0.26	0.13	7,481
Migraine headache	0.59	0.09	7,536
Ischemic heart disease	0.33	0.12	182,578
Congestive heart failure	0.19	0.09	47,519
Valvular disorder	0.37	0.06	24,036
Malignant neoplasm of pulmonary system	0.60	0.20	7,003
Kidney stones	0.56	0.20	8,998
Joint degeneration, localized—back	0.38	0.14	104,319
Joint degeneration, localized—neck	0.42	0.12	34,223
Joint derangement—knee and lower leg	0.45	0.09	9,127
Bursitis and tendonitis—shoulder	0.44	0.08	14,912
Other minor orthopedic disorders—back	0.52	0.08	13,444

Note: ETG® (Symmetry Episode Treatment Groups®, an Ingenix, Inc., product). Pearson correlation coefficients were calculated by comparing ratios of observed- to-expected imaging use with ratios of observed-to-expected total resource use (or observed-to-expected procedure use) for episodes in the same ETG®. The expected value of each ratio equals average spending for episodes within the same ETG®, patient severity level, geographic market, and physician specialty. All of the correlations are different from 0 at a statistically significant level ($p < 0.0001$). The number of episodes used to calculate the correlation of imaging and procedure use (not shown) was slightly smaller than the number used in the correlation of imaging and total resource use due to missing values.

Source: MedPAC analysis of 100 percent Medicare claims data from six markets (Boston, MA; Miami, FL; Orange County, CA; Greenville, SC; Minneapolis, MN; and Phoenix, AZ) using ETGs® version 7.0.

associated with higher total episode spending, at least for the 13 conditions in our study. There are three possible reasons why our findings differ from studies indicating that the use of certain imaging tests in specific circumstances reduces the use of other services, such as surgical procedures and hospital days:

- Our analysis examined the relationship between the use of imaging services (in aggregate or within specific modalities) and total resource use within an episode, whereas the studies cited above evaluated the impact of specific tests performed within a limited time frame on the use of a specific type of service; for example, whether immediately performing CT scans on patients with acute stroke reduces the length of a hospital stay (Wardlaw et al. 2004).
- Our analysis defined resource use as standardized Medicare payments, whereas two of the studies cited above examined costs incurred by hospitals during an admission (Ross et al. 2007, Wardlaw et al. 2004). Under the Medicare acute hospital inpatient prospective payment system, payments do not generally vary even if the length of stay and other hospital costs decline for an admission.
- We examined 13 ETGs, and the relationship between imaging use and the use of other services may vary for other clinical conditions (e.g., suspected appendicitis).

Future work

Because this chapter presents descriptive statistics from a single year of data (2005), we plan to conduct multivariate analyses with data from multiple years to help determine the relative impact of various factors on the use of imaging during an episode, such as the specialty and self-referral status of physicians involved

with the episode, the beneficiary's geographic location, and the number of physicians involved in the episode. Further, we will examine whether physicians order more imaging after their practices begin performing in-office imaging. We also plan to evaluate whether measures of appropriate imaging use can be linked to our data on self-referring physicians.

Moreover, we intend to explore policies to encourage more prudent use of imaging services. One option is to encourage greater adherence by physicians to appropriateness criteria developed by specialty societies. Another option is to increase the size of the unit of payment in the physician fee schedule to include bundles of services that physicians often furnish together or during the same episode of care. The Commission has expressed concern that the relatively small units of payment for many physician services could give physicians a financial incentive to increase volume (MedPAC 2005b). ■

Endnotes

1 For example, the services must be personally furnished by the referring physician, a physician who is a member of the group, or an individual who is supervised by the referring physician or another physician in the group. The services must be furnished in the same building where the referring physician provides non-DHS services or in a centralized building that the group uses to provide DHS services. Further, the services must be billed by the physician performing or supervising the service, the group practice, a wholly owned entity, or a third-party billing company acting as an agent of the physician or group (42 CFR § 411.355).

2 Such arrangements would have to comply with at least two other federal requirements: (1) the anti-kickback statute, which prohibits the offer, payment, or receipt of anything of value to induce the referral of patients for services reimbursed by federal health programs, and (2) the anti-markup rules, which apply to a physician who bills Medicare for diagnostic tests that are performed (or supervised) by a physician who does not share a practice with the billing physician. In such cases, Medicare will not pay more than the performing provider's net charge to the billing physician. CMS recently clarified that the anti-markup rules do not apply to tests performed or supervised by a physician in the same building where the billing physician regularly furnishes patient care (42 CFR § 414.50).

3 The comparison of charges was not based on relative value units and did not adjust for geographic differences in input prices.

4 The six episodes included cardiopulmonary disease, cardiac or coronary artery disease, extremity fracture, knee pain or injury, known or suspected abdominal malignancy, and known or suspected stroke.

5 For all but one of the comparisons, patients of self-referring physicians were 1.2 to 3.2 times more likely to have an imaging study than patients of radiologist-referring physicians.

6 The inclusion of physicians without a financial interest in imaging in the self-referral group likely reduced the overall use of imaging by that group, thereby reducing the size of the difference in imaging use between the self-referring and radiologist-referring groups.

7 To determine a physician's self-referral percentage for a specific modality, we first calculated the number of technical component and global claims billed by each physician's practice in which that physician was listed as the ordering physician. We then divided that number by the total number of professional component and global claims within the modality ordered by that physician during the year, whether they were provided in an inpatient hospital setting, hospital outpatient department, physician office, or freestanding imaging center. Most physicians did not refer any imaging services to their practice. Of those who did, about half referred more than 90 percent of the studies they ordered to their practice.

8 Because our data precede implementation of Medicare Part D, our episodes lack data on spending on outpatient prescription drugs.

9 The software uses evaluation and management, procedure, and facility claims (but not claims for imaging services) to classify patients into episodes, to determine whether patients have complications or comorbidities, and to identify patient severity levels. However, an imaging service may produce a diagnosis that leads to evaluation and management, procedure, or facility services.

10 We did not assign episodes to radiologists because, under Medicare's rules, they are generally not allowed to order imaging studies. In any event, radiologists are unlikely to bill for E&M services.

11 According to one article, 8 percent of high-cost imaging studies are repeat studies recommended by radiologists in their reports on the preceding examination (Lee et al. 2007).

12 The software assigns episodes a severity score based on the age and gender of the patient, complications and comorbidities associated with the episode, and the interaction of multiple complications and comorbidities. Episodes are classified into as many as four severity levels based on the severity score. The distribution of episodes by patient severity was similar for episodes with and without a self-referring physician.

13 However, our analysis of the percent of episodes in each self-referral category with at least one imaging service includes episodes that had a claim for an imaging interpretation but lacked an associated technical component claim for performing the study. Including these episodes does not bias the results of this analysis because we are counting episodes that received at least one imaging service rather than calculating imaging dollars per episode.

14 The correlation coefficients for the ratio of imaging use and the ratio of inpatient hospital use for four ETGs (cerebral vascular accident, spinal trauma, ischemic heart disease, and congestive heart failure) ranged from 0.07 to 0.08 and were different from 0 at the statistically significant level of $p < 0.0001$. The correlation for these variables for malignant neoplasm of the pulmonary system was not statistically different from 0.

References

Baker, L. C. 2008. Imaging diffusion and ownership: Effects on utilization and spending. Presentation to MedPAC. September 5.

Baker, L. C., S. W. Atlas, and C. C. Afendulis. 2008. Expanded use of imaging technology and the challenge of measuring value. *Health Affairs* 27, no. 6 (November–December): 1467–1478.

Casalino, L. P. 2008. Physician self-referral and physician-owned specialty facilities. *Research synthesis report no. 15*. Princeton, NJ: The Robert Wood Johnson Foundation. June.

Congressional Record. 1989. *Introduction of the Ethics in Patient Referrals Act*. 101st Cong., 1st sess. February 9. http://thomas.loc.gov/.

Deyo, R. A. 2002. Cascade effects of medical technology. *Annual Review of Public Health* 23 (May): 23–44.

Douglas, P. S. 2006. Improving imaging: Our professional imperative. *Journal of the American College of Cardiology* 48, no. 10 (November 21): 2152–2155.

Douglas, P., A. E. Iskandrian, H. M. Krumholz, et al. 2006. Achieving quality in cardiovascular imaging: Proceedings from the American College of Cardiology–Duke University Medical Center Think Tank on Quality in Cardiovascular Imaging. *Journal of the American College of Cardiology* 48, no. 10 (November 21): 2141–2151.

Gazelle, G. S., E. F. Halpern, H. S. Ryan, et al. 2007. Utilization of diagnostic medical imaging: Comparison of radiologist referral versus same-specialty referral. *Radiology* 245, no. 2 (November): 517–522.

Gibbons, R. J., T. D. Miller, D. Hodge, et al. 2008. Application of appropriateness criteria to stress single-photon emission computed tomography sestamibi studies and stress echocardiograms in an academic medical center. *Journal of the American College of Cardiology* 51, no. 13 (April 1): 1283–1289.

Government Accountability Office. 2008. *Medicare Part B imaging services: Rapid spending growth and shift to physician offices indicate need for CMS to consider additional management practices*. GAO–08–452. Washington, DC: GAO.

Government Accountability Office. 1994. *Medicare: Referrals to physician-owned imaging facilities warrant HCFA's scrutiny*. GAO/HES–95–2. Washington, DC: GAO.

Hadley, J. L., J. Agola, and P. Wong. 2006. Potential impact of the American College of Radiology Appropriateness Criteria on CT for trauma. *American Journal of Roentgenology* 186 (April): 937–942.

Hendel, R. C. 2009. Multi-center assessment of the utilization of SPECT myocardial perfusion imaging using the ACCF appropriateness criteria: The ACCF and United Healthcare SPECT pilot study. Presentation to the American College of Cardiology Scientific Sessions. March 29.

Hillman, B. J., G. T. Olson, P. E. Griffith, et al. 1992. Physicians' utilization and charges for outpatient diagnostic imaging in a Medicare population. *Journal of the American Medical Association* 268, no. 15 (October 21): 2050–2054.

Hillman, B. J., C. A. Joseph, M. R. Mabry, et al. 1990. Frequency and costs of diagnostic imaging in office practice—a comparison of self-referring and radiologist-referring physicians. *New England Journal of Medicine* 323, no. 23 (December 6): 1604–1608.

Iglehart, J. K. 2009. Health insurers and medical-imaging policy—A work in progress. *New England Journal of Medicine* 360, no. 10 (March 5): 1030–1037.

Ingenix. 2009. Ingenix makes market-leading Episode Treatment Groups® methodology available for public review. March 10. http://www.ingenix.com/News/Article/92/.

Johnson, B. A., and D. Walker Keegan. 2006. *Physician compensation plans.* Englewood, CO: Medical Group Management Association.

Kouri, B. E., R. G. Parsons, and H. R. Alpert. 2002. Physician self-referral for diagnostic imaging: Review of the empiric literature. *American Journal of Roentgenology* 179, no. 4 (October): 843–850.

Lee, S. I., A. Saokar, K. J. Dreyer, et al. 2007. Does radiologist recommendation for follow-up with the same imaging modality contribute substantially to high-cost imaging volume? *Radiology* 242, no. 3: 857–864.

Litt, A. W., D. R. Ryan, D. Batista, et al. 2005. Relative procedure intensity with self-referral and radiologist referral: Extremity radiography. *Radiology* 235, no. 1 (April): 142–147.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007a. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007b. *Report to the Congress: Assessing alternatives to the sustainable growth rate system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2006. *Report to the Congress: Increasing the value of Medicare*. Washington, DC: MedPAC.

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

Medicare Payment Advisory Commission. 2005b. *Report to the Congress: Issues in a modernized Medicare program.* Washington, DC: MedPAC.

Mitchell, J. M. 2007. The prevalence of physician self-referral arrangements after Stark II: Evidence from advanced diagnostic imaging. *Health Affairs Web Exclusives* (April 17): w415–w424.

National Committee for Quality Assurance. 2006. *The state of health care quality: 2006.* Washington, DC: NCQA.

National Council on Radiation Protection and Measurements. 2009. *Ionizing radiation exposure of the population of the United States; report no. 160; prepublication copy.* Bethesda, MD: NCRP. March.

Rao, P. M., J. T. Rhea, R. A. Novelline, et al. 1998. Effect of computed tomography of the appendix on treatment of patients and use of hospital resources. *New England Journal of Medicine* 338, no. 3 (January 15): 141–146.

Redberg, R. F., and J. Walsh. 2008. Pay now, benefits may follow—the case of cardiac computed tomographic angiography. *New England Journal of Medicine* 359, no. 22 (November 27): 2309–2311.

Ross, M. A., S. Compton, P. Medado, et al. 2007. An emergency department diagnostic protocol for patients with transient ischemic attack: A randomized controlled trial. *Annals of Emergency Medicine* 50, no. 2 (August): 109–119.

Swedlow, A., G. J. Johnson, N. Smithline, et al. 1992. Increased costs and rates of use in the California workers' compensation system as a result of self-referral by physicians. *New England Journal of Medicine* 327, no. 21 (November 19): 1502–1506.

Wardlaw, J. M., J. Seymour, J. Cairns, et al. 2004. Immediate computed tomography scanning of acute stroke is cost-effective and improves quality of life. *Stroke* 35 (November): 2477–2483.

CHAPTER 5

Medicare payment systems and follow-on biologics

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Chapter summary

Medicare spending on biologics—drug products derived from living organisms—totaled about $13 billion in 2007. Medicare pays for drugs, which includes biologics and chemically synthesized small-molecule drugs, under Part B and Part D. The top six biologics account for 43 percent of spending on separately billed drugs in Medicare Part B alone. Biologics account for a relatively small—but rapidly growing—share of Part D spending. The Food and Drug Administration (FDA) does not have an expedited approval process for follow-on versions of most biologics, so the price of these products has not fallen over time. If FDA had a process to approve follow-on biologics (FOBs), Medicare drug spending could be reduced. In December 2008, the Congressional Budget Office estimated that if the Congress established an approval pathway for FOBs, the federal government could save between $9 billion and $12 billion, depending on assumptions, over the next 10 years. Much of that savings would accrue to Medicare.

Given that Medicare spending on biologics is substantial and is expected to grow significantly, the establishment of a process to

In this chapter

approve FOBs has important implications for Medicare. We describe the issues policymakers must confront in designing a regulatory pathway for approval of FOBs. Of course, FDA would have jurisdiction over approval of FOBs. However, as a large payer for biologics, Medicare has a strong incentive to ensure that it gets value for the money it spends on these products. Thus, this chapter focuses on how the entrance of FOBs into the market could affect Medicare spending and whether changes to the Medicare payment systems would be needed to capture savings from FOBs.

Stakeholders disagree on how to design a pathway for FOBs. For example, there is debate about what data exclusivity period—the period of time after FDA approval before a follow-on competitor can submit an application for approval based on the innovator's data on safety and efficacy—would most appropriately balance the goals of achieving cost savings and maintaining incentives for innovation. Other issues raised in establishing an FOB regulatory pathway include the FDA testing requirements to determine whether an FOB is highly similar to—with the same safety and efficacy profile as—the innovator reference product and whether the agency should have the authority to determine if an FOB and an innovator product are interchangeable, signifying that the same patient could switch back and forth between the two products indefinitely with no adverse effect.

Biologics play a substantial role in Medicare Part B, with the top six biologics accounting for more than $7 billion of Medicare spending on Part B drugs in 2007. A regulatory approval process for FOBs is needed to provide more competition among biologics and generate cost savings for Medicare Part B. The amount of savings would depend in part on how biologics are treated under the Medicare Part B payment system. This chapter discusses coding and payment strategies that could be pursued to ensure that Medicare Part B benefits fully from competition between FOBs and innovator biologics. In particular, we describe three approaches that could be considered for assigning FOBs and innovator biologics to the same

billing code and authority that could be given to the Secretary to make such determinations.

In 2007, Medicare Part D spending on biologics totaled approximately $3.9 billion, or about 6 percent of Part D spending. Spending on Part D biologics has increased more rapidly than overall drug spending. Between 2006 and 2007, Part D spending on biologics grew by about 36 percent, whereas total Part D spending grew by 22 percent. Increased spending reflects, in part, higher Part D enrollment in 2007. However, prices for biologics compared with prices for small-molecule drugs also increased rapidly.

Biologics covered under Part D fall into two broad categories. The first group includes older, simpler molecules such as insulin and human growth hormone. These products may have larger markets than many of the newer biologics and are less costly for consumers, as multiple brand-name products are often available. Alternatively, newer, more complex biologics often have more limited markets and high launch prices. The commonly used newer biologics covered under Part D have seen sharp price increases since 2006. Most Part D plans list all these products on their formularies with significant beneficiary coinsurance requirements.

An approval process for FOBs is necessary but not sufficient in and of itself to generate Part D savings; the Part D benefit would also need to be structured to take advantage of the potential savings offered by FOBs. While Medicare should achieve savings on FOBs for older biologics, the current benefit structure is likely to limit savings for newer products. Biologics are generally expensive and can result in the beneficiary quickly entering the coverage gap and reaching the catastrophic limit. Plans have no risk during the coverage gap but they do have limited risk during catastrophic coverage. They may have an incentive to manage the use of these biologics but few tools with which to do so. However, Medicare would have a strong interest in reducing the government's costs of covering biologics by encouraging use of lower cost follow-on products.

Implementing a process to approve FOBs may increase competition among manufacturers of biologics, which is expected to lead to some savings for Medicare. However, given the magnitude and growth of spending for drugs, including biologics, policymakers may want to look at other ways for Medicare to achieve savings. To help improve the value of Medicare spending, we discuss three pricing strategies that use information about a drug's clinical effectiveness when paying for it under Part B and Part D:

- ***Reference pricing:*** Set a drug's payment rate no higher than the cost of currently available treatments unless evidence shows that the drug improves beneficiaries' outcomes.
- ***Payment for results:*** Link a drug's payment to beneficiaries' outcomes through risk-sharing agreements with manufacturers.
- ***Bundling:*** Create payment bundles for groups of clinically associated products and services. ■

Many high-priced new medications are biologics—that is, drug products derived from living organisms (see text box). Biologics encompass a wide range of products, including vaccines, blood and blood products, gene therapy, and recombinant therapeutic proteins. They come from a variety of natural sources and may be produced through biotechnology and other innovative methods. Medicare spending on biologics is substantial, totaling about $13 billion in 2007.[1]

Medicare Part B drug expenditures are already concentrated in biologic products, and the development of biologics covered under Part D is increasing.[2] These products generally have high launch prices and neither public nor private payers have had much leverage negotiating lower prices with manufacturers. Policymakers have proposed giving the Food and Drug Administration (FDA) the authority to approve generic or follow-on versions of biologic products that were licensed under the Public Health Service Act (PHSA). If FDA had a process to approve follow-on biologics (FOBs), Medicare drug spending could be reduced. In December 2008, the Congressional Budget Office estimated that if the Congress established an approval pathway for FOBs, the federal government could save between $9 billion and $12 billion (depending on assumptions) over the next 10 years. Much of that savings would accrue to Medicare.

In January 2009, the Commission convened a technical panel on FOBs to discuss issues related to designing a regulatory pathway for approval of FOBs. Researchers from NORC at the University of Chicago and Georgetown University conducted the meeting. Ten individuals participated in the panel, including physicians, economists, health plan executives, attorneys, a scientist, experts on Medicare payments, and consultants to brand-name and generic pharmaceutical manufacturers. Participants were selected to provide a wide range of viewpoints. They discussed the requirements for an approval pathway and how FOBs would affect the market for these products.

This chapter provides information on the issues policymakers must confront in designing a regulatory pathway for approval of FOBs. We present information on the role of the patent process administered by the U.S. Patent and Trademark Office (USPTO) and the FDA approval process in bringing FOBs to market. We describe differences between similarity and interchangeability in the FDA approval process and discuss the findings from our technical panel. We also review the literature on FOBs and the perspectives of other relevant stakeholders.

Glossary of relevant terms

Biologic: A virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, or analogous product … applicable to the prevention, treatment, or cure of a disease or condition of human beings (PHSA § 351(ii), 42 U.S.C. § 262 (i)).

Biotechnology: Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Data exclusivity: Period during which generic manufacturers are prohibited from using innovator test data submitted to the Food and Drug Administration to demonstrate the safety and efficacy of a drug to seek approval of a generic version of that drug.

Evergreening: A method by which producers of technology keep their products updated, with the intent of maintaining patent protection for longer periods of time than normally would be permissible under the law.

Highly similar: Lacking meaningful differences in terms of safety, purity, and potency.

Immunogenicity: The property enabling a substance to provoke an immune response or the degree to which a substance possesses this property.

Interchangeable: Comparable to the reference product and expected to produce the same clinical result as the reference product in a given patient.

Patent: The grant of a property right to the inventor, issued by the Patent and Trademark Office.

Reference product: Brand-name product with which a generic or follow-on product is compared to ensure safety and efficacy. ■

Policymakers must make decisions on both the requirements for approval of these products and ways to ensure that Medicare payment systems can capture savings from competition between innovators and FOBs. Of course, FDA has jurisdiction over approval of FOBs. However, Medicare is a large payer for biologics and it has a strong incentive to ensure that it gets value for the money it spends on these products. Thus, we focus on how the entrance of FOBs into the market could affect Medicare spending. We analyze Part B and Part D drug claims and consider changes to Medicare payment systems that might increase Medicare's ability to achieve savings with FOBs. Finally, we look at other ways Medicare can take value into account when setting payment rates.

Biologics, patents, and FDA approval process

Biologics and small-molecule drugs differ in many significant ways. Because of these differences, FDA faces scientific and regulatory challenges in developing an approval pathway for FOBs. Challenges include:

- balancing incentives for innovation with encouraging competition
- ensuring product safety
- developing standards for product similarity

How biologics are different

Unlike chemically synthesized (or small-molecule) drugs, biologics are large, complex molecules derived from living organisms. The Public Health Service Act defines a biologic as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, or analogous product … applicable to the prevention, treatment, or cure of a disease or condition of human beings."[3] Typically, biologics are provided as injections or are infused directly into a patient's bloodstream. They often require special handling such as refrigeration. They may be more costly to produce than synthetically produced drugs, and they are more difficult to assess for a high degree of similarity after they have been produced.

Physicians have been using biologics—such as vaccines, blood products, and hormones—for many years. However, advances in science over the last 30 years have resulted in the development of more complex biologics produced through the use of biotechnology. In 1982, Eli Lilly marketed the first artificially produced human insulin product. As technology evolved, more complex molecules have been produced to treat diseases like cancer, anemia, chronic kidney disease, rheumatoid arthritis, and multiple sclerosis. More than 400 biologic drug products and vaccines are in clinical trials, accounting for more than one-third of all medicines in development (BIO 2009, Novartis 2008).

Biologics, like all medications, have safety issues associated with them. For example, most biologics have some immunogenicity—the ability of a substance to stimulate the body's immune response, generating antibodies. For many products, immunogenicity does not result in any clinically relevant effects, but, in rare cases, it can cause severe adverse reactions including life-threatening side effects (Siegel 2007). For example, FDA recently notified the public that several patients contracted a rare brain infection after taking efalizumab, a biologic used to treat psoriasis. Any FOB should have to meet standards for immunogenicity. However, severe adverse reactions may be very rare and even large-scale clinical trials may not uncover a problem before a product is approved for sale. Some analysts have suggested that postmarketing surveillance for all new biologics, including FOBs, may be warranted.

On the other hand, some have argued that the differences between biologics and small-molecule drugs are exaggerated. For example, brand-name products and their generic counterparts may differ, within an acceptable range, in how quickly the body absorbs them. Additionally, safety risks are associated with all pharmaceuticals. For this reason, some policymakers advocate wider postmarketing surveillance of all drugs.

Because of the large size and complexity of biologics, some stakeholders argue that manufacturers cannot produce a follow-on product that is identical to the original or reference product. FDA has identified a number of potential sources of variability among biologic products:

- Biologic proteins are often composed of mixtures of molecules that can vary slightly in their structure.
- Artificially engineered products can vary slightly from lot to lot even when the same manufacturing process is used.

- Natural biologics can also vary depending on the variability of the source material and the process used to extract and purify the product (Woodcock et al. 2007).

Other stakeholders argue that the extent to which manufacturers can produce a biologic that is identical to a reference product must be determined on a case-by-case basis. In some cases, current analytical techniques can measure beyond the molecule to the nanoparticle level, potentially allowing manufacturers to demonstrate that two biologics are identical.

Small differences in products can affect the intellectual property rights of the innovator because biologic development leads to different kinds of patents than those obtained for small-molecule drugs. Depending on the properties of the molecule and the production process, patent protection can provide more protection to innovators or no protection at all. Thus, some stakeholders assert that a regulatory pathway for biologics should differ from that applied to small-molecule drugs in terms of intellectual property rights, data exclusivity, and similarity of products.

Intellectual property protection: Data exclusivity and patents

Different organizations have responsibility for drug approvals and patent rights. FDA approves drugs but patents are awarded under the Patent Act and administered by the USPTO. These processes have different requirements and provide different protections. FDA approves drugs that meet standards for safety, effectiveness, and quality. For most new products, manufacturers must support their application with clinical data, safety reports, manufacturing standards, and other relevant information.[4] Manufacturers may market their products after they receive FDA approval. Examiners at the USPTO award patents on the basis of utility, novelty, and nonobviousness. Patent applications must include specifications that describe the invention so that skilled artisans can produce it without undue experimentation (Schacht and Thomas 2008). Patent holders can exclude competitors from the market for 20 years from the date the application was filed. In the case of drugs, the inventor generally files for patent protection before FDA approves a product.

The Drug Price Competition and Patent Term Restoration Act of 1984 amended FDA law to protect new drugs and to encourage generic competition. For example, manufacturers of new drugs, including biologics, receive patent term extensions for a portion of the time spent seeking FDA approval. (See text box, pp. 110–111, for more information about the 1984 law.) In addition, the innovator company is granted five years of data exclusivity—the period of time after approval before FDA can rely on an abbreviated regulatory filing based on the innovator's evidence of safety and efficacy in evaluating a follow-on product. Stakeholders disagree about how these issues may affect biologics given the potential dynamics of this market and the different nature of patent protection for these products.

Grabowski estimates that manufacturers require between 13 and 16 years to recoup the development costs of a new biologic, and the Biotechnology Industry Organization has used that estimate to assert that at least 14 years of data exclusivity are essential to provide adequate incentive for new investments (Grabowski 2008). They argue that innovators must attract investment capital to pay for the development costs and that investors will be reluctant to enter this market without the guarantee of a sufficient period of data exclusivity.

Brill presents an alternative case (Brill 2008). Depending on assumptions, he estimates a break-even point of less than nine years and suggests that "seven years of data exclusivity would be sufficient in maintaining strong incentives to innovate while fostering a competitive marketplace." Kotlikoff makes a similar argument, stating that lengthy exclusivity provisions would delay entry of low-cost alternatives and discourage competition (Kotlikoff 2008). Brand-name companies have little incentive to improve their products without the threat of imminent competition.

At issue is how long a period of data exclusivity is necessary to promote innovation and foster competition. There was a range of opinions among members of the Commission's technical panel on an appropriate time frame. The panel did not reach consensus on this issue.

Some panelists argued that the uncertainty surrounding patents complicates the entry of follow-on products. Biologic products tend to have more patents than small-molecule drugs, and the patents may be filed over several years. Patents may be held by multiple parties including research institutes and academic institutions. Patents may cover not just the product but also the production process and even the research tools used to develop it (Harbour 2007). Yet the product itself, as a naturally occurring entity, may not always be patentable in the same way as a small-molecule drug.[5] Additionally, innovators may not

The Drug Price Competition and Patent Term Restoration Act of 1984 created a streamlined process for generic drug approvals and extended patent protections to innovator drugs

The Drug Price Competition and Patent Term Restoration Act of 1984 sought to balance incentives for innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. Key provisions of the law include:

- Creating an abbreviated approval process for generic drugs and testing generic drugs before the innovators' patents expire.
- Extending the patent protection of a brand-name drug to provide incentives to develop new drugs. It also compensates for delays that might occur as a result of regulatory review.

Changes to the approval process for generic drugs

Before 1984, generic drugs were subject to the same approval requirements as innovator drugs. The Food and Drug Administration (FDA) did not have a streamlined process by which to approve generic products of brand-name drugs whose patents had expired. By 1984, there were approximately 150 brand-name drugs whose patents had expired that had no generic equivalent (FTC 2002).

The Drug Price Competition and Patent Term Restoration Act of 1984 removed the duplicative testing requirements for generic drugs. Generic manufacturers can rely on the innovator company's data to demonstrate that their drug is bioequivalent to the innovator drug. It also gives a 180-day marketing exclusivity period to the first generic manufacturer to file an application with FDA.[6]

In addition, the law reversed a 1984 court ruling and allowed generic manufacturers to initiate the clinical tests required for FDA approval of their product before the reference innovator drug's patent expires. Before the Drug Price Competition and Patent Term Restoration Act of 1984, a generic company could not begin the required FDA approval process until after the patents on the innovator drug had expired. To begin the process earlier would have infringed the brand-name company's patents.

Thus, the law increased the probability that a generic copy would become available after patent expiration. It also reduced the average delay between patent expiration and generic entry from more than three years to less than three months (CBO 1998).

Changes to the length of patents for innovator drugs

Before passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the effective terms of many drug patents were shortened because of the time required to conduct clinical trials and FDA's review of the information submitted by the

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provide sufficient information so that a "skilled artisan" can create the product. For example, they may not be willing to provide functional cell lines as part of their patent disclosure materials (Noonan 2008). Courts have invalidated patents for these reasons.

Some panelists were concerned that approval of FOBs could also result in practices by brand-name manufacturers to extend data exclusivity or patent rights. For example, manufacturers might increase their use of "evergreening"—a term used for the practice of making marginal improvements to existing drugs. They reported that the practice is common in the small-molecule market. Biologic manufacturers have had little need to use this practice because they have not faced any competition from FOBs.

For any given product, patent length or data exclusivity may provider longer protection. Extensive litigation around patents—particularly patents filed at different

The Drug Price Competition and Patent Term Restoration Act of 1984 created a streamlined process for generic drug approvals and extended patent protections to innovator drugs (cont.)

manufacturer about a drug's safety and efficacy. Under this law, drugs that contain a chemical entity never approved by FDA can qualify for an extension of the patent. These extensions, granted after the drug is approved, equal half of the time the drug spent in clinical testing (usually six to eight years) plus all the time associated with FDA review (usually about two years). The patent extension cannot be longer than 5 years and cannot exceed 14 years after the drug is approved. This provision of the 1984 law also applies to biologics.

The Drug Price Competition and Patent Term Restoration Act of 1984 includes other provisions that postpone generic competition. One provision—referred to as data exclusivity—is the requirement that competitors wait five years after an innovator drug is approved before filing an application to sell a generic copy. This requirement benefits drugs that have no patent or that have very little time left under patent when they are approved. That exclusivity provision, together with the patent-term extensions, postpones generic entry by an average of 2.8 years for all drugs approved that contain a new chemical entity (CBO 1998).

The Drug Price Competition and Patent Term Restoration Act of 1984 also grants innovator companies a 30-month stay (postponement) if they file suit for patent infringement when a generic manufacturer submits its application to FDA. This 30-month stay allows the patent holder the opportunity to assert its rights in court before the generic competitor is permitted to enter the market.

Other exclusivity provisions that may postpone generic competition include:

- the Orphan Drug Act of 1983, which grants a 7-year marketing exclusivity period to drugs that treat diseases affecting fewer than 200,000 people;
- the FDA Modernization Act of 1997, which provides a research incentive of six months of additional marketing exclusivity for manufacturers that conducted studies of drugs commonly used to treat children; and
- a three-year period of exclusivity granted by FDA for new indications or dosage forms of a previously approved drug. ■

points in time, with different expiration dates—can last longer than a data exclusivity period. On the other hand, if a new biologic is not patentable, a manufacturer's data exclusivity is the innovator's only protection against immediate competition.

Some panelists argued that data exclusivity and patent issues are not the most important considerations in creating market competition, despite the attention these issues receive in the public debate. Instead, they argued, the design of FDA's approval process, and whether drugs will be considered highly similar or interchangeable, will be the key to making the market attractive to follow-on manufacturers. That is, FDA's decisions will determine how successfully the manufacturers will be able to compete with the innovator products they are challenging.

FDA's role determining product safety, similarity, and interchangeability

As with all drugs, safety risks are associated with biologics, and FDA must ensure that FOBs meet the safety and efficacy profile of their reference product. Any proposed regulatory pathway would require FDA to make a determination of a high degree of similarity or comparability. FDA defines comparability as "the comparison by the manufacturer of a biological product before and after a manufacturing change to demonstrate that the safety, identity, purity, and potency remain unchanged" (Behrman 2008). Assessing comparability (or, in the case of FOBs, a high degree of similarity) requires more sophisticated tools than are needed to approve generic drugs.

Before the mid-1990s, FDA required the licensing of specific manufacturing sites when manufacturers of innovator biologics made any changes to their product or production processes. Because of the time and expense involved in meeting FDA requirements, manufacturers were reluctant to make even small improvements. However, scientific advances in manufacturing techniques and comparability testing have ameliorated this situation. In 1996, FDA, working with the biotechnology industry, introduced comparability protocols to support product changes. The protocols outline a series of laboratory tests required on a case-by-case basis to ensure that manufacturing changes have not compromised the safety and efficacy of the product. Products produced under different manufacturing conditions are analyzed for structural, chemical, and biological differences. FDA determines whether differences between the products are significant enough to require additional testing. In some circumstances, it will require clinical testing in the sense of assessing how the product affects blood levels in various tissues or the short-term impact of the product in animals or humans. These tests, although clinical, are not equivalent to long-term clinical outcome studies. At any stage of this process, FDA may determine that the two products are not comparable and end the testing (Novartis 2008, Schwieterman 2007).

Testifying before the Congress in 2007, former FDA scientist William Schwieterman said: "These scientific principles [comparability protocols] not only allow for insignificant postapproval brand-name product changes, but also very significant manufacturing changes, such as cell-line replacements, manufacturing facility site changes and the like."

Using these protocols, FDA approved a follow-on version of human growth hormone, a biologic that—for unique historical reasons—was originally approved through a new drug application (NDA) and regulated under the Drug Price Competition and Patent Term Restoration Act of 1984, which gave the agency authority to approve generic or follow-on products that were originally approved through NDAs. This product is now on the market in the United States as well as in Europe. With congressional authority, FDA could use the same protocols to decide that other FOBs and their reference products are highly similar, meaning that there are no clinically meaningful differences in terms of safety, purity, and potency. The extent of the testing required for this determination will affect the incentives for innovation and competition as innovator firms and their competitors both seek to introduce follow-on products.

With congressional authority, the agency could also determine that an FOB is interchangeable with its reference product.[7] Interchangeable products are expected to have exactly the same clinical result in the same patient—that is, the patient could switch back and forth between the two products indefinitely with no effect. If FDA designates two products as interchangeable, it will have implications for costs and competition. For example, in the small-molecule drug market, most states have instituted rules that allow pharmacies to substitute with the generic product without consulting with the prescriber.

There was some debate within our technical panel about whether the science exists to demonstrate interchangeability. Many believe advances in the methodology for assessing biologics will make this determination possible over time. They argued that the Congress needs to give FDA clear authority to make interchangeability determinations if they want to maximize the potential savings that could be created by competition from FOBs.

How FOBs will affect competition is not known

Analysts cannot yet determine how the entrance of FOBs into the market will affect competition and prices. Because the market has yet to develop, policymakers estimate impacts based on the effect generic small-molecule drugs have on competition and how that effect differs from current competition among biologics. In assessing the potential effect of FOBs, our panelists considered a number of factors including:

- the effect generic drugs have had on the small-molecule drug market,
- the size of the market for biologics,
- acceptance of FOBs by physicians,
- efforts by payers to promote the use of FOBs, and
- reactions of pharmaceutical manufacturers.

Generic drugs and the market for biologics

In the small-molecule drug market, manufacturers of generic products charge lower prices to capture market share. Prices fall most rapidly when a number of generic

versions of a brand-name product are on the market. Because generics are considered interchangeable, payers can negotiate with manufacturers with confidence that the lowest priced product is equivalent to the highest priced product. Charging FDA with determining that FOBs are interchangeable with their reference products could also lead to rapid price decreases in biologics.

For some biologics, however, the market is relatively small, which may be a barrier to entry: FOB manufacturers may be concerned that there are too few potential customers to recoup their costs if they have to charge lower prices to attract market share. In addition, the costs of manufacturing biologics may make companies without experience in this field more reluctant to enter the market. For these reasons, there may be a limited number of FOBs for a particular reference product, which could affect the potential savings for FOBs relative to the expense of generic drugs.

Price competition also occurs among brand-name manufacturers of competing but not interchangeable drugs in a therapeutic class. For example, health plans may negotiate lower prices for one statin and favor it on their formulary over another even though the two products are not identical. One panelist noted that, in biologic classes, this practice is less common. A certain percentage of people may have an adverse reaction to one biologic in a class and a certain percentage will not be helped by the product. This situation is more common with biologics than with other drugs—in part due to the characteristics of biologics, such as the risk of causing immune system reactions. However, some price competition does exist in Medicare Part B.

In their estimate of the extent of competition that could be expected as a result of one approach to follow-on legislation (S. 1695), the Congressional Budget Office assumed that a follow-on product would gain a 10 percent share of its market in the first year it becomes available and 35 percent by the fourth year on the market (CBO 2008a), resulting in price discounts of 20 percent to 25 percent in the first year and 40 percent in the fourth year.

Will doctors prescribe follow-on biologics?

The success of FOBs in the market depends on whether physicians trust the products and are willing to prescribe them for their patients. Physicians are likely to be influenced by the findings of FDA and the decisions of key opinion leaders in their specialty. Innovator companies, generic companies, patients, and payers are also likely to try to influence their decisions.

Physicians may be cautious about prescribing FOBs that have newly entered the market. Some members of our technical panel drew a clear distinction between prescribers' behavior. They may be willing to start patients on a new product but unwilling to switch patients who are stable on one product to another. If FDA does not determine that an FOB is interchangeable with the innovator product, this distinction could be important. In that case, follow-on products may be treated more like an additional product in the same class rather than the same product produced by a different manufacturer. Physicians are unlikely to switch existing patients to an FOB but may consider prescribing the new product for new patients. If the FOB is less expensive, patients may want to use it and get treatments that otherwise are unaffordable.

Several panelists noted the importance of manufacturers' direct marketing to physicians in maintaining physician prescribing for brand-name drugs. Just as they do with small-molecule drugs, manufacturers may make the case to physicians that FOBs are not truly similar to the innovator product. One panelist who has been watching the biosimilar process in Europe stated that manufacturers are pursuing this strategy there. They are saying "These drugs aren't the same, just similar." This marketing strategy could limit physician adoption of FOBs (see text box, pp. 114–115).

Payers may prefer follow-on biologics

Because new biologics tend to be expensive, payers have an incentive to encourage physicians to prescribe FOBs. For small-molecule drugs, public and private efforts have been made to counteract physicians' slow adoption of generics. Many states have laws that allow or require automatic substitution of the generic at the point of sale. Elsewhere, health plans may give pharmacists incentives to contact the physician's office for permission to fill a prescription with a generic alternative, including generics to replace competing brand-name drugs in the same class. Health plans also give enrollees an incentive to ask their physicians about generics. For example, the median cost sharing charged by stand-alone Medicare Part D plans for 2009 is $7 for a generic, compared with $38 for a preferred brand-name drug or $75 for a nonpreferred drug (Hoadley et al. 2008). Many plans also remove the brand-name version from their formularies when a generic becomes available. As one panel participant who works for a health plan described: "You start [the patient] on the generic so that they don't get started on the brand,

Follow-on biologics: The European experience

In 2005, the European Union (EU) adopted legislation that established the world's first explicit regulatory approval pathway for FOBs (called "similar biological medicinal products" or "biosimilars" in Europe) (EU Directive 2004/27/EC). The European Medicines Agency (EMEA) later released regulatory guidelines to govern the approval of biosimilars. In 2006, Omnitrope, a version of somatropin, became the first biosimilar to be authorized by the EMEA in accordance with the EU's legal framework (MIP 2008). As of June 18, 2008, the EMEA had approved more than 10 biosimilar products (MIP 2008).

The EU uses a case-by-case approach

According to EU law, the EMEA must review each biosimilar application individually to determine the degree and type of preclinical and clinical data required for the approval of each product. This case-by-case approach reflects the range of molecular complexity among biologic products. Depending on the product class-specific scientific determination made by the EMEA, any given biosimilar application could, in theory, require as few data as a generic small-molecule drug application or as many as a full, stand-alone application.

EU law grants manufacturers 10 to 11 years of market exclusivity for biologic products

European law applies the same data and market exclusivity periods to all medicinal product applications submitted to the EMEA. Manufacturers are granted eight years of data exclusivity for each product, which means that—during the first eight years after a drug is approved—disclosure of data to a competitor is prohibited, as is regulatory reliance on such data. Furthermore, during this time competitors are prohibited from entering the market, even if they submit original data. Once the eight-year period of data exclusivity expires, competitors may use innovator data to file biosimilar applications but cannot bring biosimilar products to market for another two years. An additional year of market exclusivity may be granted if a new indication is discovered during the initial eight-year data exclusivity period. This "8+2+1" exclusivity scheme allows for a maximum of 8 years of data exclusivity and 11 years of market exclusivity.[8] New combinations of old medicinal products are treated as new products eligible for 8+2+1 years of exclusivity.

European law does not treat biosimilars as biogenerics

Under European law, biosimilars are distinct from generic products. Consequently, biosimilars are not seen as universally interchangeable with innovator products, as generics are, and decisions about substituting a biosimilar for its reference product are made at the national level (EMEA 2005). Nearly all EU member states limit substitution to some degree, but specific provisions governing substitutability vary. Several countries prohibit automatic substitution of

(continued next page)

and prescribing physicians get used to that very quickly, because they know they'll get back [from us] that the generic is covered."

Medicare also has the power to steer physician prescribing within Part B by using financial incentives. Whether states, plans, and the federal government are willing to make these policies to require or encourage the substitution of an FOB for the innovator product will likely depend heavily on what FDA says about similarity.

Biologics and Part B

While the development of a regulatory pathway for FOBs clearly lies within FDA's jurisdiction, Medicare has a strong interest in the potential outcome of such a pathway. Medicare Part B spending on biologics is substantial. In 2007, the top six drugs that accounted for the most Medicare Part B spending were biologics. By themselves, these 6 biologics accounted for more than $7 billion of nearly $17 billion in total Medicare Part B spending on the

Follow-on biologics: The European experience (cont.)

biosimilars (e.g., France, Germany, Spain), others have guidelines that caution against substitution (e.g., Denmark, Norway), and still others require that physicians prescribe medicines by brand name to ensure that patients receive the appropriate product (e.g., Austria, Greece, United Kingdom). In nearly all EU nations, the responsibility to determine the appropriateness of substitution rests in the hands of physicians.

Although European biosimilars are not treated as biogenerics, EU law does allow for an eventual shift in this paradigm, pending scientific advancement.

The EMEA takes steps to maximize patient safety

The EMEA requires that every manufacturer of medicinal products for human use develop a plan for continuous postmarketing pharmacovigilance to ensure that its products do not exhibit immunogenicity problems or provoke other adverse reactions once on the market. This stipulation is particularly important in the case of biosimilars, as they are more likely than small-molecule drugs to react to slight manufacturing changes that may not be detected in clinical trials.

In addition to the manufacturer-based system, each member state has implemented its own national pharmacovigilance system for collecting and evaluating information relevant to the risk–benefit balance of medicinal products in its territory. Furthermore, the EMEA has developed a centralized computer database called EudraVigilance to be used for data collection, management, and sharing among member states.

Biosimilars in Europe have launched at lower prices than their reference products

The EMEA has approved more than 10 biosimilars and has denied authorization to 2. Approved substances include human growth hormone, epoetin, and filgrastim. These biosimilars have entered the market at prices that are, overall, 15 percent to 25 percent lower than those of their reference products (Towse 2008).

Developments elsewhere

New regulatory frameworks and biosimilar guidelines are in development in Canada and Japan. Additionally, the World Health Organization has issued draft guidelines to be used by countries that may not have the capacity to develop their own legal frameworks. ■

roughly 650 Medicare Part B separately paid drugs (Table 5-1, p. 116). If a regulatory approval process for FOBs is established, FOBs would likely provide competition for innovator biologics, generating cost savings to Medicare Part B and beneficiaries. Lowering the cost of expensive biologics could also increase access to these products for some beneficiaries. The amount of savings Medicare Part B would realize from FOBs would depend on a variety of factors, including the way FOBs are treated under the Medicare Part B payment system.

How biologics and small-molecule drugs are paid and coded under Medicare Part B and the effect of price competition among products can be instructive with regard to Medicare payment for FOBs. The level of potential program savings resulting from FOBs would depend, in part, on the approach used to code and pay for these products. This section discusses coding and payment strategies that could be pursued to ensure that Medicare Part B benefits fully from competition between FOBs and innovator biologics. Changes to the Medicare statute may be needed for Medicare to adopt these approaches.

How Medicare pays for and codes Part B drugs

Most drugs covered by Medicare Part B are physician-administered drugs. Physicians purchase them in the marketplace and administer them to patients. In accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare program pays physicians for drugs covered by Medicare

TABLE 5–1

The top six biologics account for more than $7 billion in Medicare Part B drug spending in 2007

Biologic	Primary indication(s)	Medicare Part B spending, 2007 (in billions)
Epoetin alfa	Anemia	$2.6
Darbepoetin alfa	Anemia	1.3
Rituximab	Cancer, rheumatoid arthritis	1.1
Bevacizumab	Cancer	0.8
Infliximab	Rheumatoid arthritis, Crohn's disease	0.8
Pegfilgrastim	Cancer	0.8
Total		7.3

Note: Figures do not sum to total due to rounding.

Source: MedPAC analysis of Medicare Part B claims data for physicians and suppliers, hospital outpatient departments, and end-stage renal disease facilities.

Part B at a payment rate equal to the average sales price (ASP) plus 6 percent.[9,10] The ASP reflects the manufacturer's average price for sales to all purchasers (with certain exceptions) net of all rebates, discounts, and price concessions.[11] Regardless of the price the physician pays a wholesaler or distributor for the drug, Medicare pays the physician 106 percent of ASP, which gives the physician a financial incentive to seek the lowest available price for the product.

In establishing payment rates for drugs, Medicare assigns drugs to billing codes. Typically, each billing code refers to a unique form and strength of a biological or chemical entity. All products assigned to the same billing code receive the same payment rate. For a multiple source drug (i.e., a small-molecule drug that has both brand-name and generic versions), the brand-name and generic products are included in the same billing code and receive a payment rate equal to 106 percent of the volume-weighted average ASP for all manufacturers' products. The MMA requires that biologics and single-source drugs (i.e., brand-name small-molecule drugs without a generic version) be paid based on their own ASP and not averaged with other products. Consequently, these products receive their own billing code. Before the MMA, CMS had grouped a small number of closely related single-source drugs and biologics in the same billing code and paid all products in the billing code the same rate. The MMA grandfathered any billing codes that grouped different manufacturers' single-source drugs and biologics together as of October 1, 2003, and continued to pay these products at the same rate, now based on the average ASP for all products assigned to the code. Any new single-source drug or biologic that enters the market after October 1, 2003, is required to receive its own payment rate. Once a small-molecule generic drug enters the market, the single-source drug becomes a multiple-source drug and receives a payment rate based on the average ASP for the brand-name and generic products.

Competition among Part B biologics

Competition among Medicare Part B biologics has been quite limited because of the lack of clinically similar products on the market. However, erythropoiesis-stimulating agents (ESAs) are an example of an area where price competition has occurred in Part B. ESAs are used to treat anemia in cancer patients as well as patients with end-stage renal disease and certain other conditions. Two different ESAs marketed in the United States are used for cancer patients. In our site visits to oncologists in 2005 for our report to the Congress on the impact of the ASP payment system, we heard from oncologists that the two ESA manufacturers engaged in significant price competition to encourage oncologists to choose their product over their competitor's. During 2005, the first year of the ASP payment system, the Medicare payment rates for the two ESA products declined steadily each quarter, with total decreases in 2005 of 13 percent and 14 percent, respectively, likely reflecting this competition. The ASPs for these products later oscillated but overall trended downward, until mid-2008 when the prices of both products began to increase moderately.

Competition among Part B small-molecule drugs

Competition among small-molecule drugs covered under Medicare Part B is more common, particularly among products with generic alternatives. Medicare assigns generic and brand-name versions of the same drug to the same billing code, which fosters competition. Because all brand-name and generic versions of a particular drug receive the same payment rate based on the average ASP for all products, physicians have a financial incentive to seek the lowest priced product available. A two-quarter lag in the ASP payment rates further promotes competition among brand-name and generic versions of a drug. For example, the Medicare payment rate for the third quarter of the year is based on the ASP for the first quarter of that year. As a result of the lag, during the first two quarters generic drugs are on the market, they are paid based on the higher ASP for the brand-name product. Therefore, the Medicare payment rate typically is substantially higher than the physician's acquisition costs for a generic drug during the first two quarters generic drugs are on the market, creating a substantial incentive for physicians to purchase it. After generics have been on the market for two quarters, their prices are represented in the ASP data used to calculate the product's ASP payment rate, typically resulting in a substantial decline in Medicare's payment rate for the product. This situation creates further incentives for use of the generic product and spurs additional price competition among manufacturers to obtain market share.

The savings can be substantial when generic drugs come on the market. For example, a major chemotherapeutic drug, which accounted for more than $100 million in Medicare Part B spending in 2007, became generic in 2008. Between 2008 and 2009, the Medicare payment rate for the product declined by more than 85 percent. As another example, since generic versions of an intravenous antibiotic drug were introduced in 2006, the Medicare payment rate has declined by nearly 80 percent.

When several brand-name drugs exist to treat a condition, the entry of generic versions of one brand-name drug can generate competition for all brand-name drugs in the class. An example of this situation is a class of intravenous drugs to prevent or treat chemotherapy-induced nausea and vomiting. There are four brand-name drugs in this class; each is a different chemical entity and has its own billing code: dolasetron, granisetron, ondansetron, and palonosetron (Figure 5-1, p. 118). After generic versions of ondansetron became available, Medicare's payment rate for it dropped substantially (as that payment rate is based on the volume-weighted ASP for the brand-name and generic versions of that drug). The other three drugs in that therapeutic class each continued to receive separate payment rates based on each one's ASP.[12] Since the availability of generic versions of ondansetron, the ASPs for the other three drugs in the class have declined, although not nearly as much as the ASP for ondansetron.

The percentage savings from the entry of FOBs would not be expected to be as great as the savings obtained from generic drugs. Nonetheless, the generic drug examples illustrate some of the same market forces that are likely to be present with FOBs. The example of nausea drugs shows that when a generic product has the same billing code as the brand-name product, large decreases occur in the Medicare payment rate for that drug, and more moderate price decreases often result for other products in the same therapeutic class that have different billing codes, because of the effects of competition. The degree to which products are viewed as clinically similar affects how much price competition is likely to take place throughout the therapeutic class.

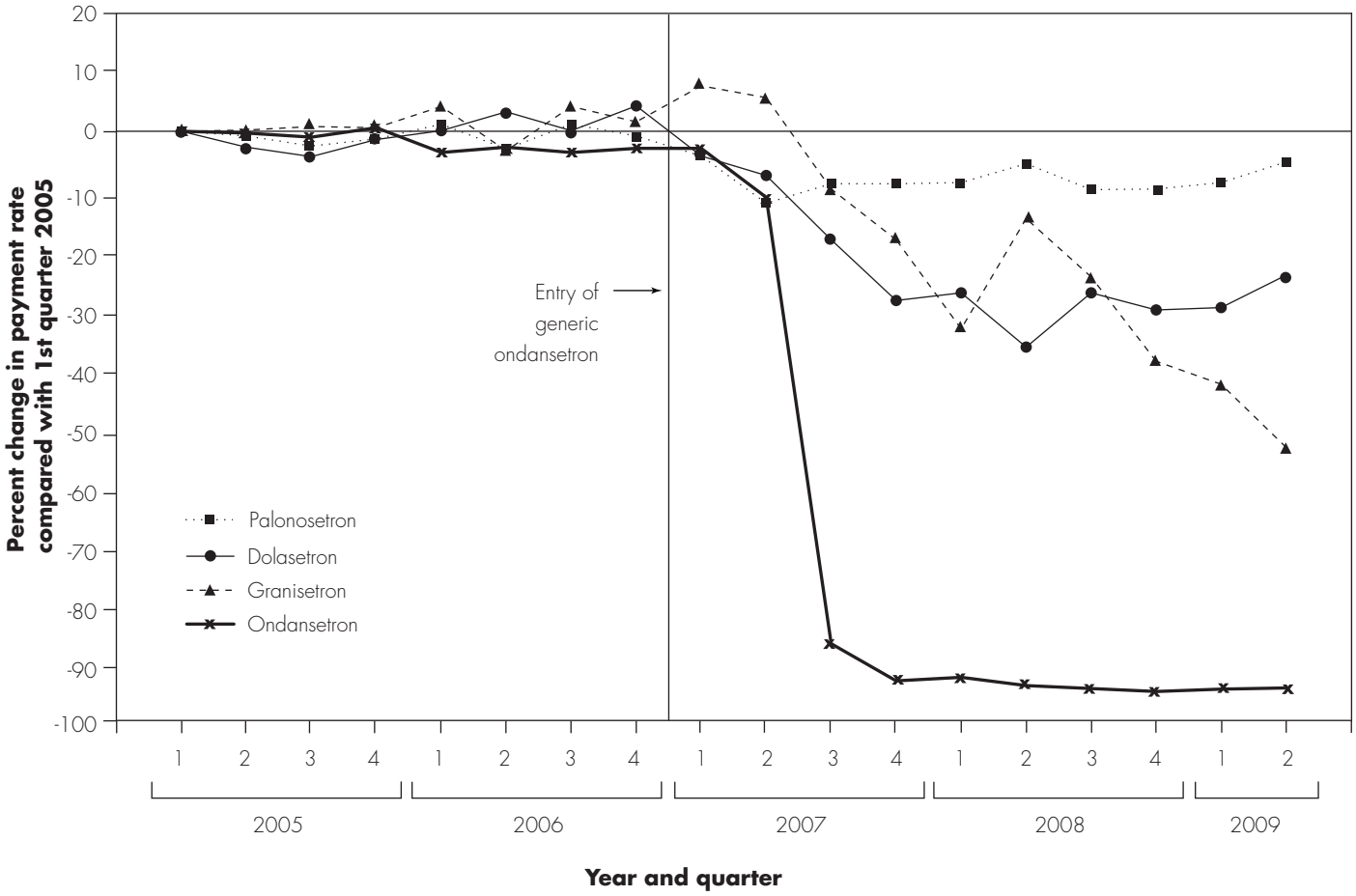
Potential for additional savings from coding changes

The extent to which a regulatory pathway for FOBs could achieve savings in Medicare Part B would depend in part on how these products are coded and paid under the Medicare Part B payment system. Currently, the statute requires that each biologic paid for under Part B receive a separate payment rate based on the product's ASP; consequently, each biologic has its own billing code.

Overall, assigning FOBs and innovator biologics to the same billing code would be expected to generate more competition among products and yield greater savings than assigning them to separate billing codes. Putting an FOB in the same Medicare Part B billing code as the innovator biologic would create incentives to use the lower priced product. Conversely, FOBs and innovator biologics assigned to separate codes and paid based on their individual ASPs in some cases may create financial incentives to use the more expensive product, as the 6 percent paid by Medicare in excess of ASP is larger for a more expensive product.[13] (In the aggregate, some savings would be expected to occur, however, since FOBs are expected to cost less than the innovator biologic). The Congressional Budget Office estimated that over the 2010–2019 period, an abbreviated FOB approval process would lead to federal savings of $9 billion if FOBs were

FIGURE 5–1

Example of generic entry causing a sharp decline in the Medicare payment rate for a drug, with moderate decreases among other drugs in the class



Source: MedPAC analysis of the quarterly average sales price drug pricing files. http://www.cms.hhs.gov/McPartBDrugAvgSalesPrice/.

assigned to separate Medicare Part B billing codes and $12 billion if they were assigned to the same billing code as the innovator biologic (CBO 2008b).

The clinical appropriateness of coding and payment of FOBs is an important consideration. FDA approval of an FOB would reflect the agency's judgment that any differences between the FOB and innovator biologic do not affect the safety and efficacy of the product. However, it would not necessarily mean that an individual patient could switch back and forth between the FOB and innovator biologic. Thus, placing FOBs and innovator biologics in the same billing code may raise concerns about the incentives for switching an individual patient from one product to another. As mentioned previously, members of our technical panel indicated that physicians would be more likely to start new patients on FOBs than to switch existing patients who are stable on one product to another one.

If policymakers choose to assign an FOB to the same billing code as the innovator biologic, one question would be what criteria should be used to assign an FOB and an innovator biologic to the same billing code. Arguments can be made for a standard based on interchangeability or a high degree of similarity. As noted previously, requiring an FDA interchangeability determination would signify that FDA has determined that an individual patient could switch back and forth between the FOB and innovator biologic multiple times without adverse effects. Any

clinical concerns about Medicare coding and payment policy influencing the use of one product versus another would be alleviated by such an interchangeability determination. However, interchangeability is a higher standard than similarity and may not necessarily be the appropriate threshold for determining whether FOBs should be assigned to the same billing code as innovator biologics.

Alternatively, one could argue that an FOB and an innovator biologic, which have been determined by FDA to be highly similar, should be treated similarly under the Medicare payment system and paid the same rate. As noted previously, there is precedent for putting closely related single-source drugs and biologics in the same billing code. Before the MMA, certain closely related single-source drugs and biologics, such as clotting factors and viscosupplements, were assigned the same billing code. The MMA grandfathered these preexisting coding decisions and required the grandfathered products to receive a payment rate based on the average ASP for the related products. These "grandfathered products" have not been subject to a determination of similarity by FDA—in contrast to FOBs, which FDA would have determined to be highly similar to the innovator product to receive approval.

Several different approaches could be considered for placing FOBs and innovator biologics in the same billing code depending on whether interchangeability or a high degree of similarity was the criterion used. A statutory change may be required to adopt any of these approaches. Three approaches include:

- ***FDA interchangeability determination.*** Under this approach, an FOB would be assigned to the same billing code as the innovator biologic if FDA determined that the products were interchangeable. Stakeholders disagree about whether the science currently exists to permit a determination that an FOB and innovator biologic are interchangeable. For this reason, it is unclear in the short run whether FDA would exercise the authority to make an interchangeability determination if given the statutory authority to do so. Thus, tying Medicare coding and payment to an FDA determination of interchangeability might lead to few, if any, follow-on products being included in the innovator product's billing code in the short run. However, this approach could have a more significant impact over time as the science evolves for determining interchangeability.
- ***Secretary's determination based on input from an advisory committee or a public comment process.*** This approach would give the Secretary authority to make a determination about assigning an FOB to the same billing code as the innovator product after obtaining input from a special advisory committee of medical and scientific experts developed for this purpose or from a public comment process. While generally relying on a standard of similarity, the Secretary would have the flexibility to base the decision on all available information about a particular biologic. Stakeholders' interest in such decisions could lead to a lengthy decision-making process before an FOB could be assigned to the same billing code as an innovator product. To partially mitigate the length of this process, a two-pronged approach could be considered where: (1) an FDA interchangeability determination results in automatic assignment of the FOB and innovator product to the same billing code, and (2) the Secretary has authority to assign an FOB and an innovator biologic that do not have an FDA interchangeability determination to the same billing code after input from an advisory committee or a public comment process.
- ***Require FOBs to be assigned to the same billing code as the innovator product.*** The Congress could require that FOBs be assigned to the same billing code as the innovator product. Underlying this approach would be the premise that a high degree of similarity is an appropriate standard for assigning FOBs and innovator biologics to the same billing code. If there were concerns that this standard might not be appropriate in all instances, the Secretary could be given the authority to exempt products from being grouped together if there is evidence that it is not clinically appropriate for a particular product. This approach would likely achieve greater savings than the other options outlined above because it would likely result in FOBs and innovator biologics being placed in the same billing code more quickly and more often.

Assigning FOBs and innovator products to the same billing code is not the only way to achieve equivalent payment rates for the two products. Payment rates equivalent to those resulting from the above approaches could be achieved by using separate billing codes if payment rates for biologics were based on the average ASP calculated across FOB and innovator product codes (based on an interchangeability or a high-degree-of-similarity standard).[14] Other innovative pricing

mechanisms could also be considered for payment of drugs, such as not paying a higher price for a product than the price of a similar product, unless there is evidence to suggest that it is clinically superior, as discussed in more detail later.

Biologics and Part D

Because most biologics are injected or infused directly into the patient, they are more likely to be covered under Medicare Part B. Consequently, biologics account for a relatively small share of gross Part D spending.[15] In 2007, spending on biologics totaled approximately $3.9 billion, or about 6 percent of Part D spending.[16] However, spending on Part D biologics has increased more rapidly than overall drug spending. Between 2006 and 2007, spending grew by about 36 percent compared with total Part D spending, which grew by 22 percent. Increased spending reflects, in part, higher enrollment in Part D in 2007. However, prices for biologics compared with prices of small-molecule drugs also increased rapidly. As more biologics enter the market, Part D is likely to see increased use of them.

Biologics covered under Part D fall into two broad categories. The first group includes older, simpler molecules such as insulin and human growth hormone. These products may have larger markets than many of the newer biologics but are less costly for consumers. Although there are no generic versions of older biologics, multiple brand-name products are often available.[17] Alternatively, newer, more complex biologics may have more limited markets. They tend to have high launch prices and many face high cost-sharing requirements.

Since Part D was implemented, biologics experienced faster price growth than other covered drugs. The Commission contracted with researchers at Acumen, LLC, to analyze price trends under Part D. They used claims data to construct a volume-weighted price index.[18] The index does not reflect rebates that plans may have received from manufacturers after the fact. It does reflect transaction prices. Measured by individual drug names, Part D drug prices rose by 7 percent from January 2006 through December 2007. However, prices declined by 6 percent when the index controlled for generic substitution. On the other hand, prices for biologics increased by 14 percent over the same period (or 10 percent when substitution is taken into account).[19]

How Medicare pays for Part D drugs

The Part D benefit is a much broader benefit than Part B. Part D covers most prescriptions that do not fall under the Part B coverage rules—particularly those filled at a retail pharmacy or in a long-term care facility. The benefit is administered by competing private plans, following a basic structure but with a great deal of flexibility and variety from plan to plan.

For 2009, the defined standard benefit includes:

- a $295 deductible,
- 25 percent coinsurance until the enrollee reaches $2,700 in total covered drug spending,
- a coverage gap in which the enrollee is responsible for the full discounted price of covered drugs until true out-of-pocket spending reaches $4,350, and
- about 5 percent coinsurance for drug spending above the catastrophic limit.

Plans can and often do offer alternative benefit structures. For example, a plan can offer a deductible lower than $295 or use tiered copayments rather than coinsurance—provided that the alternative benefit meets certain tests of actuarial equivalence. Plans place drugs on different cost-sharing tiers to encourage beneficiaries to use specific drugs in a therapeutic class that are both clinically appropriate and cost the plan less. Typically, plans' formularies include a generic tier, a preferred brand-name tier, and a nonpreferred brand-name tier.

Most plans also have a specialty tier where they list particularly high-cost drugs. In 2008 and 2009, plans could place drugs with prices that exceed $600 per month on their specialty tier. Specialty tiers have high cost sharing and beneficiaries may not appeal the level of coinsurance charged. For 2009, the median Part D enrollee in a plan with a specialty tier faces 33 percent coinsurance for drugs listed on that tier. Beneficiaries who regularly use drugs on a specialty tier are likely to reach the coverage gap in a short time and face 100 percent coinsurance until their drug spending reaches the catastrophic limit (MedPAC 2009).

For each Medicare enrollee in a Part D plan, Medicare provides plans with a subsidy that averages 74.5 percent of basic coverage, including a per capita subsidy to the plans and individual reinsurance. Under reinsurance, when an enrollee has drug expenditures over the catastrophic limit, Medicare subsidizes 80 percent of additional drug

TABLE 5–2

The top six Part D biologics that were eligible for specialty tier status, 2006–2007

Biologic	Primary indication	Total spending (in millions) 2006	Total spending (in millions) 2007	Percent change in spending, 2006–2007
Etanercept	Rheumatoid arthritis	$180	$262	45.8%
Epoetin alfa	Anemia	253	250	–1.6
Interferon beta-1a	Multiple sclerosis	169	223	32.4
Adalimumab	Rheumatoid arthritis	157	219	40.0
Teriparatide	Osteoporosis	123	179	44.6
Interferon beta-1b	Multiple sclerosis	74	87	17.3

Source: MedPAC analysis of prescription drug event data.

spending, the enrollee pays 5 percent, and the plan is at risk for the remaining 15 percent (MedPAC 2008).

In addition, Medicare subsidizes coverage for individuals eligible for a low-income subsidy (LIS), including beneficiaries dually eligible for Medicare and Medicaid. Individuals receiving the full subsidy have no deductibles, nominal copays, and no coverage gap. As of January 2008, about 9.4 million beneficiaries were receiving the subsidy, out of about 25 million Part D enrollees (MedPAC 2009). LIS recipients account for most spending on new biologics.

Of an estimated $50.7 billion total spending on Part D in 2008, enrollees paid $5 billion in premiums, and Medicare paid $18 billion in direct subsidies, $18 billion for LIS, and $6.5 billion in reinsurance payments. Medicare also paid $3.6 billion in subsidies to employers who provide drug coverage to their retirees (Boards of Trustees 2008).

Competition among Part D biologics

There is some price competition among the older biologic products for which alternatives are available. There are often multiple manufacturers producing older biologics like insulin, human growth hormone, and other hormones. Competition among these brands can result in lower prices. An entire vial of the most expensive insulin analog, for example, costs less than a single dose of many newer biologic products. There are at least three rapid-acting insulin brands, three regular or short-acting brands, three intermediate brands, and two long-acting brands. The competition in the insulin market results in relatively low Medicare expenditures, despite the widespread use of insulin. Although insulin made up more than 76 percent of Part D biologic prescriptions dispensed in 2007, it accounted for only about 17 percent of total spending on Part D biologics.

However, we see little sign of price competition among the newer biologics covered under Part D, even when several products are available in the same therapeutic class (e.g., rheumatoid arthritis). Of the top 20 Part D drugs by spending that were eligible for specialty tier status in 2007, 6 were biologics (Table 5-2). These six products include treatments for rheumatoid arthritis, anemia, multiple sclerosis, and osteoporosis.

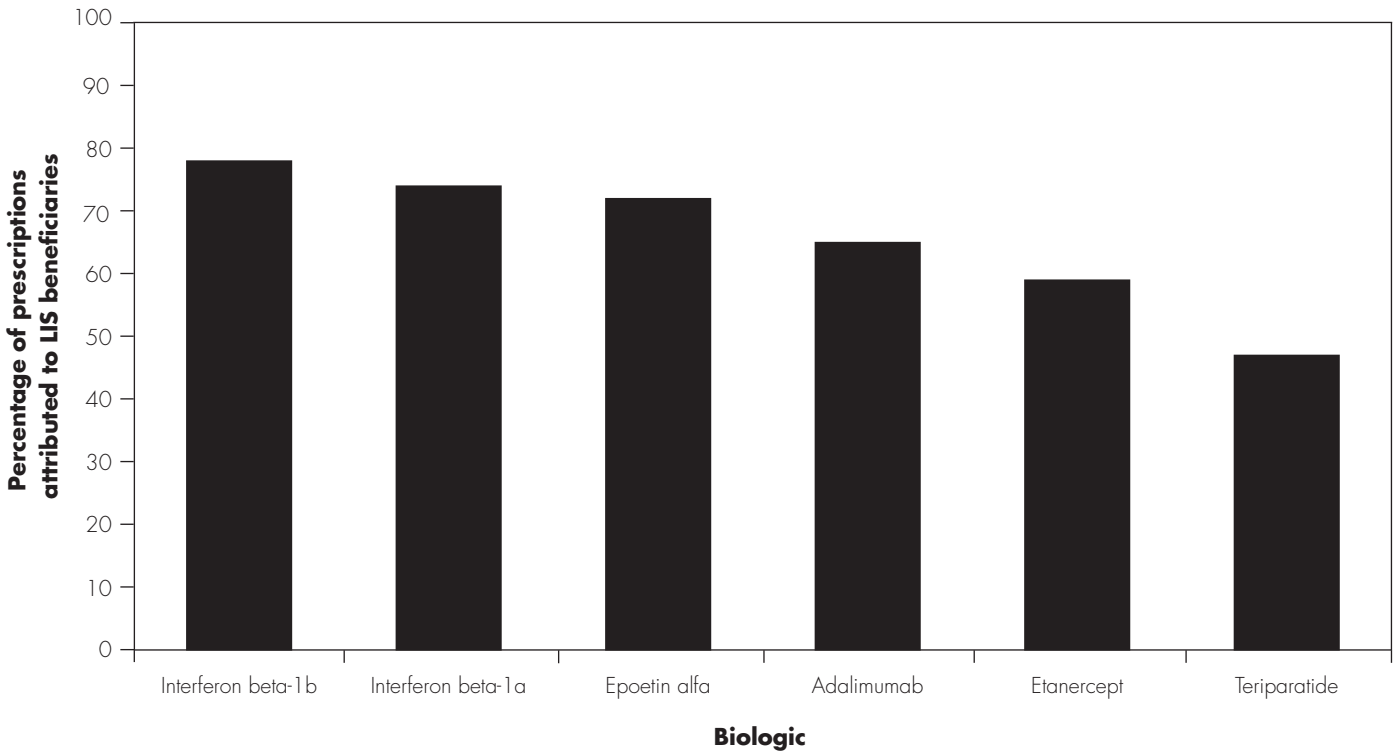
Prices for a volume-weighted market basket of these six drugs increased by 16 percent from January 2006 to December 2007. Most plans list all these products on their formularies at very similar prices (adjusted for dosage) with 25 percent to 33 percent beneficiary coinsurance requirements.

Plan risk for high-cost biologics is limited

New biologics are among the most expensive products covered under Part D. For example, Walsh estimates the average annual cost of biologics that treat multiple sclerosis at around $30,000 while biologics that treat rheumatoid arthritis can exceed $20,000 (Walsh 2009). A beneficiary taking one of these products will reach Part D's $2,700 initial coverage limit within a few months. At this point, the plan bears none of the cost of continued coverage until a beneficiary reaches the catastrophic limit. If the beneficiary is able to continue paying for the drug during the coverage gap, he or she will receive

FIGURE 5–2

LIS beneficiaries account for a large proportion of prescriptions for many high-cost biologics, 2007



Note: LIS (low-income subsidy).

Source: MedPAC analysis of 2007 prescription drug event records.

catastrophic coverage for several months of the year. At this point, plan liability is limited to 15 percent of all covered drug spending for the rest of the year.[20]

FOBs will be less expensive but may still be expensive. For example, the Congressional Budget Office estimates that in the initial year of competition, prices for FOBs would be about 20 percent below the prices of their reference products (CBO 2008c). Many will likely cost enough to result in catastrophic coverage if a beneficiary uses them for a full year. Because plans have no risk during the coverage gap and risk is limited during catastrophic coverage, they may have little incentive to tightly manage the use of the biologics or create incentives for beneficiaries to use FOBs. Plans may also have few tools to manage use of these products.

Many new biologics are covered on all formularies

Part D plans have the flexibility to establish a formulary that covers some drugs and not others. However, Part D rules require formularies to cover drugs in every therapeutic class and "key drug type." This policy protects some drugs that are the only drug available for treating a certain condition, while encouraging competition in most classes with multiple products. If a biologic is the only drug of its type, CMS generally requires Part D plans to cover it. For six drug classes in which access to a particular product may be especially important, Part D plans must cover "all or substantially all" drugs in the class. Those classes are: antineoplastics, antidepressants, antipsychotics, antiretrovirals, anticonvulsants, and immunosuppressants used by transplant patients. Although most drugs in the protected classes are not biologics, new biologics tend to be in small therapeutic classes where all or most products must be covered.

Plan representatives at our panel noted that they were unable to negotiate lower prices when manufacturers knew the plans would have to cover the manufacturers' products on the plans' formularies. Plans negotiate rebates

or other price concessions with manufacturers based on their ability to encourage enrollees to use one drug and not another. In the case of the protected classes or classes with few products, plans have little ability to steer utilization. In a few cases, drugs in different therapeutic classes may be used to treat the same medical condition. In those cases, plans may steer beneficiaries toward lower cost alternatives through differential cost sharing.

This situation may not change with the advent of FOBs. Unless an FOB is determined to be interchangeable with its reference product, plans may cover both products on their formularies. Unless a number of FOBs are introduced for the same product (an unlikely possibility initially), FOBs may not be substantially lower in price than innovator products for Part D beneficiaries. If more than one FOB for a reference product is introduced, plans may limit coverage to FOBs and savings may be greater.

LIS recipients are most likely to use new biologics

LIS beneficiaries make up a disproportionately large share of the market for biologics under Part D. In fact, LIS beneficiaries accounted for the majority of prescriptions for many high-cost biologics such as adalimumab, epoetin alfa, and etanercept in 2006 and 2007 (Figure 5-2).

As noted earlier, LIS beneficiaries have nominal cost sharing and no coverage gap. As a result, cost-sharing differences among products are less likely to affect their use.

For the same reason, beneficiaries receiving LIS would have little incentive to ask their physicians to prescribe FOBs. Because plans have limited ability to use cost-sharing differences to steer LIS recipients to FOBs, they may have few tools to influence use even though they may have incentives to do so. Other forms of drug management such as prior authorization also involve considerable administrative expense for plans. Further, if LIS beneficiaries' use of biologics resulted in losses in a given year, plans would raise their premiums the following year. Premiums could rise above the low-income threshold and beneficiaries would be reassigned to other plans.

Plans may experience selection bias if they provide more generous coverage of new biologics

In a few instances, plans may choose among more than one new biologic in a therapeutic class that is not one of the protected classes. For example, tumor necrosis factor inhibitors are used to treat several autoimmune disorders, especially rheumatoid arthritis. There are three drugs in this class. For Medicare patients, one (infliximab) is typically covered as a Part B drug, while the other two (adalimumab and etanercept) are generally Part D drugs. Plans have the option of favoring one drug on a preferred tier and negotiating for lower prices with the manufacturer.

In 2006, plans experimented with a range of formulary designs to cover drugs in this class. Some plans treated the drugs uniformly but others preferred one over the other and instituted wide cost-sharing differences between products to negotiate better prices with manufacturers. For example, one national plan charged a flat $17 copayment for one product and required 75 percent coinsurance for another. However, by 2009, plan treatment of these products was much more homogeneous. Part D formularies tend to list all three drugs (even though infliximab is not commonly paid under Part D), and plans with specialty tiers place all three on the specialty tier. Prices, adjusted for dosage, are also similar (Hoadley 2009).

Plans may have had multiple reasons for changing the way they cover this class of drugs. However, cost-sharing differences from 2006 to 2009 suggest that plans may be concerned that lower cost sharing for new biologics may lead beneficiaries with high-cost medical conditions to enroll in their plan. If that is the case, plans may be reluctant to offer FOBs at lower cost-sharing tiers if they believe it will increase selection into their plans.

FOBs may produce limited savings for Medicare Part D

While Medicare should achieve savings on FOBs for older biologics, the current benefit structure is likely to limit savings for FOBs for newer products. Because plans have no risk during the coverage gap and risk is dampened during catastrophic coverage, they may have limited incentive and few tools to tightly manage the use of these biologics. However, Medicare would have a strong interest in reducing the government's costs of catastrophic coverage by encouraging use of lower cost follow-on products.

If FDA determines that an FOB is interchangeable with its reference product, Part D could achieve significant savings from FOBs. Under current Part D policy, in classes in which plans must cover all drugs, or in small classes in which plans must cover at least two drugs, this rule is applied at the chemical level; plans can choose to cover the generic version of a drug and leave the brand name uncovered. Thus, plans could have the option of covering the innovator or the FOB or covering both products. No matter what decision the plan made, plan representatives would have more leverage negotiating with manufacturers.

However, most analysts do not expect FDA to determine that FOBs are interchangeable with their reference products in the near future.

In the more likely case that FOBs are not designated as interchangeable, opportunities for savings may be limited. Policymakers might need to consider changes to Part D to increase use of FOBs. Some potential options include:

- Modify the current Part D risk adjusters in a budget-neutral way to take into account drug utilization. In general, this practice would increase payments for LIS beneficiaries, who tend to take more drugs than other beneficiaries, and could increase plan willingness to enroll LIS beneficiaries and manage their use of high-cost biologics. If the risk adjuster were based on an indication of drug use within specific therapeutic classes rather than drug spending, plans would have more incentive to steer beneficiaries toward lower cost alternatives in a therapeutic class. In this case, plans might then create incentives for beneficiaries to use FOBs. However, it is not clear what tools would be available for them to use.
- Increase plan risk for coverage of drugs over the catastrophic limit. For example, Medicare could pay 80 percent of the lowest cost drug in a therapeutic class. Like the previous strategy, this situation could lead plans to design incentives to increase the use of FOBs.

Even if Medicare implemented one or both of these strategies, plans might still have difficulty convincing physicians and beneficiaries to use FOBs initially. If utilization of FOBs is minimal, plans would continue to have difficulty negotiating lower prices with innovator companies.

Any consideration of these options would require considerably more analysis. The Commission may want to look further into these issues. Alternatively, policymakers may want to focus more broadly on mechanisms to control costs for high-priced drugs.

Innovative ways to pay for biologics under Part B and Part D

Implementing a process to approve FOBs is one way to increase competition, put downward pressure on prices, and help lower expenditures on biologics. Given the magnitude and growth of Medicare's spending on biologics under Part B and the substantial increase in spending for biologics under Part D, policymakers could also consider adopting innovative pricing strategies to help alleviate rising expenditures for these products.

Some experts support pricing strategies in which Medicare takes into account a product's clinical effectiveness when setting reimbursement rates (Orszag 2008, Wilensky 2008). Whether paid for under Part B or Part D, a biologic's price does not usually account for the benefit of the product to beneficiaries or whether the product is a substantial improvement over existing treatments. This lack of flexibility leads to instances in which Medicare and Part D plans pay different rates for products that are clinically comparable and pay more for a new product without evidence that it is any better than currently available treatments.

In addition, Medicare's fee-for-service payment system lacks the flexibility to group—bundle—clinically associated products and services provided during an episode of care or to treat an illness or disease. For example, the program does not bundle drugs and doctor visits in the treatment of chronic illnesses. Paying for individual products and services fuels economic incentives for providers to increase the volume of medical services they furnish. This volume growth increases costs for beneficiaries and taxpayers, but in the aggregate there appears to be no correlation between higher spending and higher quality of care or improved health outcomes; in fact, the opposite may be true (Baicker and Chandra 2004, CBO 2008b, Fisher et al. 2003a, Fisher et al. 2003b, MedPAC 2003).

We have examined three payment strategies that, by considering information about a drug's clinical effectiveness, have the potential to improve the value of Medicare spending on drugs:

- ***Reference pricing:*** Set a product's payment rate no higher than that for currently available products unless evidence shows that the service improves beneficiaries' outcomes.
- ***Payment for results:*** Link a drug's payment to beneficiaries' outcomes through risk-sharing agreements with manufacturers.
- ***Bundling:*** Create payment bundles for groups of clinically associated products and services.

These approaches aim to improve the value of Medicare spending for drugs, including biologics, by making providers and patients more sensitive to the relative prices of treatments, reducing financial incentives for providers to furnish services that may have limited clinical benefits regardless of cost, and offsetting the efforts by manufacturers to market their products to providers and consumers. These policies can also be used to improve the value of Medicare spending for other products, items, and services that the program pays for. However, a statutory change would likely be necessary for widespread implementation of these pricing strategies. As discussed by Jost, the ability of Medicare to move to value purchasing strategies is greatly limited by the nature, structure, and terms of the Medicare statute (Jost 2009).

Reference pricing

Under reference pricing strategies, a single payment rate is set for a group of clinically comparable drugs; patients can pay the difference if they and their provider decide on a higher priced item. The rationale is that Medicare, beneficiaries, and taxpayers should not reimburse more for a product when a similar product can be used to treat the same condition and produce the same outcome but at a lower cost. Reference pricing policies do not control the price that manufacturers charge providers for their products.

A key aspect of reference pricing policies is determining the method for setting the reference price for each group of clinically comparable drugs. Alternative ways to calculate a reference price include basing it on the average price of the drugs within the group, the lowest cost drug within the group, the median, or the drug considered to be the most cost effective within the group.

Another key aspect of reference pricing policies is determining how to group drugs for the purpose of pricing. Reference pricing strategies rely on the ability to conclude that products are clinically comparable. A group could be narrowly defined to include all drugs with a similar substance—that is, an innovator small-molecule drug and its generics or an innovator biologic and its FOBs. Alternatively, a group could be more broadly defined based on drugs' pharmacologic equivalence. For example, such a group might consist of the biologics used to treat anemia—ESAs. An even broader definition would be to group drugs that are neither chemically similar nor pharmacologically equivalent but have similar therapeutic indications. For example, for payment purposes, the Canadian Patented Medicine Prices Review Board groups together five biologics (which have different active substances) used to treat rheumatoid arthritis.

Reference pricing strategies generally have not been used in the United States, although Medicare has some limited experience as we describe in the text box (p. 127) (Huskamp et al. 2000). Under the least costly alternative (LCA) policy, Medicare sets the payment rate for a group of clinically comparable products based on the least costly product within the group. However, a recent court decision may limit the widespread use of LCA payment policies for drugs.

The Congressional Budget Office (CBO) estimated that expanded use of reference pricing policies would result in savings for the Medicare program. In its 2008 report on reducing federal spending on health care, CBO included as a policy option use of the LCA approach to pricing for five products that physicians use to treat osteoarthritis of the knee. Although each product differs slightly, they are all approved by FDA for the same indication—osteoarthritis—and they work through the same mechanism of clinical action. Therefore, it could be argued that Medicare should not pay more for one product than for another if both are likely to have the same effect in a patient when prescribed for the same condition. CBO estimated savings of about $200 million between 2010 and 2014 and almost $500 million between 2010 and 2019 if Medicare set the payment for these five products based on the lowest priced product (CBO 2008c).

First implemented in Germany in 1989, the use of reference pricing for drugs including biologics is common internationally. Nearly all the 30 member countries of the Organisation for Economic Co-operation and Development (OECD) use some type of reference pricing strategy. Most OECD countries (24 of them) use some type of external reference pricing, in which the payer sets the price based on drug prices in other countries (OECD 2008a). However, there are differences across countries in the products paid for and the methods used to calculate prices. Table 5-3 (p. 126) highlights some of these differences for six selected OECD countries—Australia, Canada, Germany, Italy, the Netherlands, and Spain. For example, some countries (Australia, Canada, Germany, and the Netherlands) use reference pricing policies to set the price of patented and off-patent drugs, while other countries use such policies to set the price of only off-patent drugs (Italy and Spain).

TABLE 5–3 **Features of reference pricing policies vary across OECD countries**

Country	Method used to set the price	International comparison	Includes patented drugs
Australia	Lowest price of the drugs in the therapeutic group	New Zealand and U.K.	Yes
Canada	Prices generally cannot exceed cost of existing drugs in the therapeutic group	Cannot exceed France, Germany, Italy, Sweden, Switzerland, U.K., U.S.	Yes
Germany	Statistically derived from regression analysis; price set at the lowest third of the price in the therapeutic group	No	Yes
Italy	Lowest priced product in the group	Other European Union countries, particularly France and Spain	No
Netherlands	Price of the drug equal to or directly below the average of the prices in the therapeutic group	Maximum price cannot exceed average wholesale price in Belgium, France, Germany, and the U.K.	Yes
Spain	Mean of the three lowest cost drugs in the group	Selected countries within the European Union	No

Note: OECD (Organisation for Economic Co-operation and Development), U.K. (United Kingdom), U.S. (United States). Patented drugs include small-molecule drugs and biologics.

Source: Australian Government Department of Health and Ageing 2009; Kanavos and Reinhardt 2003; Österreichisches Bundesinstitut Für Gesundheitswesen 2006; OECD 2008a; OECD 2008b; Patented Medicine Prices Review Board 2009.

Other strategies that are used internationally to control drug expenditures include implementing price freezes, price cuts, and mandatory rebates; creating formularies; implementing coverage policies that set forth the indications, settings, and populations for which the payer will pay for the product; using pharmacoeconomic evaluations to determine launch prices; and determining reasonable limits for the profits to be made from innovator products.

These pricing policies generally result in lower prices for biologics and small-molecule drugs internationally than in the United States. Danzon and Furukawa used data from IMS Health, Inc. (which include data from all payers) to compare the prices of biologics in the United States with prices in Australia, Canada, France, Germany, Italy, Japan, Mexico, Spain, and the United Kingdom (Danzon and Furukawa 2006). Compared with the United States, biologics launched after 1996 were more costly in Mexico, while biologics launched before 1996 were more costly in Canada and France. Also using IMS data, the U.S. Department of Commerce reported that in 2003 prices for all patented drugs (small-molecule drugs and biologics) were 18 percent to 60 percent lower in Australia, Canada, France, Germany, Greece, Japan, Poland, Switzerland, and the United Kingdom than in the United States (DOC 2004). Several factors can affect the international comparison of drugs, including changes in currency rates between the year the data were published and 2009.

Proponents of reference pricing argue that it makes patients and their providers more sensitive to the relative prices of different services and more likely to consider cost when choosing among treatment options (Commonwealth Fund 2003). The Commission noted that LCA policies can stimulate price competition among alternative ways to treat a given illness (MedPAC 2007). Some observers argue that Medicare should not pay more for one product than another if both are likely to have the same effect in a patient when prescribed for the same condition (CBO 2008c).

Critics of reference pricing argue that these policies will negatively affect:

- patient outcomes
- patient access to new technology
- manufacturers' incentives to invest in research and development

Medicare has had some success in using reference pricing policies, but a recent court ruling discourages widespread use

Least costly alternative (LCA) policies, which are similar to reference pricing strategies, set the payment rate of a service based on the payment rate of a less costly, clinically comparable service. LCA policies are in place for: advanced prostate cancer drug regimens, alefacept therapy, nebulizers (inhalation drugs), manual wheelchair bases, power mobility devices, seat lift mechanisms, and supplies for tracheostomy care. Medicare's regional contractors establish such policies through the local coverage determination process.

In the Commission's January 2007 report, we stated our support for LCA policies (MedPAC 2007). We also noted that some providers have complained that LCA policies vary from region to region and that some contractors change their LCA policies frequently. We recognized that local coverage determinations promote innovation and flexibility but suggested that Medicare clarify the contractors' LCA policies when sufficient variation and inconsistency exist.

A 2008 ruling by the federal district court may affect the ability of Medicare's contractors to continue to apply LCA policies to drugs. The U.S. District Court for the District of Columbia ruled that Medicare can no longer use LCA policies to pay for Part B inhalation drugs. The court concluded that the statute's specific provision that sets the payment rate for Part B drugs (based on its average sales price) precludes Medicare from using LCA policies under the statute's broader authority of covering services that are reasonable and necessary (U.S. District Court for the District of Columbia 2008).

In addition to LCA policies, Medicare also has implemented a "functional equivalence" policy for two biologics (darbepoetin alfa and epoetin alfa) on a national level. The concept behind the functional equivalence policy is similar to the LCA policy; the payment rate of products that are considered to be close substitutes is based on the rate of the least expensive product. In 2003, Medicare set the payment rate for a new biologic at the same rate as that of an existing product after concluding that both products were clinically comparable because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells. Medicare used the functional equivalence policy for these biologics in 2004 and 2005. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limited the use of the functional equivalence standard. The Congress prohibited the use of this standard for other drugs and biologics in the hospital outpatient setting. However, the Congress did not preclude the agency from continuing to use the policy for the two biologics in the hospital outpatient setting or for setting the payment rate the same for other clinically comparable services in other settings. In response to passage of the MMA, the payment rate for each product was set based on its average sales price plus 6 percent beginning in 2006. ■

Some critics contend that physicians should be given discretion in selecting among clinically comparable services because the effectiveness of those services may vary among patients. The literature on the effect of reference pricing on patients' outcomes is mixed. One rigorous evaluation found that reference pricing for angiotensin-converting enzyme inhibitors for treatment of hypertension among patients 65 years or older did not result in patients (in British Columbia, Canada) discontinuing treatment or increasing the overall rate of physician visits or hospital admissions (Schneeweiss et al. 2002). By contrast, an uncontrolled study found an increase in complications when patients switched therapies under a system of reference pricing in New Zealand (Thomas and Mann 1998).

Some critics also contend that reference pricing policies may decrease access to innovations and may not encourage competition among clinically similar services. Danzon and Ketcham concluded that reference pricing policies of pharmaceuticals in New Zealand resulted in decreased availability of new compounds, particularly high-priced new products, and found no evidence that reference pricing encouraged competition, which they concluded is

consistent with the hypothesis that prices tend to converge to the reference price (Danzon and Ketcham 2003).

Critics of reference pricing also argue that grouping an innovator's product with other clinically similar products might change or reduce manufacturers' incentives to invest in research and development. Manufacturers might shift their research toward diseases not currently treated by multiple drug therapies or reduce investment in products that are incremental improvements of other products (Farkas and Henske 2006). Reference pricing might particularly discourage the development of incremental drugs and biologics. However, proponents of reference pricing policies counter that such policies might increase manufacturers' incentive to develop truly innovative products and to compare their product with other products in the clinical trials they sponsor. Kanavos and Reinhardt noted the lack of empirical evidence documenting the impact of reference pricing policies on the pace of innovation in the drug industry (Kanavos and Reinhardt 2003).

If the statute gave Medicare more flexibility to use reference pricing policies on a national level, the program would need to define the process that would be used to group clinically similar products. Ensuring transparency and stakeholder input would be key; establishing an advisory group to help Medicare's process might improve transparency and provide an opportunity for public input. Finally, the program could establish a process by which beneficiaries could petition to be reimbursed for using a higher priced product.

Payment for results

Another strategy is to explicitly link a drug's payment to patient outcomes through risk sharing with manufacturers. With performance-based pricing, the basis of risk is the quality of the drug's performance, as measured by agreed upon outcomes. For example, the manufacturer might guarantee clinically defined biomarker or surrogate outcomes, such as decreased low-density lipoprotein goals for a cholesterol drug.

Performance-based strategies might be particularly applicable for drugs that are costly and have different success rates among subgroups of patients. According to Garber and McClellan, payment by results represents an innovative approach to address a central dilemma in the allocation of drugs to patients (Garber and McClellan 2007). If the price of a product is uniform, patient access might be limited to those groups identified by clinical trial testing that showed substantial improvement in outcomes. In results-based payment, payers face less financial risk from treating groups that were either not included in clinical trial testing or did not show substantial improvement.

Challenges associated with performance-based pricing include defining objective measures of outcomes that are not heavily confounded by patient characteristics or by other treatments and developing and maintaining a mechanism to track patients' outcomes, such as via clinical registries or electronic medical records (Garber and McClellan 2007). The effects of providers' practice patterns and patients' adherence to the prescribed regimen are other variables that need to be considered when designing performance-based pricing strategies.

The United Kingdom uses performance-based pricing policies for several drugs. For example, in 2007, the British National Institute for Health and Clinical Excellence implemented an agreement with the manufacturer of bortezomib, an anticancer drug used to treat multiple myeloma. Under this agreement, the manufacturer rebates the full cost of the drug for patients who, after four cycles of treatment, have less than a partial response (i.e., less than 50 percent reduction in serum M-protein). Medicare pays for bortezomib under Part B using the ASP methodology; Medicare payment is estimated at about $4,500 for four cycles of treatment.[21]

Bristol-Myers Squibb offers a performance-based approach in the United States to patients with commercial insurance who are new users of the company's drug abatacept to treat rheumatoid arthritis. For the first six months, the company pays for patients' copayments for the product. For patients not satisfied with their outcomes after six months, the company will pay the first copayment of another rheumatoid arthritis medicine (up to $500). One study estimated the first-year costs of abatacept to be $19,000 (Vera-Llonch et al. 2008). Medicare pays for abatacept under Part B using the ASP methodology, but beneficiaries are not eligible for Bristol-Myers Squibb's program.

Bundling

Under a bundling strategy, providers are paid a prospectively set rate for a group—or bundle—of services they furnish during an episode of care. For Part B services that are currently paid for separately, a bundle could, for example, cover the Part B drugs, outpatient physician services, imaging tests, and laboratory tests associated with treating a chronic disease. Alternatively, a bundle could cover services associated with an event, such as

hospital and physician services during an inpatient hospital stay.

Creating a payment bundle for a group of associated items and services provided during an episode of care would encourage providers to operate efficiently, as they would retain the difference between the payment rate and their costs. Greater bundling of payments to cover all the services associated with a treatment or disease could reduce incentives to provide additional services that might be of low value. On the other hand, such approaches might raise concerns about the financial risk that providers face and their incentives to provide too little care (Orszag 2008).

Medicare's approach for paying for most services provided by institutional providers (and paid for under Part A)—including acute care hospitals, skilled nursing facilities, and home health agencies—is to pay for bundles of services using a prospectively set payment rate. The ultimate in bundled payments is a single capitated payment that covers all Medicare services, such as that used for Medicare Advantage plans.

With few exceptions, Medicare generally pays for each service physicians furnish under Part B. The exceptions include Medicare's monthly payment to physicians for the outpatient care of dialysis patients and the physician fee for major surgeries that encompasses the total physician inputs used during what is termed the global period, which includes the day of the surgery and postsurgery care. For example, the global period for a total hip replacement is 90 days.

Bundling is one option that might improve the value of Medicare spending. In our June 2008 report, the Commission recommended changes in fee-for-service payment for care provided around a hospitalization. The Commission noted that bundling Medicare payment to cover all services associated with an episode of care could improve incentives for providers to deliver the right mix of services at the right time.

Some researchers have suggested bundling physician services covered under Part B. Bach observed that Medicare might consider prospective payment for cancer care that stretches over the course of an episode of illness (Bach 2009). Under such a strategy, Medicare could pay a lump sum to cover all the costs of doctor visits, chemotherapy treatments, and the chemotherapy itself over a period of care. Wilensky recommended developing payments that cover all the services a single physician provides to a patient to treat one or more chronic diseases (Wilensky 2009). She also suggested bundling payments for high-cost high-volume stays to include, at a minimum, all physician services associated with the episode and the hospital payment.

Conclusions

This chapter summarized key issues that are being discussed as policymakers and stakeholders consider establishing a regulatory pathway for FDA to approve FOBs. While FDA has jurisdiction over approval of FOBs, Medicare is a major payer for biologics and has a strong incentive to ensure that it gets value for the money it spends on these products. Medicare spending on biologics is substantial and expected to grow significantly in future years. The lack of an expedited approval process for FOBs has kept the prices of innovator biologics high over time. Establishing an approval process for FOBs could put pressure on the prices of biologics, generating savings for Medicare. The Commission intends to continue to monitor the issues associated with implementing an expedited approval process for FOBs.

Because biologics have safety issues associated with their use, increased postmarketing surveillance to detect side effects of these products in a timely manner may be warranted. Some observers also argue for increased surveillance efforts to detect adverse events of small-molecule drugs. Existing postmarketing surveillance programs are unsystematic and rely on doctors, patients, and manufacturers to report adverse events. CMS is collaborating with FDA to use Medicare claims to create a postmarketing safety assessment program.

Changing Medicare's payment systems may be necessary to capture savings from FOBs. We described three approaches to the Part B payment system that could be considered for assigning FOBs and innovator biologics to the same billing code and authority that could be given to the Secretary to make such determinations. In addition, we explored ways to increase incentives to use FOBs under Part D. The chapter also examined three broader strategies to improve the value of Medicare spending on drugs—reference pricing, payment for results, and bundling. The Commission plans to continue to look at ways for Medicare to improve the value of spending for drugs. ■

Endnotes

1 The $13 billion in Medicare spending on biologics encompasses those biologics for which Medicare makes separate payment. It does not include biologics administered to hospital inpatients or a subset of biologics (low-cost biologics) administered in hospital outpatient departments that are subject to bundled payment.

2 The Food and Drug Administration defines drugs as encompassing both biologics and chemically synthesized, small-molecule drugs. This chapter uses the term "drug" to include biologics and other products and uses the term "small-molecule drug" to differentiate between biologics and other products.

3 PHSA § 351(ii), 42 U.S.C. § 262(i).

4 Technically, requirements for biologics approved under the Public Health Service Act may vary.

5 In the case of Diamond v. Chakrabarty (1980), the Supreme Court first ruled that a biologic could be patented. The product was a substance used for cleaning up oil spills.

6 During the 180-day marketing exclusivity period, FDA may not approve subsequent applications for the same drug product.

7 In Europe, determinations of comparability are made by the European Union but individual states have their own processes for determining interchangeability.

8 Article 14(11) of Regulation (EC) No. 726/2004.

9 Medicare also makes a separate payment for administration of the drug (e.g., injection or infusion).

10 In addition to drugs administered in physicians' offices, Medicare Part B also covers injectable drugs furnished in hospital outpatient departments, injectable drugs furnished in end-stage renal disease facilities, drugs used with durable medical equipment (e.g., inhalation drugs used with a nebulizer or infusion drugs furnished with an external pump), and a small number of oral drugs and other types of drugs. The Part B payment rates for separately paid drugs are 106 percent of ASP, with the exception of separately paid drugs furnished in hospital outpatient departments (104 percent of ASP in 2009), infusion drugs furnished with an external pump (95 percent of the October 1, 2003, average wholesale price), and certain vaccines and blood products other than clotting factor (95 percent of current average wholesale price).

11 The ASP calculation does not include sales at a nominal price and sales exempt from the calculation of Medicaid best price (e.g., sales to certain other federal programs, sales under the Federal Supply Schedule, sales at prices offered through state pharmaceutical assistance programs, depot or single contract sales to a government agency, and sales at prices negotiated by Medicare Part D plans and qualified retiree prescription drug plans).

12 Generic versions of intravenous granisetron have recently become available in the market and are reflected in the Medicare payment rates starting in late 2008. Thus far, we have seen steady quarterly declines in the payment rate for granisetron but little change in the payment rates for the other drugs in the therapeutic class. The minimal price changes among competitor products may reflect the effects of generic entry having already been realized with the earlier entry of generic ondansetron and differences in the degree to which the competitor products are considered substitutable.

13 Whether having separate codes creates a financial incentive for use of the more expensive product would depend on how an individual physician's acquisition cost compared with the ASP of each product and whether there were cash flow issues associated with stocking higher priced drug inventory.

14 CMS has adopted this type of approach for some of the grandfathered biologics and single-source drugs that were placed in the same billing code before the MMA. For programmatic reasons, CMS has established separate codes for some of the grandfathered products (e.g., certain skin substitutes) but maintained identical payment rates for the grandfathered products based on the ASP calculated across the codes. As a result, some of the products now have their own code for billing purposes, but they are paid a rate based on the ASP for the products that have been grandfathered together. A statutory change may be needed to apply this approach more broadly.

15 All spending estimates in this section were calculated using prescription drug event records and include dispensing fees, sales tax, and beneficiary cost sharing.

16 There is no single generally accepted list of approved biologics. These spending estimates are based on an amalgamation of several lists of biologic products, including lists from Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Center for Biologics Evaluation and Research, and Center for Drug Evaluation and Research, as well as a list of drugs expected to cost more than $600 per month that we reviewed using the Orange Book, drugs@FDA, and DrugBank to identify

biologics. We used the combined lists to calculate spending based on 2006 and 2007 prescription drug event records, which include dispensing fees, sales tax, and beneficiary cost sharing.

17 As noted on p. 112, due to a historical quirk FDA has approved a follow-on version of one brand of human growth hormone.

18 For additional findings and discussion of methodology see MaCurdy and colleagues (2009, forthcoming).

19 Although there are no generic substitutes for biologics, this measure takes into account other kinds of substitution—for example, when a cheaper brand of insulin is substituted for a more expensive one.

20 If the annual cost of the drug is high enough, 15 percent of the total may still be a considerable sum.

21 Medicare payment is based on administering bortezomib twice weekly during the first six weeks of treatment to an individual with a body surface area of 1.6 square meters.

References

Australian Government Department of Health and Ageing. 2009. *Better health and active ageing for all Australians.* Canberra: Australian Government Department of Health and Ageing. http://www.health.gov.au.

Bach, P. B. 2009. Limits on Medicare's ability to control rising spending on cancer drugs. *New England Journal of Medicine* 360, no. 6: 626–633.

Baicker, K., and A. Chandra. 2004. Medicare spending, the physician workforce and beneficiaries' quality of care. *Health Affairs Web Exclusives* (April 7): W4-184–W4-197.

Behrman, R. 2008. Follow-on biologics: A brief overview. Presented to the Federal Trade Commission. November 2008.

Biotechnology Industry Organization. 2009. Biotechnology industry facts. Washington, DC: BIO. www.bio.org/speeches/pubs/er/statistics.asp?p=yes.

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2008. *2008 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Washington, DC: Boards of Trustees.

Brill, A. 2008. *Proper duration of data exclusivity for generic biologics: A critique.* November. http://www.tevadc.com/Brill_Exclusivity_in_Biogenerics.pdf.

Commonwealth Fund. 2003. *Reference pricing for drugs: Is it compatible with U.S. health care?* New York: Commonwealth Fund.

Congressional Budget Office 2008a. *S. 1695: Biologics Price and Innovation Act of 2007*. Washington, DC: CBO. June 25.

Congressional Budget Office. 2008b. *Geographic variation in health care spending*. Washington, DC: CBO.

Congressional Budget Office. 2008c. *Budget options, volume one: Health care*. Washington, DC: CBO.

Congressional Budget Office. 1998. *How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry*. Washington, DC: CBO.

Danzon, P. M., and M. F. Furukawa. 2006. Prices and availability of biopharmaceuticals: An international comparison. *Health Affairs* 25, no. 5: 1353–1362.

Danzon, P. M., and J. D. Ketcham. 2003. *Reference pricing of pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand*. Cambridge, MA: National Bureau of Economic Research.

Department of Commerce. 2004. *Pharmaceutical price controls in OECD countries: Implications for U.S. consumers, pricing, research and development, and innovation.* Washington, DC: DOC. http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf.

European Medicines Agency. 2005. *CHMP guideline on similar biological medicinal products*. CHMP/437/04. London: EMEA. October 30.

Farkas, C., and P. Henske. 2006. *Reference pricing for drugs.* http://www.forbes.com. April 14.

Federal Trade Commission. 2002. *Generic drug entry prior to patent expiration: An FTC study*. Washington, DC: FTC.

Fisher, E., D. Wennberg, T. Stukel, et al. 2003a. The implications of regional variations in Medicare spending. Part 1: The content, quality, and accessibility of care. *Annals of Internal Medicine* 138, no. 4 (February 18): 273–287.

Fisher, E., D. Wennberg, T. Stukel, et al. 2003b. The implications of regional variations in Medicare spending. Part 2: Health outcomes and satisfaction with care. *Annals of Internal Medicine* 138, no. 4 (February 18): 288–298.

Garber, A. M., and M. B. McClellan. 2007. Satisfaction guaranteed—"payment by results" for biologic agents. *New England Journal of Medicine* 357, no. 16: 1575–1577.

Grabowski, H. 2008. Follow-on biologics: Data exclusivity and the balance between innovation and competition. *Nature Reviews: Drug Discovery* 7 (June): 479–488.

Harbour, P. 2007. The competitive implications of generic biologics. Presented to the ABA Sections of Antitrust and Intellectual Property Law. June. http://www.ftc.gov/speeches/harbour/070614genbio.pdf.

Hoadley, H., E. Hargrave, K. Merrell, et al. 2008. Medicare Part D benefit designs and formularies, 2006–2009. Presented to MedPAC. December 5.

Hoadley, J. 2009. E-mail message to author, March 17.

Huskamp, H. A., M. B. Rosenthal, R. G. Frank, et al. 2000. The Medicare prescription drug benefit: How will the game be played? *Health Affairs* 19, no. 2: 8–23.

Jost, T. S. 2009. *Value-based purchasing: Laws and regulations.* http://www.newamerica.net/files/Jost-ppt.pdf.

Kanavos, P., and U. Reinhardt. 2003. Reference pricing for drugs: Is it compatible with U.S. health care? *Health Affairs* 22, no. 3: 16–30.

Kotlikoff, L. 2008. *Stimulating innovation in the biologics industry: A balanced approach to marketing exclusivity.* http://www.tevadc.com/Kotlikoff_Innovation_in_Biologics.pdf.

MaCurdy, T., N. Theobald, T. Lau, et al. 2009. *Price indices for Part D prescription drugs*. Prepared for MedPAC. Washington, DC: MedPAC. Forthcoming.

Managing Intellectual Property (MIP). 2008. Biosimilar debate heats up at BIO. *MIP Week*, June 18.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008. *Payment basics: Part D payment system.* Washington, DC: MedPAC.

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

Medicare Payment Advisory Commission. 2003. *Report to the Congress: Variation and innovation in Medicare*. Washington, DC: MedPAC.

Noonan, K. 2008. Follow-on biologic drugs and patent law: A potential disconnect? *Snippets Review of Developments in Intellectual Property Law* 6, no. 1 (May):1–10 .

Novartis. 2008. Comments in response to Federal Trade Commission questions on follow-on biologics. Basel: Novartis. September 30.

Organisation for Economic Co-operation and Development. 2008a. *Pharmaceutical pricing policies in a global market*. Paris: OECD. http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html.

Organisation for Economic Co-operation and Development. 2008b. *Pharmaceutical pricing and reimbursement policies in Germany*. Paris: OECD. http://www.oecd.org/dataoecd/6/57/41586814.pdf.

Orszag, P. R., Congressional Budget Office. 2008. The long-term budget outlook and options for slowing the growth of health care costs. Written statement before the Committee on Finance, U.S. Senate. 110th Cong., 2nd sess. June 17. http://www.cbo.gov/ftpdocs/93xx/doc9385/06-17-LTBO_Testimony.pdf.

Österreichisches Bundesinstitut Für Gesundheitswesen. 2006. *Surveying, assessing, and analyzing the pharmaceutical sector in the 25 EU member states.* Luxembourg: European Communities. http://ec.europa.eu/competition/mergers/studies_reports/oebig.pdf.

Patented Medicine Prices Review Board. 2009. http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1.

Schacht, W. H., and J. R. Thomas. 2008. *Follow-on biologics: Intellectual property and innovation issues*. Congressional Research Service Report for Congress. Washington, DC: Congressional Research Service. Updated May 21.

Schneeweiss, S, A. M. Walker, R. J. Glynn, et al. 2002. Outcomes of reference pricing for angiotensin-converting enzyme inhibitors. *New England Journal of Medicine* 346, no. 11: 822–829.

Schwieterman, W. 2007. Safe and affordable biotech drugs—the need for a generic pathway. Testimony before the Committee on Oversight and Government Reform, U.S. House of Representatives. 110th Cong., 1st sess. March 26.

Siegel, J. 2007. Follow-on biologics. Oral testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. 110th Cong., 1st sess. March 8.

Thomas, M., and J. Mann. 1998. Increased thrombotic vascular events after change of statin. *Lancet* 352, no. 9143: 1830–1831.

Towse, Adrian. 2008. Competition issues involving follow-on biologic drugs. Submission to the FTC. #537778–00049. December 31.

U.S. District Court for the District of Columbia. 2008. Ilene Hays and Dey, L.P., plantiffs, v. Michael O. Leavitt, Secretary of the United States Department of Health and Human Services, et al., defendants. Memorandum opinion. https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2008cv1032-22.

Vera-Llonch M., E. Massarotti, F. Wolfe, et al. 2008. Cost-effectiveness of abatacept in patients with moderately to severely active rheumatoid arthritis and inadequate response to methotrexate. *Rheumatology* 47: 535–541.

Walsh, B. 2009. *The tier 4 phenomenon: Shifting the high cost of drugs to consumers*. Research report. Washington, DC: AARP.

Wilensky, G. R. 2009. Reforming Medicare's physician payment system. *New England Journal of Medicine* 360, no. 7: 653–655.

Wilensky, G. R., Project HOPE. 2008. Comparative clinical effectiveness: Leveraging innovation to improve health care quality for all Americans. Written statement before the Committee on Finance, U.S. Senate. 110th Cong., 2nd sess. July 17. http://finance.senate.gov/hearings/testimony/2008test/071708gwtest.pdf.

Woodcock, J., J. Griffin, R. Behrman, et al. 2007. The FDA's assessment of follow-on protein products: A historical perspective. *Nature Reviews Drug Discovery*. April 13.

CHAPTER 6

Improving traditional Medicare's benefit design

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Chapter summary

Fee-for-service (FFS) Medicare does not protect beneficiaries against catastrophic levels of out-of-pocket (OOP) spending. Lack of catastrophic protection means that beneficiaries with high spending on health care must pay substantial amounts unless they have supplemental insurance to cover Medicare's significant cost-sharing requirements. Yet coverage that fills in most or all of Medicare's cost sharing can lead to higher use of services and Medicare spending, and its prevalence prevents Medicare from being able to use cost sharing as a policy tool.

The most widely used sources of secondary coverage today are employer-sponsored retiree insurance, individually purchased medigap policies, and Medicaid coverage. There are important differences in beneficiaries' access to and prices for those sources of coverage. In turn, those differences lead to wide variation in beneficiaries' spending for premiums and cost sharing.

A Commission-sponsored study on the relationship between secondary coverage and Medicare spending provides evidence that beneficiaries

In this chapter

are sensitive to cost sharing and that spending for beneficiaries with secondary insurance tends to be higher for:

- elective hospital admissions compared with emergency and urgent admissions for conditions that require more immediate medical attention,
- preventive care,
- office-based care compared with hospital-based care,
- medical specialists compared with primary care or generalist physicians, and
- services such as minor procedures, imaging, and endoscopy.

In the future, cost sharing could be used as a tool to complement various policy goals such as: improving financial protection for Medicare beneficiaries and distributing cost-sharing liability more equitably among individuals with different health care costs, encouraging use of high-value services and discouraging use of low-value ones, and reinforcing reforms in the payment system that seek better value for health care expenditures. An additional goal may be to improve Medicare's financial sustainability.

Inherent conflicts exist among these goals. For example, an OOP cap to the FFS benefit could improve financial protection for the sickest beneficiaries, but, without other measures, such catastrophic protection would result in substantially higher Medicare program spending and worsen the program's long-term financial situation. Several of the goals require more nuanced and targeted approaches to cost sharing than Medicare uses today and would need further development of methods to evaluate quality, compare effectiveness of therapies, and measure provider resource use. Steps toward each of the goals would be more effective if changes were made to Medicare's deductibles and coinsurance while the role of supplemental coverage was redefined. ■

Introduction

If policymakers were drawing up Medicare's fee-for-service (FFS) benefit from scratch, they would probably design it differently. For example, they might include catastrophic protection and design cost-sharing provisions in ways that encourage beneficiaries to weigh their use of discretionary care without discouraging needed care.

The structure of Medicare's traditional FFS benefit has shortcomings in its coverage that lead most beneficiaries to take up secondary insurance through former employers, individually purchased medigap policies, or Medicaid. Supplemental coverage often protects beneficiaries from high out-of-pocket (OOP) spending and reduces their paperwork burden. At the same time, some of the most widely used sources of secondary coverage fill in nearly all of Medicare's cost sharing without deductibles or copayments. Because access to secondary coverage is not equal across beneficiaries, the distribution of beneficiaries' financial liability varies widely. Supplemental coverage also leads to higher Medicare spending because it reduces or eliminates cost sharing for the services beneficiaries use.

Today, the prevalence of supplemental coverage prevents Medicare from being able to use cost sharing as a policy tool. Since Medicare's inception in 1965, employers and private insurers have experimented with benefit design to control growth in health spending. Some approaches have been more effective at redistributing the incidence of health costs than at affecting when and from whom patients seek care. Other approaches hold promise by using cost sharing in more targeted ways to steer beneficiaries toward preferred providers or more valuable therapies. For the future, FFS benefit design and cost sharing could be used to pursue policy goals, such as to encourage use of providers with better track records on quality and resource use, to encourage specific patients to adhere to certain treatments, and to discourage provision of overused services. But, for such measures to be effective, decision makers would also need to redefine when supplemental coverage may fill in Medicare's cost sharing.

Beneficiaries find it difficult to predict OOP costs in FFS Medicare

Under Medicare's FFS benefit alone, beneficiaries cannot easily predict their OOP costs. The FFS benefit has cost-sharing requirements that vary by type of service and site of care (see text box, pp. 142–143). A major shortcoming of the FFS benefit is that it has no catastrophic limit on OOP spending. These features, combined with the fact that patients rarely know what their providers charge or what detailed list of services they will need, make it difficult to predict OOP costs. For example, if a beneficiary has a hospitalization, she is responsible for a large inpatient deductible ($1,068 in 2009) and, after a separate Part B deductible ($135 in 2009), 20 percent coinsurance for services associated with the hospitalization, such as ambulance transportation and physician care (e.g., for the attending physician, surgeon, and anesthesiologist). The beneficiary cannot predict Medicare's cost sharing for these services.

For Medicare beneficiaries with lower incomes, unpredictable financial liability for health care (i.e., amounts paid OOP for cost sharing and premiums) can be especially burdensome. In 2005, 16 percent of beneficiaries had income less than the federal poverty level ($9,570 for a single person and $12,830 for a couple); 45 percent had income at 200 percent of that level or less (MedPAC 2008a). In 2006, Social Security payments were 50 percent or more of annual income for 52 percent of aged beneficiary couples and 72 percent of aged unmarried beneficiaries (Social Security Administration 2008).

About 90 percent of FFS beneficiaries take up secondary coverage

To reduce uncertainty about OOP spending, most FFS beneficiaries have some form of secondary insurance. Supplemental coverage increases predictability for beneficiaries by covering Medicare cost sharing at the point of service in return for regular monthly premiums. Excluding beneficiaries in private Medicare plans and those who were institutionalized, in 2005, 89 percent of beneficiaries had some form of secondary coverage (Figure 6-1). Employer-sponsored retiree coverage that wrapped around Medicare's benefit was the most common source, followed by individually purchased medigap policies and Medicaid. (A portion of beneficiaries included in the medigap category report that they have both employer-sponsored and medigap policy coverage.) Just 11 percent of FFS beneficiaries relied on Medicare alone.[1]

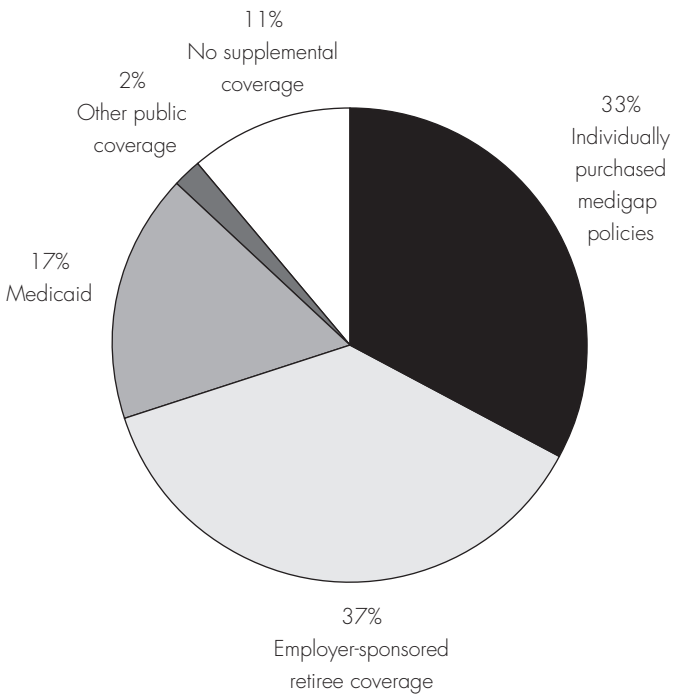
There are important differences among sources of supplemental coverage.

Employer-sponsored retiree coverage

The combination of FFS Medicare with an employer-sponsored policy often provides beneficiaries with

FIGURE 6–1

Most FFS beneficiaries have supplemental coverage that fills in some or all of Medicare's cost-sharing requirements



Note: FFS (fee-for-service). Analysis excludes beneficiaries with any enrollment in Medicare Advantage plans and those living in institutions such as nursing homes. It also excludes beneficiaries who were not in both Part A and Part B throughout their enrollment in 2005 or who had Medicare as a secondary payer. Beneficiaries were assigned to the supplemental coverage category that applied for the most time in 2005. Beneficiaries with both individually purchased policies and employer-sponsored coverage are included in the medigap category.

Source: MedPAC analysis of Medicare Current Beneficiary Survey, Cost and Use files, 2005.

broader coverage for relatively low premiums. However, this combination may not fill in all cost sharing and is not available to everyone. Retiree policies through large employers typically include a lower deductible for hospitalizations than Medicare's; a cap on OOP spending; and sometimes benefits that FFS Medicare does not cover, such as dental care (Yamamoto et al. 2008). Employers who offer retiree plans often pay for much of the premium for supplemental coverage. One 2007 survey found that, on average, large employers subsidized 60 percent of the total premium for single coverage; retirees paid 40 percent, or about $1,600 annually ($133 per month) (Gabel et al. 2008). Many employer plans require retirees enrolled in Medicare to pay deductibles and cost sharing just as is common of active workers and younger retirees.

Retiree coverage is not available to all. Large employers in certain industries have been more likely to offer benefits than others; the availability of this source of coverage is correlated with the location of large firms in certain industries (KFF/HRET 2008).[2] The percentage of Medicare beneficiaries with retiree coverage has remained fairly constant since the early 1990s (Merlis 2006). However, the number of large employers offering retiree coverage to new retirees has been declining, which will affect future cohorts of Medicare beneficiaries. One survey found steady declines in the percent of large employers offering health insurance to Medicare-eligible retirees—from 40 percent in 1993 to 19 percent in 2006 (EBRI 2008). Evidence also suggests that a declining share of new entrants to Medicare (ages 65 to 69) have employer-sponsored insurance as a source of secondary coverage (Stuart et al. 2003).

Medigap policies

By comparison, individually purchased Medicare supplement (medigap) policies are available to most beneficiaries, cover nearly all of Medicare's cost sharing, and tend to have higher premiums. All beneficiaries age 65 or older are guaranteed the opportunity to purchase a medigap policy, regardless of health status, during the 6-month period beginning the month when they enroll in Part B.[3] Federal law does not require insurers to sell medigap policies to Medicare beneficiaries who are younger than 65 and are disabled or have end-stage renal disease. For these individuals, access to medigap policies is uneven—27 states require insurers to offer at least one type of medigap policy—and premiums may be higher because policies may be subject to medical underwriting. The most popular types of medigap policies—standardized Plan C and Plan F—completely fill in the FFS benefit's Part A and Part B deductibles, Part B coinsurance, and other Part A cost sharing, effectively providing catastrophic protection.[4] However, most do not cover additional benefits such as prescription drugs, dental care, or vision care. Enrollment in medigap policies has remained fairly steady, and beneficiary satisfaction with them is generally high (AHIP 2008a, AHIP 2008b). However, premiums for medigap policies can be expensive because individuals with higher health spending are more likely to purchase policies, and these policies have higher administrative costs (Moon 2006, Scanlon 2002).[5] In 2005, the median premium nationwide for a 65-year-old woman purchasing Plan C or Plan F was about $143 per month, or $1,700 annually, ranging between $1,400 and $2,600 across states (Weiss Ratings 2005). Although

prohibited in some states, in other states insurers have moved to attained-age rating, meaning that premiums increase as the beneficiary ages (Moon 2006).

Policymakers, insurers, and regulators have taken several steps to develop more affordable types of medigap policies, but so far those products have not attracted a large share of enrollment. Medicare SELECT plans have the same standard designs as other medigap policies but require beneficiaries to use a provider network in return for lower premiums.[6] A 1997 evaluation found that SELECT plans provide a weak form of managed care in that they recruit hospitals willing to provide a discount for their networks but generally do not form physician networks (Lee et al. 1997). In 2006, insurers had 1.1 million Medicare SELECT plans in place—11 percent of all medigap policies (AHIP 2008b). After 1997, insurers were allowed to sell high-deductible versions of Plan F and Plan J in return for lower premiums.[7] Likewise, the Medicare Prescription Drug, Modernization, and Improvement Act of 2003 created two other types of standard products—Plan K and Plan L—that fill in less of Medicare's cost sharing in return for lower premiums.[8] As of 2006, Plan K and Plan L combined made up less than 0.5 percent of all medigap policies (AHIP 2008b). Effective June 2010, insurers may introduce two new types of medigap policies—Plan M and Plan N. Plan M will cover 50 percent of the Part A deductible but none of the Part B deductible. Plan N will cover all of the Part A deductible and none of the Part B deductible, and it will institute copays of up to $20 for office visits and up to $50 for emergency room visits (NAIC 2008).

Medicaid

Among all types of secondary coverage, Medicaid provides the most comprehensive benefits, but only to individuals with incomes and assets low enough to qualify for the program and who enroll in it. For all categories of dual eligibles (i.e., beneficiaries with both Medicare and Medicaid coverage), state and federal governments pay for their Medicare premiums and cost sharing. Most dual eligibles qualify for Supplemental Security Income cash assistance because of very low incomes or have "spent down" their resources to pay for health and long-term care (called medically needy).[9] In 2005, these beneficiaries made up 81 percent of the 8.8 million dual eligibles and they qualified to receive full Medicaid benefits (so-called "full duals"), including additional services not covered by Medicare, such as long-term care and dental and vision care. The remaining 19 percent had incomes or assets just above the other group; they received help only with Medicare's premiums and cost sharing (Holahan et al. 2009). Roughly two-thirds of dual eligibles are age 65 or older; one-third consists of younger individuals with disabilities or end-stage renal disease (Kaiser Commission on Medicaid and the Uninsured 2009). Although Medicaid supplemental coverage is comprehensive, in many states providers consider Medicaid payment rates to be relatively low, which may affect access to care (Moon 2006). Moreover, participation in the program is low. In one category of duals with incomes at or below 100 percent of the federal poverty level—known as Qualified Medicare Beneficiaries—only 33 percent of eligible beneficiaries participate (MedPAC 2008b).

States differ in their eligibility criteria for Medicaid benefits and in the degree to which they make individuals aware of the program. For example, about two-thirds of states have a medically needy program in which beneficiaries with incomes above eligibility criteria may qualify for Medicaid benefits if they qualify after netting out health costs from income (CMS 2005b). The remaining states do not have medically needy programs.

Beneficiaries' financial liability varies widely

All 45 million beneficiaries who use Part A are subject to cost sharing for those services.[10] The 92 percent of Medicare beneficiaries who are enrolled in Part B pay a premium—$96.40 per month in 2009, or about $1,157 annually for single beneficiaries with incomes of $85,000 or less or couples with incomes of $170,000 or less. They also incur cost-sharing requirements as they use Part B care. About 58 percent of Medicare beneficiaries pay an additional premium (about $29 per month in 2009, or $347 annually) to enroll in Part D for prescription drug coverage, along with cost sharing per prescription.[11] Further, many beneficiaries also pay premiums for supplemental coverage. For nearly all, these costs have been increasing more rapidly than income. However, FFS Medicare's benefit design puts relatively more cost sharing on beneficiaries who require hospital stays than benefit designs used by other payers. At the same time, differences in access to and affordability of supplemental coverage have led to wide variation in beneficiaries' financial liability for their health care.

Premiums and cost-sharing requirements in fee-for-service Medicare

Part A, Hospital Insurance, covers stays in hospitals and skilled nursing facilities, hospice care, and some home health care. Part A is a compulsory social insurance program tied to employment covered by Social Security. Beneficiaries who are entitled to Part A based on work history do not pay any premium. Others may enroll voluntarily for a monthly premium (Table 6-1).

Part B, Supplementary Medical Insurance (SMI), is voluntary and covers services such as physician visits and outpatient hospital care. Part B is available to all individuals eligible for Part A benefits as well as other citizens and permanent resident aliens age 65 or older. Part B enrollees must pay a monthly premium that varies according to income (Table 6-2). When Part B began in 1966, premiums were to finance 50 percent of

(continued next page)

TABLE 6–1 **Premiums and cost-sharing requirements for Part A services in 2009**

Category	Amount
Premiums	$0 if entitled to Social Security retirement or survivor benefits, railroad retirement benefits, Social Security or railroad retirement disability benefits, or end-stage renal disease benefits. $443 per month for individuals who are 65 or older and not described above.
Hospital stay	$1,068 deductible for days 1–60 each benefit period. $267 per day for days 61–90 each benefit period. $534 per "lifetime reserve day" after day 90 each benefit period (up to 60 days over lifetime).
Skilled nursing facility stay	$0 for the first 20 days each benefit period. $133.50 per day for days 21–100 each benefit period. All costs for each day after day 100 in the benefit period.
Home health care	$0 for home health care services. 20% of the Medicare-approved amount for durable medical equipment.
Hospice care	$0 for hospice visits. Up to a $5 copay for outpatient prescription drugs. 5% of the Medicare-approved amount for inpatient respite care.
Blood	All costs for the first 3 pints (unless donated to replace what is used).

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

Source: CMS. 2008b. *Medicare & You* 2009. Baltimore, MD: CMS. http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

Increasing financial liability for all Medicare beneficiaries

The combination of Medicare's cost sharing, premiums for supplemental coverage, and spending for services not covered by Medicare (e.g., long-term care) requires a significant and growing share of elderly income. One recent study notes that, at the median, health care spending among Medicare beneficiaries required 16 percent of their incomes in 2005, up from about 12 percent in 1997 (Neuman et al. 2009).

Rapid growth in Medicare spending has important implications for beneficiaries' cost sharing and premiums. Between 2000 and 2007, growth in Part B spending (mostly spending on physician services) led to average

Premiums and cost-sharing requirements in fee-for-service Medicare (cont.)

covered benefits, with the reminder paid from general revenues. In 2009, most Medicare beneficiaries pay a premium of $96.40 per month, which finances roughly 25 percent of SMI program spending. However, about 5 percent of beneficiaries (those with higher incomes) pay considerably more. ■

TABLE 6–2 **Premiums and cost-sharing requirements for Part B services in 2009**

Category	Amount	
Premiums	$96.40 per month:	Single beneficiaries with incomes of $85,000 or less Couples with incomes of $170,000 or less
	$134.90 per month:	Single beneficiaries with incomes between $85,001 and $107,000 Couples with incomes between $170,001 and $214,000
	$192.70 per month:	Single beneficiaries with incomes between $107,001 and $160,000 Couples with incomes between $214,001 and $320,000
	$250.50 per month:	Single beneficiaries with incomes between $160,001 and $213,000 Couples with incomes between $320,001 and $426,000
	$308.30 per month:	Single beneficiaries with incomes above $213,000 Couples with incomes above $426,000
Deductible	The first $135 of Part B-covered services or items during the year	
Physician and other medical services	20% of the Medicare-approved amount for physician services, outpatient therapy (subject to limits), and most preventive services	
Outpatient hospital services	A coinsurance or copayment amount that varies by service, averaging 27% in 2009. These rates are scheduled to phase down to 20% over time. No copayment for a single service can be more than the Part A hospital deductible ($1,068 in 2009).	
Mental health services	50% of the Medicare-approved amount for outpatient mental health care. This coinsurance rate is scheduled to phase down to 20% by 2014.	
Clinical laboratory services	$0 for Medicare-approved services	
Home health care	$0 for home health care services	
Durable medical equipment	20% of the Medicare-approved amount	
Blood	All costs for the first 3 pints, then 20% of the Medicare-approved amount of additional pints (unless donated to replace what is used)	

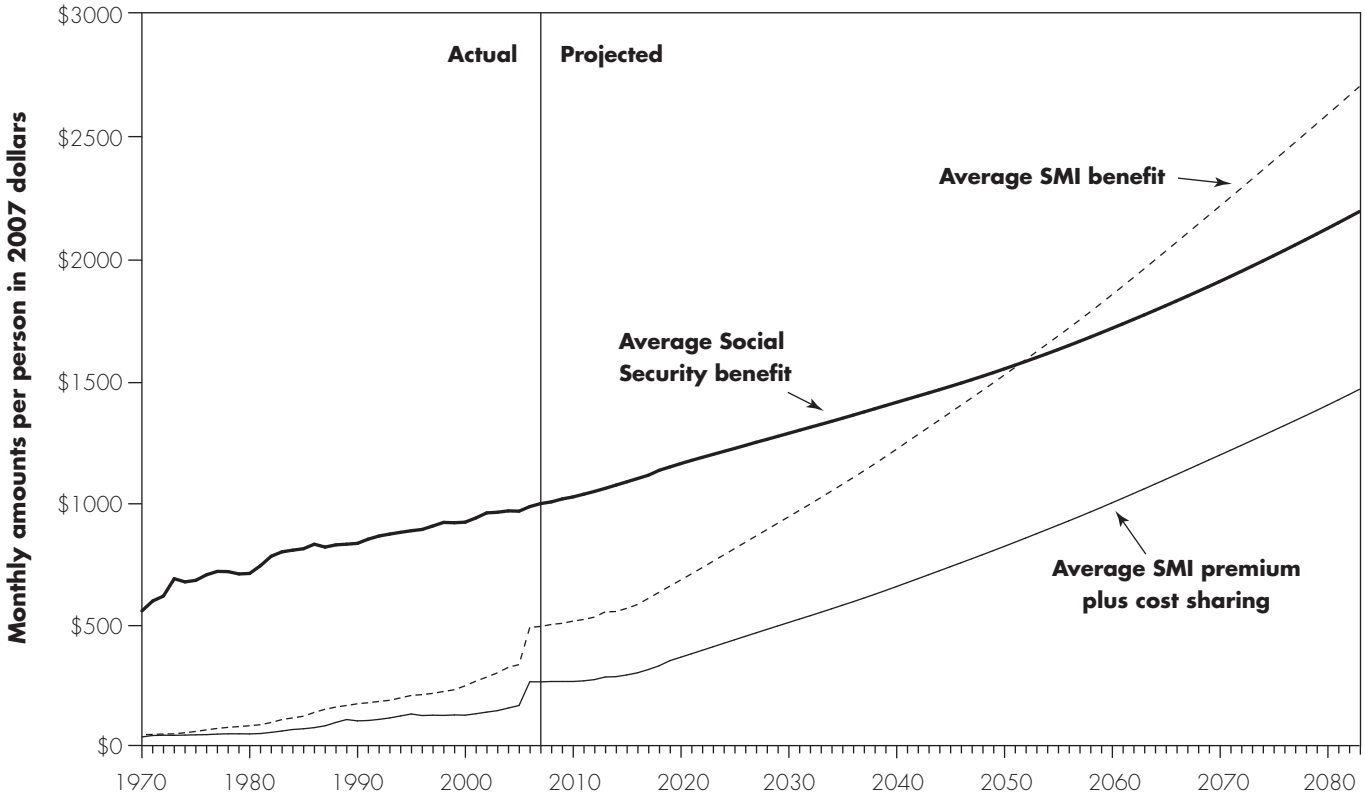
Note: Medicare began phasing in income-related premiums over a three-year period beginning in 2007. By 2010, higher income individuals will pay monthly premiums equal to 35 percent, 50 percent, 65 percent, or 80 percent of Medicare's average Part B costs for aged beneficiaries, depending on income. Usually all other individuals pay premiums equal to 25 percent of average costs for aged beneficiaries. CMS estimates that about 5 percent of Medicare beneficiaries pay the higher premiums. The Part B deductible increases over time by the rate of growth in per capita spending for Part B services.

Source: CMS. 2008b. *Medicare & You* 2009. Baltimore, MD: CMS. http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

annual increases in the Part B premium of nearly 11 percent. By comparison, monthly Social Security benefits grew by about 3 percent annually over the same period.[12] Medicare began offering Part D in 2006, which subsidizes a significant portion of beneficiaries' spending on prescription drugs. Yet, even with this financial relief, steep growth in Supplementary Medical Insurance benefit spending (which covers Part B and, after 2006, Part D services) in future years will bring with it increases in premiums and cost sharing that will outpace projected growth in Social Security benefits (Figure 6-2, p. 144).

FIGURE 6–2

Average monthly SMI benefits, premiums, and cost sharing are projected to grow faster than the average monthly Social Security benefit



Note: SMI (Supplementary Medical Insurance). Average SMI benefit and average SMI premium plus cost-sharing values are for a beneficiary enrolled in Part B and (after 2006) Part D. Beneficiary spending on outpatient prescription drugs prior to 2006 is not shown.

Source: 2008 annual report of the Boards of Trustees of the Medicare trust funds.

FFS benefit design contributes to highly concentrated cost sharing

All beneficiaries are subject to the effects of rising Medicare premiums, but for beneficiaries in FFS Medicare, cost sharing puts inordinate liability on relatively few individuals. In 2007, 6 percent of FFS beneficiaries incurred more than $5,000 in cost sharing for Part A and Part B services (Figure 6-3). (Because many beneficiaries have supplemental coverage, the figure does not reflect OOP spending, just FFS Medicare's cost sharing.) Another 16 percent had between $2,000 and $5,000 in cost sharing. The 22 percent of beneficiaries who each had $2,000 or more in Medicare cost sharing together incurred about two-thirds of the $50 billion in aggregate cost sharing.[13] By comparison, 43 percent incurred less than $500 in cost sharing, making up just 7 percent of the $50 billion.

Several parts of FFS Medicare's benefit design lead to highly concentrated cost-sharing liability. Medicare's inpatient deductible is relatively high—$1,068 in 2009. A patient who requires several hospital stays in a year would have to pay the inpatient deductible repeatedly. Beneficiaries who require longer stays in hospitals or skilled nursing facilities are liable for sizable daily copays. In addition, patients who are hospitalized have little control over care associated with their stay—inpatient professional services for physicians, imaging, and physical therapy, among other services—and pay 20 percent coinsurance for those services. Beneficiaries who are hospitalized typically use outpatient therapies and procedures extensively as well, for which they

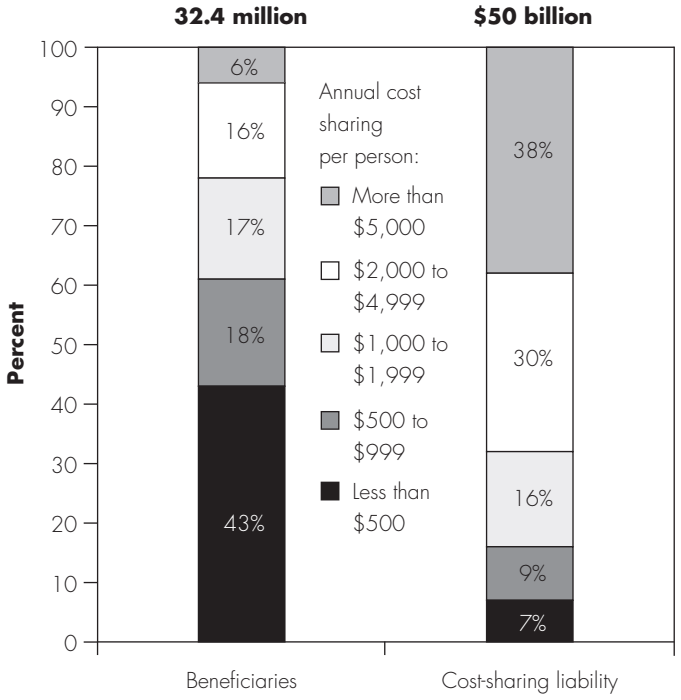
pay 20 percent coinsurance (or more). Twenty percent coinsurance for services such as expensive Part B drugs can amount to a substantial OOP cost for the beneficiary. At the same time, Medicare's FFS benefit design does not include a cap on beneficiaries' OOP spending.

By comparison, cost sharing would be lower than Medicare's for an average elderly beneficiary if a typical retiree health plan of a large employer or if the Blue Cross Blue Shield (BCBS) standard option preferred provider organization (PPO) of the Federal Employees Health Benefits (FEHB) program provided the primary coverage (Yamamoto et al. 2008). Researchers note that, in 2007, a typical large employer used a combined deductible for inpatient and outpatient care of $500 per individual ($1,000 per family) for in-network care. (For out-of-network providers, it was $1,000 per individual ($2,000 per family).) The enrollee also paid 20 percent of allowed charges for in-network inpatient professional services (40 percent out-of-network plus 100 percent of the difference between the provider's charge and allowed charges). The typical large employer capped enrollee deductibles and coinsurance at $2,500 for in-network services ($5,000 for out-of-network services).[14] By comparison, in 2007, FFS Medicare had a $992 inpatient deductible, a $131 deductible for Part B services (to include inpatient professional care), and then 20 percent coinsurance (or more) on allowed charges. Yamamoto and colleagues estimated that, for an average elderly beneficiary, Medicare paid a smaller share of total covered benefits than would be paid by a typical large employer's retiree plan or by the BCBS standard option in the FEHB program if they had provided primary coverage (Yamamoto et al. 2008).

Regardless of whether a beneficiary has high or low use of Medicare services, Part B coinsurance tends to make up most of the cost-sharing liability. Among patients with hospitalizations during the year, one might expect that Medicare's inpatient deductible would account for much of their cost sharing. However, among the 6 percent of FFS beneficiaries who incur costs of $5,000 or more, 58 percent of that liability comes from Part B coinsurance, compared with 12 percent from the Part A deductible (Figure 6-4, p. 146). In other words, coinsurance for Part B services associated with the inpatient stay such as physician care, imaging, and therapy—in addition to the patients' outpatient care—are larger contributors to OOP liability. Among beneficiaries who incurred less than $500 in cost sharing, Part B coinsurance made up 53 percent of their liability.

FIGURE 6–3

In 2007, the top 22 percent of FFS beneficiaries incurred two-thirds of all Medicare FFS cost-sharing liability



Note: FFS (fee-for-service). The bar on the left shows the distribution of FFS beneficiaries ranked by the Medicare cost sharing they incurred. The bar on the right shows the percent of all FFS Medicare cost-sharing liability incurred by each group of beneficiaries.

Source: MedPAC analysis of 2007 data from CMS's Medicare & Medicaid Statistical Supplement.

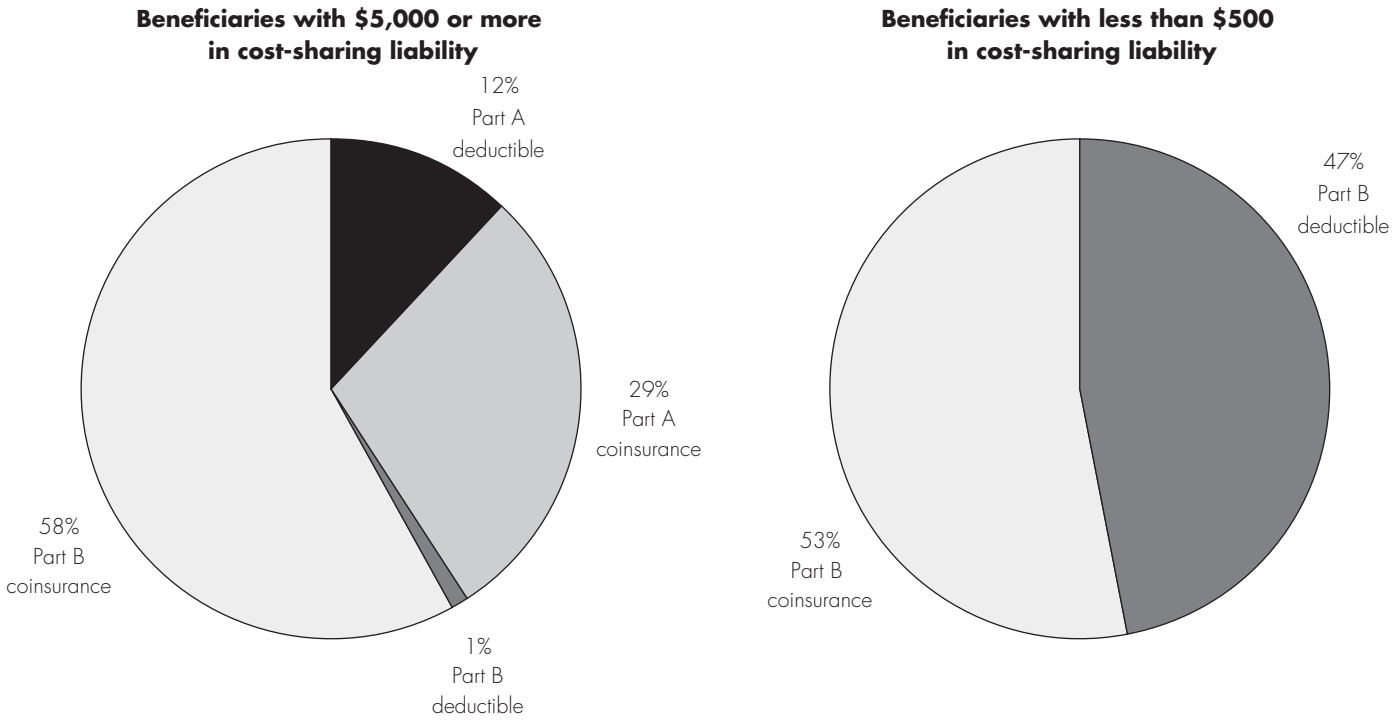
Beneficiaries' spending on premiums and cost sharing varies widely

At the median, Medicare beneficiaries spent about 16 percent of their income on premiums and other OOP health spending in 2005 (Neuman et al. 2009). However, that figure masks considerable variation across individuals. Generally, beneficiaries with higher Medicare spending pay a larger proportion of their income than those with lower Medicare spending, but the relative burden of financial liability depends on the beneficiary's type of supplemental coverage (Figure 6-5, p. 147).

Typical beneficiaries with Medicare and Medicaid coverage paid 5 percent or less of their incomes for premiums and OOP spending in 2005, whether they were ranked among the highest or lowest in terms of Medicare spending.[15] At the other extreme, individuals

FIGURE 6–4

Part B coinsurance accounts for most of FFS cost-sharing liability



Note: FFS (fee-for-service).

Source: MedPAC analysis of 2007 data from CMS's Medicare & Medicaid Statistical Supplement.

with no supplemental coverage in the lowest quartile of FFS spending paid about 8 percent of their income for Part B premiums and cost sharing, while those lacking secondary coverage in the highest spending group spent about 35 percent of their income. Beneficiaries who purchase medigap policies typically pay about 12 percent of their income on premiums and OOP costs. Individuals who receive retiree coverage as a form of deferred compensation for past employment tend to have both higher incomes and relatively lower spending on premiums and OOP health spending.

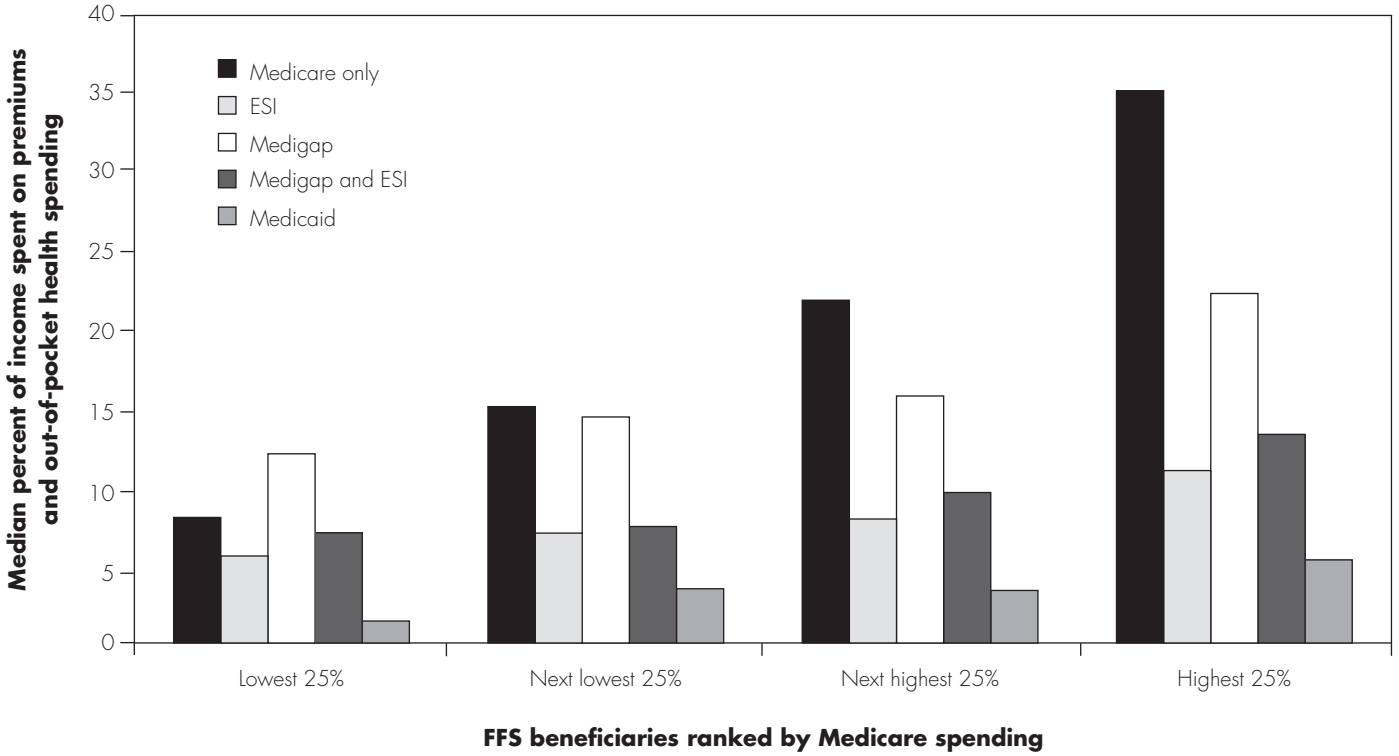
The dollar amount that FFS beneficiaries pay in premiums and cost sharing varies substantially, depending on their use of care and whether they have supplemental coverage. Two groups tend to pay comparatively more than others: 1) beneficiaries with medigap policies, and 2) those with no supplemental coverage and high use of Medicare services (Figure 6-6, p. 148). Unlike retiree health plans in which employers often pay part of the premium for supplemental coverage of their former workers, beneficiaries with medigap policies pay the full premium. In 2005, a typical beneficiary with a medigap policy paid $2,500 to $3,000 in combined premiums for Medicare Part B and for their medigap coverage and then also incurred other OOP expenses such as FFS cost sharing and prescription drugs. Individuals with no supplemental coverage and high use of Medicare services also tend to pay more. In 2005, the typical individual who ranked in the top 25 percent of FFS Medicare spending and had no supplemental coverage paid more than $5,400—nearly $4,500 on OOP costs and more than $900 for Part B premiums.

Supplemental coverage can lead to higher Medicare spending

By filling in FFS Medicare's cost-sharing requirements, supplemental insurance can spare beneficiaries from catastrophic financial liability. At the same time, supplemental coverage shields beneficiaries from seeing

FIGURE 6–5

Medicare FFS beneficiaries' financial burden varies considerably, depending on their use of care and type of supplemental coverage, 2005



Note: FFS (fee-for-service), ESI (employer-sponsored insurance). Bars show median percent of income spent on premiums including for Part B, Part A (if applicable), supplemental coverage, and other types of policies (e.g., for dread diseases and long-term care) and out-of-pocket health costs (e.g., prescription drugs) by category of supplemental coverage. Beneficiaries are grouped in the supplemental coverage category in which they spent most of the year. Some beneficiaries have several sources of coverage during a year. Note that 2005 was prior to the start of Part D, Medicare's prescription drug benefit.

Source: MedPAC analysis of 2005 Medicare Current Beneficiary Survey, Cost and Use files.

the cost of care which, in turn, can lead them to use more or higher priced services than if they had to pay more of the cost themselves. A pattern of higher service use may reflect, in part, beneficiaries' greater willingness to seek care when they pay less OOP. In addition, higher service use may reflect differences in providers' willingness to deliver more care or more intensive care to beneficiaries who have supplemental coverage.

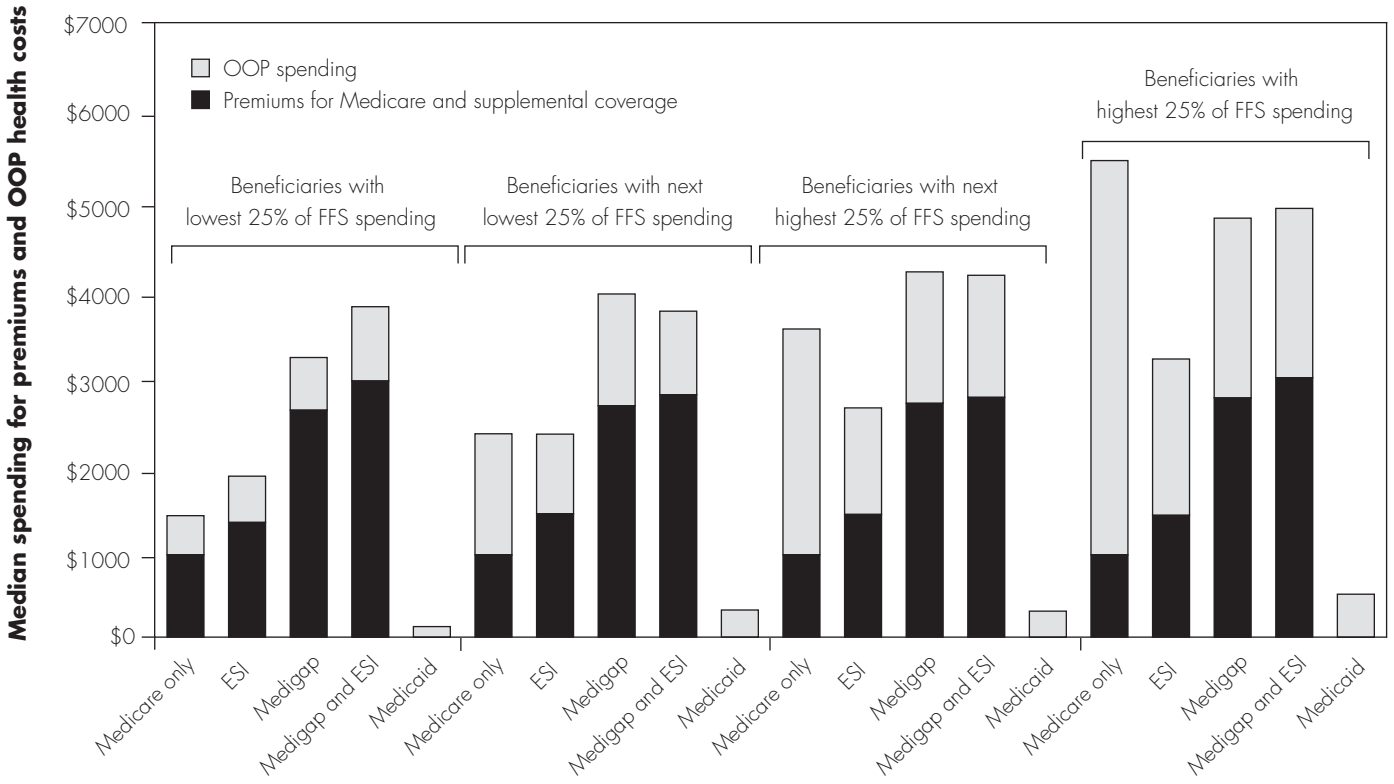
Previous health services literature showed mixed effects of health insurance on spending

The issue of how much Medicare spending is induced by supplemental coverage is contentious. Researchers agree that beneficiaries with supplemental coverage tend to have higher use of services and spending than those with no supplemental coverage. However, they disagree about what proportion of this difference is due to the pure effect of insurance (called moral hazard or insurance effect) compared with the tendency of sicker individuals to seek insurance coverage (adverse selection).

Studies that attribute at least a portion of higher spending to this "insurance effect" find an average increase of about 25 percent, but estimates vary widely from 6 percent to 44 percent (Atherly 2001). Separate analyses in 1997 by the Physician Payment Review Commission (PPRC) and Congressional Budget Office (CBO) staff were consistent with this range of results (Christensen and Shinogle 1997, PPRC 1997). Using data for elderly and disabled individuals in the Medicare Current Beneficiary Survey (MCBS), the PPRC estimated that medigap coverage was associated with a 35 percent increase in Medicare spending.[16] Using the National Health Interview Survey, CBO estimated that use of services ranged from 17 percent higher for those with employer coverage to 28

FIGURE 6–6

Beneficiaries with medigap policies and those with high FFS spending and no supplemental coverage pay the largest dollar amounts for premiums and cost sharing, 2005



Note: FFS (fee-for-service), OOP (out of pocket), ESI (employer-sponsored insurance). Bars show median dollar amount spent on premiums for Part B, Part A (if applicable), supplemental coverage, other types of policies (e.g., for dread diseases and long-term care) and OOP health costs (e.g., prescription drugs). Beneficiaries are grouped in the supplemental coverage category in which they spent most of the year. Some beneficiaries have several sources of coverage during a year. Note that 2005 was prior to the start of Part D, Medicare's prescription drug benefit.

Source: MedPAC analysis of 2005 Medicare Current Beneficiary Survey, Cost and Use files.

percent higher for those with medigap policies. Both analyses suggested that larger differences occurred for Part B services like office visits than for Part A services like hospitalizations.

Other researchers find a small or statistically insignificant insurance effect from supplemental insurance after controlling for adverse selection (Wolfe and Goddeeris 1991).[17] Some contend that previously reported differences in spending might be overstated, as supplemental coverage encourages beneficiaries to adhere to medical therapies that prevent hospitalizations or future use of other services. Because most studies on supplemental coverage are cross sectional or have short time horizons, they may not detect lower use of services over a longer period (Chandra et al. 2007).[18] Yet another line of research suggests that the responsiveness of beneficiaries to cost sharing is varied and the effects of supplemental coverage are more modest for individuals in poorer health (Remler and Atherly 2003).

New analysis of secondary coverage

The Commission contracted with Direct Research, LLC, to look at the effects of secondary insurance on the use of and spending for Medicare services (see text box, pp. 150–151). The analysis concludes that after controlling for demographics, income, education, and health status, the presence of secondary insurance is strongly associated with higher Medicare spending, notably for Part B services (Hogan 2009).

Secondary coverage affects use of Part A and Part B services differently

To take a "big-picture" look at the relationship between secondary coverage and use of care, our contractor

TABLE 6–3

Beneficiaries with private secondary insurance had significantly higher Medicare spending than beneficiaries with no secondary coverage

	Total	Part A	Part B
Average spending for Medicare-only beneficiaries	$4,015	$2,335	$1,680
Percent increase associated with secondary insurance:			
Individually purchased	33%*	18%	54%*
Employer sponsored	17*	9	30*
Individually purchased plus employer sponsored	25*	9	48*

Note: *Significantly different from the Medicare-only group at p = 0.05 level or lower, after adjusting for survey design.

Source: Direct Research, LLC, using Medicare Current Beneficiary Survey, Cost & Use files pooled for 2003–2005.

examined each MCBS respondent's amount of Medicare spending with respect to demographic characteristics, health status, income, education, and indicators of whether the individual had an employer-sponsored retiree plan, an individually purchased medigap policy, or both. Consistent with researchers' 1997 estimates, total Medicare spending was 33 percent higher for beneficiaries with medigap policies than for those with no supplemental coverage (Table 6-3). Beneficiaries with employer-sponsored coverage had 17 percent higher Medicare spending, and those with both types of secondary coverage had spending 25 percent higher.

Results of this analysis were also consistent with earlier findings on the effect of secondary insurance on Part A and Part B spending individually. Specifically, it found no statistically significant difference in spending for Part A services but large effects on Part B spending. Beneficiaries with medigap policies spent 54 percent more on Part B services than individuals without supplemental coverage, after adjusting for covariates. Those with employer-sponsored secondary coverage had a slightly smaller effect—30 percent higher spending—and beneficiaries with both a medigap policy and employer coverage had 48 percent higher spending on Part B.

Effects by type of service

We analyzed different components of beneficiaries' Medicare spending in some detail to see what patterns emerged with respect to secondary coverage.

Emergency and urgent care appear unaffected by secondary coverage It is expected that beneficiaries are less likely to consider cost sharing in emergency, life-threatening situations when the health benefit is more immediate. For example, an individual facing an emergency appendectomy would not likely weigh the cost of the Part A deductible in seeking care. However, the inpatient deductible might be more of a consideration when deciding about treatments that could be postponed, such as knee-replacement surgery.

Our contractor's results are consistent with these expectations. For example, using a pertinent variable from inpatient claims data, the contractor classified MCBS respondents' inpatient admissions as emergency, urgent, or elective.[19] This variable is admittedly crude, as it does not distinguish among elective hospital stays for clinically important procedures that, if delayed or avoided, would likely lead to emergency hospitalizations.[20] Notwithstanding this caveat and after controlling for numerous covariates, the analysis found that beneficiaries with private supplemental coverage did not have statistically different spending for emergency and urgent admissions (Table 6-5, p. 152). For elective admissions, however, average Medicare spending for those with private secondary coverage was 90 percent higher than for those without it.

Office-based care more responsive than hospital-based care Along the same lines, the effects of secondary coverage on Medicare Part B spending for care provided in office-based settings were statistically significant and of larger magnitude than effects for physician care provided in a hospital setting. Physician care provided in physicians' offices was 75 percent higher among beneficiaries with supplemental coverage, compared with 32 percent to 33 percent higher spending for care provided in inpatient facilities, hospital outpatient departments,

Method for analysis of the effects of secondary insurance

To examine the effects of secondary insurance on Medicare spending and utilization of services, Direct Research, LLC, performed a regression analysis controlling for several factors. It used data from the cost and use files of the Medicare Current Beneficiary Survey (MCBS) pooled for the three years between 2003 and 2005. The analysis reflects the average annual experience over the three years and accounts for MCBS's survey design. Roughly half of the MCBS's panel of survey respondents overlaps across years—meaning that some of the individuals surveyed one year were surveyed in later years. To ensure that results were not skewed by any extreme cases among these individuals, Direct Research considered only statistically significant results that represented effects for at least 30 different respondents.[21]

The regression analysis included individuals age 65 or older and excluded beneficiaries who were institutionalized, had any enrollment in Medicare Advantage plans, or had not enrolled in both Medicare Part A and Part B. It excluded disabled Medicare beneficiaries younger than 65 because in many states those individuals have more limited opportunities to purchase supplemental coverage. The analysis also excluded beneficiaries who reported any use of care through the Department of Veterans Affairs (VA) to address a concern that the substitution of VA care could artificially lower average levels of Medicare spending among beneficiaries labeled in the MCBS as having no supplemental coverage (Lemieux et al. 2008).[22]

Although Medicaid is an important source of secondary insurance, most of this analysis compares beneficiaries with private supplemental insurance (individually purchased medigap policies and employer-sponsored retiree policies) and those with no supplemental coverage. While having Medicaid benefits is also associated with higher Medicare spending, we assumed that policymakers would want to retain some type of secondary coverage for beneficiaries with low incomes and assets. In addition, there are considerable differences among the states in their eligibility rules for Medicaid and their degree of outreach.

The regressions shown here use several controls for health status. One is a series of indicators for the presence of conditions in the hierarchical condition category (HCC) model based on same-year diagnoses in MCBS claims.[23] A second control is self-reported general health status scored on a five-point scale from excellent to poor. The analysis also includes a count of limitations in activities of daily living, an indicator for current employment, and an indicator for death.

Complex factors affect whether individuals have supplemental coverage, including their aversion to risk, health status, knowledge about Medicare, income, demographic characteristics, and the availability of coverage. Interactions among these factors make it very hard to disentangle selection bias from moral hazard. In fact, short of running a randomized controlled trial like the RAND Health Insurance Experiment, it may be impossible to estimate the "pure" effect of insurance on spending. Econometric studies have used different ways to correct for adverse selection—including the choice of instrumental variables for identification—resulting in a wide range of estimates (Atherly 2001). The analysis by Direct Research attempts to control for adverse selection through variables that reflect health status and other factors, rather than through instrumental variables. We believe this analysis provides convincing evidence that supplemental coverage is associated with higher Medicare spending. Still, analysts will disagree about how much lower Medicare spending would be if supplemental policies could not fill in FFS cost sharing. To the extent that our approach does not fully capture differences between beneficiaries with and without secondary coverage, it would tend to overstate potential savings.[24]

We asked Direct Research to further investigate the role of factors such as individuals' underlying predilection for insurance in their use of Medicare services. In each category of supplemental insurance, beneficiaries with coverage that filled in nearly all of Medicare's cost sharing had statistically significant higher Medicare spending than individuals with no supplemental coverage (Table 6-4). Results for individuals with less generous coverage were not statistically significant and

(continued next page)

Method for analysis of the effects of secondary insurance (cont.)

were relatively small. This pattern held not only for beneficiaries with medigap policies but also for those with employer-sponsored retiree plans or Medicaid coverage. It suggests that the design of supplemental coverage—that is, whether the insurance fills in virtually all of Medicare's cost sharing or retains some that the beneficiary must pay—strongly affects Medicare spending.

As a final piece of evidence about the role of secondary coverage, our contractor turned to the responses of individuals who participated in the MCBS about their use of health care. Compared with beneficiaries with private secondary coverage, those without supplemental insurance were more likely to worry about their health and more likely to avoid going to a doctor (CMS 2005a). When asked why they avoided seeing a doctor, 19 percent of individuals without secondary coverage reported that it was due to cost, compared with 5 percent or less for those with private supplemental coverage. ■

TABLE 6–4

In each category of secondary coverage, beneficiaries with little or no cost sharing spent significantly more on Part B services than beneficiaries without secondary coverage

Category of secondary coverage	Percent of beneficiaries within the secondary coverage category	Percent change in Part B spending associated with secondary coverage relative to the average spending of a beneficiary with no secondary coverage
Individually purchased (medigap) policy		
No use of Part B services	5%	–44%
Paid less than 5 percent of allowed costs OOP	50	68*
Paid 5 percent or more of allowed costs OOP	45	0
Employer-sponsored retiree health policy		
No use of Part B services	1	–31
Paid less than 5 percent of allowed costs OOP	52	77*
Paid 5 percent or more of allowed costs OOP	46	23
Individually purchased plus employer-sponsored		
No use of Part B services	3	–30
Paid less than 5 percent of allowed costs OOP	63	85*
Paid 5 percent or more of allowed costs OOP	34	12
Medicaid coverage		
No use of Part B services	5	–43
Paid less than 5 percent of allowed costs OOP	71	96*
Paid 5 percent or more of allowed costs OOP	24	32

Note: OOP (out of pocket). Percent increases in Part B spending are negative for individuals with no use of Part B services because the comparison group is made up of all individuals with no supplemental coverage, some of whom used Part B care. Full regression results include the OOP groups shown above and control for demographics, health status (self-reported and claims-based condition indicators), income, and education.
*Significantly different from the Medicare-only group at p = 0.001 level, after adjusting for survey design.

Source: Direct Research, LLC, using Medicare Current Beneficiary Survey, Cost and Use files pooled for 2003–2005.

TABLE 6–5

Secondary coverage was associated with higher Medicare spending for elective hospital admissions, office-based care, specialist care, and preventive services

	Average Medicare spending for beneficiaries with no supplemental coverage	Percent change associated with private secondary coverage
Part A inpatient claims by admission type		
Elective	$405	90%*
Urgent	$405	6
Emergency	$1,221	–6
Part B carrier claims by place of service		
Office	$643	75*
Hospital outpatient department or ambulatory surgical center	$261	33*
Inpatient	$281	32*
Other	$127	23*
Part B carrier claims by self-designated physician specialty (nonphysicians omitted)		
Medical specialists	$341	89*
Surgical specialists	$329	50*
Generalists	$316	36*
Radiologists	$119	30
Preventive services (Part B physician office and outpatient department claims combined)		
Payments for preventive services	$21	97*

Note: *Significantly different from the Medicare-only group at p = 0.05 level or lower, after adjusting for survey design.

Source: Direct Research, LLC, using Medicare Current Beneficiary Survey, Cost & Use files pooled for 2003–2005.

or ambulatory surgical centers. (See Table 6-5, data for carrier claims by place of service.)

Specialist care and preventive care strongly associated with secondary coverage Several related hypotheses can be made about secondary coverage and the use of specialist care and preventive care. One is that beneficiaries are more amenable to pay OOP for short, noninvasive, low-risk treatments and procedures relative to therapies that carry risks of mortality and morbidity that the individual can anticipate. For example, if promised equal outcomes from drug-based or surgically based treatment, beneficiaries—with or without secondary coverage—would be more likely to pay for drug treatment than for surgery. A second hypothesis is that, to the extent that specialists are more likely to deliver therapies perceived as riskier or more invasive, a larger effect of supplemental coverage on the use of specialist care is expected. Our empirical analysis supports these hypotheses. We estimate statistically higher use (36 percent) of Part B generalist care among beneficiaries with secondary coverage, but the magnitude of higher spending is larger for surgical and medical specialist care (50 percent and 89 percent, respectively).

We found similar results when we grouped services by Berenson-Eggers Type of Service codes. Individuals with private secondary insurance had significantly higher Medicare spending for services such as office visits, imaging, minor procedures, and endoscopy than did beneficiaries without supplemental coverage. However, there was no statistically significant difference in spending for ambulance services, emergency visits, and major procedures between individuals with and without secondary insurance (Hogan 2009).

Individuals may believe they can delay receiving preventive care. For example, a beneficiary may not see any immediate health effects from waiting a year before receiving a mammogram. Patients are expected to be less

TABLE 6–6

The presence of private secondary coverage was strongly associated with Part B spending, even among beneficiaries with serious conditions

	Total spending		Part A spending		Part B spending	
Beneficiary category	Average Medicare spending for Medicare-only beneficiaries	Percent change associated with private secondary coverage	Average Medicare spending for Medicare-only beneficiaries	Percent change associated with private secondary coverage	Average Medicare spending for Medicare-only beneficiaries	Percent change associated with private secondary coverage
Diabetes	$8,481	6%	$5,198	–4%	$3,283	22%*
Cancer	$12,070	13	$7,146	–1	$4,924	32*
CHF	$15,260	20	$10,692	13	$4,568	36*
Cardiovascular other than CHF	$11,786	14	$8,023	4	$3,763	34*
COPD	$10,945	23	$7,068	13	$3,877	41*
Decedents	$20,367	25	$15,873	20	$4,494	44*
None of the above	$1,003	67*	$357	51	$646	76*

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Estimates reflect total spending for beneficiaries with these conditions, not spending only for those conditions. Beneficiaries with conditions identified through diagnoses on Medicare claims.
*Significantly different from the Medicare-only group at p = 0.05 level or lower, after adjusting for survey design.

Source: Direct Research, LLC, using Medicare Current Beneficiary Survey, Cost and Use files pooled for 2003–2005.

inclined to seek preventive services when they must pay cost sharing OOP. Our contractor's estimates support this expectation. Among beneficiaries with secondary coverage, spending for preventive services was nearly double that of those without secondary coverage, and more beneficiaries with supplemental coverage sought preventive care.

Decedents and beneficiaries with serious chronic illnesses are sensitive to cost sharing Direct Research also analyzed Medicare spending for beneficiaries with serious illnesses. Specifically, they examined spending for MCBS respondents who had died during the year as well as those who had at least one of the five most common causes of death in the elderly (diabetes, cancer, congestive heart failure (CHF), cardiovascular disease other than CHF, and chronic obstructive pulmonary disease). The expectation was that those diagnosed with these serious conditions would be insensitive to OOP costs—that is, the presence of secondary coverage would not matter to these individuals.

Our analysis suggests that individuals with a severe illness are somewhat less sensitive to cost sharing, but they do not ignore it entirely. For each condition, beneficiaries with and without secondary coverage did not exhibit statistically significant differences in Part A spending, but there were large and significant differences in Part B spending (Table 6-6). For example, beneficiaries with diabetes and supplemental coverage had 22 percent higher Part B spending than diabetics with no supplemental coverage. Even among the seriously ill, cost sharing can affect when and from whom patients seek care.

At the same time, however, the effects of private secondary coverage were much more pronounced on Part B spending among beneficiaries who had not died or did not have a diagnosis for any of the common conditions causing death (Table 6-6). Their Part B spending was 76 percent higher than a comparable beneficiary with no supplemental coverage.

Differential effects of cost sharing by income

A further issue of interest is whether the presence of supplemental coverage affects low-income and high-income individuals differently. One might expect filling in Medicare's cost sharing to be more valuable to low-income people, and therefore it might have a stronger effect on their willingness to seek care. In general, Direct Research found similar results for low-income and high-income beneficiaries. However, there was some evidence that, relative to individuals without supplemental coverage, the presence of secondary insurance had a moderately

TABLE 6–7

The effects of secondary insurance are modestly stronger among beneficiaries with incomes of $10,000 or less

Beneficiary category	Total spending	Part A spending	Part B spending
Beneficiaries with incomes less than $10,000			
Average spending for Medicare-only beneficiaries	$3,530	$1,962	$1,569
Percent change associated with secondary insurance:			
Individually purchased	39%*	19%	63%*
Employer sponsored	10	–4	28*
Employer sponsored plus individually purchased	55	82	20
Beneficiaries with incomes greater than or equal to $10,000			
Average spending for Medicare-only beneficiaries	$4,372	$2,611	$1,762
Percent change associated with secondary insurance:			
Individually purchased	31%*	17%	50%*
Employer sponsored	18*	11	28*
Employer sponsored plus individually purchased	22*	4	48*

Note: *Significantly different from the Medicare-only group at p = 0.05 level or lower, after adjusting for survey design.

Source: Direct Research, LLC, using Medicare Current Beneficiary Survey, Cost and Use files pooled for 2003–2005.

stronger effect on Medicare spending for lower income beneficiaries. For example, beneficiaries with incomes less than $10,000 who purchased medigap policies had 63 percent higher Part B spending than low-income beneficiaries with no secondary coverage (Table 6-7). By comparison, individuals with incomes of $10,000 or more who purchased medigap policies had Part B spending 50 percent greater than higher income beneficiaries with no supplemental coverage.

Beneficiaries without secondary insurance use less care

Other findings from the contractor's analysis indicate that beneficiaries with only Medicare coverage and no secondary insurance obtain less health care. These beneficiaries appear to get acute care services in response to serious illness, but they appear to get less well-patient care, less preventive care, fewer scheduled inpatient admissions, and fewer procedures that are costly but do not address life-threatening conditions. On the basis of MCBS data, Direct Research estimated that 20 percent of elderly individuals with no supplemental coverage had no Part B spending at all during the year, compared with 5 percent of beneficiaries who had private secondary insurance.[25] Whether Medicare's cost sharing impedes the use of care for people without secondary coverage, who typically have lower incomes, or whether cultural reasons or other factors make these beneficiaries less inclined to seek care needs to be studied further.

Benefit design as a policy tool

The Medicare program allows private plans that deliver Part C and Part D benefits to vary their benefit designs within certain limits (see text box, pp. 156–157). Cost-sharing strategies used by these private plans to achieve quality and efficiency gains may have lessons for FFS Medicare and raise questions about the role of supplemental coverage.

Cost sharing is an important part of benefit design

The literature suggests that, in some circumstances, cost sharing may keep patients from seeking appropriate care (Rice and Matsuoka 2004). There is also substantial evidence that beneficiaries are sensitive to cost sharing for prescription drugs—higher copays and capped benefits are associated with lower medication adherence and spending (Goldman et al. 2007, Goldman et al. 2006, Hsu and Huang 2006, Rice and Matsuoka 2004). To the extent that secondary insurance reduces cost-sharing hurdles, it may

encourage the use of therapies that avoid exacerbations of chronic conditions.[26]

At the same time, many supplemental policies fill in all or nearly all of FFS Medicare's cost-sharing requirements, while covering services regardless of their value. That is, the policies are no more selective about covering medical services that have better evidence of preventing hospitalizations than services that tend to be used inappropriately. Thus, some portion of higher spending by beneficiaries with this coverage is arguably due to the pure inducement effect of insurance. Our empirical analysis supports this argument.

Most economists believe that well-designed insurance should, from society's perspective, both reduce a beneficiary's financial risk and leave some spending for covered services unreimbursed to deter the use of services that are of low value. The crux of insurance design involves understanding beneficiaries' price sensitivity to health care and the circumstances under which medical services are of more or less value to them.

Potential goals for redesigning Medicare's FFS benefit

Cost sharing could be used as a tool to complement various policy goals such as: improving financial protection for Medicare beneficiaries and distributing cost-sharing liability more equitably among individuals with different health care costs, encouraging use of high-value services and discouraging use of low-value services, and reinforcing payment system reforms that seek better value for health care expenditures. An additional goal may be to improve Medicare's financial sustainability.

Inherent conflicts exist among these goals. For example, adding an OOP cap to the FFS benefit could improve financial protection for the sickest beneficiaries, but without other measures that catastrophic protection would result in substantially higher Medicare program spending and worsen the program's long-term financial situation. Several of the goals require more nuanced and targeted approaches to cost sharing than Medicare uses today and would need further development of methods to evaluate quality, compare effectiveness of therapies, and measure provider resource use. Steps toward each of the goals would be more effective if changes were made to Medicare's deductibles and coinsurance at the same time the role of supplemental coverage was redefined.

Improve financial protection and distribute cost-sharing liability more equitably among individuals with different health care costs

FFS Medicare lacks fundamental protections against catastrophic levels of OOP spending. Medicare's cost-sharing requirements and its lack of catastrophic protection have been important catalysts behind supplemental coverage. However, coverage that fills in most or all of Medicare's cost sharing can lead to higher Medicare spending. As a consequence, Part B premiums are somewhat higher for all beneficiaries—including those without secondary coverage.

One design difficulty is that if catastrophic protection were added to the FFS benefit without adding to Medicare program costs, a sizable percentage of beneficiaries with lower health care spending would face higher FFS cost-sharing requirements. As an example, the CBO estimated the effects of replacing current FFS benefits with a single combined deductible that applies to the first $525 of Part A and Part B services, uniform 20 percent coinsurance for amounts above the deductible (including inpatient expenses and other services such as lab and home health to which no cost sharing currently applies), and a cap set at $5,250 in OOP spending (CBO 2008). CBO estimated this option would lower federal mandatory spending by $26.4 billion between 2010 and 2019. Under the option, cost sharing would rise by an average of $500 for three-quarters of FFS enrollees, would remain the same for 13 percent, and would be lower by an average of $4,500 for 9 percent of enrollees. Even under an option that breaks even (rather than reducing federal spending), most beneficiaries would see increases in cost sharing.

If adding a combined deductible and catastrophic protection were the only changes to the FFS benefit (unlike the CBO option described above), such a measure would lower the cost of benefits that supplemental insurers must pay, potentially leading to lower medigap premiums.[27] Lower supplemental premiums could, in turn, offset some of the higher Medicare cost sharing that many beneficiaries would face under a combined deductible.

As an alternative to making changes to the basic FFS benefit design, some analysts would like the Medicare program to offer supplemental benefits—including a catastrophic cap—directly to beneficiaries (Aaron and Lambrew 2008, Davis et al. 2005). The proposal would not fill in all of Medicare's cost sharing and so would raise OOP spending for some beneficiaries, but it could also lead to premiums

How private Medicare plans use benefit design

In 2009, more than 28 million beneficiaries enrolled in private Medicare plans (CMS 2009a). Nearly 11 million of them are in Part C Medicare Advantage (MA) and other capitated managed care plans that deliver Part A and Part B services (and typically Part D as well). Another 17.5 million are in stand-alone Part D prescription drug plans. Private Medicare plans are permitted to use a combination of benefit design, restricted networks of providers, and utilization management tools (e.g., prior authorization) to manage enrollees' care.

The Medicare program gives Part C and Part D plan sponsors flexibility in designing their benefits and cost sharing within certain limits. The program allows this flexibility because cost sharing can be an important tool for managing care when applied to discretionary services—when enrollees play more of a role in initiating care and determining how much to use. A recent analysis found that MA plans tend to simplify the Medicare benefit structure, generally using copayments rather than deductibles and coinsurance (Gold and Cupples Hudson 2009). Many plans use cost sharing as a tool to steer members toward certain types and levels of care and toward preferred providers. But there are inherent trade-offs between giving plans flexibility and protecting beneficiaries from discriminatory behavior.

Part C plans must provide all services covered by Part A and Part B, and many provide extra benefits or lower cost sharing than fee-for-service (FFS) Medicare to enrollees at no or low additional premiums beyond those for Part B. Generally, these premiums have been much lower than premiums for medigap policies. Plan benefits and cost-sharing requirements must apply uniformly to plan enrollees. Part C plans must not discriminate, discourage enrollment, or hasten disenrollment of sicker beneficiaries through the design of their benefit packages. Each year, CMS sets a maximum out-of-pocket (OOP) amount for FFS Medicare-covered services that serves as a "safe harbor" threshold for Part C plans. CMS gives plan sponsors that set an OOP cap at this amount (or lower) greater flexibility in setting cost sharing for individual services. Plans that do not use an OOP cap or that apply a cap only to a subset of services are subject to greater scrutiny.

In a 2004 mandated report, the Commission noted that while most MA enrollees had lower OOP spending than FFS beneficiaries, a small number of MA plans charged more than FFS's cost sharing for certain services, such as Part B-covered drugs (MedPAC 2004). The Commission encouraged CMS to monitor the issue and recommended ways to strengthen the agency's role in preventing discriminatory benefit designs. In plan guidance for 2010, CMS includes additional criteria to its "safe harbor" provision: The agency will likely not consider a benefit design discriminatory if—in addition to having an OOP cap of $3,400 or less that applies to all Part A and Part B services—it uses cost sharing no greater than that of FFS Medicare for Part B drugs, renal dialysis, psychiatric hospitalizations, and skilled nursing facility services (CMS 2009b).

In 2009, more than a million beneficiaries are enrolled in special needs plans (SNPs)—a type of MA plan that provides Part A, Part B, and Part D benefits. SNPs generally function like and are paid the same as other MA plans, but they can target certain types of enrollees: dual eligibles, institutionalized beneficiaries, and individuals with severe or disabling chronic conditions. In practice, beneficiaries in other categories are also enrolled in SNPs. SNPs follow the same guidelines as other MA plans with respect to benefit designs, and they must also apply cost-sharing requirements uniformly to all members.[28] However, to the extent that their enrollees have health conditions in common, SNPs could use benefit design as a mechanism for encouraging enrollees to adhere to therapies of high value or for discouraging use of low-value therapies. In 2008, the Commission made a number of recommendations to help ensure that SNPs limit their enrollment to targeted populations and provide members with specialized care (MedPAC 2008b).

CMS also gives Part D plans flexibility in designing prescription drug benefits. Sponsors may offer a plan with Part D's defined standard benefit (Table 6-8) or, within certain constraints, basic coverage that has the

(continued next page)

How private Medicare plans use benefit design (cont.)

same average dollar value of insured benefit spending. Many basic actuarially equivalent plans charge no deductible and use tiered copays that result in the same average benefit value (MedPAC 2009). (Under tiered copays, for example, a plan might charge $7 per prescription for a generic drug, $38 for a preferred brand-name drug, and $75 for a nonpreferred brand-name drug. The differences in cost sharing are meant to steer plan enrollees toward generic and preferred brand-name drugs.) Once a sponsor offers at least one basic benefit package, it may also offer an enhanced plan—one that includes basic and supplemental benefits.

One aspect of Part D benefits that CMS monitors is how plan sponsors operate their formularies—the list of drugs they cover and the terms under which they cover them. When designing formulary systems, sponsors strike a balance between providing enrollees with access to medications and controlling growth in drug spending by negotiating drug prices and managing use. Plan sponsors must also select the cost-sharing tier for each listed drug and whether any utilization management tools apply to the drug, taking into account clinical and financial factors. In recent years, most Part D plans have moved toward using specialty tiers for high-priced drugs and biologics. Cost-sharing requirements for specialty tier drugs are at least 25 percent of the plan sponsor's negotiated price, until the enrollee reaches Part D's true OOP limit. In addition, enrollees may not appeal cost sharing as they can for other drugs, such as those on nonpreferred brand tiers. ■

TABLE 6–8

Premiums and cost-sharing requirements for Part D's defined standard benefit in 2009

Category	Amount
Premiums	$30.36 per month*
Deductible	295
25% coinsurance after the deductible up to the initial coverage limit of	2,700
100% coinsurance between the initial coverage limit and the true OOP spending limit of	4,350
Total covered drug spending at true OOP limit	6,153.75
Minimum cost sharing above the true OOP limit:	
Copay for generic/preferred multisource prescription drug	2.40
Copay for other prescription drugs	6.00

Note: OOP (out of pocket). The term true OOP refers to a feature of Part D that directs fewer federal subsidy dollars toward enrollees who have supplemental coverage. Only certain types of spending on behalf of the beneficiary count toward the catastrophic threshold: the beneficiary's own OOP spending, that of a family member or official charity, supplemental drug coverage provided through qualifying state pharmacy assistance or Part D's low-income subsidies, and, under CMS's demonstration authority, supplemental drug coverage paid for with Medicare Advantage rebate dollars.
*Base beneficiary premium. Premiums for specific Part D plans may be more or less than this amount.

Source: CMS. 2008. Notification of changes in Part D payment for calendar year 2009. Baltimore, MD: CMS. http://www.cmhs.hhs.gov/MedicareAdvtgSpecRateStats/downloads/PartDAnnouncement2009.pdf.

for supplemental coverage that are substantially lower than those for many existing medigap policies.

Our analysis of the role of private secondary coverage on Medicare spending suggests some ways policymakers may want to rethink FFS benefits. For example, our analysis showed that the presence or absence of secondary coverage does not appear to affect whether beneficiaries receive emergency or urgent inpatient care. Rather than a benefit design tool that affects whether a beneficiary will seek hospital care, Medicare's high inpatient deductible seems to be more of a mechanism for apportioning some hospitalization costs to beneficiaries. An alternative approach could use a lower inpatient deductible for emergency hospitalizations and a higher inpatient deductible for stays where there is less evidence of a procedure's comparative effectiveness. However,

identifying which hospitalizations are for care that is of greater or lesser value would be difficult, as information on comparative effectiveness is limited.

A variant of capping beneficiaries' OOP costs under FFS would be to require nominal copays above a catastrophic threshold—similar to what Part D requires. Our analysis showing that even beneficiaries with very serious illnesses are somewhat sensitive to cost sharing suggests that nominal cost sharing above the catastrophic cap could encourage beneficiaries to be mindful of their use of care without imposing excessive financial burden on them.

Create incentives for beneficiaries to consider the value of services

Medicare could set different levels of cost sharing for the same medical intervention based on its clinical benefit to the patient. For example, patients with diabetes could be charged lower cost sharing for medical interventions shown to prevent or reduce long-term complications of the disease, such as drugs that control blood pressure. A patient with only slightly elevated blood pressure but no diabetes would face higher cost sharing for the same medication. When evidence shows that certain therapies are comparatively more effective for certain patients, lowering their cost sharing to help increase their adherence could improve health outcomes. If higher adherence leads to fewer exacerbations of the patient's condition, this approach could also lower spending. However, to achieve net savings, value-based insurance design (VBID) requires careful targeting. Spending would be reduced if medical interventions were not used as often when the cost outweighs the clinical benefit (Chernew et al. 2007, Fendrick et al. 2001).

Insurers, large employers, and researchers have tested key elements of VBID with some success at increasing adherence to medication therapies. In a study of the nonelderly, researchers found that charging individuals at higher risk of coronary heart disease lower copays for cholesterol-lowering drugs increased their adherence and reduced their use of hospital and emergency services (Goldman et al. 2006). Another study examining the use of angiotensin-converting enzyme inhibitors among Medicare beneficiaries with diabetes found that lower cost sharing for these drugs could extend life and reduce overall program spending (Rosen et al. 2005). The University of Michigan, Pitney Bowes, and the municipality of Asheville, North Carolina, have implemented programs that lower copays for diabetes patients for certain high-value interventions related to their condition, while maintaining lower cost sharing for generic drugs (Chernew et al. 2007).

A program that lowers copays for a drug or service for everyone would not save resources. Instead, a targeted VBID approach could lead to savings by encouraging greater adherence only for patients most likely to benefit clinically. However, this approach requires solid evidence about the comparative effectiveness of alternative therapies as well as the ability to accurately identify patients' conditions and their severity. Therapies for some diseases have a thorough body of evidence on comparative effectiveness. For others, policymakers and payers need significantly more investment in comparative effectiveness research and alternative methods of identifying relevant patient characteristics (e.g., information typically found in an electronic medical record). For insurers, other key barriers to implementation include higher administrative costs, near-term cost increases associated with lower copayments, legal issues, and the potential for fraud. Other stakeholders might be concerned about the complexity and equity of the benefit design as well as the need to protect the privacy of patient data (Chernew et al. 2007).

Today, examples of VBID among private payers typically aim to increase beneficiaries' adherence to prescription drug therapies to avoid hospitalizations and other medical services. However, one specific obstacle to using VBID in Medicare arises because prescription drug benefits are not part of an integrated package of medical services; FFS beneficiaries obtain prescriptions through stand-alone prescription drug plans that have no financial incentive to consider the combined cost of delivering Part A, Part B, and Part D services.

Reinforce payment reforms that seek better value for health care expenditures

We may want to use FFS cost sharing in ways that reinforce payment system reforms. For example, as CMS develops its ability to measure providers' quality of care and resource use, Medicare could use tiered copays for Part A and Part B services in the way that Part D plans use them today: to steer beneficiaries toward preferred providers. Medicare could also use differential cost sharing, such as tiered copayments, to discourage the use of services prone to overuse and to encourage the use of recommended services.

An understanding of the relationship between secondary coverage and higher Medicare spending—for nonurgent hospital admissions, preventive care, office visits,

specialist services, and diagnostic imaging—underlies recommendations the Commission has made in its annual payment update reports to the Congress. For example, in March 2009, the Commission recommended changes in how Medicare reimburses providers for imaging because of concern about rapid growth in the use of those services, regardless of their value (MedPAC 2009). The Commission also recommended that CMS revisit how it pays for primary care based on analysis that those services are undervalued (MedPAC 2009, MedPAC 2008c). In both cases, policymakers could use Medicare's cost-sharing requirements as a tool to steer beneficiaries toward care of better value—charging higher copays for certain discretionary imaging services and lower copays for primary care visits. In this way, Medicare cost sharing would serve as a tool to reinforce broader payment system reforms focused on attaining greater value for dollars spent.

Help improve Medicare's financial sustainability

Changes to the FFS benefit have become more urgent in view of the Medicare program's serious financial challenges. Raising cost-sharing requirements could rein in spending for health services that are more prone to overuse, particularly if accompanied by limits on the portion of Medicare's cost sharing that secondary coverage could fill in. Increasing the share of Medicare's costs borne by beneficiaries through premiums would also reduce the federal government's share of Medicare spending. Because indiscriminate increases could impose financial barriers to essential care or cause hardship for some Medicare beneficiaries, policy changes would need to balance these concerns with the goal of improving Medicare's financial sustainability.

One approach is to levy an excise tax on medigap policies, with the revenue dedicated to offsetting Medicare program costs. This tax could reduce incentives for Medicare beneficiaries to purchase medigap policies, encourage them to purchase less expensive plans, and help compensate the Medicare program for the added costs that stem from supplemental coverage. CBO estimates that a 5 percent tax on each medigap policy premium would increase federal revenues and decrease mandatory spending by $12.1 billion between 2009 and 2018 (CBO 2008). Drawbacks to this approach are that it would treat medigap policies differently from employer-sponsored retiree plans, which are also associated with higher Medicare spending, and could boost enrollment in Medicare Advantage, which the Commission and others have found currently requires more program spending per beneficiary than FFS Medicare (MedPAC 2009).

Under another approach, policymakers could redefine medigap policies so that they no longer completely filled in FFS cost-sharing requirements. For example, CBO estimates that if medigap policies did not pay any of the first $525 of a beneficiary's FFS cost sharing, and if coverage of the next $4,725 in Medicare cost sharing were limited to 50 percent, those measures would lead to $41 billion in federal mandatory savings between 2010 and 2019 (CBO 2008). Savings could be even larger by combining changes to medigap policies with other FFS benefit design changes. CBO estimated that if medigap policies no longer covered any of a new $525 combined deductible and covered only 50 percent of the new uniform coinsurance on services up to a Medicare OOP cap set at $5,250, it could reduce federal mandatory spending by $73 billion between 2010 and 2019 (CBO 2008).

Addressing the goal of Medicare's financial sustainability may require setting priorities among health coverage needs. That is, society may need to "differentiate between health care that supports the most essential aspects of human functioning and that which serves to enhance an individual's quality of life" (Ginsburg 2007). ■

Endnotes

1 The percent of Medicare beneficiaries who enrolled in Medicare Advantage plans increased considerably between 2005 and 2008, from about 13 percent of enrollees to about 20 percent. We do not know yet how this situation affected the distribution of supplemental coverage among those beneficiaries who remained in FFS Medicare.

2 Firms in the Midwest and Northeast are more likely to offer retiree coverage than firms in the South and West. Historically, manufacturing industries and federal, state, and local governments have been more likely to offer retiree coverage.

3 During this open enrollment period, medigap insurers may not use medical underwriting to refuse to issue a beneficiary a policy or charge her a higher premium because of her health status. However, the insurer may refuse to cover OOP costs for a preexisting condition for up to 6 months unless the beneficiary had creditable coverage before Part B. If an individual does not purchase medigap coverage during the open enrollment period and later applies, insurers are permitted to use medical underwriting: They may decide not to write the policy, or they may charge a higher premium based on health status. The law gives beneficiaries guaranteed issue rights to purchase certain medigap policies under other circumstances such as if creditable coverage through an employer ends, or if the individual was enrolled in a Medicare Advantage plan that withdrew from the beneficiary's service area (CMS 2008a).

4 Plan C does not provide coverage for Part B balance billing while Plan F does. Neither Plan C nor Plan F covers home health care, preventive care, or outpatient prescription drugs.

5 On average, administrative load for medigap plans is 20 percent and sometimes higher, largely due to the need for medigap insurers to market directly to individuals.

6 When a policy holder does not use a network provider for nonemergency care, she must pay some or all of Medicare's cost sharing.

7 Under the terms of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, insurers cannot issue new Plan J policies because they would compete with Part D by including prescription drugs in their covered benefits. In 2009, enrollees must pay the first $2,000 in Medicare cost sharing under the high deductible of Plan F.

8 Neither of the new plans—designated Plan K and Plan L—covers the Part B deductible. After the Part B deductible, Plan K pays for 50 percent of most Medicare cost sharing and, once the beneficiary has paid a yearly limit of $4,620 in OOP spending (in 2009), it pays remaining cost sharing for covered services. After the Part B deductible, Plan L covers 75 percent of FFS cost sharing and has a yearly OOP limit of $2,310 (in 2009).

9 Generally, individuals qualify to receive Supplemental Security Income if their income is at or below 74 percent of the federal poverty level. In 2009, 100 percent of the federal poverty level is an income of $10,830 for a single person and $14,570 for a two-person household.

10 A small share of individuals also pay a premium for Part A services because they or their spouse do not have enough credits of paying payroll taxes to automatically receive Part A benefits. In 2009, the Part A premium is $443 per month.

11 Persons with high drug spending may also have to pay 100 percent of their Part D plan's negotiated price for a drug if they reach the coverage gap—a dollar limit on covered benefits before the enrollee incurs enough cost sharing to qualify for catastrophic protection.

12 Under hold-harmless policies, Medicare Part B premiums cannot increase by a larger dollar amount than the cost-of-living increase in an individual's Social Security benefit. Still, in many recent years the dollar amount of increases in Part B premiums has absorbed 20 percent to 40 percent of the dollar increase in the average Social Security benefit. Part D premium increases are not subject to a hold-harmless provision.

13 Some Medicare beneficiaries do not pay their hospital deductibles and coinsurance. In a report prepared under contract to the Commission, Direct Research estimated that in 2005, hospitals incurred about $1.1 billion of bad debt (calculated from Sutton et al. 2007). It is probably reasonable to assume that much of this is for the care of beneficiaries with no supplemental coverage.

14 In 2007, the BCBS standard PPO option in the FEHB program had a $100 per admission inpatient copay for unlimited days at preferred providers ($300 for nonpreferred providers). In addition, after a deductible of $250 per person ($500 per family), the enrollee paid 10 percent of allowed charges for inpatient professional services from preferred providers (25 percent from nonpreferred). The BCBS standard option capped OOP spending at $4,000 in cost sharing from preferred providers ($6,000 for a combination of preferred and nonpreferred providers). For 2009, the BCBS standard option in the FEHB program has become somewhat less generous. It uses an inpatient copay of $200 per admission for preferred providers ($300 nonpreferred), a general deductible

of $300 per person ($600 per family), and then 15 percent coinsurance for inpatient professional services (30 percent for nonpreferred).

15 This estimate of 5 percent reflects the experience of a typical (median) beneficiary with Medicaid and Medicare coverage. Note, however, that some individuals must "spend down" their income and assets to become eligible to receive Medicaid benefits. When we examined the average (mean) percentage of income spent on premiums and cost sharing, duals in the highest ranking quartile of FFS spending spent about 21 percent of their incomes.

16 Costs for beneficiaries with no secondary insurance were 20 percent below the all-Medicare average, while costs for those with medigap were 8 percent above average, after adjusting for health status and demographic differences (PPRC 1997).

17 One recent analysis contends that previous studies that find a relatively large "insurance effect" did not take into account care that beneficiaries who do not report having supplemental coverage receive through the Department of Veterans Affairs and the military health care system (Lemieux et al. 2008). Under contract for the Commission, Direct Research was unable to replicate this result.

18 The topic of whether lower cost-sharing requirements could lead to "spending offsets" due, for example, to lower rates of hospitalizations is controversial. One recent study using data for a commercially insured population found evidence that higher cost sharing for prescription drugs led to the substitution of greater outpatient care a year later. However, the magnitude of higher outpatient spending was smaller than the revenue from raising drug copays: 35 percent of the savings from reductions in drug spending were offset by increases in other medical spending. The study found little measurable substitution between drugs and inpatient care (Gaynor et al. 2007).

19 The admission type variable on inpatient claims categories classifies admissions these ways:

• *Emergency*—the patient required immediate medical intervention as a result of severe, life-threatening, or potentially disabling conditions. Generally, the patient was admitted through the emergency room.

• *Urgent*—the patient required immediate attention for the care and treatment of a physical or mental disorder. Generally, the patient was admitted to the first available and suitable accommodation in the hospital.

• *Elective*—the patient's condition permitted adequate time to schedule the availability of suitable accommodations.

20 Our contractor looked at admission source and other information to validate this variable. Almost 90 percent of Medicare admissions occurred either through the emergency department or from a physician referral. By admission source, fewer than 2 percent of emergency department admissions were marked as elective, while nearly 60 percent of physician referral admissions were marked as elective. The contractor also examined a specific clinical indication, segregating hip replacement admissions by the presence of fracture. Almost all fracture cases were marked as emergency or urgent, while almost all other cases were marked as elective. Both of these tests suggest that the type of admission variable provides a reasonable average measure of admission urgency.

21 To confirm that aggregate results were not sensitive to this issue, the contractor repeated our regressions on each individual year of data. The results were not sensitive to pooling data across years. For the service-specific analysis, the contractor applied the screen of needing at least 30 different people because statistics used for significance tests may be inaccurate when there are few cases. This criterion helps weed out findings that are most likely the result of outliers and helps present a more conservative estimate.

22 Direct Research could not replicate the findings of Lemieux and colleagues (Lemieux et al. 2008). They were correct that VA users make up a larger fraction of the Medicare-only population than they do of the rest of the Medicare population. However, Direct Research's analysis found that VA users were too few to affect average spending levels by insurance category, and they tended to have significant levels of Medicare spending even though they also used VA care.

23 Using HCC disease categories as a control for health status raises a methodological issue. The HCC model was designed as a prospective rather than a concurrent model—that is, predictive of spending in the subsequent year rather than in the current year. In addition, including a concurrent HCC risk score raises the question of endogeneity of health care use. In other words, is the presence of fewer disease markers among Medicare-only individuals due to their relative health or to having fewer claims on which diagnoses were reported? A beneficiary might appear to have fewer disease markers because she is healthy, or she might have fewer because she is part of a population that is underserved or faces barriers to access. Including indicators for HCC disease categories in the regressions should give a more conservative estimate of the impact of secondary insurance. If one excluded those variables, they might mistakenly attribute part of the lower health care use of the Medicare-only population to better health status. To the degree that HCC indicators over- or misstate the good health of the Medicare-only population, they will "explain" their lower spending and result in attributing a smaller portion of the spending differential solely to the effects of insurance coverage.

24 A recent study of the effects of insurance on Medicare beneficiaries' drug spending found some evidence of nonobservable selection (i.e., not measurable with variables like those in the regressions by Direct Research). However, the authors estimated that this effect had a small magnitude (Shea et al. 2007).

25 Beneficiaries without supplemental coverage also had a somewhat higher rate of mortality averaged across all three years of MCBS data, but that result did not hold true in each year, 2003 to 2005. Also, other aspects of the analysis, such as our exclusion of residents of long-term care facilities, suggest a need to look more closely at this issue rather than concluding that it is a problem.

26 Because most studies on supplemental coverage are cross sectional or have short time horizons, they may not detect lower use of services over a longer period (Chandra et al. 2007).

27 The same is true even if medigap policies filled in the combined deductible, because secondary coverage would no longer cover catastrophic costs.

28 Dual-eligible SNPs (and MA plans generally) are obligated to ensure that cost sharing for dual-eligible beneficiaries is the same as under FFS Medicare—generally close to zero.

References

Aaron, H. J., and J. M. Lambrew. 2008. *Reforming Medicare: Options, tradeoffs, and opportunities.* Washington, DC: Brookings Institution Press.

America's Health Insurance Plans, Center for Policy and Research. 2008a. *Medigap: What you need to know.* Washington, DC: AHIP.

America's Health Insurance Plans, Center for Policy and Research. 2008b. *Trends in medigap policies, December 2004 to December 2006.* Washington, DC: AHIP.

Atherly, A. 2001. Supplemental insurance: Medicare's accidental stepchild. *Medical Care Research and Review* 58, no. 2 (June): 131–161.

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2008. *2008 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.* Washington, DC: Boards of Trustees.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009a. *Medicare Advantage, cost, PACE, demo, and prescription drug plan contract report, monthly summary report.* Baltimore, MD: CMS. http://www.cms.hhs.gov/MCRAdvPartDEnrolData/MCESR/list.asp#TopOfPage.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009b. *Issuance of the 2010 call letter.* Baltimore, MD: CMS. March 30.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008a. *Choosing a medigap policy 2009: A guide to health insurance for people with Medicare.* Baltimore, MD: CMS. http://www.medicare.gov/Publications/Pubs/pdf/02110.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008b. *Medicare & you 2009.* Baltimore, MD: CMS. http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2005a. *Characteristics and perceptions of the Medicare population; Data from the 2003 Medicare current beneficiary survey, chapter 5*. Baltimore, MD: CMS. http://www.cms.hhs.gov/MCBS/Downloads/CNP_2003_dhsec5.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2005b. *Medicaid at-a-glance 2005.* Baltimore, MD: CMS. http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/Downloads/maag2005.pdf.

Chandra, A., J. Gruber, and R. McKnight. 2007. Patient cost-sharing, hospitalization offsets, and the design of optimal health insurance for the elderly. Working paper 12972, National Bureau of Economic Research: Cambridge, MA. March.

Chernew, M. E., A. B. Rosen, and A. M. Fendrick. 2007. Value-based insurance design: By abandoning the archaic principle that all services must cost the same for all patients, we can move to a high-value health system. *Health Affairs* 26, no. 2 (January): w195–w203.

Christensen, S., and J. Shinogle. 1997. Effects of supplemental coverage on use of services by Medicare enrollees. *Health Care Financing Review* 19, no. 1 (Fall): 5–17.

Congressional Budget Office. 2008. *Budget options, volume I: Health care.* Washington, DC: CBO.

Davis, K., M. Moon, B. Cooper, et al. 2005. Medicare Extra: A comprehensive benefit option for Medicare beneficiaries. *Health Affairs Web Exclusives* 12 (October 4). http://www.healthaffairs.org.

Employee Benefit Research Institute. 2008. *The future of employer-based health benefits: Have employers reached a tipping point?* EBRI notes 29, no. 2. Washington, DC: EBRI.

Fendrick, A. M., D. G. Smith, M. E. Chernew, et al. 2001. A benefit-based copay for prescription drugs: Patient contribution based on total benefits, not drug acquisition cost. *American Journal of Managed Care* 7, no. 9 (September): 861–867.

Gabel, J., H. Whitmore, and J. Pickreign. 2008. *Survey of retiree health benefits, 2007: A chartbook.* New York: Commonwealth Fund/NORC. http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2008/Sep/Retiree%20Health%20Benefits%20After%20Medicare%20Part%20D%20%20A%20Snapshot%20of%20Prescription%20Drug%20Coverage/Gabel_surveyretireehltbenef2007_1171_chartpack%20pdf.

Gaynor, M., J. Li, and W. B. Vogt. 2007. Substitution, spending offsets, and prescription drug benefit design. *Forum for Health Economics & Policy* 10, no. 2: article 4.

Ginsburg, M. 2007. *Balancing act: Creating a sustainable health care benefits package.* Washington, DC: New America Foundation.

Gold, M., and M. Cupples Hudson. 2009. *Medicare Advantage benefit design: What does it provide, what doesn't it provide, and should standards apply?* Washington, DC: AARP Public Policy Institute.

Goldman, D. P., G. F. Joyce, and Y. Zheng. 2007. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Journal of the American Medical Association* 298, no. 1 (July 4): 61–67.

Goldman, D. P., G. F. Joyce, and P. Karaca-Mandic. 2006. Varying pharmacy benefits with clinical status: The case of cholesterol-lowering therapy. *American Journal of Managed Care* 12, no. 1: 21–28.

Hogan, C. 2009. *Exploring the effects of secondary coverage on Medicare spending for the elderly*. Washington, DC: Contractor report for MedPAC. http://www.medpac.gov.

Holahan, J., D. M. Miller, and D. Rousseau. 2009. *Rethinking Medicaid's financing role for Medicare enrollees.* Washington, DC: Kaiser Commission on Medicaid and the Uninsured. February. http://www.kff.org/medicaid/7862.cfm.

Hsu, J., M. Price, and J. Huang. 2006. Unintended consequences of caps on Medicare drug benefits. *New England Journal of Medicine* 354, no. 22 (June 1): 2349–2359.

Kaiser Commission on Medicaid and the Uninsured. 2009. *Dual eligibles: Medicaid's role for low-income Medicare beneficiaries.* Washington, DC: Kaiser Commission on Medicaid and the Uninsured. http://www.kff.org/medicaid/7846.cfm.

Kaiser Family Foundation and Health Research and Educational Trust. 2008. *Employer health benefits annual survey*. Menlo Park, CA: KFF/HRET.

Lee, A. J., S. A. Garfinkel, R. K. Khandker, et al. 1997. Impact of Medicare SELECT on cost and utilization in 11 states: Innovations in fee-for-service financing and delivery. *Health Care Financing Review* 19, no. 1 (Fall): 19–40.

Lemieux, J., T. Chovan, and K. Heath. 2008. Medigap coverage and Medicare spending: A second look, *Health Affairs* 27, no. 2 (March/April): 469–477.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008a. *A data book: Healthcare spending and the Medicare program*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008b. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008c. *Report to the Congress: Reforming the delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2004. *Benefit design and cost sharing in Medicare Advantage plans*. Washington, DC: MedPAC.

Merlis, Mark. 2006. *Health benefits in retirement: Set for extinction?* National Health Policy Forum background paper (February 8). Washington, DC: NHPF.

Moon, M. 2006. *Medicare: A policy primer.* Washington, DC: Urban Institute Press.

National Association of Insurance Commissioners. 2008. *Implementation materials for revisions to medigap model.* Kansas City, MO: NAIC.

Neuman, T., J. Cubanski, and A. Damico. 2009. *Revisiting 'skin in the game' among Medicare beneficiaries: An updated analysis of the increasing financial burden of health care spending from 1997 to 2005.* Washington, DC: KFF. February.

Physician Payment Review Commission. 1997. *Annual report to Congress.* Washington, DC: PPRC.

Remler, D. K., and A. J. Atherly. 2003. Health status heterogeneity of cost-sharing responsiveness: How do sick people respond to cost-sharing? *Health Economics* 12: 269–280.

Rice, T., and K. Y. Matsuoka. 2004. The impact of cost sharing on appropriate utilization and health status: A review of the literature on seniors. *Medical Care Research and Review* 61, no. 4 (December): 415–452.

Rosen, A. B., M. B. Hamel, M. C. Weinstein, et al. 2005. Cost-effectiveness of full Medicare coverage of angiotensin-converting enzyme inhibitors for beneficiaries with diabetes. *Annals of Internal Medicine* 143, no. 2 (July): 89–99.

Scanlon, W. J. 2002. Medigap: Current policies contain coverage gaps, undermine cost control incentives. Oral testimony before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives. 107th Cong., 2nd sess. GAO–02–533T. March 14.

Shea, D. G., J. V. Terza, B. C. Stuart, et al. 2007. Estimating the effects of prescription drug coverage for Medicare beneficiaries. *Health Services Research* 42, no. 3, Part I (June): 933–949.

Social Security Administration. 2008. *Fast facts and figures about Social Security 2008.* SSA publication no. 13–11785. September. http://www.ssa.gov/policy/docs/chartbooks/fast_facts/2008/fast_facts08.html.

Stuart, B., P. K. Singhal, C. Fahlman, et al. 2003. Employer-sponsored health insurance and prescription drug coverage for new retirees: Dramatic declines in five years. *Health Affairs Web Exclusives* (July 23). http://www.healthaffairs.org.

Sutton, J. P., A. Kennedy, L. Hammer, et al. 2007. *How will elimination of hospital bad debt reimbursement affect rural PPS hospitals?* Bethesda, MD: NORC.

Weiss Ratings, Inc. 2005. *2005 medigap premium rates.* Palm Beach, FL: TheStreet.com. http://www.weissratings.com/News/Ins_Medigap/20050829medigap_rates.pdf.

Wolfe, J. R., and J. H. Goddeeris. 1991. Adverse selection, moral hazard, and wealth effects in the Medigap insurance market. *Journal of Health Economics* 10: 433–459.

Yamamoto, D, T. Neuman, and M. Kitchman Strollo. 2008. *How does the benefit value of Medicare compare to the benefit value of typical large employer plans?* Washington, DC: KFF.

CHAPTER 7

Medicare Improvements for Patients and Providers Act of 2008 Medicare Advantage payment report

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Chapter summary

Section 169 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires a Commission study and report on Medicare Advantage (MA) payments. The Commission is directed to:

- evaluate CMS's measurement of county-level spending.
- study the correlation between MA plan costs (as reflected in plan bids) and county-level spending under fee-for-service (FFS) Medicare.
- examine approaches to MA payment other than "county-level payment area equivalents," and make recommendations as appropriate.

CMS's estimates of spending in traditional FFS Medicare are reasonably accurate and capture the important administrative costs associated with the FFS program. To increase accuracy, we encourage CMS to adjust for services provided by the Department of Veterans Affairs and the Department of Defense at the county payment level where warranted. Another way to enhance the reliability of FFS

In this chapter

estimates is to increase the size of the MA payment areas. An appendix to this chapter includes the Commission's previous recommendation on payment areas and our supporting analysis.

We find that MA plan costs to deliver Part A and Part B benefits and county-level per capita spending under FFS Medicare are highly correlated, which we take into account in our development of new approaches to payment.

The Commission supports private plans in Medicare and the innovative delivery systems and care management techniques they can offer. But plans will innovate only if payment rates encourage them to do so. The current high payments have resulted in some plans that bring no innovation but simply mimic FFS Medicare at a much higher cost to the program. This situation is unfair to taxpayers and beneficiaries not enrolled in MA, who subsidize the higher costs.

In response to the mandate, we have developed a number of options for setting MA "benchmarks" administratively. (A benchmark is the maximum MA payment amount, set by law, for each payment area.) Each option is financially neutral to FFS Medicare in the aggregate in the first year; any one of them will cost the same as traditional Medicare, saving an estimated $12 billion. In later years, spending relative to FFS for each option will vary depending on where enrollment is encouraged or discouraged. Because all the options remove money from the current MA program, each would result in fewer plans and reduced extra benefits in some areas. For each option, we consider the effect on the availability of high-quality plans and plans that can provide care coordination. We discuss a modification that would differentiate payment for extra benefits in high- and low-use areas, balancing extra benefits among areas and helping mitigate concerns about equity.

Another alternative is to set benchmarks through a competitive bidding process. We present the fundamental issues to address when designing a competitive bidding system and outline some possible behavioral responses. The approach could result in approximate financial neutrality with FFS in

the first year if plans' bids are similar to those made in 2009. However, we expect that plans would alter their bidding practices; thus, we cannot rely on current bidding data to simulate future behavior under this option. Therefore, we do not present a quantitative analysis of the option.

In the commentary section of this chapter, we reflect on how the goals for private plans in Medicare have shifted over time. The shifting of goals has resulted in the MA program of today, with plans available to all beneficiaries in all parts of the country providing enhanced benefits but at a high price to Medicare:

- We estimate that in 2009 Medicare pays about $12 billion more for enrollees of MA plans than it would if they were in FFS Medicare. The Congressional Budget Office estimates the additional 10-year cost at more than $150 billion.
- These excessive payments encourage inefficient plans to enter the program, further raising the costs to Medicare. The program pays on average $1.30 to subsidize each dollar of enhanced benefits. In the case of private FFS plans, Medicare pays more than $3.00 in subsidies for each dollar of enhanced benefits. (By contrast, Medicare subsidizes HMOs $0.97 for each dollar of enhanced benefits.)
- The cost of MA subsidies is borne by taxpayers who finance the Medicare program and by all Medicare beneficiaries via Part B premiums: The Part B premium for all beneficiaries is increased by about $3.00 a month, regardless of whether they receive any of the benefit.
- The additional MA payments hasten the insolvency of the Medicare Part A trust fund by about 18 months.
- Further, although many plans are available (e.g., 1 county has more than 90 plans), only some are of high quality. Only about half of beneficiaries nationwide (and only one-third in rural areas) have access to a plan that CMS rates as above average in overall plan quality.

The MA payment system could be improved by recasting the goals of the program to emphasize financial neutrality, efficiency, equity, and quality. A new framework needs to be achieved that includes care coordination and cost savings (the original goals of the program), realizes greater equity (as intended by later changes to the program), and improves quality. Encouraging plans to be efficient is a key element. Plans that are more efficient than FFS Medicare can provide extra benefits while maintaining financial neutrality with FFS. In a transition to new benchmarks, quality improvements could be promoted by paying more for better quality. After the transition, if plans' quality can be measured relative to FFS, plans providing better quality care than FFS would be paid more than FFS.

In the analytics section of this chapter, we present our findings on each task of the MIPPA mandate. We preface the discussion with a background section on the current MA program, including the mechanics of payment, payment statistics, and plan quality.

In the commentary section of this chapter, we review the goals of the MA program and how those goals can influence the evaluation of various payment options. We also discuss some considerations for the MA program as it transitions to a different system of payment. ■

Background

The current Medicare Advantage (MA) payment system has evolved and now presents many complexities and raises many issues. The principal issue is that payment benchmarks are too high, resulting in excessive payments that encourage the entry of inefficient plans and increase Medicare spending. The higher spending hastens the insolvency of the Part A trust fund and increases the burden on taxpayers and beneficiaries—and all beneficiaries face higher Part B premiums to pay for higher spending in MA plans that benefits only a fraction of the Medicare population. Although some of that spending is translated into enhanced benefits, 13 percent goes for overhead expenses (administrative costs and margins).[1] Medicare pays on average $1.30 to subsidize each dollar of enhanced benefits and more than $3.00 in subsidies in the case of private fee-for-service (PFFS) plans. (By contrast, Medicare subsidizes HMOs $0.97 for each dollar of extra benefits.) The problems with the current system will become evident as we review the current status of the MA program.

Current MA program status

The MA program provides Medicare beneficiaries with an alternative to the fee-for-service (FFS) Medicare program. It enables them to choose a private plan for their Medicare benefits. Private plans can use alternative delivery systems and care management techniques, and—if paid appropriately—they have the incentive to innovate and be efficient.

About 22 percent of Medicare beneficiaries were enrolled in MA plans in 2008. All beneficiaries have access to an MA plan in 2009, with an average of 34 plans available in each county. In 2009, 88 percent of Medicare beneficiaries have an HMO or local preferred provider organization (PPO) plan in their county, and all beneficiaries have a PFFS plan available.[2]

MA payment system mechanics

Plan payment rates are determined by the MA plan "bid" (the dollar amount of revenue the plan estimates it needs to cover the Part A and Part B benefit for a beneficiary of average health status) and the "benchmark" in the payment area (the maximum Medicare payment set by law for an MA plan in a payment area). If a plan's bid is above the benchmark, then the plan's payment rate is equal to the benchmark, and enrollees have to pay an additional premium equal to the difference. If a plan's bid is below the benchmark, the plan's MA payment rate is its bid plus 75 percent of the difference between the plan's bid and its benchmark. Because benchmarks are often set well above what it costs Medicare to provide benefits to similar beneficiaries in the traditional FFS program, MA payment rates usually exceed FFS spending.[3]

In the MA program, an individual county defines a payment area. Each county has a benchmark rate against which MA plans must bid if they want to serve the county. CMS is required to adjust each county's benchmark annually by a "minimum update," defined as the percentage projected change in overall Medicare expenditures over the preceding year.[4] However, CMS is legally required at least every three years to "rebase" the benchmarks by estimating per capita spending in FFS Medicare in each county, which CMS calculates based on a five-year moving average (for description, see text box, pp. 176–177).[5] In rebasing years, the FFS spending becomes the benchmark if it exceeds the amount that results from the minimum update. These adjustments can only increase a county's benchmark; they cannot decrease it. Since the introduction of the rebasing concept, CMS has made rebasing calculations more frequently than the statute requires: in 2004, 2005, 2007, and 2009.

The use of counties as payment areas in conjunction with using county-level FFS spending in setting benchmarks creates two problems. First, many counties have small populations in the FFS program. In these counties, unusually high or low health care use by just a few FFS beneficiaries can cause substantial annual changes in FFS spending. For example, from 2007 to 2009 FFS spending (adjusted for risk) increased by more than 30 percent in Loving County, Texas, which has fewer than 20 FFS beneficiaries. The second problem is that adjacent counties often have very different levels of FFS spending. This difference can be due to one county having an unusually costly year or because adjacent counties have persistently different costs. In either event, basing benchmarks on FFS spending can result in adjacent counties having very different benchmarks. When this situation occurs, plans tend to offer more limited benefits in the county with the lower benchmark—or avoid that county altogether—which creates appearances of inequity between adjacent counties (MedPAC 2001).

To mitigate these problems, the Commission has recommended larger payment areas for the MA program

TABLE 7–1

Medicare Advantage payments exceed FFS spending for all plan types in 2009

Plan type	Enrollment November 2008 (in millions)	Percent of FFS spending in 2009		
		Benchmarks	Bids	Payments
All MA plans	9.9	118%	102%	114%
HMO	6.6	118	98	113
Local PPO	0.7	121	108	118
Regional PPO	0.3	114	106	112
PFFS	2.3	120	113	118
Restricted availability plans included in totals above				
SNP*	1.3	122	99	116
Employer group*	1.7	117	109	115

Note: FFS (fee-for-service), MA (Medicare Advantage), PPO (preferred provider organization), PFFS (private fee-for-service), SNP (special needs plan). Benchmarks are the maximum Medicare program payments for MA plans. FFS spending by county is estimated using the 2009 MA rate book. Spending related to the double payment for indirect medical education payments made to teaching hospitals was removed. Data are enrollment weighted.
*SNPs and employer group plans have restricted availability and their enrollment is included in the statistics by plan type. They are presented separately to provide a more complete picture of the MA program.

Source: MedPAC analysis of data from CMS on plan bids, enrollment, benchmarks, and fee-for-service expenditures.

(MedPAC 2005). Those payment areas would make the estimates of FFS spending more stable and would more closely approximate insurance plan market areas. Our analysis of this issue and detailed recommendations are presented in the appendix to this chapter.

Current benchmarks, bids, and payments

We estimate that, on an enrollment-weighted average basis, 2009 MA benchmarks will be 118 percent of spending in Medicare's traditional FFS program, bids will be 102 percent of FFS spending, and payments will be 114 percent of FFS spending (Table 7-1). In 2009, the Medicare program is paying about $12 billion more for the beneficiaries enrolled in MA plans than it would be spending if they were in FFS Medicare. (We include plans in Puerto Rico in our totals, although its MA market has some unusual characteristics.)[6]

We report benchmarks by plan type in Table 7-1. County benchmarks do not vary by plan type, but different plan types tend to draw their enrollment from counties with different characteristics, which have different benchmarks.[7] Hence, in aggregate, benchmarks vary by plan type as an artifact of their enrollment patterns. By law, certain counties have higher benchmarks to increase plan availability. Those counties, called "floor" counties (there are two types: the large urban floor and a lower floor that applies to all other counties), have benchmarks that average 120 percent of FFS spending, whereas nonfloor counties' benchmarks average 112 percent of FFS spending.[8] Local PPOs and PFFS plans tend to operate in counties with higher benchmarks than other plan types. Local PPOs draw their enrollment more heavily from urban floor counties and PFFS plans draw more heavily from rural floor counties.

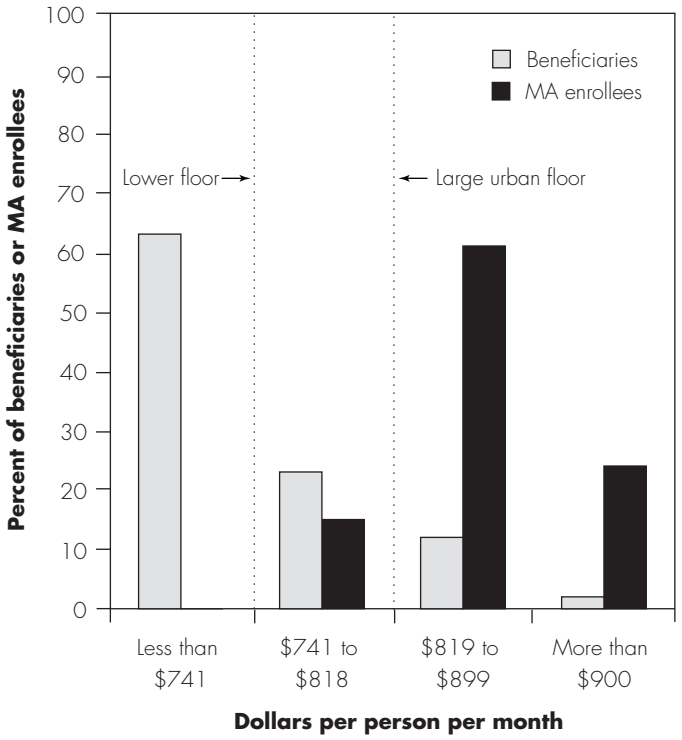
Plan bids also vary by plan type. We estimate that HMO bids were on average 98 percent of FFS spending, which suggests that HMOs can provide Part A and Part B services for less than the cost of FFS. Plan bid averages for other plan types exceeded the overall average. PFFS plan bids average 113 percent of FFS, up from 108 percent in 2008. The presence of plans bidding over FFS in the program means that the current payment system is encouraging inefficient plans to participate. These plans by definition are less efficient than Medicare FFS; their bids indicate that it costs them more than Medicare FFS to provide the basic Part A and Part B benefit. Plans do not have to be efficient to thrive under the current payment system, but they would have to be more efficient if they faced the financial pressure of benchmarks closer to Medicare FFS levels. As the Commission has stated, organizations are more likely to be efficient when they face financial pressure, and the Medicare program needs to exert consistent financial pressure on providers in the FFS program and plans in the MA program.

In 2009, MA plan payments in relation to FFS spending vary by the type of MA plan, but the levels for all plan types are substantially higher than 100 percent. We estimate that 2009 payments to plans overall will average 114 percent of FFS spending. More than 13 percent of those payments are used for overhead (administrative costs and margins) and not for direct medical care for beneficiaries. HMO payments are estimated to average 113 percent of FFS, while payments to PFFS plans are estimated to average 118 percent. Each of these payment levels is a percentage point higher relative to FFS than we estimated for 2008.[9] Because payments are so much higher than FFS spending for similar beneficiaries, the overall cost of the Medicare program is higher, which increases the burden on taxpayers and beneficiaries. All beneficiaries have to pay higher Part B premiums to fund higher payments to MA plans that benefit only some individuals. Higher spending also hastens the insolvency of the Medicare Part A trust fund.

Although higher spending for MA plans may provide extra benefits, Medicare pays a high price for the benefits. Overall, the Medicare subsidy per dollar of enhanced benefit is $1.30 for all plans. In the case of HMOs, because their bids for the Medicare benefit package are below Medicare FFS spending, the program subsidy is $0.97 for each $1.00 of enhanced benefits. HMOs are the only MA plan type that finances any part of enhanced benefits through plan efficiencies: $0.03 of every dollar. Medicare fully subsidizes enhanced benefits in other plan types (MedPAC 2009). At the extreme, Medicare pays a subsidy of $3.26 for each dollar of enhanced benefits a member receives in a PFFS plan.

FIGURE 7–1

Over 60 percent of beneficiaries live in counties with FFS spending below the lower floor



Note: FFS (fee-for-service), MA (Medicare Advantage). For beneficiaries, dollars per person per month is FFS spending in their county of residence; for MA enrollees, it is benchmarks for their county of residence.

Source: MedPAC analysis of CMS enrollment and payment data.

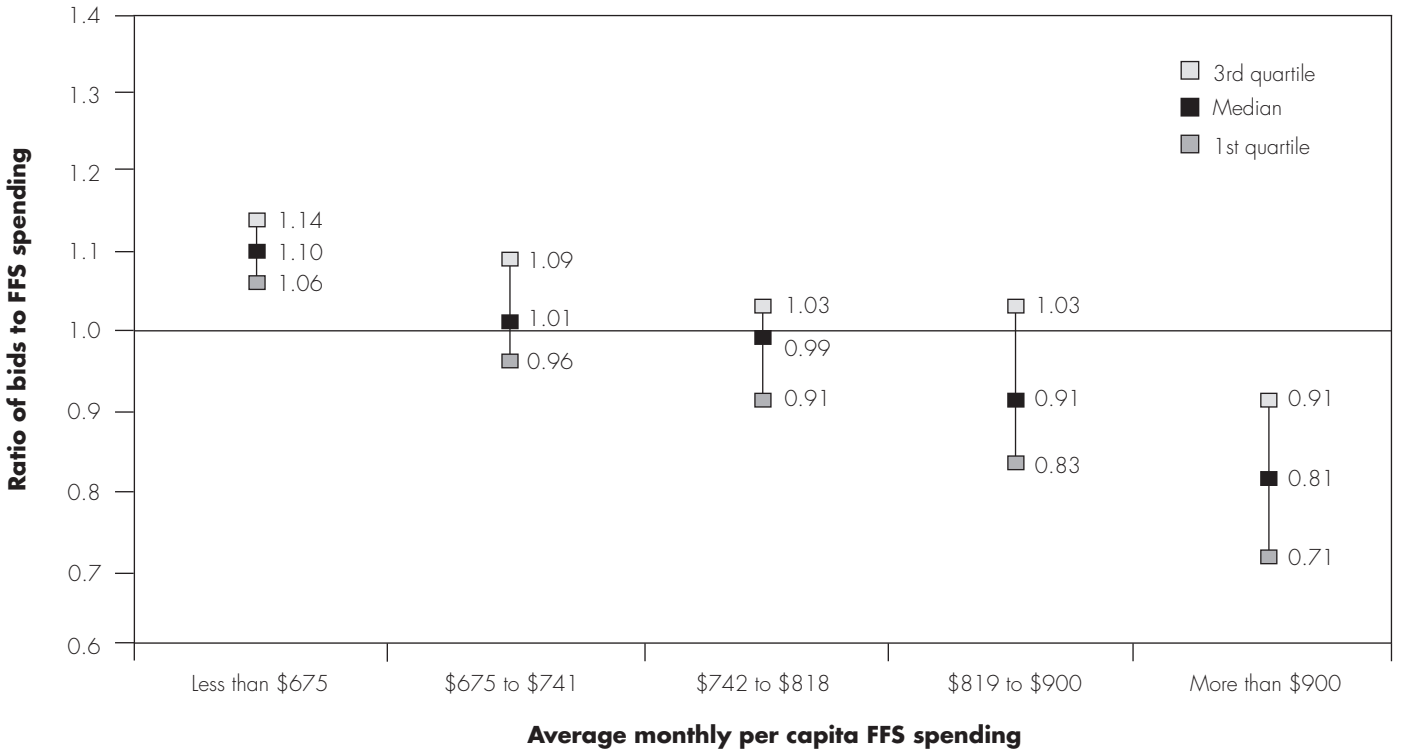
Distribution of spending and benchmarks

As discussed, a county's benchmark can be well above its FFS spending. Figure 7-1 shows two data series: Light bars show the percent of beneficiaries by FFS spending in their county of residence and dark bars indicate the percent of MA enrollees by the MA benchmarks in their county of residence. More than 60 percent of beneficiaries live in counties with monthly FFS payments per capita less than $741, and only 2 percent of beneficiaries live in counties with monthly FFS payments exceeding $900. By contrast, no MA enrollees live in an area with a benchmark below $741 because that is the lower floor value (applicable almost exclusively in rural counties). (Puerto Rico is not included in this figure because its benchmarks have a different floor rate prescribed by statute.) The large urban floor is $819 a month. About 15 percent of MA enrollees live in areas with benchmarks between these two floors. Most MA enrollees (about 60 percent) live in areas with benchmarks at or above the large urban floor and below $900 a month. Almost 25 percent of MA enrollees live in areas with benchmarks higher than $900 a month. This disparity in the distributions is reflected in the disparity in payments per beneficiary between FFS and MA.

Relation of bids and FFS spending

The ratio of plan bids to FFS spending in their payment area decreases as FFS spending increases (Figure 7-2, p. 174). For areas with FFS spending below $742 a month, the median bid to provide the Part A and Part B benefit is greater than FFS spending (the ratio is greater than 1.00). For example, in areas with average per capita FFS spending less than $675 per month, the median bid was 1.10 times FFS spending. More than 30 percent of

FIGURE 7–2 **Ratio of bids to FFS spending decreases as level of FFS spending increases**



Note: FFS (fee-for-service).

Source: MedPAC analysis of CMS bid data.

beneficiaries live in those areas. Another 30 percent of beneficiaries live in areas with FFS spending between $675 and $741 a month. The median bid in those areas is 1.01 times FFS spending (but 25 percent of plans bid at or below 96 percent of FFS spending). In higher spending areas, with FFS spending at or above $742, median bids are lower than FFS spending. For example, in areas with FFS spending above $900, the median bid was 81 percent of FFS spending. However, only 3 percent of beneficiaries live in those areas. If benchmarks were set equal to median bids, most beneficiaries would live in areas with benchmarks above FFS spending. Conversely, if benchmarks were set to FFS spending, many beneficiaries would live in areas with no bids below the benchmark.

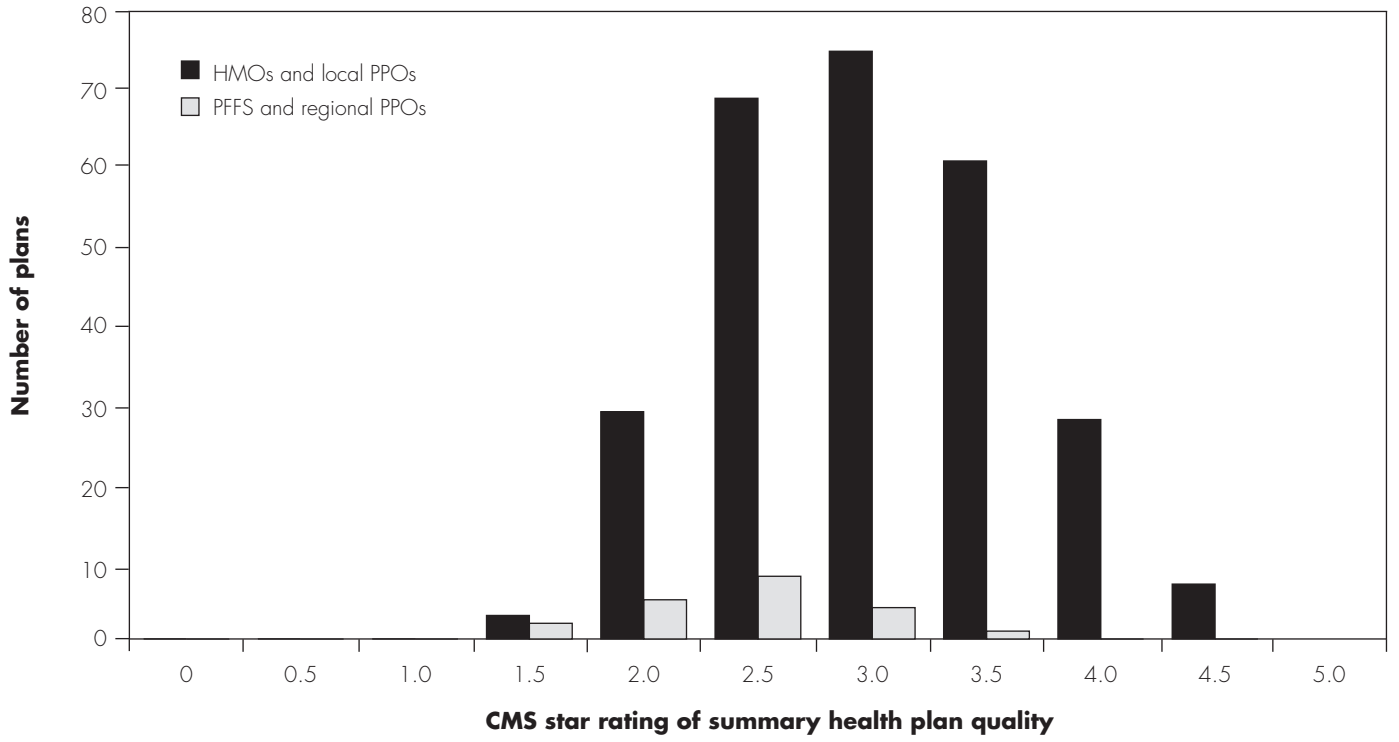
Plan quality

The CMS star rating system is based on plan performance on a combination of quality measures, including Healthcare Effectiveness Data and Information Set® (HEDIS®) (process and outcomes data that plans report to CMS), Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) (survey-based measures of enrollee perceptions of care), and Health Outcomes Survey (HOS) data (survey-based information on perceived improvement or deterioration in health over time and certain measures of the types of care received), as well as other data on quality and member satisfaction that CMS tracks. CMS uses a five-point scale for its star ratings.[10]

Looking at the current landscape of CMS star ratings among local HMOs and PPOs, we see that some plans perform much better than others and many plans have room for improvement in their quality measures (Figure 7-3). The highest star rating of any plan for overall quality is 4.5, and the lowest is 1.5—with many plans not yet rated. (In this section, we use the term "plan" to mean the Medicare contracting entity because CMS determines plan ratings at the contract level, rather than at the level of the individual plan.) The average plan score for overall health plan quality is 3.0 for the 272 local HMO or PPO plans

FIGURE 7–3

Some plans have high quality ratings, but many plans have lower ratings that could be improved



Note: PPO (preferred provider organization), PFFS (private fee-for-service). There are no plans rated below 1.5 or above 4.5. The average plan rating for HMOs and local PPOs is 3.0. The averages for PFFS and regional PPOs are, respectively, 2.3 and 2.6.

Source: MedPAC analysis of CMS plan rating data.

with ratings.[11] These 272 plans include 96 percent of the enrollees in HMOs and local PPOs as of March 2008 and 67 percent of overall MA enrollment.[12] Of the 272 plans, 96 (about one-third) have an above-average star rating of 3.5 or higher; 100 plans have a star rating below average (2.5 or lower). Forty-one percent of HMO or local PPO enrollment is in plans that have an above-average star rating of 3.5 or higher. By contrast, the highest star rating among the regional PPOs with ratings is 3.0, and the average is 2.6. Eleven PFFS plans have ratings averaging 2.3, with the highest rating at 3.5 for a plan in Minnesota.

We explored the relationship between plan quality and plan bids and between plan quality and rebates (75 percent of the difference between the benchmarks and a plan bid). In neither case did we find any consistent correlation, indicating an absence of a relationship between quality rankings, on the one hand, and plan payments and extra benefits on the other. A possible explanation for this result is that quality for plans that have broad networks is related more to the general quality of providers in the area than to specifics of MA payment.

Calculating MA payment rates: Are county-level estimates of per capita spending accurate?

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) mandate asks the Commission to examine "the accuracy and completeness of county-level estimates of per capita spending under … original Medicare." These county-level estimates are the adjusted average per capita costs (AAPCCs)—estimates of each county's FFS spending—adjusted for the risk status of beneficiaries and to exclude direct graduate medical education payments.[13]

Accuracy of the calculation of the AAPCC (the county-level estimate) is important in two ways. First, for every

Process for calculating projected county fee-for-service rates

The first component of the calculation of projected county fee-for-service (FFS) rates is the development of projected national expenditures—the United States per capita cost (USPCC) projections. Six separate USPCC rates are determined: Part A rates and Part B rates for the disabled, the aged, and beneficiaries with end-stage renal disease (ESRD).

The expenditure data used to develop the USPCCs include 100 percent of Medicare's claims costs and administrative costs in each past year for FFS enrollees and MA enrollees. Because the USPCCs are a projection for a coming year based partly on previous years' projections, the statute requires CMS to adjust a forthcoming year's estimate of the rate of growth in expenditures to reflect the preceding years' over- or underestimates of the USPCCs (for years after 2004). That is, the rate of growth between the current (prospective) rate year and the preceding years compares the USPCC for the rate year in question with the most recent, updated estimates of the USPCC for the preceding years and incorporates an adjustment when earlier years' USPCC estimates are revised. Each yearly rate announcement that CMS publishes includes information about revised USPCCs (prospective versus retrospective) and the effect of any over- or underestimate on the forthcoming year's rates.

To arrive at each county's projected FFS expenditures (the adjusted average per capita cost, or AAPCC), CMS develops an average geographic adjustment (AGA) for each of the USPCCs for each county. For ESRD beneficiaries, the geographic adjustment is statewide because of the small number of beneficiaries involved.

The AGA is the historical relationship (ratio) between a county's past expenditures and the national level of actual past expenditures. The ratio of local-to-national expenditures used for geographic adjustment is a five-year rolling average—meaning that CMS uses the most recent five years for which county-level expenditure

(continued next page)

rebasing year, the newly calculated AAPCC and the minimum update payment rate are compared, and the higher of the two rates becomes the county benchmark. Second, if, as a result of this comparison, a county's rate is the AAPCC, then it is important that the AAPCC reflect the projected FFS costs in the county as accurately as possible.

Although the MIPPA mandate requires the Commission to assess the accuracy of the county-level estimates of per capita spending, accuracy of the national-level calculation of expenditures (the United States per capita cost, or USPCC) is also important because it too affects payments for all MA payment areas. The national estimates are:

- the basis of the national per capita MA growth percentage—which for most counties determines a given year's benchmark, and
- a component of the calculation of the county-level estimates.

Computation of the USPCCs and the AAPCCs is described in the text box.

In assessing the accuracy of the AAPCC calculations, we looked specifically at three issues, as mandated:

- administrative expenses,
- expenditures for Medicare beneficiaries receiving care through facilities of the Department of Veterans Affairs (VA), and
- MA rates in Puerto Rico.

We also considered aspects of the MA payment methodology that might result in inaccurate MA payment rates.

We did not conduct a formal audit of the methodology CMS uses to calculate the USPCCs and AAPCCs. Our evaluation was based on discussions with staff of the Office of the Actuary of CMS, along with a review of the methodology the agency uses to determine the USPCC

Process for calculating projected county fee-for-service rates (cont.)

data are available to determine the relationship between local (county) expenditures and national expenditures. This approach smooths out variations from year to year in the ratio of county-to-national expenditures.

FFS expenditures are assigned to the county of residence of the Medicare beneficiary. There is a lag period of three years in the inclusion of county expenditure data. That is, for 2009 projected rates, the five-year average is for the period 2002 to 2006. There is also a cutoff for including claims information for the county computations (unlike the USPCC computations, which have 100 percent of the expenditure data). Claims and cost settlements dating from more than six months after the end of the year are not included in the county data.

After the AGA factors are developed, the next step in the process is to remove Medicare expenditures associated with plan enrollees. Because the AAPCC is intended to be a projection of what program costs would have been for an individual not enrolled in MA, MA expenditures (and expenditures for non-MA Medicare plans, such as cost-reimbursed HMO plans) are removed at the county level. Plan enrollees are also removed from the denominator to arrive at a new average per capita cost for FFS enrollees for each of the per capita rates (Part A aged, Part B aged, etc.), which is then multiplied by the AGA.

The resulting projected FFS per capita rates at the county level (or state level for ESRD) are then standardized for the risk status of the population of each county (or state). The variations in Medicare expenditures that are due to demographic (age, sex, institutional status, and Medicaid status) and health risk factors are established at the national level using the CMS–hierarchical condition category model. Each county's standardized rate is expressed as a monthly dollar amount for a beneficiary residing in the county with a nationally average risk profile (a person with a "risk score" of 1.0). ■

and AAPCC amounts. We find that CMS's methods for developing projections of the USPCC and AAPCC are reliable and produce results that are as accurate as possible for projections, but we have concerns about two issues that affect specific counties or areas—the exclusion of costs associated with care provided in VA facilities and the calculation of AAPCCs for Puerto Rico. In addition, we find that the distortions in payments introduced by the so-called "ratchet effect" (p. 181) should be addressed.

Administrative costs

The MIPPA mandate asks the Commission to examine whether the county FFS estimates "include all appropriate administrative expenses, including claims processing." The concern, which the industry has raised in the past, is that if MA plans are replacing the FFS system for their enrollees, and the plans are expected to perform administrative functions that CMS would otherwise perform, the plans should be compensated appropriately for these functions. We believe the current method of determining the administrative costs to include in MA payment rates is appropriate.

Under the current methodology, CMS includes the administrative costs specified in the statutory definition of the AAPCC. The statute identifies the includable administrative costs as consisting solely of the costs of carrier and intermediary functions in FFS Medicare ("administrative costs incurred by organizations described in sections 1816 [intermediaries] and 1842 [carriers]," which are the Medicare administrative contractor (MAC) costs). Calculation of the MAC costs is a straightforward calculation of the ratio of cash administrative expenses to cash benefits, and therefore they accurately represent the administrative expenses referred to in the statute.

Some argue that including only MAC administrative costs in the AAPCC calculation shortchanges the plans. The plans assert that additional costs that CMS incurs in administering the FFS Medicare program should be included in plan payments if the intent is to have plans paid for costs that otherwise would have been incurred by CMS in administering the FFS program. However, the amount of administrative expenses over and above the MAC costs that can be attributed exclusively

to administration of the FFS program is negligible and, arguably, should not be included in the AAPCC calculation.

Using budget documents for the Department of Health and Human Services, we calculated that the CMS administrative costs attributable to the Medicare program are about $2.7 billion, with about $1.4 billion attributable to claims processing costs for FFS Medicare (i.e., MAC costs). The remaining administrative costs within CMS—about $1.3 billion—would make up less than 0.5 percent of total FFS spending of about $320 billion in 2009. Even if the entire $1.3 billion were attributable exclusively to CMS administrative functions in the Medicare FFS program that health plans also undertake, including all the additional CMS administrative costs would raise the USPCC (the basis for the AAPCC) by only about 0.4 percent, or $2.40 per month.

However, it is not appropriate to include the entire $1.3 billion in the USPCC calculation. The $1.3 billion represents costs of operations for the entire Medicare program, including Part A, Part B, Part C (MA), and Part D. CMS uses much of this funding for administrative functions for the Medicare program as a whole, such as preventing fraud and abuse. CMS retains these functions even for beneficiaries who have enrolled in MA plans.

In summary, the MAC costs of claims processing accrue solely to FFS and are included in the FFS spending estimates, while other administrative costs are spread across the Medicare program and thus are not added to the FFS estimates. We find this allocation of costs to be appropriate, and even if there were some additional costs that could be attributed solely to FFS, the amount would be negligible.

Adjustment for use of Department of Veterans Affairs facilities

The MIPPA mandate asks the Commission to examine whether the AAPCC calculation includes "expenditures with respect to Medicare beneficiaries at facilities of the Department of Veterans Affairs" (reflecting a provision of the current statute requiring inclusion of such expenditures). We have determined that this is a county-specific issue that does not have a material effect on rates in the aggregate but may affect the calculation of AAPCCs in some counties.

The concern is that in counties where many Medicare beneficiaries use VA facilities, projections of Medicare per capita costs to determine MA payments would be incorrect. If Medicare beneficiaries receive Medicare-covered services at facilities that are not paid by Medicare and do not submit claims to Medicare, the projections of per capita spending for Medicare-covered services may be understated or overstated. If the VA is providing Medicare-covered services to individuals in lieu of care they would have received through providers billing Medicare, total Medicare program expenditures for them will be less than they would otherwise be. However, the absence of claims associated with Medicare-covered services could also lower the risk scores of beneficiaries using VA services, because risk scores use diagnosis information from claims. Whether underreporting of expenditures has a greater effect than undercalculation of risk scores would determine whether the result is an underpayment or an overpayment.

CMS is investigating the extent to which beneficiaries' use of VA facilities affects MA payments. The method that CMS uses to determine whether an adjustment is appropriate is to compare risk-adjusted Medicare reimbursements for the two populations—those with VA coverage and those without such coverage. If the VA coverage group has risk-adjusted Medicare reimbursements significantly different from what other Medicare beneficiaries receive, CMS will make the necessary adjustment by removing the VA coverage group when determining projected per capita FFS expenditures for purposes of MA payment. That is, if for the VA coverage group there is a significant mismatch between expenditures and risk scores—resulting in an understatement or an overstatement of expenditures for a person with average risk—then an adjustment is warranted. As CMS noted in its February 22, 2008, advance notice of possible methodologic changes for MA rates in 2009, an adjustment could result in higher or lower MA payments depending on the outcome of the CMS analysis (CMS 2008). The CMS approach is described in the text box (pp. 180–181).

CMS announced the results of its analysis of VA data in the announcement of MA payment rates for 2010 (CMS 2009a). CMS found that an adjustment to MA rates was not called for at this time, concluding that "the differences observed between [VA beneficiaries and the total population] … appear to be normal, random variations and not indicative of true underlying differences of the FFS costs between the two populations." In an earlier notice about a possible adjustment, CMS found that if a VA adjustment were warranted, about half the counties would receive an increase and half would receive a decrease,

with most counties close to the overall average effect of a decrease of 56 cents per beneficiary per month and with "most of the values … tightly clustered about the mean" (CMS 2009b). CMS found that 54 counties would have an increase of more than $12.50 per beneficiary per month. However, CMS will not make adjustments even in those 54 counties because it has concluded that the expenditure differences reflect "random, normal" variations in FFS expenditures that are not attributable to the use of VA facilities.

CMS will continue to study the VA issue. CMS is also in the process of evaluating the effect of health care services received through the Department of Defense (DoD) as required by the statute. The addition of DoD data should help address the question of whether the effects are random rather than systematic differences. If counties have substantial, nonrandom differences when the VA and DoD data are analyzed, CMS should adjust the county rates.

MA rate calculations for Puerto Rico

The MIPPA mandate specifically mentions the rate calculation for Puerto Rico as a potential concern. The small proportion of FFS beneficiaries in Puerto Rico with Part B coverage could compromise the accuracy of both calculated AAPCCs and risk scores.[14] Because only one *municipio* (the equivalent of a county) with a very small population has its benchmark set at an AAPCC rate, the Commission concludes that these are primarily theoretical issues that will come into play in the calculation of MA rates only in future years.[15]

All MA enrollees must have both Part A and Part B coverage. Historically, however, comparatively few beneficiaries in Puerto Rico have opted to enroll in Part B due to the high cost of the Part B premium relative to the cost of medical care in Puerto Rico and the income of the population. As a result, it is common for MA plans in Puerto Rico to attract enrollees by buying down some, or all, of a person's Part B premium.[16] This type of enhanced benefit has attracted large numbers of beneficiaries in Puerto Rico to MA plans; as of 2009, 60 percent of the Medicare population is enrolled in MA.

Of the remaining Medicare beneficiaries in FFS in Puerto Rico, only a small share—30 percent in 2007, compared with a national average of 97 percent—have Part B coverage. Part B AAPCCs calculated on such a small population may be extremely volatile, with large changes from year to year. In addition, there may be an issue for Part A estimates, because expenditures under Part A are likely to be different for individuals who have only Part A coverage compared with those who have both Part A and Part B. The risk scores of individual Medicare beneficiaries in Puerto Rico could be affected as well. If beneficiaries do not have Part B coverage, there are no physician claims that can be used (together with hospital claims) as a source of diagnosis codes for establishing an individual's risk score. Risk scores for such a population could be systematically understated compared with a population in which nearly all beneficiaries have Part B coverage. That understatement of risk could affect the geographic adjustment component of the AAPCC.

Currently, only one *municipio* with a very small population has its benchmark set at an AAPCC rate that would be affected by these issues. All other *municipios* are paid at the statutory floor rate for Puerto Rico, which is now about 180 percent of local FFS. Thus, these issues will come into play only in the calculation of future rates. Should an adjustment be necessary in the future, the statute provides CMS with relatively broad authority to use actuarial methods to address situations in which the usual method of determining the AAPCC would yield an anomalous or potentially inaccurate result. In the case of Puerto Rico, CMS should expeditiously use its authority to employ an alternative calculation method to determine AAPCC rates if CMS finds that the current calculations are anomalous or potentially inaccurate, though we recognize that an alternative calculation may be difficult with the currently available data.

The usual AAPCC methodology relies on actual claims experience over five years in a given county to determine the geographic adjuster, along with adjustments to normalize the population for purposes of risk adjustment.[17] If an alternative is necessary for Puerto Rico, a difficult analytic problem would arise. CMS might have to base the rates on an examination of use and spending patterns among a similar set of beneficiaries. It is unlikely, however, that there is a geographic area with a similar distribution of beneficiaries who do not have Part B coverage. Therefore, national-level data may have to be used to determine how the absence of Part B coverage affects Part A expenditures. CMS would also have to be able to adjust for the demographic characteristics of the Puerto Rico population. Given that most Medicare beneficiaries in Puerto Rico are in MA plans, CMS might need to require Puerto Rico MA plans to submit expenditure and utilization data to help CMS accurately estimate county-level FFS expenditures for Puerto Rico.

CMS approach to adjustment for use of Department of Veterans Affairs facilities

CMS's approach to determine whether an adjustment for use of Department of Veterans Affairs (VA) facilities is warranted is illustrated in Table 7-2, using a simplified example of two beneficiaries with different risk scores and illustrating how a payment level is computed for a person of average (1.0) risk. Scenario 1 illustrates how per capita costs for a person of average risk are determined based on the expenditures of two individuals with different risk scores and different levels of expenditures associated with those risk scores. In Scenario 1, there is no VA involvement, and the computation is a straightforward computation that "normalizes" (to a 1.0 level) the expenditures of the healthier person who has a risk score of less than 1.0 and then averages the expenditures for the two individuals.

Scenario 2 shows what happens when fee-for-service (FFS) claims data produce an accurate risk score for a person, but the use of VA services reduces FFS

(continued next page)

TABLE 7–2

Comparing risk-adjusted expenditures to evaluate the need for a VA adjustment to MA rates

	Beneficiary total Medicare expenditures	Beneficiary risk score	Risk-adjusted expenditures (total expenditures divided by risk score)	Is VA adjustment necessary?
Scenario 1: No VA involvement; computation of per capita expenditures for a person with average risk				
Beneficiary A	$10,000	1.0	$10,000	
Beneficiary B	8,000	0.8	10,000	
Total risk-adjusted expenditures			20,000	
FFS expenditures per person for a person of average risk			10,000	
Scenario 2: VA involvement; missing expenditures but correct beneficiary risk scores; material effect				
Beneficiary A, with no VA involvement	10,000	1.0	10,000	Yes,
Beneficiary B, receiving $1,000 in services at VA	7,000	0.8	8,750	otherwise
Total risk-adjusted expenditures			18,750	plans
FFS expenditures per person for a person of average risk, unadjusted			9,375	underpaid
Scenario 3: VA involvement; missing expenditures also resulting in lower risk score; no effect				
Beneficiary A, with no VA involvement	10,000	1.0	10,000	No
Beneficiary B, receiving $1,000 in services at VA	7,000	0.7	10,000	
Total risk-adjusted expenditures			20,000	
FFS expenditures per person for a person of average risk			10,000	
Scenario 4: VA involvement; missing expenditures also resulting in lower risk score; material effect				
Beneficiary A, with no VA involvement	10,000	1.0	10,000	Yes,
Beneficiary B, receiving $1,000 in services at VA	7,000	0.6	11,667	otherwise
Total risk-adjusted expenditures			21,667	plans
FFS expenditures per person for a person of average risk, unadjusted			10,833	overpaid

Note: VA (Department of Veterans Affairs), MA (Medicare Advantage), FFS (fee-for-service). A person with average risk has a risk score of 1.0.

CMS approach to adjustment for use of Department of Veterans Affairs facilities

expenditures. In such a case, average expenditures for a person with a risk score of 1.0 are understated and an adjustment would be warranted. Removing the VA population from the calculation—as CMS proposes—would give the accurate expected level of expenditures for Medicare-covered services for a beneficiary with a risk score of 1.0 ($10,000), based on the per capita expenditures of the one remaining person in this scenario.

Scenario 3 is the case in which there is VA involvement but no adjustment is necessary because, at the same time that Medicare FFS expenditures for a VA user are declining, the person's risk score is also declining in a parallel manner (i.e., the risk score accurately represents the level of expected Medicare FFS expenditures). Scenario 3 is analogous to the first scenario of the table—the claims data and risk scores of FFS for the two beneficiaries accurately determine the expected FFS costs of a beneficiary with a risk score of 1.0.

Scenario 4 shows the case in which the absence of diagnostic data from VA services results in a lower risk score, but FFS expenditures are relatively higher than the risk score would indicate. In that case, removing the VA population from the calculation would produce an accurate estimate of FFS expenditures for a person with a risk score of 1.0 ($10,000), while failing to remove the VA population would overestimate average expenditures as $10,833 for a person with a risk score of 1.0.

The CMS approach also addresses the issue of the pattern of use of VA services by VA eligibles when they enroll in Medicare Advantage (MA). If, for example, the VA-eligible person continued to use the same level of VA services as before MA enrollment, the person's risk score—which is now determined by claims and services within the MA plan—would be the same as the person would have had in FFS Medicare. If the person stops using VA services, the person's risk score would match that of an individual with no VA coverage. ■

The "ratchet" effect in MA benchmarks

One reason that MA benchmarks are higher than FFS spending in some counties has to do with the rebasing provision of the law and the frequency of rebasing—causing an effect known as the "ratchet." (MA benchmarks are also high in relation to FFS because of various statutory provisions, such as the introduction of payment floors.) The ratchet results in persistently high benchmarks in a county even as FFS spending there decreases. Consequently, payments to MA plans will be higher than warranted by the underlying FFS spending.

In most years, a county's benchmark is established by adjusting the preceding year's benchmark by the national rate of growth in Medicare expenditures. In a rebasing year, CMS compares this adjusted benchmark with the projected FFS rate for each county (the AAPCC). The higher of the two becomes the benchmark for the rebasing year. Benchmarks are rebased to the FFS level only when a county's projected per capita FFS expenditures are growing. In counties where projected per capita FFS expenditures have declined, the benchmark remains at the previous year's higher rate, adjusted by the national growth rate. Thus, the county's benchmark will be above its current FFS rate as a result of this one-sided approach to rebasing payment rates to equal FFS only if the rebasing yields a higher rate for the county.

This ratchet effect is illustrated by the case of West Baton Rouge Parish in Louisiana (Table 7-3, p. 182). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 introduced the rebasing concept as of March of 2004. The 2004 rate for West Baton Rouge was set at $813, the estimated FFS rate for the parish for 2004. Since then, FFS expenditures in the parish have not increased appreciably. As a result, in each subsequent rebasing year, West Baton Rouge's benchmark has been set at the preceding year's rate, adjusted for the national rate of growth in Medicare expenditures, because that adjusted rate is higher than the projected FFS rate in the parish. Because of the ratchet effect of continuing minimum updates to the West Baton Rouge MA benchmark, by 2009 the difference between the MA benchmark and estimated FFS expenditures widened to

TABLE 7–3

Example of ratchet effect: West Baton Rouge Parish, Louisiana, has MA benchmarks that are now 54 percent over local FFS

	2004	2005	2008	2009
County FFS estimate	$813	$690	Not rebasing year	$727
MA benchmark rate	$813	$866	$1,075	$1,122
Rate basis	FFS	Minimum update	Minimum update	Minimum update
Percent by which benchmark exceeds FFS	0%	25%	Unknown	54%

Note: MA (Medicare Advantage), FFS (fee-for-service). MA benchmark shown is before budget-neutrality adjustment that raises benchmark. Percent benchmark over FFS does not include effect of budget-neutrality adjustment or duplicate indirect medical education payments, which would raise the percent by which the benchmark exceeds FFS.

Source: MedPAC analysis of Medicare Advantage benchmark rates.

the point where the benchmark is now 54 percent higher than estimated FFS expenditures for the parish.

Overall, in 2009, 818 counties (representing 3.8 million MA enrollees) had benchmarks higher than warranted by their FFS spending, due to the ratchet effect. On average, benchmarks exceeded FFS spending in those counties by 15 percent. The Congressional Budget Office (CBO) has estimated that if all counties that had benchmarks set at FFS rates in a rebasing year had their rates set at FFS in all following years, the resulting savings would be $21 billion over five years (2010–2014), or $61 billion over 10 years (2010–2019) (CBO 2008).

This effect, and the past effect of the ratchet provision, could be remedied by doing two things. First, rates would need to be rebased every year.[18] For counties with benchmarks newly set at projected FFS rates in a given year, this action avoids the situation of a benchmark exceeding FFS rates in later years because of minimum updates. Second, for each county that in the past had its payment rate set at FFS, the basis of payment would need to be reset at the current county FFS rate. Then, only counties with rates above FFS because they were historically floor counties—rather than because of the ratchet effect—would continue to have rates above FFS. Alternatively, the past effects of the ratchet and anticipated future effects (i.e., volatility in rates between years because of volatility in projected FFS expenditures between years) can be remedied in part by limiting both increases and decreases in rates from year to year when rebasing is an issue. For example, increases or decreases in rates could be limited to 5 percent each year. If a county that had its MA benchmark set at FFS in one year had an increase of 7 percent over the preceding year, that increase would be limited to 5 percent in the first year, followed by a 2 percent increase, and similarly for counties facing reductions. Another alternative to dampen the effect of a large decline from one year to another is to not apply the minimum update when FFS spending declines in a county. This action would leave the county's benchmark at the previous year's level (CBO 2008).

If more comprehensive changes are made to the MA payment system, such as larger payment areas or other options we discuss in later sections of the chapter, the ratchet issue may diminish in importance or even cease to exist. Until that time, the distortions that the ratchet effect introduces should be addressed.

Correlation analysis

The Congress asked us to study the correlation between plan costs to deliver Medicare Part A and Part B benefits and the Medicare program's expected spending in FFS Medicare. The mandate asks us to use the plan bids as the measurement of plan costs and CMS estimates of per capita county-level spending as the measurement of FFS Medicare spending.

Plan costs and FFS spending

Each year, plans submit bids to offer Part A and Part B coverage to Medicare beneficiaries within a service area. A plan defines its own service area as one or more counties where it chooses to offer coverage (the exception is regional plans, which must serve entire CMS-defined

regions). The bid is the plan's estimate of its cost to cover an average beneficiary's (average with respect to health risk) Part A and Part B benefit and includes plan administrative cost and margins. Included in the plan's bid submission are the expected enrollments from each county in the service area as well as the expected health risk scores in each county. The bids do not include separate bids for each county within a service area.

Bids are made in response to county-level benchmarks computed by CMS. The benchmarks are bidding targets for the Part A and Part B benefits. CMS publishes estimates of expected county-level Medicare FFS spending periodically to help set the MA benchmarks. As with the bids, the CMS estimates are standardized to represent the spending of an average beneficiary with respect to health risk.

While the MIPPA mandate (text box, p. 203) asks us to examine how the bids in a county are correlated with FFS spending in the county, the data do not allow us to do that in a straightforward manner. As we stated above, plans do not submit bids for counties, they submit bids for multicounty service areas. The bids, however, do contain county-level estimates of enrollment and the average risk of that enrollment. Therefore, we took the plans' enrollment and risk assumptions and estimated the FFS spending that would be expected for a population with the same health status located proportionately in the same counties for which the plan submitted its bid. In that way, we can measure the correlation between the plan bid and the expected FFS spending for the enrollee population in its service area.

Bids and spending are highly correlated

We find a strong correlation between plan bids for 2009 and expected FFS spending.[19] Overall, the correlation was 0.88, which means that plans serving areas with high FFS spending were very likely to have high bids, and plans serving areas with low FFS spending were very likely to have low bids. It does not mean that plan bids equal FFS spending. For example, if plan bids were exactly twice FFS spending in all counties, they would still be perfectly correlated.

We calculated the correlations separately for four plan types (HMOs, local PPOs, regional PPOs, and PFFS plans) and found a high correlation within each (Table 7-4). HMOs had a correlation of 0.89, PFFS had a correlation of 0.93, and the correlation for PPOs was even higher. The correlations were higher for plan types that tend not to have relatively tight networks of providers (all but HMOs), which means that the bids of plans that are more likely to pay providers based on Medicare rates are more closely correlated to the level of FFS spending in their service areas.

TABLE 7–4 **Strong correlation between MA plan bids and FFS spending**

Plan type	All areas	Urban areas	Rural areas
All MA plans	0.88	0.85	0.91
HMO	0.89	0.86	0.94
Local PPOs	0.94	0.92	N/A
Regional PPOs	0.95	N/A	N/A
PFFS	0.93	0.92	N/A

Note: MA (Medicare Advantage), FFS (fee-for-service), PPO (preferred provider organization), PFFS (private fee-for-service), N/A (not available). Correlations near 1.0 show high correlation and correlations near zero show low correlation. Data are noted as N/A if insufficient data are available to determine correlation.

Source: MedPAC analysis of plan bid data from CMS.

Although our mandate asks us to look at differences by geographic area, we are limited because we do not have county-level bids. However, we were able to explore differences between urban and rural plans. We selected a group of 1,500 plans that drew their entire enrollment from urban counties and designated them as urban plans. Rural-only plans were rarer, but we found 125 plans that expect to receive 90 percent or more of their enrollment from rural counties. We designated these 125 plans as rural plans.

We found a high correlation of plan bids and FFS spending within both urban and rural areas; however, the correlation was somewhat stronger in rural areas (0.91) than in urban areas (0.85). As with the plan type differences, this finding suggests that plans that are more likely to have to pay providers based on FFS Medicare rates (rural plans) are more likely to have bids that are highly correlated with FFS spending.

Although bids and FFS spending are highly correlated, as shown in Figure 7-2 (p. 174), the ratio of plan bids to FFS spending is much higher in areas with low levels of FFS spending than in areas with high FFS spending. For example, as noted previously the median bid for areas with FFS spending below $675 per person per month is 110 percent of the FFS spending level, but in areas with FFS spending above $900 per person per month,

the median bid is only 81 percent of FFS spending. This situation illustrates how certain plans in certain areas (such as HMOs in high-use areas) can use mechanisms to bring down the level of utilization and costs, but such mechanisms may not be available in lower cost areas (e.g., plans may have limited negotiating ability vis-à-vis providers, and the FFS system in certain areas may be relatively efficient).

Alternative approaches to MA payment

The Congress asked the Commission to examine approaches to MA payment other than "county-level payment area equivalents." We previously recommended payment areas larger than the county level, as we discuss in the appendix to this chapter. In this section, we examine other approaches for setting payment benchmarks for the MA program.

The Commission supports private plans in the Medicare program and the innovative delivery systems and care management techniques they potentially can bring to beneficiaries. But plans will be encouraged to innovate only if payment rates are set correctly. Paying too much is unfair to taxpayers and other beneficiaries and can result in plans that bring no innovation but simply mimic FFS Medicare at a much higher cost to the program. It now costs the Medicare program more for beneficiaries in MA than it would if the same beneficiaries were in traditional FFS. CBO estimates this additional cost over 10 years at more than $150 billion. Setting payment levels that are financially neutral to FFS Medicare could save that $150 billion, while creating incentives for private plans to innovate and prove themselves in the marketplace and still providing beneficiaries with a desirable alternative to the traditional FFS program.

The Commission has maintained that 100 percent of FFS is the correct target for benchmarks because it would encourage plans that are more efficient than Medicare FFS. An MA plan that is more efficient than Medicare FFS could provide the traditional benefit at a lower cost and would be able to provide additional benefits to beneficiaries, who would be encouraged to enroll in the plan. An MA plan that is not more efficient than FFS Medicare would likely not enter the program.

Therefore, we have created and analyzed a number of options the Congress might consider for setting MA payment benchmarks. All these options are financially neutral to FFS Medicare in the aggregate—any one of them would cost the program the same as traditional Medicare in the first year, saving $12 billion. However, the savings over 10 years may vary for some of the options from the $150 billion CBO estimated for the 100 percent of FFS option, because all the options are based on the presumption of lower MA program spending; consequently, they all will result in fewer plans being available in some payment areas and in reduced extra benefits. We show those results for each option. We also show the availability of plans of particular value to beneficiaries: those that can provide care coordination and innovative delivery systems and those that demonstrate high quality.

Options for setting benchmark rates

There are two broad alternatives for setting benchmarks in the MA program: using competitive bidding to set the rates or setting the rates administratively. The current system uses administratively set rates.

Setting benchmarks through competitive bids

Using competitive bids from MA plans to set the benchmarks in an area is a potentially attractive concept. The theoretical argument for setting benchmarks through bids is that a competitive market would provide the best price information, and getting bids on a set benefit package (such as the Medicare Part A and Part B benefit) is as close as we can come to a competitive market. We present the fundamental decisions that would have to be made when designing a competitive bidding system and outline some possible behavioral responses. We also review a previous demonstration of bidding for private plans (see text box, pp. 186–187).

However, there is a practical problem for quantitative simulation of a competitive bidding option: Plans do not make county-level bids; they make one bid for an entire service area, which usually includes multiple counties. If bids determine benchmarks, plans will face pressure to vary their bidding by county across a service area. The current bidding data thus will not be a good proxy for their resulting bids. (The existing bids can be useful as a proxy for bids under different options for setting administrative benchmarks because the benchmarks would not be changed by plan bids, and no disaggregation by county level is necessary to simulate the results of options.) For this technical reason, and because the results of the simulations would be very sensitive to the assumptions made, we do not present a quantitative analysis of setting benchmarks through competitive bidding.

Basic design features of competitive bidding A specific bid design would have to decide about features such as:

- What would be the minimum number of plans required for a competitive bidding system to work?
- Should there be an upper limit on benchmarks?
- If the benchmark is based on bids, what point in the distribution would determine the new benchmark—the lowest bid, the median bid, the second highest bid?
- How would quality enter into the bidding process?
- Should Medicare FFS "bid" alongside MA plans?[20]

We explore certain of these design decisions below.

Number of competitors. Competitive bidding requires multiple competitors to participate in the bidding process. With an average of 34 plans in a county, the MA program would probably have no dearth of bidders. However, the number of insurers in an area is often significantly fewer than the number of plans because a single insurer may offer multiple plans. For example, Cook County, Illinois (Chicago), has 30 MA plans available to beneficiaries there, but only 6 insurance companies offer these 30 products, and 1 of those companies offers only PFFS products. Thus, under a competitive bidding model involving only coordinated care plans, Chicago would have 5 organizations submitting bids, not 30.

If only one Medicare health plan were to bid in an area, there would be no competition to establish a benchmark. Several options are possible under this circumstance: (1) An administered pricing system could set the benchmark (e.g., using 100 percent of local FFS or one of the other options we discuss later). (2) The single plan's bid could be the benchmark for the area (which could exceed 100 percent of FFS if the benchmark amount is not capped). (3) Medicare would not have any private plans in the area because of the lack of a sufficient number of competitors to establish a benchmark. The rule for what to do when only one plan bids would have to be specified in advance of bidding.

Upper limit on benchmarks. Competitive bidding might attract plans to certain areas if a pure competitive bidding approach were used and there were no upper limit on the benchmarks. For example, as shown in Figure 7-2 (p. 174), in areas with FFS spending below $675 a month, median plan bids exceed FFS Medicare expenditures by 10 percent. Whether there should be an upper limit on benchmarks is a design feature policymakers would have to consider. If benchmarks are allowed to be well above FFS Medicare, two questions arise: What product is Medicare buying with the additional expenditures, and is the product worth the cost difference? Related to this question is whether savings achieved through competitive bidding in one area (because expenditures are brought below FFS rates) should be used to finance a competitive bidding approach in areas where the bid-based benchmarks would exceed FFS.

Choosing what point in the distribution to set the benchmark. Deciding how bids are used to set the benchmark has implications for the availability of enhanced benefits. If the low bid for the Medicare Part A and Part B benefit is set as the benchmark, no enhanced benefits are financed by the government contribution to the premium. The plan with the lowest bid offers the Medicare Part A and Part B benefit package at no premium. All other plans charge a premium for the package, and all plans, including the one with the lowest bid, charge an additional premium for enhanced benefits.

If the benchmark is the median bid, weighted average, or otherwise set at some higher point, then the difference between the benchmark and the bid can be used to finance extra benefits (as is the case now). Another alternative for ensuring the provision of enhanced benefits is to set the benchmark at the lowest bid but have plans bid on an enriched benefit package beyond the Medicare Part A and Part B package.

Quality as a factor in payment. The competitive bidding model, like the administered pricing options, can include quality as a factor in plan payments. For example, once a benchmark is established based on the bids of competing plans, higher quality plans can receive add-on payments that reward those plans with demonstrably higher quality.

Long-run issue Some have raised concerns about the long-term effect of competitive bidding. They worry that, after several rounds of competition, extra benefits would erode, leading to lower enrollment in plans and less interest among plans in participating in the program.

In each round of bidding, the plan with the lowest bid in relation to the benchmark will have the highest level of extra benefits. It is therefore in a plan's interest to bid as low as possible. However, low bids bring down the benchmark for all plans, resulting in less money to finance enhanced benefits, which are funded by the difference between the bid and the benchmark. Over

Lessons learned from previous demonstrations of competitive bidding for Part C

In previous demonstrations of competitive bidding in Part C, certain themes became evident:

- Stakeholders were united in opposing the demonstrations.
- Plans wanted to have benchmarks set in advance.
- Plans resisted being judged on the level of their premiums rather than on the benefits they offered.
- Plans objected to third-party marketing.
- Some thought Medicare fee-for-service (FFS) should be included as a plan for bidding purposes.

In 1996, the Health Care Financing Administration (HCFA, now CMS) began developing a demonstration of competitive pricing. Baltimore was selected as the site for the demonstration because of the large number of available plans, the small number of beneficiaries enrolled in the plans at the time, and the relatively high adjusted average per capita cost rates that allowed plans to offer a substantial level of enhanced benefits. The latter feature of the Baltimore market was important because the demonstration had to be budget neutral, and no additional Medicare dollars could be used to finance extra benefits that would attract enrollment.

The design of the bidding process called for plans to bid on a standard benefit package that HCFA specified. On receiving the bids, HCFA would determine the level of the government contribution, and plans with bids above that level would charge a premium. HCFA did not specify the level of the government contribution in advance but stated that it would not be set at the lowest bid for the standard benefit package. Marketing and enrollment would be through a third party, not through the health plans.

The demonstration ended before implementation because of unified opposition from stakeholders. The industry objected to certain design features, including not knowing the government contribution in advance, using member premiums as the basis for distinguishing among bidding plans in the market, and using a third party for marketing and enrollment. Dowd and colleagues state that "plans repeatedly asked HCFA to forgo the competitive bidding process and simply to announce an administrative price that achieved whatever cut in payments the agency sought. HCFA rejected this approach as just another variant of administrative pricing, which would not produce information on the efficient price of the standard benefit package" (Dowd et al. 2000).

HCFA then chose Denver as the demonstration site. The Denver market was similar to Baltimore in the number of plans, enrollees, and benefits offered. One design feature was changed: Plans that had to charge premiums when their bids exceeded the government contribution were allowed to waive all or some of the

(continued next page)

the years, as plans seek to be the lowest bidder, only the lowest bidding plans remain viable, and they could be bidding at extremely low levels. As the difference in the financial benefit of being in MA versus FFS narrows, more beneficiaries may decide to remain in the FFS option. This decision has a consequence for the Medicare program if a decline in MA enrollment occurs in areas where FFS is the more expensive option. In such areas, competitive bidding will have resulted in increased program expenditures because the bidding process has brought MA benchmarks to levels that do not permit plans to offer a rich benefit package.

This scenario may not transpire. Plan bidding behavior may result in an equilibrium for a given area, with most plan bids clustering around a level where they can do a good job of providing the Part A and Part B benefit. They may also be able to provide supplemental coverage for less than medigap because they have better control over service use. Beneficiaries may want to enroll in plans because of the less expensive supplemental coverage or because plans have brand recognition for better quality or other features beneficiaries find attractive, such as the ability to obtain the full range of Medicare coverage (Part A and Part B as well as Part D drug coverage) through one entity. In some market areas, beneficiaries have been willing to pay

Lessons learned from previous demonstrations of competitive bidding for Part C

premium if they also accepted a payment reduction equal to the waived amount. Plans opposed the Denver demonstration for the same reasons as in Baltimore, with the added concern that FFS Medicare was not being considered a bidding plan. As they did in Baltimore, plans also asked HCFA to set administered pricing rates if the goal was to reduce plan payments. Some of the Denver HMOs initiated a lawsuit that resulted in a temporary restraining order just as plan bids were being submitted, and opposition led to the end of the demonstration before full implementation.

One thing HCFA learned from the Denver demonstration is the range of plan bids for the enriched standard benefit package (which included drug coverage) and the Medicare Part A and Part B benefit package. According to Dowd, "HCFA … made it known that the … bids they examined in Denver for the standard benefit package (the 'market norm' benefit package that included prescription drugs) were 5 percent to 17 percent below the published Balanced Budget Act (BBA) payment rates, which reflect the cost of entitlement benefits (that is, no drugs) in FFS Medicare. The … bids for the entitlement benefit package [Medicare Part A and Part B] were 25 percent to 38 percent below the BBA rates" (Dowd 2001).

The Balanced Budget Act of 1997 (BBA) mandated competitive pricing demonstrations at various sites, with the design of the demonstrations to be determined by a national Competitive Pricing Advisory Committee (CPAC) with additional input from Area Advisory Committees (AACs). Under the CPAC design, FFS Medicare was excluded as a bidding plan because no statutory authority allowed its inclusion, but CPAC urged the Congress to consider including FFS. CPAC established a national standard enhanced benefit package that included drug coverage, but each AAC could further enhance the benefit if the local standard was to have a more generous benefit package in Medicare plans. CPAC specified that the government contribution should be at the median bid (adjusted for plan capacity) or at the enrollment-weighted average bid. At each of the two demonstration sites (Kansas City and Phoenix), the AACs chose the amount resulting in a higher government contribution. Plans bidding above the contribution level would charge a premium; plans bidding below that amount could retain the difference or provide extra benefits. CPAC also considered ways to have financial incentives to promote quality of care. In addition to decisions about the standard benefit package and the level of the government contribution, the AACs would determine whether plans would bid on a county-by-county basis (separate bids for each county) or on a "reference" county, with ratios established for payments in each county.

After a number of delays, the Kansas City and Phoenix demonstrations ended before implementation because of mounting stakeholder opposition. ■

premiums to enroll in Medicare HMOs not offering rich extra benefits (Brown and Gold 1999).

This erosion effect could be mitigated partly by stating benchmarks in advance (based on the previous year's bids). Doing so could mitigate the possible effect as plans adjust their bids based on a specific target. The specific target (the known benchmark) enables the plan to establish in advance its level of enhanced benefits rather than relying entirely on a "blind" process that would lead it to bid in such a way as to ensure that it was the lowest bidder.

Another way to mitigate the erosion effect is for plans to bid on a package consisting of Medicare Part A and Part B benefits plus a specified set of benefit enhancements. The strategy would still create pressure to lower bids through competition, but they would not be so low as to eliminate enhanced benefits. This alternative would be along the lines of the approach of the Competitive Pricing Advisory Committee to enhanced benefits (see text box). A benchmark is established based on bids for the entire benefit package—meaning that the benchmark incorporates payment for enhanced benefits. All plans would provide the Medicare benefit plus at least the specified set of extra benefits. The Medicare payment could be capped at 100 percent of FFS.

Behavioral responses to setting benchmarks through competitive bids Any design would also have to take into account plan behavior in response to the incentives inherent in the specific design. For example:

- Would plans bid strategically to eliminate a competitor? Some plans might bid low to stay in the program and eliminate other plans and then expect to make up the difference in following years.
- What level of extra benefits would plans perceive as necessary to attract members? Might they think other aspects of the plan such as provider network would be enough to retain members?
- Would all plans participate if they had to charge a premium? There are examples now of plans that charge a premium coexisting in markets with plans that do not.
- How would plans react to larger payment areas? If plans were required to serve all areas, would they bid some average cost across areas or assume they could market selectively and hence gain enrollment in only some locations?

Comparison of administered pricing and competitive bidding as the basis for setting MA benchmarks

Before we look at options for administered pricing, we compare the features of using administered pricing versus competitive bidding to determine MA benchmarks (Table 7-5).

Options for setting benchmark rates administratively: Assumptions in modeling

We designed four options for setting benchmarks administratively. The first two options—local FFS benchmarks and hybrid benchmarks—link benchmarks closely to 100 percent of FFS spending in the local payment area. The last two options are blends that link to expected plan costs. All four options are designed to reduce the average MA benchmark from the current 118 percent of average FFS Medicare spending to 100 percent of FFS spending nationally. However, each option could produce different results for different areas. We simulate some of these effects and compare the different options.

We modeled each of the benchmark options with data from 2009 plan bids. We included all plan types but excluded special needs plans and employer group plans because they are available only to subgroups of Medicare beneficiaries. We also excluded Puerto Rico, both because of data comparability questions and because benchmarks in Puerto Rico have been treated differently under Medicare statute (e.g., floors set at 180 percent of FFS spending).

For the most part, the results assume that plan bids and service areas do not change. We expect that any overhaul of the benchmarks would cause plans to change their bidding strategies. Our simulations examine first-year static effects and may not be informative over time as we did not model any behavioral changes.

A plan's bid—based on service area data rather than on individual county data—includes calculations of a plan-level benchmark based on the area's county benchmarks and the plan's expected enrollment and average risk score from each county. Our simulations work the same way. We assume that the plan's bid and projected enrollment are the same and we use the new county benchmarks that would result from each of the options to build a new plan-level benchmark to compare against the bid and then calculate the payment from Medicare. In this way, a plan is calculated to be either under or over the benchmarks across its service area.

Local FFS

One of the most straightforward ways to set benchmarks at 100 percent of average FFS spending is to set each county's benchmark at 100 percent of local FFS spending. We have examined this approach frequently in the past. The mandate specifies that we need to examine alternatives to this option, but we include it (along with the current benchmarks) as a good basis of comparison for the other options. Figure 7-4 (p. 190) displays a simplified representation of the current benchmarks and local FFS rates. As mentioned earlier, average FFS spending in a county is as low as $453, but the benchmarks can be no lower than the floor of $741. Above the floor (for this illustration, we ignore the large urban floor of $819), the benchmarks are based on, and are above, local FFS spending.

Hybrid: Floor, ceiling, and local FFS

One criticism of the local FFS approach is that some counties have very high FFS spending because of very high service volume per capita. Some policymakers may consider it inequitable that these counties receive high MA benchmarks based on their FFS spending. The high benchmarks in some markets enable plans to offer significantly more generous benefits than in other markets. Similarly, some counties, where providers and

TABLE 7–5

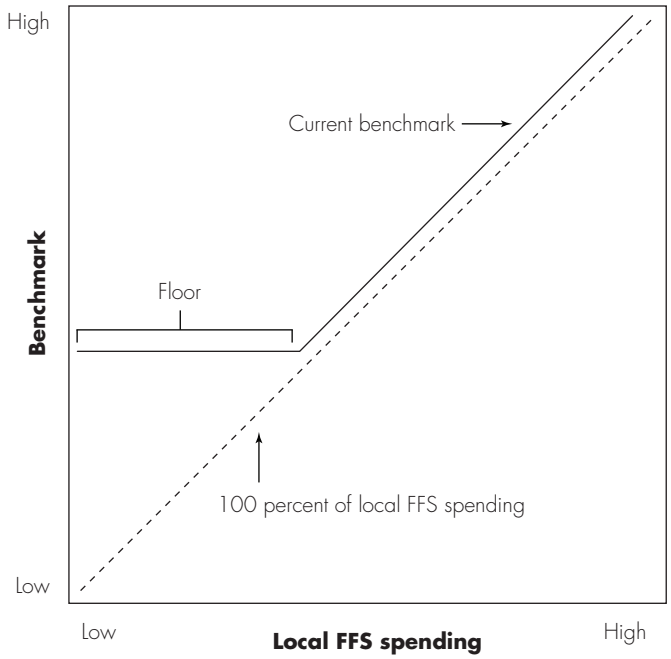
Features of administered pricing versus competitive bidding as the basis for setting MA benchmarks

	Administered pricing/current MA	Competitive bidding
Description	The contribution toward a health plan benefit package is a fixed amount set by the government and known to plans in advance. For local MA plans, this is the local county benchmark as determined by statute. Bids below the benchmark allow plans to provide higher levels of extra benefits and thus attract enrollment.	Plan bids are the basis for determining the benchmark amount. Plans bid against each other to offer their best price for the product the buyer (Medicare) seeks to purchase. Low bidders are rewarded for their low bids (through higher enrollment), and the plan bid should reflect the plan's costs of providing the product in the most efficient manner possible. The bidding process establishes a market-based price for the product in a given area.
Treatment of bids below or above benchmark	Bids above the benchmark require the enrollee to pay a premium to join the plan. Bids below the benchmark require plans to provide enhanced benefits.	Same.
Preconditions (plan participation)	No minimum number of plans. (There can be areas with only one Medicare plan participating.)	More than one competitor (probably three or more) necessary for competitive bidding. If fewer plans are in an area, or there is only one plan, an alternative approach to setting the benchmark would be necessary (e.g., administered pricing).
Geographic area issues	In MA, local plans can serve a single county or multiple counties. Regional plans are required to serve the entire region. (The Commission has recommended forming larger geographic areas for MA and requiring plans to serve the entire area.)	All bidding plans could be required to bid for the entire defined geographic area (larger than a plan's current area in some cases). The bidding process occurs at a local market area level. That is, benchmarks are set within competitive areas for just those areas.
CMS role and administrative burden/cost	Setting benchmarks is a more mechanical process based on payment formulas and calculations.	Managing a competitive bidding process in many geographic areas requires resources. For areas with an insufficient number of bidders, administered pricing might have to continue in order to have plans available. (CMS might have to administer two different systems for setting benchmarks, depending on local market conditions.)
Plan availability after bidding process and over multiyear period	All plans meeting contracting standards (including an evaluation of plan capacity) are allowed to participate each year. Multiyear participation prospects for a particular plan depend on future benchmark levels as determined by legislation and administrative changes, trends in health care costs, and the competitive environment. Plan availability may erode over time.	Generally, in the Medicare competitive pricing models, all plans are allowed to participate regardless of the level of their bid. However, it is especially important to ensure that a low-bid plan has the capacity to serve the expected number of enrollees at the submitted bid level, particularly if the plan might be expected to have a large increase in enrollment as a result of its bid. Plan availability may erode over time.
Plan quality	Can be made a factor in payment (through a legislative change).	Can be made a factor in payment.

Note: MA (Medicare Advantage).

FIGURE 7–4

Current benchmarks and 100 percent of local FFS spending alternative benchmark



Note: FFS (fee-for-service). The simplified illustration of the current benchmark presented in this figure includes only one floor and ignores the fact that individual benchmarks may be significantly above FFS for a variety of reasons.

beneficiaries have used fewer services, have low FFS spending, and MA benchmarks based on these counties' FFS spending would result in rates too low for plans to survive and provide extra benefits. One option to help address these equity concerns is to set a floor at the low end, use FFS spending rates in the middle, and set a ceiling at the high end (Figure 7-5).

The floor and ceiling could be set in a number of ways. For the simulations, a floor and ceiling should combine to produce benchmarks that average 100 percent of FFS spending, so that the option is comparable to the other options. A hybrid system with a floor at $618 and a ceiling at $926 results in benchmarks that average 100 percent of FFS spending; thus, we used that floor and that ceiling for the simulations.[21]

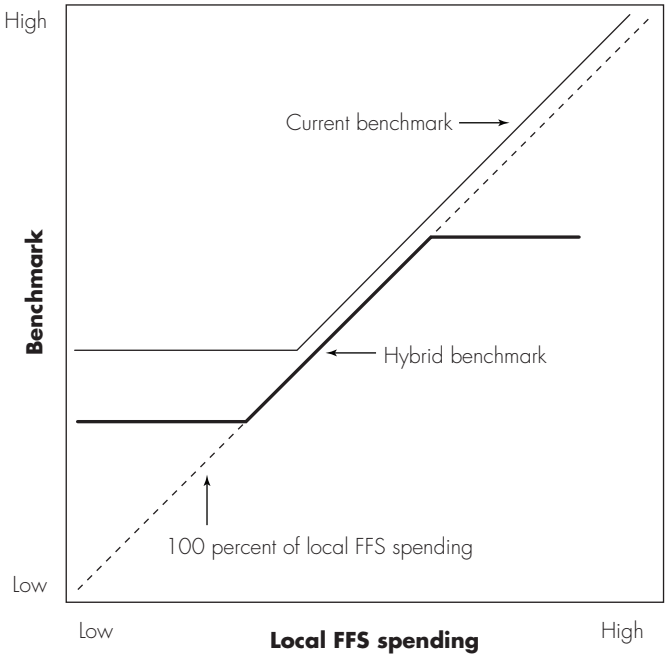
Blend of local FFS spending and national spending

Another option is to set benchmarks that take into account expected plan costs as well as expected FFS spending. That is, areas where MA costs were expected to be higher than FFS spending (these areas tend to be rural or low-spending urban counties) would have benchmarks exceeding 100 percent of FFS spending, and areas where MA costs were expected to be lower than FFS spending (these areas tend to be urban markets with high FFS spending) would have benchmarks below 100 percent of FFS spending. In addition, we interpret MIPPA as asking for an examination of an option where the benchmarks would be set by using a blend of local FFS spending and national average FFS spending so as to reflect expected plan costs.

As a result of the correlation analysis and a regression analysis that predicted plan bids based on local FFS spending (we found that bids tended to rise about $0.75 for each $1.00 increase in FFS spending), we simulate an option using a blend of 75 percent of the county's local FFS spending and 25 percent of the national average FFS spending (Figure 7-6). This particular blend of national and local FFS spending best approximates plan costs (as represented by the plans' bids). Under this option the benchmarks would range from $524 to $1,147.

FIGURE 7–5

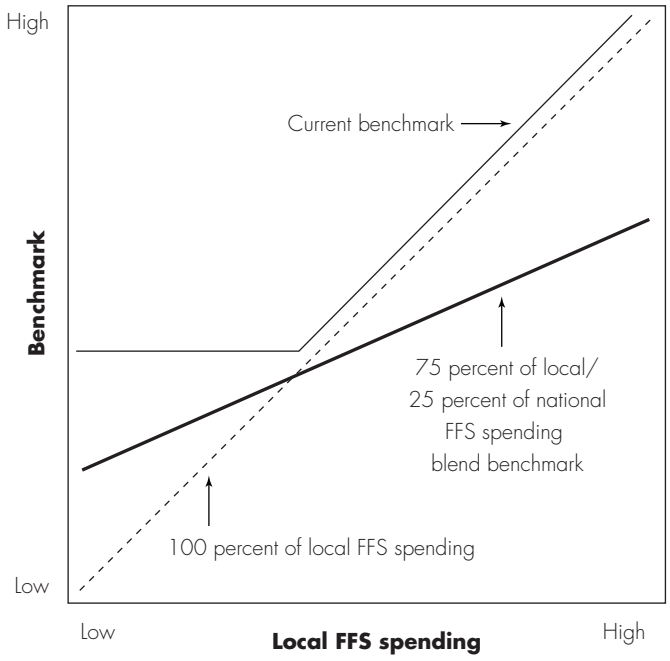
Current benchmarks, 100 percent of local FFS spending, and a hybrid alternative benchmark



Note: FFS (fee-for-service). The simplified illustration of the current benchmark presented in this figure includes only one floor and ignores the fact that individual benchmarks may be significantly above FFS for a variety of reasons.

FIGURE 7–6

Current benchmarks, 100 percent of local FFS spending, and a 75 percent of local/25 percent of national average FFS spending blend alternative benchmark



Note: FFS (fee-for-service). The simplified illustration of the current benchmark presented in this figure includes only one floor and ignores the fact that individual benchmarks may be significantly above FFS for a variety of reasons.

National FFS spending adjusted for local input prices

We examine another option for setting benchmarks that takes expected plan costs into account. Benchmarks that are based on local FFS spending adjust for both local service use and local input prices. However, in theory, managed care plans can manage utilization so there would be less variation in plan costs across the country. In this option, we take the national average FFS spending and adjust it by local input prices to set benchmarks.

This option would set benchmarks higher in areas where plans might be expected to have to pay providers more, but it would not set higher benchmarks based on higher service utilization. That is, we have created a normative standard for utilization. We would be saying that plans should be able to provide the Medicare benefit using no more than average utilization.

We computed the national average FFS spending rate as the average expected Medicare FFS spending for beneficiaries projected to be enrolled in MA plans. This national average is $734 per member per month for an enrollee with average health risk. We used the two primary Medicare price indices—the hospital wage index and the geographic adjuster that is used for the physician fee schedule—as our price indicators. We then regressed the bids on the national rate adjusted for local prices and found that a blend of 85 percent of the national price-adjusted rate and 15 percent of the unadjusted national rate was the best predictor of the bids. This input-price-adjusted blend option produced benchmarks that were more predictive of the bids than the benchmarks based on the blend of national and local FFS spending, particularly for HMOs.

Under this option, the benchmarks would range from $618 to $926. Counties with very high use would see their benchmarks fall from current levels; counties with low use (particularly those in low price areas) would see less of an effect. Unlike the other options, some benchmarks would rise from current levels. The range in benchmarks would be much narrower than under current law or under the local FFS option.

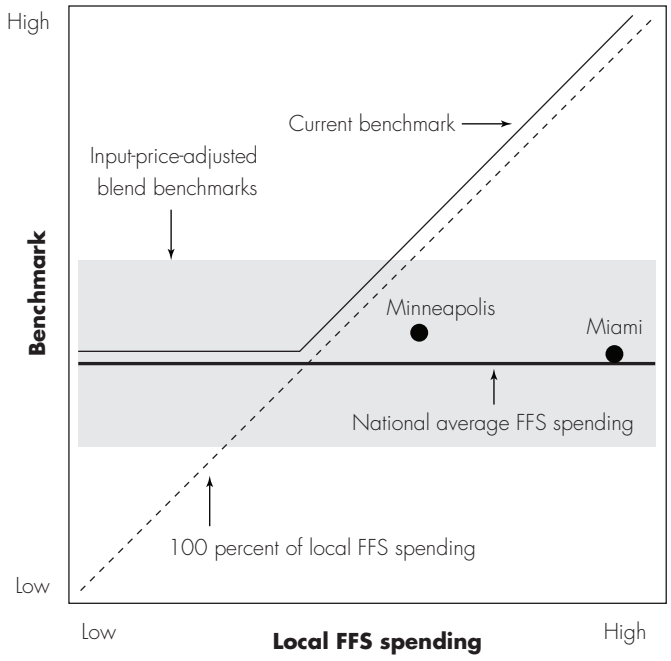
Figure 7-7 (p. 192) shows the national average FFS spending as a horizontal line slightly below the floor and illustrates the range in benchmarks that would result from this option. Our analysis suggests that most of the variation in county-level FFS spending is caused by variation in service use rather than by price differences. Counties with very different levels of FFS spending—caused by differences in the volume of services used rather than by prices—could have very similar benchmarks under this option. For example, Minneapolis would have a slightly higher benchmark than Miami under this option, although FFS spending in Miami is significantly higher than it is in Minneapolis.

Results of simulations

Each option, by design, reduces average benchmarks to about 100 percent of FFS spending from the current average benchmark that equals 118 percent of FFS spending. This reduction would cause substantial changes in plan availability, extra benefits, and cost to the program. We estimate that in 2009 this benchmark reduction would save the program $12 billion. CBO estimates that such a reduction would save approximately $150 billion over its 10-year budget window. However, CBO has scored only the 100 percent of local FFS option. Other options might produce similar savings in

FIGURE 7–7

Current benchmarks, 100 percent of local FFS spending, and an input-price-adjusted blend alternative benchmark



Note: FFS (fee-for-service). The input-price-adjusted blend benchmark is the national average level of FFS expenditures adjusted for local prices and would vary across areas, as illustrated by the two examples—Minneapolis and Miami. The simplified illustration of the current benchmark presented in this figure includes only one floor and ignores the fact that individual benchmarks may be significantly above FFS for a variety of reasons.

the first year, but shifts in enrollment patterns over time could reduce the savings.

Although all four options would likely produce similar first-year cost savings, they would also produce different benchmarks in different areas. The 100 percent of local FFS option would produce the largest benchmark differences between high- and low-spending counties, but each county would have its benchmark equal to local FFS (Table 7-6). The input-price-adjusted blend (along with the hybrid option) would produce the narrowest range of benchmarks but would have benchmarks in some counties about 50 percent above and in others 50 percent below local FFS spending.

We examined several additional metrics for each option:

- plan availability by plan type and quality ranking, with separate analyses for urban and rural areas;
- level of extra benefits; and
- cost to the Medicare program.

Availability of plans by plan type and quality rankings and by urban and rural areas

Policymakers want to know whether plans will be available if the benchmarks change. The simulations measure plan availability by whether the current plan bids are above or below the simulated new benchmarks. We assume that plans that bid below the simulated

TABLE 7–6

MA benchmark characteristics vary by option

	Benchmark		Ratio of benchmark to FFS spending	
Benchmark type	**Minimum**	**Maximum**	**Minimum**	**Maximum**
Current benchmarks (118% of FFS)	$ 741	$1,366	1.01	1.83
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):				
100% of local FFS	$453	$1,285	1.00	1.00
Hybrid	618	926	0.72	1.36
75% of local/25% of national FFS blend	524	1,147	0.89	1.15
Input-price-adjusted blend	618	926	0.54	1.56

Note: MA (Medicare Advantage), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

TABLE 7–7

Percent of beneficiaries with any MA plan available varies under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	100%	100%	100%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	80	84	67
Hybrid	82	85	69
75% of local/25% of national FFS blend	88	90	78
Input-price-adjusted blend	94	96	88

Note: MA (Medicare Advantage), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

benchmarks would continue to do so and therefore would be "available," although the extra benefits they offer would probably be reduced. We also assume that plans bidding above the benchmarks would not stay in the program because they would not be able to offer attractive benefits.

These two assumptions would not hold in all cases. For example, some plans may bid above their benchmarks and remain in the program. Some plans might bid lower than they currently do to stay in the program and attract or retain market share. In contrast, some plans that bid slightly below the new benchmarks could decide to pull out if they thought they could not offer benefits attractive enough to draw or retain members. On balance, the assumptions we use should produce reasonable approximations.

All options presented here would likely result in much lower Medicare spending and in reduced plan availability. We report plan availability separately for urban and rural areas because the difference between those areas can be large. (We define urban areas as counties in metropolitan statistical areas (MSAs) and rural areas as counties not in MSAs.)

Currently, 100 percent of beneficiaries live in counties with plans bidding below the benchmark. Of the four options presented, the one setting benchmarks at 100 percent of local FFS spending would reduce availability the most (Table 7-7). Under the local FFS option, 80 percent of beneficiaries, and 67 percent of rural beneficiaries, would have a plan available. The option basing benchmarks on the input-price-adjusted blend would reduce availability the least, largely because benchmarks in this option are designed to reflect plan costs. Plan bids tended to track the input-price-adjusted blend closer than the other options. Ninety-four percent of all beneficiaries and 88 percent of beneficiaries in rural counties would have a plan available under that option. Each option would result in lower availability in rural areas than in urban areas.

We also examine the likely effects of benchmark changes by simulating plan availability for current MA enrollees. Although plans may be available in all areas, enrollment penetration varies. Thus, if plans left low penetration areas, proportionately fewer MA enrollees than Medicare beneficiaries would be affected. Plan availability would be higher under all options if it were measured for current (February 2009) MA enrollees rather than for all Medicare beneficiaries (Table 7-8). Under the 100 percent of local FFS option, for example, 83 percent of current MA enrollees would have a plan available, compared with 80 percent of all Medicare beneficiaries (shown in Table 7-7). Availability would reach 98 percent of all MA enrollees and 94 percent of rural enrollees under the price-adjusted blend option. For the remainder of the tables in this section, we present

TABLE 7–8

Percent of current MA enrollees with any plan available under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	100%	100%	100%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	83	85	70
Hybrid	85	87	71
75% of local/25% of national FFS blend	89	90	80
Input-price-adjusted blend	98	98	94

Note: MA (Medicare Advantage), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

TABLE 7–9

Percent of beneficiaries with any MA plan available using 2011 PFFS rules under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	99%	100%	96%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	77	82	61
Hybrid	79	83	62
75% of local/25% of national FFS blend	85	89	69
Input-price-adjusted blend	85	89	70

Note: MA (Medicare Advantage), PFFS (private fee-for-service), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings. As of 2011, network requirements will apply to PFFS plans in certain circumstances.

Source: MedPAC analysis of CMS bid and payment data.

availability in terms of all Medicare beneficiaries, but availability for current enrollees is likely to be higher.

The simulations all assume the 2009 bidding rules, but MIPPA requires that PFFS plans have provider networks where two other network plans are available starting in 2011. CMS recently published the list of counties where PFFS plans would need a network in 2011. To address this impending change, we simulated plan availability assuming that PFFS plans would not be available in the listed counties. It is possible that the PFFS plans could develop networks in these counties, but we did not assume any behavioral change. Plan availability would drop under the base case and all options when the 2011 PFFS rules are included. The general pattern among the options remains the same as under the 2009 rules, except that the two blends are more comparable (Table 7-9).

We also simulated overall plan availability using the MSA–health service area (HSA) definition of payment areas (see the appendix to this chapter). We assumed that if a plan (at the contract level) served more than 50 percent of the Medicare beneficiaries in the area it would serve the entire payment area; otherwise, it would not serve any of the service area. The findings (Table 7-10) show the same patterns of lower availability in rural areas, lowest availability under the 100 percent of FFS spending option, and highest availability under the input-price-adjusted blend option. Compared with the same simulations using county-level payment areas, these simulations show slightly lower or the same level of availability. Because we found little difference and we need to make more assumptions about plan behavior, we do not show any other results with the larger payment areas. Instead, we present all the other results based on county-level payment areas.

Table 7-11 shows availability for local coordinated care plans (CCPs), which include HMOs and local PPOs only. We report separately on the local CCPs because the Commission has raised concerns about the need to design programs that support plans committed to coordinating care. The plans with the most potential to coordinate care are the local CCPs, so we look at how widely available they might be under different payment alternatives (Table 7-11). Despite currently high benchmarks, local CCPs are not widely available in rural areas. Only 60 percent of rural Medicare beneficiaries have a local CCP available. As before, the 100 percent of local FFS benchmarks would reduce availability the most, and the input-price-adjusted blend would reduce it the least.

TABLE 7–10

Percent of beneficiaries with any MA plan available using MSA–HSA payment areas under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	100%	100%	100%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	79	82	65
Hybrid	81	85	67
75% of local/25% of national FFS blend	87	90	76
Input-price-adjusted blend	93	95	85

Note: MA (Medicare Advantage), MSA (metropolitan statistical area), HSA (health service area), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

TABLE 7–11

Percent of beneficiaries with a local CCP available varies under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	87%	95%	60%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	66	76	31
Hybrid	68	77	33
75% of local/25% of national FFS blend	73	82	40
Input-price-adjusted blend	75	83	46

Note: CCP (coordinated care plan), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

The Commission is also interested in ensuring beneficiary access to high-quality plans. Thus, we also conducted simulations to observe the effect of each option on the availability of plans that have demonstrated high quality, defined as those that achieved a score of at least 3.5 stars in CMS's quality ranking (Table 7-12). By identifying the plans with high quality that would likely have bids below the new benchmarks, we determined the share of beneficiaries who would have high-quality plans available under each option.

Currently, 55 percent of all beneficiaries, and 34 percent of rural beneficiaries, live in counties where they could enroll in a high-quality plan, compared with lower proportions under our four options. (The current share of beneficiaries for whom quality plans are available may be understated, as we counted only those plans that have a CMS star rating, which would exclude newer plans.) For the input-price-adjusted blend option, the drop in availability is not steep. Overall availability drops from 55 percent to 49 percent and availability in rural areas drops only 3 percentage points.

Level of extra benefits

Policymakers have also been concerned about the level of extra benefits plans may offer. To estimate that level under the four options, we calculated the extent to which plans would receive rebates for submitting bids below the alternative benchmarks.

The rebate dollars paid to the plans when their bids are below the benchmark are used to finance the extra benefits; plans offer the extra benefits to attract beneficiaries. In the group of plans we used in our benchmark-setting simulations, the average rebate paid by Medicare is $96 per member per month for those in plans that bid below the benchmark (about 98 percent of all plan enrollees). Plans use the rebate dollars primarily to reduce cost sharing for Medicare Part A and Part B services (MedPAC 2009). The average rebate is $101 for urban plan enrollees and $59 for rural enrollees (Table 7-13, p. 196).

Of the four options, the 100 percent of local FFS spending option had the highest level of rebates. The next two highest rebate options incorporate local FFS spending: the 75 percent of local/25 percent of national FFS spending blend and the hybrid. These options provide the largest rebates because they lower the benchmarks in the highest spending areas the least. The input-price-adjusted blend provides the lowest level of rebates.

Currently, Medicare retains 25 percent of the difference between the benchmark and the bid and provides the remaining 75 percent to the plans as the rebate, as shown in Table 7-13. Under the options we present, with benchmarks set at 100 percent of FFS, financial neutrality

TABLE 7–12

Beneficiaries with a high-quality MA plan available under different alternatives

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	55%	60%	34%
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	33	38	15
Hybrid	34	39	15
75% of local/25% of national FFS blend	39	44	21
Input-price-adjusted blend	49	54	31

Note: MA (Medicare Advantage), FFS (fee-for-service). A high-quality plan is a plan that received an overall quality rating of 3.5 stars or greater in the CMS star ranking system. The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

TABLE 7–13 **Average rebate dollars per member per month for projected membership in MA plans bidding below benchmarks under different alternatives**

Benchmark type	All areas	Urban areas	Rural areas
Current benchmarks (118% of FFS)	$96	$101	$59
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):			
100% of local FFS	75	76	35
Hybrid	59	59	29
75% of local/25% of national FFS blend	62	63	34
Input-price-adjusted blend	38	40	20

Note: MA (Medicare Advantage), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

would be maintained without Medicare retaining the 25 percent. Rather than being retained, the 25 percent could be put in a quality incentive pool and returned to high-quality plans through a pay-for-performance program, as we have recommended in the past. Alternatively, the 25 percent could go toward extra benefits. Both policies would effectively increase by one-third the rebate dollar amounts shown for the options.

Cost of alternatives

In the first year, these administrative options are financially neutral to FFS Medicare in the aggregate—any one of them would cost the program the same as traditional Medicare, saving $12 billion by our estimate. This savings translates to a 15 percent reduction in the benchmarks. Under these options all beneficiaries would no longer see their Part B premium increasing to subsidize extra benefits for the minority of beneficiaries enrolled in certain plans, and taxpayers would not have to subsidize the costs of the additional benefits out of general revenues. In later years, the level of spending for a given option relative to FFS spending will vary as it is influenced by where enrollment is encouraged and where it is discouraged. For the 100 percent of local FFS option CBO estimates savings to be worth $150 billion over 10 years.

Commentary

To put the options we have presented into context, we first review them and their implications, discuss a modification that would help balance extra benefits across geographic areas, and present a transition strategy that would limit disruption for beneficiaries and encourage high-quality plans. We then reflect on how the goals for private plans in Medicare have shifted and how the current MA payment system could be improved by recasting the goals of the program to emphasize financial neutrality, efficiency, equity, and quality.

Alternative approaches to MA payment

The Commission believes there should be overall financial neutrality between traditional FFS and private plans, with differential payment for higher quality. Achieving overall financial neutrality should be a design goal for establishing benchmarks; quality should be a factor in plan payments. For example, once a benchmark is established, either through bidding or administratively, higher quality plans should be rewarded with add-on payments. The Commission has also recommended that larger payment areas be used for the MA payment system to lessen year-to-year volatility in benchmarks and payment rates and to decrease differences between neighboring areas (see the appendix to this chapter). Either of the alternatives we have discussed—setting benchmarks through competitive bidding or any of the administrative options—could be designed to use larger payment areas.

Defining a preferred option depends on one's perspective and the program goals one considers most important. The administrative options other than 100 percent of local FFS, as well as competitive bidding, would introduce differences between local FFS payments and plan benchmarks. Therefore, in some areas benchmarks will be above FFS payments, introducing the possibility of paying plans more than FFS and increasing overall Medicare payments. At the same time, those differences can make it less likely that plans will enter areas where they might save Medicare money. Administratively setting benchmarks for private plans at 100 percent of local FFS is the only alternative that ensures neither of those situations occurs. It would also create an incentive for plans to be more efficient than Medicare FFS by managing care—that is, reducing costs and improving quality. With the resulting savings, plans could offer additional benefits to beneficiaries and in turn attract enrollment, provide incentives for efficiency, and

TABLE 7–14

Key parameters of current and alternative MA benchmark options

Benchmark type	Benchmark		Ratio of benchmark to FFS spending		Availability (any plan)	Average extra benefits
	Minimum	Maximum	Minimum	Maximum		
Current benchmarks (118% of FFS)	$ 741	$1,366	1.01	1.83	100%	$96
Alternative benchmarks (100% of FFS; *potentially saves $150 billion over 10 years*):						
100% of local FFS	$453	$1,285	1.00	1.00	80	75
Hybrid	618	926	0.72	1.36	82	59
75% of local/25% of national FFS blend	524	1,147	0.89	1.15	88	62
Input-price-adjusted blend	618	926	0.54	1.56	94	38

Note: MA (Medicare Advantage), FFS (fee-for-service). The hybrid alternative benchmark is 100% of local FFS with specified minimum and maximum benchmark amounts. The input-price-adjusted blend alternative benchmark is the national average level of FFS expenditures adjusted for local prices. The Congressional Budget Office has scored only the 100% of local FFS alternative. Other options might start at similar savings, but shifts in enrollment patterns over time could reduce the savings.

Source: MedPAC analysis of CMS bid and payment data.

keep average extra benefits relatively high. But those extra benefits will be concentrated in very few areas and plans; plans in general, and high-quality plans, would not be as widely available as in other options—particularly in areas with low FFS payments. This situation would lead to additional concerns about inequities.

Setting benchmarks through bids

Competitive bidding can be used to set benchmarks for MA plans. We outlined some decisions that would have to be made to set benchmarks through competitive bidding—for example, where to set the benchmark in relation to the distribution of bids and whether bids should be limited at some point above or below local FFS spending. With no modifications, a competitive strategy cannot guarantee that a sufficient number of bids will be made in all areas or that the level of extra benefits in a competitive system will be sufficient to attract beneficiaries.

It is also not clear at what point a bidding system will reach an equilibrium and whether that equilibrium will approximate payment neutrality of 100 percent of FFS spending in the long term. Because plans' benefits and characteristics are sensitive to the rules and design of the bidding process, our evaluation of this alternative is limited. A quantitative simulation of this alternative is particularly difficult because county-level bids are not available. Under the current system, plans submit one bid for an entire service area, which may contain multiple counties. If county-level benchmarks are set by bids, then plans will likely vary their bids by county within a service area. As a result, county-level bids will be essential to model plan behavior under competitive bidding.

Options for setting benchmarks administratively

We described four options for setting benchmarks administratively (Table 7-14). Each could be designed to use larger payment areas. We set each option equal to 100 percent of FFS spending overall in the first year to attempt to create financial neutrality between MA and FFS. As our analysis of the 100 percent of local FFS option shows, setting benchmarks at 100 percent of local FFS will by definition be financially neutral in all years. However, that will not necessarily be true for the other options.

Each administrative option other than 100 percent of local FFS would lower benchmarks in very high FFS areas and redistribute some of the payments that finance extra benefits in those areas to other areas where benchmarks can increase (relative to the 100 percent of local FFS option), which increases the availability of plans and makes extra benefits available in more areas and to more people, although it lowers the average extra benefit nationwide. (The average of extra benefits is computed only in areas where extra benefits exceed zero.) Because these options also increase the difference between local FFS and the benchmarks (the maximum and minimum ratio of benchmarks to FFS spending shown in Table 7-14), plans will react and change where they offer services. Although we have set the options equal to 100

percent of FFS overall in the first year, we cannot tell how long the other options will maintain financial neutrality because of the dynamics of the process.

Reviewing the results of our simulations as shown in Table 7-14:

- The 100 percent of local FFS option has the widest dollar range of benchmarks, no differences between local FFS and the benchmarks (by definition), estimated first-year plan availability of about 80 percent, and the highest level of extra benefits. (But the highest level of extra benefits will be concentrated in few areas and plans, which has created concerns about inequities.)
- The hybrid option limits the dollar range among benchmarks but has differences between benchmarks and local FFS payments of around 30 percent above or below, little difference in plan availability (82 percent) relative to 100 percent of local FFS, and lowers the average extra benefit relative to 100 percent of local FFS (but makes them available to more beneficiaries in more areas).
- The blend of 75 percent of local and 25 percent of national FFS plan decreases benchmarks in areas with the highest levels of FFS payment and increases benchmarks in areas with low levels of FFS spending but still has a fairly wide dollar range of benchmarks. It allows differences between local FFS spending and benchmarks, setting benchmarks 15 percent higher than FFS in lower FFS payment areas. It increases plan availability (88 percent) and lowers average extra benefits ($62) relative to 100 percent of local FFS (but makes them available to more beneficiaries in more areas).
- The input-price-adjusted blend option is a different option encompassing plan costs. It decreases the dollar range in benchmarks and has the largest percentage differences between local FFS and benchmarks, with benchmarks in some areas 50 percent more and in others 50 percent less than FFS spending. It increases the availability of extra benefits (94 percent) and decreases their average dollar value ($38) relative to 100 percent of local FFS.

Whichever option is chosen, in some markets private plans will find it difficult to contract with providers because there may be monopoly providers in areas with low population density, there may not be providers with efficient practice patterns, or plans may face other barriers. In those markets, Medicare's low administrative costs and the ability to set prices will mean private plans cannot compete with Medicare successfully. However, there may be providers who are willing to organize in those markets to improve care coordination and increase quality but who cannot take on full insurance risk as MA plans do. The Commission will be discussing the viability of possible options in future work.

A modification to balance extra benefits across geographic areas

There is a modification that could mitigate some of the concerns about the equity of extra benefits in the 100 percent of local FFS option and the 75 percent of local/25 percent of national FFS spending blend option. In those options, greater extra benefits would probably be available in areas with very high FFS spending than in other areas.

FFS Medicare is more efficient in some areas than in others. In areas with very high service use and many providers, MA plans have scope for efficiency gains because private plans have the latitude to coordinate care and to select providers with efficient practice patterns. In low-use areas, FFS Medicare may be a reasonable proxy for an efficient plan because of judicious practice patterns and the fact that Medicare has low administrative costs and the ability to set prices.

Medicare could differentiate payment for extra benefits between high- and low-use areas. For example, Medicare's share of the difference between the bid and the benchmark could vary according to an area's service use. Currently, Medicare retains 25 percent of the difference between the bid and the benchmark, and the remaining 75 percent goes to enhanced benefits. This share could be varied, with Medicare retaining a larger share as service use increases above the national average and a smaller share where service use is low, which would tend to balance extra benefits across geographic areas and promote equity. This adjustment could be made prospectively each year and could be designed to be budget neutral.

Table 7-15 illustrates that under the new policy the share Medicare retains is higher (60 percent) in the higher-service-use area and lower (0 percent) in the lower-service-use area. (The numbers in the table are illustrative and were chosen to simplify explication.) In the higher-service-use area, the bid in the example is 70 percent of

the benchmark. Under current rules, Medicare retains 25 percent of the difference and extra benefits (rebate) are 22.5 percent. If Medicare instead were to retain a larger share (60 percent) of the difference, extra benefits would decrease to 12 percent under the new policy. Conversely, in the lower-service-use area the extra benefits would increase from 7.5 percent to 10 percent. The result would be less of a difference between the extra benefits available in the higher- and lower-service-use areas.

Considerations during transition

Under any of the options we have analyzed, benchmarks will decrease. As benchmarks decrease, plans will change their benefit packages and possibly their provider networks; in some cases, they may leave the program. All these steps will be disruptive for beneficiaries enrolled in MA plans. They may have to switch plans, return to FFS Medicare, or adjust to changes in their benefits and cost sharing.

At the same time, other changes already in law or regulation will be changing the MA marketplace. For example, MIPPA requires that PFFS plans have provider networks where two other network plans are available starting in 2011. The likely result will be PFFS plans either becoming network plans or in some cases withdrawing from the program. (See text box, p. 200, for a discussion of previous periods of changing health plan participation.)

To reduce disruption to beneficiaries, it may be advisable to have a transition period during which benchmark rates will decrease to the proposed rates over a period of time rather than all at once. If we define as the desired endpoint an MA program that encourages high-quality plans that are financially neutral to FFS, then a key objective of the transition should be to preserve high-quality plans in the program. During the transition, as the program continues to pay plans more than it would have cost to provide care in FFS Medicare for the plan's enrollees, a condition for a plan to receive extra payments should be that it has demonstrated good performance on quality indicators. As benchmarks are lowered to attain financial neutrality, high-quality plans' payments would not decrease as fast, and low-quality plans would either improve or their payments would decrease and they would exit the program.

At the end of the transition, under any benchmark alternative (competitive or administrative), high-quality plans could be paid more than FFS if their quality were higher than FFS. Payments would be in essence a quality-adjusted 100 percent of FFS. Plans would be free to use the extra payments to provide extra benefits. It is not now possible to make a direct, broad-based comparison of quality in MA plans versus FFS. The methodology CMS might use to compare the two sectors is the subject of a separate Commission report mandated in MIPPA.

For example, if benchmarks move from 118 percent of FFS to 100 percent of FFS over a three-year transition period, the average rate of decrease would be about 6 percent a year. For a high-quality plan the decrease could be buffered by an additional payment known in advance of bidding based on the previous year's quality performance. In effect, payments could change at a slower rate than benchmarks if plan quality were high. For a low-quality plan, payments could decrease more than 6 percent per year if low quality were directly penalized by a payment decrease. The intent would be to retain high-quality plans in the MA program. After the transition, if plan quality can be measured relative to FFS, MA payments could be set to quality-adjusted financial neutrality with Medicare FFS. That is, if MA plans provide better quality care than FFS, they would be paid more than FFS.

TABLE 7–15

Beneficiaries in areas with lower service use would benefit under alternative formula for extra benefits

	Higher-service-use area	Lower-service-use area
Bid as percent of benchmark	70%	90%
Difference	30	10
Extra benefits current formula		
Percentage of difference Medicare retains	25	25
Percentage of difference for extra benefits	75	75
Extra benefits (75% of difference)	22.5	7.5
Extra benefits alternative formula		
Percentage of difference Medicare retains	60	0
Percentage of difference for extra benefits	40	100
Extra benefits	12	10

Note: "Extra benefits" is the rebate amount that the plan has to use to provide extra benefits to enrollees; the actual amount of extra benefits the enrollee receives will be reduced by the plan's load factor.

Previous changes in health plan participation in Medicare

The last major round of health plan withdrawals from Medicare occurred from 1998 through 2003. Plan participation started to decline in 1998 and enrollment started to decline the next year. The number of Medicare plans dropped from 346 in 1998 to 151 in 2003. Plan enrollment dropped from its then-historic high of 6.3 million in 1999 to 5 million in 2003. (The rapid decline in enrollment was preceded by a rapid increase; plans added 2.2 million Medicare enrollees during the years 1997 through 1999.) The percent of beneficiaries with access to at least one managed care plan in their county declined from 74 percent in 1998 to 59 percent in 2003 (CMS 2007).

In terms of the types of benefits offered, access to plans with no premium declined from 61 percent in 1999 to 29 percent in 2003. Premiums and cost sharing for enrollees increased, and drug coverage—the principal extra benefit that attracted Medicare enrollment—became much less generous.

The cause of plan departures and reduced benefits

It is commonly thought that payment changes made in the Balanced Budget Act of 1997 (BBA) led to Medicare plan withdrawals and declines in enrollment. The story is more complicated. The Center for Studying Health System Change (HSC) noted that "While the BBA often is blamed for this turnabout … private market forces also played a key role in [Medicare+Choice's] growing instability."

As Grossman and colleagues of HSC stated in their analysis, "Positive market conditions before the BBA's passage helped to spur Medicare managed care's growth, while declining market conditions, especially rising health care costs, intensified the impact of BBA policy changes. This collision of public policy and private market forces, rather than policy changes alone, brought … growth to a halt" (Grossman et al. 2002). They mention three market factors influencing both the rapid growth and the decline in Medicare health plans: "health care cost trends … the commercial insurance underwriting cycle … [and] plans' ability to negotiate discounts from providers." The latter has been commonly referred to as the "managed care backlash" that forced plans to have wider networks and loosen utilization management practices.

The rise and decline of Medicare managed care roughly matched the rise and decline of managed care in the commercial sector. The market conditions that allowed health plans to bring health care costs down (or slow the rate of the growth in costs) applied in both the commercial market and the Medicare market. The market conditions that led to increases in health care costs applied in both market sectors as well.

How the current situation differs from the 1990s

One difference between the period of enrollment growth in the 1990s and the current period of Medicare enrollment growth is that the new growth in plans is primarily the result of what HSC would call "policy changes alone" in Medicare. The prime example is the growth of Medicare private fee-for-service plans, an exclusively Medicare product introduced by the BBA and whose growth is attributable to the establishment of floor payments in Medicare Advantage. Similarly, the BBA opened the door to Medicare-only health plans or plans that have only Medicare and Medicaid enrollees, which would not have been possible before the BBA (because of what was known as the 50/50 rule governing the composition of enrollment in Medicare plans, which had to have at least 50 percent of their enrollment in non-Medicare, non-Medicaid products).

These changes have allowed companies to enter new areas without the need to compete in the commercial market or without "having roots" in a particular community. Although the BBA introduced these new options, it was primarily payment policy changes after the BBA that allowed their rapid growth. Plans entered new geographic areas because of benchmarks well above Medicare fee-for-service expenditure levels. If the sole reason for plan entry was a change in payment rates, a change in rates in the other direction could lead to rapid plan departures. ■

Understanding the goals of the Medicare Advantage program

The decision of which alternative for setting benchmarks in the MA program is preferable depends on one's perception of the program's goals. Those goals have shifted.

Original goals of the program

Private plans were included in Medicare to provide a mechanism for introducing innovation into the program while saving money for Medicare (the plans were paid 95 percent of FFS between 1982 and 1997).[22] Private plans were expected to achieve efficiencies by, for example, negotiating lower payment rates with providers, selectively contracting with efficient providers, managing the provision of services, and coordinating care—payment and delivery strategies that were not possible in traditional FFS Medicare. In addition, there was the possibility that more efficient MA practice patterns might "spill over" into the FFS program, leading to greater efficiency there as well. The original goals were thus to import innovation through efficient private plans using care coordination and to save money for Medicare.

Perceptions of geographic inequity spurred change

As the Medicare private plan option evolved, some areas of the country had many private plans available to beneficiaries that offered benefits beyond those included in Medicare Part A and Part B—often at a lower cost to beneficiaries. For example, some plans included, at no additional cost, coverage for prescription drugs, which at the time was not available in the regular Medicare program. At the same time, there were areas of the country where no private plans were available to beneficiaries. Representatives of the latter areas pointed out that their beneficiaries paid the same Part B premium as beneficiaries in other parts of the country yet had no choice of private plans and no access to additional benefits; in their eyes, the system was inequitable.

Private plans tended to enter geographic areas where conditions were favorable—that is, areas where the prevailing level of service use was high, and health care market conditions allowed for negotiation of favorable rates. Efficient private plans could take advantage of those conditions and provide the Part A and Part B benefit package for less than FFS Medicare. They could then provide enhanced benefits to the extent Medicare payments exceeded their cost of providing the Medicare Part A and Part B benefit package.

In geographic areas with high levels of service use in FFS Medicare, plans are able to provide a substantial level of extra benefits because they are able to reduce service use among their enrollees. In other areas, where FFS service use is lower, plans have not been able to provide rich benefit packages because it is more difficult to reduce service use below the prevailing level. The differences in extra benefits across different geographic areas were in part a manifestation of differences in FFS service use across areas. However, they led to the problem of perceived geographic inequities in the private plan options because beneficiaries in areas where FFS service use has been more judicious were less likely to have plans offering the extra benefits found in the areas with highest service use.

Market conditions differ among areas as well. In some areas, there may be a monopoly provider and private plans are not able to negotiate favorable payment rates; hence, they do not enter the market. In contrast, in areas with many providers who are willing to accept lower rates to gain market share, private plans are more willing to enter. This situation led to some areas not having private plans and to further concerns about inequity.

In a discussion of inequities, it is also important to consider differences in the situation of beneficiaries in the FFS program in the two kinds of areas. First, consider FFS beneficiaries in the higher-service-use areas; they have higher out-of-pocket expenses—either directly, related to their higher use of services, or indirectly through higher cost for supplemental plans. This higher use does not result in higher quality. In fact at the state level the opposite is true: Higher use is correlated with lower quality (Baicker and Chandra 2004, MedPAC 2003). Considering the FFS beneficiaries in lower-service-use areas, their out-of-pocket spending is less and supplemental premiums are lower than in higher-service-use areas. At the state level, quality is higher in lower-service-use areas. In terms of equity, although beneficiaries do not have access to extra benefits through private plans, they do have access to providers that produce high-quality care from fewer services, which translates to higher quality at less cost to beneficiaries. In some sense, the inequities in the FFS program are the opposite of those in the private plans.

Changes in program shifted goals

In response to the issue of geographic inequity, beginning with the BBA in 1997, the goals of the program shifted to:

- making private plans of some type available to all beneficiaries even in areas where they had not been

economically viable because of low service use or market conditions, and

- providing benefits beyond those in traditional Medicare through private plans to all beneficiaries.

To meet these goals, benchmarks for plan payment were raised. As we described earlier, legislation established floors for benchmarks. The update mechanism was also changed and benchmarks in many areas increased—in some cases beyond the expected level—because of the ratchet mechanism that allows county benchmarks to only increase and never decrease. New types of plans were created that did not require contracted provider networks, and enrollment in those plans increased rapidly under higher payment rates.

The goals of enhanced benefits and availability for all have been met, although certain areas still have more benefits available than others. However, the other result is that the Medicare program now pays much more for beneficiaries who join MA plans than for similar beneficiaries in FFS.

Current MA system encourages inefficiency Successive changes have resulted in today's MA program and the current situation in which:

- excessive payments encourage inefficient plans and increase Medicare spending.
- higher spending hastens the insolvency of the Part A trust fund.
- the burden on taxpayers is increased.
- all beneficiaries pay higher Part B premiums.
- new inequities are created.

Instead of encouraging innovative plans, the current MA payment system encourages inefficient plans, because the benchmarks used as bidding targets are set too high, and plan payments are not linked to performance.[23] Current benchmarks are on average 118 percent of what Medicare would spend for similar beneficiaries in FFS, and payments are 114 percent of that amount; more than 13 percent of those payments are used to pay for plans' overhead (administrative costs and margins) and not for direct medical care for beneficiaries. The high payment benchmarks increase payments and distort incentives. Plans do not have to be efficient to thrive under the current payment system.

Higher payments in MA than in FFS for similar beneficiaries hasten the insolvency of the Medicare Part A trust fund. The CMS Office of the Actuary estimates that the trust fund will become insolvent 18 months earlier than it otherwise would have if current MA payment and enrollment trends continue (U.S. House 2008). The burden on taxpayers to pay for the system is also increasing as part of the cost of Medicare is funded with general tax revenues.

All beneficiaries have to pay higher Part B premiums ($3 more per month) to subsidize the MA plans and extra benefits for the minority of beneficiaries who are in those plans, creating a new form of inequity. The MA plans with the highest level of extra benefits tend to be in the areas where use of services in FFS is very high. One approach to address the perceived inequity is to reduce Part B premiums in lower-service-use areas. Note, however, that this would result in lower Part B revenues, which would have to be offset by higher premiums for beneficiaries in high-cost areas (by law 25 percent of the cost of Part B has to come from beneficiary premiums).

Although MA plans may provide extra benefits, Medicare pays a high price for them to do so. Overall, the Medicare subsidy per dollar of enhanced benefit is $1.30 for all plans. In the case of HMOs, because their bids for the Medicare benefit package are below Medicare FFS spending, the program subsidy is $0.97 for each $1.00 of enhanced benefits. HMOs are the only MA plan type that finances any part of enhanced benefits through plan efficiencies: $0.03 of every $1.00. Medicare subsidizes enhanced benefits in other plan types (MedPAC 2009). At the extreme, Medicare pays a subsidy of $3.26 for each $1.00 of enhanced benefits a member receives in a PFFS plan.

Although plans are being paid more, the extra payments do not necessarily result in higher quality of care. The National Committee for Quality Assurance found that the most recent results for MA plans show the "second year in a row of relatively flat performance" among MA plans on HEDIS quality measures (NCQA 2008). Although an MA plan is available to every beneficiary, plans with above-average quality rankings are available to only about half of beneficiaries.

The growth in less efficient plans heightens our concerns about equity issues that arise with MA relative to the traditional Medicare program, about equity for beneficiaries and taxpayers, and about ensuring a level playing field among the different MA plan types. The

Section 169 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

SEC. 169. MEDPAC STUDY AND REPORT ON MEDICARE ADVANTAGE PAYMENTS.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study of the following:

(1) The correlation between—

(A) the costs that Medicare Advantage organizations with respect to Medicare Advantage plans incur in providing coverage under the plan for items and services covered under the original Medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, as reflected in plan bids; and

(B) county-level spending under such original Medicare fee-for-service program on a per capita basis, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. The study with respect to the issue described in the preceding sentence shall include differences in correlation statistics by plan type and geographic area.

(2) Based on these results of the study with respect to the issue described in paragraph (1), and other data the Commission determines appropriate—

(A) alternate approaches to payment with respect to a Medicare beneficiary enrolled in a Medicare Advantage plan other than through county-level payment area equivalents.

(B) the accuracy and completeness of county-level estimates of per capita spending under such original Medicare fee-for-service program (including counties in Puerto Rico), as used to determine the annual Medicare Advantage capitation rate under section 1853 of the Social Security Act (42 U.S.C. 1395w–23), and whether such estimates include—

(i) expenditures with respect to Medicare beneficiaries at facilities of the Department of Veterans Affairs; and

(ii) all appropriate administrative expenses, including claims processing.

(3) Ways to improve the accuracy and completeness of county-level estimates of per capita spending described in paragraph (2)(B).

(b) REPORT.—Not later than March 31, 2010, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Commission determines appropriate. ■

equity and efficiency issues are of particular concern when Medicare is not financially sustainable in the long run.

Current MA system could threaten access to care for FFS beneficiaries In the attempt to reach the goal of MA plans everywhere, very high rates must be paid in areas with low FFS use and markets that do not support low negotiated rates for MA plans. MA plans that enter such markets may actually have to pay rates to physicians, for example, that are higher than Medicare rates and they can afford to do so because benchmarks are set too high. If this trend is allowed to continue, Medicare could face a situation in which physicians accept only the higher MA plan rates, making it difficult for FFS beneficiaries to find physicians who accept Medicare FFS rates. This "hollowing out" of FFS may already have started in certain areas. For example, a large medical group in Oregon is not accepting new patients enrolled in traditional Medicare or Medicare PFFS plans but continues to accept Medicare patients enrolled in all of the MA CCPs operating in its county (Oregon Medical Group 2009). The concern here is that those CCPs may be paying rates that are higher than traditional FFS rates.

Recasting the goals for MA

Reconciling the original efficiency goals of the program with the goal of alleviating perceived geographic inequities is essential for the MA program going forward. The geographic inequities that resulted from including private plans in Medicare were a reflection of geographic differences in the use of Medicare FFS. In areas where the use of services was inordinately high in FFS, private plans could offer very high levels of extra benefits. Beneficiaries in lower-service-use areas perceived that they were paying higher premiums in FFS to support high FFS use in other areas and were also supporting higher benefits from private plans in other areas. The current MA program, while providing private plans in all areas, continues to fund higher extra benefits in higher-service-use areas and also encourages inefficient plans at a time when maintaining Medicare sustainability should be the overriding goal. But MA cannot be the vehicle for addressing the underlying problem of some areas having very high FFS use and poor quality; Medicare must develop and implement separate policies to ensure the efficient and appropriate delivery of high-quality care under the FFS benefit.

The goal of the MA program ought to be to enlist private plans in the task of improving efficiency and quality, thereby reducing Medicare expenditures. This goal is in some sense a return to the original goals of the program, with the important addition of encouraging high quality of care. Ideally, one wants efficient, high-quality plans with innovative delivery systems and care management techniques available in every area where FFS use levels and market conditions allow. Plans that can provide the basic Medicare benefit more efficiently than FFS Medicare by definition can provide extra benefits yet be financially neutral to FFS Medicare. Balancing extra benefits across geographic areas can then be addressed directly as we have described, removing inequity arising from the MA program itself. More plans then could compete with each other on quality and benefits, providing meaningful choices for beneficiaries. ■

Endnotes

1 Administrative costs include items such as member service activities, provider contracting, provider relations, medical management, quality improvement activities, information systems, claims processing, marketing, and other nonmedical costs. These costs vary among plans. Private fee-for-service plans are likely to have high administrative costs associated with claims processing but few costs associated with provider contracting. Generally, an HMO with salaried physicians that owns its own hospitals has little in the way of claims processing costs, while a preferred provider organization has both claims processing and provider contracting costs. Plans that serve employer-group enrollees exclusively generally have much lower marketing costs than plans that enroll Medicare beneficiaries individually.

2 The plan types in MA are:

• HMOs and local PPOs. These plans have provider networks and can use tools such as selective contracting and utilization management to coordinate and manage care. They can choose to serve individual counties and can vary their premiums and benefits across counties.

• Regional PPOs. Regional PPOs are required to serve and offer a uniform benefit package and premium across designated regions made up of one or more states. They are the only plan type required to have limits, or caps, on out-of-pocket expenditures. Regional PPOs have less extensive network requirements than local PPOs.

• PFFS plans (and plans tied to medical savings accounts). These plans typically do not have provider networks. They use Medicare FFS payment rates, have fewer quality reporting requirements, and have less ability to coordinate care than other types of plans.

• Coordinated care plans (CCPs). CCP is a larger grouping that includes all HMOs, local PPOs, and regional PPOs.

3 Actual plan payments, as opposed to payment rates, are risk adjusted. A more detailed description of the MA program payment system can be found at http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_MA.pdf.

4 The update is based on the statutory requirement of subsection 1853(k)(1)(B) of the Social Security Act, which is the national per capita MA growth percentage, adjusted for past over- or underestimates. As of 2007, there is no longer a minimum percentage increase for MA payments (as had been provided for under subsection 1853(c)(1)(C) of the Social Security Act).

5 For example, CMS estimated per capita FFS spending for each county in 2009. To obtain these estimates, CMS calculated per capita FFS spending in each county over five years, 2002 through 2006. The estimated FFS spending is equal to an average for these five years.

6 The statute set benchmarks in Puerto Rico effectively at 180 percent of FFS expenditures. Excluding Puerto Rico from the overall statistics in the updated analysis results in benchmarks of 117 percent (rather than 118 percent) of FFS and puts MA payments at 113 percent (rather than 114 percent) of FFS.

7 Regional PPO plans have different benchmarks than local plans. The uniform region-wide benchmark for such plans is based on county MA payment rates along with a component based on plan bids. See the description in the payment basics document at http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_MA.pdf.

8 The Balanced Budget Act of 1997 set a floor for all counties, which we refer to as the lower floor. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 then created a second floor for counties in urban areas with 250,000 or more residents, which is referred to as the "large urban" floor. In 2009, the lower floor is $741 and the large urban floor is $819.

9 The figures shown in Table 7-1 are based on CMS's estimates of payments in relation to FFS expenditures for 2009. In the rate announcement for 2010 (CMS 2009b), CMS compared the published estimates and updated estimates of per capita Medicare expenditures for 2009. For Part A and Part B of Medicare, for the aged and disabled combined, the ratio of the published estimate to the current estimate was 0.989; that is, FFS expenditures at the U.S. per capita level were underestimated in the published estimate by 1.1 percentage points. This underestimate would mean the ratios of Table 7-1 are overstated. At the same time, however, MA payments in relation to percent of FFS shown in Table 7-1 may be understated because of the differences CMS has observed in coding of diagnoses between MA and the FFS sector. For 2010, CMS will make a downward adjustment to plan risk scores of 3.41 percentage points to reflect the coding differences. (We do not know what adjustment would be applicable to the single year of 2009.) The figures of Table 7-1 are based on values for a person of average risk in each sector—that is, a person with a risk score of 1.0. More extensive coding in the MA sector would understate the level of plan payments when adjusted to a risk score of 1.0. The two adjustments—for the revised estimate of FFS expenditures and an adjustment for risk-coding differences—would therefore work in opposite directions.

Another factor to consider is that there is some interaction between FFS and MA that can affect the comparisons. The MA program can reduce expenditures in the Part D program. Since bids for both stand-alone prescription drug plans and MA drug plan bids make up the overall national average Part D bid and affect Medicare's payments to drug plan sponsors, lower average bids by MA plans somewhat reduce federal program spending for Part D.

10 In past reports, we noted that some of the low HEDIS scores plans reported may reflect poor reporting practices rather than poor quality of care. Poor reporting may occur because payments are not tied to quality and quality ratings may not be important in competition among Medicare plans. In addition, much of the quality data reported by CMS is at the Medicare plan contract level (or "H number" level), including the plan star ratings. As we will discuss in more detail in a separate MIPPA report on quality reporting for MA, contract-level reporting results in some plans having a single score reported for a very wide geographic area. Despite these limitations, the star rating system is a useful indicator of the availability of high-quality plans.

11 Under some circumstances, newer plans or plans with small enrollment may have insufficient information for a star rating to be assigned. For example, they may not have enough members to meet thresholds for HEDIS reporting (MedPAC 2008).

12 We use enrollment numbers for early 2008 because the plan ratings are based on 2007 quality indicators.

13 The statutory basis for the AAPCC is subsection 1876(e)(4) of the Social Security Act, a provision that predates the MA program. Under the MA payment provisions of subsection 1853(c)(1)(D) of the Social Security Act, the AAPCC is to be used as a basis of payment "adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h)" (i.e., excluding graduate medical education payments).

14 Part of the reason fewer beneficiaries enroll in Part B in Puerto Rico is the high cost of the Part B premium in relation to the cost of medical care in the Commonwealth and the income of the population. For example, in 1997, when the monthly Part B premium was $43.80, the published AAPCC rates for Cabo Rojo *municipio* show that per capita Medicare program expenditures averaged $148 per month, consisting of $58 in Part A expenditures and $90 in Part B expenditures. The higher per capita Part B expenditures (expenditures per Part B enrollee compared with Part A expenditures over a larger count of beneficiaries) may indicate that beneficiaries electing Part B are sicker and have higher costs. Outside of Puerto Rico, only one county in the United States had a 1997 per capita Part B expenditure exceeding the Part A level (Banner, Nebraska, with 92 beneficiaries).

15 All other *municipios* are paid based on updates from the floors for Puerto Rico established in the Balanced Budget Act of 1997 (BBA) and revised in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). The BBA established the Puerto Rico floors as 150 percent of the 1997 AAPCC amounts for each *municipio*, and BIPA established a new floor for Puerto Rico (and other areas outside the United States) at 120 percent of the payment rate for the year 2000. The only nonfloor area in Puerto Rico is Culebra *municipio* (an island off the main island), which in 2005 and 2007 had its benchmark set at FFS rates.

16 Most dual eligibles have their Part B premium paid by the Medicaid program. The Commonwealth of Puerto Rico does not have such a "buy in" program for the Part B premium for Medicare–Medicaid duals. Most MA enrollees in Puerto Rico are in special needs plans (SNPs) for dual eligibles—53 percent as of February 2009 (with another 7 percent in chronic care SNPs, many of which have dual eligibles as enrollees). Each organization offering dual SNPs in Puerto Rico has at least one option in which the enhanced benefit (financed by MA rebate dollars) includes a reduction of some or all of the Part B premium.

17 The Congress did, in one instance, provide CMS with very broad authority to establish an alternative payment rate in subsection 1853(c)(3)(D) of the Social Security Act: "Treatment of areas with highly variable payment rates.—In the case of a … payment area for which the annual per capita rate of payment … for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area."

18 However, this solution may lead to more year-to-year variation in MA benchmarks for smaller counties if geographic areas are not reconfigured (as we discuss in the appendix to this chapter).

19 Correlation measures how two variables move in relation to each other. If one variable is relatively high, is the other one relatively high or relatively low? The correlation coefficient (known as r) measures the degree to which two variables move together. It can vary between +1.0 and –1.0. If two variables were perfectly positively correlated, the coefficient would be +1.0, which means the two variables are always high and low together. A coefficient of –1.0 means that when one variable is high, the other variable is always low and vice versa. A coefficient of 0 means they do not vary together at all (no correlation); if one variable were high the other variable would be equally likely to be high or low. Coefficients near 1.0 show high correlation and those near 0 show low correlation.

20 Including FFS as a bidding plan would involve a number of additional design decisions, such as the possible effect on the premiums for the FFS option in a given competitive area.

21 Another option that we describe later, the input-price-adjusted blend option, produces benchmarks that are always between $618 per month and $926 per month. To increase the comparability of the options, we used the minimum from one option as the floor for this option, and the maximum as the ceiling.

22 The original Medicare risk program set payments at 95 percent of FFS. Plans were expected to be more efficient than traditional FFS and to have money left over to provide extra benefits to attract enrollees. Payments were not adjusted to take into account enrollees' health status, so there was some concern about plans selecting healthier than average enrollees and essentially receiving higher payment than the 95 percent number suggests. Although the Medicare risk contracting program was authorized in 1982 legislation (the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)), no "TEFRA risk" plans were able to operate until the payment system was put in place through regulations promulgated in 1985. Predecessors to the MA program are discussed further elsewhere (MedPAC 2001).

23 By design, the statutorily set benchmarks in some localities exceeded FFS spending to encourage plans to enter the MA program in areas they had not traditionally served. The process for setting benchmarks is rooted in a payment system for Medicare's private plan option established in 1997 legislation and modified through later legislation. As a result, MA payment rates in the vast majority of counties are now higher than local per capita spending in the FFS program. CMS is required to make two adjustments to county benchmarks—updates and rebasing—which exacerbates the problem. These adjustments can only raise county benchmarks but never lower them.

References

Baicker, Katherine, and Amitabh Chandra. 2004. Medicare spending, the physician workforce, and beneficiaries' quality of care. *Health Affairs Web Exclusives* (April): W4-184–W4-197.

Brown, Randall, and Marsha Gold. 1999. What drives Medicare managed care growth? *Health Affairs* 18, no. 6 (November–December): 140–149.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009a. Advance notice of methodological changes for calendar year (CY) 2010 for Medicare Advantage (MA) capitation rates and Part D payment policies. Note from Abby L. Block, director, Center for Beneficiary Choices, and Paul Spitalnic, director, Parts C & D Actuarial Group, Office of the Actuary, to Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties. February 20.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009b. Announcement of calendar year (CY) 2010 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies. Note from Jonathan D. Blum, acting director, Center for Drug and Health Plan Choice, and Paul Spitalnic, director, Parts C & D Actuarial Group, Office of the Actuary, to Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties. April 6.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Advance notice of methodological changes for calendar year (CY) 2009 for Medicare Advantage (MA) capitation rates and Part D payment policies. Note from Abby L. Block, director, Center for Beneficiary Choices, and Paul Spitalnic, director, Parts C & D Actuarial Group, Office of the Actuary, to Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties. February 22.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2007. *Health care financing review. Statistical supplement, 2007*. Baltimore: CMS.

Congressional Budget Office. 2008. *Budget options, volume 1: Health care*. Washington, DC: CBO. December.

Dowd, Bryan. 2001. More on Medicare competitive pricing. Letter to the editor. *Health Affairs* 20, no. 1 (January–February): 206–207.

Dowd, Bryan, Robert Coulam, and Roger Feldman. 2000. A tale of four cities: Medicare reform and competitive pricing. *Health Affairs* 19, no. 5 (September–October): 9–29.

Grossman, Joy M., Bradley C. Strunk, and Robert E. Hurley. 2002. *Reversal of fortune: Medicare+Choice collides with market forces*. Issue brief no. 52. Washington, DC: The Center for Studying Health System Change. May.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2005. *Report to the Congress: Issues in a modernized Medicare program*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2003. *Report to the Congress: Variation and innovation in Medicare.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

National Committee for Quality Assurance. 2008. *The state of health care quality 2008*. Washington, DC: NCQA. October.

Oregon Medical Group. 2009. http://www.oregonmedicalgroup.com/patientservices.php?page=insurance.

U.S. House. 2008. Committee on Ways and Means. Rick Foster, CMS Office of the Actuary. *Hearing on the 2008 Medicare trustees report: Hearing before the Subcommittee on Health of the Committee on Ways and Means*. 110th Cong., 2nd sess. April 1. Serial 110–76.

Medicare Advantage payment areas

In the Medicare Advantage (MA) program, an individual county defines a payment area. Each county has a benchmark rate against which MA plans must bid if they want to serve the county. Each year CMS is required to adjust each county's benchmark by a "minimum update" defined as the percentage projected change in overall Medicare expenditures over the preceding year. However, CMS is legally required at least every three years to estimate per capita spending in fee-for-service (FFS) Medicare in each county, which CMS calculates based on a five-year moving average (see text box, pp. 176–177, for description).[1] In the rebasing years when CMS calculates counties' FFS spending, that spending becomes the benchmark if it exceeds the amount that results from the minimum update.

Using counties as payment areas in conjunction with using county-level FFS spending in setting benchmarks creates two problems. First, many counties have small populations in the FFS program. Among these counties, unusually high or low levels of health care use by just a few FFS beneficiaries can cause substantial annual changes in FFS spending. For example, from 2007 to 2009 FFS spending (adjusted for risk) increased by more than 30 percent in Loving County, Texas, which has fewer than 20 FFS beneficiaries.

Large annual changes in county-level FFS spending are a problem because benchmarks based on counties' FFS spending can be either too high or too low. For example, if CMS calculates FFS spending by using data from a year when a county experienced unusually high FFS spending, the county could have a benchmark much higher than its "true" FFS spending. Moreover, the large annual changes that can occur with benchmarks based on FFS spending can make it difficult for plans to formulate long-term business strategies.

Large annual changes in FFS spending are more common in counties with small Medicare populations. For example, 2004 was one of the years when CMS used counties' FFS spending to set county benchmarks. From 2004 to 2005, the average change in county FFS spending was 10.1 percent among the counties with the 10 percent smallest Medicare populations and 5.1 percent among the counties with the 10 percent largest Medicare populations. Relatively unstable payment rates in small counties may make them less attractive to plans than larger, more stable counties.

The second problem that using counties as payment areas presents is that adjacent counties often have very different levels of FFS spending. This situation can be due to one county having an unusually costly year or it can happen because adjacent counties have persistently different costs. In either event, basing benchmarks on FFS spending can result in adjacent counties having very different benchmarks. When that occurs, plans tend to offer more limited benefits in the county with the lower benchmark—or avoid that county altogether—which creates appearances of inequity between adjacent counties (MedPAC 2001).

These two problems are not unique to the current method for setting benchmarks. Any method of setting county benchmarks that bases them on counties' FFS spending has the potential to result in benchmarks with large annual fluctuations and benchmarks for adjacent counties that are substantially different.

The problems can be addressed by any payment area definition that groups contiguous counties into larger geographic units. Such a definition would increase the number of Medicare beneficiaries within payment areas, making FFS spending more stable over time. In addition, grouping contiguous counties would reduce the frequency of having large differences in FFS spending among adjacent counties. Although plans often create service areas that consist of clusters of contiguous counties, these clusters do not address the problems presented by the

county definition of payment areas. Instead, payment areas should be defined groups of contiguous counties and plans should, in general, be required to cover the entire payment area. The Secretary could make exceptions when plans have difficulty maintaining a provider network throughout a payment area.

Developing an appropriate payment area involves more than simply grouping counties, however. When we consider alternative payment areas, we must be attentive to two issues:

- Although we advocate larger payment areas, they must not be so large that the cost of serving beneficiaries varies widely within payment areas.
- Payment areas should closely match the market areas that plans serve.

If a payment area definition fails to address either of these issues, plans may find that their payments exceed their costs in some parts of a payment area and fall short of their costs in other parts. Plans would have an incentive to serve the parts of the payment area where they are profitable and avoid the parts where they are not. However, if Medicare required plans to serve the entire payment area, they could not act on that incentive. In that situation, the potential for financial losses in some parts of a payment area may cause plans to avoid that area altogether, and any definition of payment areas should be mindful of that issue.

Alternative to the county definition of payment areas

In our June 2005 report, the Commission made the following recommendation to address the issues presented by the county definition of payment areas (MedPAC 2005):

The Congress should establish payment areas for MA local plans that have the following characteristics:

- Among counties in metropolitan statistical areas (MSAs), payment areas should be collections of counties located in the same state and the same MSA.
- Among counties outside MSAs, payment areas should be collections of counties in the same state that are accurate reflections of health care market areas, such as health service areas (HSAs).

We refer to this combined use of MSAs and HSAs as the MSA–HSA definition (see text box, p. 213, for a description of HSAs).

In our June 2005 report, the Commission considered several alternatives for combining counties into larger payment areas. The Commission recommended the MSA–HSA definition because it not only addressed the problems presented by the county definition but it was the best match to the market areas served by private-sector plans, so it was likely a better match to the markets served by MA plans. We have no reason to believe plan market areas have substantially changed since the June 2005 report, so we use the MSA–HSA definition as an illustration of how payment areas larger than the county can address the problems presented by counties.

Benefits of larger payment areas

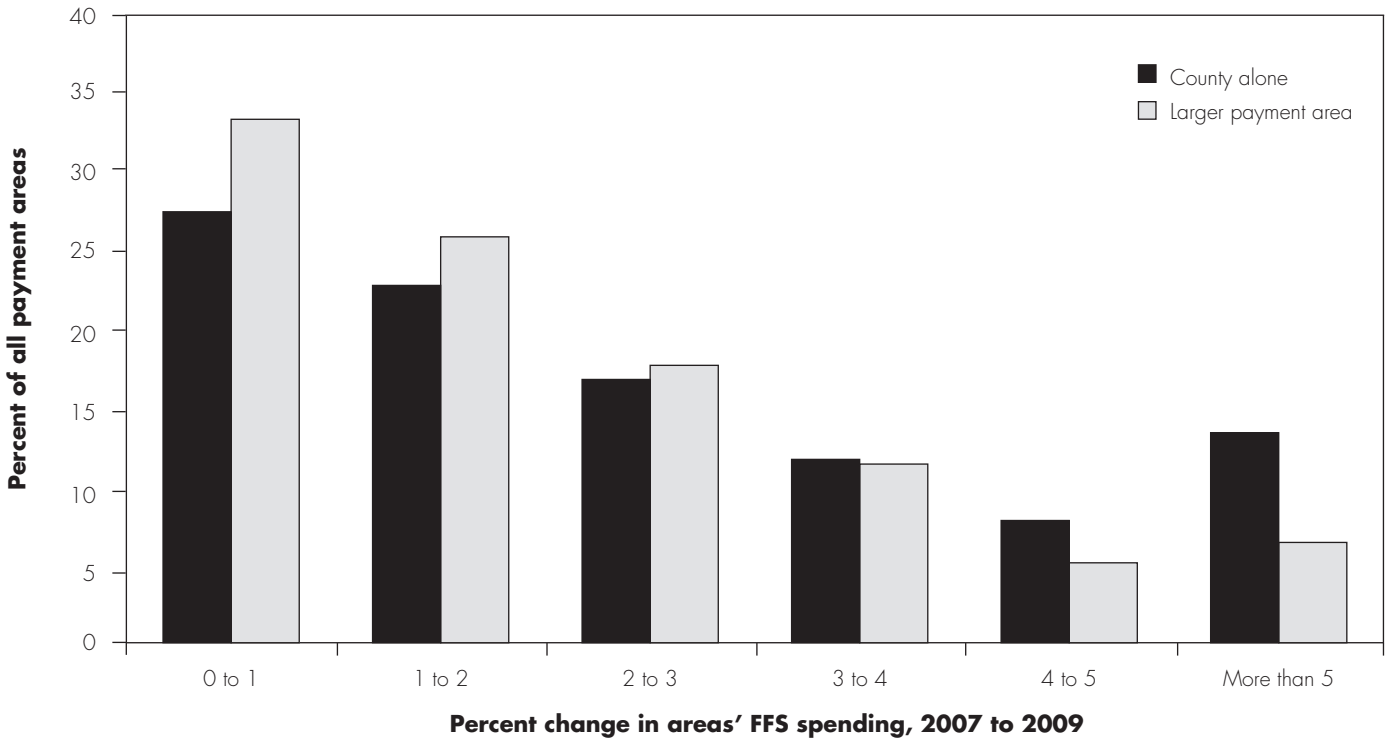
We used CMS's estimates of counties' per capita FFS spending to evaluate how larger payment areas affect stability of FFS spending and the differences in FFS spending between adjacent counties.

To evaluate the stability of FFS spending, we used CMS's estimate of county-level FFS spending that the agency used to set benchmarks in 2007 and 2009. We found that FFS spending is more stable under the MSA–HSA payment areas than under the county payment areas. At the county level, the average change in FFS spending from 2007 to 2009 is 2.0 percent under the MSA–HSA definition but 2.6 percent under the county definition. More important is that the MSA–HSA definition has fewer large annual changes in FFS spending than the county definition. Under the county definition, 13 percent of counties had a change in FFS spending of more than 5 percent from 2007 to 2009 compared with only 6 percent under the MSA–HSA definition. Conversely, 34 percent had a change of less than 1 percent under the MSA–HSA definition compared with 28 percent under the county definition (Figure 7-1A).

Greater stability under the MSA–HSA definition reflects the fact that it would generally increase (and never decrease) the number of beneficiaries in each payment area. Larger payment areas are especially helpful in improving measured stability of FFS spending in the counties with the lowest Medicare enrollment. For the counties with the lowest 10 percent of Medicare enrollment, the average change in per capita FFS spending from 2007 to 2009 is

FIGURE 7–1A

Larger payment areas result in more stable FFS spending



Note: FFS (fee-for-service). Larger payment areas are a combination of counties in a metropolitan statistical area (MSA) for urban counties and health service areas (HSAs) for rural counties. If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. The results reflect absolute values of the percent change in county per capita FFS spending from 2007 to 2009.

Source: MedPAC analysis of county-level per capita FFS spending from CMS.

4.7 percent under the county definition but only 2.8 percent under the MSA–HSA definition.

We also found that large differences in FFS spending between adjacent counties occur half as frequently under the larger payment areas. Under the MSA–HSA definition, 12 percent of counties have an adjacent county with per capita FFS spending at least 15 percent higher. Under the county definition, 24 percent of counties have an adjacent county with per capita FFS spending at least 15 percent higher (Figure 7-2A, p. 212).

CMS should use larger payment areas in the MA program

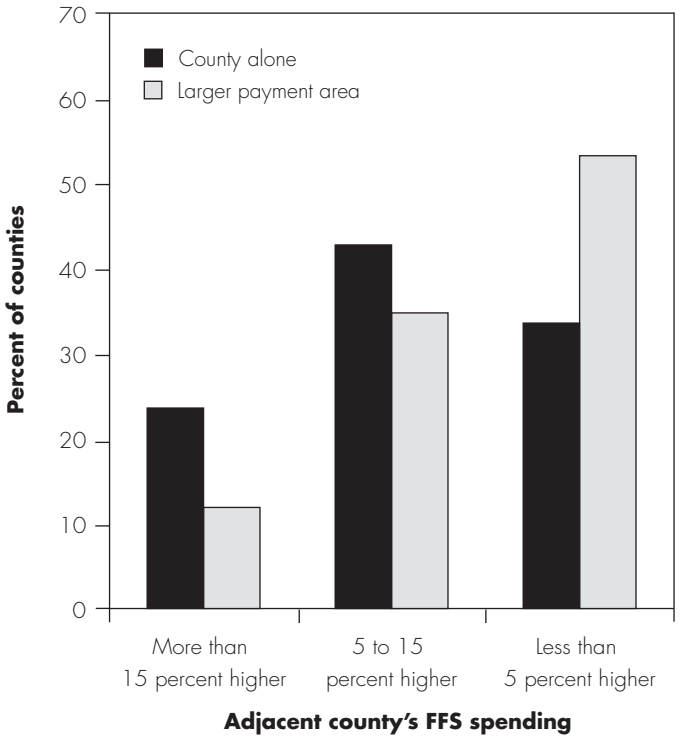
We do not consider the MSA–HSA definition to be an optimal payment area definition, which is to be expected; no single method of grouping counties can perfectly match all plan market areas because markets differ. However, the Commission finds the MSA–HSA definition preferable to the county definition. Moreover, the Commission finds it preferable to other alternatives because it is the best match to plan market areas (see our June 2005 report for analysis).

More recent data indicate the MSA–HSA definition is still a reasonably good match to plan market areas. We have identified two measures that provide a sense of how well a payment area definition matches plan market areas:

- If a plan currently serves at least one county of an MSA–HSA, what percent of the beneficiaries in the MSA–HSA does it serve? For example, if an MSA–HSA has three counties with a total of 500,000 beneficiaries and a plan serves two of these counties that have 400,000 beneficiaries, we would say the plan serves 80 percent of the beneficiaries in the MSA–HSA.
- If a plan serves at least one county in an MSA–HSA, does it serve the entire MSA–HSA?

FIGURE 7–2A

Larger payment areas smooth differences in FFS spending among counties



Note: FFS (fee-for-service). Larger payment areas are a combination of metropolitan statistical areas (MSAs) for urban counties and health service areas (HSAs) for rural counties. If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area.

Source: MedPAC analysis of county-level per capita spending from CMS.

The logic underlying both measures is to identify how likely a plan is to cover an entire MSA–HSA given that the plan has chosen to serve at least one county in the MSA–HSA.

Our analysis indicates that if a plan covers at least one county in an MSA–HSA, it covers 86 percent of the beneficiaries in the MSA–HSA, on average. Also, if a plan covers at least one county in an MSA–HSA, it covers the entire MSA–HSA about 72 percent of the time. We also find that private FFS plans are a little more likely to cover entire MSA–HSAs than are HMOs or local preferred provider organizations (Table 7-1A). (We also examined this issue in relation to the availability of higher quality plans (those with CMS star ratings of 3.5 or higher) and found that 75 percent of those plans cover an entire MSA–HSA (not shown).)

One consequence of larger payment areas is that, relative to current benchmarks, some counties will have higher benchmarks and other counties will have lower benchmarks. Revenue will increase for plans in counties where benchmarks increase and will decrease for plans in counties where benchmarks decrease. It is difficult to say what method the Congress would mandate for setting benchmarks under larger payment areas, but we evaluated what would happen under one possibility: Set the benchmark for each payment area under the MSA–HSA definition equal to a weighted average of the current benchmarks for the counties that make up the payment area. The weights are equal to each county's total Medicare population. We estimate that 20 percent of counties would have lower benchmarks, 31 percent would have higher benchmarks, and 49 percent would have the same benchmark.

The MSA–HSA definition would redistribute MA program spending among counties located in MSAs as well as among counties located outside MSAs. However, spending would not be redistributed from counties outside MSAs to counties located in MSAs, or the other way around, which means that total revenue going to metropolitan counties would not change, nor would total revenue change for nonmetropolitan counties. The way that revenue would be redistributed is an artifact of the way the MSA–HSA definition is constructed. Counties in MSAs are combined with other counties in MSAs. Likewise, counties outside MSAs are combined with other counties outside MSAs.

The MSA–HSA definition also would not redistribute MA program spending among states. Each state would have the same MA revenue as it has under the county definition of payment areas, assuming MA enrollment does not change. This situation again is an artifact of the way the MSA–HSA payment areas are constructed. Counties must be in the same state to be in the same payment area. Therefore, even though revenue is redistributed among counties, it is done among counties in the same state. Therefore, each state has the same amount of MA revenue under the MSA–HSA definition as it has under the county definition.

Because the MSA–HSA definition would redistribute spending among counties, plan participation and beneficiary enrollment would likely change. However, we do not know the extent or magnitude of these changes. Relative to the county definition, the MSA–HSA definition would tend to increase plan participation and beneficiary enrollment in counties whose benchmarks would increase

Defining health service areas

The health service areas (HSAs) we used in our analysis consist of collections of counties in which most of the short-term hospital care received by beneficiaries living in those counties occurs in hospitals in the same collection of counties. Very little short-term care occurs in hospitals outside those counties.

A study by Makuc and colleagues defines the HSAs (Makuc et al. 1991). Their method for grouping counties has the following features:

- They predetermined that the number of HSAs should be about 800. They based this number on previous work that defined health care market areas.
- In the initial step, the number of groups equaled the number of counties (about 3,100).
- In the second step, they combined the two groups (counties) with the greatest "flow" of short-term hospital care among Medicare beneficiaries. They defined flow as the proportion of all hospital stays among beneficiaries in one group that occurs in hospitals in another group.
- In each subsequent step, they combined the two groups with the greatest flow of short-term hospital care.

They continued until they obtained the predetermined number of HSAs. ■

and would decrease plan participation and beneficiary enrollment where benchmarks decrease.

An issue that occurs no matter how we define payment areas is that costs of serving beneficiaries vary within a single payment area. Consequently, some parts of a payment area are more profitable to a plan than other parts. Plans benefit financially if they are able to serve the parts of a payment area where they are profitable and avoid the parts where they are not profitable. To prevent this selection from occurring, plans should, in general, be required to bid on and serve entire payment areas. Provider networks should be required to have reasonably convenient access for enrollees to obtain care in any part of a payment area. Current law largely addresses these issues of enrollees' access by stating that an MA plan must "make their benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits."

However, as payment areas increase in size, it becomes increasingly likely that plans would have difficulty maintaining provider networks throughout a payment area. Therefore, the Secretary should be allowed to make exceptions if plans can prove that it is difficult to maintain provider networks throughout a payment area.[2]

TABLE 7–1A

The MSA–HSA definition of payment areas provides a good match to market areas served by MA plans

	All types of local MA plans	HMOs	Local PPOs	PFFS
If plan serves MSA–HSA, percent of beneficiaries served	86.0%	83.8%	85.7%	87.4%
If plan serves one county of MSA–HSA, likelihood all counties served	71.7	62.2	63.7	74.3

Note: MSA (metropolitan statistical area), HSA (health service area), MA (Medicare Advantage), PPO (preferred provider organization), PFFS (private fee-for-service). The MSA–HSA definition collects metropolitan counties into MSAs and nonmetropolitan counties into HSAs. The HSAs were developed by Makuc et al. (1991).

Source: MedPAC analysis of Medicare Advantage and total Medicare enrollment data for 2008, by county.

One way that plans could try to circumvent rules that require them to serve entire payment areas is to market their products so they target beneficiaries in the parts of a payment area where the benchmark is favorable relative to costs of care. CMS would need to ensure that plans market their products so information about them is widely known throughout each payment area a plan serves.

Finally, no payment area definition is perfect. One problem with the MSA–HSA definition is that payment areas in HSAs may be in noncontiguous counties. Nevertheless, the MSA–HSA definition is better than the current county definition. If the MSA–HSA definition does create noncontiguous payment areas, the Secretary could examine those situations to determine whether to break up an HSA into smaller groups of counties.

On the basis of our assessment of payment areas in the MA program, we reiterate our recommendations from the June 2005 report.

We caution that the HSA definition we used in our analysis is purely for illustrative purposes. Makuc and colleagues defined HSAs by using data from hospital inpatient stays that occurred in 1988 (Makuc et al. 1991). If the Congress chooses HSAs as a payment area, the Secretary should update those HSAs and keep them up to date. The Secretary should use the most recent source data and make sure the updates reflect changes in service areas. The update will be a complicated process, and the Secretary should allow ample time for it to be done properly. ■

Endnotes

1 For example, CMS has estimated per capita FFS spending for each county in 2009. To obtain these estimates, CMS calculated per capita FFS spending in each county over five years, 2002 through 2006. Estimated FFS spending is based on the average for these five years.

2 The Secretary has this authority under the county definition and has used it in these counties: Los Angeles (CA), Kern (CA), Orange (CA), Riverside (CA), and Pinal (AZ).

References

Makuc, D. M., B. Haglund, D. D. Ingram, et al. 1991. *Vital and health statistics: Health service areas for the United States*, Series 2, no. 112. Hyattsville, MD: National Center for Health Statistics. November.

Medicare Payment Advisory Commission. 2005. Report to the Congress: *Issues in a modernized Medicare program.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

CHAPTER 8

Improving Medicare chronic care demonstration programs: Section 150 of the Medicare Improvements for Patients and Providers Act of 2008 report

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Chapter summary

Over the last several years, the Commission and others have examined and expressed serious concerns about persistent gaps in care coordination for beneficiaries enrolled in traditional fee-for-service (FFS) Medicare. The Commission's analyses and work by other researchers suggest that poor care coordination and the growing prevalence of chronic disease have created a large and growing financial strain on the Medicare program and its beneficiaries while undermining the quality of care. The Congressional Budget Office estimated that in 2001 the costliest 25 percent of Medicare beneficiaries accounted for 85 percent of total Medicare spending and that more than 75 percent of these high-cost beneficiaries had one or more of seven major chronic conditions (CBO 2005). The Commission believes we must act expeditiously to find innovative ways to change the misaligned cost and quality incentives in the health care delivery system that contribute to this problem.

The Congress and CMS have initiated a number of demonstration and pilot programs to test different approaches to improve care coordination

In this chapter

for Medicare beneficiaries. Results suggest that some of these programs may have modest effects on the quality of care and mixed impacts on Medicare costs, with most programs costing Medicare more than would have been spent had they not been implemented. In the Medicare Improvements for Patients and Providers Act of 2008, the Congress directed the Commission to study the results of two of the largest Medicare chronic care coordination demonstration and pilot programs and advise the Congress on the feasibility of establishing a "Medicare chronic care practice research network" as another approach to testing models of care coordination for beneficiaries with chronic conditions. The Commission proceeded with the following three issues foremost in mind: the evidence that gaps in care coordination for FFS beneficiaries contribute to the unsustainable rate of growth in Medicare costs and adversely affect the quality of care, the paucity of successful outcomes from the care coordination demonstrations implemented to date, and overarching concerns about the inadequate amount and flexibility of resources committed to Medicare research and development activities. The Commission believes that any proposal must be evaluated in light of all three considerations.

We have reviewed a proposal from a group of 12 health care provider and research organizations called the Medicare Chronic Care Practice Research Network (MCCPRN). The group's members—academic medical centers; providers of care coordination, disease management, or quality improvement services; and long-term care providers—have proposed serving as testing sites to be governed by a board of directors led by CMS, representatives from each site, and possibly other federal agencies such as the Agency for Healthcare Research and Quality (AHRQ). The proposed entity would include an expert advisory panel and several administrative units. The network would be financed by Medicare, and the providers of care coordination services in the network would not be at risk for Medicare benefit cost increases or reductions that were attributable to the network's interventions.

On the basis of our review, the Commission has several key concerns, including the following:

- The initial group of network sites would not be selected competitively through a transparent public process, which could set an undesirable precedent for future proposals.
- The fees paid by Medicare to the network sites for their care coordination interventions would not be at risk for rates of growth in Medicare medical costs that exceeded cost growth rates for a comparison group nor would the sites have the opportunity to share in any savings they may achieve from lower rates of cost growth in the intervention group.
- The role of CMS in selecting research projects and administering the network may not be prominent enough to ensure accountability for the Medicare funds spent on the network's activities, and, if it were, CMS may not have sufficient resources under current funding, which affects the agency's ability to adapt Medicare's administrative infrastructure to comport with many requests of demonstration sites (e.g., providing real-time data and more frequent data feeds, reinstatement of notice of hospital admission, and use of prior authorization).
- The proposed network could duplicate some of the existing financial and administrative resources devoted by AHRQ to its two practice– and delivery-system–based research networks.

While the Commission in this report is not making a recommendation supporting or opposing the specific MCCPRN proposal we reviewed, we look forward to further exploring, in partnership with CMS and interested parties, the feasibility of using practice-based research to advance our shared goal of improving the quality and reducing the cost of care for Medicare beneficiaries with chronic illnesses.

The results of our review suggest larger issues with the structure and funding of research and development in Medicare. Funding levels for

Medicare research activities are low relative to the overall size of the program, CMS often has externally imposed constraints on redirecting research funding as program needs and priorities shift, and administrative process requirements—such as the Medicare demonstration approval process—are time-consuming (Guterman and Serber 2007). In future work, the Commission intends to examine these and other issues that affect how quickly and effectively Medicare can test, implement, evaluate, and disseminate policy innovations that could improve quality and slow the rate of cost growth in FFS Medicare. ■

Background on care coordination in Medicare

Over the last several years, the Commission has examined and expressed serious concerns about persistent gaps in care coordination for beneficiaries enrolled in traditional fee-for-service (FFS) Medicare (MedPAC 2007, MedPAC 2006, MedPAC 2004). The Commission's analyses and work by other researchers suggest that poor care coordination practices and the growing prevalence of chronic disease have created a large and growing financial strain on the Medicare program and its beneficiaries, while undermining the quality of care and frustrating those providers in the health care delivery system who want to do better. Most Medicare beneficiaries with one or more chronic diseases, their families, and in many cases their primary care providers struggle to navigate an increasingly complex and fragmented health care delivery system (Bodenheimer 2008). Care coordination, defined in a recent comprehensive clinical evidence review as "the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services" (AHRQ 2007), has the potential to improve the quality and efficiency of Medicare.

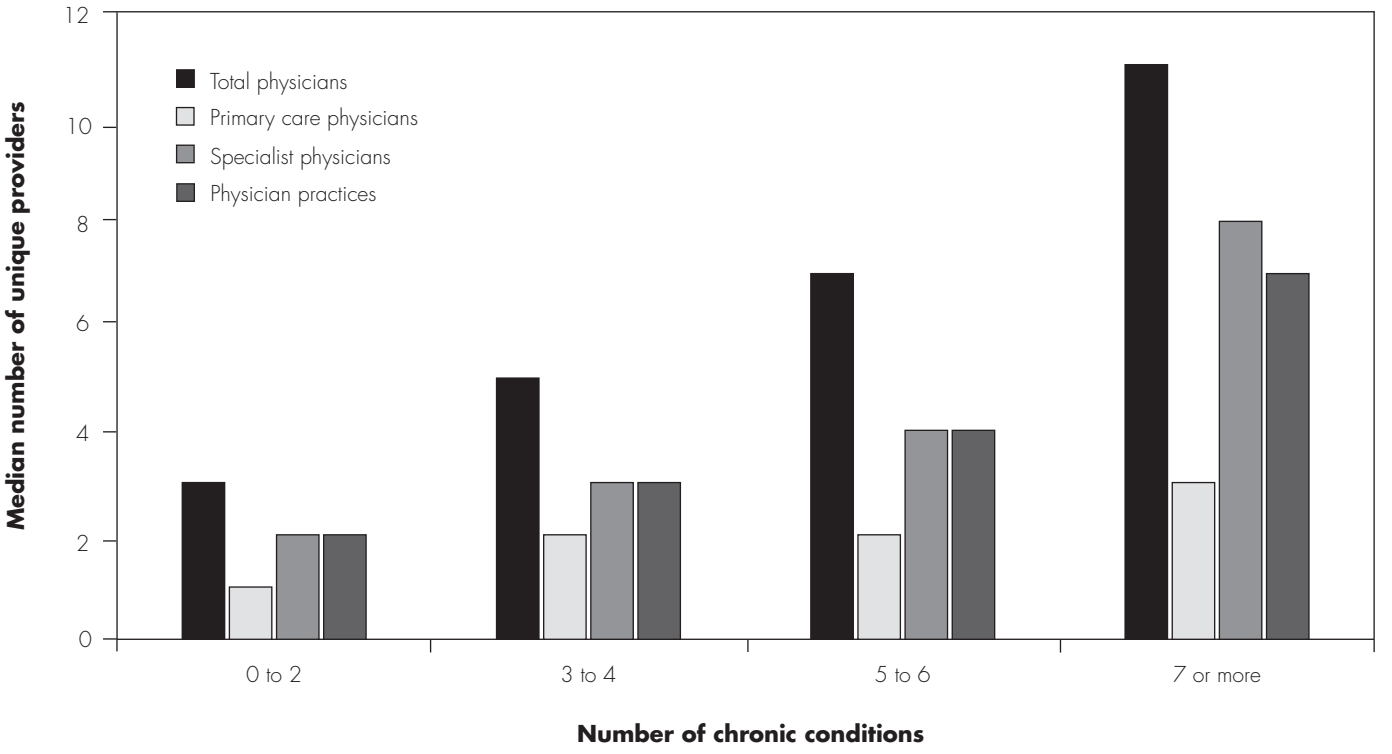
Problems with care coordination are not unique to Medicare. The Institute of Medicine identified care coordination as 1 of 20 national priorities for action to improve quality along its 6 dimensions of making care safe, effective, patient centered, timely, efficient, and equitable (IOM 2003). The National Priorities Partnership has identified care coordination as 1 of 6 areas of focus for its 28-member coalition of key health care stakeholders from the public and private sectors (National Priorities Partnership 2008).[1] In a recent survey of adults in the United States and residents of seven other industrialized countries, respondents in the United States with at least one of seven prevalent chronic diseases reported significantly higher out-of-pocket costs, higher rates of forgoing needed care because of costs, and more instances of poorly coordinated care, such as medical records or test results not being available during a scheduled visit, having tests duplicated unnecessarily, and experiencing lab and diagnostic test errors (Schoen et al. 2008).[2] A recent paper in the *New England Journal of Medicine* summarized 11 studies that involved a range of patient populations and care settings and documented how common care coordination failures are among Medicare and non-Medicare patients and how they negatively affect the quality of care (Bodenheimer 2008).

In Medicare, the challenges presented by chronic disease and the cost and quality consequences of poorly coordinated care are magnified. An estimated 83 percent of Medicare beneficiaries have at least one chronic condition (Anderson 2005). The proportion of beneficiaries with five or more chronic conditions grew from an estimated 31 percent in 1987 to more than half of all Medicare beneficiaries by 2002 (Thorpe and Howard 2006b).[3] These beneficiaries must navigate a daunting number of provider relationships, treatment decisions, and follow-up prescriptions. One study estimated that beneficiaries with 5 or more chronic conditions see an average of 13 physicians and fill an average of 50 prescriptions per year (Anderson 2005). A Commission analysis of 2003 Medicare claims data found that an average Medicare beneficiary saw 5 different physicians that year, but 61 percent of those diagnosed with three common chronic conditions—coronary artery disease (CAD), congestive heart failure (CHF), and diabetes—saw 10 or more different physicians that year. A study by researchers at the Center for Studying Health System Change found similar patterns of care being increasingly dispersed across more physicians and more practices as the number of chronic conditions per beneficiary increased (Figure 8-1, p. 224) (Pham et al. 2007).

The financial impact on the Medicare program and on beneficiaries with multiple chronic conditions is significant and growing. In 2002, treatment costs for beneficiaries with five or more chronic conditions accounted for three-quarters of total spending (including out-of-pocket and other costs); beneficiaries with three or more conditions accounted for about 93 percent of total spending (Thorpe and Howard 2006b).[4] A Congressional Budget Office (CBO) analysis of high-cost Medicare beneficiaries found a link between the prevalence of chronic conditions and high expenditures (CBO 2005).[5] CBO estimated that about 30 percent of high-cost beneficiaries had four chronic conditions—CAD, CHF, diabetes, and chronic obstructive pulmonary disease (COPD). A Commission analysis in 2004 found that 70 percent of inpatient hospital spending was for beneficiaries with three chronic conditions—CAD, CHF, and diabetes.

The Commission and others have noted for several years that the FFS payment systems in Medicare exacerbate the clinical challenges of treating and managing patients with multiple chronic conditions (Berenson and Horvath

FIGURE 8–1 **Beneficiaries with more chronic conditions are treated by greater number of physicians**



Source: Pham et al. 2007.

2003, Bodenheimer 2008, Lawrence 2005, MedPAC 2006, Sochalski et al. 2009, Tynan and Draper 2008, Wolff and Boult 2005). Medicare was designed as insurance against the costs of diagnosis and treatment of relatively short-duration illnesses, and it largely remains organized that way almost 45 years after its implementation. By their structure, Medicare's FFS policies perpetuate the traditional "silos" of care delivery settings (e.g., hospital services, physician services, post-acute care services) and create incentives for providers within each of those silos to treat beneficiaries with an increasing volume and intensity of services. At the same time, the program's payment incentives discourage providers from engaging in the labor-intensive and time-consuming tasks of coordinating and managing care for beneficiaries with one or more chronic conditions. The poor alignment between the financial incentives in FFS Medicare and the care coordination needs of beneficiaries with one or more chronic conditions can leave these beneficiaries at risk for poor outcomes, including acute exacerbations of their chronic disease and potentially preventable hospital admissions and readmissions.

Given the lack of compelling evidence to support the effectiveness of any single definitive approach to care coordination interventions (AHRQ 2007), the Congress and CMS initiated several demonstration and pilot programs over the past decade that took a variety of approaches to find out what does and does not work in improving care coordination for beneficiaries with one or more chronic illnesses. As part of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provision that directed the Commission to undertake this study, the Congress specifically required us to examine two of the initiatives: the Medicare Coordinated Care Demonstration and the Medicare Health Support pilot (see text box). We believe it is also informative to look at the results to date of two ongoing demonstrations that use different types of care coordination interventions to improve quality of care and reduce costs: the Care Management for High-Cost Beneficiaries (CMHCB) demonstration and the Physician Group Practice (PGP) demonstration.

Section 150 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on the feasibility and advisability of establishing a Medicare Chronic Care Practice Research Network that would serve as a standing network of providers testing new models of care coordination and other care approaches for chronically ill beneficiaries, including the initiation, operation, evaluation, and, if appropriate, expansion of such models to the broader Medicare patient population. In conducting such study, the Commission shall take into account the structure, implementation, and results of prior and existing care coordination and disease management demonstrations and pilots, including the Medicare Coordinated Care Demonstration Project under section 4016 of the Balanced Budget Act of 1997 (42 U.S.C. 1395b–1 note) and the chronic care improvement programs under section 1807 of the Social Security Act (42 U.S.C. 1395b–8), commonly known as ''Medicare Health Support''.

(b) REPORT.—Not later than June 15, 2009, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a). ■

Review of Medicare care coordination demonstration and pilot programs

For each of the four Medicare care coordination demonstrations and pilots reviewed, we examined program structure; implementation details; and results achieved in terms of cost, quality, and current program status.

Medicare Coordinated Care Demonstration

Section 4016 of the Balanced Budget Act of 1997 mandated that the Secretary conduct a demonstration project to evaluate whether methods of care coordination could improve the quality of care and reduce Medicare expenditures for beneficiaries enrolled in FFS Medicare.

Structure

In 2000, CMS released a request for proposals to solicit organizations to participate in the Medicare Coordinated Care Demonstration (MCCD). CMS sought applicants with experience operating disease management programs who could present evidence of decreased hospitalizations, decreased costs, or both. Each applicant was allowed to define its own intervention and target population within broad parameters established by CMS. In January 2002, CMS selected 15 of 58 proposals to participate in the demonstration (Table 8-1, p. 226). These 15 programs served a variety of target populations in 16 states and the District of Columbia:

- Five programs served beneficiaries in rural areas.
- Six programs targeted beneficiaries with single conditions, including four targeting beneficiaries diagnosed with CHF, one targeting those with CAD, and one targeting those with cancer.
- One program targeted people with both CAD and CHF.
- Eight programs targeted beneficiaries diagnosed with multiple chronic diseases (Brown et al. 2007).

Implementation

Between April and September 2002, each program began enrolling patients on a voluntary basis. As of June 30, 2005, the programs had enrolled about 18,400 beneficiaries, who were randomly assigned upon enrollment into either a treatment group or a control group for each site. The size of the treatment groups across the MCCD sites as of June 2005 ranged from 92 (University of Maryland) to 1,511 (CorSolutions), with most sites (9 of 15) having treatment groups of between 400 and 750 beneficiaries. Notable characteristics of the beneficiaries enrolled in the programs include:

- Four programs (Avera, Charlestown, Hospice of the Valley, and Jewish Home and Hospital) had from 20 percent to more than 40 percent of their enrollment

TABLE 8–1

Baseline characteristics of Medicare Coordinated Care Demonstration sites and enrolled beneficiaries

Project site sponsor	Sponsor location	Sponsor type	Beneficiary location	Rural/ urban	Targeted diseases	Total number of beneficiaries enrolled through June 2005	Medical use during the year before randomization	
							Average annualized number of hospitalizations	Average monthly Medicare expenditures
Carle Foundation Hospital	Urbana, IL	IDS	Eastern IL	Rural	Various chronic conditions	2,657	0.52	$590
CorSolutions, Medical, Inc.	Buffalo Grove, IL	DM/CC provider	Houston, TX	Urban	CHF	2,646	2.60	2,934
Washington University	St. Louis, MO	AMC	St. Louis, MO	Urban	Various chronic conditions	2,289	1.88	2,311
Health Quality Partners	Doylestown, PA	DM/CC provider	Eastern PA	Both	Various chronic conditions	1,466	0.32	476
CenVaNet	Richmond, VA	DM/CC provider	Richmond, VA	Urban	Various chronic conditions	1,445	0.76	862
QMED, Inc.	Laurence Harbor, NJ	DM/CC provider	Northern CA	Urban	Coronary artery disease	1,406	0.30	539
Medical Care Development	Augusta, ME	Hospital	ME	Rural	Heart conditions	1,329	1.38	1,495
Hospice of the Valley	Phoenix, AZ	Hospice	Maricopa County, AZ	Urban	Various chronic conditions	1,048	1.65	2,059
Mercy Medical Center	Mason City, IA	Hospital	Northern IA	Rural	Various chronic conditions	934	1.43	1,356
Jewish Home and Hospital	New York, NY	LTC provider	New York City	Urban	Various chronic conditions	872	0.86	1,629
Avera McKennan Hospital	Sioux Falls, SD	Hospital	SD, IA, MN	Rural	CHF	858	2.18	1,725
Charlestown Retirement Communities[a]	Baltimore, MD	Retirement community	Baltimore County, MD	Urban	Various chronic conditions	830	0.89	1,108
Georgetown University Medical Center[b]	Washington, DC	AMC	DC, MD suburbs	Urban	CHF	230	3.01	2,898
Quality Oncology, Inc.[c]	McLean, VA	DM/CC provider	Broward County, FL	Urban	Cancer	211	0.88	2,303
University of Maryland[d]	Baltimore, MD	AMC	Baltimore, MD	Urban	CHF	181	2.28	2,945
Medicare total in 2003	N/A	N/A	Entire US	Both	N/A	42.3 million	0.30	552

Note: IDS (integrated delivery system), AMC (academic medical center), DM/CC provider (provider of disease management, coordinated care, or quality improvement services), LTC (long-term care), CHF (congestive heart failure), AMI (acute myocardial infarction), N/A (not applicable).
a. Demonstration ended 3/31/06.
b. Demonstration ended 12/31/05.
c. Demonstration ended 8/31/06.
d. Demonstration ended 6/30/06.

Source: Peikes et al. 2009, Peikes et al. 2008.

composed of beneficiaries age 85 or older, compared with about 11 percent of all Medicare beneficiaries.

- All but three programs enrolled no or a relatively small proportion (compared with Medicare overall) of beneficiaries under age 65—that is, those eligible on the basis of disability. However, in one program (Washington University), about 26 percent of enrollees were under age 65, compared with about 14 percent for Medicare overall.
- Six sites had a higher than average percentage of enrollees who were dual eligibles (Medicare beneficiaries who are also enrolled in Medicaid), while five of the seven largest sites had a smaller than average percentage of dual-eligible enrollees.
- Six sites, including two of the largest, enrolled a much higher than average percentage of beneficiaries identified as black/non-Hispanic, ranging from about 15 percent to 63 percent of the site's enrollees, compared with about 10 percent of Medicare beneficiaries overall. Eight of the nine other sites had smaller than average percentages of beneficiaries identified as black/non-Hispanic, ranging from 0 percent to about 5 percent of their enrollment.
- As expected, enrollees in most programs had high rates of hospitalizations and high monthly expenditures the year before their enrollment compared with Medicare overall. However, two sites (Health Quality Partners and QMed) enrolled beneficiaries with prior-year hospitalization rates and average monthly expenditures that were about the same as the average for all Medicare enrollees (Peikes et al. 2009).

Treatment intervention protocols varied widely across sites, but many shared certain strategies and characteristics. For instance, all the programs assigned patients to a care coordinator who assessed their needs and used that information to develop patient care plans. In all but one program, the care coordinators were required to be registered nurses (the other program used licensed practical nurses). All the programs routinely contacted patients, primarily by telephone, with four programs also contacting patients in person nearly once a month. Eleven programs contacted patients from 1 to 2.5 times per month, and 3 programs contacted patients from 4 to 8 times per month (the remaining program did not report complete data on contacts).

Almost all the programs relied on patient education as the foundation of their interventions. Within each program, the interventions used standardized curricula based on established guidelines designed to improve patients' diets, exercise regimens, and adherence to medications. Most programs evaluated the effectiveness of their patient education interventions by reviewing clinical indicators or home monitoring data for evidence of improved health, by asking patients to report changes in behavior, or by testing patients' knowledge of the curricula. Most programs tried to minimize demands on physicians and their office staff and focused primarily on patient-centered approaches to care coordination. Ten programs paid physicians either a monthly stipend per patient or a fee for participating in meetings or for sharing medical records with care coordinators (Peikes et al. 2008).

With regard to information about whether the programs affected the costs or quality of care while the interventions were under way, some program sites reported that there was little opportunity for them to perform interim or process evaluations that they could use to change their programs' directions or strategies. Similar to experiences reported by sites in other demonstrations, some of the MCCD sites reported that CMS and its claims-processing contractor could not provide timely data about program participants' use of Medicare services such as inpatient admissions and emergency department visits, which could have been used to inform ongoing adjustments to program interventions (MCCPRN 2008a). However, nine of the programs implemented their own procedures to learn about hospitalizations quickly, either by having hospitals notify program staff when they admitted a program's patients, having program staff review hospital and emergency room admission lists, or following up when a patient did not submit a telemonitoring report (Peikes et al. 2008).

Results

The *Third Report to Congress on the Evaluation of the Medicare Coordinated Care Demonstration* reflects four years of program implementation experience (Peikes et al. 2008). The evaluation estimated the impacts of each of the 15 programs on Medicare costs and several quality measures and assessed which program features appeared to be associated with program success. The evaluation concluded that "most of the care coordination programs tested … had limited or no improvements in quality of care, few achieved cost neutrality, and none reduced total Medicare expenditures when care coordination fees were included." Five of the programs (Georgetown University,

Health Quality Partners, Medical Care Development, QMed, and Quality Oncology) had modest favorable effects on some quality indicators without significantly increasing total Medicare expenditures. An analysis of the differences between more and less successful programs generated little information about best practices, and Mathematica Policy Research, Inc., concluded that "no particular program types or target populations were consistently associated with favorable cost and quality outcomes." Overall, the programs appeared to have no consistent discernible effect on participating beneficiaries' behaviors and outcomes except receipt of health education (Peikes et al. 2008).

Costs Mathematica's evaluation of the financial outcomes of the programs found that none significantly reduced Medicare expenditures, even without counting the care coordination fees paid (Peikes et al. 2009). Medicare paid a negotiated fee to each program ranging from $80 to $444 per beneficiary per month (PBPM). For total Medicare spending including care coordination fees, treatment groups for 9 of the 15 programs had significantly higher spending—ranging from 8 percent to 45 percent higher—than the control groups (Table 8-2). For the remaining six programs, the differences in total spending between treatment and control groups were statistically indistinguishable from zero.

Examination of the use of inpatient hospital services revealed that only 2 of the 15 programs (Georgetown University Medical Center and Mercy Medical Center) had lower hospitalization rates in their treatment groups by a statistically significant amount (–24 percent and –17 percent, respectively). However, one of these sites, Mercy Medical Center, had statistically significantly higher total Medicare costs (11 percent) relative to the control group. This result was due to the relatively large ($236 PBPM) care coordination fee that Medicare paid this program not being fully offset by savings from lower Medicare spending for the treatment group.

Quality of care and patient satisfaction None of the programs had favorable effects on any of the adherence measures tracked for the intervention group, and there were only a few scattered statistically significant positive outcomes on the 18 self-reported and claims-based process-of-care quality indicators. Surveys conducted on patients in the 12 programs with more than 300 enrollees by the end of their first year and on physicians in all 15 programs suggest that the programs were popular with beneficiaries and providers. The latest evaluation of the demonstration, however, reported that one in seven control group members surveyed said they had received care coordination services (i.e., they thought they had been affected by the intervention even though they were in the control group) and one in three treatment group members stated they had not received care coordination services. To the extent that these self-reported statistics accurately reflect the unintentional spillover of the interventions to the control group and their less than complete penetration into the intervention group, the programs would have had to have proportionally greater impacts on the beneficiaries with whom they did intervene to demonstrate statistically significant impacts on their satisfaction with care compared with the control group.

Current status of MCCD In January 2008, CMS reached agreements with two of the MCCD sites—Health Quality Partners and Mercy Medical Center—to continue their programs for another two years, with payment rates consistent with the estimated savings in Part A and Part B expenditures for each program as reported in the third report to the Congress (Peikes et al. 2008). Mathematica is expected to deliver a fourth and final evaluation of the MCCD to CMS in 2010.

Medicare Health Support pilot

Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized a phased-in pilot program to test voluntary programs in chronic care improvement designed to improve the quality and control the growth in costs of care for FFS beneficiaries diagnosed with at least one of three chronic illnesses: CHF, diabetes, and COPD. Originally named the Chronic Care Improvement Program, CMS renamed it Medicare Health Support (MHS) shortly before program implementation in 2005.

The Congress set out a two-phase model for MHS. First, sites would be selected for a pilot phase to test various interventions targeting CHF, diabetes, and COPD. If these pilot programs proved successful, the Secretary could authorize expanding the program's successful elements into the Medicare program without further congressional authorization. Expansion into the second phase of the pilot was contingent on findings determined by an independent evaluation contractor for CMS that the programs, or components of them, resulted in improvements in clinical quality of care and beneficiary satisfaction and achieved target savings. At first, the savings target was set at 5 percent, including the fees paid to the participating

TABLE 8–2

Most Medicare Coordinated Care Demonstration sites increased Medicare costs relative to control group

Project site sponsor	Sample size through June 2005		Average number of follow-up months through June 2006	Average monthly program fee received	Impact (as percentage of control group mean)		
						Monthly Medicare expenditures	
	Treatment group	Control group			Annualized number of hospital admissions	Excluding care coordination fees	Including care coordination fees
University of Maryland[a]	92	89	23.5	$268	–7.3%	35.3%[e]	45.4[f]%
Charlestown Retirement Communities[b]	413	417	30.5	215	19.0[f]	18.6[f]	40.6[f]
Carle Foundation Hospital	1,338	1,319	37.0	148	4.2	8.7	30.1
Jewish Home and Hospital	435	437	30.8	227	11.2	9.9	23.0[f]
Avera McKennan Hospital	430	428	25.4	270	–1.8	–2.7	17.0[f]
CenVaNet	722	723	35.2	72	5.9	4.6	13.0[f]
Washington University	1,150	1,139	29.3	155	–1.4	4.5	12.9[f]
Mercy Medical Center	467	467	32.6	236	–17.1[f]	–9.3	11.1[e]
Hospice of the Valley	531	517	20.4	177	–7.2	0.9	9.6[e]
QMED, Inc.	707	699	37.7	83	1.4	–2.2	9.0
CorSolutions, Medical, Inc.	1,511	1,135	25.2	215	–3.2	0.6	8.2[e]
Health Quality Partners	740	726	30.1	103	–11.4	–11.9	2.8
Medical Care Development	669	660	26.2	134	–3.4	–6.0	1.7
Quality Oncology, Inc.[c]	107	104	18.4	60	4.4	–1.1	0.8
Georgetown University Medical Center[d]	115	115	27.7	240	–24.0[e]	–14.0	–4.4

Note: a. Demonstration ended 6/30/2006.
b. Demonstration ended 3/31/2006.
c. Demonstration ended 8/31/2006.
d. Demonstration ended 12/31/2005.
e. Indicates a statistically significant difference between the treatment and control group averages at a 90 percent confidence interval.
f. Indicates a statistically significant difference between the treatment and control group averages at a 95 percent confidence interval.

Source: Peikes et al. 2009.

TABLE 8–3

Medicare Health Support organizations served diverse geographic areas and most ended early

Medicare Health Support organization	Beneficiary location	Launch date	Termination date	
			Revised	Original
Healthways	Maryland and DC	8/1/2005	N/A	7/31/2008
Lifemasters Supported SelfCare	Oklahoma	8/1/2005	12/31/2006	7/31/2008
Health Dialog Services	Pennsylvania (western region)	8/15/2005	N/A	8/14/2008
McKesson Health Solutions, LLC	Mississippi	8/22/2005	5/31/2007	8/21/2008
Aetna Life Insurance Company	Chicago, IL (surrounding areas)	9/1/2005	N/A	8/31/2008
CIGNA Health Support	Georgia (northern region)	9/12/2005	1/14/2008	9/11/2008
Green Ribbon Health*	Florida (west-central region)	11/1/2005	8/15/2008	10/31/2008
XLHealth Corporation	Tennessee (selected counties)	1/16/2006	7/31/2008	12/31/2008

Note: N/A (not applicable).
*Partnership between Humana and Pfizer Health Solutions.

Source: McCall et al. 2008.

Medicare Health Support Organizations (MHSOs); that is, the MHSOs would have had to reduce Medicare spending for their assigned intervention group by 5 percent plus an additional percentage equal to the monthly fees they were paid by Medicare. CMS later amended this requirement after the Office of Management and Budget approved the less stringent condition of budget neutrality.

Structure

CMS selected programs to participate in MHS through a competitive solicitation process. In their bids, applicants were required to provide a rationale for the geographic areas of operations selected; the clinical focus of their targeted populations; a description of their proposed chronic care improvement programs, which was expected to comply with statutory programmatic requirements; proposed fee amounts; and measures of and performance guarantees for clinical quality and beneficiary satisfaction.

CMS selected nine programs to participate in the pilot, and eight programs chose to proceed with implementation (Table 8-3). All eight programs targeted beneficiaries with diabetes, CHF, or both; none of the programs specifically targeted beneficiaries with COPD.

CMS used Medicare claims data to identify Medicare FFS beneficiaries diagnosed with heart failure (HF) or diabetes or both and a hierarchical condition categories (HCC) score of 1.35 or greater.[6] Excluded from the sample were beneficiaries with end-stage renal disease and those enrolled in a Medicare Advantage plan, a CMS-sponsored Medicare FFS chronic care demonstration, or hospice care. After identifying eligible beneficiaries, CMS used block randomization to assign 30,000 of them to intervention and comparison groups in a ratio of 2:1 in each geographic area. Beneficiary names, addresses, available demographic data, available telephone numbers from Social Security Administration records, and Medicare claims from 2003 and 2004 for the intervention group were provided to each MHSO before the start date of the MHS operations. CMS sent eligible beneficiaries in the intervention groups a letter from Medicare introducing the program and provided approximately two weeks to opt out of being contacted by the MHSO. MHSOs were then permitted to contact beneficiaries to confirm their willingness to participate in the program and begin providing services (McCall et al. 2007).

Across the entire population of MHS eligible beneficiaries, the program's independent evaluators observed high levels of comorbidity during the year prior to randomization. Almost one-half of the MHS eligible beneficiaries had diagnoses of CAD; almost one-third had diagnoses related to respiratory diseases, such as COPD; 15 percent to 20 percent had evidence of acute or chronic renal disease; and roughly 10 percent had diagnoses related to valve disorders, cardiomyopathy, peripheral vascular disease, and renal failure. In the groups of beneficiaries randomly assigned to the MHSOs, average HCC scores ranged from 2.2 to 2.6, and average PBPM total Medicare payments ranged from $1,209 to $1,524 in the year

before randomization. About one-half had the threshold condition of diabetes only, and about one-quarter each had HF only and HF with diabetes. Rates of all-cause hospitalizations across all beneficiaries originally randomized to the intervention group ranged from 633 to 935 per 1,000 beneficiaries, but only a small fraction of these admissions were for the principal reason of HF or diabetes. Rates of all-cause emergency room (ER) visits for these beneficiaries ranged from 732 to 1,448 per 1,000 beneficiaries and very few of these ER visits were principally for HF or diabetes (McCall et al. 2008, McCall et al. 2007).

Implementation

During the initial six-month outreach period, MHSOs received a negotiated monthly management fee for all assigned beneficiaries except those who declined participation or were deemed ineligible before the program started. After the initial six-month period, each MHSO received a monthly fee for each actual participant. All fees paid to the MHSOs were at risk for the clinical and financial performance of the full population randomized to the intervention group whether the beneficiaries in this group elected to participate in the MHSOs' programs or not. This model was designed to provide strong incentives for MHSOs to develop and implement effective outreach and intervention strategies. To keep all their management fees, MHSOs had to reduce Medicare costs for the entire intervention group by at least the amount of the accrued fees—that is, achieve budget neutrality. To the extent that the MHSOs actually engaged only a portion of their assigned populations, they would have had to achieve a greater percentage savings on this portion to have met the overall budget-neutrality requirement. CMS also required MHSOs to put a portion of their fees at risk for several clinical process-of-care measures and one patient satisfaction measure (McCall et al. 2008).

During an initial six-month outreach period, MHSOs were expected to contact all their assigned beneficiaries to encourage participation in their programs. MHSOs recruited participants systematically, rather than randomly, but used varied methods across sites and target populations to engage potential participants (McCall et al. 2007). Most programs ranked beneficiaries as being at immediate, high, or moderate risk for adverse events, in order to target interventions accordingly and ideally maximize the effects of their program interventions and ultimately cost savings. More than three-quarters of all intervention beneficiaries verbally consented to participate in the MHS program during the first 18 months of the pilot. MHSOs were unable to contact between 4 percent and 15 percent of their assigned beneficiaries.

The independent evaluations of the MHS observed that the populations randomly assigned to the MHSOs had on average high HCC scores, high rates of acute care and ER use, and high total Medicare costs (as, by design, did the comparison group), but they also found that the beneficiaries assigned to the intervention group who then actually agreed to enroll in the MHSOs' programs were on average healthier and had lower Medicare costs than the intervention group overall (McCall et al. 2008, McCall et al. 2007). The evaluations found several statistically significant differences between beneficiaries who were assigned to the intervention group but who chose not to enroll in an MHSO or who could not be contacted (referred to as nonparticipants) and beneficiaries who chose to enroll when contacted by an MHSO (referred to as participants). These differences between nonparticipants and participants included the following:

- In all but one of the MHSOs, the proportion of participating beneficiaries with Medicaid coverage was between 3 percentage points and 14 percentage points lower than among nonparticipants, suggesting that most of the MHSOs were not as successful in recruiting Medicare–Medicaid dual eligibles to participate.
- Six of the MHSOs had lower rates of Medicare beneficiaries under age 65 (i.e., beneficiaries with disabilities) among participants than nonparticipants.
- Five MHSOs had lower rates of African American beneficiaries as participants than nonparticipants, while three had higher rates.
- Across all the MHSOs, average HCC risk scores for one year before MHS start-up were 20 percent to 40 percent lower for participants than for nonparticipants.
- All-cause hospitalization and ER visit rates during the year before MHS start-up were significantly lower for beneficiaries who became participants than for those who chose not to participate. Depending on the MHS site, all-cause hospitalization rates for participants in the year before program start-up were lower by 196 to 631 per 1,000 beneficiaries, and ER visit rates were lower by 41 to 568 per 1,000 beneficiaries.
- Average Medicare spending PBPM for participants was $267 to $792 lower in the year before start-up than it was for nonparticipants.

Although the MHSO participants still had higher HCC scores, rates of acute care utilization, and total Medicare costs than the average for the Medicare population overall, this phenomenon of the MHSOs enrolling relatively healthier members of their assigned intervention groups had an important implication for budget neutrality. Because the pilot design was an intent-to-treat model, the MHSOs' engagement of less costly intervention beneficiaries required the MHSOs to have a larger effect on participants to achieve the required savings (McCall et al. 2008).

Each of the MHSOs conducted a comprehensive health assessment after beneficiaries agreed to participate. Assessments varied substantially across sites. However, all sites used the information garnered during initial patient health assessments to help determine the type and level of intervention to deliver and to set self-management goals (McCall et al. 2008). All MHS programs focused on providing telephonic care management services and all included the following additional patient services components:

- intensive case management for beneficiaries identified as high cost
- patient education and skill building
- medication management and support
- referrals for provision of community-based services

The MHSOs received monthly CMS claims data for their intervention group participants, and comparison group data were provided to the MHSOs quarterly, both in aggregate reports and as de-identified claims data sets. Some MHSOs developed other data strategies to enhance their ability to manage MHS operations by obtaining hospital and nursing home inpatient census, Medicare claims, or other administrative data on a more frequent basis, including in some cases negotiating data-sharing agreements with Medicare carriers, fiscal intermediaries, or other major health care partners. Other MHSOs relied primarily on the data provided from CMS and its MHS contractors. By the middle of year 2 of the pilot, the operating MHSOs received CMS data on Part D prescription drug events and used them to different degrees to better understand the clinical conditions of their participants and to look for drug–drug interactions (McCall et al. 2008).

Results

The findings of the most recent independent evaluation and report to the Congress on MHS are based on the first 18 months of implementation and the experience of approximately 290,000 chronically ill Medicare beneficiaries randomized to the program's intervention and control groups in 8 geographic areas (there were approximately 30,000 intervention and control group members in each of 8 MHSOs' original populations and between 4,000 and 8,000 intervention and control group members in each of 7 MHSOs' refresh populations).[7] According to this report, MHS is the largest randomized experiment to date of population-based care management (McCall et al. 2008). The report concluded with five key findings:

- Several vulnerable subpopulations of Medicare FFS beneficiaries were less likely to agree to participate in the MHS pilot program. The programs' difficulty in engaging sicker, more costly beneficiaries raises questions about the success of a broad, population-based approach to Medicare chronic disease management.
- The level of interventions provided in these programs with the participating beneficiaries is unlikely to produce significant behavioral change and savings.
- There was limited effect in improving beneficiary satisfaction, care experience, self-management, and physical and mental health functioning during the first 18 months.
- Seven of the MHSOs had a positive intervention effect on one or more process-of-care measures, such as cholesterol and blood glucose screening, but had no positive effect on reducing acute care utilization or mortality. There were no statistically significant decreases in hospital admission or readmission rates or ER visits in the intervention groups.
- Through the first 18 months of the program, cumulative fees paid to MHSOs far exceeded savings produced, making it very difficult for MHSOs to reduce Medicare Part A and Part B costs in the remaining 18 months of the pilot by the amount needed to offset the fees paid and achieve budget neutrality.

Costs Table 8-4 summarizes the individual financial outcomes of each MHSO through the first 18 months of the program. Before taking into account the fees paid to the MHSOs, four of them had average Medicare expenditures for their intervention group that were 1.0 percent to 2.1 percent lower than expenditures for the

comparison group on a PBPM basis, while the other four MHSOs had costs higher than or no different from costs in the comparison group. After factoring in the negotiated monthly fees that Medicare paid to the MHSOs, each pilot program cost Medicare more than it would have spent in the absence of the pilot. Across the programs, net costs to Medicare ranged from 3.5 percent to 9.4 percent of PBPM costs of the comparison group ($50 to $130). None of the observed differences in costs between the intervention and comparison groups was statistically significant. CMS will conduct a final financial reconciliation to determine each MHSO's actual refund obligation (McCall et al. 2008).

Quality Patient surveys were conducted with the intervention and control groups to assess the effect of the intervention on beneficiaries' self-management behaviors. The surveys focused on patients' willingness to set self-management goals, their ratings of self-efficacy, and the number of self-care activities in which they engaged. Five of the seven MHSOs showed positive effects related to setting goals, and two MHSOs showed positive effects related to creating a self-management plan (Table 8-5, p. 234). In contrast, there was little meaningful improvement in ratings of self-efficacy or in the number of self-care activities performed. This result was not surprising, given the high level of reported compliance with self-care guidelines in baseline survey data. Of the seven MHSOs included in this analysis, only two demonstrated a positive effect related to helping beneficiaries cope with their chronic condition, which was considered the primary measure of patient satisfaction. Seven of the eight MHSOs demonstrated at least one positive intervention effect.

Quality impacts were also assessed by tracking changes in evidence-based process-of-care measures for the intervention populations compared with the control groups. The evaluation found modest improvement in the process measures tracked. Across 40 measures (5 measures for each of the 8 MHSOs), 16 showed improvement. For beneficiaries with HF (with or without diabetes), rates of cholesterol testing in the year before the pilot ranged from 55 percent to 71 percent, and during months 7 through 18 of the pilot, the intervention groups' rates of change of cholesterol testing were 2 percentage points to 4 percentage points higher for four of the MHSOs relative to their comparison groups' rates (changes in the rates for the other four MHSOs were not statistically significant). For beneficiaries with diabetes (with or without HF), four evidence-based process measures were evaluated: cholesterol screening (rates ranged from 65 percent to 85 percent in the year before the pilot), hemoglobin A1c testing (81 percent to 88 percent in the year before the pilot), urine protein screening (65 percent to 74 percent in the year before the pilot), and retinal eye examination (32 percent to 42 percent in the year before the pilot). During months 7 through 18 of the pilot, intervention groups at 6 of the MHSOs showed modest positive intervention effects on these measures (McCall et al. 2008).

TABLE 8–4

All MHSOs increased Medicare costs through the first 18 months of operation

MHSO	Difference in 18-month intervention and comparison group PBPM growth rates*: Excluding MHSO fees	Including MHSO fees
Health Dialog Services	1.9%	9.4%
McKesson Health Solutions, LLC	0.0	8.4
Lifemasters Supported SelfCare	2.7	8.1
Healthways	1.6	7.5
CIGNA Health Support	–1.0	7.2
XLHealth Corporation	–2.1	7.2
Aetna Life Insurance Company	–1.5	5.4
Green Ribbon Health	–1.2	3.5

Note: MHSO (Medicare Health Support Organization), PBPM (per beneficiary per month).
*Medicare costs are for original assigned population and do not include "refresh" population.

Source: McCall et al. 2008.

The program evaluation also analyzed whether the MHSO interventions were associated with any changes in the use of hospital and ER services. Across the 120 comparisons evaluated (15 measures for each of the 8 MHSOs), there were no statistically significant reductions in the rate of growth in hospitalizations, readmissions, or ER visits in the original MHSO population intervention groups relative to the comparison groups.

Current status of MHS On the basis of interim results, CMS announced in January 2008 that it would end MHS phase I as scheduled and not renew the five remaining active contracts beyond their scheduled termination dates in 2008. CMS also announced it will evaluate the results of the third and fourth MHS evaluations expected sometime in 2010 or 2011 before making a final decision about whether to proceed to phase II.

TABLE 8–5

MHSOs had few significant effects on surveys of beneficiary satisfaction, self-management activities, and functional status

	Statistically significant intervention effect						
	Aetna	**Healthways**	**CIGNA**	**Health Dialog**	**McKesson**	**Green Ribbon Health**	**XLHealth**
Beneficiary satisfaction							
Health care team helped beneficiary cope with chronic condition	+			++			
Beneficiary experience with care							
Number of helpful discussion topics			++	++	+		
Quality of communication with health care team			++	++			
Self-management							
Percent helped set goals		+		+	+	+	+
Percent helped make a plan				++	+		
Self-efficacy ratings (level of confidence)							
Take all medication	+						
Plan meals and snacks							
Manage your blood sugar level	+				–		
Check feet for sores or blisters	+						+
Exercise 2 or 3 times weekly	+						
Limit salt							
Weigh yourself							
Limit fluids							
Self-care activities (number of days per week)							
Prescribed medications taken							––
Blood sugar tested		++			++		
30 minutes of continuous physical activity	+						
Feet were checked		+					
Followed healthy eating plan							
Weight was measured					+		
Salt was limited							
Fluids were limited				++			
Physical and mental health functioning							
PHC score							
MHC score							
PHQ–2 score							
Percent PHQ–2 score indicating depression	+						
Number of ADLs—difficult to do				+			
Number of ADLs—receiving help							

Note: MHSO (Medicare Health Support Organization), PHC (Physical Health Component [of the Veterans RAND–12 (VR–12) instrument]), MHC (Mental Health Component [of the VR–12 instrument]), PHQ–2 (Patient Health Questionnaire–2), ADLs (activities of daily living). Statistical significance determined using analysis of covariance: positive intervention effect denoted as + $p < 0.05$, ++ $p < 0.01$; negative intervention effect denoted as – $p < 0.05$, –– $p < 0.01$. LifeMasters is not included in the beneficiary survey reporting because LifeMasters' termination occurred prior to the follow-up survey being fielded.

Source: McCall et al. 2008.

Medicare Care Management for High-Cost Beneficiaries demonstration

In 2005, CMS announced establishment of the Care Management for High-Cost Beneficiaries (CMHCB) demonstration to test various models of care coordination aimed at high-cost FFS Medicare beneficiaries. In a press release issued at the time, the agency noted that "While CMS has a number of planned and ongoing care coordination and disease management demonstrations and programs, the CMHCB demonstration will be the first effort to focus specifically on provider-directed models of care for high-cost fee-for-service Medicare beneficiaries" (CMS 2005).

Structure

Six care management organizations (CMOs) were selected to participate in the demonstration. In contrast to MHS, this demonstration was not designed to target beneficiaries with a preidentified set of chronic disease diagnoses—each CMO was allowed to propose its own screening criteria for beneficiary enrollment and its own set of intervention protocols. All the programs were designed to increase adherence to evidence-based care, reduce unnecessary hospital stays and ER visits, help participants avoid costly and debilitating complications, and target high-risk individuals likely to incur particularly high Medicare costs (CMS 2005).

As in MHS, beneficiaries were enrolled by using a population-based intent-to-treat model. CMS used the beneficiary selection criteria approved for each site to establish control and treatment populations for each site. Because of this design, enrollment and assignment methodologies differed across sites. Two of the sites have randomized control groups and four sites have matched comparison groups.

CMS pays each site a monthly fee for each enrolled beneficiary, and each site is at risk for reducing Medicare costs for the intervention group by an amount equal to the fees it has been paid plus an additional percentage reduction. CMS set this additional reduction target at 5 percent for the original demonstration population but reduced it to 2.5 percent for the refresh populations assigned to the sites. Net savings are calculated by comparing FFS costs for the control group with FFS costs plus care management fees for the intervention group. To date, CMS has not released a financial evaluation of the demonstration or details of the financial arrangements with the CMOs, such as monthly fee amounts.

Implementation

The CMOs launched their programs between October 2005 and August 2006 (Table 8-6, p. 236). As of January 2009, total enrollment for the four sites still participating in the demonstration was 5,667 beneficiaries, ranging from 540 to 2,267 beneficiaries per site (Kapp 2009). Interventions incorporate a wide range of services, including support programs for health care coordination, physician and nurse home visits, use of in-home monitoring devices, use of electronic medical records, self-care and caregiver support, education and outreach, patient tracking, reminders of beneficiaries' preventive care needs, 24-hour nurse telephone lines, behavioral health care management, and transportation services.

Each CMO uses Medicare claims data to track its patients' use of Medicare services and costs as one way to identify and prioritize high-risk patients and monitor trends in the effectiveness of their individual care management interventions. According to CMS staff, the sophistication and use of these data systems have varied across the demonstration sites. The sites' internal data capabilities are important because inherent delays in Medicare claims processing can result in a lag of three months or more between the provision of a service (especially an inpatient admission) and its appearance in claims data, which then may take up to another month to be transmitted to the demonstration sites (based on experience in the MHS pilot). CMS has been working to improve the timeliness of hospital claims data reporting to the CMOs and recently began providing the sites with their enrolled beneficiaries' hospital claims on a monthly basis, though the time lag will remain between a beneficiary's hospital admission and when the hospital's claim for that admission is submitted to Medicare. CMS also receives quarterly financial reports for each site from the demonstration's independent implementation and monitoring contractor and shares that information with the CMOs.

An independent evaluation contractor monitors and evaluates each site's performance with respect to quality and patient satisfaction. The contractor is using a pre- and post-longitudinal study design to collect quality and patient satisfaction data directly from beneficiaries. A November 2008 report prepared by the independent evaluation contractor summarized the findings from the initial round of quality and patient satisfaction surveys, which are discussed later.

TABLE 8–6

Three Care Management for High-Cost Beneficiaries demonstration sites have been extended

Name of project	Initial approval period	Current status	Population focus	Program features	Beneficiary location
Care Level Management	October 1, 2005 to September 30, 2008	Terminated by CMS effective February 29, 2008	Beneficiaries with advanced, progressive chronic disease(s) and comorbidities with two or more condition-related hospital admissions in the past year	Provides care management via a distributed network of personal visiting physicians who see patients in their homes and nursing facilities and are available 24/7	California Texas Florida
Health Hero Network "Health Buddy"	February 1, 2006 to January 31, 2009	Three-year extension, subject to annual renewals, approved to begin February 1, 2009	Beneficiaries with congestive heart failure, diabetes, and or chronic obstructive pulmonary disease 540 participating beneficiaries as of January 2009	Patients receive a Health Buddy appliance that coaches them about their health, collects vital signs and symptoms, and transmits results back to multi-specialty medical groups	Oregon Washington
Massachusetts General Care Management	August 1, 2006 to July 31, 2009	Three-year extension, subject to annual renewals, approved to begin August 1, 2009	Beneficiaries who seek care from Massachusetts General health care system 2,267 participating beneficiaries as of January 2009	Provides comprehensive care management by a dedicated team of doctors and nurses, with specialized programs for patients with chronic conditions; home visits and home telemonitoring; electronic medical record	Massachusetts
Montefiore Care Guidance "Care Management Organization"	June 1, 2006 to May 31, 2009	Not extended by CMS	Beneficiaries with multiple chronic conditions residing in naturally occurring retirement communities and fee-for-service beneficiaries cared for within Montefiore healthcare network	Provides enhanced home-based services to participants using telemonitoring equipment and home visit programs; medication management, falls prevention, palliative care, and disease management programs	New York
RMS DM, LLC – RMS "KEY to Better Health"	November 1, 2005 to October 31, 2008	Three-year extension approved to begin November 1, 2008	Beneficiaries with chronic kidney disease 1,603 participating beneficiaries as of January 2009	Provides intensive disease management directed by nephrologists in supplementary clinics to identify potential problems and avoid complications, coordinate early intervention plans, and prevent acute hospitalization	New York
Texas Senior Trails	April 1, 2006 to March 31, 2009	Withdrew July 31, 2007	Beneficiaries who receive care from Texas Tech Physician Associates and at risk for readmission or adverse events	Care team coordination of home and office-based care	Texas

Source: CMS, Care Management for High-Cost Beneficiaries demonstration site-specific fact sheets (updated February 5, 2009) and "Medicare extends demonstration to improve care of high cost patients and create savings" press release.

Results

In January 2009, CMS announced that three of the CMHCB sites would be granted extensions to continue their programs for up to an additional three years beyond their original end dates: RMS Key to Better Health, Massachusetts General Care Management Program, and Health Hero Network's Health Buddy Project. In a press release announcing the extensions, CMS stated that "Each program has had a positive impact on selected high cost Medicare beneficiaries and has met and/or exceeded the savings target required in the demonstration agreement" but released no further details of the analysis behind its decision (CMS 2009).

The independent evaluation contractor, RTI International, submitted a report to CMS in November 2008 summarizing the findings from a survey of enrolled beneficiaries that was conducted to determine the effects of each care management program on beneficiaries' ability to cope with chronic illness, self-management behavior, and physical and mental functioning. The report found that overall beneficiaries in the intervention groups did not report more favorable experiences getting help to set goals, create a care plan, or cope with a chronic condition than did those in the control groups. With few exceptions, the interventions appeared to have little impact on the frequency of self-care activities or self-efficacy to perform these activities. RTI found that none of the six CMOs demonstrated consistently positive intervention effects across both domains of satisfaction with care experience and self-management activities. One of the six CMOs had a positive satisfaction intervention effect for at least one measure in each of the three domains. However, none of the CMOs achieved a positive intervention effect for all five satisfaction measures.

Medicare Physician Group Practice demonstration

In January 2005, CMS announced the establishment of the Physician Group Practice (PGP) demonstration in response to a legislative mandate in section 412 of the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000. The demonstration is the first pay-for-performance initiative for physicians under the Medicare program; it offers 10 large physician practices the opportunity to earn performance payments for improving the quality and cost efficiency of health care delivered to Medicare FFS beneficiaries. By rewarding improvements in quality and cost efficiency, the demonstration aims to encourage care coordination of Part A and Part B services and promote investment in care management programs, process redesign, and tools for physicians and their clinical care teams. Initially designed to be a three-year project, the demonstration was extended and is now in its fifth and final year.

Structure

CMS selected 10 sites to participate in the demonstration through a competitive process. Sites were selected based on technical review panel findings, organizational structure, operational feasibility, geographic location, and demonstration implementation strategy. Each participating physician group comprises at least 200 physicians, and they collectively include more than 5,000 physicians. The groups include freestanding group practices, components of integrated delivery systems, faculty group practices, and a physician network organization comprising small and individual physician practices. Together, they provide the largest portion of primary care services for more than 220,000 Medicare FFS beneficiaries. Under the demonstration, the participating groups are paid as usual under Medicare Part A and Part B, but after each "performance year" CMS analyzes the claims data for beneficiaries assigned to each group and from a local comparison group to determine whether (on a risk-adjusted basis) each group succeeded in having a lower rate of growth in total Medicare expenditures for its treatment group than for the comparison group.

The demonstration includes a base year and performance years covering the following periods:

- *base year:* January 1, 2004, to December 31, 2004
- *performance year 1:* April 1, 2005, to March 31, 2006 (results announced in July 2007)
- *performance year 2:* April 1, 2006, to March 31, 2007 (results announced in August 2008)
- *performance year 3:* April 1, 2007, to March 31, 2008
- *performance year 4 (extension):* April 1, 2008, to March 31, 2009
- *performance year 5 (extension):* April 1, 2009, to March 31, 2010

Implementation

CMS initiated the demonstration in April 2005. Once sites were selected and beneficiaries were enrolled,

participating PGPs began implementing care management strategies designed to improve quality and reduce costs. These strategies included electronic medical record modules; disease-specific patient registries; patient education programs; risk stratification tools; reports to track progress on quality measures; patient follow-up and outreach initiatives; telephonic remote monitoring systems; and automated identification, notification, and scheduling services.

These systems and tools were established, enhanced, and adopted at different speeds during the demonstration. Some PGPs reported issues implementing their care management strategies fast enough to have a sizable effect in the first year. Several PGPs indicated that motivating physician and organizational change took longer than expected, and their interventions did not become fully operational until performance year 2.

Some PGPs also reported lags in data reporting from CMS, making the PGPs' information systems important in tracking clinical and cost information. Ideally, rapid feedback of data on assigned beneficiaries would enable PGPs to evaluate the impact of specific interventions more quickly and revise them as needed during the demonstration. However, because claims data take time to accumulate, rapid feedback has been difficult to achieve.

Performance indicators on both quality and cost efficiency are used to calculate performance payments. Quality measures were developed by CMS working in an extensive process with the American Medical Association's Physician Consortium for Performance Improvement and the National Committee for Quality Assurance. The measures have undergone review or validation by the National Quality Forum, and CMS worked with the physician groups to develop a consensus agreement on how to report the measures and how to use them to assess performance and reward quality under the demonstration (CMS 2008). The measures have been phased in, beginning with the diabetes mellitus measures that were used to assess performance and reward quality care during performance year 1. Additional measures focusing on CHF and CAD were added in performance year 2. Hypertension and cancer screening measures were added in performance year 3, and all measures are in effect in performance years 4 and 5.

Medicare savings for each PGP demonstration site are calculated by comparing actual spending with a target. The target is set at each PGP's base-year per capita expenditures, trended forward by the comparison group's expenditure growth rate. Case-mix adjustments are made to account for changes in the severity of illness over time in the patients treated by the PGP and in the comparison group. Up to 80 percent of Medicare savings in excess of 2 percent is distributed to each PGP based partly on the magnitude of savings achieved and partly on the group's performance on the quality measures in effect for the given performance year.

Results

The PGP demonstration is in progress, but interim results from the first two performance years indicate that the quality of care for participating beneficiaries has improved, although financial outcomes are less clear.

Cost Two of the PGP sites earned performance payments of $7.3 million in performance year 1 as their share of $9.5 million in total demonstration savings estimated by CMS to have accrued to Medicare. Both sites that shared in savings in the first year had risk-adjusted expenditure growth rates for their assigned populations that were lower than those of their comparison group populations. In August 2008, CMS announced that four of the demonstration sites had earned a total of $13.8 million in performance payments as their share of $17.4 million in Medicare savings for performance year 2. As in the previous year, other sites also had rates of growth in their intervention groups' expenditures that were lower than growth rates for their comparison groups, but not sufficiently lower, under the demonstration's performance-based payment methodology, to share in the savings generated.

The apparent success of the sites in constraining the rate of cost growth is less clear once risk adjustment effects are taken into account. According to unpublished data from CMS staff, the rates of total expenditure growth without risk adjustment from the base year to performance year 2 were higher or about the same in 8 of the 10 demonstration sites as in their comparison groups. After adjusting for population risk differences (using a methodology similar to that used in Medicare Advantage), only three of the sites had higher total spending growth rates than did their comparison groups. The difference between the unadjusted and adjusted results stems from the fact that 9 of the 10 demonstration sites also reported that their patient risk scores grew faster than risk scores for the sites' comparison groups. The relatively faster increase in risk scores for the sites may be due to their attracting a greater share of sicker patients than the comparison group, their patients could be getting sicker while enrolled

in the demonstration, or the sites may be more fully documenting and coding diagnoses to identify patients for care management and quality improvement initiatives. Because the increased risk scores of patients at the sites may be due to improved detection and coding of acute and chronic conditions, actual cost savings in the first two years of the demonstration are unclear.

Quality In performance year 1, all the demonstration sites improved the clinical management of their diabetes patients. Specifically, all 10 sites achieved benchmark or better performance on at least 7 of the 10 diabetes quality measures, and 2 sites met all 10 benchmarks. In addition, all sites increased their scores on at least four diabetes measures, eight sites increased their scores on at least six of these measures, and six sites increased their scores on nine or more measures. In performance year 2, overall performance on quality measures among the sites continued to improve, even as more quality measures were introduced. All 10 sites achieved benchmark or better performance on at least 25 of the 27 quality measures covering patients with diabetes, CAD, and CHF. Five of the physician groups achieved benchmark performance on all 27 quality measures.

Summary of demonstration and pilot program results and implications for Medicare chronic care research

Taken together, the results of the three demonstrations and one pilot program are as follows:

- In almost all cases, the cost to Medicare of the intervention exceeded the savings generated by reduced use of inpatient hospitalizations and other medical services.
- Significant improvements in quality were sporadic, with the notable exception of the PGP demonstration, where almost all the program sites significantly increased performance on the clinical process and intermediate outcome measures being tracked.

The most significant reasons for these empirical results are more difficult to isolate and identify because of the multiple complex interactions that affect outcomes in a clinical intervention program for beneficiaries with multiple chronic illnesses. Nonetheless, the evidence appears to support the following points:

- A commentary accompanying a journal article on the MCCD results suggests that the evaluation "offers 2 important insights to guide Medicare policy on coordination of chronic disease care," which are that "care coordinators must interact in person with patients" and that "care coordinators must collaborate closely with patients' physicians to have a reasonable prospect of influencing care" (Ayanian 2009).
- CMS's administrative resource constraints may limit the agency's capacity to deliver timely information and program feedback to demonstration sites in some instances, which may have inhibited the potential of some programs to affect outcomes positively since the programs did not have the information they needed to assess whether their interventions were producing the desired outcomes. In the most recently launched demonstration (CMHCB), it appears that CMS is providing the demonstration sites with more of the information they seek in a timely fashion. In a larger sense, there is a question about how much providers can reasonably rely on CMS to provide operational data, when part of what is expected of them is to have the internal data collection, analysis, and reporting capabilities to inform their care management interventions.
- In some cases, the participating organizations may have limited their investment of resources in the demonstration programs, because the programs were relatively small and therefore given less priority than other organizational activities or because the programs were known to be time limited and therefore not worth the amount of investment that could be recouped over a longer time.

These observations suggest the critical success factors for Medicare in developing its ability to improve the quality and reduce the costs of care for beneficiaries with one or more high-cost chronic conditions. These factors should be taken into account in evaluating proposals to improve chronic care management, including the proposed MCCPRN.

Proposed Medicare Chronic Care Practice Research Network

The MCCPRN proposal has been advanced by a group of 12 health care provider and research organizations with a goal, in the group's words, "to serve as the leading

TABLE 8–7

Seven of the proposed MCCPRN sites also were Medicare Coordinated Care Demonstration sites

Proposed MCCPRN site	Location	Organization type	Site in Medicare Coordinated Care Demonstration?
Avera Research Institute (Avera McKennan Hospital and University Health Center)	Sioux Falls, SD	Hospital	Yes
Care Management Plus, Oregon Health & Science University	Portland, OR	Academic medical center	No
Central Virginia Health Network (CenVaNet)	Richmond, VA	DM/CC provider	Yes
Health Quality Partners	Doylestown, PA	DM/CC provider	Yes
Hospice of the Valley	Phoenix, AZ	Hospice	Yes
The Jewish Home & Hospital for the Aging	New York, NY	LTC provider	Yes
Mercy Medical Center–North Iowa	Mason City, IA	Hospital	Yes
Partners in Care	Los Angeles, CA	DM/CC provider	No
Rush University Medical Center	Chicago, IL	Academic medical center	No
Scott and White Memorial Hospital, Texas A&M Health Science Center	Temple, TX	Academic medical center	No
University of Illinois at Chicago, College of Nursing	Chicago, IL	Academic medical center	No
Washington University	St. Louis, MO	Academic medical center	Yes

Note: MCCPRN (Medicare Chronic Care Practice Research Network), DM/CC provider (provider of disease management, coordinated care, or quality improvement services), LTC (long-term care).

Source: MCCPRN 2008a, Peikes et al. 2009.

national resource available to advance the science and operational standards of care management for the chronically ill Medicare population, with special focus on their widespread adoption and relevance to new and improved payment policies" (MCCPRN 2008a). Under the proposal, "CMS would be directed to establish via federal legislation" a "standing network" of 12 preselected organizations—several academic medical centers, two long-term care providers, and three providers of care coordination, disease management, or quality improvement services (Table 8-7). Seven of the 12 proposed network member organizations also participated in the MCCD. Only one of these organizations' MCCD programs was found in the most recent evaluation to be close to budget neutral for Medicare. The proposed network would build on the MCCD infrastructure to create a standing network of sites that could "reduce elapsed time from concept to study design" and shorten the "long cycle times" that occur in setting up, implementing, and evaluating new Medicare demonstrations (MCCPRN 2008b).

As described in the proposal, the network's mission would "be to develop, execute and evaluate innovative, evidence-based chronic care initiatives focused on high cost fee-for-service Medicare beneficiaries." The network would "implement care management components based on evidence and best practices and focused on adoption by beneficiaries, health care providers and administrators and other entities critical to successful deployment" (MCCPRN 2008a).

Design features of the proposed MCCPRN

According to the materials submitted to the Commission in the course of our review, the proposed network would have

a governance and administrative structure in addition to the 12-site standing research network (Figure 8-2, p. 242).[8] The network would be led by a board of directors that would include a CMS representative, representatives from each of the network sites, and possibly a representative from the Agency for Healthcare Research and Quality (AHRQ) and the National Institute on Aging; an advisory panel of outside professional experts and patient advocates; a coordinating center; an evaluation center; and four workgroups—an organizational group, a project design and implementation group, a financial group, and an evaluation design and implementation group.

As described in the proposal, CMS's involvement in the network would be through the board of directors, which would be responsible for setting overall policies to guide network development and specific project activities. The board of directors also would be responsible for contracting with an external evaluator to analyze the outcomes of the research projects undertaken by the network. The MCCPRN proposal also states that CMS would be responsible for determining the "implications for replication potential and policy changes to facilitate wide adoption of the most promising innovations" that emerge from the network's activities (MCCPRN 2008a). However, the proposal does not call for explicit authorization of new administrative flexibility for CMS to implement promising care coordination interventions program wide.

As for the use of the network to test the effectiveness of payment policy innovations, the proposal mentions the network's "ability to contribute to defining mechanisms for incentives to physicians to provide more cost effective care" through "use of physician incentives" (MCCPRN 2008a). Based on the experience in the MCCD—where 10 of the programs paid physicians either a monthly stipend per patient (typically $20 or $30) or a fee for participating in meetings or for sharing medical records (Peikes et al. 2008)—it is not clear that these types of payments to physicians by a separate care coordination entity are effective in increasing quality or reducing total costs. According to the MCCPRN materials reviewed by the Commission in preparation of this report, the network would not be designed to test the types of fundamental payment reforms recommended by the Commission to change the current incentives inherent in Medicare's FFS payment system. Similar to the financial arrangements in the MCCD, Medicare would pay a monthly care coordination fee for each beneficiary enrolled in the network, and providers of services covered by Medicare Part A and Part B would continue to be reimbursed through traditional FFS Medicare.

The concept of a practice-based research network (PBRN) embodied in the MCCPRN has been explored and refined over the past several years under programs administered by AHRQ (see text box, pp. 244–245). In contrast to the MCCPRN proposal, the current AHRQ PBRNs were created through an open, competitive solicitation process. To construct the networks, AHRQ released a request for proposals outlining the program criteria and contractual requirements participating organizations would have to meet and used a formal proposal review process to select the organizations that form each network. Once the networks are created, specific projects and interventions are fielded and evaluated quickly under task orders, which are less time-consuming to implement than demonstrations, typically taking 12 months to 18 months from initiation to completion (AHRQ 2009). While the networks have produced some practice-based research results focused on specific conditions (e.g., improving colorectal cancer screening in primary care practice), the programs have not undergone an independent evaluation to date (Lanier 2008).

Financing the proposed MCCPRN

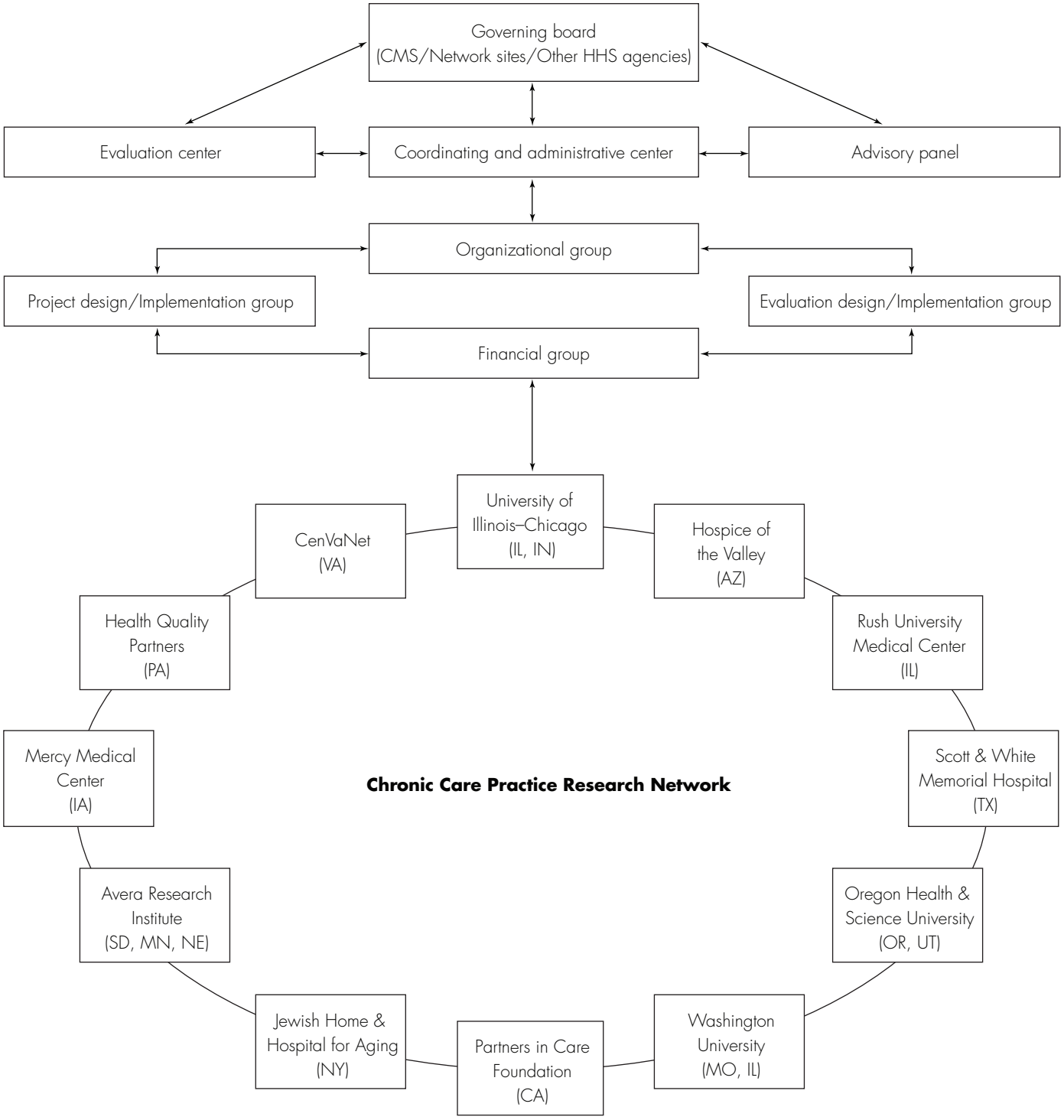
Funding for ongoing operations of the MCCPRN is not addressed in the materials submitted to the Commission for this report, but related legislation introduced but not enacted in the 110th Congress (H.R. 4327) would have authorized $60 million in Medicare funds over five years to finance the network. The average annual amount provided by this funding authorization would be $12 million per year, but this amount could vary in a given year depending on specific administrative and project funding needs (e.g., more funding could be required up front for capital expenses to support information technology acquisition for data collection and administrative staffing).

According to the MCCPRN proposal, Medicare funding would support four areas of activity:

- It would fund collaboration and networking among the sites, including conference calls, meetings and other forms of direct communication, publication of guidelines and findings, and developing and disseminating "tool kits."
- It would fund infrastructure support such as information systems to enable participation in research protocols at individual sites. This activity would build on information systems and other decision support

FIGURE 8–2

Administrative structure of proposed MCCPRN



Note: MCCPRN (Medicare Chronic Care Practice Research Network), HHS (Department of Health and Human Services).

Source: MCCPRN 2008a.

tools that some of the network sites have already developed and implemented with success while participating in the MCCD. Amounts allocated to each network site may be based on the site's enrollment size or success in realizing targets and compliance with data submission requirements.

- It would fund patient recruitment and care management support at the sites to deliver specific services to large patient panels and regularly test improvements.
- It would fund internal and external evaluation activities, including expenses incurred at the level of the individual sites and the network (MCCPRN 2008a).

Assuming the network's funding would work in a manner similar to the MCCD, the network sites would be paid a monthly care coordination fee for each beneficiary enrolled in the project intervention group. These fees would be paid in addition to any Medicare Part A and Part B payments to the providers treating program participants. The MCCPRN proposal explicitly rejects the policy of budget neutrality: "Achieving 'budget neutrality' from the funding agency's perspective (as is the requirement of current CMS demonstrations) or placing Network members at financial risk is contrary to the research purpose of the Network. Financial incentives should reward the efficient development and flawless execution of promising research designs involving improvements in care coordination and chronic care management" (MCCPRN 2008a).[9] While the MCCPRN proposal envisions using cost outcomes as one component (along with quality) in program evaluations, the proposal does not accept applying a budget-neutrality requirement on the network as a whole or having the network sites assume financial risk for cost outcomes.

Evaluation of the MCCPRN proposal

The Commission's evaluation of the proposed MCCPRN is based on our analysis of the evidence from the chronic care demonstration and pilot programs that we reviewed as well as our past work on methods Medicare could use to improve care coordination for beneficiaries with chronic conditions. Our review of the MCCPRN proposal did not evaluate—and should not be interpreted to comment on—the capabilities of the specific organizations that make up the network in its currently proposed configuration or the potential efficacy of the proposed interventions discussed in the MCCPRN proposal.

In essence, the practical effect of the MCCPRN proposal would be to continue the MCCD with the following important differences:

- About half of the network sites are organizations that CMS selected through a competitive solicitation process to participate in the MCCD (Table 8-7, p. 240), while the others have not been evaluated by CMS as to their research, information systems, and intervention delivery capabilities.
- The MCCPRN sites' interventions would be targeted to a subset of Medicare beneficiaries with multiple chronic conditions who have been identified through algorithms based on the network's analysis of the data collected by the sites and CMS over the five-year course of the MCCD. A significant portion of the planning funds MCCPRN has received has been allocated to analyzing the MCCD results and developing evidence-based algorithms to identify the clinical and utilization characteristics of those beneficiaries who experienced the most positive outcomes from the MCCD interventions.
- Care coordination and other interventions would be standardized across all MCCPRN sites through the use of clinical protocols, provider education and training, and continuous monitoring of implementation metrics and routine feedback to the sites of this program management performance data.
- A new administrative structure would be constructed for program operations with CMS playing a significantly different administrative and research role than it has in the MCCD and other Medicare demonstrations and pilots.

Our evaluation of the proposal raises the following concerns:

- The group of organizations submitting the MCCPRN proposal—which also would comprise the initial set of network sites—was not selected through an open, competitive solicitation process. A transparent solicitation process administered by CMS could be used to ensure that participating organizations had the necessary technical capabilities to implement and evaluate the selected care coordination interventions and that they shared characteristics (e.g., organization types and patient demographics) that would increase the prospects of being able to generalize and scale up from successful results. Although the process of

Practice-based research networks administered by the Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) administers two types of practice-based research networks (PBRNs): primary care PBRNs and integrated delivery system PBRNs.

Primary care PBRNs

AHRQ has devoted funds to support primary care PBRNs since 1999. AHRQ defines a PBRN as a group of ambulatory care practices devoted principally to the primary care of patients and to the investigation of questions related to community-based practice and improving the quality of primary care. PBRNs often link practicing clinicians with investigators experienced in clinical and health services research, while enhancing the research skills of network members.

In 2006, AHRQ created the PBRN contract partnership as a mechanism to fund rapid-cycle practice-based research and implementation projects at 10 selected PBRNs. Through this mechanism, AHRQ funds a variety of projects, including observational studies of primary care practices, field testing of evidence-based interventions and tools in real-world primary care practices, and research into best practices for dissemination of successful results.

The PBRN contract partnership began with an open competition among all interested primary care PBRNs, which AHRQ administered through a request-for-proposals process. AHRQ's evaluation criteria included the size and diversity (in terms of age, race or ethnicity, socioeconomic status, and location of residence) of the patient population served by the PBRN and its information systems capabilities. In February 2007, AHRQ awarded 10 contracts to establish the program. The 10 contractors include 4 groups with multiple networks and 6 individual networks, for a total of 28 networks. According to AHRQ, these networks are composed of 2,209 primary care practices distributed across the 48 contiguous states and roughly equally distributed across urban, suburban, and rural areas. The providers within the practices include 7,875 physicians, 1,217 nurse practitioners, and 895 physician assistants. These practices provide primary care for roughly 11.8 million patients, of whom 58 percent are age 65 or older (Lanier 2009). All the PBRNs that were awarded contracts are prequalified to compete for specific projects under a relatively rapid administrative procedure known as a task order. Through this vehicle, AHRQ can design, field, and evaluate projects with timelines ranging from 12 months to 24 months, with costs ranging from $100,000 to $300,000 (AHRQ 2009).

AHRQ also provides a support program by operating a PBRN resource center to provide technical assistance, facilitate peer learning-group activities, sponsor an annual PBRN conference, maintain an electronic repository of all PBRN research, and host a secure website for the PBRNs.

Accelerating Change and Transformation in Organizations and Networks

AHRQ also administers an integrated delivery system PBRN called the Accelerating Change and Transformation in Organizations and Networks

(continued next page)

drafting a request for proposals, reviewing proposals, and setting up a Medicare-specific practice research network would incur costs and take time, these hurdles must be weighed against the risks of eliminating the bidding process. For example, it could be more difficult for CMS to limit the size and number of additional networks if it were to adopt the MCCPRN proposal as given without first setting clear selection criteria and a transparent selection process for awarding the associated funding.

- The MCCPRN proposal rejects the use of budget neutrality or other financial incentives to hold the network sites at risk for Medicare costs incurred by beneficiaries participating in the network's treatment protocols. We are concerned that only

Practice-based research networks administered by the Agency for Healthcare Research and Quality (cont.)

(ACTION) program. AHRQ describes ACTION as "a 5-year implementation model of field-based research that fosters public-private collaboration in rapid-cycle, applied studies. ... ACTION promotes innovation in health care delivery by accelerating the development, implementation, diffusion, and uptake of demand-driven and evidence-based products, tools, strategies and findings. ACTION develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems" (AHRQ 2006).

ACTION is organized around 15 large partnerships between AHRQ and 15 prime contractors, each of which subcontracts with several collaborating organizations. ACTION participants span all states and include health plans, physicians, hospitals, long-term care facilities, ambulatory care settings, and other care sites. Each partnership includes health care systems with large databases, clinical and research expertise, and the authority to implement health care interventions (AHRQ 2006).

The program began with an open competition administered by AHRQ through a request-for-proposals process in 2006. The 15 contracted ACTION partnerships operate under multiyear cost reimbursement contracts, and each of the contractors is prequalified to compete for individual projects that are solicited on a rolling basis throughout each of several years. Projects are designed, implemented, and evaluated on a rapid-cycle basis; they are awarded under separate task orders and are completed within 15 months on average. Projects that require clearance from the Office of Management and Budget need on average an additional nine months (Meyers 2009). Project costs typically range from $350,000 to $500,000 but have cost as much as $3,000,000. From 2006 to 2008, AHRQ made 58 ACTION project awards with total funding of $30.2 million (Palmer 2008).

Independent evaluation of other AHRQ PBRNs

To date, there has been no independent evaluation of these two AHRQ programs, but a predecessor to the ACTION program, called the Integrated Delivery System Research Network (IDSRN) program, was independently evaluated for AHRQ by Mathematica Policy Research in 2004. That evaluation concluded that "[t]he operational impact of IDSRN has been mixed, and widespread diffusion was rare over the period studied" (Gold and Taylor 2007). Overall, 30 of the 50 completed IDSRN projects were found to have had some operational effect, but most often the effects occurred within the system in which the research had been conducted. The report points out that the IDSRN had little formal infrastructure to support more widespread dissemination, particularly outside of the entities participating in the program. According to AHRQ, the agency applied this experience when designing the ACTION program, which includes some infrastructure to gather and share input from participating organizations toward designing program-wide and individual research projects. ACTION also is designed to put more emphasis on funding projects that have broad applicability and potential scalability and on funding sequential projects in which results from one phase are built on in the next phase of implementation (AHRQ 2006). ■

one of the six proposed MCCPRN sites that also participated in the MCCD was found in the most recent independent evaluation to have approached budget neutrality, including the care coordination fees. Given the challenge of the long-term sustainability of the Medicare program, the incentives for care providers in FFS Medicare to increase the volume and intensity of services they deliver to beneficiaries, the limited evidence to date on cost savings from care coordination interventions, and the Commission's stated position on the need for Medicare to move to value-based purchasing, we believe that putting care coordination service providers at some financial risk is necessary to create a strong incentive to provide cost-effective, quality-enhancing interventions for beneficiaries in FFS Medicare.

In its previous work on care coordination (MedPAC 2006), the Commission discussed two types of at-risk payment—shared savings and an at-risk care management fee—both of which could be considered for use in a PBRN. While requiring care coordination providers to bear some financial risk is not a guarantee of success in reducing costs and improving quality, preliminary evidence from the PGP demonstration (which uses the shared savings model) and the CMHCB demonstration (which uses the at-risk care management fee model) suggests that these approaches may contribute to spurring quality improvements while reducing costs.

In the specific case of designing a Medicare chronic care research network, it will be important to consider whether requiring any amount of risk sharing could affect the types of organizations that would elect to participate. For example, it may not be financially or legally feasible for some types of organizations to bear a significant amount of financial risk, even if the risk-sharing arrangement offered the potential to share any savings achieved. In those cases, Medicare would need to evaluate the trade-off between requiring risk sharing (including how much and in what form) and the implications for the types of organizations that would agree to participate.

- The administrative oversight structure of the proposed MCCPRN would include CMS as one representative on the governing board along with one representative from each of the network sites. While the materials provided by MCCPRN to the Commission indicate CMS would play the lead role in the governing board, it is not clear how much control CMS would have over the identification, design, and evaluation of the research projects carried out by the network. CMS should have sufficient authority to fully meet its responsibilities as the administrator of Medicare and the public steward of Medicare funds. Even if this were the case, however, we are concerned about CMS's current resources—given the existing constraints on the agency's funding and administrative flexibility—to take on these new responsibilities, particularly given the new and unfamiliar challenges CMS would encounter in leading and administering a PBRN.
- A Medicare PBRN could duplicate some of the existing financial and administrative resources AHRQ devotes to its two practice– and delivery-system–based research networks, the primary care PBRNs and ACTION. It may be useful to explore whether either of these programs could be adapted to provide a platform for relatively rapid turnaround practice-based research into coordinated care interventions for Medicare beneficiaries. Doing so would require a thorough evaluation of several aspects of the AHRQ networks, including an assessment of whether the participating organizations have the requisite skill sets to meet the needs of Medicare beneficiaries with one or more chronic illnesses, whether they serve a sufficient number of Medicare beneficiaries to permit statistically robust research results, and what their capacity would be to bear financial risk for participating in the network if that were determined to be a requirement. Also, AHRQ's funding for its existing networks is usually distributed upon each project's initiation as a lump-sum grant, as opposed to the PBPM fees envisioned in the current Medicare research network proposal.

  According to the MCCPRN proposal materials the Commission reviewed, the MCCPRN would specifically target the Medicare population and test interventions expressly designed to improve care coordination for Medicare beneficiaries with multiple chronic conditions. The MCCPRN also would test interventions that are more comprehensive than most of those tested to date by the AHRQ networks. Whereas the AHRQ networks typically evaluate the effects of individual clinical tools or programs, the MCCPRN would test sets of tools and programs. For instance, rather than test the value of a particular telemonitoring system, the MCCPRN would evaluate the effectiveness of an entire care coordination package that may include the use of a telemonitoring system combined with a series of clinical protocols and standardized staff training.

Other options for improving Medicare chronic care delivery

As the Commission stated in its recent report on a medical home pilot program, it is appropriate to test new policies before fully committing Medicare to them, and it is also imperative that we seek ways to hasten the testing process (MedPAC 2008). In addition to, or instead of, implementing the proposed MCCPRN, other options for accelerating the design, implementation, and evaluation of care coordination and other interventions for Medicare

beneficiaries with one or more chronic conditions could include the following:

- The Secretary could be encouraged to explore setting up a coordinated care PBRN within AHRQ in close collaboration with CMS (or vice versa), building on one or both of AHRQ's existing PBRN programs. One advantage of this approach is that it could build on the nearly 10 years of AHRQ experience in administering practice-based research programs and take advantage of the existing infrastructure of primary care practices, integrated delivery systems, and other provider organizations in the existing AHRQ networks. The Congress could be asked to appropriate more funding for CMS and AHRQ specifically to manage this new array of research projects and to invest in CMS data systems dedicated to supporting the expected levels of research, implementation, and evaluation activity.

- CMS could expedite further analysis and research into the rich trove of data on interventions, service utilization, costs, and quality that have been amassed through the MCCD, MHS pilot, PGP demonstration, and CMHCB demonstration. As part of this effort, CMS could create a central database that houses data from all of its care coordination demonstration and pilot activities (including data from control group beneficiaries) and contract with independent analytic organizations and health services researchers to analyze it thoroughly. One researcher recently pointed out that CMS "now has longitudinal data (claims and program-generated data) on well-characterized cohorts of 20,000 chronically ill beneficiaries for each of the eight MHS pilot programs, along with 10,000-person control groups. Some of the MHS programs also received additional cohorts for the second program year. Allowing researchers to tap these rich data sets would allow further analysis of the recent programs and greatly advance the field" (Foote 2009).

  Any research studies that used a large database combining data from several different demonstrations and the MHS pilot would need to be carefully assessed, not only for producing statistically significant results, but also for supporting plausible hypotheses of causal relationships in the care delivery system that could have produced those results. Such a database would be complex because it would combine data from programs with different beneficiary populations, implemented across different time periods, and involving different types of care coordination interventions. The database also would need to include details of the specific interventions that took place in the intervention groups in order to reliably establish associations between interventions and results.

  One example of the type of analyses that could be performed with these data is described in a Mathematica research proposal recently awarded a grant by the Changes in Health Care Financing and Organization (HCFO) initiative of The Robert Wood Johnson Foundation. In this project, Mathematica is analyzing MCCD data (to which it has access as the program evaluator) to test the ability of care coordination programs to control health care costs, examine the design features and target populations that make certain programs effective, and determine how programs can be replicated (HCFO 2008).[10]

Possible directions for broader consideration and further work on improving Medicare's research and development activity

The concerns expressed by the Commission and others about the slow pace of Medicare's chronic care demonstrations and pilots are emblematic of larger issues concerning the constraints CMS faces in carrying out research and development for Medicare. Current funding levels for Medicare research and development activities are very low relative to the overall size of the program. The amount enacted in fiscal year 2008 for Medicare research, demonstrations, and evaluations was $31.3 million, which is equal to 0.007 percent of the $460 billion in spending on Medicare benefits estimated for that year (HHS 2008). CMS also often has no or limited flexibility to redirect research funding as program needs and priorities shift, and administrative process requirements for research and demonstration projects—such as Medicare demonstration approvals through the executive branch—are time-consuming and resource intensive. In future work, the Commission intends to examine these and other issues affecting how quickly and effectively Medicare can test, implement, evaluate, and disseminate policy innovations that could improve quality while slowing the rate of cost growth in FFS Medicare. ■

Endnotes

1 The National Priorities Partnership is a coalition of 28 major national organizations representing health care payers and purchasers (including CMS), patients (including AARP), providers, and quality improvement organizations. The group was convened by the National Quality Forum in 2008 and in November 2008 announced six priority areas for the group's efforts to improve the U.S. health care system, including to "ensure patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care" (National Priorities Partnership 2008).

2 The seven diagnoses used as screening conditions in this analysis were hypertension, heart disease (including heart attack), diabetes, arthritis, lung disease (asthma, emphysema, and chronic lung obstruction), cancer, and depression.

3 Different estimates of the prevalence and rates of growth of chronic illness in the Medicare population may be attributable to analysts' different definitions of chronic illness (Goldman and Sood 2006, Thorpe and Howard 2006a).

4 In this analysis, total spending is defined as "total health care spending linked to Medicare beneficiaries regardless of the source of payment (out of pocket, Medicaid, supplemental coverage)." The authors noted that a separate analysis they performed using only Medicare program spending found similar results (Thorpe and Howard 2006b).

5 CBO defined high-cost beneficiaries as the costliest 25 percent of beneficiaries enrolled in FFS Medicare. These beneficiaries accounted for 85 percent of total spending in 2001 (including out-of-pocket spending and payments from supplemental insurance coverage), with average spending of about $24,800.

6 A beneficiary with an HCC score of 1.35 is predicted to have Medicare payments in the following year that are 35 percent greater than estimated payments for the average Medicare FFS beneficiary.

7 After one year of operation, 47,000 more beneficiaries were added to the study at the request of some of the MHSOs who thought a "refresh" population would be helpful to account for beneficiaries in the original "intent-to-treat" cohort who had died or disenrolled because of loss of eligibility. These 47,000 beneficiaries were randomly assigned and distributed across the program sites that agreed to receive new patients.

8 We received new information clarifying the role CMS would play in directing the network and other aspects of its structure as this report was going to press. We attempted to reflect as much of this new information as possible in this report, but time constraints prevented the Commission from reviewing all the new information.

9 Under a budget-neutrality policy, the accountable entity (e.g., the entire network or each individual network site participating in a given project to implement a care coordination intervention with an assigned group of beneficiaries) may not be paid for its services or may not be paid the full cost for them unless the costs of care for the population it serves are less than they would have been absent the care coordination intervention.

10 The timeline for this HCFO grant project is March 2008 to August 2009. According to information on the HCFO website, at the end of these grants the principal investigator is responsible for submitting a final written report of a quality that would be suitable for publication in a refereed scholarly or policy journal.

References

Agency for Healthcare Research and Quality. 2009. *AHRQ PBRN contract partnerships.* Rockville, MD: AHRQ.

Agency for Healthcare Research and Quality. 2007. *Closing the quality gap: A critical analysis of quality improvement strategies. Vol. 7—Care coordination.* AHRQ publication no. 04(07)–0051–7. Rockville, MD: AHRQ. June.

Agency for Health Care Research and Quality. 2006. *Accelerating Change and Transformation in Organizations and Networks (ACTION): Field partnerships for applied research.* AHRQ publication no. 06–P011. Rockville, MD: AHRQ. Fact sheet.

Anderson, G. 2005. Medicare and chronic conditions. *New England Journal of Medicine* 353, no. 3 (July 21): 305–309.

Ayanian, J. Z. 2009. The elusive quest for quality and cost savings in the Medicare program. *Journal of the American Medical Association* 301, no. 6 (February 11): 668–670.

Berenson, R., and J. Horvath. 2003. Confronting the barriers to chronic care management in Medicare. *Health Affairs Web Exclusives* (January 22): w3-37–w3-53.

Bodenheimer, T. 2008. Coordinating care—a perilous journey through the health care system. *New England Journal of Medicine* 358, no. 10 (March 6): 1064–1071.

Brown, R., D. Peikes, A. Chen, et al. 2007. *The evaluation of the Medicare Coordinated Care Demonstration: Findings for the first two years*. Princeton, NJ: Mathematica Policy Research, Inc.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Medicare extends demonstration to improve care of high cost patients and create savings. Baltimore, MD: CMS. Press release.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. *Medicare Physician Group Practice demonstration: Physician groups continue to improve quality and generate savings under Medicare physician pay for performance demonstration*. Baltimore, MD: CMS. Fact sheet. August.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2005. Medicare to award contracts for demonstration projects to improve care for beneficiaries with high medical costs. Baltimore, MD: CMS. Press release. July 1.

Congressional Budget Office. 2005. *High-cost Medicare beneficiaries*. Washington, DC: CBO.

Department of Health and Human Services. 2008. *Fiscal year 2009 Centers for Medicare & Medicaid Services justification of estimates for appropriations committees*. Washington, DC: HHS.

Foote, S. M. 2009. Next steps: How can Medicare accelerate the pace of improving chronic care? *Health Affairs* 28, no. 1 (January–February): 99–102.

Gold, M., and E. F. Taylor. 2007. Moving research into practice: Lessons from the US Agency for Healthcare Research and Quality's IDSRN program. *Implementation Science* 2, no. 9 (March 29).

Goldman, D. P., and N. Sood. 2006. Rising Medicare costs: Are we in crisis? *Health Affairs Web Exclusives* (August 22): w389–w390.

Guterman, S., and M. P. Serber. 2007. *Enhancing value in Medicare: Demonstrations and other initiatives to improve the program*. New York: The Commonwealth Fund. January.

Health Care Financing and Organization. 2008. Can disease management control costs? Grant no. 63996. Washington, DC: HCFO. Abstract.

Institute of Medicine. 2003. *Priority areas for national action: Transforming health care quality.* Washington, DC: National Academies Press.

Kapp, M. 2009. E-mail message to author, January 22.

Lanier, D. 2009. E-mail message to author, February 26.

Lanier, D. 2008. Practice-based research networks: Laboratories for improving colorectal cancer screening in primary care practice. *Medical Care* 46, no. 9, suppl. 1 (September): S147–S152.

Lawrence, D. M. 2005. Chronic disease care: Rearranging the deck chairs. *Annals of Internal Medicine* 143, no. 6 (September 20): 458–459.

McCall, N., J. Cromwell, C. Urato, et al. 2008. *Evaluation of phase I of the Medicare Health Support pilot program under traditional fee-for-service Medicare: 18-month interim analysis—report to Congress*. Washington, DC: RTI International.

McCall, N., J. Cromwell, and S. Bernard. 2007. *Evaluation of phase I of Medicare Health Support (formerly voluntary Chronic Care Improvement) pilot program under traditional fee-for-service Medicare*. Washington, DC: RTI International.

Medicare Chronic Care Practice Research Network. 2008a. Working paper, MCCPRN, Sioux Falls, SD. September 16.

Medicare Chronic Care Practice Research Network. 2008b. Response to MedPAC questions. Working paper, MCCPRN, Sioux Falls, SD. November 7.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Reforming the delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2006. *Report to the Congress: Increasing the value of Medicare*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2004. *Report to the Congress: New approaches in Medicare*. Washington, DC: MedPAC.

Meyers, D. 2009. E-mail message to author, April 6.

National Priorities Partnership. 2008. *National priorities and goals: Aligning our efforts to transform America's healthcare*. Washington, DC: National Quality Forum.

Palmer, Cynthia. 2008. Turning research to ACTION through delivery systems. Presentation. Rockville, MD: AHRQ.

Peikes, D., A. Chen, J. Schore, et al. 2009. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries: 15 randomized trials. *Journal of the American Medical Association* 301, no. 6 (February 11): 603–618.

Peikes, D., R. Brown. A. Chen, et al. 2008. *Third report to Congress on the evaluation of the Medicare Coordinated Care Demonstration.* Princeton, NJ: Mathematica Policy Research, Inc.

Pham, H. H., D. Schrag, A. S. O'Malley, et al. 2007. Care patterns in Medicare and their implications for pay for performance. *New England Journal of Medicine* 356, no. 11 (March 15): 1130–1139.

Schoen, C., R. Osborn, S. K. H. How, et al. 2008. In chronic condition: Experiences of patients with complex health care needs, in eight countries, 2008. *Health Affairs Web Exclusives* 28, no. 1 (November 13): w1–w16.

Sochalski, J., T. Jaarsma, H. M. Krumholz, et al. 2009. What works in chronic care management: The case of heart failure. *Health Affairs* 28, no. 1 (January–February 2009): 179–189.

Thorpe, K. E., and D. H. Howard. 2006a. Rising Medicare costs: The authors respond. *Health Affairs Web Exclusives* (August 22): w391–w392.

Thorpe, K. E., and D. H. Howard. 2006b. The rise in spending among Medicare beneficiaries: The role of chronic disease prevalence and changes in treatment intensity. *Health Affairs Web Exclusives* (August 22): w378–w388.

Tynan, A., and D. Draper. 2008. Getting what we pay for: Innovations lacking in provider payment reform for chronic disease care. Washington, DC: Center for Studying Health System Change. Research brief. June.

Wolff, J. L., and C. Boult. 2005. Moving beyond round pegs and square holes: Restructuring Medicare to improve chronic care. *Annals of Internal Medicine* 143, no. 6 (September 20): 439–445.

APPENDIX A

Review of CMS's preliminary estimate of the physician update for 2010

APPENDIX A

Review of CMS's preliminary estimate of the physician update for 2010

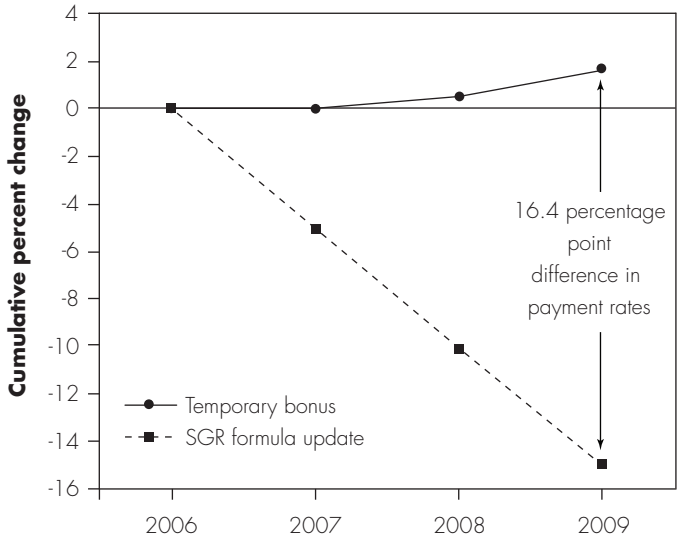
In CMS's annual letter to the Commission on the update for physician services, the agency's preliminary estimate of the 2010 update is –21.5 percent (Richter 2009). Most of the reduction is due to a series of temporary bonuses enacted over several years that will expire at the end of 2009. These bonuses prevented negative updates under the sustainable growth rate (SGR) formula—the statutory formula for updating Medicare's payment rates for physician services—that would have occurred in 2007, 2008, and 2009. Expiration of the bonuses will require an update of –16.4 percent to bring payment rates to the level where they would have been had the SGR formula's updates occurred. The remainder of CMS's estimate is the formula's update for 2010: –6.1 percent.[1]

This appendix provides our mandated technical review of CMS's estimate. We find that—absent a change in law—the update is very unlikely to differ substantially from –21.5 percent. The bonuses to override the SGR formula's updates were specified in law and are not subject to change. The SGR update for 2010 could change between now and when CMS implements the update in January but only by a small amount. According to the formula, the update is the projected change in input prices for physician services, adjusted by a factor to align spending with a target. While CMS's estimate of a 1.0 percent change in input prices may change, the agency's estimate of an update adjustment of –7.0 percent is the dominant factor, and it is very unlikely to change. By law, the update adjustment is limited to –7.0 percent. Without this limit, the adjustment calculated with the formula would be more than four times larger: –29.6 percent. Because the calculated adjustment exceeds the limit by such a large margin, it is very unlikely that an input to the calculations—such as the level of physician spending—will change enough to make the adjustment any amount other than –7.0 percent.

Before presenting the details of our technical review, we remind readers that the Commission is not satisfied with the current physician payment update mechanism. It does not provide incentives for individual physicians to control volume growth, and it is inequitable to those physicians who do not increase volume unnecessarily. And it continues to call for substantial negative updates through at least 2016. Such reductions in physician payment rates, if they take place, would threaten beneficiaries' access to physician services. Our report *Assessing Alternatives to the Sustainable Growth Rate System* examined several alternative approaches for updating physician payments and made suggestions to improve the accuracy of Medicare's payments, create incentives for physicians to provide better quality of care, coordinate care across settings, and use resources judiciously (MedPAC 2007).

FIGURE A–1

Temporary bonuses prevented the SGR formula's negative updates



Note: SGR (sustainable growth rate). The 16.4 percentage point difference is the ratio of the cumulative SGR formula updates to the cumulative temporary bonuses (0.8495/1.0161=0.8360 or –16.4 percent).

Source: Richter 2009 and Office of the Actuary 2009.

How temporary bonuses and other legislative provisions have affected payments for physician services

The SGR formula is intended to limit growth in Medicare spending for physician services. If aggregate spending exceeds a specified target in a given year, the formula calls for a downward adjustment in the physician fee schedule's conversion factor.

In recent years, the Congress has overridden the formula's updates. Spending has exceeded the target, and updates calculated with the formula have been negative. However, except for the negative update implemented in 2002, the Congress has passed specific legislation for each year to prevent further negative updates. The most recent of these overrides prevented negative updates that would have occurred in 2007, 2008, and 2009.

These three overrides were temporary bonuses that will expire at the end of 2009, totaling a cumulative increase in payment rates of 1.6 percent (Figure A-1).[2] Had the Congress not overridden the formula with these bonuses, the cumulative decrease in payments would have been 15.0 percent. The difference is the –16.4 percent figure mentioned earlier.

The bonuses for 2007, 2008, and 2009 were among a series of temporary updates that started with the update for 2004. Unlike the earlier interventions, however, the 2007–2009 bonuses were enacted with explicit expiration dates. In other words, legislation specified that, when the bonuses expire, updates are to be calculated with the formula as if the bonuses had never been applied. By contrast, when the Congress acted to override the SGR formula's updates for years before 2007, the updates were not set to expire on a specific date. Instead, legislation prescribed a positive update for a given year, allowing spending to rise above the level called for in the formula. The expectation was that the formula would gradually recoup the spending increase in later years.

In addition to the temporary bonuses, recent legislation has increased payments for physician services in other ways. For instance, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) increased bonuses under the Physician Quality Reporting Initiative to 2 percent of allowed charges for 2009 and 2010. Previously, the bonuses were 1.5 percent of allowed charges. MIPPA also established incentives for electronic prescribing. This program allows physicians to receive in 2009 and 2010 a 2 percent bonus on their allowed charges if they meet the program's requirements.[3] Through 2009, MIPPA extended higher payments for some areas through the floor on the physician fee schedule's geographic practice cost index (GPCI) for physician work.

How CMS estimated the SGR formula's update for 2010

Calculating the physician update is a two-step process. CMS first estimates the SGR—the target growth rate for allowed spending on physician services—for the coming year. The agency then computes the update using that SGR and historical information on actual and allowed spending.

SGR for 2010

The SGR 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 fee-for-service (FFS) Medicare—an allowance for fluctuations in the number of FFS beneficiaries, and
- spending attributable to changes in law and regulation—an allowance for policy changes that affect spending on physician services.

Allowing for these four factors, CMS's preliminary estimate of the SGR for 2010 is –8.2 percent (Table A-1).

The first of these factors—the estimated change in input prices of 1.2 percent—is lower than the figure for previous years. Given economic conditions, CMS projects relatively modest increases for physician compensation, staff earnings, rent, and other inputs. The Congressional Budget Office (CBO) is also projecting low inflation in input prices (CBO 2009a).

The next factor in the 2010 SGR—growth in real GDP per capita—is a 10-year moving average. It includes estimates of economic growth for 2001 through 2008 and projections for 2009 and 2010. CMS's estimate of 0.8 percent for this factor is not far from the 0.7 percent estimate that we calculate when we replace CMS projections for 2009 and 2010 with like projections from CBO (CBO 2009a).

For the factor on the change in FFS enrollment, CMS projects a decrease of 0.3 percent. CBO has a similar (fiscal year) projection: a decrease of 0.2 percent (CBO 2009b). A decrease would occur because of a shift in enrollment from Medicare FFS to Medicare Advantage.

The remaining factor in the 2010 SGR is a –9.7 percent change in spending due to law and regulation. Here, CMS anticipates that some changes in spending—such as a decrease when the floor on the work GPCI expires at the end of 2009 and an increase when incentives for electronic prescribing start in 2010—will mostly offset each other. That leaves expiration of the temporary bonuses as the primary source of the –9.7 percent change in spending that CMS estimates for the factor.

A change in spending of this magnitude may appear small relative to the –16.4 percent change in payment rates cited earlier. Note, however, that the expiring bonuses would affect only about 80 percent of the spending that meets the SGR formula's definition of spending for physician services. The other 20 percent is spending for Part B drugs and laboratory services. In addition, the law and regulation factor in the SGR is not an estimate of a change in payment rates; it is an estimate of a change in spending. A change in payment rates would not necessarily equal a change in spending if the change in payment rates were accompanied by a change in the volume of services. Indeed, when projecting a decrease in payment rates, CMS offsets the decrease by almost a third to account for a volume increase, consistent with the agency's research (Codespote et al. 1998). This perspective makes clearer the rationale for CMS's estimate of the law and regulation factor in the 2010 SGR: If volume goes up when the bonuses expire and payment rates go down, spending will decrease by less than the decrease in payment rates.

TABLE A–1

Preliminary estimate of the sustainable growth rate, 2010

Factor	Percent
2010 change in:	
Input prices for physician services*	1.2%
Real GDP per capita	0.8
Fee-for-service enrollment	–0.3
Change due to law or regulation	–9.7
Sustainable growth rate	–8.2

Note: GDP (gross domestic product). Percentages are converted to ratios and multiplied, not added, to produce the sustainable growth rate. Estimates shown are preliminary.
*The change in input prices includes inflation measures for services furnished by a physician or in a physician's office. It is adjusted for productivity growth.

Source: Richter 2009.

Calculating the SGR formula's update for 2010

After estimating the SGR, CMS calculates the update, which is a function of:

- the change in productivity-adjusted input prices for physician services, as measured by the Medicare Economic Index (MEI);[6] 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.

TABLE A–2

Preliminary estimate of the SGR formula's update for 2010

Factor	Percent
Change in input prices	1.0%
Update adjustment factor	–7.0
Update	–6.1

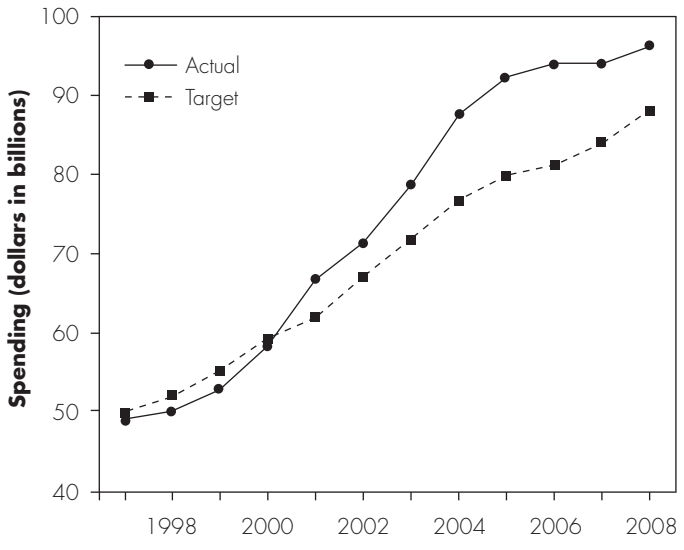
Note: SGR (sustainable growth rate). Percentages are converted to ratios and multiplied, not added, to produce the update. Estimates shown are preliminary.

Source: Richter 2009.

The estimate of the change in input prices for use in the 2010 update is 1.0 percent (Table A-2).[7] The part of the update calculation that has the larger effect, however, is the UAF. For 2010, CMS estimates a UAF of –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 estimate of –6.1 percent.

FIGURE A–2

Since 2001, actual spending for physician services has exceeded the target



Note: Estimates shown are preliminary.

Source: Office of the Actuary 2009.

The UAF is negative because actual spending for physician services has exceeded the target every year since 2001 (Figure A-2). As the deficit has grown, the formula has called for payment reductions, but the Congress has overridden the formula. According to CMS's estimates, the UAF without the statutory limit would now be –29.6 percent. Thus, CMS's update estimate (–6.1 percent) is unlikely to change by a substantial amount because a UAF of –29.6 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.

The only remaining issue in calculating the update concerns CMS's estimates of actual spending. When calculating the preliminary estimate of the 2010 update, CMS had data on actual spending that were nearly complete for the first three quarters of 2008 but less so for the last quarter of that year (OACT 2009). As more data become available, the estimate of actual spending in 2008 may change somewhat before CMS issues a final rule on the update in November. The estimates of actual spending for 2009 could change also. In any case, any uncertainty in these estimates is very unlikely to overcome a UAF of –29.6 percent. Therefore, we anticipate that CMS will revise the update calculations this fall, in preparation for implementing the 2010 update on January 1, and that—absent a change in law—the update will not differ substantially from CMS's preliminary estimate of –6.1 percent. In turn, when the formula's update for 2010 is implemented at the same time that the temporary bonuses expire, the combined effect is very unlikely to differ substantially from CMS's estimate of a physician update of –21.5 percent. ■

Endnotes

1 For the update calculations discussed in this appendix, percentages are not added. Instead, they are converted to ratios and multiplied. For instance, the estimate of the update for 2010 is the arithmetic product of the expiring bonuses (–16.4 percent, or 0.836) and the formula's update for 2010 (–6.1 percent, or 0.939). The multiplication is $0.836 \times 0.939 = 0.785$, or –21.5 percent.

2 For 2007, the Tax Relief and Health Care Act of 2006 maintained payment rates at 2006 levels. For the first six months of 2008, the Medicare, Medicaid, and SCHIP Extension Act of 2007 raised payment rates by 0.5 percent. For the second six months of 2008, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) maintained payment rates at the levels for the first six months of that year. For 2009, MIPPA raised payment rates by 1.1 percent.

3 The bonuses gradually fall to 0.5 percent in 2013. Starting in 2012, physicians are subject to payment reductions if they do not use electronic prescribing.

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 billable under the physician fee schedule.

7 In its March 2009 report, the Commission discussed a CMS forecast of change in the MEI in 2010 that equaled 2.4 percent. The forecast in the Commission's report differs from the MEI increase of 1.0 percent in CMS's preliminary estimate because—as required by law—the increase in the preliminary estimate is adjusted for productivity growth. That is, the 1.0 percentage point increase includes an adjustment for productivity growth of 1.3 percentage points. The other reason the MEI numbers differ is that the increase of 1.0 percent is not a forecast for 2010. Instead, it is an estimate of historical change—in this case, from 2008 to 2009.

References

Codespote, S. M., W. J. London, and J. D. Shatto. 1998. *Physician volume and intensity response*. Baltimore: CMS. http://www.cms.hhs.gov/ActuarialStudies/downloads/PhysicianResponse.pdf.

Congressional Budget Office. 2009a. *A preliminary analysis of the president's budget and an update of CBO's budget and economic outlook.* Washington, DC: CBO. March. http://www.cbo.gov/ftpdocs/100xx/doc10014/03-20-PresidentBudget.pdf.

Congressional Budget Office. 2009b. *CBO's March 2009 baseline: Medicare.* Washington, DC: CBO. March 24.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Assessing alternatives to the sustainable growth rate system.* Washington, DC: MedPAC. http://www.medpac.gov/documents/Mar07_SGR_mandated_report.pdf.

Office of the Actuary, Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. *Estimated sustainable growth rate and conversion factor, for Medicare payments to physicians in 2010.* Baltimore: CMS. March. http://www.cms.hhs.gov/SustainableGRatesConFact/Downloads/sgr2010p.pdf.

Richter, Elizabeth, Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Letter to Glenn M. Hackbarth, Medicare Payment Advisory Commission. March 1. http://www.cms.hhs.gov/SustainableGRatesConFact/Downloads/medpacfinal.pdf.

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: Medical education in the United States: Supporting long-term delivery system reforms

No recommendations

Chapter 2: Accountable care organizations

No recommendations

Chapter 3: Physician resource use measurement

No recommendations

Chapter 4: Impact of physician self-referral on use of imaging services within an episode

No recommendations

Chapter 5: Medicare payment systems and follow-on biologics

No recommendations

Chapter 6: Improving traditional Medicare's benefit design

No recommendations

Chapter 7: Medicare Improvements for Patients and Providers Act of 2008 Medicare Advantage payment report

No recommendations

Chapter 8: Improving Medicare chronic care demonstration programs: Section 150 of the Medicare Improvements for Patients and Providers Act of 2008 report

No recommendations

Appendix A: Review of CMS's preliminary estimate of the physician update for 2010

No recommendations

Acronyms

Acronyms

AAC	Area Advisory Committee
AACOM	American Association of Colleges of Osteopathic Medicine
AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
AAPCC	adjusted average per capita cost
AARP	(formerly) American Association of Retired Persons
ABMS	American Board of Medical Specialties
ACCME	Accreditation Council for Continuing Medical Education
ACGME	Accreditation Council for Graduate Medical Education
ACO	accountable care organization
ACOVE	Assessing Care of Vulnerable Elders
ACTION	Accelerating Change and Transformation in Organizations and Networks
ADL	activity of daily living
AGA	average geographic adjustment
AHA	American Hospital Association
AHIP	America's Health Insurance Plans
AHME	Association for Hospital Medical Education
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
AMA	American Medical Association
AMC	academic medical center
AMI	acute myocardial infarction
AOA	American Osteopathic Association
ASP	average sales price
BBA	Balanced Budget Act of 1997
BCBS	Blue Cross Blue Shield
BIO	Biotechnology Industry Organization
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CACMS	Committee on the Accreditation of Canadian Medical Schools
CAD	coronary artery disease
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CBO	Congressional Budget Office
CCP	coordinated care plan
CHF	congestive heart failure
CME	continuing medical education
CMHCB	Care Management for High-Cost Beneficiaries
CMO	care management organization
CMS	Centers for Medicare & Medicaid Services
CMSS	Council of Medical Specialty Societies
COGME	Council on Graduate Medical Education
COPD	chronic obstructive pulmonary disease
CPAC	Competitive Pricing Advisory Committee
CPI–U	consumer price index for all urban consumers
CT	computed tomography
DHS	designated health services
DM/CC	disease management, coordinated care
DOC	Department of Commerce
DoD	Department of Defense
E&M	evaluation and management
EBM	evidence-based medicine
EBRI	Employee Benefit Research Institute
ECFMG	Educational Commission for Foreign Medical Graduates
EHMS	extended hospital medical staff
EMEA	European Medicines Agency
EMR	electronic medical record
ER	emergency room
ESA	erythropoiesis-stimulating agent
ESI	employer-sponsored insurance
ESRD	end-stage renal disease
ETGs®	Symmetry Episode Treatment Groups®
EU	European Union
FDA	Food and Drug Administration
FEHB	Federal Employees Health Benefits [Program]
FFS	fee-for-service
FOB	follow-on biologic
FSMB	Federation of State Medical Boards
FTC	Federal Trade Commission
FTE	full-time equivalent
GAO	Government Accountability Office
GDP	gross domestic product
GME	graduate medical education
GPCI	geographic practice cost index
HCC	hierarchical condition category
HCFA	Health Care Financing Administration
HCFO	Health Care Financing and Organization
HEDIS®	Healthcare Effectiveness Data and Information Set
HF	heart failure

HHS	Department of Health and Human Services
HI	Hospital Insurance (Medicare Part A)
HIV	human immunodeficiency virus
HMO	health maintenance organization
HOS	Health Outcomes Survey
HRET	Health Research and Educational Trust
HRSA	Health Resources and Services Administration
HSA	health service area
HSC	Center for Studying Health System Change
IDS	integrated delivery system
IDSRN	integrated delivery system research network
IDTF	independent diagnostic testing facility
IME	indirect medical education
IMG	international medical graduate
IMS	International Monetary System
IOM	Institute of Medicine
IT	information technology
KFF	Kaiser Family Foundation
LCA	least costly alternative
LCME	Liaison Committee on Medical Education
LIS	low-income [drug] subsidy
LTC	long-term care
MA	Medicare Advantage
MAC	Medicare administrative contractor
MCBS	Medicare Current Beneficiary Survey
MCCD	Medicare Coordinated Care Demonstration
MCCPRN	Medicare Chronic Care Practice Research Network
M_E	multiple attribution based on evaluation and management dollars
MedPAC	Medicare Payment Advisory Commission
MEG®	Medical Episode Grouper®
MEI	Medicare Economic Index
MHC	Mental Health Component (of the Veterans RAND–12 instrument)
MHS	Medicare Health Support
MHSO	Medicare Health Support Organization
MIP	Managing Intellectual Property
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MITS	Medical Imaging & Technology Alliance
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MOC	maintenance of certification
MRI	magnetic resonance imaging
MSA	metropolitan statistical area
M_T	multiple attribution based on total dollars
N/A	not applicable
N/A	not available
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NCRP	National Council on Radiation Protection and Measurements
NDA	new drug application
NHPF	National Health Policy Forum
NMA	National Medical Association
NORC	(formerly) National Opinion Research Center
NRMP	National Residency Matching Program
OACT	Office of the Actuary
O/E	observed-to-expected [ratio]
OECD	Organisation for Economic Co-operation and Development
OOP	out-of-pocket
PAC	post-acute care
PACE	Program of All Inclusive Care for the Elderly
PATH	Payment for Academic Teaching Hospitals
PBPM	per beneficiary per month
PBRN	practice-based research network
PFFS	private fee-for-service
PGP	Physician Group Practice [demonstration]
PHC	Physical Health Component (of the Veterans RAND–12 instrument)
PHO	physician–hospital organization
PHQ–2	Patient Health Questionnaire–2
PHSA	Public Health Service Act
PPO	preferred provider organization
PPRC	Physician Payment Review Commission
PPS	prospective payment system
QA	quality assurance
RRC	residency review committee
RUR	resource use report
S_E	single attribution based on evaluation and management dollars
SGR	sustainable growth rate
SMI	Supplementary Medical Insurance (Medicare Part B)
SNP	special needs plan
S_T	single attribution based on total dollars
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982
UAF	update adjustment factor
U.K.	United Kingdom

U.S.	United States
U.S.C.	United States Code
USMLE	United States Medical Licensing Examination
USPCC	U.S. per capita cost
USPTO	U.S. Patent and Trademark Office
VA	Department of Veterans Affairs
VBID	value-based insurance design
VR–12	Veterans RAND–12

More about MedPAC

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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.

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Peter W. Butler, M.H.S.A., is a nationally recognized health care executive with more than 25 years of experience in teaching hospitals and health care systems. In addition to being executive vice president and chief operating officer of Rush University Medical Center in Chicago, Illinois, Mr. Butler is an associate professor and chairman of the Department of Health Systems Management at Rush University. Before joining Rush in 2002, he served in senior positions at The Methodist Hospital System in Houston and the Henry Ford Health System in Detroit. Mr. Butler holds an undergraduate degree in psychology from Amherst College and a master's degree in health services administration from the University of Michigan.

Ronald D. Castellanos, M.D., has practiced urology for more than 30 years. For the past four years Dr. Castellanos has been a member, and for the last year the chair, of the Practicing Physicians Advisory Council on issues related to physician payment. Dr. Castellanos was president of the Florida Urologic Society and has worked with several other organizations on health policy, including the American Urologic Association and the American Lithotripsy Society. Dr. Castellanos earned his medical degree from Hahnemann Medical College. His undergraduate degree is from Pennsylvania State University.

Michael Chernew, Ph.D., has been a professor in the Department of Health Care Policy at Harvard Medical School since 2006. Dr. Chernew taught previously at the University of Michigan, where he was co-director of the Robert Wood Johnson Scholars in Health Policy Research Program. He has served on a number of health care committees organized by federal and state governments as well as nonprofit and professional groups. Dr. Chernew co-edits the *American Journal of Managed Care* and serves on the editorial boards of several prominent health care journals. Dr. Chernew earned his undergraduate degree from the University of Pennsylvania and a doctorate in economics from Stanford University.

Francis J. Crosson, M.D., is the associate executive director of the Permanente Medical Group. He was previously senior medical director of the Permanente Federation of medical groups that make up the physician component of Kaiser Permanente. He joined Kaiser Permanente in 1977. He was the founder and executive director of the Federation from 1997 to 2007. He also has experience with prescription drug arrangements and has led efforts on comprehensive public report cards on clinical quality, management of a drug formulary, and adoption of a state-of-the-art electronic medical record. He serves on the boards of the California Medical Association Foundation, the American Medical Group Foundation, and the Advisory Board of the Mayo Health Policy Institute. Dr. Crosson received his undergraduate degree in political science from Georgetown University and his M.D. degree from Georgetown's School of Medicine.

Thomas M. Dean, M.D., is a board-certified family physician who has practiced in Wessington Springs, South Dakota, 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.

Glenn M. Hackbarth, J.D., M.A., chairman of the Commission, lives in Bend, OR. He has experience as a health care executive, government official, and policy analyst. He was chief executive officer and one of the founders of Harvard Vanguard Medical Associates, a multispecialty group practice in Boston that serves as a major teaching affiliate of Harvard Medical School. Mr. Hackbarth previously served as senior vice president of Harvard Community Health Plan and president of its Health Centers Division, as well as Washington counsel of Intermountain Health Care. He has held various positions at the U.S. Department of Health and Human Services, including deputy administrator of the Health Care Financing Administration (now known as CMS). He currently serves as the vice chairman of the board of the Foundation of the American Board of Internal Medicine. He is also a board member at the National Committee for Quality Assurance (NCQA) and at the Commonwealth Fund. He is also a member of the Commonwealth Fund's Commission on a High Performance Health System. Mr. Hackbarth received his B.A. from Pennsylvania State University and his J.D. and M.A. from Duke University.

Jennie Chin Hansen, R.N., M.S.N., F.A.A.N., of San Francisco, is president of AARP and a senior fellow at University of California's Center for the Health Professions. Ms. Hansen was executive director of On Lok Senior Health Services, the prototype for the Program of All Inclusive Care for the Elderly (PACE), which integrates Medicare and Medicaid finances and care 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 is 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 healthcare organizations. She has taught health care accounting, payment systems, financial analysis, and competitive strategy. Her research interests include measuring hospital financial performance, quantifying community benefits and the value of tax exemption, the competitive structure and performance of hospital and insurance industries, and nonprofit hospital governance. Professor Kane consults with federal and state agencies involved in health system design, oversight, and payment. She is an outside director of the Urban Medical Group, a nonprofit physician group practice providing care to frail elderly in institutional and home settings, and is a member of the Special Commission on the Health Care Payment System in Massachusetts. 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.

George N. Miller, Jr., M.H.S.A., has, over the last two decades, managed a series of hospitals, leading financial turnarounds at four of them. Since 2006, Mr. Miller has been president and CEO of Community Mercy Health Partners and senior vice president of Catholic Health Partners, a hospital chain in the Springfield, Ohio, area. Previously, he ran hospitals in Illinois, Texas, and Virginia and is the immediate past president of the National Rural Health Association. Mr. Miller has been an adjunct professor in health services administration at Central Michigan University since 1998. He has an undergraduate degree in business administration from Bowling Green State University and a master's of science in health services administration from Central Michigan University.

Arnold Milstein, M.D., M.P.H., is the medical director of the Pacific Business Group on Health (PBGH) and the chief physician at Mercer Health & Benefits. PBGH is the largest employer health care purchasing coalition in the U.S. 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 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 also a consultant to the National Health Policy Forum. Dr. Scanlon is a member of the National Committee on Vital and Health Statistics. Before his current positions, Dr. Scanlon was the managing director of health care issues at the U.S. General Accounting 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, Dr. Stuart has directed grants and contracts with various federal agencies, private foundations, state governments, and corporations. Dr. 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, Dr. Stuart was director of the health research division in the Michigan Medicaid program. Dr. 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. Dr. Stuart received his economics training at Whitman College and Washington State University.

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