

J U N E 2 0 0 5

REPORT TO THE CONGRESS

Issues in a Modernized Medicare Program

MEDPAC Medicare
Payment Advisory
Commission



The Medicare Payment Advisory Commission (MedPAC) is an independent federal body 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+Choice program and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

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

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

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

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 15, 2005

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

Dear Mr. Vice President:

I am pleased to submit the Medicare Payment Advisory Commission's June 2005 *Report to the Congress: Issues in a Modernized Medicare Program*. This report fulfills MedPAC's legislative mandate to examine issues affecting the Medicare program and to make specific recommendations to the Congress.

In this report, we:

- examine issues related to the implementation of Part D, Medicare's new outpatient prescription drug benefit;
- provide an overview of the Medicare Advantage program as well as recommendations regarding payment policy;
- address payment system refinements for dialysis and post-acute care; and
- consider the use of clinical- and cost-effectiveness analysis to improve Medicare's ability to be a value-based purchaser.

The report also fulfills three specific mandates from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to:

- assess the method used for determining the adjusted average per capita cost (MMA Section 211(f)) (*Chapter 2 of this report*);
- report on adjustment of payment for ambulatory payment classifications for specified drugs to take into account overhead and related expenses (MMA Section 621(a)(1)) (*Chapter 6 of this report*); and
- study the impact of legislated changes on critical access hospitals (MMA Section 433) (*Chapter 7 of this report*).

The report concludes by fulfilling our statutory obligation to analyze the Secretary of HHS's estimate of the update for physician services (*Chapter 9 of this report*).

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth".

Glenn Hackbarth, J.D.
Chairman

Enclosure



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June 15, 2005

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
U.S. House of Representatives
H232 Capitol Building
Washington, DC 20515

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Glenn Hackbarth, J.D.
Chairman

Enclosure

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Executive summary

Executive summary

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) makes many changes to the Medicare program. In its preparation to implement the MMA, CMS has had to deal with complicated issues balancing administrative complexity, burden on providers, beneficiary protection, and protection of the Medicare trust funds and taxpayers. In this report, the Commission speaks to some of these key implementation issues.

It also looks at the larger questions of how the Medicare program can pay more accurately for services within and across settings. We also report on three issues that the Congress mandated in the MMA: (1) Medicare Advantage (MA) program payment areas and risk adjustment, (2) pharmacy and nuclear medicine handling costs, and (3) critical access hospitals.

Monitoring the implementation of Part D

The MMA introduced a voluntary Medicare prescription drug benefit, which begins in 2006. In this program, private plans will deliver a drug benefit to their enrollees, and Medicare will pay the plans based on a nationwide average of bids. Beneficiaries who elect to participate in Part D will pay a premium, which will vary to some extent across the country. In Chapter 1, we examine several aspects of Medicare's new prescription drug coverage. We review measures that CMS could use to evaluate plan performance and monitor Part D. CMS will collect a large amount of data on Part D—including drug utilization, and measures such as enrollee satisfaction and claims processing accuracy. The Commission recommends that the Secretary develop a plan to assure the timely delivery of Part D data to congressional support agencies so that they can better inform the Congress about the drug benefit's impact on cost, quality, and access.

Plans are likely to use techniques developed in the commercial market both to help manage utilization (formularies and varied cost sharing) and to ensure members' access to needed drugs (appeals processes). In established commercial plans, few members appeal denied formulary exceptions—and when physicians pursue appeals for members, plans report high approval levels. However, as beneficiaries join plans for the first time, the appeals process could be more important, particularly for beneficiaries dually eligible for Medicare and Medicaid because appeal rights under Part D may differ from those under Medicaid. Judging from implementation of the discount drug card program, CMS will face challenges in educating Medicare beneficiaries

about prescription drug plan choices. Federal, state, and private outreach proved relatively ineffective in enrolling large numbers of beneficiaries in the discount drug card program. Automatic enrollment (with an option for the beneficiary to decline) for beneficiaries in state-sponsored and MA plans accounted for a large share of the overall enrollment.

Medicare Advantage payment areas and risk adjustment (mandated study)

The MMA directs MedPAC to study several issues related to the payment system for MA local plans. Our findings, discussed in Chapter 2, are: county-level adjusted average per capita costs (AAPCCs) vary widely, many counties have large annual changes in AAPCCs, and adjacent counties often have very different AAPCCs.

To stabilize rates and approximate private-sector market areas, the Commission recommends that the Congress establish larger payment areas for MA local plans. Specifically, among counties in metropolitan statistical areas (MSAs), payment areas should consist of counties that are located in the same state and the same MSA. Among counties outside MSAs, payment areas should consist of counties in the same state that accurately reflect health care market areas—such as health service areas. We also recommend that the Secretary update the health service areas.

As requested, we also evaluated the predictive accuracy of the CMS—hierarchical condition category risk-adjustment model. We found that it performs significantly better than a model similar to the demographic model that CMS has used in the past.

The Medicare Advantage program

The Commission strongly supports giving Medicare beneficiaries a choice to join private plans, because these plans have greater flexibility to improve the efficiency and quality of beneficiaries' health care services. The Commission recognizes that the Congress created the Medicare Advantage program in the MMA in part to encourage expansion of private plans. The MA program—among other changes—introduces bidding by plans and includes certain payment provisions that raise payment rates. The Commission has long recommended that there should be financial neutrality between private plans and fee-for-service (FFS) Medicare. Neutrality will exert consistent financial pressure on FFS and private

plans and encourage the entry of viable plans that will remain in markets long term. In Chapter 3, the Commission recommends that the Congress and CMS maintain neutrality between private plans and FFS Medicare, as well as among private plans, by:

- collecting quality measures for the FFS program that would enable comparison with the MA program;
- eliminating the preferred provider organization (PPO) stabilization fund;
- clarifying that regional plans should submit bids that are standardized for the region's Medicare Advantage-eligible population;
- putting in law the scheduled phase-out of the hold-harmless policy;
- removing the effect of payments for indirect medical education from the MA plan benchmarks; and
- linking payment benchmarks for MA plans to 100 percent of FFS costs, while returning savings from bidding to plans by rewarding quality performance. The Commission also finds that since the bidding process is underway and a sharp change in payments could be disruptive, alternative methods could link payments to 100 percent of FFS.

Payment for dialysis

The MMA improved payment for dialysis services—for example, it added a case-mix adjuster to the payment system. But under current law and regulations, Medicare pays dialysis providers differently based on site of care and type of drug. In Chapter 4, the Commission recommends a series of changes to rationalize payment policies. Medicare should pay the same amount for composite-rate services at hospital-based and at freestanding dialysis facilities and should then combine the composite rate with the add-on adjustment the MMA created. In addition, Medicare should use the same payment method—average sales price (ASP)—to pay for all dialysis drugs provided by both facility types. Because of concerns about the accuracy of the ASP, we also recommend that the Secretary collect acquisition cost data from dialysis providers to determine whether ASP accurately reflects the prices that dialysis providers pay. However, rationalizing payment for composite-rate services and dialysis injectables is only an interim

solution; Medicare should also broaden the payment bundle and link payment to quality to modernize this payment system.

Payment for post-acute care

Doctors and discharge planners should help beneficiaries choose their post-acute care setting based on patient characteristics, their care needs, and the outcomes in different settings. In Chapter 5—after comparing hip and knee replacement patients in different settings—we find that costs and outcomes differ by setting. However, we found it difficult to evaluate the comparisons because the characteristics of patients differ across settings and because there is no common assessment instrument. In fact, each post-acute care setting uses a different patient assessment tool; we describe the tools' characteristics in the chapter. Until a common instrument becomes available, it may be useful to specify admission criteria for each setting, as we have recommended previously for long-term care hospitals.

We also examined the prospective payment systems (PPSs) that CMS uses to pay for skilled nursing facility and home health care. Refining the skilled nursing facility PPS to better distribute payment for nontherapy ancillary costs and adjusting payments based on patient characteristics would improve this system's performance. The home health PPS may fail to adequately account for cost differences across patient categories and agencies. Future work should examine how to correct problems with payments in these settings to ensure that the payments better track the resource needs of different patients.

Payment for pharmacy handling costs in hospital outpatient departments (mandated report)

The MMA mandated that MedPAC report on whether the Secretary should adjust payments in the outpatient PPS to account for pharmacy and nuclear medicine handling costs. The issue arises because Medicare will begin to pay for certain drugs, biologicals, and radiopharmaceuticals based on acquisition costs in 2006. Previously, Medicare's payment rates for these items were higher, providing hospitals with sufficient resources to cover handling costs.

In Chapter 6, we conclude that handling costs are nontrivial and an adjustment is warranted. Any adjustment should be budget neutral, because when CMS established the outpatient PPS, it based payments on hospital charges

that reflected these handling costs. The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals. The Secretary should also: define a set of handling fee ambulatory payment classifications (APCs) that group the products based on their attributes that affect handling costs; instruct hospitals to submit charges for those APCs; and base payment rates for the handling fee APCs on submitted charges, reduced to costs. However, although warranted, creating handling fee APCs would continue the trend toward further separating payments for individual items and services in the outpatient PPS. Larger payment bundles would create stronger incentives for efficiency in the outpatient PPS, including incentives for efficiently furnishing drugs.

Critical access hospitals (mandated report)

The Congress mandated that MedPAC study the effects of the critical access hospital (CAH) provisions in the MMA. In Chapter 7, we find that the CAH program has succeeded in protecting the financial viability of many small rural hospitals and that closures of CAHs have almost ceased. We estimate that about 1,300 hospitals will be in the program by the end of 2005. We expect cost-based payments for those CAHs to total about \$5 billion in 2006—roughly \$1.3 billion more than what PPS payments would have been for those same services. As a result of the CAH provisions in the MMA, a few more hospitals will convert this year, but conversions will effectively end after 2005.

Additionally, we found that some CAHs are located quite close to other providers. In 2003, approximately 17 percent of cost-based Medicare payments to CAHs went to CAHs that were 15 or fewer miles from another hospital. This finding raises the issue of competition between CAHs and providers paid under a Medicare PPS. For example, Medicare payments to CAHs for post-acute patients in swing beds (beds that CAHs can use for both acute and post-acute patients) exceed rates paid to competing SNFs. In addition, CMS does not require CAHs to report on quality of care for SNF patients. Payment modifications and other adjustments may need to be made to ensure fair competition.

Using clinical and cost effectiveness in Medicare

Policymakers are looking for ways to use Medicare's resources more efficiently. Using information about

clinical effectiveness is one way to do so. MedPAC supports the evidence-based process that CMS uses to make coverage decisions and, more recently, to link coverage with a requirement for data collection. Cost-effectiveness analysis has the potential to promote care that is more cost efficient and higher quality. Medicare does not explicitly consider cost-effectiveness information in either the coverage or payment process. As we discuss in Chapter 8, before Medicare can routinely use cost-effectiveness analysis, valid concerns will need to be addressed about its methods. The Secretary could play an important role in standardizing the methods in these analyses. Opportunities for the program to begin considering such information include collecting it from manufacturers in the coverage process (when available), sponsoring cost-effectiveness studies, providing high-quality studies to beneficiaries and health professionals, and using available high-quality studies to prioritize pay-for-performance and disease management initiatives.

Review of CMS's preliminary estimate of the physician update for 2006

Every year, CMS calculates a preliminary estimate of the next payment update for physician services and MedPAC reviews it in our June report to the Congress. For 2006, CMS's estimate is an update of -4.3 percent. In Chapter 9, we find that CMS used estimates in calculating the update that are consistent with recent trends. The primary factor leading to this negative update is that the volume of physician services has increased at a faster rate than the economy has grown. As a result, the difference between target and actual spending in the update equation has grown, as well. Our review shows that the gap is now so large that likely changes in other parameters of the equation will not be sufficient to change the calculated update from -4.3 percent.

CMS reports a 15.2 percent one-year growth in spending for physician services in 2004. This rapid growth in spending raises questions about whether all the services are appropriate and supports recommendations that MedPAC has made on paying for performance, measuring resource use, reforming the payment update for physician services, and developing quality standards for imaging providers. Additional recommendations could come from work that the Commission is planning on laboratory services, physical therapy, and possible mispricing of payments under the physician fee schedule. ■

CHAPTER

1

**Monitoring the
implementation of Part D**

R E C O M M E N D A T I O N

The Secretary should have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

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

Monitoring the implementation of Part D

This chapter examines some of the issues that will arise as CMS implements the Medicare drug benefit. We examine performance measures, premium variation, outreach and enrollment, and beneficiary grievance and appeals protections. Building on the work of other purchasers, CMS must determine how to measure the performance of plan sponsors and the overall drug benefit. Part D enrollees will face different premiums across the nation. Medicare will provide the same subsidy to plans on behalf of each enrollee, and enrollees will pay more if their plan's benefit spending is higher. Plans may be able to reduce geographic variation in premiums by managing enrollees' use of drugs. Nevertheless, higher premiums might lead to lower enrollment in some parts of the country. CMS will auto-enroll beneficiaries dually eligible for Medicare and Medicaid in Part D, but the agency may find it difficult to reach and enroll other low-income individuals.

In this chapter

- Description of the Part D benefit
- Performance measures for evaluating Part D implementation
- Paying plans, setting premiums, and enrollment in Part D
- The Medicare discount drug card and beneficiary outreach for Part D
- Formulary exceptions and the appeals processes
- Looking forward: Electronic prescribing and other areas of future research

On January 1, 2006, Medicare will begin a voluntary outpatient drug benefit known as Part D. A combination of stand-alone prescription drug plans (PDPs) and Medicare Advantage (MA)–Prescription Drug plans (MA–PDs) will deliver the benefit. In each of 34 geographic regions, plans will compete for enrollees on the basis of annual premiums, benefit structures, degree of access to specific drug therapies, and quality of services. Plans will bear some risk for their enrollees’ drug spending. In order to encourage Medicare beneficiaries to enroll, the government will subsidize premiums by nearly 75 percent and will provide additional subsidies for beneficiaries who have low incomes and assets.

In this chapter, we describe issues related to CMS’s implementation of the Medicare Part D benefit and discuss strategies for monitoring and evaluating this new benefit in the future. Because the policy goals of appropriate access, high quality, and reasonable cost sometimes compete with one another, Medicare must strike a balance among them.

Our research on drug benefit implementation issues suggests the following key findings:

- In the commercial market, purchasers rank cost as a top priority in evaluating the performance of their plan’s drug benefit management. To evaluate drug benefit quality, purchasers use measures that track enrollees’ access to pharmacies, needed drugs, and safe utilization. Purchasers also review measures on member satisfaction and on benefit administration, such as claims processing accuracy. For Part D, CMS intends to construct and use performance measures, but it has not yet selected or announced them for either short- or long-term analysis.
- CMS will be collecting a large amount of data on Part D, including drug use and plan benefit information. Congressional agencies will need Part D data to report to the Congress about the impact of Medicare payment policies on cost, quality, and access.
- Premiums for Part D will, in percentage terms, vary more across geographic regions than per capita drug spending due to the method of calculating enrollee premiums required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Plans may be able to reduce today’s geographic variation in spending, somewhat, by

managing enrollees’ use of prescription drugs. Nevertheless, higher Part D premiums might lead to lower enrollment in some parts of the country.

- Because CMS will automatically enroll beneficiaries who are dually eligible for Medicare and Medicaid, these individuals could represent a disproportionate share of early enrollees in Part D plans. The share of dual eligibles varies considerably among each region’s Medicare population. An open question remains: How will differences in the proportion of each region’s Medicare population that CMS auto-enrolls affect geographic variation in Part D premiums?
- In the case of the Medicare discount drug card, CMS and other state agencies experienced difficulty in targeting outreach strategies to beneficiaries who are disabled, low income, less educated, or living in long-term care facilities. Auto-enrollment proved far more effective than voluntary enrollment and accounted for a larger share of the overall enrollment in the discount card program.
- Health plans and pharmacy benefit managers (PBMs) have well-established processes that involve the use of prior authorization and other techniques to manage drug utilization. Most plan members do not appeal denied formulary exceptions. Physicians frequently decide, when told of the prescribed drug’s nonformulary status, that the formulary drug is acceptable. When physicians pursue requests, plans report very high approval levels. However, given the increased level of drug utilization likely to occur in 2006, the volume of appeals may increase.
- Beneficiaries who are dually eligible for Medicare and Medicaid will have fewer appeal rights under Part D than they currently have under Medicaid. For example, Medicaid programs must continue to provide ongoing drug treatment to beneficiaries while an appeal is underway. Part D plans will not face this requirement, and beneficiaries may be unfamiliar with new processes for appealing formulary decisions. When dual eligibles begin receiving their drug benefit from Part D plans, some of these individuals may be taking drugs that are not on their plans’ formulary. Plans must develop transition policies that are adequate to ensure that beneficiaries continue to receive medications and do not delay or stop treatment because they face unfamiliar formulary exceptions processes.

Description of the Part D benefit

The MMA defines a standard drug benefit under Part D and describes the conditions under which private plans may offer alternative benefit designs. In 2006, the standard benefit will include:

- a \$250 deductible;
- coverage for 75 percent of allowable drug expenses up to a benefit limit of \$2,250;
- a \$3,600 catastrophic limit on true out-of-pocket spending¹ (or \$5,100 in total drug expenses for enrollees without supplemental drug coverage); and
- about 5 percent coinsurance for drug spending above the catastrophic limit (Figure 1-1).²

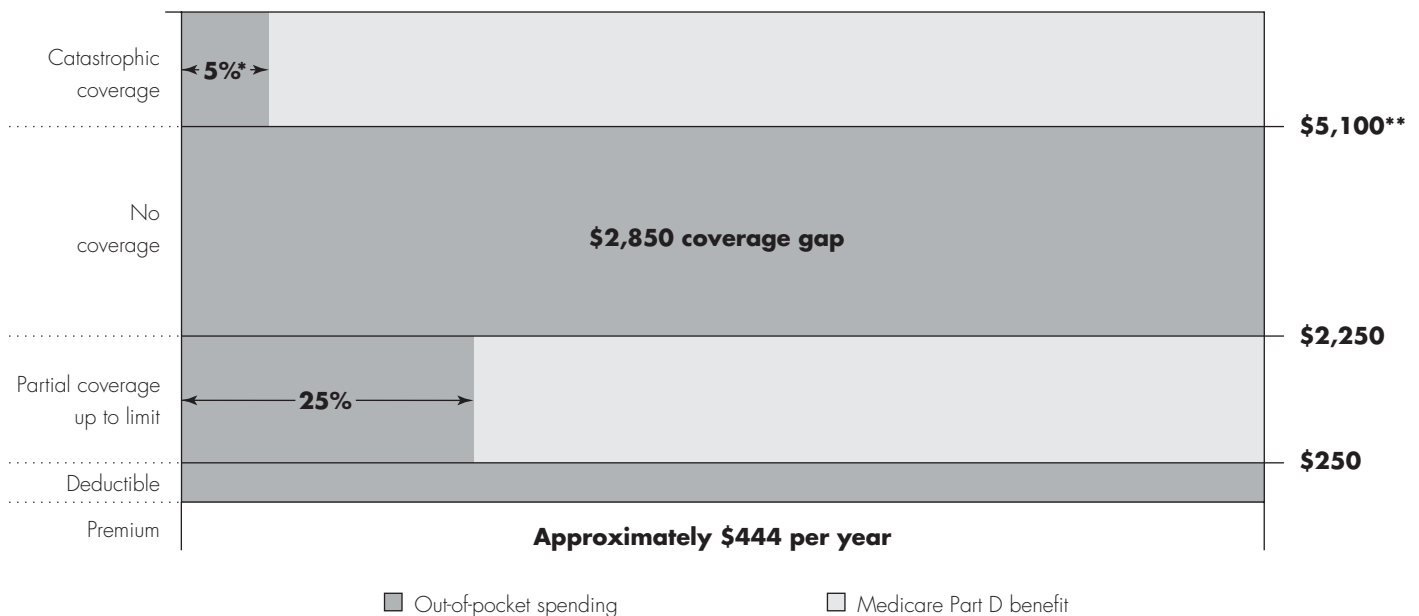
Enrollees with standard benefits will pay 100 percent coinsurance for drug spending greater than \$2,250 but less

than their catastrophic threshold. However, beneficiaries will be able to obtain their plan's discounted price for prescription drugs for drug spending in this coverage gap. They would also need to adhere to their plan's formulary, prior authorization, and formulary exceptions processes in order to receive credit for their out-of-pocket spending toward the \$3,600 catastrophic limit.

Although the MMA explicitly lays out the structure of this standard Part D benefit, the law also permits plans to offer alternative coverage. For example, a plan could use tiered copayments rather than coinsurance, provided that cost sharing averages 25 percent of allowable drug spending above the deductible and below the benefit limit. The law permits other variations from the standard benefit—such as having a deductible lower than \$250—provided that the alternative benefit meets certain tests of actuarial equivalence. CMS expects that enrollee premiums for these basic benefits will average \$37 per month in 2006, but each plan's specific premium could vary.

FIGURE 1 - 1

Standard drug benefit in 2006



Note: Benefit structure applies for an enrollee who has no supplementary drug coverage.

* Cost sharing above the catastrophic cap is the greater of either 5 percent coinsurance or a copay of \$2 for generic drugs, or \$5 for brand-name drugs.

** Equivalent to \$3,600 in out-of-pocket spending: \$250 (deductible) + \$500 (25% cost sharing on \$2,000) + \$2,850 (100% cost sharing in the "coverage gap").

Source: MedPAC analysis.

**TABLE
1-1**

Out-of-pocket spending under the low-income drug benefit, 2006

Beneficiary income	Premium	Deductible	Copayments*	Coverage gap
Dual eligibles, up to 100% FPL	none	none	\$1-3	none
Other dual eligibles and others, 100-135% FPL	none	none	\$2-5	none
135-150% FPL	sliding scale	\$50	15% of drug cost	none

Note: FPL (federal poverty level). Low-income beneficiaries must meet an asset test to qualify for low-income subsidies. In 2006, assets must be no greater than \$10,000 for an individual or \$20,000 for a couple.

*Plans may not charge copayments to dual eligibles who live in long-term care facilities.

Source: CMS 2005g.

The law provides additional subsidies for low-income beneficiaries. Medicare will begin providing primary drug coverage for individuals who are dually eligible for Medicare and Medicaid. Dually eligible individuals who earn incomes up to 100 percent of poverty will have no deductibles and nominal copays. CMS will randomly assign them to drug plans if they do not choose a plan by January 1, 2006, and these beneficiaries will be able to change plans at any time. Low-income beneficiaries who do not qualify for Medicaid may also receive subsidies: Individuals who earn incomes below 150 percent of poverty and who meet an asset test will receive full or partial coverage for premiums and cost-sharing and will not face a coverage gap (Table 1-1).

Medicare beneficiaries will likely see a variety of benefit designs available in the market. MA-PDs may offer broader coverage than the basic benefit (for example, by filling in the coverage gap) without charging an additional premium.³ If a PDP or MA-PD meets the requirement of offering basic Part D coverage, it may also offer supplemental coverage for an additional unsubsidized premium. Even two competing plans—both offering the standard benefit—may appear somewhat different from one another because they can include different mixes of preferred and nonpreferred drugs on their formularies.

Performance measures for evaluating Part D implementation

Policymakers will need to monitor the implementation of the new Medicare drug benefit to evaluate plan performance and to measure how well Part D meets cost,

quality, and access objectives for pharmaceutical care. Employers and government agencies use performance measures to evaluate how well health plans and PBMs manage the drug benefits they purchase.

MedPAC staff convened a panel of experts to discuss performance measures and to identify ways in which policymakers could use measures to monitor the Part D program over time and evaluate participating plans' performance. Under contract, Georgetown University researchers organized the panel and facilitated the meeting's full-day discussion. The panelists represented health plans, PBMs, employers, pharmacies, consumers, quality assurance organizations, and researchers.

The panelists were unable to reach a consensus on a specific set of performance measures that should be used for Part D plans, or even for drug benefits in the commercial market. However, they did discuss several areas of performance that purchasers (e.g., employers) consider when selecting and monitoring the health plan or PBM that manages their drug benefits. These areas of performance measures were:

- cost control,
- access to needed medications and quality assurance,
- benefit administration and management, and
- enrollee satisfaction.

Table 1-2 lists these areas of performance and, for illustrative purposes, provides an example of a measure in each area. Purchasers use many additional (and often more detailed) measures to assess health plan or PBM performance in managing drug benefits. Also, as we

**TABLE
1-2**

Examples of performance measures purchasers use to evaluate drug benefit management

Measurement areas	Examples
Cost control	
Plans' drug spending	Average drug spending per member per month (risk-adjusted)
Out-of-pocket drug spending	Average annual out-of-pocket spending on covered drugs (risk-adjusted)
Pharmacy discounts on drugs	Average rate of discount on brand and generic drugs
Pharmacy dispensing fees	Dispensing fees for brand and generic drugs
Manufacturer rebates	Total aggregated rebates as a percentage of total drug spending, annually
Drug utilization	Average number of prescriptions per member per year, by therapeutic category
Generic use	Ratio of generic drugs to total drugs that have an available generic
Formulary adherence	Ratio of preferred to nonpreferred brand-name drugs covered
Access and quality assurance	
Pharmacy network	Ratio of preferred network pharmacies to all pharmacies in service area
Enrollee refill adherence	Percentage of members who refill chronic medications
Formulary review process	Average time P&T committee takes for initial review of new drug
Prior authorization and nonformulary exceptions	Average time for plan decision on prior authorization request
Appeals process and rates	Percentage of appeals that are overturned
Point-of-sale electronic messaging to pharmacists	Frequency of updates to clinical safety messaging software
Utilization of drugs contraindicated for the elderly	Percentage of drugs contraindicated for the elderly on prior authorization
Adverse drug interactions, events	Number of adverse drug interactions and/or adverse drug events per 1,000 members
Drug utilization review	Presence of screening to identify drugs filled beyond maximum therapeutic duration
Electronic prescribing use	Percentage of prescriptions submitted through e-prescribing per year
Benefit administration and management	
Claims processing	Percentage of claims processed accurately per year
Eligibility determination	Percentage of claims processed for ineligible individuals per year
Data management for coordination of benefits	Accuracy of benefit-spending calculations
Enrollee satisfaction	
Enrollee survey results	Member satisfaction rates
Call-center availability	Hours per day that the call center is open
Call-center response times	Abandonment rates (percentage of time caller hangs up while on hold)
Grievance reporting	Average number of complaints reported per 100 members per year
Plan retention and disenrollment	Percentage of enrollees who voluntarily disenrolled

Note: P&T (pharmacy and therapeutics). The measures included in the second column are examples meant for illustrative purposes. Drug benefit purchasers (e.g., employers) may use many other more detailed measures to assess health plan or pharmacy benefit manager (PBM) performance. In some cases, results from these measures can be interpreted differently, depending on other plan variables.

Source: MedPAC analysis.

discuss later in this chapter, results from these measures can be interpreted in different ways, depending on other plan variables.

Under Part D regulations, CMS will collect data that CMS and other policymakers could use for performance measurement in most of these areas. For example, CMS will have information on beneficiaries' drug utilization

and spending, plans' pharmacy network breadth, claims processing accuracy, and beneficiary satisfaction rates. In addition, CMS will have medical claims data for risk adjusting many of these measures. In its Part D regulations, CMS states that it will develop plan performance measures for the drug benefit, but the agency has not yet selected these measures or determined how they will be used.

Considering the complexity of implementing a drug benefit of this size, policymakers may expect some initial challenges and difficulties that likely will be resolved over time. Therefore, both short- and long-term analyses of Part D will be important. Indeed, evaluation at the start of the benefit can help identify the most useful measures to implement in the coming years. Once appropriate measures are selected and constructed, CMS could release some publicly, use some to determine financial awards in a pay-for-performance model, or factor some into future plan contracting decisions. Ultimately, CMS may use performance measures across the entire enrolled population to evaluate the drug benefit's implementation and make operational adjustments, where needed.

Cost control

Most panelists agreed that purchasers rank cost as a top priority in evaluating the performance of their health plan's or PBM's drug benefit management. In general, PBMs and health plans control drug benefit costs by negotiating with pharmacies and pharmaceutical manufacturers and by managing members' drug utilization. Although purchasers can track overall drug spending totals, their ability to evaluate plan performance on specific cost-control activities—such as formulary design—varies.

Negotiations with pharmacies and pharmaceutical manufacturers

PBMs and health plans establish retail pharmacy networks with which they negotiate discounts on prices for brand-name and generic drugs. Plans and PBMs also include negotiated dispensing fees in their pharmacy contracts; these fees can include incentives for substituting generic for brand-name drugs, when available (Mercer 2003b). Plans and PBMs provide purchasers with information on their negotiated dispensing fees. Similarly, CMS will require Part D plans to submit dispensing fee data. This information might serve as an indicator to CMS of how well plans negotiate with their pharmacy network to lower costs.

Some expert panelists noted that because generic substitution is an effective cost-control tool, purchasers commonly examine plans' generic dispensing rates—the number of covered generics as a percentage of total covered drugs or as a percentage of total covered drugs for which generics are available. CMS will collect generic dispensing rate data by plan and could use this information

as one measure of plans' ability to control costs. CMS will also have drug claims data to allow calculation of generic dispensing rates for the Medicare population.

In addition to contracts with pharmacies, the majority of PBMs and health plans that provide pharmacy benefit services establish contractual relationships with pharmaceutical manufacturers to receive rebates. These rebates are typically based on target volumes of drug sales. Plans and PBMs provide purchasers with some information to show how much purchasers gain through rebates. For example, measures may show total dollars saved or the negotiated percent discount off the published average wholesale price. Panelists agreed that PBMs and health plans may share some portion of their rebate revenues with purchasers but do not always clearly disclose actual numbers. Several panelists commented that purchasers devote considerable resources verifying reported rebates, but they find this task difficult because PBMs generally consider the data to be proprietary.

Under Part D, Medicare will require plans to report aggregate rebates confidentially in order to estimate transaction prices. Plans will apportion a share of their total rebates to Part D utilization and report that amount. Previous lapses in government oversight of Medicaid drug pricing and manufacturer rebates highlight the challenge that Medicare will face in reviewing and auditing rebate information (GAO 2005). A few panelists suggested that CMS will need to monitor fraud and abuse and assert its right to audit participating plans. They noted previous legal actions filed against PBMs regarding misrepresentation of their cost-saving methods and objectives.

Drug utilization management

A plan's drug spending reflects the type and amount of drugs that members take. Drug utilization measures focus on both aspects. The National Committee for Quality Assurance (NCQA) has developed a few performance measures on drug utilization that employers can use when evaluating health plan performance. For example, NCQA collects data on plans' total prescription drug costs, the average cost of prescriptions per member per month, the total number of prescriptions, and the average number of prescriptions per member per year (NCQA 2005). Under Part D, CMS will collect data on some of these same measures. In combination with health claims data, these metrics will allow CMS to calculate risk-adjusted

spending and utilization trends for Part D to determine how well the drug benefit controls costs over time. These measures will also allow for some general drug-spending comparisons among Part D plan sponsors.

Much of the panel discussion on cost control focused on the broad set of activities that health plans and PBMs use to manage the drugs that members take. Among other goals (such as safety), these activities can steer enrollees toward specific drugs that the plans and PBMs determine are the most clinically appropriate and cost effective. For example, formulary design features—including drug lists, tiered cost sharing, step therapy, and prior authorization policies—can influence members’ drug utilization. The MMA states that Part D plans are expected to use a variety of drug utilization management activities, some of which they currently employ with their commercial clients.

Health plans and PBMs commonly use drug utilization review (DUR) to manage the costs associated with enrollees’ drug utilization. Such DUR activities may include screening for overutilization of drugs. These screens can help plans and PBMs achieve cost savings (in addition to improving safety) by automatically reviewing instances in which enrollees refill prescriptions beyond their maximum therapeutic timeframe.

Several panel experts suggested performance measures that assess the impact of utilization activities. For example, formulary compliance measures examine rates at which members take preferred over nonpreferred brand-name drugs. Physician prescribing and patient preferences strongly influence these rates, but health plans and PBMs have several tools to educate physicians and members on the rationale for distinguishing drugs by preferred and nonpreferred tiers. Generic dispensing rates also provide a measure of drug utilization management. Experts in our panel emphasized that physicians have considerably more impact on members’ drug choices than do plans’ utilization management activities. Health plans, particularly those in group staff models, typically communicate more with their prescribing physicians and thus may have more opportunities to influence prescribing patterns than do independent PBMs.

Out-of-pocket spending

Many group health purchasers also monitor enrollees’ out-of-pocket spending as it affects enrollee (employee) satisfaction. In general, plans’ success at lowering some drug prices will reduce their members’ out-of-pocket

spending on those drugs. However, depending on enrollee utilization, some drug utilization tools—such as tiered cost sharing—that lower *purchaser* costs may raise enrollee out-of-pocket costs. In their reports to purchasers, PBMs and health plans often separate out-of-pocket spending from the benefit’s covered spending.⁴

Some experts on the panel stated that beneficiaries are extremely interested in how Part D will affect their out-of-pocket spending, including premium payments. Participating plans will submit data to CMS that will enable the agency to compute beneficiaries’ average out-of-pocket spending on covered drugs. These calculations will be essential for policymakers’ evaluation of Part D over time. CMS could also calculate and monitor average, risk-adjusted, out-of-pocket spending by plan. When making enrollment decisions, this kind of information might help beneficiaries determine which plans can give them the best value.

Access and quality assurance

The Congress established Part D to improve Medicare beneficiaries’ access to needed medications, and included provisions in the program to encourage safe utilization. Panelists described a variety of measures that drug benefit purchasers use to evaluate enrollee access to medications, and whether the covered medications they take are appropriate and safe. Because pharmaceuticals are so central to effective medical treatment, some purchasers also may consider access to prescription drugs a measure of plan or PBM quality. Under Part D, plans will have financial incentives to control costs, highlighting the need for access and quality measures. CMS will be collecting some relevant data that can be used to develop access and quality measures for plans and—for the Medicare drug benefit, overall.

Pharmacy access

Some panelists noted that pharmacy access is a major factor in plan and PBM selection—both for group health plan purchasers and for individuals who are purchasing their own drug coverage. Measures of pharmacy access evaluate members’ ability to obtain their medications conveniently. When making contracting decisions, purchasers often request detailed reports on the locations of the pharmacies in health plan and PBM networks. For example, employers may compare employee zip codes to the locations of plans’ pharmacies.

Under Part D, Medicare requires a minimum level of pharmacy access based on standards set for the TRICARE program—the program that insures members of the U.S. military and their dependents. This standard specifies maximum average distances to plans’ network pharmacies within a state, based on the type of geographic area (rural, urban, or suburban). In general, these minimum pharmacy access standards are adequate for most beneficiaries, but some beneficiaries who live in rural areas may have to travel more than 15 miles to reach a network pharmacy. Some panelists stated that Part D plans with broad pharmacy networks will likely attract more consumers because beneficiaries tend to focus heavily on the convenience of a plan’s pharmacy network when selecting a plan.

Although plans may have many pharmacies in their network, and minimum access standards exist, Medicare may still need to monitor beneficiary access to pharmacies. In particular, plans can distinguish between preferred and nonpreferred pharmacies in their overall networks by offering lower cost sharing for preferred pharmacies. In such circumstances, access to preferred pharmacies may not meet TRICARE standards in some areas. To identify access problems (if they exist), CMS could examine beneficiary distances to preferred and nonpreferred pharmacies by zip code.

Access to needed medications

To ensure that drug utilization management programs do not prevent enrollees from obtaining needed medications, purchasers can examine measures that show enrollees’ access to drugs. For example, purchasers may examine the number of drugs plans list on their formulary. However, several panelists cautioned that formulary designs do not directly reveal drug access. In practice, enrollees may have either greater or lesser access to drugs than a formulary’s drug list suggests—that is, plans can cover drugs that are *off* the formulary and, alternatively, can require prior authorization for drugs that are *on* the formulary.

The panelists considered other performance measures that could reflect access, but many again noted that the data might be ambiguous. For example, the ratio of formulary to nonformulary drugs covered might be a useful measure, but it is difficult to interpret. A high share of nonformulary use could indicate that the plan employs a flexible exceptions process to ensure that members get the drugs they need. Alternatively, this high share could indicate that the formulary is out of date or

that physicians do not find it acceptable. A low exception ratio may mean that physicians consider the plan’s process for granting a nonformulary exception too onerous—or, alternatively, that the formulary is relatively unrestrictive and well-accepted by physicians. A plan’s rate of overturned appeals has similar caveats.

Panelists discussed some approaches that Medicare could use to measure access to medications under Part D. Some panelists suggested that CMS evaluate exception rates within selected therapeutic categories. This measure could show whether beneficiaries can obtain necessary drugs for a given condition. Others suggested access measures on the frequency of claim denials at the point of sale, and whether enrollees later obtained an alternative drug or got their plan to cover the drug through a prior authorization or formulary exception.

Some purchasers use other access measures to examine member adherence to treatment regimens, particularly for chronic conditions (Berman 2005). CMS could use claims data to calculate the average number of times per year that members refill their monthly prescriptions, by therapeutic class. By carefully analyzing beneficiary access to medications by therapeutic category, CMS could also examine how differences in variables, such as formulary design and cost sharing associate with differences in adherence rates.

Part D addresses access concerns for people who have expensive, chronic conditions by prohibiting plans from excluding from their formulary whole classes of drugs used to treat expensive conditions, such as AIDS. CMS will require Part D sponsors to submit for review formularies and other drug management utilization programs, such as step therapy rules that encourage the use of low-cost medications before covering high-cost medications for a given medical condition. During the bidding process, CMS intends to review plans’ drug utilization management requirements to ensure that beneficiaries receive appropriate and timely access to medically necessary drugs. CMS’s review of drug utilization programs, including formularies, is consistent with that of group health purchasers; these purchasers require their contracted PBM or health plan to demonstrate their formulary’s cost effectiveness and clinical appropriateness, thus ensuring that members can obtain the drugs they need (Mercer 2003b).

Quality assurance

By facilitating access to appropriate medications, health plans and PBMs go a long way toward ensuring health care quality. Many purchasers also look at measures that evaluate the safety and appropriateness of medication dispensing and prescribing. Integrated health plans are usually accredited and have built-in incentives to manage their drug benefits to avoid medical complications. Part D regulations require plans to develop and submit an explanation of their own quality assurance systems, but these regulations do not require specific quality assurance performance measures.

The need for quality assurance measures and systems to reduce medication errors and adverse drug interactions is well documented for the elderly population (Booz Allen Hamilton 2004, Goulding 2004, Fick et al. 2003, Beers 1997). However, peer-reviewed literature does not reach consensus on methods for determining which drugs are appropriate for the elderly, and under which circumstances. NCQA has recently proposed some prescription drug measures to examine safe drug utilization in its health plan accreditation process (see text box, p. 12). One of its proposed measures assesses how well health plans reduce their elderly members' use of drugs that are contraindicated for elderly people. CMS will have the data needed to implement this kind of quality assurance measure. With its medical and drug claims data, CMS also could begin to examine the frequency of emergency room visits due to adverse drug events and drug-to-drug interactions, depending on the adequacy of claims' diagnosis information.

A common tool that health plans and PBMs use for quality assurance is point-of-sale electronic messaging to alert pharmacists about safety concerns before dispensing particular drugs. Claims processing systems typically screen for potential drug interactions, overuse, incorrect dosage, allergy contraindications, and clinical abuse or misuse. Performance measures, therefore, often examine whether plans employ these types of alerts, whether the alerts are up to date with best clinical practice, and whether pharmacists find the messages clear and easy to understand.

Some panelists indicated that pharmacists receive a large number of messages and alerts. This barrage of messages may lead some pharmacists to ignore many alerts in order to fill prescriptions in a timely manner. One recent report to CMS noted that too many redundant messages and outdated warnings may cause pharmacists to disable

electronic messaging features or routinely override messages (Booz Allen Hamilton 2004). The Academy of Managed Care Pharmacy (AMCP) has published guiding principles on electronic messaging systems. One principle suggests that plans and PBMs revise their claims processing systems to eliminate the number of redundant messages that pharmacists receive per claim, such as the following two similar messages: “drug not covered for females” and “drug not covered for patient gender.” By eliminating such redundancies, plans and PBMs could improve pharmacists' ability to focus on important clinical safety alerts.

The expert panelists agreed that physician prescribing remains the most important and influential component of quality assurance in drug utilization. Accordingly, health plans and PBMs are exploring ways to educate physicians at the moment in which they prescribe medication therapies. Electronic prescribing (e-prescribing) technology can help physicians make safe prescribing decisions, prescribe formulary medications, and reduce errors due to illegible handwriting. We discuss e-prescribing further on page 33.

Health plans typically focus more broadly on quality assurance than PBMs because they provide an integrated benefit package and seek accreditation. Health plans have a greater opportunity to integrate measures of pharmaceutical quality with broader measures of quality of care. A number of organizations measure and evaluate health plans' quality assurance programs for accreditation purposes. Because PBMs usually are not independently accredited, they do not necessarily evaluate their performance on the same specific measures, but PBMs may adopt practices that are consistent with the accreditation standards required of their client health plans (Booz Allen Hamilton 2004).⁵ Also, health plans are typically at risk if prescription drug utilization or underutilization results in medical complications; thus, health plans have built-in incentives to monitor and improve the safety of members' prescription drug utilization. PBMs are not usually at risk for medical costs—such as hospitalizations—that are associated with underutilization of needed medications or unsafe drug utilization. Additionally, PBMs that are not integrated within a health plan or insurer do not typically collect data on their enrollees' health status and health care utilization.

To encourage plans to connect health outcomes with prescription drug use, the MMA requires that all Part D plans offer a medication therapy management program

(MTMP) to targeted beneficiaries—namely, those who have multiple chronic conditions, are taking multiple medications, or have high expected drug expenses. MMA introduced the MTMP to improve therapeutic outcomes through activities such as pharmacist consultations. These consultations could include a review of member beneficiaries' full drug regimens to detect the potential for adverse drug interaction as well as patterns of

prescription drug overuse and underuse. In the early stages of the Medicare drug benefit, CMS will allow plans to determine the methods and types of providers they will use to implement MTMP services. CMS is delaying the collection of performance measures for these programs but will require plans to report some operational data, such as the numbers of eligible and participating beneficiaries. Considering that the MMA expects MTMPs to improve

Current and proposed drug utilization and quality measures in HEDIS

The Health Plan Employer Data and Information Set (HEDIS) is a set of standardized performance measures designed to allow purchasers and consumers to compare managed care organizations on the basis of quality. HEDIS is a model for emerging systems of performance measurement in other areas of health care delivery. The National Committee for Quality Assurance (NCQA), a not-for-profit organization that evaluates and publicly reports on the quality of managed care organizations, maintains HEDIS.

In 2006, health plans will report on more than 60 HEDIS performance measures, including measures that assess appropriate medication treatment for patients with asthma, depression, heart attack, and other conditions. Below are some of NCQA's current and proposed HEDIS measures that relate specifically to prescription drugs:

- **Outpatient drug utilization.** This current measure summarizes data on outpatient utilization of prescription drugs. It includes the total cost of prescriptions, the average cost of prescriptions per member per month, the total number of prescriptions, and the average number of prescriptions per member per year.
- **Antibiotic utilizations.** For 2006, NCQA proposes to look also at possible overutilization of selected antibiotics known to contribute to antibiotic drug resistance compared with overall antibiotic use. The measure provides information on outpatient antibiotic use by drug class, including total and average number of antibiotics per member per year and average days per antibiotic prescription.
- **Pharmacotherapy management of chronic obstructive pulmonary disease (COPD) exacerbations.** This proposed measure assesses whether members who were discharged home following a COPD exacerbation episode treated in the emergency department or in an inpatient hospital setting received systemic corticosteroids within 7 days and/or bronchodilators within 21 days.
- **Drugs to be avoided in the elderly.** Among health plan enrollees age 65 and older and in Medicare, proposed HEDIS measures include two rates: (1) the percentage who received at least one prescription for a drug to be avoided in the elderly, and (2) the percentage who received prescriptions for at least two different drugs to be avoided in the elderly. The first rate assesses the extent to which elderly patients have had some exposure to potentially harmful drugs. The second rate further assesses if elderly patients have been exposed to multiple harmful drugs. NCQA identifies drugs to be avoided in the elderly population based on clinical journal publications and clinical consensus.
- **Annual monitoring of patients on persistent medications.** This proposed patient safety measure would assess whether adults taking medications for chronic conditions are receiving timely monitoring to prevent potential problems associated with persistent use of these drugs, including drug toxicity, electrolyte imbalances, renal failure, and liver damage. ■

therapeutic outcomes, performance measures that assess reductions in adverse health events due to drug-to-drug interactions may be an important future measure.

Benefit administration and management

Purchasers rely on health plans and PBMs for administrative functions such as processing prescription drug claims, managing drug identification cards, and adjudicating primary and secondary payer information. The expert panelists stated that performance measures for these tasks are relatively common, and CMS could monitor them under Part D.

Generally speaking, PBMs and health plans are able to process most drug claims almost instantaneously through electronic communication links with their network pharmacies, but delays and errors can occur. Many purchasers routinely look at the accuracy of their PBM's eligibility determinations, dispensing fee payments, and cost-sharing charges (Mercer 2003b). Many panelists noted that if CMS monitored these administrative tasks at the beginning of Part D implementation, beneficiaries may experience smoother enrollment into the Medicare drug benefit.

Under Part D, plans will need to provide pharmacies with drug price information so that they can calculate beneficiary cost sharing at the point of sale. Additionally, plans must provide monthly statements to beneficiaries explaining their year-to-date drug spending, if any. CMS will contract with a single company that will provide Part D plans and CMS with electronic information regarding other payers (e.g., employer-sponsored supplemental plans that wrap around the Medicare plan).⁶ Plans will use this information to track members' out-of-pocket spending for covered drugs. CMS could implement performance measures on the accuracy of cost-sharing charges to ensure that beneficiaries are paying the correct amounts for their medications.

Enrollee satisfaction

Health plans and PBMs commonly measure member satisfaction rates and offer relevant performance guarantees to their clients. In addition to survey results, purchasers can also examine plans' call-center performance and disenrollment rates to evaluate member satisfaction. Panelists noted that both CMS and Part D plans could conduct some of these activities.

Satisfaction surveys

Health plans and PBMs routinely provide their current and potential clients with results of enrollee satisfaction surveys (Mercer 2003b). Purchasers typically determine their own target threshold for enrollee satisfaction, recognizing that they may not be able to compare rates between plans that use different survey instruments. However, purchasers can track enrollee satisfaction over time when the plan or PBM presents the purchasers with periodic survey results.

Under Part D regulations, CMS will conduct consumer satisfaction surveys of Part D enrollees and provide the results to beneficiaries as they are making enrollment decisions. CMS is reviewing possible survey instruments and anticipates working with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey that measures beneficiaries' experience with their prescription drug coverage.⁷ Using this survey, CMS can obtain consumer satisfaction rates directly from beneficiaries.

Call center operations

Many panelists stated that the performance of plans' and PBMs' customer-service call centers plays an important role in influencing enrollee satisfaction. Purchasers commonly examine the length of time that callers wait on hold, as well as abandonment rates (the share of calls in which the caller hangs up while waiting on hold to talk with a service representative). Under Part D, CMS could collect the same performance measures that it currently collects for the discount drug card program—namely, hours of operation and call-center response times. Some panelists also suggested that CMS collect data on call centers' ability to serve non-English speakers.

Retention and disenrollment rates

By examining the extent to which members voluntarily stay in or disenroll from plans, CMS will have additional indicators of consumer satisfaction. Under Part D, beneficiaries will be able to switch plans once during the year, and more frequently if they are eligible for Medicaid or if they reside in long-term care facilities.⁸ In general, plans with high retention rates are likely to show higher consumer satisfaction than plans with lower retention rates. In addition, Medicare can use this information to track beneficiary satisfaction with the Part D benefit, as a whole.

Data needs

As noted above, CMS will be collecting a large amount of data on Part D, including drug utilization and plan benefit information. In addition to claims and spending data, Part D sponsors must submit data on pharmacy discounts, aggregate pharmaceutical manufacturer rebates, generic dispensing rates, formulary design, prior authorizations, nonformulary exceptions, appeals, coordination of benefits for out-of-pocket determination, call-center operations, grievances, and enrollment/disenrollment. CMS will also collect satisfaction survey data from beneficiaries and additional health claims data from other providers. Therefore, CMS will have a rich and comprehensive set of data for Part D analysis. Indeed, CMS will have more robust information on Part D than it collects on Part C—the Medicare Advantage program.

CMS has stated that it intends to construct and use performance measures to monitor the Part D benefit. At this time, CMS has not yet selected these measures or determined how they will be used. In the long term, these uses could include (but are not limited to) releasing some measures publicly, using some measures to determine financial awards in a pay-for-performance model, or factoring some measures into future plan contracting decisions. In addition to using measures to assess plan performance, CMS could also use them to assess how well the overall benefit is meeting its objectives for the beneficiary population and could design operational changes accordingly.

At the start of the benefit, plans are likely to encounter several logistical challenges. Therefore, analysis of plan performance in the initial year should take these difficulties into consideration. Data analysis of the early stages of Part D will be essential to help policymakers identify and shape important and useful performance measures for the program over time.

In addition to CMS, congressional support agencies are charged with reporting to the Congress about the impact of Medicare payment policies on cost, quality, and access. Data on Part D are necessary for analyzing program performance and making policy recommendations. Therefore, CMS will need to develop a process for the timely dissemination of Part D data to congressional support agencies.

RECOMMENDATION

The Secretary should have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

RATIONALE

Congressional agencies need these data to monitor and evaluate the new Part D benefit in the initial stages of the program and over the long term.

IMPLICATIONS

Spending

- This recommendation would not increase federal program spending.

Beneficiary and provider

- This recommendation would have no direct impact on beneficiaries. It also would not affect provider cost or administrative burden because it does not require submission of additional data.

Paying plans, setting premiums, and enrollment in Part D

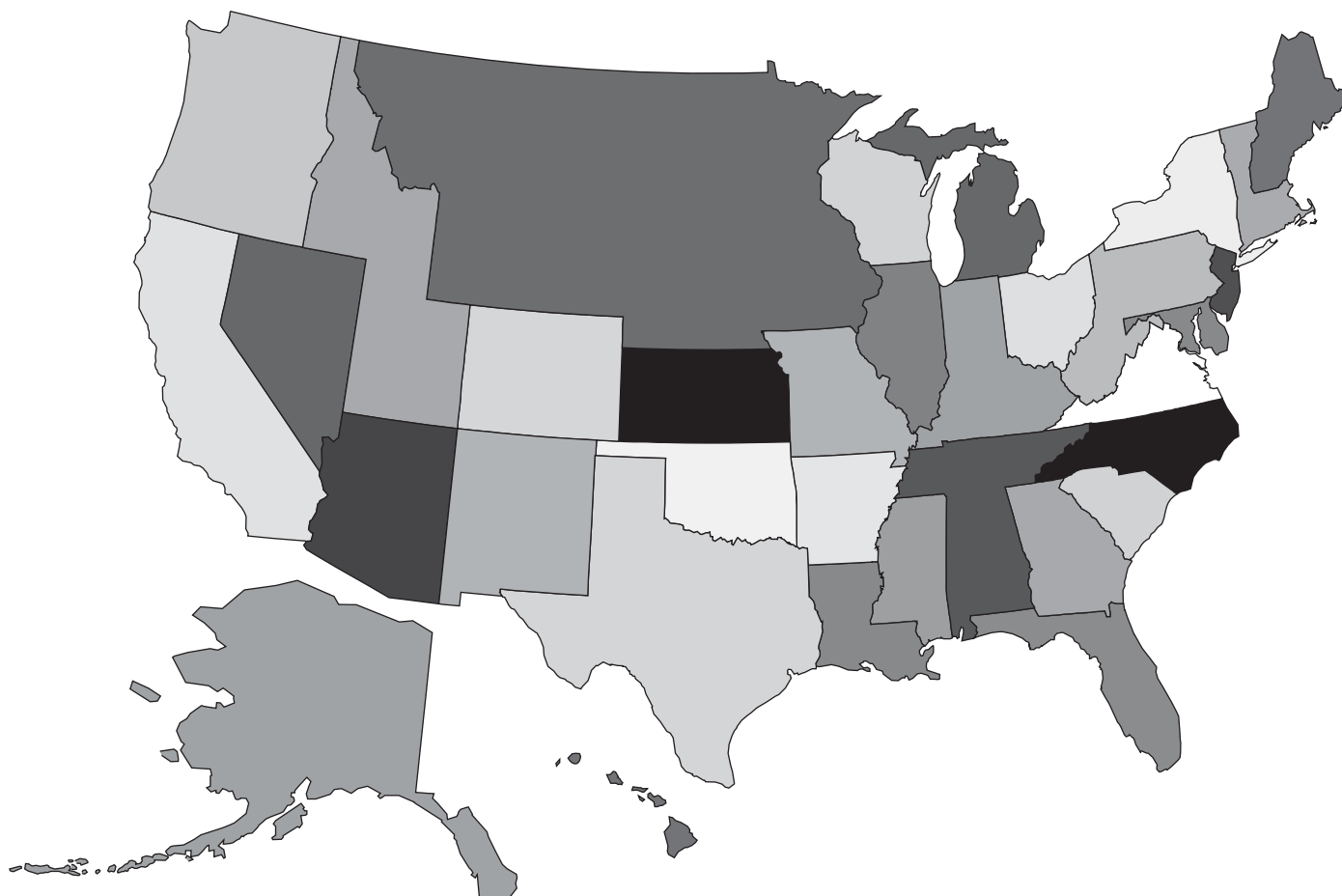
A number of private organizations have announced that beginning next year, they intend to offer PDPs nationwide, offer them in several PDP regions, or offer MA-PDs.⁹ Although plan entry constitutes an important half of the equation in establishing Part D, uncertainty remains about how many Medicare beneficiaries will choose to enroll. Beneficiaries' decisions about whether to sign up for a Part D plan will depend, in part, on what premiums they must pay.

In this section, we review how CMS will pay Part D plans, how it will set enrollee premiums, and why premiums may vary across geographic regions. We discuss the following:

- ***Under Part D, enrollee premiums are likely to differ around the country.*** One implication of Part D's premium-setting approach is that beneficiaries who live in parts of the country with higher use of prescription drugs could face higher premiums than people who live in areas with lower use. Plans may be able to reduce this geographic variation by managing enrollees' use of prescription drugs. Nevertheless,

**FIGURE
1-2**

CMS established 34 PDP regions



Note: PDP (prescription drug plan).

Source: CMS 2005h.

higher Part D premiums might lead to lower enrollment in some parts of the country.

- ***Because CMS will auto-enroll beneficiaries who are dually eligible for Medicare and Medicaid, these individuals could represent a disproportionate share of early enrollees in Part D plans.*** The share of dual eligibles varies between 9 percent and 29 percent of each region's Medicare population. An open question remains: How will differences in the proportion of dual eligibles in each region's population affect geographic variation in Part D premiums?

Prescription drug plan regions

In late 2004, CMS announced its decision to establish 34 separate PDP regions, or groupings of states (Figure 1-2). Stand-alone drug plans must offer the same benefit and charge the same premium to all Medicare beneficiaries who enroll within a given PDP region.¹⁰ A single legal entity may offer PDPs in several or all regions; CMS considers each of that company's regional PDPs a separate plan. Entities that have drug plans in several regions may choose to use the same formulary everywhere that they operate, but they are not required to do so. However, the company must submit separate bids to CMS for each PDP; as a result, premiums for that entity's plans could vary across regions.

When creating the regions, CMS considered three factors. First, it looked for combinations of states in which sufficient numbers of Medicare beneficiaries live, in order to ensure that at least two PDPs would have an economically viable risk pool.¹¹ At the same time, CMS did not want to make the eligible population of regions too large—potential Part D plan offerors expressed concern about the degree of insurance risk to which they would be exposed, particularly during Part D’s startup. Second, CMS aimed to keep PDP regions as compatible as possible with MA regions; in doing so, CMS would avoid beneficiary confusion and simplify operations for MA–PDs. Finally, CMS sought to group states that had similar average levels of drug spending.

Medicare’s payments to plans

Each plan (stand-alone PDP and MA–PD) will submit bids annually to CMS by the first Monday in June. Those bids should reflect the plan’s expected benefit payments plus administrative costs after they deduct expected federal reinsurance subsidies. (See text box on federal subsidies at the end of this chapter.) Plans will base their bids on expected costs for a Medicare beneficiary of average health; CMS will then adjust payments to plans based on the actual health status of the plans’ enrollees.

CMS will pay plans a monthly prospective payment (called a direct subsidy) for each enrollee. This payment equals the plan’s approved bid times the enrollee’s risk adjustment factor, minus the enrollee’s premium for standard coverage. In addition, CMS may pay plans monthly prospective payments for average estimated individual reinsurance on high-cost enrollees with drug spending above the true out-of-pocket threshold. CMS will also pay plans monthly prospective payments for beneficiaries who are enrolled in Medicare’s low-income subsidy program. Although CMS will provide these payments prospectively each month, the agency will reconcile actual levels of enrollment, risk factors, levels of incurred allowable drug costs (after rebates and other discounts), reinsurance amounts, and low-income subsidies at the end of each year.

Enrollee premiums

The main reason that beneficiary premiums will vary among plans is that enrollees must pay for any difference between their plan’s bid and the national average bid amount. CMS bases the direct subsidy on a national weighted average of plan bids. Thus, enrollees in costlier

plans could face higher-than-average premiums for standard Part D coverage; similarly, enrollees in less expensive plans would pay lower-than-average premiums. This situation will likely happen within a given PDP region. Likewise, beneficiaries who live in a part of the country with higher-than-average spending on prescription drugs may find that all plans in their area charge premiums that are higher than the national average. The situation would be reversed in regions with lower spending.

To calculate Medicare’s direct subsidy, CMS will average the bids of risk plans (MA–PDs and PDPs), weighting each bid by expected levels of enrollment. Enrollees will pay a portion of the national average bid plus any difference between their plans’ bid and the national average. (See text box for an example of how CMS will calculate enrollee premiums.)

Policymakers disagree on the extent to which geographic variation in Part D premiums is appropriate and acceptable. Differences in opinion stem from whether one believes that the costs of geographic variation in drug benefits should be borne by the individuals who live in regions that use more prescriptions, or redistributed more broadly across all enrollees. Some believe that Part B’s approach—in which enrollees pay the same premium everywhere—is the fairer approach. Others believe that—like the Part D benefit—it would be fairer for Medicare to provide the same federal dollar subsidy to plans (adjusted for each member’s health status) and require enrollees to pay more if their region’s benefit spending is higher.

Geographic variation in prescription drug spending

The specific way in which Part D premiums are calculated—with the enrollee premiums picking up the full difference from the national average—tends to magnify, in percentage terms, geographic variation in drug spending. (See text box on p. 18 for a simulation of premium variation for a sample of Medicare beneficiaries.) But to what extent does drug spending vary? Such variation could occur if prices for the same drugs differ around the country, or if prescription drug use varies geographically.

Variation in drug prices

Several factors suggest that drug prices should not vary much across the country. Many of the entities involved in making, delivering, and managing prescription drugs (such as pharmaceutical manufacturers, retail pharmacy chains,

and PBMs) are large organizations with national contracts. As a result, one might not expect to see much variation in retail prices for drugs, except perhaps for differences in transportation expenses or the cost of retail operations.

Past research finds only limited evidence of geographic variation in prices. One recent study analyzed retail prices of prescription drugs posted on the website for the Medicare-endorsed drug discount cards. Researchers

How will CMS calculate enrollee premiums for Part D?

As a hypothetical example, assume that three plans submit bids to offer Medicare's new prescription drug benefit in 2006, and each plan has one-third of the total expected enrollment in Part D (Table 1-3). Plan 2 expects to have monthly drug claims, administrative costs, and profits that are about average, while Plans 1 and 3 expect to have costs that are higher and lower, respectively. To submit their bids to CMS, each plan will calculate monthly costs for a Medicare beneficiary of average health, and then subtract an estimate of the average monthly amount of individual reinsurance subsidies that the plan expects to receive from Medicare for its enrollees.

CMS will calculate the average of submitted bids, weighted by the plans' share of total enrollment. From this nationwide average, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifies that plan enrollees must pay a base premium plus any difference between their plan's bid and the nationwide average bid. The basic enrollee premium equals the nationwide average times a factor with a numerator of 25.5 percent and a denominator of 100 percent minus CMS's estimate of the plan's revenues for Part D benefits that it receives from federal individual reinsurance. In the example below, this sum equals \$37 per month. Thus, the enrollee's premium is the sum of the base premium plus the difference between his or her plan's bid and the national average bid. ■

**TABLE
1-3**

Example of how monthly enrollee premiums could vary for three prescription drug plans

	Plan 1	Plan 2	Plan 3
Plan's expected cost of drug claims, administration, and profit	\$164	\$146	\$128
Plan's expected individual reinsurance subsidies	- 42	- 38	- 33
Plan bid submitted to CMS	\$122	\$108	\$95
Plan's expected share of enrollment in Part D	33%	33%	33%
National average bid	\$108	\$108	\$108
Base enrollee premium	\$37	\$37	\$37
Amount by which plan's bid exceeds the national average bid	+ 14	- 0	- 13
Enrollee's monthly premium	\$51	\$37	\$24
Enrollee's monthly premium divided by the base enrollee premium	1.36	1.00	0.64

Note: All bid costs are for basic Part D coverage for a Medicare beneficiary of average health. The national average bid is the average plan bid weighted by each plan's share of enrollment. The base beneficiary premium equals the national average bid multiplied by $[0.255 / (1 - \text{CMS's estimate of the percentage of total plan revenue attributable to individual reinsurance subsidies})]$. This example assumes no adjustment of premiums for geographic differences in the prices of prescription drugs.

Source: MedPAC analysis based on data from CMS.

Premium variation for a sample of privately insured Medicare enrollees

To demonstrate how Part D premiums will be set, we asked Direct Research, LLC, to analyze a sample of medical and drug claims for privately insured individuals who are also enrolled in Medicare—totaling about 1 million people in 2001. These data are not representative of the Medicare population as a whole: On average, the individuals for whom we have claims have more years of education, higher incomes, more comprehensive medical and drug coverage, and somewhat better health status than the typical Medicare beneficiary.

The data set includes the number and type of prescriptions filled at retail and mail-order pharmacies, by type of drug. For price information, we mapped nationwide average transaction prices for each national

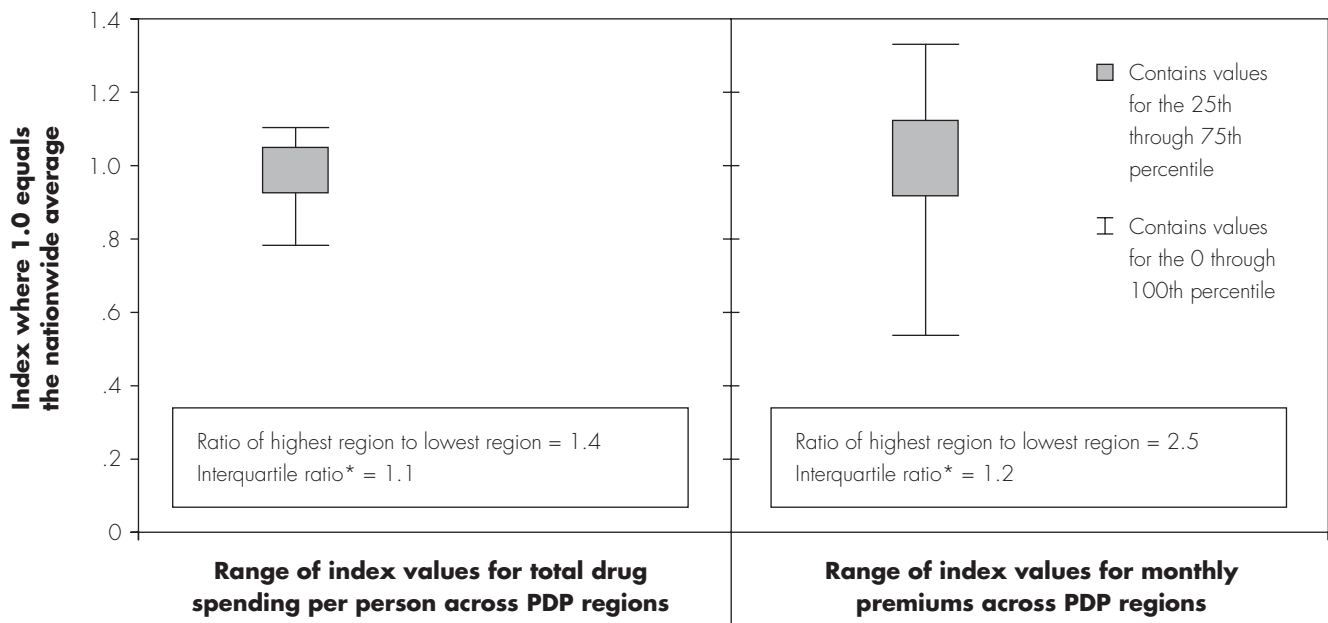
drug code (NDC) in 2001 medical expenditure panel survey (MEPS) data to NDCs listed on the private-payer drug claims. As is the case with many claims data sets, price information from MEPS excludes any manufacturers' rebates.

We used these data to examine two questions. First, how much geographic variation in drug spending exists? Second, what might premiums look like, assuming that all Part D plans have their region's average mix of enrollees? For each individual, we calculated the amount of Part D cost sharing that the enrollee would owe and what benefits a standard plan would cover, offset by federal individual reinsurance subsidies for people with very high drug spending. We calculated the average monthly cost per member for

continued on next page

FIGURE 1-3

Percentage geographic variation in drug spending and simulated premiums for a sample of privately insured individuals



Note: PDP (prescription drug plan). The nationwide averages have a value of 1.0, and regional values are depicted as an index relative to the nationwide mean. Premiums were estimated from privately insured prescription drug claims for individuals who are also enrolled in Medicare. Estimates assume that plan administrative costs are 5 percent of total enrollee drug spending. Premium estimates do not include assumptions about cost management savings or additional enrollee utilization associated with insurance coverage.

* The interquartile ratio is the value for the 75th percentile divided by the value for the 25th percentile. It measures the amount of variation across regions, an amount that is less influenced by extreme values.

Source: Direct Research, LLC, for MedPAC.

Premium variation for a sample of privately insured Medicare enrollees (cont.)

enrollees in each PDP region, adjusting for health status using risk indexes estimated with CMS's risk-adjustment model. We added costs to approximate a plan's administrative expenses. Finally, we estimated member premiums for each PDP region by following the MMA's formula—with members in each region paying the difference between their average plan costs and national average costs.

In percentage terms, our results suggest that enrollee premiums for this sample of individuals show more geographic variation than per capita drug spending (Figure 1-3). Across the 34 PDP regions, average per capita drug spending varies between a low of about 0.8 and a high of 1.1, where 1.0 equals the nationwide average. When ranked by drug spending per person, the highest-ranked region has spending that is 1.4 times that of the lowest-ranked region. In the middle of the distribution, regions at the 75th percentile have per capita spending that is 1.1 times that of regions at the 25th percentile. By comparison, the distribution of our simulated premiums is wider: ranging from about 0.5 to 1.3, where 1.0 equals the nationwide average. The highest ranked region has simulated premiums that are about 2.5 times those of the lowest ranked region, and the interquartile ratio for the distribution of premiums is 1.2. If the nationwide average Part D premium is \$37 per month in 2006, enrollees like those represented by these claims data who live in regions that fall in the middle of this distribution (the interquartile range)

might see premiums that vary by about \$8 per month. Enrollees who live in most of the regions (spanning from the 10th percentile to the 90th percentile) might see premiums that vary by about \$13 per month. Individuals who live in regions at the tails of this distribution would see greater variation in premiums.

In order to simulate premiums, we made a number of additional assumptions. We inflated each person's level of prescription drug spending in 2001 to 2006 levels, using nationwide projections of growth in drug spending. We estimated plan benefits as though no individuals would have supplemental drug coverage—and thus, they would reach Part D's catastrophic threshold at \$3,600 in out-of-pocket drug spending. We did not include any adjustment of each person's spending levels to reflect changes in the relative generosity of their prescription drug coverage. Nor did we make any adjustments to reflect plan management that is more restrictive or less restrictive than that which already occurs in the underlying drug claims. It is possible that tighter management of prescription drug spending could lead to less geographic variation in spending than is observable today—and thus, premiums might not vary as much. We assumed that plan administrative costs would average about 5 percent of each region's total drug spending. Finally, these estimates are probably most sensitive to our assumption that Part D plans operating in each region have their region's average mix of enrollees. ■

found little or no variation in the lowest available price for the same drug across geographic regions (Bryant et al. 2004). On average, they found that retail prices were slightly lower in rural states; however, variation in prices across pharmacies within the same state was the more striking phenomenon. In an analysis of 1998 retail prices for 25 high-volume prescription drugs, researchers found that third-party payers in the Northeast and West were able to obtain greater discounts relative to cash customers than purchasers in the South and Midwest (Department of Health and Human Services 2000). In another study using 2002 data, researchers found only modest variation across the country in the average price of a prescription (Sager and Socolar 2004). However, researchers in that study did not control for differences in the mix of drugs used.

The MMA specifies that when calculating enrollee premiums, CMS may adjust the national average bid for geographic variation in prescription drug prices. CMS decided not to make such an adjustment in 2006 (CMS 2005a). The Department of Health and Human Services is looking into whether an adjustment may be necessary.

Variation in the use of prescription drugs

Geographic variation in Part D premiums will probably be more closely associated with variation in prescription drug use rather than variation in drug prices. In setting enrollee premiums, the MMA does not call for any geographic variation adjustment based on the use of prescription

drugs. However, the law does call on CMS to study whether this type of an adjustment would be appropriate and to report to the Congress by January 1, 2009.

Available evidence shows considerable variation in rates of use, as well as the mix of drug therapies that individuals use. For example, one study examined drug claims for insured individuals ages 18 to 64 during 2000 (Express Scripts 2002). After adjusting for age and gender, researchers found that the average annual number of prescriptions per member across states varied by 150 percent, with higher values in the South and Midwest and lower ones in the Northeast and West. The same study documented geographic variation in prescribing certain types of drug therapies. Calcium channel blockers, prescription cough/cold/allergy medicines, corticosteroids, and diuretics exhibited the widest variation. Similarly, another study documented variation in prescribing for nine drug classes for an insured population across a smaller geographic region—Michigan hospital service areas (Wennberg 2000). Among prescriptions for adults, researchers found the widest variation in antihistamines, anti-anxiety drugs, proton pump inhibitors, and statins.

Evidence of geographic variation in prescription drug spending

Various data sources provide information about prescription drug spending. These data sources include household surveys, manufacturer and retail surveys, and information from drug claims. Unfortunately, each of these data sources has limitations that complicate the analysis of geographic variation for the Part D benefit.

The limitations vary depending on the particular data set. Data from nationally representative surveys include too few individuals to estimate geographic variation; surveys of sales provide too little information about individual people; and claims data—which typically include many individual observations—are not fully representative of the Medicare population. The most widely used household surveys are designed to capture very detailed information about use of, and spending on, health care services from a limited number of respondents. However, these surveys do not include enough individuals to allow for an analysis of drug spending at the state level.¹² Surveys of manufacturers and retail outlets (including brick-and-mortar and sometimes mail-order pharmacies) serve as another source of information, but they only allow one to look at aggregate levels of retail sales or sales by type of

drug, rather than drug spending per individual.¹³ Insurers, health plans, PBMs, and some public payers (including Medicaid and state pharmacy assistance programs) collect very detailed drug claims. Currently, however, neither private nor public drug claims data sets are fully representative of the Medicare population. Beneficiaries who have either Medicaid or retiree coverage probably use more prescription drugs, on average, than the Medicare population as a whole, because those individuals either have more comprehensive coverage, are sicker, or both.

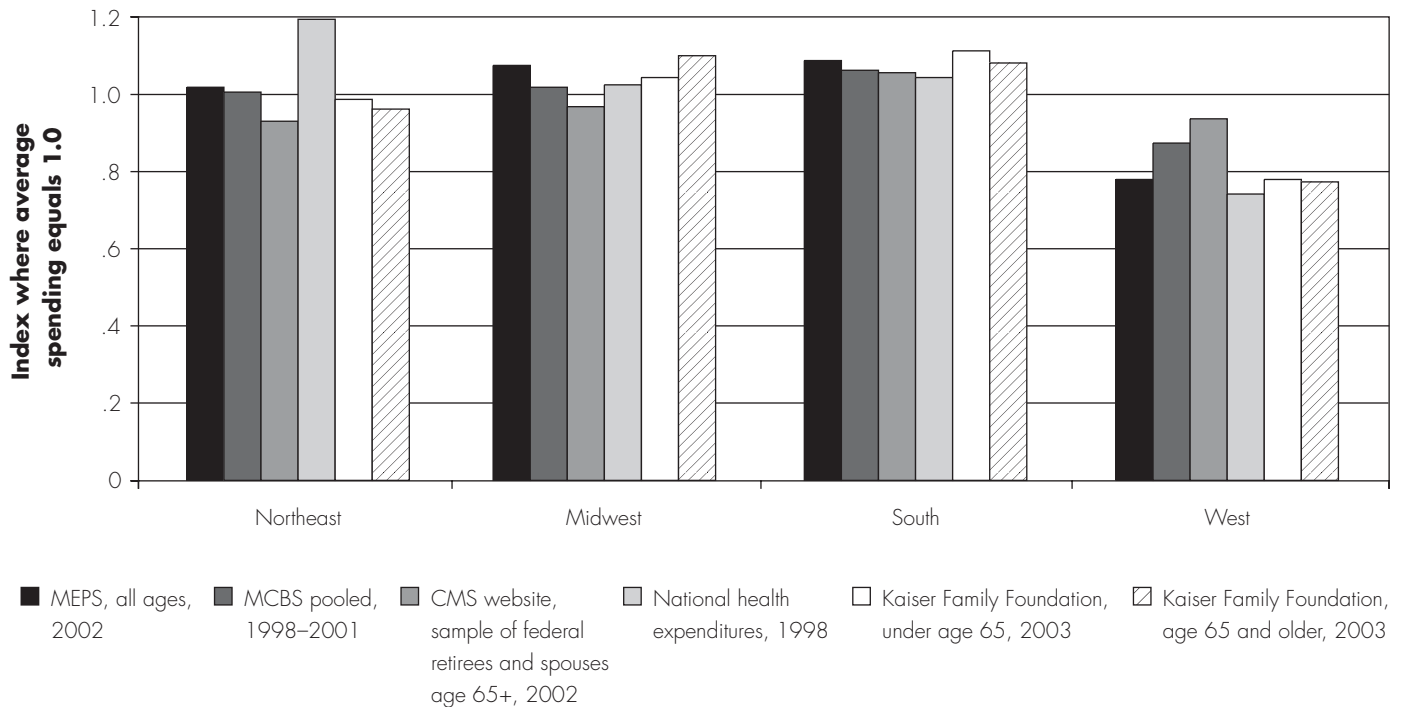
For Part D, CMS will require private plans to submit certain data from their drug claims to allow the agency to make and reconcile payments, build risk adjusters, and perform periodic audits. However, no such data are available today. CMS is using the same types of data described above—particularly the Medicare Current Beneficiary Survey, as well as Medicaid and private-payer drug claims.¹⁴ The agency has also made much of its data available to organizations that are considering bidding to become Part D plans.

Due to the lack of a gold standard among drug data sets, plans face a very difficult task in constructing their initial bids for Part D. Some potential entrants—such as MA plans, insurers, and PBMs—can use their own existing claims information to help in that effort. Nevertheless, a plan's current data probably do not fully represent the mixtures of enrollees that the plan will have after January 1, 2006.

Although no gold standard exists among drug data sets, publicly available data suggest geographic variation exists in prescription drug spending. However, patterns in that variation are not consistent and depend on which data source one uses. Figure 1-4 divides the country into four regions—the Northeast, Midwest, South, and West. We needed to aggregate the data by these regions because data limitations, such as survey sample sizes, make less aggregate estimates unreliable. For each data set, we calculated average per capita drug spending by state and then calculated an average per region, weighted by population. We did not adjust those values for differences in health status. The absolute levels of per capita drug spending differ across data sets because each source reflects somewhat different populations and time periods. For that reason, Figure 1-4 shows regional variation around an index value of 1.0, which represents the overall national average specific to each data set.

**FIGURE
1-4**

Geographic patterns of per capita drug spending vary by data source



Note: MEPS (Medical Expenditure Panel Survey), MCBS (Medicare Current Beneficiary Survey, Cost and Use file). The U.S. average per capita spending level for each data source equals one. MEPS data reflect a nationally representative sample of the U.S. population. MCBS data reflect a nationally representative sample of Medicare beneficiaries. We pooled MCBS observations during the 1998–2001 period to increase sample sizes before constructing the index. CMS provided average levels of drug spending by state for a sample of federal retirees and their spouses who are age 65 or older. CMS estimated per capita drug spending at the state level for people of all ages using a variety of data sources for its national health expenditures. The Kaiser Family Foundation’s estimates of drug spending are based on 2003 VectorOne data from Verispan collected from retail pharmacies, third-party payers, and other sources.

Source: Direct Research, LLC, for MedPAC.

Although they show some geographic variation, the data sets do not tell precisely the same story. In general, the data show that per capita drug spending in the South is somewhat higher than the nationwide average and that spending in the West is lower than average. One data set suggests that people who live in the Northeast have the highest spending per person; other data show that individuals in the Midwest or South have the highest spending per person.

Why does prescription drug spending vary?

A number of factors are likely to be associated with geographic variation in drug spending, including the health status of the individuals who live in a region, the number of providers who operate in the area, regional

differences in prescribing patterns, the average incomes of beneficiaries in each region, and the availability of health and drug coverage.

Generally, one would expect individuals who are in poorer health to use more prescription drug therapies. CMS’s Part D risk-adjustment model supports this expectation (CMS 2005a). CMS adapted its hierarchical condition category (HCC) model, which uses demographic and diagnosis information from Medicare Parts A and B claims (or comparable information submitted by MA plans) to predict plan claims’ liability for a standard Part D benefit.¹⁵ The model predicts more than 20 percent of variation in drug spending across individuals, which is higher than the risk-adjustment models CMS uses to predict spending for Parts A and B benefits.

In order to evaluate average health status across PDP regions, we used CMS’s risk-adjustment model and calculated indexes of Part D benefit spending using diagnosis codes in 2001 claims data for a 5 percent sample of fee-for-service Medicare beneficiaries.¹⁶ With a nationwide average of 1.0, those indexes range from 0.87 to 1.05 across the PDP regions (Table 1-4). The region with the highest index shows predicted drug benefit spending that is 1.2 times that for the region with the lowest index. The interquartile ratio—a measure less influenced by the tails of the distribution—is 1.1. Regions with the lowest risk indexes tend to be in the West and Midwest, but those with the highest indexes include regions in the South, East, and Midwest.

Because Medicare beneficiaries are, on average, healthier in certain parts of the country than others and because drug spending relates to an individual’s health status, risk-adjustment models can help to predict geographic variation in drug spending. But by their nature, predictions of health status from such models are imperfect. In other words, risk-adjustment factors do not reflect all of the variation in health status that exists among Medicare beneficiaries. Thus, the underlying health status of beneficiaries in a region probably accounts for more of the geographic variation in drug spending than researchers can predict. One key reason is that researchers build risk

adjustors from claims data, which have some well-known limitations. For example, providers may not record diagnoses thoroughly or consistently on claims. They are most likely to report diagnoses when they are actively treating a beneficiary for a condition. If an individual has a condition that does not require active intervention in a given year, providers may not list the diagnosis information on his or her claims.

Other factors that may explain geographic variation in drug spending include the relative supply of providers, the composition of that workforce, and physician prescribing patterns in the area. Previous research suggests that spending for Medicare Parts A and B by state is positively correlated with the number of specialists per 10,000 population and negatively correlated with the number of general practitioners per 10,000 (Baicker et al. 2004). Likewise, the relative availability and composition of a region’s physician workforce may also explain how many prescriptions a population uses, on average. Patterns of prescribing may differ across regions. For example, it may be acceptable to prescribe antibiotics more routinely in some parts of the country compared with others.

Average levels of income are also related to variation in prescription drug spending, but third-party coverage complicates that relationship. Medicare beneficiaries who

**TABLE
1-4**

Variation in characteristics of PDP regions

	Range of values	Ratio of highest region to lowest region	Interquartile ratio ^a
Region’s HCC risk index for covered drug benefit spending ^b	0.87–1.05	1.2	1.1
Percentage of region’s elderly population			
with income less than 100% FPL ^c	7–19%	2.8	1.5
with income less than 150% FPL ^c	14–34	2.4	1.4
Percentage of region’s Medicare population			
that receives a Part B buy-in ^d	9–29	3.2	1.6
who also have employer-sponsored coverage ^e	22–55	2.5	1.2
who are enrolled in Medicare Advantage plans ^f	<0.5–32	159.4	6.5

Note: PDP (prescription drug plan), HCC (hierarchical condition category), FPL (federal poverty level).

^a The interquartile ratio is the value for the 75th percentile divided by the value for the 25th percentile. It measures the amount of variation across regions, an amount that is less influenced by extreme values.

^b Estimated using CMS’s model and based on diagnoses in 2001 claims for a 5% sample of Medicare fee-for-service beneficiaries. The nationwide average is 1.00.

^c Based on the 2000 census.

^d “Part B buy-ins” are dual eligibles for Medicare and Medicaid. Their state Medicaid program pays their Part B premium.

^e Data pooled from the 1999, 2001, and 2003 Current Population Surveys.

^f CMS Medicare Advantage state and county penetration report files, June 2004.

Source: Direct Research, LLC, for MedPAC.

have very low incomes may qualify for Medicaid and may thereby receive fairly comprehensive prescription drug coverage. Likewise, people who earn higher incomes are more likely to have employer-sponsored retiree health benefits, which often include drug coverage. In general, individuals who have third-party drug coverage tend to pay lower prices for a given drug at the point of sale, but they also tend to use a costlier mix of drugs compared to individuals with no drug coverage (Department of Health and Human Services 2000).

Average incomes of Medicare beneficiaries and the availability of health coverage vary broadly across PDP regions. For example, in some regions as few as 7 percent of the Medicare population earn incomes below the federal poverty level, while in other regions nearly 20 percent fall below the poverty level. The share of each region's beneficiaries who are dually eligible for Medicare and Medicaid (as measured by the number whose states pay for their Part B premium) ranges between 9 percent and 29 percent. The availability of and enrollment in employer-sponsored health coverage or MA plans varies even more widely.

Geographic variation in each of these factors suggests that considerable variation could exist in drug spending and in Part D premiums. On the other hand, private plans' efforts to manage the Part D benefit could reduce geographic variation in drug spending and in premiums.

Who will enroll in Part D?

Although important, premiums for Part D plans are just one of several factors that Medicare beneficiaries will consider in deciding whether to enroll in the new program. Part D is quite complex, and the general level of Medicare beneficiaries' understanding about the new benefit and how it works will be important in their decision making. In order to encourage broad initial enrollment, Part D includes a penalty for late enrollment similar to that of Part B. However, many Medicare beneficiaries may not be aware of or understand that provision yet. Even those who know more about the late enrollment penalty may find its initial level—about \$5 per month for those who postpone signing up until 2007—low enough to be worth delaying enrollment until they know more about the program. The Commission suggests that CMS move as quickly as possible to determine whether the penalty amount fairly reflects any higher costs associated with delaying enrollment (MedPAC 2004). CMS should inform Medicare beneficiaries of the penalty and how it could affect their premiums if individuals delay enrollment.

More than six million Medicare beneficiaries—over 15 percent of the Medicare population—are eligible for Medicaid (MedPAC 2004). These individuals may represent a disproportionate share of early enrollees in Part D because CMS plans to auto-enroll them into plans at the end of 2005. As Table 1-4 shows, the percentage of each region's Medicare population that consists of dual eligibles varies considerably around the country. It is unclear how differences in the proportion of each region's Medicare population that CMS auto-enrolls will affect geographic variation in Part D premiums.

There is even greater uncertainty about how many other types of Medicare beneficiaries will enroll in Part D plans. Currently, Medicare beneficiaries get drug coverage from a variety of sources. In 2001, just over 30 percent of the Medicare population had retiree drug coverage. Decisions by these individuals about whether to enroll will depend on how their former employers respond to the introduction of Part D. About one-quarter of beneficiaries currently have individually purchased Medigap policies, and their response to Part D is also uncertain. Only a small share of those Medigaps currently include prescription drug coverage—this share makes up less than 10 percent of total enrollment in standard Medigap policies. It is unclear how many beneficiaries who purchase Medigap policies without drug coverage will be willing to pay an additional premium to enroll in Part D plans.

MedPAC plans to monitor enrollment trends in Part D. CMS will hold Part D's initial open enrollment period from November 15, 2005, through May 15, 2006. During that time, beneficiaries will likely receive a lot of information about Part D, both from CMS and from individual plans operating in each region. As we shall see in the next section, CMS will have to make that information easy to obtain and understand to ensure broad participation in Part D.

The Medicare discount drug card and beneficiary outreach for Part D

Before beneficiaries can enroll in Part D plans, they must learn about the program and the choices they face. In the months before Part D becomes effective, CMS, the states, beneficiary advocates, and drug plans must educate beneficiaries about the new drug benefit. In 2004, Medicare beneficiaries became eligible to enroll in the

Medicare-sponsored discount drug card program. Beneficiaries who earned incomes below 135 percent of the federal poverty level could receive additional subsidies. By implementing the drug card program, CMS provided states with some early experience in reaching Medicare beneficiaries and counseling them about prescription drug plan choices. We interviewed individuals who participated in these efforts to determine what lessons they learned that could improve outreach efforts for Part D.

Elderly and disabled Medicare beneficiaries will begin enrolling in Medicare prescription drug plans in November 2005.¹⁷ To begin receiving benefits by January 1, beneficiaries must navigate a tight timeframe. CMS, the Social Security Administration (SSA), state Medicaid programs, and beneficiary advocates will have little time to educate beneficiaries about their choices, help those who are qualified apply for low-income subsidies, and help beneficiaries make informed decisions. State Medicaid officials and beneficiary advocates have found it particularly difficult to inform low-income Medicare beneficiaries about their health insurance options.

In this section, we examine the challenges that state officials and beneficiary advocates face in educating beneficiaries about the discount drug card program. Next, we assess the relevance of this experience for the outreach efforts designed to inform dual eligibles—and other beneficiaries who are eligible for low-income subsidies—about their choices in 2006.

We draw four key lessons from state experiences with the discount drug card:

- ***CMS and drug plans must provide accurate, easily obtainable information about plan options.*** Counselors emphasized that beneficiaries need timely and accurate information. In the first weeks and months of the discount card program, counselors and beneficiaries encountered difficulties using the web-based tool, inaccuracies in the information that CMS provided, and changes in plan offerings. This confusion may have deterred enrollment in the discount card program.
- ***CMS should design federal outreach efforts so that they direct beneficiaries to state outreach and enrollment activities.*** States currently are responsible for providing prescription drug coverage to many individuals who will need to enroll in drug plans under

Part D, including dual eligibles and enrollees in State Pharmacy Assistance Programs (SPAPs). To avoid confusion and ensure access to information and counseling, CMS should send materials to Medicare beneficiaries that indicate sources of assistance available in the state in which they reside—including Medicaid, SPAPs, and State Health Insurance Assistance Programs (SHIPs)—state-based organizations that receive federal funds to provide information and counseling about insurance issues to Medicare beneficiaries.

- ***CMS needs to develop better strategies for conducting targeted outreach to Medicare populations.*** State officials found it difficult to reach low-income beneficiaries, individuals with disabilities, enrollees with low literacy, and beneficiaries with limited English proficiency. Interviewees emphasized the importance of one-on-one counseling to explain eligibility for complex programs such as Part D and noted that adequate resources for SHIPs are crucial. However, even with enhanced funding, SHIPs will not be able to counsel all beneficiaries who need help understanding their choices under Part D. CMS will need to inform physicians and pharmacists about the program because they often serve as trusted intermediaries for beneficiaries.
- ***CMS should consider auto-enrollment for prescription drug coverage and low-income subsidies for selected Medicare populations.*** Federal, state, and private outreach efforts were relatively ineffective in enrolling large numbers of beneficiaries in the discount card program. For example, of the estimated 7.3 million Medicare beneficiaries who were eligible to enroll in the transitional assistance program in 2004, only 1.5 million actually enrolled. Auto-enrollment was far more effective than voluntary enrollment and accounted for a large share of the overall enrollment. SPAPs and Medicaid officials, as well as SHIP directors and counselors, suggested that auto-enrollment will be a critically important step in the success of Part D.

The Medicare discount drug card program

The MMA included the discount drug card program to provide temporary assistance with the cost of prescription drugs to Medicare beneficiaries until the Part D benefit begins in 2006. In exchange for an annual fee of up to \$30,

drug card enrollees receive discounts off the retail price of prescription drugs. The cost of the card and the discounts vary depending on the card a beneficiary selects and the drugs a beneficiary uses. Different cards offer different combinations of discounts on different drugs, and discounts also vary across pharmacies. Beneficiaries could enroll in a discount card at any time without penalty, but once they enroll they could only change cards once—between November 15 and December 31, 2004.

Medicare beneficiaries who earn incomes below 135 percent of the federal poverty level can also receive transitional assistance. Those who qualify do not have to pay enrollment fees and they receive a credit of \$600 per year on their discount cards.¹⁸ Beneficiaries who are enrolled in Medicaid or other public or private insurance plans (except for SPAPs) cannot enroll in the card program and are not eligible for the subsidy.

Similar to Part D, the discount drug card program is voluntary. Before the program began, federal government agencies, state agencies, and private plans all engaged in efforts to inform beneficiaries about available cards and subsidies and to facilitate enrollment. CMS and SSA sent mailings to all Medicare beneficiaries about the discount card and the availability of transitional assistance. These mailings informed beneficiaries that they could call a federal customer service line or use Medicare's website to obtain comparative information on discount cards. In addition, the federal government provided new funding to SHIPs to help beneficiaries who sought assistance in making choices about the discount cards. The private companies that sponsored Medicare-approved drug discount cards also marketed their cards to the Medicare population and received enrollment applications for the cards and for the low-income subsidy.

CMS implemented the program quickly. The agency approved card sponsor applications on March 26, 2004. Beneficiary enrollment began on May 3, and cards became effective on June 1. Beneficiaries could choose from 39 national cards as well as other regional cards. CMS estimated that 15.4 million beneficiaries were eligible for the program, including 7.3 million who were eligible for transitional assistance. Despite beneficiary education and outreach efforts by CMS, SHIPs, and SPAPs,¹⁹ enrollment was lower than expected. By December 2004, 5.8 million beneficiaries had enrolled in discount card programs, including 1.5 million who were also receiving transitional

assistance (CMS 2004).²⁰ The majority of these individuals were enrolled automatically through their MA plan or SPAPs.

MedPAC contracted with researchers at the National Opinion Research Center (NORC) and Georgetown University to examine state experience in helping to implement the drug card. They focused on the successes and challenges of outreach strategies and how these experiences might inform implementation of the Medicare drug benefit. Between March and September 2004, researchers conducted structured interviews with 46 state officials, pharmacists, and beneficiary counselors in 26 states.

State outreach strategies

In early interviews that researchers conducted before CMS implemented the discount card program, state officials indicated that states would conduct outreach activities, contingent on federal funding. These interviews revealed that the level of effort and resources committed to outreach would vary across states. For example, some SHIP programs are well-funded and supplement their staff through a large base of volunteer counselors in a wide variety of field locations. Other programs may have few volunteers and few outreach sites.

None of the interviewees suggested that they would implement outreach efforts to enrollees in Medicare Savings Programs, which include the Qualified Medicare Beneficiary (QMB) program and Specified Low-Income Medicare Beneficiary (SLMB) program. Few of these state officials had developed plans to target disadvantaged, frail, and isolated populations with information about the discount card. SHIP officials suggested that they had little capacity to identify beneficiaries who were potentially eligible for transitional assistance in their state.

Because Medicaid recipients were not eligible for the discount card, SHIPs and SPAPs primarily conducted the outreach for the discount drug card program. SHIPs typically conducted broad, community-based outreach to increase awareness about the discount card and low-income subsidy programs, and responded to requests for assistance and information. SPAPs generally undertook a more targeted approach. They actively reached out to their enrollees to ensure funding for those who were eligible for transitional assistance subsidies.

In general, SHIPs:

- tried to increase community awareness of the discount card and other prescription drug assistance programs, and
- included information about the cards and transitional assistance as part of their normal counseling services.

In general, SPAPs:

- sent direct mailings to their members providing information about the discount cards, and
- sometimes chose to auto-enroll their members in a preferred drug card program.

State experience with the discount card

With some exceptions, SHIP counselors reported low levels of interest in the cards and low levels of voluntary enrollment in both the discount card and transitional assistance programs. They identified a number of factors that limited voluntary enrollment, including a perception by beneficiaries that the program was too complex and offered relatively little savings to enrollees. SHIP counselors suggested that outreach efforts had failed to reach many of the low-income individuals who would benefit most from the \$600 annual subsidy.

Interviewees emphasized the importance of one-on-one counseling for Medicare beneficiaries. In interviewees' experience, direct mailings, call centers, and website information all posed problems for communicating important information to beneficiaries. According to counselors, beneficiaries routinely receive large amounts of direct mail that advertise drugs and other health care services and items. As a result, official state mailings might attract no more attention than any other form of advertising. Low literacy, limited English proficiency, and limited understanding of health care programs also interfere with beneficiaries' ability to comprehend and act on direct mail instructions.

Additionally, counselors expressed concern that the 1-800-Medicare call center operators provided too much information, rather than helping beneficiaries narrow their options. Counselors also worried that these operators were conveying inaccurate information. In a 2004 study conducted by the GAO, researchers received inaccurate answers to 29 percent of their questions and could not obtain any answer 10 percent of the time. Among other recommendations, GAO suggested that CMS provide

more thorough testing of contractors' ability to answer questions and monitor the accuracy rate for frequently asked questions.

Lastly, counselors expressed mixed feelings about the Medicare web-based decision tool that CMS developed. The agency intended this database—The Prescription Drug and Other Assistance Programs—to allow beneficiaries to compare discount cards. Counselors found this tool useful in their offices but inaccessible to most elderly beneficiaries. Even beneficiaries who were computer literate and had Internet connections in their homes were unlikely to have the high-speed connections necessary to use the drug card website.

On the other hand, some counselors reported that the publicity over the discount card created new opportunities for beneficiary education. Beneficiaries who did not previously know about the SHIP's resources came for counseling sessions and were screened for eligibility for other programs. Depending on the state, this could include Medicaid or SPAP screening, and screening for nonhealth programs such as energy assistance.

By comparison, SPAPs experienced success with auto-enrollment and facilitated enrollment in a preferred card or cards. In cases in which programs auto-enrolled beneficiaries, programs gave beneficiaries the choice of opting out of the program after enrollment. Eleven states used auto-enrollment to sign up their program recipients for a specific or preferred discount card or cards (Fox 2005). For example, New Jersey auto-enrolled all members who were eligible for transitional assistance into a preferred card program unless those members explicitly opted out of the program. Connecticut required all state program members who were eligible for transitional assistance to apply for a discount card and supplied them with a list of all the cards available within the state (Rutgers Center for State Health Policy 2004). States that used auto-enrollment achieved high participation rates in a short period of time—these rates ranged from 80 to 90 percent of eligible members. Conversely, the five states that encouraged members to voluntarily enroll in the discount card program experienced much lower enrollment rates, ranging from 2 to 40 percent (Fox 2005).

Lessons learned for implementing Part D

Interviewees suggested that the challenges of implementing the discount card program—and the resulting low levels of voluntary enrollment, especially

of beneficiaries who were eligible for the low-income subsidies—were likely to become more problematic in 2006 with the implementation of Part D. SHIP counselors worried about the program’s complexity and noted that elderly Medicare beneficiaries would likely be confused by the drug benefit design, including the deductible, coverage gap, and catastrophic coverage. Interviewees noted that any changes to the operation of the benefit—for example, mid-year changes to the formularies—would compound the already formidable challenges to beneficiary education. SHIP counselors indicated that beneficiaries could feel overwhelmed by the number of choices they face and thus may fail to enroll in a program that could provide them with significant benefits.

Many interviewees acknowledged that their organizations are designed to assist a mainstream elderly population. However, the organizations are less equipped to effectively counsel hard-to-reach groups such as those in nursing homes or other long-term care settings; younger beneficiaries with disabilities; and members of racial and ethnic minorities who face linguistic, cultural, and educational barriers. Interviewees stressed the need for targeted strategies to reach these populations. They suggested that CMS should develop strategies that include physicians and pharmacists who experience daily contact with beneficiaries.

Interviewees repeatedly stressed the success of auto-enrollment in reaching low-income populations. When CMS implements Part D, the agency will auto-enroll Medicare beneficiaries who are also eligible for comprehensive Medicaid benefits in plans. CMS will not use auto-enrollment for other groups but will develop alternative mechanisms to facilitate enrollment for some other low-income groups. In particular, CMS may use such mechanisms to target individuals who are enrolled in the Medicare Savings Program if they have not enrolled in a Part D plan by May 2006. SPAPs had requested CMS to give them the authority to auto-enroll their members, but CMS did not accept this recommendation (CMS 2005b). CMS should monitor enrollment by low-income groups in Part D and increase auto-enrollment, if necessary.

Once beneficiaries enroll in Part D plans, they will have to learn how to use plan procedures to ensure that they receive needed drugs. In the next section, we examine plan formulary exceptions and appeals processes.

Formulary exceptions and the appeals processes

Medicare Advantage drug plans (MA-PDs) and stand-alone Medicare prescription drug plans (PDPs) can use techniques developed in the commercial market to control cost and enhance the quality of the drug benefit. These techniques include formulary development, tiered copayment benefit structures, prior authorization, pharmacy networks, and mail order pharmacies. Plans must establish formulary exceptions and appeals processes to ensure that these techniques do not deprive beneficiaries of access to needed medications.

MedPAC staff interviewed physicians, beneficiary advocates, pharmacists and representatives from health plans, and pharmacy benefit managers (PBMs) about formulary exceptions processes and beneficiary appeals. In this section, we present findings from our research on how the private market and Medicaid handle requests for prescription drugs that are not on a plan’s formulary or require prior approval. We compare current practice with requirements under the Medicare drug benefit.

We found the following key findings:

- Plans and PBMs currently have well-established processes to handle formulary exceptions and prior authorization requests. Accrediting organizations and states scrutinize these processes, and the processes are similar to those that CMS regulations prescribe.
- Patients usually do not appeal denied requests for formulary exceptions. Physicians frequently decide that the formulary drug is acceptable, when the pharmacist informs them of the nonformulary status of the prescribed drug. When patients and physicians pursue requests, plans report very high approval levels.
- The volume of appeals may increase under Part D.
- Beneficiaries who are dually eligible for Medicare and Medicaid will have fewer appeal rights under Part D than they currently have under Medicaid. For example, Medicaid programs must continue to provide ongoing drug treatment to beneficiaries while an appeal is underway. Part D plans will not face this requirement. When dual eligibles begin receiving their drug benefit from Part D plans, some may be taking

drugs that are not on their plans' formulary. CMS will need to monitor plan transition policies to ensure that beneficiaries continue to receive appropriate medications and do not delay or stop treatment because they face unfamiliar formulary exceptions processes.

Formulary exceptions: Current practice and Part D

Health plans and PBMs are experienced at handling requests for formulary exceptions. Requests for exceptions depend on the structure of the benefit. In a closed formulary,²¹ drug coverage is limited to the specific medications that the plan places on the formulary. However, plan members sometimes may get an additional drug covered if the plan determines that the drug is medically necessary. In this case, a member—with physician support—requests a formulary exception. Plans may grant exceptions provided that the physician has shown that the covered formulary drugs are ineffective or will likely result in adverse consequences for the member.

In a tiered or incentive-based formulary, the plan charges different copayments for covered drugs. Typically, copayments differ for generic drugs, preferred branded drugs, and nonpreferred branded drugs, with generic drugs carrying the lowest copayments. Plans may limit access to nonpreferred drugs by requiring the member's physician to get prior approval from the plan before dispensing the drug. State Medicaid programs also may require prior authorization for many drugs, particularly in those states that have preferred drug lists.

Under the final regulations published January 28, 2005, CMS permits plans to use tools such as tiered copayments, closed formularies, prior authorizations, and step therapy to manage utilization and cost of the Medicare drug benefit. The regulations discuss plan procedures to handle requests for formulary exceptions and prior authorizations. CMS requires plans to establish processes and notify plan members of policies for obtaining formulary and copayment exceptions, but CMS does not mandate specific methods.

Currently, plans differ on the number of drugs they restrict and the rationale for requiring prior authorization. One interviewee emphasized that his plan placed on its prior authorization list only those drugs required to treat chronic conditions because beneficiaries refill prescriptions for these drugs multiple times. However, another interviewee reported that his plan placed some new antibiotics on its prior authorization list.

Interviewees gave many examples of cases in which a particular drug might require preauthorization. Some examples include:

- the drug is not on the plan's formulary (for closed formularies);
- a lower cost formulary drug is available;
- an equally effective over-the-counter medicine is available;
- a nonpreferred drug is heavily advertised and is subject to overutilization;
- the drug is a high-cost injectable;
- the request is for a larger quantity of the drug than plan administrators believe is clinically appropriate; and
- physicians prescribe the drug for a number of conditions without sufficient supporting medical evidence.

Because the formulary exceptions and prior authorization processes are generally the same, we do not distinguish in this section between the two. However, we remind readers that a plan's benefit package sometimes excludes entire specific categories or types of drugs. For example most private plans do not cover over-the-counter medications. In those cases, the plan would not consider those drugs part of the covered benefit and thus the formulary exceptions processes would not apply. Part D plans cannot cover drugs that Medicaid programs may exclude (such as weight loss drugs) and cannot cover drugs eligible for Medicare Part A or Part B coverage.

How does the process work?

Call centers serve as the first point of contact for formulary exceptions and prior authorization. Plan representatives in call centers—often pharmacy technicians—receive preauthorization requests from providers and use written protocols to determine if the request meets clinical guidelines for approval. The plan's pharmacy and therapeutics (P&T) committee usually approves the protocols. Many of our interviewees reported that call-center workers could approve requests but could not deny them. Pharmacists or physicians who work for the PBM or health plan usually review requests that do not

meet criteria stipulated in plans' protocols. (Some states mandate that only a physician can reject a request for prior authorization.) At this point, the plan may ask the prescribing physician for additional information. If the plan physician still rejects the request, the plan administrator will ask a medical director and/or pharmacist (who has not been involved in the original decision) to review the request. An additional negative decision would constitute a coverage decision, and a patient who wished to pursue the request would then go through the health plan's formal appeals process. As discussed below, all interviewees reported that prescription drugs rarely are the focus of formal appeals.

Many requests do not go through the entire internal process. Physicians frequently decide, after they learn of the prescribed drug's nonformulary status, that the formulary drug is acceptable. When physicians pursue requests, plans report very high levels of prior authorization approvals. Most interviewees indicated that the most common reason for initially rejecting a request was the lack of evidence of medical necessity. When providers supplied such evidence, plans granted most requests.

We found considerable variation in the extent to which plans rely on prior authorization. Some interviewees reported that the costs of reviewing prior authorization requests limit the utility of the process. Because plans must meet timeframe requirements for handling prior authorization requests, they determine call-center staffing based on the number of requests that staff must handle on a daily basis. Additionally, requests for prior authorizations and other exceptions pose a burden to plan members, physicians, and pharmacists. Plans may decide that the savings realized from these processes are outweighed by the negative effects on patient and provider relationships. Several interviewees reported that some drugs were taken off prior authorization lists because nearly all requests were approved. However, other interviewees cited specific cases in which clinical evidence indicated that a drug was being overused. In those cases, plans typically deny requests for exceptions.

The following cases are typical:

- One plan representative noted that the plan required prior authorization for all nonsedating antihistamines after one product in this class became available to patients over the counter. In order for members to receive coverage for any of the prescription products

in this category, their physicians had to document that the over-the-counter medicine had not controlled their patients' allergies—a process known as step therapy. Our interviewee reported that the plan had to hire six new employees to handle the resulting volume of calls requesting exceptions. However, the plan calculated that it has saved \$10 million because of this one decision.

- Several interviewees reported that they placed all medications in the cyclo-oxygenase-2 (COX-2) therapeutic class on the prior authorization list. Their plans received many requests for exceptions, but the plans believed that the drugs were overused compared with other pain medications and thus were only appropriate for a small group of high-risk individuals. Due to the high volume of requests for exceptions, the plan reviewed its criteria. However, plan physicians concluded that their original decision was clinically appropriate and they continued to deny requests for exceptions.
- Several interviewees reported placing human growth hormone on their prior authorization list. They covered the product in cases where clinical evidence of medical necessity was available. However, they did not want to cover it for lifestyle uses such as body building. In these types of cases, plans will often ask for additional clinical information to ensure that the physician is prescribing the product for a medically necessary reason.
- One interviewee pointed out that prior authorization can be useful even when the plan approves the request in nearly all cases. He noted that when a pharmacy notifies a physician that a patient's plan does not cover the requested drug—but covers other drugs to treat the same condition—the physician often agrees to prescribe the preferred drug without a request for prior approval ever reaching the call center.

State Medicaid programs often use prior authorization as their main cost management tool. These plans cannot use tiered cost sharing or closed formularies to move beneficiaries to preferred drugs. Placing drugs on a prior authorization list is one way in which Medicaid programs can affect physician prescribing patterns.

Interviewees reported that plans keep careful records on the results of their exceptions processes. Plans then use the data to evaluate their utilization management tools and to

weigh the costs and benefits of restricting use of particular medications. If a plan receives many requests for exceptions for a specific drug, it may ask its P&T committee to review the clinical evidence on the product and determine whether to change the drug's formulary status.

Managing prior authorization

Although all interviewees agreed that, ideally, providers would receive prior authorization before they write a prescription, this is often not the case. Most physicians see patients from a variety of health plans. Each plan will have its own formulary, prior authorization list, and specific procedures for obtaining approval. Recent research indicates that the majority of physicians do not know which drugs are on their patients' formularies (Shih and Sleath 2004).

Frequently, the need for prior authorization will only become apparent when a patient brings a prescription to a pharmacy. The pharmacist who is attempting to process the prescription will receive an electronic message from the PBM indicating that the drug cannot be dispensed as written. Pharmacists say that the exact content of the message differs depending on insurer and PBM. Some messages simply report that the plan does not cover the drug. Other plans provide suggested alternative covered drugs, or provide phone numbers that physicians can call to get prior authorization. Upon receiving the electronic message, the pharmacist usually contacts the prescribing physician. At this point, the physician may change the prescription to the plan's preferred drug or request prior authorization from the plan. Alternatively, the pharmacist may tell the patient that her plan does not cover the drug. Then the patient must decide whether to pay out of pocket for the requested drug, leave without any drug, or go back to her physician and ask for a drug that is on the plan's formulary.

In most cases, plans have little control over which actions the pharmacist and physician will take and only limited data on what actually happens. In one small study, researchers analyzed what happens to patients when pharmacies reject their nonformulary prescriptions (Cox et al. 2004). They found that the majority of health plan members eventually get a drug to treat their condition. About 40 percent of surveyed individuals got the formulary drug while 15 percent got prior authorization for the prescribed branded drug. A little over 10 percent received no medication

for the treatment, and an equal share paid full price for the medication.

Pharmacists and physicians will most likely consider the prior authorization process unpaid additional work. Apart from the time it takes to contact physicians for prior authorizations, pharmacists report that the PBM or other electronic messaging company charges them a transmittal transaction fee for every message they must relay before a prior authorization is approved. One physician noted that two staff nurses each spend about one hour per day providing information for prior authorization requests. Further, plan members are likely to be unhappy with their health plan if they cannot get access to a drug that they believe is medically necessary or if they have to make multiple visits to the pharmacy to get a single prescription filled.

Plans try to alleviate provider burden in a number of ways, including notification, provider outreach, and automation:

- **Notification.** Plans and PBMs use a number of methods to inform plan members and providers about their formularies and exceptions processes. In some cases, members receive a notice at the pharmacy that details why the plan rejected their prescription, lists alternative formulary drugs, and notes the steps that the beneficiary should take if she wants to challenge the plan's decision. A recent court decision (*Hernandez v. Meadows*) requires the Florida Medicaid program to give beneficiaries written notice at the pharmacy if their prescriptions are rejected. Other states are considering similar requirements. (see text box).
- **Provider outreach.** Some plan interviewees reported spending much of their time meeting with network physicians and pharmacists. The goal was to explain their formulary and exceptions procedures, address provider complaints, and, ideally, convince providers that the evidence-based processes used to maintain the plan's formulary provide added value to clinicians. Some plans have experimented with giving physicians hand-held electronic devices that are loaded with the plan's formulary, thus enabling easy access when physicians write prescriptions.²²
- **Automation.** Several interviewees told us that their plan tried to make the prior authorization process as seamless as possible. For example, pharmacists' computer systems may have automatic edits to check

that a plan member has tried a preferred drug before dispensing a nonpreferred drug to treat the same condition. Members who tried the preferred drugs can get the nonpreferred drug without a formal prior authorization. (However, this system cannot work for new plan members.)

If plans reject prior authorization requests, members can appeal the decision through the plan’s general appeals process.

Appeals processes: Current practice and Part D

Under CMS regulations, beneficiaries may appeal many aspects of the exceptions process. Appeals may be filed by

beneficiaries, their authorized representative, or their prescribing physician, but the prescribing physician must provide a supporting statement. Beneficiaries can appeal the following:

- failure to cover a Part D drug,
- a negative decision concerning an exceptions request,
- a negative decision on a request for lowered cost sharing for a drug,²³ and
- failure to provide a coverage determination in a timely manner.

Hernandez v. Meadows

In 2002, a coalition of advocacy groups filed suit against the Florida Medicaid Agency for failure to provide fair hearings and written notice to Medicaid enrollees when denying them coverage of prescription drugs. The plaintiffs claimed that the agency violated the Social Security Act and constitutional guarantees of due process, causing beneficiaries irreparable injury due to erroneous denials of coverage for necessary medications.

The settlement agreement—approved May 14, 2004—obligates Florida Medicaid to require posting of notices in pharmacies (Figure 1-5) and to provide pharmacy providers with informational pamphlets that they can distribute to Medicaid recipients when Medicaid denies payment for a prescription. In addition to posting notices in several languages within the pharmacy itself and providing recipients with written information explaining why Medicaid denied payment of a prescription, the state must also provide an ombudsman to help beneficiaries receive timely resolution of claim payment rejections. If reasonable efforts to do so fail, enrollees are entitled to a fair hearing.

The settlement also protects beneficiaries by requiring Medicaid to ensure payment for a temporary supply of medication for three business days in the case of an emergency or ongoing therapy. Additionally, if a beneficiary requests a hearing, he or she is entitled to

payment for therapy from the date of the request until the hearing. Finally, Florida Medicaid agreed to pay the pharmacy for supplying a multisource brand drug to the enrollee if the prescriber writes on the script that the drug is medically necessary. The *Hernandez v. Meadows* settlement has become a model standard of beneficiaries’ rights that advocates in other states are attempting to replicate. ■


FIGURE 1-5

Notice required by *Hernandez v. Meadows* settlement

IMPORTANT NOTICE TO MEDICAID RECIPIENTS

If your pharmacist has told you that Medicaid, or your Medicaid HMO, will not cover your prescription today, they must give you a written notice (pamphlet) explaining the reason. The notice will advise you what steps you need to take to correct the problem.

If you do not get a notice, call **1-866-490-1901**. If you do not receive a response, then call your local legal services/legal aid office.



Source: NHeLP, National Health Law Program, 2004.

Plans will have to meet quicker timeframes for making Part D coverage decisions than private plans typically require, although many interviewees said that their plans usually make decisions quickly. Plans must make initial Medicare coverage determinations no later than 72 hours after a member requests a determination and the physician provides necessary documentation. After the plan receives the request and necessary documentation, it must make an expedited coverage decision within 24 hours.

Currently, health plans and PBMs must meet various requirements for treatment of appeals. Different standards apply depending on the provider of the drug benefit and the state in which the plan is located. In the course of our interviews, plans frequently cited NCQA accreditation criteria and state Medicaid agencies' requirements. In addition, some states have mandated that all health plans that operate within their borders do one or more of the following:

- define processes for urgent and nonurgent appeals,
- set notification requirements,
- determine timeframes for responding to appeals and notifying members, and
- establish auditable records of appeals transactions.

Some systems require plans to have an external appeals process, as well.

Although all plan representatives with whom we talked described an appeals process that applied to their drug benefit, interviewees agreed that issues involving prescription drugs rarely became the focus of external appeals. One plan representative noted that he had not seen a single case involving prescription drugs go to external appeals in three years. One consumer advocate commented that plan members rarely challenged plan decisions on drugs because they did not know that they could appeal. Another advocate suggested that patients either got their drugs when they needed them or decided that they could get along without them.

However, beneficiaries did appeal decisions on some types of drugs. For example, interviewees indicated that members have appealed decisions involving injectable drugs that physicians prescribed for off-label uses. Additionally, beneficiaries sometimes appealed decisions on psychiatric drugs such as atypical antipsychotics.

Most health plans had little or no experience with appeals of cost-sharing requirements. One plan representative noted that his plan sometimes decided, informally, to reduce cost sharing for nonpreferred drugs when the plan determined these drugs to be medically necessary. For example, an interviewee from an integrated delivery system with its own pharmacies reported that pharmacists have the authority to lower copayments when a beneficiary cannot afford the required copayment. However, another interviewee reported that his plan never grants requests for lower copayments because drugs on the third tier were always considered covered—but only for the higher copayment. Plans set premiums based on projections of utilization across the different cost-sharing tiers.

Beneficiary advocates expressed particular concern that dual eligibles would not have the same appeal rights that they have under Medicaid. Currently, Medicaid recipients have the right to a pre-termination hearing before the program can reduce or end ongoing drug treatment. Medicaid programs must continue to provide the benefits at issue until the dispute is resolved (Rosenbaum 2004). No such right exists under Part D. As beneficiaries move from Medicaid coverage to Part D coverage, they may discover that the drug they have been taking for a chronic condition is not listed on their new plan's formulary. Advocates are concerned that beneficiaries will delay or stop treatment rather than initiate a formulary exception request or appeal.

CMS regulations require plans to develop a transition policy for new members who are already taking a particular drug that is not listed on their new plan's formulary. In guidelines issued on March 16 (CMS 2005b), CMS does not mandate any specific policies but does suggest that plan sponsors consider a range of strategies to address the needs of groups such as dual eligibles and individuals who have chronic conditions. One suggested strategy includes allowing a temporary one-time refill of a past medication while allowing the plan, the enrollee, and the physician to decide if a beneficiary can switch to a formulary medication. The transition supply could vary by drug, by individual medical needs, or by an individual's location (e.g., a long-term care facility). Although CMS had not issued these guidelines at the time of our interviews, a number of interviewees suggested that their plans already have informal processes in place to accommodate beneficiaries who move from one plan to another.

Part D issues related to exceptions and appeals

Our research suggests that a number of issues involving the exceptions and appeals processes will likely arise under the Medicare prescription drug benefit. Interviewees identified the following issues:

- ***Will plans have the resources to deal quickly with a potentially high volume of appeals?*** Plans may face a higher volume of appeals than is currently the case. For example, Part D regulations could cause more beneficiaries to appeal cost-sharing tiers. In addition, notification requirements that inform beneficiaries about their appeals rights may also generate increased activity. Lastly, expedited appeals would require a decision within 24 hours, a faster turnaround time than plans today commonly require. If expedited appeals become a frequent occurrence, plans may face a significant expense in managing the appeals and exceptions process.
- ***Will the benefit structure affect the plans' ability to use the exceptions process to steer utilization?*** One interviewee pointed out the potential difficulties of putting drugs on a nonpreferred third tier or using prior authorization. Part D plan members will have to pay 100 percent of the cost sharing for spending that falls below the deductible and above the initial benefit limit (Figure 1-1, p. 5). Members and their physicians may resent the additional burden of getting a drug preauthorized when they will still have to pay its full cost, albeit at the discounted price negotiated by the plan. However, prior authorization decisions will be particularly important to beneficiaries because only spending for drugs covered by their plan will count toward the benefit's out-of-pocket limit.
- ***How will plans distinguish between drugs that should be covered under Part B rather than Part D?*** Several interviewees noted that many drugs covered under Part B for some conditions or sites of care would be considered Part D drugs in other situations. For example, physicians prescribe oral antinausea drugs to treat the side effects of chemotherapy, but they also may prescribe these drugs for other cases of extreme nausea. Part B would cover the drugs only for the first situation. Although plans may use prior authorization for all medications that might be Part B drugs, interviewees suggest that this situation may be a complex issue that cannot be easily resolved.

- ***Will CMS publicly report plan appeals and grievances statistics?*** Regulations require that plans notify beneficiaries of appeal processes. Beneficiary advocates placed a high value on public disclosure of a drug plan's appeals record. They suggest that this would be an important quality measure for beneficiaries to use when choosing a plan. Our interviewees expressed disagreement on this issue. Some representatives of health plans and PBMs agreed that public reporting would be valuable. Others suggested that differences in plan policies on formulary management would make comparison of overall statistics meaningless. Instead, they suggested that the exceptions and appeals process should be transparent to beneficiaries so that plan members and physicians could evaluate the evidentiary standards that plans use to make coverage decisions. Plans would make public the conditions under which they grant formulary exceptions and the evidence required to meet these conditions.

CMS has announced its intention to examine all aspects of formulary development and management to ensure that plans do not discriminate against beneficiaries with high-cost medical needs. The agency may scrutinize plan use of tools such as prior authorization. In its review of plan submissions, CMS will have to balance carefully the need to ensure beneficiary access to necessary medications with the plans' ability to control unnecessary utilization. If plan sponsors believe that they will not be able to use tools like prior authorization to manage drug utilization, they may charge higher premiums or be reluctant to participate in the program.

Looking forward: Electronic prescribing and other areas of future research

Members of our expert panel and other interviewees agreed that the diffusion of e-prescribing technology would improve many of the access, quality, and cost issues we discuss in this chapter. Patients, physicians, pharmacists, and drug plans would save time and money if physicians could determine a drug's formulary status and get necessary prior authorizations when they write prescriptions. However, most interviewees agreed that diffusion of the technology is still slow (although some reported recent progress). Some physicians raised questions about the technology's cost and adaptability to the way in which physicians practice. One physician commented that

the version of e-prescribing used by a partner in his practice increased the time that his partner needed to write a prescription and thus reduced his productivity.

CMS issued a proposed rule (CMS 2005e) to promote the diffusion of e-prescribing. The rule proposes preliminary standards for electronic prescribing that could form the basis of final uniform standards for the technology—standards that would promote patient safety, quality of care, efficiency, and cost savings in the delivery of care. MedPAC intends to monitor these efforts as they move forward.

In the coming months, plans will be submitting bids to become PDPs or MA-PDs. By September 2005, CMS should make available information about plan offerings, including premiums, benefit designs, and formulary systems. MedPAC intends to analyze this data and describe its impact on enrollment in Part D plans. Depending on the availability of data, we will evaluate how the Medicare drug benefit meets the goal of ensuring a quality benefit at an affordable cost in the future. ■

Federal subsidies for the Part D drug benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 designed Part D so that CMS would provide subsidies to serve three purposes:

- encourage beneficiary enrollment,
- encourage plan participation by reducing cost uncertainty, and
- reduce out-of-pocket liability for beneficiaries with low incomes and limited assets.

The forms of these subsidies are important because without high enrollment and limitations on risk, private entities might not want to offer a stand-alone drug plan.

Few examples of stand-alone drug plans exist today because beneficiaries, particularly those who have chronic conditions, can predict their drug spending fairly well. Enrollees would pick coverage that suits their prescription drug needs, thus raising the risk of adverse selection. Private plans might also be reluctant to offer drug-only coverage because they could find it difficult to predict growth in the use of new drug therapies, and, therefore, hard to set premiums reliably.

The Medicare program will provide a subsidy that averages 74.5 percent of standard coverage for all types of beneficiaries. That average subsidy will take two forms:

- **Direct subsidy**—a capitated payment calculated as a share of the adjusted national average of plan bids. Although no one can predict levels of

enrollment in Part D, in general, high direct subsidies should lead to higher enrollment, which makes private entities more likely to offer a Medicare plan.

- **Individual reinsurance**—Medicare will subsidize 80 percent of drug spending above an enrollee's catastrophic threshold. Reinsurance acts as a form of risk adjustment by providing greater federal subsidies for the highest cost enrollees.

In addition, Medicare will establish symmetric risk corridors separately for each plan to limit a plan's overall losses or profits. Under risk corridors, Medicare limits a plan's potential losses (or gains) by financing some of the higher-than-expected costs (or recouping excessive profits). Also, plans that enroll low-income beneficiaries will receive a fourth type of subsidy to cover some of these enrollees' cost sharing and premiums.

Note that although plans will get essentially the same level of direct subsidy per enrollee (albeit modified by a risk adjuster to reflect health status), the level of subsidies granted through the other three mechanisms could differ substantially from plan to plan. Subsidy dollars will vary depending on the characteristics of individuals that each plan enrolls (e.g., income, health status, and supplemental coverage stats), as well as on how each plan structures its risk corridors. ■

Endnotes

- 1 The term “true out of pocket” refers to a feature of Part D which directs fewer federal subsidy dollars toward enrollees who have supplemental coverage. Specifically, only certain types of spending on behalf of the beneficiary count toward the catastrophic threshold: the beneficiary’s own out-of-pocket spending; that of a family member or official charity; supplemental drug coverage provided through qualifying state pharmacy assistance programs or Part D’s low-income subsidies; and, under CMS’s demonstration authority, supplemental drug coverage paid for with MA rebate dollars.
- 2 These threshold amounts in the standard benefit would increase each year by CMS’s estimate of the annual change in drug spending per person. For example, CMS currently projects that by 2010, the standard benefit’s deductible would be \$331, the initial benefit limit would reach \$2,980 rather than \$2,250, and the catastrophic threshold would be \$4,767 rather than \$3,600 (Boards of Trustees 2005).
- 3 MA–PDs may use rebate dollars—that is, a portion of the difference between CMS’s payment rates and a plan’s bid for providing basic services covered by Medicare Parts A and B—to enhance the Part D benefit. Chapter 2 of this report provides further information about rebate dollars.
- 4 PBMs do not typically report members’ spending on noncovered drugs, for which members pay fully out of pocket.
- 5 A few PBMs have received accreditation from quality assurance organizations for aspects of their business, such as specific disease management programs (Booz Allen Hamilton 2004).
- 6 When beneficiaries sign up for a Medicare Part D plan, they are required to report whether they also have prescription drug coverage through a third party.
- 7 In its Part D regulations, CMS notes that these surveys will likely be adapted from the Consumer Assessment of Health Plans Survey (CAHPS).
- 8 Under certain circumstances, individuals can switch plans more than once per year, such as when they move out of the area or when their plan discontinues offering the benefit.
- 9 CMS officials have commented that it is “highly unlikely” that CMS will need to use a fallback plan in the initial operation of Part D.
- 10 Some exceptions exist. Under employer waivers, for example, a PDP could have a separate risk pool and premium for the retirees of a specific employer.
- 11 If a region does not have at least one MA–PD and one PDP—or two stand-alone PDPs—available, CMS must contract with a fallback plan to offer Part D. MA–PDs and PDPs are known as risk plans because they will bear insurance risk on enrollees’ benefit spending. Fallback plans will not bear insurance risk.
- 12 Two important household surveys that capture prescription drug spending are the Medical Expenditure Panel Survey (MEPS) and the Medicare Current Beneficiary Survey (MCBS). MEPS includes the noninstitutionalized U.S. population; it has fewer respondents who are Medicare beneficiaries than the MCBS. MCBS was specifically designed to represent the wide variety of individuals who make up the Medicare population. Household surveys are subject to the problem of recall bias—the notion that individuals may not recall accurately the number and type of prescriptions they got filled. Additionally, household surveys typically do not include information about rebates from pharmaceutical manufacturers—these rebates can lower prices for prescription drugs.
- 13 CMS uses such data from the Census Bureau and private survey organizations such as IMS Health to help it estimate nationwide prescription drug spending in the national health accounts. Other private companies, such as Verispan, similarly collect data from retail pharmacies and other sources.
- 14 According to CMS’s 45-day notice to plans, the agency used drug claims for a sample of federal retirees and spouses who also have Medicare coverage to build initial risk adjusters for nondisabled beneficiaries and those who are not dual eligibles. For the latter two groups, CMS used Medicaid claims data (CMS 2005a).
- 15 CMS initially developed a model that predicts a person’s total drug spending (plan benefit spending plus cost sharing), and then modified the model to predict Part D liability alone. This modification is particularly important given the peculiar structure of the standard Part D benefit, with a large range of spending for which the enrollee must pay 100 percent coinsurance. That coverage gap substantially reduces the amount of insurance risk that plans must bear. On average, benefit spending made up about 40 percent of total spending.

- 16 Each region's index is the average of predicted prescription drug spending divided by the predicted national average.
- 17 CMS will randomly assign those beneficiaries who are dually eligible for Medicare and Medicaid to plans beginning in October, although they will be able to switch plans at any time if their assigned plan does not meet their needs.
- 18 Low-income beneficiaries can still enroll for transitional assistance, but their credit is prorated depending on their date of enrollment.
- 19 SPAPs provide drug coverage or assistance to low-income elderly or persons with disabilities who do not qualify for Medicaid. As of March 2005, 39 states had established or authorized one of these programs (www.ncsl.org/programs/health/drugaid.htm).
- 20 As of March 4, 2005, enrollment had reached 6.3 million, with about 1.8 million beneficiaries receiving transitional assistance (CMS 2005d).
- 21 A closed formulary is defined as a list of specific drugs limited to only some of the commercially available products in each therapeutic class. An open formulary is defined as a comprehensive listing of medications typically including almost every commercially available product in each therapeutic class. A tiered or incentive-based formulary contains different cost sharing for preferred and nonpreferred brand-name drugs, as well as generic drugs, thereby giving patients a financial incentive to request preferred or generic medications. Most plans currently have open-tiered formularies, but we interviewed representatives from a number of organizations that also have closed formularies. For a more in-depth look at these issues, see MedPAC's *2004 Report to the Congress*.
- 22 Health plans that have closed physician and pharmacy networks experience much less difficulty informing providers about the formulary. Physicians have only one formulary to keep in mind when they are writing prescriptions. Additionally, providers participate in developing the formulary and may have greater confidence in it. In some cases, these physicians may be able to prescribe nonformulary drugs without going through a prior authorization process.
- 23 Under the final rule, beneficiaries may appeal to reduce cost-sharing requirements for a nonpreferred branded drug to the level of cost sharing for a preferred branded drug. Beneficiaries may not appeal other cost-sharing requirements.

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CHAPTER

2

**Medicare Advantage payment
areas and risk adjustment**

R E C O M M E N D A T I O N S

2A The Congress should establish payment areas for Medicare Advantage local plans that have the following characteristics:

- Among counties in metropolitan statistical areas, payment areas should be collections of counties that are located in the same state and the same metropolitan statistical area.
- Among counties outside metropolitan statistical areas, 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.

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

.....
2B The Secretary should update health service areas before using them as payment areas in the Medicare Advantage program. In addition, the Secretary should make periodic updates to health service areas to reflect changes in health care market areas that occur over time.

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

Medicare Advantage payment areas and risk adjustment

MedPAC is mandated to identify the appropriate payment area for Medicare Advantage (MA) local plans and assess the new risk-adjustment system in the MA program. The current county definition of payment areas presents two problems. First, some counties have too few beneficiaries to obtain stable adjusted average per capita costs. Second, adjacent counties often have very different payment rates. Plans may offer more limited benefits in the counties with the lower rates or avoid them altogether. Our recommendation addresses these problems by collecting counties into larger groups. Among urban counties, payment areas should be counties that are located in the same metropolitan statistical area. Among rural counties, payment areas should be collections of counties that are accurate reflections of health care market areas. Our assessment of the new risk-adjustment system indicates that it predicts beneficiaries' costs much better than a "demographic" system that CMS has used for a number of years.

In this chapter

- AAPCCs vary widely
- How can Medicare improve payment areas for MA local plans?
- Payment area recommendations
- How accurately does the CMS–HCC model reflect cost differences?

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs MedPAC to study three issues related to the payment system in the Medicare Advantage (MA) program (see text box for bill language):

- The factors underlying geographic variation in adjusted average per capita costs (AAPCCs), including differences in input prices, service use, and practice patterns;
- The appropriate geographic area for payment of MA local plans; and
- The accuracy of the CMS–hierarchical condition category (CMS–HCC) risk-adjustment model in terms of how well it reflects differences in costs of providing care to different groups of beneficiaries.

AAPCCs are five-year moving averages of per beneficiary spending at the county level by fee-for-service (FFS) Medicare. CMS adjusts AAPCCs for county differences in FFS beneficiaries' health status. In the Medicare risk program that preceded Medicare Advantage and Medicare+Choice (M+C), the county payment rates that served as the base rates for plan payments equaled 95 percent of the AAPCCs.

The direct link between AAPCCs and payments created perceptions of geographic inequity. Plans were more likely to serve counties with high AAPCCs and typically offered more comprehensive benefits. Many policymakers viewed the geographic differences in benefits and availability of plans as inequitable (MedPAC 2001).

In response to the variation in plan benefits and availability, the Balanced Budget Act of 1997 (BBA) created the M+C program and reduced the link between AAPCCs and payments. Under the BBA, county rates were the highest of three possibilities or prongs:

- a floor rate,
- a blend of local and national rates, or
- a minimum update from the previous year.

Under this new payment system, plan payments often increased more slowly than plan costs, causing many plans to leave the M+C program or reduce benefits. In response, the MMA created the MA program and reestablished a stronger link between payments and AAPCCs by making county rates in 2004 the maximum of four prongs: the three from the BBA plus the AAPCCs. In subsequent years, CMS will update county rates by 2 percent or the national average growth in FFS spending, whichever is

Medicare Prescription Drug, Improvement, and Modernization Act, Title II, Sec. 211(f)

(f) MedPAC study of AAPCC.

(1) Study. The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such act (as amended by subsection (a)). Such study shall include an examination of:

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns.

(B) the appropriate geographic area for payment of MA local plans under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) Report. Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1). ■

larger. However, the MMA also requires CMS to recalculate AAPCCs at least every three years. For counties in which the recalculated AAPCCs exceed the updated amounts, CMS will use the recalculated AAPCCs as the county rates.

In 2004 and 2005, CMS used the county rates as the base rates for paying MA plans. In 2006 and subsequent years, CMS will use county rates to create benchmarks against which plans will bid. The benchmark for each plan will be a weighted average of the county rates for the counties in the plan's service area; the weights will be the projected enrollment from the counties in the plan's service area.

A plan that bids below its benchmark will have a base rate equal to its bid, adjusted in each county in its service area to reflect differences in the county rates. In addition, the plan will receive 75 percent of the difference between its bid and its benchmark, which the plan must return to its enrollees in the form of additional benefits, reduced cost sharing, or lower premiums. The federal government will retain the remaining 25 percent. Chapter 3 of this report provides more detail on the bidding process. A plan that bids above its benchmark will have a base rate equal to its benchmark, adjusted in each county in its service area to reflect differences in the county rates. The plan's enrollees will pay a premium equal to the difference between its bid and its benchmark.

Medicare's use of county payment rates to create benchmarks reflects the fact that counties serve as the payment area for MA local plans. These plans are "local" in that their service areas can be as small as a single county. This contrasts with regional plans that will begin service in 2006. Regional plans must serve entire regions, the smallest of which are entire states.

MA local plans receive capitated payments for each enrollee. Each payment is the product of two factors: a base payment rate (described above) and a beneficiary-level risk score that reflects the expected costliness of a beneficiary relative to the national average. Risk scores, which CMS obtains from a method of risk adjustment, have the purpose of adjusting plan payments so that Medicare pays plans appropriately based on their enrollees' risk profiles. If risk adjustment does not function properly, payments will not accurately reflect the risk profiles of plans' enrollees. Some plans will be overpaid while others will be underpaid, depending on their enrollees' risk profiles. This can lead to competitive

advantages for plans with favorable risks. Further, inaccurate accounting for risk can lead Medicare to pay more or less than intended to the MA program.

The Medicare risk program's risk-adjustment model used administrative data including beneficiaries' age, sex, and other demographic features as well as some program features. Research shows that this "demographic" model does not effectively account for differences in beneficiaries' expected costliness to the Medicare program. Consequently, Medicare paid more for MA enrollees who were in good health and less for those who were in poor health than for similar FFS beneficiaries.

The BBA required the Secretary to improve the risk-adjustment system. As a first step, CMS began using the principal inpatient diagnostic cost group (PIP-DCG) model in 2000. The PIP-DCG measures beneficiaries' health status using demographic information and principal diagnoses from hospital inpatient stays in a defined prior 12-month period.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 mandated that in 2004, Medicare base its risk adjustment system on data from hospital inpatient and ambulatory settings. CMS has developed this model—the CMS-HCC—and began using it in 2004. By law, CMS must phase in the CMS-HCC, so the agency currently uses two systems to risk adjust payments to MA plans: The CMS-HCC adjusts 50 percent of each payment, and the demographic system adjusts the remaining 50 percent. The percentage of each payment that the CMS-HCC will adjust will increase to 75 percent in 2006 and 100 percent in 2007. CMS will introduce a new version of the CMS-HCC in 2007 that will include more diseases than the current version.

AAPCCs vary widely

In MedPAC's June 2003 report, we examined an issue similar to variation in AAPCCs: state-level variation in FFS spending per beneficiary (MedPAC 2003). We sought to identify how much of the variation in FFS spending by state we can attribute to:

- the price of inputs such as wages and office rents;
- special payments received by some hospitals, including graduate medical education (GME) payments, indirect medical education (IME)

payments, and disproportionate share (DSH) payments to hospitals that provide indigent care; and

- beneficiaries' health status.

We calculated measures of variation among states before and after we adjusted for these factors.¹ We found that adjusting FFS spending for geographic differences in these factors reduces the variation by nearly 40 percent.

In this study, we use largely the same method to analyze variation, with three differences: a different geographic unit (counties), a slightly different variable (AAPCCs), and we did not identify variation due to differences in beneficiaries' health because CMS adjusts AAPCCs for health already (see text box). Without the need to adjust for differences in health, our analysis identified variation in AAPCCs attributable to geographic differences in the price of inputs and IME, GME, and DSH payments.

Adjusting for differences in the price of inputs and in IME, GME, and DSH payments reduces the variation in AAPCCs by about 14 to 17 percent, depending on the measure (Table 2-1).² We attribute the variation that remains after we adjusted AAPCCs for these factors to providers' practice patterns, beneficiaries' preferences for care, and the mix of providers.

This remaining variation largely reflects differences in service use. These differences are not related to quality. In fact, measures of quality tend to be higher in low-use areas (Fisher et al. 2003, MedPAC 2003).

Even though AAPCCs are strongly related to per beneficiary FFS spending, the proportion of the variation in county-level AAPCCs for which we have accounted is much smaller than the proportion of variation in state-level per beneficiary FFS spending for which we accounted in MedPAC's June 2003 *Report to the Congress*. This discrepancy reflects the fact that CMS already adjusts AAPCCs for differences in beneficiaries' health. We analyzed county-level per beneficiary spending and attributed about 40 percent of the variation to the combination of health, input prices, and IME, GME, and DSH payments, similar to our findings for state-level per beneficiary spending.

TABLE 2-1

Differences in price of inputs and special payments to hospitals account for about 15 percent of variation in AAPCCs

AAPCC	Measure of variation		
	Standard deviation	Coefficient of variation	Average of absolute difference
Adjusted for health	76.2	14.4	60.7
Adjusted for health; input prices; and IME, GME, and DSH payments	65.8	12.3	50.1
Percent change	13.6%	14.4%	17.4%

Note: AAPCC (adjusted average per capita cost), IME (indirect medical education), GME (graduate medical education), DSH (disproportionate share). The measures of variation are weighted by number of beneficiaries in each county.

Source: MedPAC analysis of county-level fee-for-service spending and other data from CMS.

How can Medicare improve payment areas for MA local plans?

We have identified two problems in using counties as payment areas for MA local plans. First, many counties have small Medicare populations. Among these counties, unusually high or low health care use by just a few beneficiaries can cause substantial annual changes in AAPCCs, which are based on moving averages of per beneficiary spending in FFS Medicare. For example, we estimate that the AAPCC for White Pine County, Nevada (which has 1,300 FFS beneficiaries) increased by 12 percent from 2001 to 2002.

Large annual changes in AAPCCs become an issue when CMS makes annual updates to county payment rates. For example, if CMS recalculates AAPCCs using data from a year in which a county experienced unusually large FFS spending, the county could have a county rate much higher than its "true" AAPCC. CMS could carry forward that erroneously high rate through the update mechanism that increases county rates by the larger of 2 percent or the percentage increase in the national average FFS spending.

A second problem that counties present is that adjacent counties often have very different AAPCCs. When this occurs, plans tend to offer more limited benefits in the county with the lower AAPCC—or to avoid that county altogether (MedPAC 2001).

Method for measuring variation in adjusted average per capita costs

We estimated an adjusted average per capita cost (AAPCC) for each county using data on Part A and Part B spending from 1998 through 2002. We calculated per beneficiary Part A and Part B amounts in each county for each of those years. We then calculated five-year averages of the Part A and Part B amounts and added those results to create a per beneficiary FFS spending amount for each county.

CMS standardizes AAPCCs using beneficiaries' risk scores from the CMS–hierarchical condition category risk-adjustment model. To be consistent with CMS, we divided each county's per beneficiary FFS spending by the average risk score for FFS beneficiaries living in that county. The end result of this method is the AAPCCs that we used to analyze variation among counties.

In our measures of variation, we weight each county by its Medicare population. The result is we weight beneficiaries— not counties—equally. Without weighting, beneficiaries in less populous counties would have more influence on the variation than those in more populous counties.

Variation in the price of inputs to care has an important effect on variation in AAPCCs. The Medicare program uses hospital wage indexes (HWIs) and three geographic practice cost indexes (GPCIs) to adjust provider payments for geographic differences in input prices. CMS uses the three GPCIs to create geographic adjustment factors (GAFs) that are weighted averages of the GPCIs. We used the HWIs and GAFs to determine the effect that differences in input prices have on the variation in AAPCCs. ■

These two problems are fairly easy to solve. Any payment area definition that groups counties into larger geographic units would increase the number of Medicare beneficiaries within payment areas, making AAPCCs more stable over time.³ In addition, grouping would reduce the frequency of large differences in AAPCCs 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 counties and plans should, in general, be required to cover the entire payment area. The Secretary could make exceptions in situations in which plans have difficulty creating 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 would vary widely within payment areas. Indeed, some counties in the western United States cover very large areas already.

- 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 in which they are profitable and avoid the parts in which they are not. However, if Medicare requires 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 the payment area altogether.

Alternatives to the county definition of payment areas

In response to the problems presented by counties, we have developed and evaluated three alternative definitions of payment areas, all using counties as the building block:

- *Within each state, MSAs for urban counties and statewide rural areas for rural counties.*⁴ We grouped urban counties into MSAs. If an entire MSA lies within the boundaries of a single state, the MSA

would serve as a single payment area. But if an MSA crosses state borders, the portion of the MSA in each state would serve as a distinct payment area. Within each state, we grouped all rural counties into a single statewide rural area that would serve as a distinct payment area. The first diagram in Figure 2-1 illustrates how the MSA/statewide rural area definition would look in southern Texas around the Corpus Christi, Brownsville, McAllen, and Laredo MSAs. The counties with patterns are located in MSAs, and the unshaded counties are part of the statewide rural area of Texas.

- Health service areas (HSAs) for urban and rural counties.** We grouped urban and rural counties into HSAs as defined by Makuc et al. (1991) (see text box for description). If an HSA lies within the boundaries of a single state, the HSA would serve as one payment area. But if an HSA crosses state borders, the portion of the HSA in each state would serve as a distinct payment area. The second diagram in Figure 2-1 illustrates how the HSA definition would look in the same part of southern Texas shown in the first diagram.

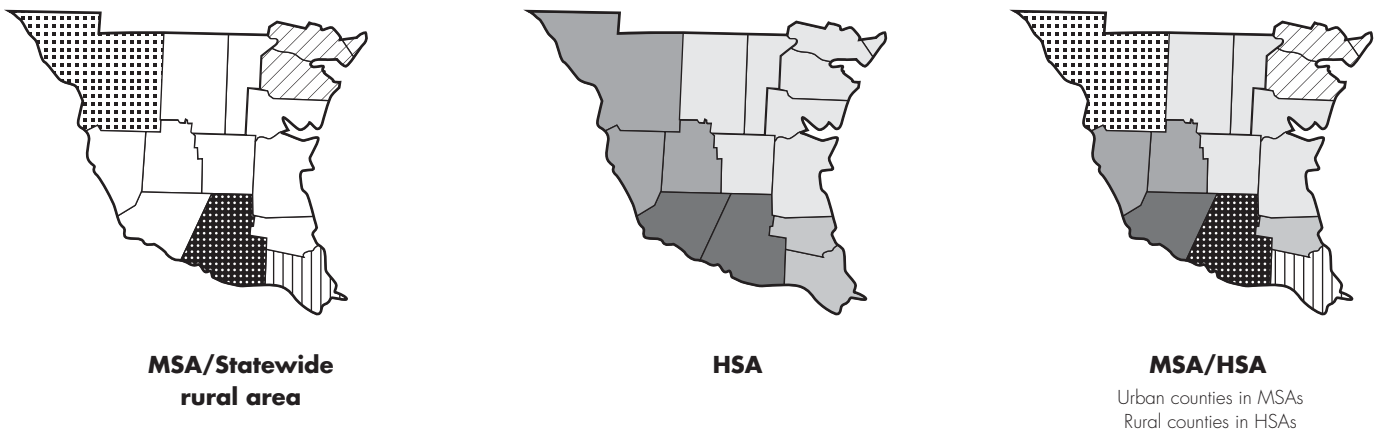
- MSAs for urban counties and HSAs for rural counties.** This definition is a hybrid of the other two alternatives. We grouped urban counties into MSAs and rural counties into HSAs. The third diagram in Figure 2-1 illustrates how the MSA/HSA definition would look around the same part of southern Texas shown in the first two diagrams. The counties with patterns are located in MSAs, and the gray-shaded counties are located in HSAs.

We chose to treat MSAs and HSAs that cross state borders as more than one payment area because plans typically face different laws, rules, and guidelines in different states. We identified 20 MSAs that cross state borders and have at least one county served by one or more coordinated care plans that participate in Medicare. In only six of these MSAs did plans consistently cross state borders and serve all the states covered by the MSA. In the other 14 MSAs, most or all plans that serve an MSA did not serve all states of that MSA.

In addition to the three alternatives discussed above, we also considered using hospital referral regions (HRRs) as a payment area definition (Wennberg and Cooper 1999). HRRs have an attractive attribute in that they represent health care market areas for tertiary medical care. Nevertheless, we chose not to use them for two reasons.

FIGURE 2-1

Three definitions of payment areas, southern Texas



Note: MSA (metropolitan statistical area), HSA (health service area). If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. Statewide rural areas are counties in the same state lying outside MSAs. The counties with patterns represent MSAs. The gray-shaded areas represent HSAs. The counties without patterns, in the first diagram, are part of the statewide rural area of Texas.

Source: MedPAC analysis of metropolitan statistical areas defined by the Office of Management and Budget and health service areas defined by Makuc et al. 1991.

Defining health service areas

The health service areas (HSAs) we used in our analysis consist of sets of one or more counties in which most of the short-term hospital care received by beneficiaries who live in an HSA occurs in hospitals that are in the same HSA. Very little short-term care occurs in hospitals outside the HSA.

A study by Makuc et al. (1991) defines the HSAs. Their method for grouping counties has the following features:

- They predetermined that HSAs would number about 800.⁵
- In the initial step, the number of groups equaled the number of counties (approximately 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 occur 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 combining groups until they obtained the predetermined number of HSAs. ■

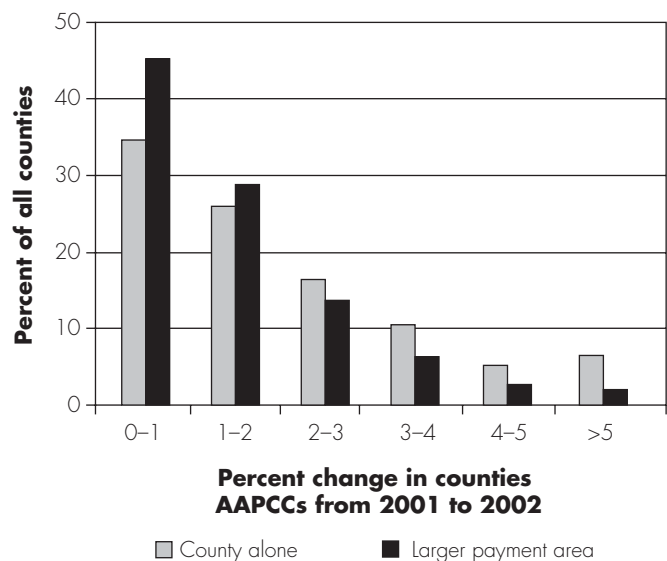
First, some are very large, covering more than half the area of large states such as New Mexico and Kansas. In these circumstances, we are concerned about large variations in cost of care within payment areas. Second, we are concerned that some HRRs—such as Albuquerque—include both urban areas and large rural areas, yet other HRRs—such as Miami—are strictly urban. Plans already behave differently in different payment areas, offering comprehensive benefits in some areas, while offering more limited benefits in other areas or avoiding them altogether. The lack of homogeneity among urban payment areas that would be caused by HRRs could exacerbate those differences.

Using larger payment areas reduces annual changes and large differences between adjacent counties

We use the MSA/HSA definition of payment areas as an illustrative example in a statistical analysis that demonstrates the advantages of payment areas that are larger than counties. We estimated AAPCCs from 2001 and 2002 that are based on four-year moving averages of per capita spending by FFS Medicare, removing the effect of increases over time in national average per capita FFS spending.⁶ We then compared the 2001 and 2002 AAPCCs.

FIGURE 2-2

Larger payment areas result in more stable AAPCCs



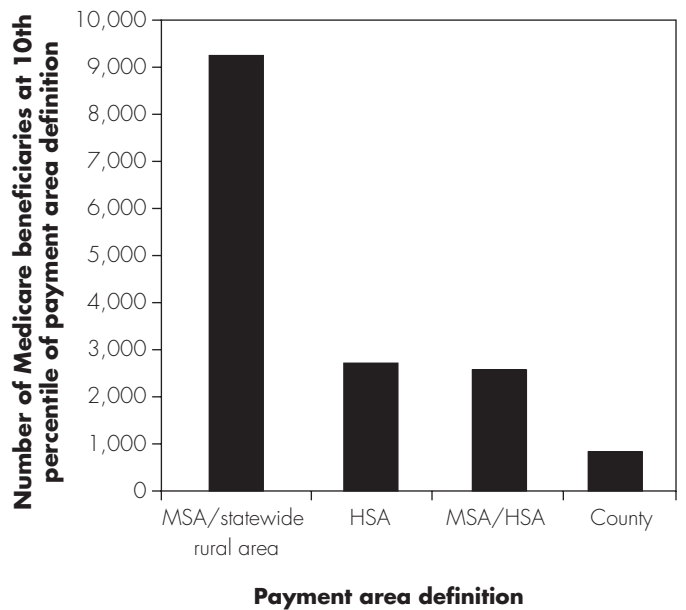
Note: AAPCC (adjusted average per capita cost). Larger payment areas are a combination of metropolitan statistical areas (MSAs) for urban counties and health service areas (HSAs) for rural counties. If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. The results reflect absolute values of the percent change in AAPCCs from 2001 to 2002.

Source: MedPAC analysis of county-level fee-for-service spending and other data from CMS.

We found that using a larger payment area would produce more stable AAPCCs. The average change in AAPCCs from 2001 to 2002 under the MSA/HSA definition of payment areas is 1.4 percent, compared with 2.1 percent for the county definition. Also, larger payment areas have a less dispersed distribution of annual changes. Under the MSA/HSA definition, 45 percent of counties have an annual change of less than 1 percent, and 2 percent of counties have an annual change of more than 5 percent. Under the county definition, 35 percent of counties have an annual change of less than 1 percent, and 7 percent of counties have an annual change of more than 5 percent (Figure 2-2, p. 47).

We also found that large differences in AAPCCs between adjacent counties occur much less frequently under the larger payment areas. Under the MSA/HSA definition, 14 percent of all beneficiaries live in counties that have an adjacent county with an AAPCC that is at least 15 percent

FIGURE 2-4 Larger payment areas have more Medicare beneficiaries and more stable AAPCCs



Note: AAPCC (adjusted average per capita cost), MSA (metropolitan statistical area), HSA (health service area). If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. Statewide rural areas are counties in the same state lying outside MSAs.

Source: MedPAC analysis of county-level fee-for-service spending and other data from CMS.

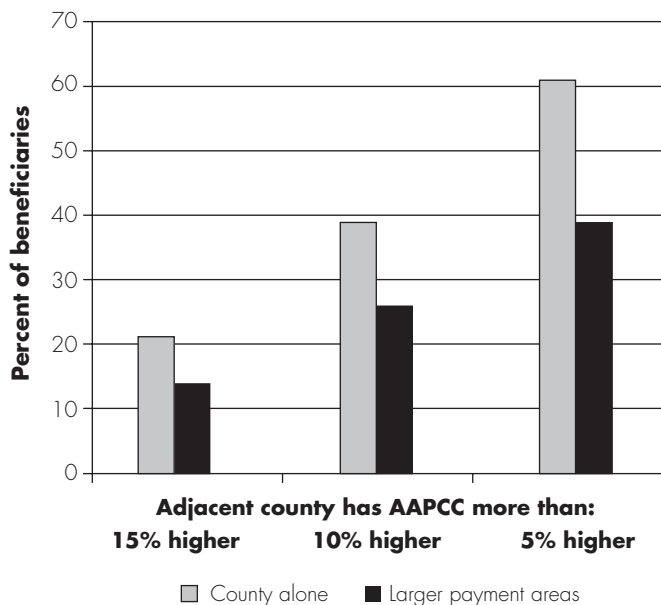
higher, compared to 21 percent of beneficiaries under the county definition (Figure 2-3).

One consequence of larger payment areas is that they would reduce AAPCCs for some counties and increase them for others. We estimate that 43 percent of beneficiaries live in counties that would have lower AAPCCs under the larger payment area, 37 percent live in counties that would have higher AAPCCs, and 20 percent live in counties that would have the same AAPCC.

Evaluating alternative payment area definitions

The statistical analysis in the previous section showed that larger payment areas have clear advantages and are preferable to the county definition. In this section, we address the question: Given that larger payment areas are better than the county definition, what is the best method for grouping counties to obtain the best payment areas?

FIGURE 2-3 Larger payment areas smooth differences in AAPCCs among counties



Note: AAPCC (adjusted average per capita cost). 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 fee-for-service spending and other data from CMS.

We evaluate the three larger payment area alternatives described on pages 45–46, basing our evaluation on four criteria:

- Will CMS and plans face substantial burdens in collecting the data necessary to determine plan payments?
- Will payment areas have enough beneficiaries to obtain reliable AAPCCs?
- How well do payment areas match the market areas that plans serve?
- Would payment areas be too large to be fairly homogeneous in terms of costs of serving beneficiaries?

Will CMS and plans face substantial burdens from data collection?

Because the three alternatives that we considered use the county as their building block, neither CMS nor plans would have any additional burden from collecting the data necessary to determine plan payments. Also, plans often use counties as the building block for their service areas. Therefore, our use of counties as the basis for building payment areas has some favorable attributes.

Will the three alternatives have enough beneficiaries?

Relative to the county definition, all three alternatives would tend to increase the number of Medicare beneficiaries in payment areas (Figure 2-4). Therefore, each alternative would increase the stability of AAPCCs.

For example, when we consider the distribution of the number of beneficiaries among payment areas, the county at the 10th percentile had 809 beneficiaries in 2002. In contrast, the MSA/statewide rural area definition had more than 9,200 beneficiaries at the 10th percentile, HSAs had 2,700 beneficiaries, and the MSA/HSA definition had 2,600. The MSA/statewide rural area definition had the highest number of beneficiaries because statewide rural areas often encompass more counties than MSAs and HSAs.

How well do payment areas match plan market areas?

Ideally, payment areas should perfectly match the geographic areas that plans serve (plan market areas). We have identified two measures that can give us a sense of how well a payment area definition matches plan market areas:

- If one county of a payment area is served by at least one plan, are all counties in the payment area served by at least one plan? For example, if a payment area has two counties and we know that at least one plan serves one of those counties, we ask: Does at least one plan serve both counties? Note that the same plan does not have to serve all counties of a payment area.
- If a plan serves at least one county in a payment area, does it serve the entire payment area?

Under both measures, if some parts of a payment area are covered but other parts are not, the payment area might not accurately represent plan market areas. In our analysis,

TABLE 2-2

How payment areas compare with market areas of Medicare Advantage and private-sector plans

Payment area definition	If one county in an area is served by plans, likelihood all counties are served		If a plan serves one county in an area, likelihood it serves all counties	
	Private-sector plans	MA plans	Private-sector plans	MA plans
MSA/HSA	94.9%	69.6%	69.8%	59.4%
MSA/Statewide rural area	93.8	65.6	63.4	52.5
HSA	93.3	49.0	55.4	41.8

Note: MA (Medicare Advantage), MSA (metropolitan statistical area), HSA (health service area). If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. Statewide rural areas are counties in the same state lying outside MSAs.

Source: MedPAC analysis of data from CMS and InterStudy.

we considered how well our three proposed alternatives match the market areas of coordinated care plans that participate in MA as well as the market areas of HMOs in the private sector.

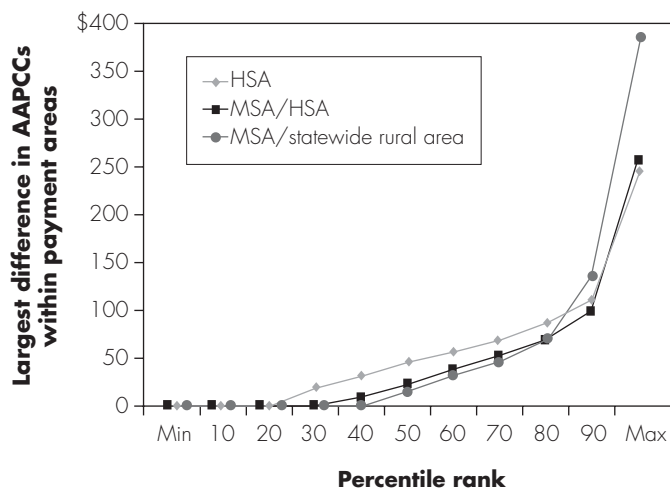
Among the three alternatives, the MSA/HSA definition performs the best, when we consider market areas of MA plans and those of private-sector HMOs. The HSA definition performs the worst (Table 2-2, p. 49).

Would payment areas be too large?

We want payment areas that are large enough to obtain stable AAPCCs, but small enough so that the cost of serving beneficiaries is fairly homogeneous. We measured the homogeneity of cost under each alternative as the difference between the largest and smallest AAPCCs among counties in the same payment area. When we consider the payment areas within each definition that show the largest differences (90th percentile and higher), the MSA/statewide rural area definition has the largest differences relative to the other definitions (Figure 2-5). We are not surprised by this result because statewide rural areas can encompass relatively large geographic areas, increasing the likelihood of large differences in per capita spending.

FIGURE 2-5

Geographic differences in AAPCCs are greater in larger payment areas



Note: AAPCC (adjusted average per capita cost), HSA (health service area), MSA (metropolitan statistical area). If an MSA or HSA is divided by state borders, the part in each state is a distinct payment area. Statewide rural areas are counties in the same state lying outside MSAs.

Source: MedPAC analysis of county-level fee-for-service spending and other data from CMS.

Payment area recommendations

We do not consider any of the three alternatives an optimal payment area. This is to be expected; no single method of grouping counties can perfectly match all plan market areas because markets differ.

Despite the shortcomings of our alternatives, the Congress can improve payment areas over the county definition by making the following changes:

- MSAs should serve as the payment area for urban counties.
- Payment areas for rural counties should be collections of counties that represent health care market areas for Medicare beneficiaries. An example is the HSAs we examined in this report.

We prefer MSAs to HSAs for urban counties because MSAs match plan market areas better (Table 2-2, p. 49).⁷ For rural counties, we prefer to use payment areas that are smaller than statewide rural areas because statewide rural areas often have high variations in the cost of serving beneficiaries. This could make them unattractive to plans and unnecessarily hinder plans from serving rural areas. The Secretary generally should require plans to serve entire payment areas, irrespective of the payment area definition. But plans also should have the opportunity to obtain waivers allowing them to serve only specific portions of a payment area if they can show that it is difficult to form provider networks throughout the payment area.

If the Congress chooses to implement our recommended payment area definition, three issues should be considered before the Secretary puts it into practice. First, the Secretary should confirm whether plans have any concerns that a few payment areas have unusual characteristics that the Secretary should address. Second, if an MSA is so large that most MA local plans do not serve all of it, the Secretary could consider dividing the MSA into smaller groups of counties. Third, MA plans are facing substantial changes in the near future, including a new payment system based on plan bids and a prescription drug benefit. It may be prudent to allow plans time to become accustomed to these other changes before introducing new payment areas.

The effect of this recommendation on plan participation and beneficiary enrollment in MA plans is uncertain. Relative to the county definition, the MSA/HSA definition tends to increase plan payments in counties that currently have low county rates, which could increase plan participation and beneficiary enrollment. In contrast, the MSA/HSA definition tends to decrease payments in counties with high rates, which could decrease plan participation and beneficiary enrollment. Consequently, we cannot predict the effect that changes in beneficiary enrollment would have on overall program spending.

Finally, no payment area definition is perfect. One problem presented by the MSA/HSA definition is that payment areas may have 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 he should break up an HSA into smaller groups of counties.

RECOMMENDATION 2A

The Congress should establish payment areas for Medicare Advantage local plans that have the following characteristics:

- **Among counties in metropolitan statistical areas, payment areas should be collections of counties that are located in the same state and the same metropolitan statistical area.**
- **Among counties outside metropolitan statistical areas, 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.**

RATIONALE 2A

Counties are often too small to serve adequately as payment areas for MA local plans. However, counties should be the building block for larger payment areas because plans and CMS would have no additional data collection burden. Our assessment of alternatives to the county definition shows that among urban counties, MSAs are reasonably good matches for plan market areas. Among rural counties, payment areas must not be so large that the cost of providing care varies widely within payment areas. HSAs are reasonable matches to that criterion and have the additional attribute of reflecting market areas for short-term inpatient stays among Medicare beneficiaries.

IMPLICATIONS 2A

Spending

- This recommendation should have no direct effect on program spending.

Beneficiaries and plans

- The effect on plan participation is ambiguous. On the one hand, plans may decrease the areas they serve if larger payment areas sufficiently reduce opportunities for isolating payment areas in which payments are favorable relative to costs. On the other hand, plans may increase the areas they serve if payments increase sufficiently in counties that they currently do not serve. Because of the uncertain effect on plan participation, this recommendation would have an ambiguous effect on beneficiaries' access to MA plans.

We caution that the HSA definition we used in our analysis is purely for illustrative purposes. Makuc and colleagues (1991) defined HSAs using data from hospital inpatient stays that occurred in 1988. If the Congress chooses HSAs as a payment area, the Secretary should first update those HSAs and keep them up to date over time. 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.

RECOMMENDATION 2B

The Secretary should update health service areas before using them as payment areas in the Medicare Advantage program. In addition, the Secretary should make periodic updates to health service areas to reflect changes in health care market areas that occur over time.

RATIONALE 2B

Makuc and colleagues (1991) developed the current version of HSAs using data from hospital inpatient stays that occurred in 1988. The Secretary should update HSAs to reflect changes in health care markets that have occurred since then. In addition, health care markets will continue to change, and the HSAs should receive periodic updates to reflect those changes.

Spending

- This recommendation should have no direct effect on program spending.

Beneficiaries and plans

- This recommendation should have no effect on plan participation or beneficiaries' access to plans.

How accurately does the CMS-HCC model reflect cost differences?

The measure that we use to evaluate the accuracy of the CMS-HCC model is the predictive ratio, which indicates how well a risk adjuster predicts the costliness of a group of beneficiaries to the Medicare program. The definition of a predictive ratio for a group is the group's mean costliness predicted by a risk adjuster divided by the mean of the group's actual costliness. If a risk adjuster predicts a group's costliness perfectly, predicted costliness equals actual costliness and the predictive ratio equals 1.0. But if a risk adjuster overpredicts a group's costliness, the predictive ratio will be greater than 1.0. Alternatively, if a risk adjuster underpredicts a group's costliness, the predictive ratio will be less than 1.0. In summary, the closer a predictive ratio is to 1.0, the better the risk adjuster has performed.

We based the predictive ratios in our analysis on predicted and actual costliness in 2002. The data that we used to obtain predicted and actual costliness are from administrative and claims information from a random sample of 5 percent of beneficiaries in FFS Medicare. We used the same version of the CMS-HCC that CMS has used in 2004 and 2005.

In our analysis, we grouped beneficiaries using characteristics that reflect either good or bad health. These characteristics include:

- quintile of costliness in 2001;
- number of hospital inpatient stays in 2001; and
- conditions diagnosed in 2001, including alcohol or drug dependence, diabetes with complications, diabetes without complications, congestive heart failure, acute myocardial infarction (AMI), chronic obstructive pulmonary disease, unspecified stroke, cerebral hemorrhage, and hip fracture.

For each of these groups, we compared the predictive ratios from the CMS-HCC to predictive ratios from a model similar to the demographic system. We chose not to use the actual demographic system because some of the data used in that model—such as institutional status—are difficult to obtain. Instead, we chose a model that uses beneficiaries' age and sex to predict their costliness to the Medicare program. Other researchers have used the age/sex model in several studies as a point of reference for the performance of other risk-adjustment models (Pope et al. 2000, Pope et al. 1999, Ellis et al. 1996).

TABLE 2-3

CMS-HCCs better predict beneficiaries' costliness than a demographic model

Beneficiary group	Predictive ratios from two risk adjusters	
	CMS-HCCs	Age/Sex
Quintile of costliness in 2001		
Lowest	1.34	2.53
Second	1.30	1.96
Third	1.19	1.47
Fourth	0.98	0.96
Highest	0.83	0.44
Number of inpatient stays in 2001		
Zero	1.07	1.38
One	0.96	0.65
Two	0.92	0.49
Three or more	0.80	0.29
Conditions diagnosed in 2001		
Alcohol/drug dependence	0.99	0.39
Diabetes w/complications	0.99	0.44
Diabetes w/o complications	0.99	0.72
Congestive heart failure	0.90	0.50
Acute myocardial infarction	0.98	0.64
COPD	0.93	0.67
Unspecified stroke	1.03	0.79
Cerebral hemorrhage	1.09	0.65
Hip fracture	1.08	0.80

Note: CMS-HCCs (CMS-hierarchical condition category); COPD (chronic obstructive pulmonary disease). A predictive ratio for a group of beneficiaries is the mean of their costliness predicted by a risk-adjustment model divided by the mean of their actual costliness. The age/sex model uses beneficiaries' age and sex to predict costliness. All conditions listed are used in the CMS-HCC model.

Source: MedPAC analysis of 5 percent sample of beneficiaries participating in fee-for-service Medicare in 2001 and 2002.

Our results show that in each group, predictive ratios are closer to 1.0 under the CMS–HCC than under the age/sex model (Table 2-3). This indicates the CMS–HCC does a better job than the age/sex model of predicting the costliness of beneficiaries who are in good health and those who are in bad health.

However, the CMS–HCC leaves room for improvement. For example, the predictive ratio is 1.34 for beneficiaries in the lowest quintile of costliness in 2001 and 0.83 for beneficiaries in the highest quintile, indicating the CMS–HCC overpredicts the costliness of beneficiaries who are in good health and underpredicts for those who are in poor health. CMS will introduce an improved version of the CMS–HCC in 2007 that should reduce these prediction errors.

A final issue is that CMS will use the CMS–HCC to predict how much MA enrollees would cost Medicare if they were enrolled in the FFS program. This can be a problem if Medicare’s goal is to pay MA plans accurately

for the costs plans incur in providing care to their enrollees and the relative costs of treating conditions are markedly different between FFS Medicare and MA plans. For example, the relative cost of treating a beneficiary who had an AMI to a beneficiary who has no conditions could be different between the FFS and MA programs. Conversely, if FFS Medicare and MA plans have the same relative costs in treating conditions, this issue is irrelevant.

Some observers have found little or no difference between health care delivery systems in terms of the relative costs of treating conditions. But to definitively determine whether relative costs are different or similar between MA plans and FFS Medicare, we must have data on the costs that plans incur in providing care to individual enrollees. These data are not available to Medicare, but CMS might wish to explore this issue by collecting the necessary data from one or more MA plans. Those that pay their providers on an FFS basis would be less burdened than other plans in compiling such a database. ■

Endnotes

- 1 The measures of variation include the standard deviation, which is the square root of the variance; the coefficient of variation, which is the standard deviation divided by the mean of the distribution; and the average of the absolute differences from the mean.
- 2 We also estimated the variation in AAPCCs attributable to input prices and the variation due to IME, GME, and DSH payments. We found that adjusting for input prices reduces the variation by about 15 percent and adjusting for differences in special payments to hospitals reduces the variation by about 8 percent. When we adjust for these factors simultaneously, the reduction in variation is about 15 percent, less the sum of the individual effects—23 percent. This occurs because input prices and special payments to hospitals interact in such a way that their impacts are mitigated when taken together.
- 3 By law, state governors can request that payment areas in their states be groups of counties rather than single counties, but none have done so. The law allows three possibilities: (1) making the entire state one payment area; (2) grouping counties that are located in metropolitan statistical areas (MSAs) into payment areas and grouping counties that are not located in MSAs into a single payment area; and (3) grouping noncontiguous counties.
- 4 Our definitions of urban and rural are based on definitions of metropolitan and micropolitan statistical areas created by the Office of Management and Budget (OMB) in 2004. OMB grouped counties into metropolitan statistical areas, micropolitan statistical areas, and rural areas. We define urban counties as those that are located in metropolitan statistical areas, and we define rural counties as those that are located in either micropolitan statistical areas or rural areas.
- 5 The basis for this decision was results from work with health care commuting areas (HCCAs), which were developed in 1976 using data from 1968 to 1970. Makuc and colleagues decided it was reasonable for the number of HSAs to be about equal to the number of HCCAs. They found that the HCCAs performed well as health service areas and there had not been a major change in the number of hospital beds between 1970 and 1988 (where 1988 is the year of their data).
- 6 Earlier, we used five-year averages to analyze the variation in AAPCCs among counties. We used four-year averages to analyze annual changes because we have data from 1998 through 2002. We used data from 1998 through 2001 to obtain four-year averages for 2001 and data from 1999 through 2002 to obtain four-year averages for 2002.
- 7 We also examined the 20 largest metropolitan areas to see how well the MSA/HSA definition and the HSA definition match the areas served by HMOs participating in the Federal Employees Health Benefits (FEHB) Program. In general, the MSA/HSA definition performs better because the HSA definition often includes more rural counties that the FEHB Program plans do not serve.

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CHAPTER

3

**The Medicare
Advantage program**

R E C O M M E N D A T I O N S

3A The Congress should eliminate the stabilization fund for regional preferred provider organizations.

.....
COMMISSIONER VOTES: YES 15 • NO 1 • NOT VOTING 0 • ABSENT 1

3B The Secretary should calculate clinical measures for the fee-for-service program that would permit CMS to compare the fee-for-service program to Medicare Advantage plans.

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

3C The Congress should clarify that regional plans should submit bids that are standardized for the region's Medicare Advantage-eligible population.

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

3D The Congress should remove the effect of payments for indirect medical education from the Medicare Advantage plan benchmarks.

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

3E a) The Congress should set the benchmarks that CMS uses to evaluate Medicare Advantage plan bids at 100 percent of the fee-for-service costs.

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

b) At the same time, the Congress should also redirect Medicare's share of savings from bids below the benchmarks to a fund that would redistribute the savings back to Medicare Advantage plans based on quality measures.

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

3F The Congress should put into law the scheduled phase-out of the hold-harmless policy that offsets the impact of risk adjustment on aggregate payments through 2010.

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

The Medicare Advantage program

MedPAC supports giving Medicare beneficiaries a choice among health care delivery systems. Where private plans can improve the efficiency and quality of health care services for Medicare beneficiaries they should be encouraged to do so and beneficiaries should be given an opportunity to choose them. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) introduced a number of changes to the program of private plans in Medicare and created the Medicare Advantage (MA) program. New types of plans were introduced, plan quality requirements were altered, and payment policies were modified. Some of these changes raise issues concerning financial neutrality and the conditions of competition between choices. This chapter provides an overview of major changes and provides recommendations on a number of provisions related to the MA program.

In this chapter

- Overview of changes to the managed care program under the MMA
- What are the new types of plans?
- Quality
- Enrollment
- Benefits
- The MA bidding process for 2006
- Financial neutrality under the 2006 bidding system

MedPAC supports private plans in the Medicare program. In general, Medicare beneficiaries should be able to choose between the fee-for-service (FFS) Medicare program and the alternative delivery systems that private plans can provide, as long as the choices are efficient for the program. Private plans may have greater flexibility in developing innovative approaches to care, and these plans can more readily use tools such as care coordination and other health care management techniques to improve the efficiency and quality of health care services that Medicare beneficiaries receive.

Since 1982, Medicare beneficiaries in many areas of the country have been able to choose between whether to receive care under the traditional FFS program or through private plans—which, in return for a fixed monthly payment from the Medicare program, agree to provide a benefit package at least equivalent to that available in FFS. Often, these plans have supplemented Medicare benefit packages and have offered them for less than the price beneficiaries pay for supplemental Medigap policies. Private plans in Medicare have experienced varying degrees of enrollment over the years, peaking at 17 percent of the Medicare population in 1999 but declining to 12 percent by 2004 (MedPAC 2004a).

MedPAC also supports financial neutrality between payment rates for the FFS program and private plans. Additionally, MedPAC supports equitable payment rates among private plans. Financial neutrality means that the Medicare program should pay the same amount, regardless of which Medicare option a beneficiary chooses. If a beneficiary chooses a more expensive plan, that beneficiary can choose to pay additional premiums. In paying private plans more than FFS—or paying certain private plans more than other private plans—the payment system encourages inefficiency and contributes to increased overall spending for the Medicare program (MedPAC 2004b).

Financial neutrality is important because Medicare costs are high and will continue to increase rapidly for the foreseeable future, particularly with the impending eligibility of the baby boom generation. The Medicare program needs to offer private options that will help reduce, not increase, overall program spending. In raising MA plans' rates above FFS rates in order to attract plans to new areas of the country, Medicare does not create incentives for the efficient provision of high-quality care. Medicare should set payment rates to encourage plans to

achieve high quality with lower resource use. It may be consistent with the Congress's goal of increased availability of MA plans to set MA rates higher than FFS rates in the short term to help plans build infrastructure; however, to continue to do so would be a disservice both to Medicare beneficiaries and—in these times of increasing budget deficits—the taxpayer. If MA plans exist in markets only because payment rates are higher than FFS rates, any reduction in those rates would likely lead to considerable disruption for beneficiaries; they would have to switch to another MA plan or return to the FFS program. This change could make Medicare beneficiaries' perceptions of the MA program unfavorable—as happened after plans withdrew from Medicare in the late 1990s—and could ultimately undermine the ability of efficient, high-quality MA plans to succeed under Medicare.

However, MedPAC is also aware that the Congress has raised payment rates for private plans and has introduced new types of private plans, such as regional preferred provider organizations (PPOs), to encourage expansion of the MA program to new areas and to try to reverse several years of declining enrollment. Lowering rates to achieve financial neutrality in the short run would likely reduce the participation of plans and beneficiaries in the MA program; doing so in the midst of the 2006 bidding process would cause significant disruption. Regional PPOs and new local MA plans are preparing to enter the MA program, but they might reconsider whether to enter certain markets—or whether to leave certain markets after a short period of time. Additionally, some provisions in the MMA, such as the more competitive system, may provide valuable information to inform our thinking about more appropriate payment rates.

Thus, MedPAC supports a policy of financial neutrality for the MA program, coupled with incentives for delivering high-quality care. We have found that organizations are more likely to be efficient when they face financial pressure. The Medicare program needs to exert consistent financial pressure on both the FFS and MA programs, coupled with meaningful quality measurement and pay-for-performance programs, in order to maximize the value it receives for the dollars it is spending. MedPAC recognizes that the Congress may not be able to achieve this objective immediately. We designed the recommendations in this chapter to provide future, as well as immediate, steps toward this objective.

Overview of changes to the managed care program under the MMA

The MMA is the Congress's most recent attempt to increase private plans' participation in the Medicare program. The MMA changed several major elements of the program for private plans that participate in Medicare. These changes include:

- **Types of plans.** The MMA added two new types of plans: regional PPOs and special needs plans.
- **Payment method.** The MMA changed the method of payment from one in which Medicare pays plans based on an administered price to one in which plans will bid against an administered price.

- **Drug benefit provision.** All MA plans—except private fee-for-service (PFFS) and Medicare Savings Account (MSA) plans—will offer the minimum drug benefit that will be available to all beneficiaries under Part D.
- **Enrollment period.** Current policy allows beneficiaries to change plans on a monthly basis. Beginning in 2006, the enrollment process will change to an annual open enrollment period. However, dual eligibles (that is, beneficiaries who are eligible for both Medicare and Medicaid) will be allowed to change plans at any time.
- **Name of program.** The MMA renamed the program from Medicare+Choice (M+C) to Medicare Advantage (MA).

Table 3-1 details the full list of MMA changes in the MA program.

**TABLE
3-1**

Medicare Advantage changes as a result of the MMA

Program feature	Medicare+Choice	Medicare Advantage
Types of plans	HMOs, PPOs, PFFS, MSA, specialized plans	HMOs, regional and local PPOs, PFFS, MSA, special needs plans
Cost plans	Were to expire 12/31/04	Expire 12/31/07 unless fewer than two Medicare Advantage plans in an area
Quality	Quality assurance focus	Quality improvement focus
Enrollment	ESRD allowed only if beneficiary already enrolled in Medicare+Choice plan prior to onset of ESRD	ESRD allowed only if beneficiary already enrolled in Medicare Advantage plan prior to onset of ESRD or if beneficiary enrolled in special needs plan that accepts ESRD beneficiaries
Open enrollment period	Continuous monthly	Annual, with several exceptions
Medicare benefits package	All Part A and Part B services except hospice	All Part A and Part B services except hospice; certain types of plans must offer a Part D drug plan. Regional PPOs must offer a combined deductible and stoploss
Payment	Administered prices based on three-prong system	Bidding with administered prices as a benchmark in a two-prong system
Additional benefits	Difference between plan costs and price must be returned as additional benefits. If Part B premium reduction, 80% of difference available and 20% retained by Medicare	75% of difference between plan bid and benchmark must be returned as additional benefits/premium reductions; 25% of difference retained by Medicare
Payment areas	County	County, for local plans; regions, for regional plans
Basic risk adjustment	CMS-HCC method	CMS-HCC method

Note: HMO (health maintenance organization), MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), PPO (preferred provider organization), PFFS (private fee-for-service), MSA (medical savings account), ESRD (end-stage renal disease), CMS-HCC (CMS-hierarchical condition category).

Source: Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

What are the new types of plans?

The MMA allowed two new types of plans under the MA program and changed several features of the existing plans.

Regional PPOs

The addition of regional PPOs was probably the most visible change to the types of plans allowed to participate in the program. PPOs in the private market generally contract with a set of providers to offer services at discounted fees. Providers accept the lower fees in return for anticipated higher patient volume, because PPO members generally have financial incentives—structured through differences in cost sharing—to seek care from preferred providers. Unlike a health maintenance organization (HMO), PPO members can receive care from providers outside the preferred PPO network, although they generally pay higher cost sharing for doing so. PPOs and point-of-service plans (POS)—which have a similar plan design—existed under the earlier M+C program. But until CMS established a PPO demonstration program in 2003, these types of plans were slow to emerge. However—perhaps in preparation for the emergence of regional PPOs in 2006 and the subsequent moratorium on local PPOs (discussed later in this chapter)—CMS received new applications from 70 local PPOs for 2005, 26 of which the agency approved. These were available to beneficiaries as of January 2005. These new PPO offerings are in addition to those from the existing demonstration PPOs. Regional PPOs differ from local PPOs in that they must serve the entire region that CMS has defined for this type of plan.

PPO regions

Some policymakers hope that requiring plans to serve larger regions will bring MA plans to more parts of the country and give beneficiaries more choices. Policymakers also expect that specific provisions in the MMA relating to payment, network adequacy, and cost sharing will encourage private plans to serve rural as well as urban areas in a region. The MMA specified a minimum of 10 regions and a maximum of 50 regions for regional PPOs and required that the Secretary construct the regions based on an analysis of current health insurance markets. (As we discuss later, the Secretary ultimately decided on 26 PPO regions.) During the course of Medicare's managed care program, the Congress has often taken steps to encourage private plans to broaden their service areas, hoping that

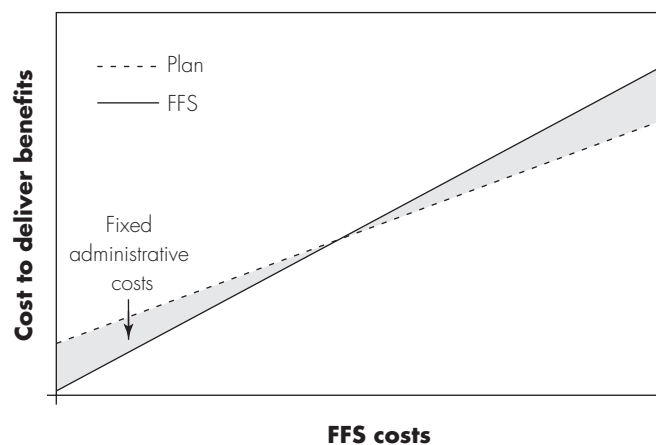
these plans—with their often attractive benefit packages—would make themselves available to more beneficiaries. Most notable have been congressional increases in payment rates in areas that have below-average levels of FFS program spending. (We discuss the payment rates later in this chapter.) These areas often tend to be rural.

MedPAC and others have cited two primary reasons (other than Medicare payment rates) why MA plans are less likely to serve rural, sparsely populated areas (MedPAC 2001). First, unlike managed care products sold to employers (in which plans market to an employer to win the business of an entire group of employees), MA plans sell policies to individual Medicare beneficiaries. Marketing individual products is expensive, and the return on investment is lower in areas that contain few Medicare beneficiaries.

Second, plans face difficulty in building provider networks in less densely populated areas. In areas that have many competing hospitals and physicians, these providers are more willing to accept a plan's contracting terms. In rural areas, less competition among providers means less incentive to negotiate with plans over fees and other plan requirements. Additionally, health plans face certain fixed costs before they can enroll a single member. Thus, plans face problems in establishing programs in low-cost (generally rural) areas, and they have certain advantages in higher cost (generally urban) areas.

FIGURE 3-1

Comparison of private plan versus FFS costs, by market area, 2004



Note: FFS (fee-for-service).

Source: MedPAC analysis of Adjusted Community Rate Proposal data.

MedPAC illustrates these problems in an analysis of private plan adjusted community rate (ACR) data. In areas that have low levels of FFS costs, plan costs exceed FFS costs. However, in areas that have high levels of FFS costs, plans are increasingly able to provide Medicare benefits at less than FFS costs (either by managing care more efficiently or negotiating reduced prices from providers)—even considering their initial fixed costs (Figure 3-1). This helps to explain why the majority of MA enrollment is in higher cost, urban areas.

One type of MA plan—the PFFS plan—specifically targets enrollees in rural areas where Medicare payment rates are high relative to spending under the traditional FFS program.¹ Because PFFS plans do not need to contract with providers to meet Medicare’s access and participation requirements, they face lower fixed costs. These PFFS plans are considered to have met the access requirements by paying providers at least the fees that would apply under the traditional FFS program, thus enabling them to compete in lower cost rural counties. Although for several years only one company offered these types of plans, several more companies offered them in 2004 and 2005—and we expect more in 2006. As of March 2005, total enrollment in PFFS plans was 71,000, a small share of the 5.6 million total enrollment in private plans, but an increase of more than 150 percent from March 2004 (Figure 3-2).

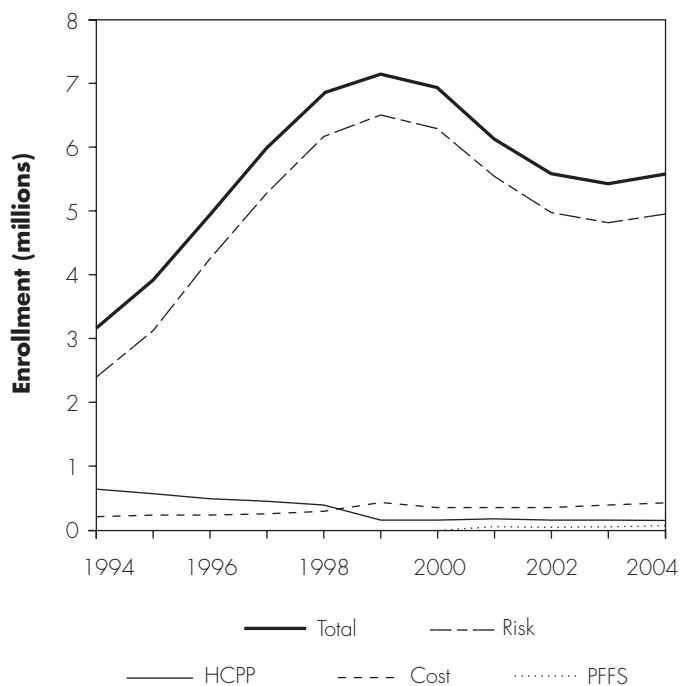
The Congress hopes that regional PPOs will have much broader appeal to Medicare beneficiaries than existing plan types because PPOs have become the most popular health insurance option in the private sector, following a consumer backlash against HMOs in the late 1990s. If many of these plans enter the program to serve regions across the country, private plans will be more widely available to beneficiaries. The ultimate popularity of the regional PPO offering will not be evident for a number of years, but as of May 2005, plans had indicated an interest in becoming regional PPOs in 21 of the 26 PPO regions (Inside Washington Publishers 2005).

CMS analyzed a number of factors in determining how to establish regions to encourage regional PPOs’ participation in the MA program (CMS 2004) (Figure 3-3, p. 64). These factors included the following:

- **Population size.** CMS concluded that an area needs at least 200,000 eligible beneficiaries for a plan to be able to form networks. CMS also concluded that the region should include no more than 3 million beneficiaries because of potential start-up costs.

FIGURE 3-2

Enrollment in Medicare private plans, by plan type



Note: HCPP (health care prepayment plan), PFFS (private fee-for-service).

Source: CMS.

- **Sufficient number of existing competitors.** CMS looked at whether existing competitors were already located in the area, expecting that the regional PPO plans would be developed by companies already offering health insurance coverage.
- **Limited variation in payments within regions.** CMS grouped states that had similar average plan payments.
- **The preservation of geographic patient flows.** CMS grouped states in which beneficiaries typically receive care across state borders.

Based on this analysis of existing insurance markets, CMS chose 26 PPO regions.

Regional PPO features

Regional PPOs and local MA plans must cover the same Medicare Part A and B benefits as under the FFS program (with the exception of hospice care). All MA plans must follow local coverage decisions, but regional PPOs that span multiple areas with differing policies can select a set

Regional PPOs that use a combination of in- and out-of-network services cannot require beneficiaries to get services preauthorized. However, plans can warn beneficiaries that they do not cover certain services and they can encourage beneficiaries to first call the plan to determine whether it covers the services in question. Plans can offer an incentive for beneficiaries to call by charging less cost sharing when beneficiaries notify them of their intent to use out-of-network services.

To the extent that they have deductibles, the MMA requires regional PPOs to provide a combined deductible for Part A and Part B services (thus combining the deductibles for hospital, physician, and post-acute care), and an overall cap on beneficiary cost-sharing liability. The deductible may be waived for preventive services, and the cap may differ for in-network and out-of-network cost sharing. Neither the MMA nor its subsequent regulations set parameters for these benefit design elements, although the actuarial value of the deductible, coinsurance, and copayments in an MA plan may not exceed the actuarial value of the deductible, coinsurance, and copayments that would apply, on average, to FFS enrollees. Additionally, CMS continues to have the authority to disallow the offering of an MA plan if CMS determines that the benefit design is likely to substantially discourage enrollment by certain MA-eligible individuals. Local MA plans do not have to offer a combined deductible, or the overall cap on beneficiary out-of-pocket liability.

Financial incentives to attract regional PPOs

The Congress added three types of financial incentives to encourage regional PPOs to participate in MA: risk sharing for 2006 and 2007, a regional stabilization fund, and essential hospital payments that may go to certain hospitals in a regional PPO plan's network. In addition, the MMA established a moratorium on local PPO plan entry in 2006 and 2007 (the act permits existing local PPOs to offer new products within the existing service area). This moratorium is intended to prompt private plans to consider participating as regional PPOs.

Risk sharing for 2006 and 2007

Risk sharing for regional PPOs is structured through "risk corridors"—plan-specific spending targets against which actual plan spending is compared. Risk corridors may function as a valuable protection for plans that serve large regions with variable conditions. If costs exceed the target,

Medicare gives additional payments to the plans; if costs fall below the target, plans must return funds to Medicare following a set schedule (Figure 3-4, p. 66). For example, a regional PPO that Medicare paid \$700 per member per month but that spent \$735 on benefits net of administrative expenses would receive an additional \$7 per member per month under this formula (but would lose an additional \$28). By contrast, a regional PPO that Medicare paid the same amount per month but that had actual costs of \$630 would remit \$29 back to Medicare (but would retain \$41 in additional profits).

The risk corridor provision does not extend to drug benefits that MA plans may cover under Part D; Part D already includes separate risk-sharing arrangements for these benefits through reinsurance and risk corridors. Risk sharing applies to Part A and Part B services, as well as any additional benefits that the MA plan provided through the rebate process (which we describe later in this chapter). However, risk sharing does not apply to administrative costs. The target with which CMS compares the costs is the plan's payment less the portion of administrative expenses assumed in the plan's bid.

Regional stabilization fund

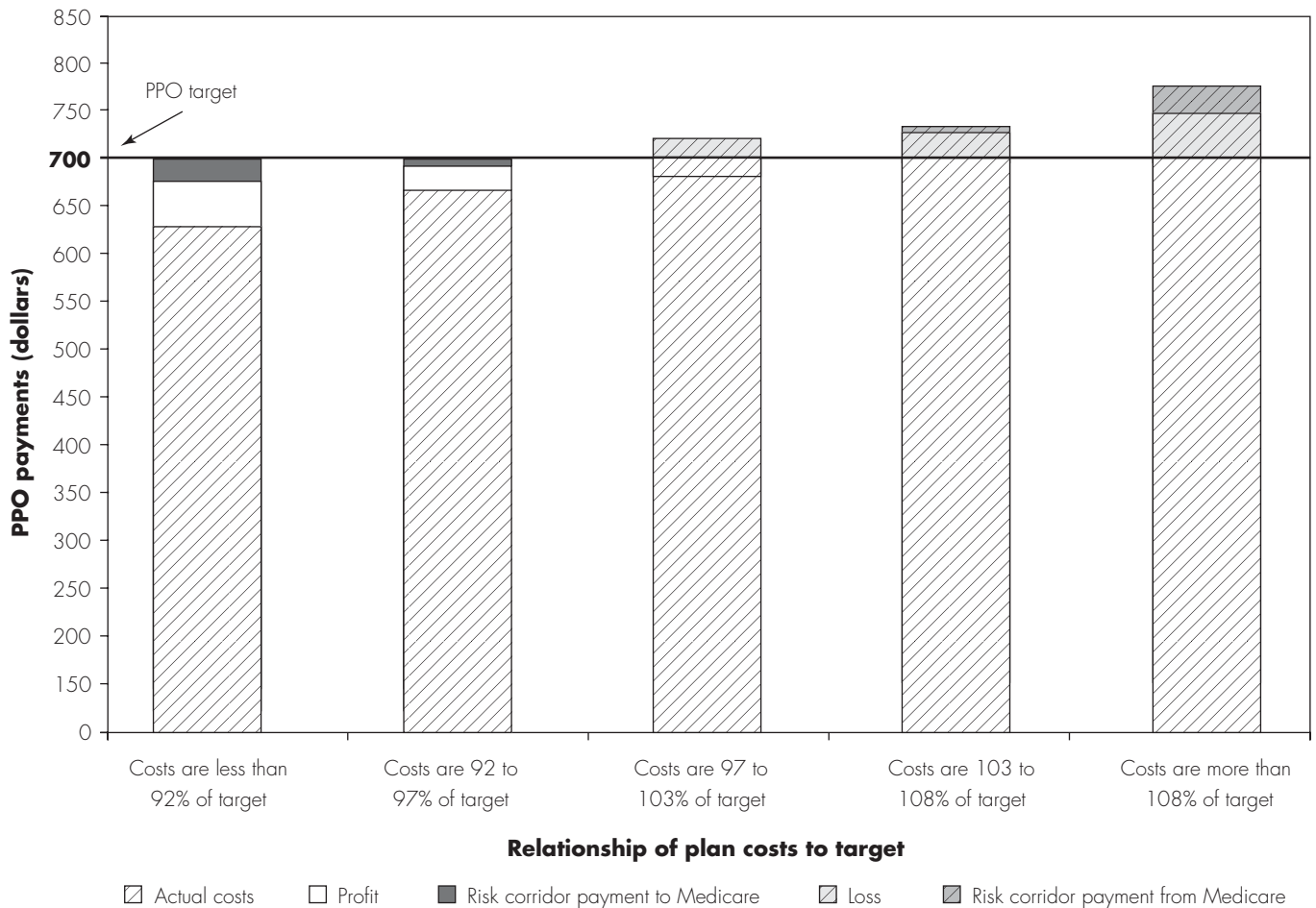
The MMA provided for a regional PPO stabilization fund. This fund would make additional payments to regional PPOs, thus encouraging them to not only enter but remain in markets. Beginning in 2007, \$10 billion will be available for the fund, and the fund will remain in operation until December 2013. The \$10 billion in initial funding will be supplemented by 50 percent of any government savings that accrue as a result of regional PPOs bidding below the benchmarks (we discuss the benchmarks and bidding process later in this chapter). If CMS uses the fund for two years in a row, it must report to the Congress on the market conditions that led to the fund's use. In response, the Congress could then change the regions or payment systems.

Payments from the fund may be available in the following circumstances:

- The regional PPO plan or plans that become the first national plan or plans to serve all regions of the country will receive a bonus amount equivalent to 3 percent of the benchmark amount for each regional plan the PPO offered.

FIGURE 3-4

Risk corridors for regional PPOs under Medicare Advantage, 2006–2007



Note: PPO (preferred provider organization). When costs are less than 92 percent of target, plan pays Medicare 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target and actual costs. When costs are between 92 and 97 percent of target, plan pays Medicare 50 percent of the difference between actual costs and 97 percent of the target. When costs are between 97 and 103 percent of target, there are no risk corridor payments. When costs are between 103 and 108 percent of target, Medicare pays plan 50 percent of the difference between actual costs and 103 percent of the target. When costs are more than 108 percent of target, Medicare pays plan 2.5 percent of the target amount plus 80 percent of the difference between actual costs and 108 percent of the target.

- If no national plans are offered, the Secretary may increase the benchmark for a regional PPO plan that becomes the first to serve a region. The Secretary will determine this extra amount. The Secretary also has the discretion to raise the benchmark in a region that did not have any regional PPOs the previous year.
- If a regional PPO intends to depart from a region—thus leaving the region with fewer than two regional PPO plans—and a national plan does not exist, the Secretary may increase the benchmark in order to retain plans.

Note that the national plan bonus is the least targeted of these circumstances because the bonus will be paid to the national plan(s) in all regions, even if regional PPOs already serve many regions. Additionally, the payments for regional PPOs that intend to depart a region may be administratively difficult to implement and may create incentives for regional PPOs to threaten to leave the program in order to receive additional payments.

RECOMMENDATION 3A

The Congress should eliminate the stabilization fund for regional preferred provider organizations.

RATIONALE 3A

MedPAC supports a level playing field, not only between MA plans and the FFS program but also among different types of MA plans. The PPO stabilization fund explicitly makes available additional funds to regional PPOs—funds that are not available to other MA plans. MedPAC understands that Congress intends the stabilization fund to encourage regional PPO plans' participation and that plans may be unsure of the risk they face by participating in the regional PPO program. The Commission also notes that the risk corridor system will shield regional PPOs from risk during the first two years of the program. As discussed earlier, regional PPOs will have more flexibility in assembling a provider network because of the looser network adequacy requirements. If, over time, specific problems emerge regarding regional PPO market entry or exit, the Congress could revisit the kinds of incentives that may be appropriate to attract plans to certain areas.

IMPLICATIONS 3A

Spending

- This recommendation has no spending implications over one year, as Medicare will not make payments from the stabilization fund until 2007. This recommendation would decrease federal spending by \$1 billion to \$5 billion over five years.

Beneficiaries and plans

- Although it is unclear what the PPO stabilization fund's precise impact would be on stimulating plan entry and preventing plan exits, this recommendation could potentially discourage regional PPOs from entering certain regions. Similarly, certain PPOs may exit regions in which they otherwise might have chosen to stay had they received payments from the stabilization fund. As a result, beneficiaries in certain areas may have fewer private-plan options from which to choose.

Essential hospital payments

Regional PPOs that have trouble contracting with hospitals may ask CMS to make additional payments to those hospitals in order to secure an adequate network.

The MMA defines these hospitals as “essential hospitals.” They are not critical access hospitals (CAHs), but rather are hospitals paid under the inpatient prospective payment system (IPPS) for FFS Medicare. The regional PPO must demonstrate that the hospital's inclusion in the network is necessary to meet the plan's access requirements and that the PPO has made a good-faith effort to contract with the hospital, paying it IPPS payment rates. To satisfy the access requirement, the regional PPO must also show that no competing hospitals in the area will contract with the PPO. Additionally, the hospital must demonstrate that IPPS rates are too low to cover the hospital's costs.

The MMA limits essential hospital payments to \$25 million per year in the aggregate (adjusted for inflation). CMS makes essential hospital payments directly to eligible hospitals. The payment to the hospital constitutes the difference between the payment that the hospital would receive under the IPPS and the amount that the program would pay a CAH. CMS will make essential hospital payments on a first-come, first-served basis until the annual amount is spent. This program represents an additional source of funding that CMS makes available to regional PPOs and not to other MA plans—a situation that does not align with the Commission's position on financial neutrality. Additionally, some regional PPOs may view the essential hospital program as more of a deterrent than an aid, as it provides an incentive for hospitals to refuse to contract with regional PPOs in the hope of securing essential hospital payments.

Specialized plans

The MMA created another new category of MA plans called specialized MA plans for special needs individuals, or special needs plans (SNPs). SNPs are local or regional MA plans that enroll a disproportionate share (defined as a greater proportion of the target group of special needs individuals than that which occurs nationally in the Medicare population) of special needs individuals. In the MMA, the Congress suggests that eligible beneficiaries might include institutionalized patients, dual eligibles, and other individuals who have severe or disabling chronic conditions. Rather than defining these plans in advance, CMS has opted to allow the plans themselves to propose target populations; CMS will then evaluate the proposals on a case-by-case basis. The criteria for choosing specialized plans include the existence of clinical programs or special expertise for that plan's target population. CMS has approved 48 SNPs and is reviewing 18 applications for

services to be offered later in 2005. In addition, more than 100 SNPs have submitted applications to provide services in 2006 (CMS 2005b).

Specialized plans are not new to the Medicare program but have generally existed as CMS demonstration programs. These specialized plans include social HMOs, Evercare, plans for beneficiaries with end-stage renal disease (ESRD), and plans for dual eligible beneficiaries offered through both Medicare and Medicaid. The Program of All-Inclusive Care for the Elderly (PACE) was a demonstration program and is now a permanent program under Medicare and available under Medicaid at individual state discretion. All of these programs provide targeted services and care management to their enrollees.

Many observers of these earlier specialized demonstration plans questioned whether Medicare's payment method accurately accounted for the potentially higher costs of these specialized populations. Plans and beneficiary advocates expressed concern that even with risk adjustment, CMS still might not pay plans accurately for beneficiaries who have limitations in activities of daily living. CMS devised a special payment policy called a frailty adjuster for some of these demonstration plans and for PACE. When MedPAC reviewed the social HMO program, it suggested that the Secretary investigate the need for broader payment adjustments for all frail populations who are enrolled in private plans under Medicare (MedPAC 2003).

By statute, CMS will pay specialized MA plans the same way it pays all other MA plans: It will use the bidding process and the same risk-adjustment factors detailed in the subsequent sections of this chapter. The frailty adjuster will not apply to MA plans—although it will continue to apply to demonstration plans. The preamble to the final MA regulation indicates that in 2006, CMS plans to include more diagnoses in its risk-adjustment model. The broader model should better capture disease burden among the Medicare population (CMS 2005a). CMS also plans to refine its risk-adjustment model over time, perhaps including a frailty adjuster that the agency can apply across the entire MA population (not just by type of plan)—a policy that MedPAC supports.

Treatment of existing types of MA plans

Along with the addition of two new types of plans under MA, the MMA also made several changes to existing plans' participation in Medicare.

The Congress introduced MSAs combined with a high-deductible insurance product to the Medicare program in the Balanced Budget Act of 1997. The pilot MSA program was limited both in the number of enrollees permitted to participate (390,000) and in the length of time during which insurers could offer such products (the law permitted no new enrollments after January 1, 2003). As a result, no organization decided to offer an MSA plan in the Medicare market. The MMA then permanently removed these limits. However, even setting aside these constraints, MedPAC concluded that two market characteristics contributed to the absence of MSA offerings in the earlier program:

- little demand from the risk-averse Medicare beneficiary population because of the high deductible, and
- the difficulty of marketing a complex new product (MedPAC 2000).

However, it is possible that as more beneficiaries become accustomed to health savings-type accounts, high-deductible insurance products in the non-Medicare market, and high-deductible Medigap products, they may become interested in Medicare MSAs as well.

The MMA also introduced health savings accounts (HSAs) as a health insurance option outside the Medicare program. Similar to MSAs, these plans combine (a) an account into which an employer can deposit funds to be used to pay for health expenses and (b) a high-deductible plan that limits the holder's overall financial liability. Medicare beneficiaries may not make HSA contributions. However, people who participated in HSAs before they became eligible for Medicare may use funds deposited earlier to pay Medicare Part A, Part B, or MA supplemental premiums and to pay (tax free) the employee share of employer-related supplemental coverage. Beneficiaries may not use HSA funds to pay for Medigap premiums without incurring a tax penalty.

CMS reimburses cost plans for 100 percent of their costs instead of receiving a fixed monthly payment. Both the Congress and CMS have considered eliminating cost plans from Medicare many times. The plans will be eliminated starting in 2008, provided that their area contains at least two MA plans. Risk plans have raised concerns that cost plans can receive higher payments and charge their enrollees lower premiums than plans that accept risk for the full benefit package. These plans enroll

about 300,000 beneficiaries (another 100,000 are enrolled in cost plans that provide Part B services only). CMS has not permitted any new cost plans to join Medicare since 1997, although it has permitted service area expansions for existing plans.

Quality

In this section, we review the current situation regarding quality in MA plans, explore the ability of beneficiaries and others to make quality comparisons between the FFS program and MA plans, and review the requirements for quality improvement that the MMA and related regulations lay out. Finally, we look at the role that pay-for-performance might play in improving quality in MA plans.

What do we know about the quality of care in MA plans?

One of the ways in which CMS measures the quality of care for MA plans is through the Health Plan Employer Data and Information Set (HEDIS). Plans collect data on HEDIS measures by reviewing administrative claims and medical charts. Among MA plans, only HMOs report on all HEDIS measures (MSAs do not report any HEDIS measures, and PPOs only report those HEDIS measures that they can assess without reviewing medical charts). HEDIS measures for HMOs (which cover more than 90 percent of MA enrollees) indicate that the clinical effectiveness of care in Medicare plans is generally improving over time, although some measures continue to show low rates (NCQA 2004). While certain MA plans generally perform extremely well on the HEDIS measures, the data on overall plan scores vary considerably, suggesting that certain plans could work to improve their overall quality of care.

**TABLE
3-2**

Plans improve, but rates are still low on some measures

Measure	2000	2001	2002	2003
Advising smokers to quit	59.7%	60.8%	61.5%	63.3%
Beta-blocker treatment after heart attack	89.3	92.9	93.0	92.9
Breast cancer screening	73.9	75.3	74.5	74.0
Cholesterol management				
Control	52.9	58.4	62.3	66.7
Screening	70.6	75.5	77.7	81.0
Controlling high blood pressure	46.7	53.6	56.9	61.4
Comprehensive diabetes care				
Eye exams	62.8	66.0	68.4	64.9
HbA1c testing	82.5	85.7	85.0	87.9
Lipid control	50.9	57.5	62.6	67.7
Lipid profile	80.5	85.7	87.9	91.1
Monitoring diabetic nephropathy	45.0	51.9	57.3	53.6
Poor HbA1c control*	33.4	26.8	24.5	23.4
Antidepressant medication management**				
Acute phase	N/A	51.3	52.1	53.3
Continuation phase	N/A	36.8	37.7	39.2
Contacts	N/A	11.9	10.8	10.5
Follow-up after hospitalization for mental illness				
Less than 7 days	37.5	37.2	38.7	38.8
Less than 30 days	59.3	60.6	60.6	60.3

Note: HbA1c (hemoglobin A1c), N/A (not available). Rates refer to patients who received the clinically indicated treatment.

* Lower rates are better than higher ones for this measure.

** "Acute phase" refers to the percentage of patients who received effective treatment after a new episode. "Continuation" refers to the percentage of patients who remained on antidepressants continuously for six months after initial diagnosis. "Contacts" refers to the percentage of patients who received at least three follow-up office visits in a 12-week acute phase.

Source: National Committee for Quality Assurance 2004.

Data on these HEDIS measures show the rate at which members who are eligible for the clinical care being measured receive that care. For example, the measure for provision of a beta blocker after a heart attack tracks the number of beneficiaries with a heart attack who received a prescription for a beta blocker upon discharge from a hospital. Care on almost all of the 17 reported measures improved during the last three years (Table 3-2, p. 69). Only two measures noticeably declined, and the rest improved or stayed the same.³ As part of HEDIS, MA plans also report Health Outcomes Survey (HOS) measures, which assess MA enrollees' physical functioning and mental well-being over time (Haffer and Bowen 2004).

As with other measure sets, MedPAC recognizes the importance of processes that improve and refine quality measures to ensure that measure sets continuously evolve. As performance on some measures reaches a high level, CMS needs to support a process that adds new dimensions. To avoid unnecessary burdens on plans and providers, this evolution should use processes that convene a variety of interested parties to agree on a standard set of measures. As these new measures emerge, CMS should also collect them in the FFS program (to the extent practical).

CMS can also compare quality between Medicare private plans and FFS by using patient-centered measures of quality. CMS collects information from beneficiaries on their perceptions of care while enrolled in MA plans and in the FFS program through the Consumer Assessment of Health Plans (CAHPS) survey. Levels of satisfaction with

access, such as getting care when one needs it, are generally similar for MA and FFS beneficiaries, although the latter are less likely to report problems in accessing specialists (Table 3-3). FFS beneficiaries and beneficiaries enrolled in MA rate their plan and overall health care similarly. In general, the measures have proven stable over time, with the exception that beneficiaries in both MA plans and the FFS program are reporting declining overall levels of satisfaction. However, this CAHPS question is broad and not specific to any type of provider or service, asking both FFS and managed care participants to rank their 'plan' on a scale of 0 to 10, in which 0 is the "worst health plan possible" and 10 is the "best health plan possible."

Comparing quality between FFS and MA plans

Although HEDIS measures provide the ability to compare quality among MA plans, CMS does not routinely publish the HEDIS measures for the FFS program. Therefore, apart from the CAHPS survey, quality comparisons between MA plans and the FFS program are difficult nationally and locally. CMS does collect information at the state and national level that permits comparison of the FFS program to MA plans on the HEDIS measure, Access to Ambulatory Health Services (CMS 2005a). Further, CMS can derive some of the HEDIS measures—most notably those that PPOs report—from administrative data. CMS could begin to routinely calculate and publish HEDIS measures for the FFS program derived from administrative data. CMS could also explore existing approaches—and data sources such as those used by

TABLE 3-3

MA plans and the FFS program have similar patient experience scores

Measure	MA plans			FFS program		
	2001	2002	2003	2001	2002	2003
None or small problem getting care when needed	94%	93%	94%	97%	95%	95%
Usually or always got care quickly	87	81	83	87	81	84
Doctors usually or always communicate well	93	93	93	94	94	94
Rated health care overall 8–10	84	84	84	84	85	86
Rated plan 8–10	77	76	70	78	77	69
None or small problem seeing a specialist	N/A	92	92	N/A	95	95

Note: MA (Medicare Advantage), FFS (fee-for-service), N/A (not available).

Source: 2001–2003 Consumer Assessment of Health Plans Survey (CAHPS) data for Medicare Advantage plans and the fee-for-service program from CMS.

quality improvement organizations (QIOs)—that draw samples of medical records in defined geographic areas in order to calculate additional HEDIS measures that require medical record abstraction.

RECOMMENDATION 3B

The Secretary should calculate clinical measures for the fee-for-service program that would permit CMS to compare the fee-for-service program to Medicare Advantage plans.

RATIONALE 3B

In order for beneficiaries to make informed choices between the FFS program and the array of MA plans, they need a consistent set of quality measures that they can use to compare their options. Further, CMS should be able to compare the two programs' performance.

IMPLICATIONS 3B

Spending

- This recommendation has no federal budget implications. CMS should find most measures relatively easy to implement by using analyses of existing claims data. Some measures might require additional resources—particularly if they require the creation of new, or the expansion of current, survey instruments.

Beneficiaries and providers

- Beneficiaries will have an additional set of comparisons on which to evaluate the FFS program and MA plans; this new data source will foster competition between the two programs.

CMS does not collect the measures that MA plans collect as part of the HOS for the FFS program. CMS administered a version of the HOS to 10 subsamples of the Medicare FFS population in 1998 (Pope et al. 2000), but this was on a pilot basis and the agency has no plans for further data collection in the FFS program. CMS can potentially use the HOS as a tool for comparison between MA plans and the FFS program. However, the HOS also has limited clinical information, relying on self-reported measures of health and functional status.

In its March 2005 report, MedPAC recommended that CMS develop measures of physicians' processes of care using claims data (enhanced by pharmacy and laboratory data) for a physician pay-for-performance program

(MedPAC 2005). As CMS develops these clinical measure sets for FFS, the agency may learn that these sets allow better comparison between the quality of care for Medicare beneficiaries in private plans and for those in the FFS program.

What are the requirements for quality programs?

The MMA and related CMS regulations specified certain quality requirements and measures for the MA program. In general, the requirements that CMS imposed on MA plans are considerably less prescriptive than they were under the old M+C program. Under M+C, plans adhered to a defined list of requirements that its quality assurance plan should address and were required to participate in national or statewide quality assurance and performance improvement projects. CMS replaced these requirements with the following new ones:

- Each MA plan (other than a PFFS plan or an MSA plan) must have an ongoing quality improvement program.
- Each quality improvement program must include a chronic care improvement program.
- Each MA plan must provide for the collection, analysis, and reporting of data that permit CMS to measure health outcomes and other indices of quality (CMS 2005a).⁴

The specific type of quality improvement approach and the sets of measures that plans will collect will vary by type of plan (Table 3-4, p. 72). For example, all plans must maintain a health information system. But MSA and PFFS plans do not have to institute a quality (or chronic care) improvement program. CMS will allow some variation in measure reporting for HMOs and PPOs, at least in the early stages of the MA program. CMS expects to collect measures from HEDIS, CAHPS, and the HOS for both HMOs and PPOs. However, the HEDIS measures will vary: PPOs will not have to submit HEDIS measures that require medical record review. CMS indicates that it expects to move to the same measures over time, as PPOs build the capacity to report measures derived from medical records.

SNPs that target institutionalized beneficiaries will not report on HEDIS and HOS measures. Instead, these plans will report on measures similar to those on which long-term care facilities report in the Nursing Home Compare

**TABLE
3-4**

Selected quality requirements and measures vary by type of Medicare Advantage plan

Type of plan	Quality improvement program	HEDIS measures	Quality improvement projects	Health information system
Local plan: HMO	✓	All	✓	✓
Local plan: PPO	✓	Some	✓	✓
Specialized plan	✓	Depends on target enrollees	✓	✓
Regional PPO	✓	Some	✓	✓
PFFS	X	Some	X	✓
MSA	X	X	X	✓

Note: HEDIS (Health Plan Employer Data and Information Set), MSA (medical savings account), PPO (preferred provider organization), PFFS (private fee-for-service).

Source: CMS 2005a.

database. CMS expects to derive these measures from the Minimum Data Set (MDS) that the agency requires of nursing facilities.

Should MA plans have pay-for-performance standards?

In its March 2004 report, MedPAC concluded that Medicare should introduce pay-for-performance incentives to provide high-quality care in the MA program because MA meets all the Commission’s criteria for successful implementation (MedPAC 2004c). CMS collects standardized, credible performance measures on all MA plans. Every year, plans collect data on specific clinical process measures and data that reflect members’ satisfaction with the plan’s service provision. Together, these data show a widely accepted, broad cross-section of plan quality. Most of the process measures in these data sets do not require risk adjustment, and CMS has developed risk adjusters for the satisfaction measures. Plans have developed various strategies to improve their scores on these measures by working with providers in their networks.

MedPAC has argued that by including all private plans in a pay-for-performance program, CMS would maintain a level playing field between plan types and simultaneously reward those plans that invest in improving quality. CMS would not require plans to report on all measures, but the plans would not receive pay-for-performance funds if they opted not to do so. Later in this chapter, we discuss how the mechanics of a pay-for-performance system might work within the structure of the current bidding system.

Enrollment

The MMA deals with several issues related to enrollment in MA plans, including:

- implementing an annual open enrollment process; and
- permitting beneficiaries who have ESRD to join specialized MA plans—should a specialized plan exist that covers those who have ESRD—while continuing to prohibit beneficiaries who have ESRD from enrolling in other MA plans.

Coordinated annual open enrollment period

The MA program moves private-plan enrollment to an annual process, starting in 2006. Previously, beneficiaries could enroll and disenroll on a month-to-month basis—a provision that could limit a plan’s ability to provide enrollees with coordinated care. Now, beneficiaries who elect to enroll in MA plans will generally have only a single opportunity each year to switch plans or return to the FFS program. In 2006, beneficiaries will have a six-month window at the beginning of the year during which they may switch plans; in 2007 and thereafter, they will have a three-month window. If beneficiaries do not elect to change within this window, they will need to stay in their current plan until the end of the calendar year.

During the annual open enrollment period, beneficiaries choose whether to join an MA plan and whether to buy into Part D for drug coverage. (Later in this chapter, we

discuss the rules about which types of plans must offer Part D coverage.) As is the case with Part B, beneficiaries who do not enroll in Part D during open enrollment will pay a penalty. This penalty is based on the number of months they delay enrolling in Part D after they are eligible and whether they are enrolled in the FFS program or in a private plan. Beneficiaries will pay this penalty every remaining month in which they are enrolled in the Part D program.

CMS will need to dedicate resources to explain these new enrollment rules to beneficiaries who are making changes, particularly changes among MA plans. For example, beneficiaries who choose a private plan will need to understand that (a) in order to receive the prescription drug benefit, they will need to enroll in the MA plan that offers prescription drug coverage and (b) they cannot enroll in an MA plan that does not offer prescription drug coverage (unless they are enrolled in a PFFS plan). Beneficiaries will also likely experience confusion regarding the decreasing window of time in which they may switch among MA plans.

Medicare beneficiaries who have ESRD

The MMA generally continues to prohibit beneficiaries who have ESRD from enrolling in MA plans. However, CMS does permit beneficiaries who are enrolled in MA plans and later develop ESRD to remain in their plans. Beneficiaries who have ESRD are allowed to join specialized MA plans (which we discussed earlier in this chapter) if these plans choose to admit them.

CMS has improved its risk-adjustment system for beneficiaries who have ESRD: The agency designed a new risk-adjustment system specifically for ESRD beneficiaries who are receiving dialysis. This model should perform much better than the current demographic risk-adjustment system; therefore, payments to plans will more accurately reflect the costs of treating these beneficiaries. Despite CMS's general prohibition on enrollment of these beneficiaries in MA plans, evidence from a recent demonstration showed that quality of care for ESRD patients in M+C plans was good. Most participants' quality of care and outcomes equaled or exceeded those of ESRD patients enrolled in the FFS program (The Lewin Group 2002).

MedPAC has recommended that CMS allow ESRD beneficiaries to enroll in plans once the agency has implemented adequate risk adjustment. CMS should allow all beneficiaries to choose private plans, provided

that payment is accurate. Further, many private plans offer care coordination and disease management services that may benefit these beneficiaries, as they often have multiple chronic conditions in addition to ESRD—such as diabetes, congestive heart failure, and hypertension.

Benefits

The MMA added voluntary outpatient prescription drug coverage for all Medicare beneficiaries, including those who are enrolled in MA plans. Medicare subsidizes drug coverage through the combination of a direct subsidy of the premium and reinsurance, and beneficiaries pay a portion of the premium that increases with the plan's bid. In this section, we discuss the implications of the Medicare program paying MA plans to provide prescription drug coverage.

Coverage of drugs under MA

Most types of local and regional MA plans must offer at least one benefit package, including coverage under Part D (although they may offer packages that do not cover Part D, as well). PFFS plans may offer Part D coverage, and MSA plans may not.

MA plans that offer drug coverage under Part D (MA–Prescription Drug [MA–PD] plans) must meet the same program requirements as prescription drug plans (PDPs). Similar to PDPs, MA–PDs participate in the Part D bidding process to set their premiums. They may use any savings they achieve from bidding on the furnishing of Part A and Part B services (which we detail later in this chapter) to lower beneficiaries' Part D premiums or to enhance the Part D benefit. In enhancing the benefit, MA plans might cover drugs that Part D does not, or MA plans might reduce the deductible, cost sharing, or initial coverage limit.

Some MA plans would like to help their enrollees by filling in the coverage gap—that is, the portion of drug spending that falls above the initial coverage limit and below the catastrophic cap of Part D's benefit (see Chapter 1). For an individual without drug coverage that supplements Part D, this coverage gap could amount to high out-of-pocket spending—up to \$2,850 in 2006. Thus, a benefit that fills in the coverage gap would likely be attractive to Medicare beneficiaries. But under a feature of Part D that the Congress designed to direct more federal subsidies toward beneficiaries who do not have

supplemental coverage (called the true out-of-pocket provision), only certain types of spending on behalf of the enrollee counts toward the enrollee's catastrophic threshold. In particular, most types of supplemental coverage would not count. In other words, every dollar of supplemental coverage that an enrollee receives would raise the level of drug spending at which that individual would qualify for Part D's catastrophic protection and federal reinsurance subsidies.

CMS recently announced that it will conduct a demonstration allowing both PDPs and MA-PD plans to fill in the coverage gap and still receive the reinsurance payments (CMS 2005c). In one option, CMS would allow either type of plan to receive their estimated reinsurance payment through a capitated payment. In the other option, CMS would allow only MA-PD plans to take rebate funds from the Part A and Part B bidding process and apply them to an enhanced drug benefit, then count this supplemental coverage toward the out-of-pocket spending limit. These MA-PD plans then would presumably receive reinsurance payments following the usual schedule. CMS will provide additional information about this demonstration in the future; the agency intends the demonstration to be budget neutral.

The MA bidding process for 2006

Beginning in 2006, private plans will submit formal bids to participate in the MA program. The Medicare program will pay plans based on their bids rather than on administratively set rates, although CMS will compare the bids to administratively set benchmarks to determine how much of the payment will come from Medicare and how much will come from beneficiary premiums. The bids are due to CMS by the first Monday in June each year.

Components of a plan's bid

Every plan will submit a separate set of bids to cover beneficiaries in each of their service areas. Each bid will consist of up to three separate components:

- The bid for all Medicare Part A and Part B benefits (except hospice). This portion of the bid must assume that the plan would collect the standard Medicare cost sharing from its enrollees. This bid is standardized to a nationally average beneficiary (a CMS risk factor of 1.0) enrolled in the plan's service area.

- The bid for supplemental benefits (if any) that the plan covers. Supplemental benefits may include lower cost sharing on Medicare services, as well as benefits that FFS Medicare does not cover.
- The bid for the Medicare Part D drug benefit (if offered).

The first component, the Part A/B bid, is the only component CMS uses to determine Medicare's payments to the plan for the standard Medicare nondrug benefits. CMS compares each plan's Part A/B bid with a benchmark. (See text box for the methods CMS uses to set benchmarks.)

How does CMS determine payment?

CMS will base the Medicare payment for private plans on the relationship between their bids and the benchmarks. If the plan's bid falls above the benchmark, then the plan receives the benchmark and the enrollees will have to pay an additional premium that equals the difference between the bid and the benchmark. If the plan's bid falls below the benchmark, the MMA defines the difference as the plan's savings. The Medicare program retains 25 percent of the savings (if it is a regional plan, CMS places half of this 25 percent into the regional PPO stabilization fund), and the plan receives the other 75 percent of the savings as a rebate. The plan must then return the rebate to its enrollees in the form of supplemental benefits or lower premiums. The plan can apply any premium savings to the Part B premium (in which case the government retains the amount for that use), to the Part D premium, or to the premium for the total package that may include supplemental benefits.

The easiest way to illustrate the effects of the bidding process on beneficiaries' choices is to assume that the plan returns the entire rebate in the form of a reduction in the Part B premium (Table 3-6). This example shows the effects of returning the rebate to beneficiaries. If the rebate exceeds the Part B premium, which is a possibility, the plan would have to provide some of the rebate in the form of supplemental coverage (including reduction of the Part D premium).

Payments to regional plans will differ from payments to local plans

For regional MA plans, CMS bases the regional benchmark on the number of eligible Medicare beneficiaries in each county. However, when a regional

How does CMS set benchmarks?

The benchmark is a bidding target. CMS sets the benchmarks administratively, but in the case of regional PPOs, plan bids influence the benchmarks. Under MMA, CMS sets the benchmarks for local plans at the county-level payment rates used to pay MA plans before 2006. Generally, the law directs CMS to update the benchmarks each year by the national growth rate in per capita Medicare spending.⁵ If a local MA plan serves a multicounty area, the benchmark against which it bids consists of an average of the different benchmarks for the counties it serves, weighted by its projected enrollment from each county.

CMS determines the benchmarks for the MA regional PPOs by using a more complicated formula that incorporates the plan bids. A region's benchmark is a weighted average of the average county rate and the average plan bid. As directed by the MMA, CMS computes the average county rate as the individual county rates weighted by the number of Medicare beneficiaries who live in each county—not by the plan's projected enrollment, which CMS uses as the weighting for local plans. The average plan bid is each plan's bid weighted by each plan's projected number of enrollees. CMS then combines the average county rate and the average bid into an overall average. In calculating the overall average, the average bid is weighted by the number of enrollees in all private plans across the country, and the average county rate is weighted by the number of all Medicare beneficiaries who remain in FFS Medicare.

For example, suppose that 1 million Medicare beneficiaries live in the region, in one of two local MA payment areas (Table 3-5). Local area 1 contains 800,000 beneficiaries and has a local MA payment rate of \$900. Local area 2 has 200,000 beneficiaries and a rate of \$600. Thus, the average county MA rate is \$840 ($0.8 \times 900 + 0.2 \times 600$). Assume that the average plan's Part A/B bid was \$715 and that nationally, 20 percent of Medicare beneficiaries were enrolled in MA plans. The regional benchmark under these assumptions would be \$815 ($0.8 \times 840 + 0.2 \times 715$). ■

**TABLE
3-5**

Example of calculating a regional benchmark

	Number of Beneficiaries	Average rate or bid
Local MA payment area 1	800,000	\$900
Local MA payment area 2	200,000	600
Average MA rate	N/A	840
Average regional plan bid	N/A	715
Regional benchmark		\$815

Note: MA (Medicare Advantage), N/A (not applicable). This example assumes a national Medicare Advantage penetration of 20 percent of Medicare beneficiaries.

**TABLE
3-6**

Example of premium calculations under 2006 bidding process

Plan	Bid	Benchmark	Part B premium	Premium rebate	Total premium
FFS	N/A	\$1,000	\$100	\$0	\$100.00
Plan 1	\$950	1,000	100	37.50	62.50
Plan 2	900	1,000	100	75.00	25.00

Note: FFS (fee-for-service), N/A (not applicable).

PPO bids, it takes into account where it projects its enrollment will originate. Averaging over all members, the PPO will receive its bid plus any rebate. As a result, two regional plans that are bidding the same amount in the same region would get different Medicare payments in the same county if their enrollment patterns among all counties in the region differ. The reason is because their bid is based on their average cost over all beneficiaries they serve, yet the benchmark is not.

For local plans, CMS bases the benchmarks and plan bids on a plan's projected enrollment. This difference in treatment between local and regional plans could create a situation in which local plans are disadvantaged relative to regional plans in some counties (see text box for example).

Many policy and industry observers thought that the MMA included a geographic adjustment that would better align regional plans' bids to the benchmarks. However, the final regulation did not include an adjustment for this issue. Instead, it takes into account differences between projected and actual enrollment.

To ensure more equal competition among regional plans and between regional and local plans, the Commission makes the following recommendation:

RECOMMENDATION 3C

The Congress should clarify that regional plans should submit bids that are standardized for the region's Medicare Advantage-eligible population.

RATIONALE 3C

The MMA requires that CMS adjust plan payments for health risk and MA local payment rates. CMS standardizes the benchmarks for risk and local MA payment rates; therefore, CMS should require that plans standardize their bids for risk and local payment rates. In not doing the parallel adjustment, the payment system may cause regional plans to have a competitive advantage over local plans in certain areas.

IMPLICATIONS 3C

Spending

- This recommendation would likely decrease Medicare spending relative to current law by \$200 million to \$600 million over one year, and by \$1 billion to \$5 billion over 5 years.

Beneficiaries and plans

- This recommendation could lower payments to regional plans under some circumstances. Therefore, this recommendation may cause regional plans to reduce the generosity of benefits or reduce the extent of their participation in the MA program. However, some regional plans (namely those that have disproportionately high enrollment from high-rate areas) would benefit from the payment recommendation, and the recommendation could prevent some local plans from leaving certain markets.

Financial neutrality and private plans

The Commission has long supported giving Medicare beneficiaries a choice in health care delivery systems, provided that such choices do not increase Medicare program expenditures. Private plans have the flexibility to use care management techniques that FFS Medicare does not encourage, and they have greater incentive to innovate. Thus, for some beneficiaries in some parts of the country, private plans may provide the same Medicare benefits with fewer resources, more benefits with the same resources, or higher quality than the FFS Medicare program.⁶ If beneficiaries are able to choose between Medicare FFS and an array of private plans—and if the Medicare program pays the same on behalf of the beneficiaries making the choice—then over time, beneficiaries will gravitate either to the FFS system or to the plan that provides the best value in terms of efficiency and quality. The Medicare program would not subsidize one choice more than another. The Medicare program should be financially neutral regarding whether the beneficiary chooses to remain in the FFS system or enroll in a plan. This neutrality provides beneficiaries with the incentive to select the system that they perceive has the highest value, while maintaining their ability to choose a more generous plan by paying additional premiums.

With plans competing for Medicare enrollment, individual providers would want to improve the quality and efficiency of their services so that these providers can stay in the plans' preferred networks. In addition, if a provider follows the best practices of one payer, the provider's behavior may translate into better practice for all payers with which the provider participates.

Previous system was not financially neutral

Through 2005, Medicare will pay plans based on administratively set rates that are county based and partially risk adjusted. The formula that governs the rates

Payments to local and regional MA plans may differ

In this simplified example, two payment areas exist—one low-rate and one high-rate—with local MA payment rates of \$600 and \$900 per month, respectively. We assume the local plan in each payment area bids \$100 below its benchmark rate and gets paid the bid amount plus a \$75 rebate.

A regional plan that serves both areas also bids \$100 below its benchmark. In the example, 20 percent of the eligible population lives in the low-rate area and 80 percent lives in the high-rate area. The resulting benchmark is \$815 (as computed in the text box on page 75). Therefore, the regional plan will get, on average, \$715 (the benchmark minus \$100) plus the \$75 rebate—or \$790.

The payments to a regional plan in each area will depend on how its enrollee population splits between the two areas relative to the benchmark split of 20/80. If the projected enrollment for the plan splits evenly between the low- and high-rate areas (50/50), the payments for members in the two areas will be \$647 in the low-rate area and \$933 in the high-rate area. The average will be \$790.

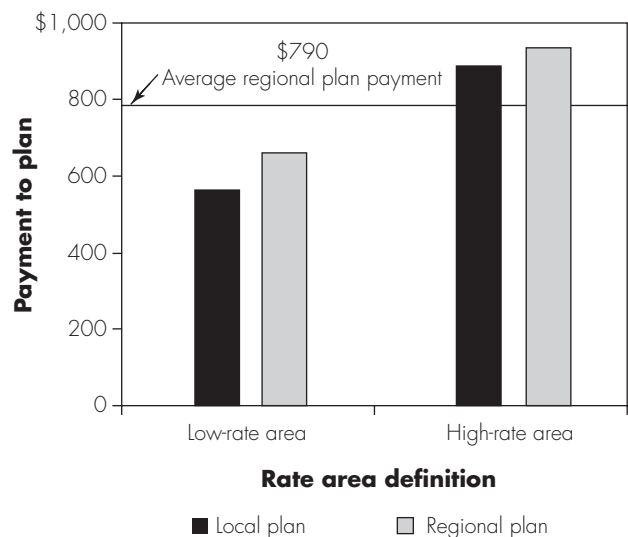
Figure 3-5 shows the result. The dark bars represent the payment rates for local plans, and the light bars represent the payment rates for the regional plan members in the two areas. Note that in both areas, the regional plan receives a higher rate, which would presumably give it a competitive advantage over the local plans in both areas.

Regional plans that have different mixes of projected enrollment will see different payments from one another. The plan in the example above, with the enrollment split 50/50, has an advantage over local

plans in both areas. A plan that has a 10/90 split would be disadvantaged in both areas relative to local plans and would be disadvantaged more relative to the 50/50 regional plan shown in the figure.

A regional plan with a split of 20/80—identical to the underlying population mix—would have a slight advantage in the low-rate area and a slight disadvantage in the high-rate area. This asymmetry results from a different cause: The rebate is identical in both areas and thus constitutes a larger proportion of total plan payment in the low-rate area than in the high-rate area. ■

FIGURE 3-5 Example of payments to plans with different enrollment patterns



Note: In this example, 20 percent of Medicare beneficiaries in the region live in low-rate areas and 80 percent live in high-rate areas. The regional plan enrolls 50 percent of its members from low-rate areas and 50 percent from high-rate areas.

is only loosely based on county FFS costs.⁷ Although the formula ensures that plan payments will not fall below FFS costs, rates in individual counties are as high as 85 percent above FFS cost, as measured by the adjusted average per capita cost (AAPCC).

Current plan payment rates average 107 percent of county FFS costs. The plans' payment rate advantage has come

primarily from two sources. One is the result of two "floor rates" that the Congress created to raise the rates in low-rate counties. One floor rate, which mostly applied in rural areas and small cities, was often well above the comparable county FFS costs. Only 3 percent of plan enrollees live in these areas, but rates average 123 percent of the county FFS costs. Another 26 percent of plan enrollees live in large metropolitan areas where the

Congress created a higher floor rate. Payments in those areas averaged 116 percent of the county FFS costs.

The other main source of higher rates is Medicare's treatment of indirect medical education (IME) payment to hospitals. For the 40 percent of plan enrollees who live in counties where the MMA raised the rate to 100 percent of county FFS costs, the rates actually are higher than the comparable cost in FFS Medicare. The reason is that the measure the MMA used in that calculation includes spending for IME payments to hospitals, even though the Medicare program continues to make separate IME payments to hospitals on behalf of MA enrollees. In effect, the Medicare program is making IME payments on behalf of MA enrollees twice: once to the MA plans, and once to the teaching hospitals.

On the other hand, the AAPCC might underestimate the cost of Medicare services that beneficiaries receive because some beneficiaries receive services from Department of Veterans Affairs' (VA) facilities that Medicare would otherwise cover. The Congress instructed CMS to add the cost of these services when calculating county AAPCCs, but the agency has not been able to do so yet. We urge CMS to implement the VA adjustments as soon as possible. Note that the Congress had instructed that the calculation include Department of Defense (DoD) spending, but because of major changes to DoD supplemental coverage, we expect very few beneficiaries with DoD coverage to have lower use of Medicare benefits due to their use of DoD facilities.

In the future, all local benchmarks will increase at the same national growth rate (or by 2 percent, if the national growth rate is lower than 2 percent) using the result of earlier formulas as the base rate. The exception is that counties which fall below 100 percent of their AAPCC will see their rates rise to the 100 percent level.⁸

Financial neutrality under the 2006 bidding system

The 2006 bidding process will create a hybrid system that includes administratively set payment rates and competitive bidding. Although administratively set plan payment rates will no longer exist per se (except for MSA plans), Medicare will still have administratively set benchmarks, against which the plans will bid.

This process, as currently configured, will not result in Medicare making financially neutral payments relative to FFS cost. As we discussed earlier, the benchmarks are often well above the AAPCC. Therefore, plans bidding at or above the benchmark would often receive payments in excess of the local cost of FFS Medicare. Plans bidding below the benchmark will receive less than the benchmark, but the resulting payment might be higher or lower than the local cost of FFS Medicare. One way the system could be financially neutral is if the benchmarks were more reflective of the cost of FFS Medicare, and if Medicare used program savings from bids below the benchmarks to encourage quality-of-care improvement. However, Medicare could take other approaches to adjusting total payments so that payments to plans in the aggregate do not exceed FFS Medicare.

Adjusting the bidding system for consistency with the financial neutrality principle

The benchmarks currently average about 107 percent of FFS Medicare costs for plan enrollees. About two points of the seven-point difference are due to the treatment of IME payment to hospitals. In our March 2002 report, MedPAC supported Medicare's removal of graduate medical education costs from plan rates and direct payments to teaching hospitals that treat plan members. The Commission wanted to help ensure that plans have incentives to direct enrollees to use teaching hospitals when appropriate. With that goal in mind, we recommend removing the effect of IME payments from the benchmarks to bring the system closer to financial neutrality.

RECOMMENDATION 3D

The Congress should remove the effect of payments for indirect medical education from the Medicare Advantage plan benchmarks.

RATIONALE 3D

In removing the effect of these payments from the benchmarks while continuing to make payments directly to teaching hospitals on behalf of plan members, the Congress would bring the system closer to financial neutrality and would not change plan incentives to use teaching hospitals. The recommended action would also correct Medicare's double payment for these teaching costs.

Spending

- This recommendation would decrease Medicare spending relative to current law by \$200 million to \$600 million over one year and would decrease spending by \$1 billion to \$5 billion over five years.

Beneficiaries and plans

- This recommendation would lower payments to plans in some areas. This result, in turn, may cause some plans to reduce their level of participation in the MA program—and thus reduce plan choice for some beneficiaries. Plan incentives to use teaching hospitals would not change.

Reaching financial neutrality under the current system

The Commission has previously recommended that Medicare set plan payment rates at 100 percent of local FFS costs. In 2006, a parallel recommendation might be to set the benchmarks against which plans will bid at 100 percent of local FFS Medicare costs, to ensure that the Medicare program does not pay MA plans more than the cost of covering the same beneficiaries under FFS Medicare. However, even this parallel recommendation would not result in financial neutrality because under the new bidding system, plans have the incentive to bid lower than the benchmark—with Medicare keeping part of the savings. Thus, the payment system would not be financially neutral because Medicare would pay (to plans that bid less than the benchmark) less than the county FFS rate. MedPAC has also recommended that payment policy provide stronger incentives for plans to improve the quality of care that they provide to Medicare beneficiaries (MedPAC 2004a). One solution would be to set benchmarks at 100 percent of FFS costs in each area and return any Medicare savings from bids below the benchmarks to the plans. Medicare would return the savings in the form of pay-for-performance payments based on quality measures.

However, financial neutrality is just one goal of payment policy. The Commission recognizes that the Congress may not achieve its wish of attracting plans to more areas of the country if it immediately begins reducing benchmarks in many areas. Also, the MA bidding process is just beginning, and MedPAC does not want to derail the system with sharp changes in expected payment rates. Moreover, the bidding process might produce instructive

results. Perhaps CMS could adjust benchmarks in response to the level of bidding in such a way that benchmarks would be at 100 percent of FFS costs, on average. As long as the result appears stable, Medicare could maintain overall financial neutrality and fund performance payments with the savings relative to FFS costs. Under either scenario, if the bids are substantially lower than FFS costs, the Commission may suggest that some of the savings should fund a quality pool and the rest should return to the Treasury.

The following recommendation strives to achieve financial neutrality and improve quality through two steps:

- **Step 1: Set the benchmarks to 100 percent of the costs of FFS Medicare, on average.** One way the Congress can accomplish this part of the recommendation would be to set the benchmarks for each payment area equal to the costs of FFS Medicare in the area. However, it is possible to use other formulations or adjustments so that benchmarks increase in areas that have trouble attracting plans and decrease in areas where plans are able to bid below the benchmarks, while keeping the average benchmark at 100 percent of FFS cost.
- **Step 2: Reward quality by redistributing savings from bids below the benchmarks back to the plans in the form of pay-for-performance payments.** When a plan bids below the benchmark, the plan would receive its bid and retain 75 percent of the difference to rebate to its enrollees. Medicare would place the remaining 25 percent of the savings in a quality pool and redistribute it to plans as a reward for high or improving measures of quality performance. (The Commission also continues to support placing 1 to 2 percent of base MA payments into a quality pool, so that the savings contributions to the pool would be in addition to the initial 1 to 2 percent.)

RECOMMENDATION 3E

The Congress should set the benchmarks that CMS uses to evaluate Medicare Advantage plan bids at 100 percent of the fee-for-service costs.

At the same time, the Congress should also redirect Medicare’s share of savings from bids below the benchmarks to a fund that would redistribute the savings back to Medicare Advantage plans based on quality measures.

RATIONALE 3E

On average, the Medicare program would pay the same amount for a beneficiary's enrollment in an MA plan as Medicare would expect to pay to cover the beneficiary in FFS Medicare. Plans would also have increased incentive to improve their quality scores in order to receive these quality incentive payments.

IMPLICATIONS 3E

Spending

- If fully implemented for 2006, this recommendation would decrease Medicare spending by more than \$1.5 billion over one year and by more than \$10 billion over five years, relative to current law. More gradual implementation would decrease savings.

Beneficiaries and plans:

- This recommendation would decrease the average payment to MA plans, but some plans may receive higher payments through pay-for-performance payments.
- It is likely that some plans would choose not to participate in some areas, thus leaving some beneficiaries with fewer choices.
- Plans would have greater incentives to improve quality, which could then lead to better quality of care for beneficiaries.

Concerns about hold-harmless modifications to payments under risk adjustment

Beginning in 2004, CMS has been transitioning from risk adjusting plan payments based on a demographic model to adjusting payments based on a health-risk model (see Chapter 2 for details on the models). For 2004, 2005, and 2006, CMS estimated that aggregate plan payments adjusted with the health risk model would be lower than payments adjusted with the demographic model. CMS is applying proportional increases to county payment rates so that in aggregate, total plan payments are held harmless for the effect of switching from the demographic model to the health-risk model. The net effect of this policy is that aggregate payments to MA plans are equal to what they would be if CMS adjusted 100 percent of payments using the demographic system, although payments to individual plans will still vary based on their specific risk scores.

The President's most recent budget proposal includes a phase-out of this hold-harmless policy from 2007 to 2010.

The effect of the phase-out would be to increase risk-adjusted payments by progressively smaller proportions from 2007 through 2010, and to completely eliminate the policy in 2011. Despite the phase-out, this policy increases payments above levels assumed by the Administration. The President's proposed budget indicates that under the planned phase-out, federal spending from 2006 through 2010 would be \$8.3 billion above the level that would occur if CMS did not increase MA payments above risk-adjusted levels.

Whether CMS continues this policy in full force or phases it out, any policy that increases risk-adjusted payments prevents risk adjustment from addressing risk-profile differences between beneficiaries in the MA and FFS programs. The ultimate effect is that payments for MA enrollees will be systematically higher than payments for those same beneficiaries if they enrolled in FFS Medicare.

MedPAC and its predecessor Commissions have strongly supported CMS's adoption of more accurate risk adjustment as a necessary step toward achieving the goal of financial neutrality. Increasing plan payments (as CMS has done) to offset the effect of more accurate risk adjustment is inconsistent with the Commission's view on payment equity. However, at this point, the Commission recognizes that payment reductions—resulting from removing the hold-harmless policy immediately—would be steep. In addition, some plans claim that they have not yet fully succeeded in collecting all the diagnostic information that feeds into the health-risk model, because some physicians are not accustomed to reporting it to plans. These plans believe that their payments under the new system do not reflect their enrollees' true health risk. Therefore, the Commission supports putting the Administration's phase-out of the hold-harmless policy contained in the 2006 budget proposal into law.

RECOMMENDATION 3F

The Congress should put into law the scheduled phase-out of the hold-harmless policy that offsets the impact of risk adjustment on aggregate payments through 2010.

RATIONALE 3F

MedPAC and its predecessor Commissions have strongly supported CMS's adoption of more accurate risk adjustment as an important step toward achieving payment equity between the Medicare FFS program and private plans in Medicare. Increasing plan payments to offset the

effect of more accurate risk adjustment is inconsistent with the Commission's views on payment equity. The President's budget indicates an intended phase-out of this policy from 2007 through 2010, and the Commission supports that schedule.

IMPLICATIONS 3 F

Spending

- This recommendation would decrease Medicare spending by more than \$10 billion over five years relative to current law.

Beneficiaries and plans

- Because the President's budget includes this hold-harmless policy, plans are likely to expect the resulting per member payment levels and should not change their offerings to beneficiaries. ■

Endnotes

- 1 The PFFS program allows private plans to offer Medicare benefits to enrollees without restricting them to a network of providers. PFFS plans reimburse providers using the same payment rates that apply in the traditional Medicare FFS program (MedPAC 2004a).
- 2 Balance billing refers to the practice of making patients pay for any difference between a provider's full charge and a health plan's (in this case, Medicare's) payment.
- 3 The eye exam and kidney screening measures had specification changes in 2003 that required more frequent screening for certain patients. These changes are likely responsible for the observed decreases in the measure rates.
- 4 The health information system requirements for the MA plans are very general: Plans must maintain health information systems that collect, analyze, and integrate data necessary to implement their quality improvement programs; ensure that the information they receive from providers is reliable and complete; and make all collected information available to CMS.
- 5 CMS must rebase the county benchmarks at least every three years. Rebasing will lift those benchmarks that are below the AAPCC to the county AAPCC.
- 6 As discussed earlier, CMS does not provide measures that permit comparison of private MA plans with the FFS Medicare system.
- 7 Medicare uses the adjusted average per capita cost (AAPCC) as its formal measure for setting rates (see Chapter 2 of this report for further discussion of this measure). The AAPCC rate is a risk-adjusted county-level measure and hence directly reflects local per capita spending in the FFS sector.
- 8 As noted earlier (endnote 5), CMS may not compare rates to the AAPCC every year.

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CHAPTER

4

Payment for dialysis

R E C O M M E N D A T I O N S

4A The Congress should direct the Secretary to:

- eliminate differences in paying for composite rate services between hospital-based and freestanding dialysis facilities; and
- combine the base composite rate and the add-on adjustment.

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

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4B The Secretary should:

- eliminate differences in paying for injectable drugs between hospital-based and freestanding dialysis facilities; and
- use average sales price data to base payment for all injectable dialysis drugs that are separately billable in 2006.

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

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4C The Congress should give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare it with average sales price data. The Secretary should collect data on the acquisition cost and payment per unit for drugs—other than erythropoietin—that hospital-based providers furnish.

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

Payment for dialysis

Through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Congress improved payment for dialysis services—for example, by adding a case-mix adjuster to the payment system.

In this chapter

- Improving the current payment system
- Modernizing the outpatient dialysis payment system

But Medicare continues to pay dialysis providers differently based on site of care and type of drug. MedPAC recommends a series of changes to improve current payment policies. The Congress should eliminate differences in paying for composite rate services between freestanding and hospital-based facilities and should combine the composite rate and the add-on adjustment. The Secretary should use the same payment method—average sales price (ASP)—to pay for all dialysis drugs provided by both facility types. The Congress should require that the Secretary implement these recommendations so that aggregate payments in 2006 are equal to what payments would have been under pre-MMA policies. The Secretary should also collect acquisition cost data from dialysis providers to determine whether ASP represents the purchase price that providers incur. However, rationalizing payment for composite rate services and dialysis injectables serves only as an interim solution; broadening the payment bundle would modernize this payment system.

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. This illness occurs at the last stage of progressive impairment of kidney function and is a consequence of a number of conditions, including diabetes, hypertension, glomerulonephritis, and cystic kidney disease. Most individuals with ESRD undergo chronic dialysis treatment to stay alive. The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD. In 2003, the Medicare program covered about 300,000 patients, representing nearly 93 percent of all dialysis patients in the United States.¹

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and regulations that CMS issued to implement the new law substantially changed the outpatient dialysis payment system by:

- paying acquisition cost for most (but not all) separately billable injectable drugs;
- shifting some of the profits previously associated with payments for separately billable drugs through an add-on payment to the prospective payment rate for outpatient dialysis services (the composite rate); and
- adjusting the composite rate for differences in case mix.²

However, the MMA does not change the basic structure of the dialysis payment system—separate payment for dialysis treatments and injectable drugs. Providers will continue to receive the composite rate for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes.³ In 2005, the base composite rate for hospital-based facilities is \$132—on average, \$4 more than for freestanding facilities. This difference stems from the Omnibus Budget Reconciliation Act of 1981, by which the Congress mandated separate rates for the two types of facilities.

The Commission has considered whether current payment policies achieve MedPAC's payment policy objectives, which include providing cost-effective, quality care to patients using the most suitable modality in the most suitable setting; promoting access to services; and giving dialysis providers incentives to control costs. This chapter explores these issues in two sections.

The first section discusses how Medicare pays for outpatient dialysis services. We find that the MMA has

improved payment for dialysis in some respects—for example, by adding a case-mix adjustment to the payment system. But the MMA continues to pay freestanding and hospital-based facilities differently for providing the same services. This payment method is not consistent with MedPAC's principle of paying the costs incurred by efficient providers who furnish appropriate care, regardless of the care setting. In addition, the new law makes the payment system more complex by creating an add-on adjustment to the composite rate. Consequently, MedPAC's recommendations advise the Congress and the Secretary to:

- pay the same amount for composite rate services and injectable drugs furnished by freestanding and hospital-based providers, and
- simplify the composite rate by combining the base rate and the add-on adjustment.

In the second section of this chapter, we review MedPAC's past recommendations that the Congress (a) broaden the dialysis payment bundle to include commonly furnished services that are not currently in the bundle and (b) account for factors that affect providers' costs, including dialysis method, dose, and patient case mix. We also discuss potential issues that the Commission may explore in the future.

Finally, MedPAC has concluded that an annual review of rates—for the current payment system and one in which the Congress establishes a larger bundle—is essential for dialysis, especially given the current low margins (MedPAC 2005). The Congress and the Secretary should not assume, as they did in the 1990s, that regular rate increases are not necessary because of large margins.

Improving the current payment system

MedPAC recommends that the Congress and the Secretary equalize the composite rate for hospital-based and freestanding providers, combine the composite rate with the add-on adjustment, use the same methodology to pay for all drugs regardless of setting or type, and periodically check the data on drug payment rates. The following two principles underlie these recommendations:

- Medicare should pay the same rate for the same services across different settings;

- Payment should reflect the costs of efficient providers and should be adjusted to reflect the effects on costs of factors that are beyond providers' control.

The intent of these changes is to rationalize the system in the interim, but a better system would combine payment for composite rate services and drugs into a broader bundle.

Paying for composite rate services

The new law does not change Medicare's policy of paying hospital-based facilities \$4 more, on average, for composite rate services than it pays freestanding facilities. This difference began with the Omnibus Budget Reconciliation Act of 1981, which mandated separate rates for the two types of facilities. In the 1983 rule implementing the composite rate, the Secretary attributed this \$4 difference to overhead, not to patient complexity or case mix.

Some stakeholders have raised concerns that hospital-based providers employ more nurses to deliver care and, consequently, should receive a higher level of payment. MedPAC analyzed staffing levels using 2003 cost report data submitted by freestanding and hospital-based providers. We also analyzed dialysis quality using CMS's Dialysis Compare database. This online database contains information, by facility, on the proportion of patients in 2002 who received adequate dialysis (i.e., having a urea reduction ratio greater than or equal to 65 percent) and the proportion of patients who had their anemia under control (i.e., having a hematocrit greater than or equal to 33 percent).

MedPAC's analysis of these two data sources did find that hospitals reported higher labor costs and employed more nurses, but quality did not differ between the two types of facilities. MedPAC concludes that Medicare should reward facilities based on quality—rather than pay a higher rate simply because the facilities employ more nurses, which *may* lead to better quality. Pay-for-performance programs hold providers more accountable by rewarding those providers who furnish high-quality care and who improve the care that they furnish.

As Table 4-1 shows, hospitals rely more heavily on registered nurses—who are more highly educated and paid—than on dialysis technicians. The opposite is true for freestanding facilities. Hospital-based providers are also less productive than freestanding providers in terms of (a) the total treatments per patient-care staff and

TABLE 4-1

Staffing and productivity vary between freestanding and hospital-based providers

	Freestanding providers	Hospital-based providers
Technicians as a percentage of patient-care staff	49%	30%
Registered nurses as a percentage of patient-care staff	31	50
Total treatments per patient-care staff	711	461
In-center hemodialysis treatments per station	587	522

Note: Patient-care staff comprises registered nurses, licensed practical nurses, nurses' aides, dialysis technicians, dieticians, and social workers.

Source: MedPAC analysis of cost reports submitted by freestanding and hospital-based dialysis providers in 2003.

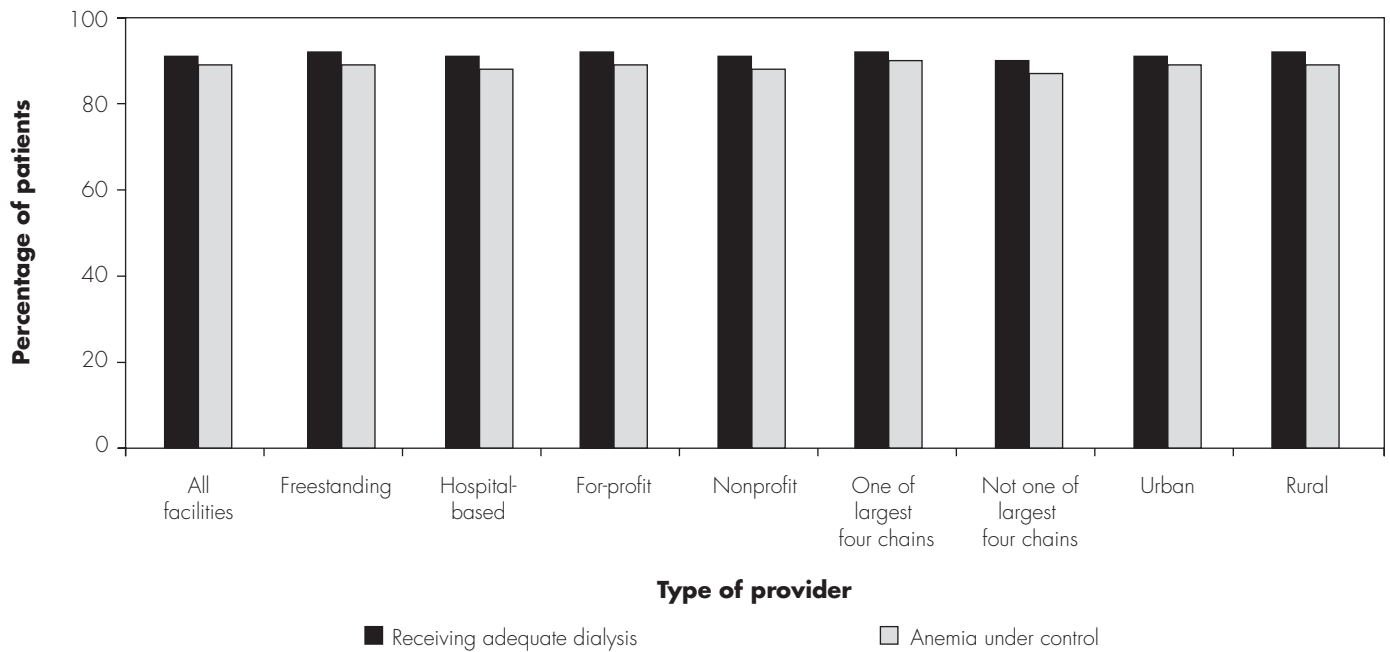
(b) in-center hemodialysis treatments per station. This productivity difference relates more closely to the volume of dialysis treatments that a facility provides rather than the facility's location. Analysis of CMS's facility survey shows that hospital-based facilities provided about 20 percent fewer annual dialysis treatments than freestanding facilities (7,800 versus 9,800 treatments, respectively). MedPAC found about the same percentage difference when comparing the number of annual dialysis treatments provided by hospital and freestanding providers in rural areas (5,300 versus 6,600 treatments, respectively) and in urban areas (9,100 versus 11,100 treatments, respectively).

MedPAC's analysis of dialysis quality shows little difference in the proportion of patients who are receiving adequate dialysis and are not anemic (Figure 4-1, p. 90). For both provider types, about 91 percent of all patients received adequate dialysis and about 89 percent of all patients had their anemia under control.

Figure 4-1 also shows few differences in the levels of quality achieved by for-profit versus nonprofit providers; by facilities that are affiliated with one of the four largest chains versus those that are not; and by urban versus rural providers. For each provider type, the proportion of patients who received adequate dialysis is more than 90 percent, and the proportion of patients who had their anemia under control is more than 87 percent.

**FIGURE
4-1**

Dialysis adequacy and anemia status did not differ among providers in 2002



Note: A total of 3,791 facilities reported information about dialysis adequacy, and 3,831 facilities reported information about anemia status.

Source: MedPAC analysis of data from CMS's Dialysis Compare database.

Many investigators have reported differing results about whether dialysis quality varies based on facilities' ownership and profit status. Previous work by MedPAC showed no association between freestanding facilities' quality of care and their profit status (MedPAC 2003). CMS investigators found no association between profit status and quality measures (that is, adequacy of dialysis, anemia, and nutritional status) (Frankenfield et al. 2000). Port and colleagues (2001) concluded that the risk of mortality does not differ based on facilities' profit status. By contrast, Garg and colleagues (1999) reported higher mortality rates and lower rates of wait-list placement for a kidney transplant for patients who received care at freestanding for-profit facilities than for those who received care at freestanding nonprofit and hospital-based facilities. Other researchers also have found a correlation between facilities' profit status and rates of mortality and transplantation (Devereaux et al. 2002, Ebben et al. 2000, McClellan et al. 1998).

In addition to the different rate that Medicare pays to freestanding and hospital-based providers, the MMA increases the payment system's complexity by creating the add-on adjustment for injectable drugs. The Congress required that the Secretary derive the add-on adjustment by moving dollars associated with the profit margin for the following injectable drugs to the composite rate payment:

- erythropoietin and all other separately billable drugs that freestanding facilities provide, which CMS estimates to be \$385 million in 2005, and
- erythropoietin that hospital-based facilities provide, which CMS estimates to be \$5 million in 2005.

The resulting add-on adjustment to the composite rate is 8.7 percent.

If the Congress's objective of creating the add-on adjustment is to address how providers subsidize relatively low payments for composite rate services with excessive payments for injectable drugs, combining the base

payment rate and the add-on adjustment is the best way to realize this objective.

In addition, we have concerns about the mechanism that the MMA lays out for recalibrating the add-on adjustment. Beginning in 2006, the new law updates the value of the add-on adjustment—which CMS has currently set at \$11.17 for freestanding facilities and \$11.52 for hospitals—based on the growth in separately billable drug expenditures. CMS has not yet indicated how it will implement this section of the MMA. Linking the value of the add-on adjustment to post-MMA spending for separately billable drugs may give providers incentives for inappropriate use of the drugs. Linking the add-on adjustment to pre-MMA spending also presents problems because previous payment policies provided incentives for the inappropriate use of drugs.

RECOMMENDATION 4A

The Congress should direct the Secretary to:

- **eliminate differences in paying for composite rate services between hospital-based and freestanding dialysis facilities; and**
- **combine the base composite rate and the add-on adjustment.**

RATIONALE 4A

This recommendation aims to implement a uniform payment policy across settings. Doing so will ensure that Medicare pays the same amount for the same services across different settings. Further, by combining the base composite rate and the add-on adjustment, Medicare will simplify the outpatient dialysis payment system.

IMPLICATIONS 4A

MedPAC considers the implication of this recommendation on spending, beneficiaries, and providers together with the implications of recommendation 4B (pp. 94–95).

It is not clear whether the composite rate and add-on adjustment together form the appropriate level of payment for a dialysis treatment. Dialysis care has changed since 1983, but the Secretary has not rebased the composite rate.⁴ Similar to other prospective payment bundles, the product has changed: New technologies have replaced older technologies, and the bundle now includes services that were not available in 1983. As we discuss later in

this chapter, when broadening the payment bundle the Secretary will need to identify the medications, services, and equipment that will increase the efficiency of patient care and improve patient outcomes.

In addition, for the current payment system and for one in which Medicare establishes a larger bundle, MedPAC has concluded that an annual review of rates is essential for dialysis, especially given the current low margins (MedPAC 2005). The Congress and the Secretary should not assume, as they did in the 1990s, that regular rate increases are not necessary because of high margins.

Paying for dialysis injectable drugs

Under current law, which reflects both the MMA and previous policy, the Secretary pays dialysis providers differently depending on the specific drug and the site of care. All the payment policies we discuss in this sub-section relate to injectable drugs that CMS pays separately from the composite rate. MedPAC recommends rationalizing payment policy by (a) paying for all dialysis drugs using the same methodology (that is, the same method used for other Part B providers) and (b) periodically checking the ASP data to verify its appropriateness.

Before the MMA, payment for injectable drugs also varied depending on the site of care and on the specific drug.⁵ The payment methods—a rate for erythropoietin set in the statute and average wholesale price (AWP) for drugs other than erythropoietin—generated excessive profits for these drugs. Through the MMA, the Congress addressed this overpayment issue by requiring a new payment approach.

Payment methods vary by site of care and type of drug

Under current law created by the MMA, Medicare pays three different ways for dialysis drugs.

Paying for the “top 10 drugs” in freestanding facilities For the 10 injectable drugs that make up the highest share (98 percent) of volume, Medicare now pays freestanding providers using a method called average acquisition payment (AAP).⁶ To calculate the AAP, CMS used the acquisition costs that the Office of Inspector General (OIG) collected in a 2003 survey of freestanding providers (OIG 2004).⁷ CMS derived the 2005 rates for these drugs by updating the 2003 values using the producer price index (PPI).

Paying for other drugs in freestanding facilities

For all other injectable drugs, Medicare pays freestanding providers using a different method—ASP. This method uses prices that manufacturers report to CMS every quarter. CMS set the 2005 rates for these drugs at ASP plus 6 percent.

Paying for drugs in hospital-based facilities Unlike freestanding providers, hospitals' payment for most dialysis drugs uses a third approach—reasonable cost—with one exception: erythropoietin, for which Medicare pays the same AAP rate as that of freestanding providers. CMS derives reasonable cost from a hospital's cost report; the agency calculates this payment by reducing hospital-set charges, including overhead, to costs using a cost-to-charge ratio. Researchers do not yet clearly understand the relationship between payment based on reasonable cost and payment based on hospital-incurred acquisition cost.

What is the best way for Medicare to pay dialysis facilities for drugs?

Through the MMA, the Congress intended that the payment rates for dialysis drugs more closely approximate the costs that providers incur. Results from a MedPAC-sponsored survey and the OIG suggest that different types of providers use different approaches to purchase drugs, and this sometimes results in different prices. However, the prices that freestanding and hospital-based facilities pay do not vary much based on an analysis of pricing data that MedPAC obtained from IMS Health.

The three different approaches—ASP, AAP, and reasonable cost—all try to estimate the above costs. Paying reasonable costs is probably the least accurate approach, as it may reflect the facilities' charging and accounting practices. In our discussion below, we contrast the two other methods and find that they attempt to measure the same concept. However, ASP shows several advantages over AAP in that the Secretary already collects ASP data for all drugs and ASP data are more up to date.

How do different providers acquire drugs?

The Commission sponsored a series of interviews with hospital-based and smaller freestanding dialysis providers to understand their purchasing strategies for dialysis injectables. Our objective was to better understand how smaller dialysis providers acquire injectable drugs—including whether they purchase drugs directly or through other agents (such as a parent company or hospital

pharmacy) and how they negotiate prices with manufacturers. The text box describes how we constructed the sample and the characteristics of the participating dialysis providers.

We found that the smaller providers try to competitively negotiate to obtain dialysis drugs, but manufacturers generally give direct discounts only to the largest volume facilities—those typically affiliated with chains. Respondents to our survey usually acquire drugs from:

- **Wholesalers**—the primary source used by smaller non-chain-affiliated freestanding facilities. It is common for facilities to obtain drugs from more than one wholesaler. Facilities that agree to purchase most of their drugs from one wholesaler often receive a better price from that wholesaler. Respondents to our survey reported it was difficult to find a wholesaler for drugs not routinely used.
- **Group purchasing organizations (GPOs)**—an important source for facilities seeking lower prices that GPOs make available through volume purchases. For a fee, the GPO functions as a buying unit for a group of facilities that can take advantage of discounts that manufacturers might offer to volume purchasers.
- **Manufacturers**—the primary source for facilities that are members of regional chains that can negotiate volume discounts. Providers that purchase directly from manufacturers avoid fees that wholesalers charge.

Respondents indicated that they attempt to negotiate:

- **Price**—Respondents reported that they can better negotiate for drugs in which clinical substitutes are available. Of the top 10 dialysis injectables, only one has generic alternatives. However, alternative therapies exist among two classes of drugs—those used to treat bone disease and iron deficiency.
- **Volume**—Providers that purchase larger volumes of drugs can obtain lower prices through discounts and rebates. However, patient needs and cash flow limit the volume of drugs that providers can inventory at any given time.

By contrast to the smaller providers, we learned that the large national chains generally negotiate directly with manufacturers.

Survey of small freestanding and hospital-based dialysis providers

On behalf of MedPAC, the National Opinion Research Center (NORC) and Georgetown University conducted a series of interviews with a small sample of hospital-based dialysis providers and freestanding providers who were not affiliated with the four largest chains. Beginning in March 2005, our contractors conducted interviews by telephone using a semistructured interview guide. NORC and Georgetown

University interviewed respondents—including directors of purchasing, directors of pharmacy, and other facility administrators—about how they negotiate prices and acquire dialysis drugs. To date, our contractors have completed 11 interviews with freestanding providers and 4 interviews with hospital-based providers. ■

How do prices vary by type of facility?

Findings from the OIG's report suggest that the price dialysis facilities pay varies between the largest freestanding providers—that is, those affiliated with one of the four largest dialysis chains—and all other freestanding facilities (OIG 2004). The average acquisition cost for the three leading drugs, in terms of Medicare payments, was 8 to 22 percent lower for the largest providers compared with other freestanding providers in 2003.⁸ The largest providers reported drug acquisition costs that were 6 percent lower than the ASP of the top 10 drugs; by contrast, other freestanding facilities reported drug acquisition costs that were 4 percent above the ASP. The OIG based its report on data collected from each of the four largest dialysis providers and a sample of all other freestanding facilities. The OIG did not include hospital-based providers in its report.

To compare the purchasing strategies of freestanding and hospital-based providers, MedPAC obtained data from IMS Health on the national average purchase prices for the top 10 dialysis injectables during the fourth quarter of 2004. This database included the national average purchase prices for “clinics,” which include sales to freestanding dialysis providers, and “nonfederal hospitals,” which include sales to hospital-based dialysis providers.⁹ Because IMS collects data from sales invoices and these sales invoices do not include off-invoice discounts or rebates, the average purchase price overstates the amount that providers actually pay for drugs. In addition, the average purchase price includes purchases by both dialysis and nondialysis providers.

Our analysis suggests that the purchase prices for the top dialysis injectables do not vary substantially between freestanding providers and hospitals. The weighted average purchase price for all of the study drugs was, on average, 4 percent greater for “nonfederal hospitals” compared with “clinics.” We calculated the weighted average purchase price by weighting the average purchase price for each drug by its proportion of total Medicare payments.

How do AAP and ASP compare?

Ideally, Medicare should arrive at the same payment rate for a particular dialysis injectable by using either ASP or AAP data. Both data sources aim to determine the purchase price of drugs—that is, the net of all rebates and discounts. CMS derives AAP data from a special survey of dialysis providers. By contrast, CMS collects ASP data from all manufacturers for all drugs, updates ASP data quarterly, and uses this data source to pay for injectables that other Part B providers furnish.¹⁰

The most important difference between the two methods is the frequency by which CMS will update AAP data to reflect actual transaction prices. AAP data may not accurately reflect providers' acquisition costs in 2006 and beyond if the negotiating process changes the price that manufacturers charge. In 2005, the OIG will determine the prices of new drugs (which did not have a billing code before 2004). Otherwise, the update may include an inflation factor (such as the PPI). In addition, AAP does not provide information on all injectable drugs that dialysis facilities currently use. Finally, AAP does not provide information about the prices that hospitals pay.

**TABLE
4-2**

AAP and ASP for dialysis injectables vary somewhat in 2005

	AAP 2005	ASP plus 6 percent (1st quarter 2005)	ASP plus 6 percent (2nd quarter 2005)
Erythropoietin	\$9.76	\$9.32	\$9.25
Calcitriol	0.96	0.71	0.86
Doxercalciferol	2.60	2.80	2.78
Iron dextran	10.94	11.06	11.22
Iron sucrose	0.37	0.36	0.37
Levocarnitine	13.63	14.65	11.12
Paricalcitol	4.00	4.02	3.97
Sodium ferric gluconate complex	4.95	4.83	4.73
Alteplase, recombinant	31.74	30.15	30.09
Vancomycin	2.98	2.42	3.19

Note: AAP (average acquisition payment), ASP (average sales price). Average acquisition payment for 2005 reflects the average acquisition cost for 2003 updated by the producer price index.

Source: CMS 2005.

MedPAC compared the payment rate under AAP to the corresponding rate for each of the top 10 dialysis drugs if ASP plus 6 percent were the reference price (that is, the rate used to pay other Part B providers [Table 4-2]). This comparison shows similar rates for some drugs but shows that for others, notably erythropoietin, the ASP rates have been falling over the last quarter.¹¹ The more recent ASP data will more likely reflect current negotiations between manufacturers and purchasers rather than the AAP rates.

Based on our analysis of how different providers acquire and receive payment for injectable drugs—and of the similarities and differences between ASP and AAP—MedPAC concludes that:

- Medicare’s current method of paying for separately billable drugs should not vary between provider types.
- Both ASP and AAP aim to determine the purchase price of drugs (which is the net of all rebates and discounts); thus, CMS should derive a similar price from either data source.
- Similar incentives exist for providers to obtain the best possible purchase price under both ASP and AAP.
- CMS regularly collects ASP data and uses it to pay for other Part B injectables. By contrast, CMS does not

regularly collect AAP data and does not use this data source to pay for other Part B injectables.

- CMS updates ASP data regularly to reflect actual transaction prices; thus, ASP data would better reflect the prices paid by dialysis providers over time than would AAP data.

RECOMMENDATION 4B

The Secretary should:

- **eliminate differences in paying for injectable drugs between hospital-based and freestanding dialysis facilities; and**
- **use average sales price data to base payment for all injectable dialysis drugs that are separately billable in 2006.**

RATIONALE 4B

This recommendation would make a uniform payment policy across settings. In contrast to AAP data, ASP data are already collected by the Secretary, are regularly updated by the agency, and include data for all drugs.

Spending

- Through recommendations 4A and 4B, MedPAC intends to maintain overall budget neutrality with pre-MMA spending in 2006.

Beneficiary and provider

- Some facilities could receive higher payments or lower payments. We do not expect this recommendation to affect providers' willingness and ability to provide quality care to Medicare beneficiaries. These recommendations do not substantially change beneficiary cost sharing, nor should they have a negative effect on beneficiary access to quality care.

At what level should Medicare set ASP?

At issue is the level that Medicare should set ASP for dialysis drugs. By setting the initial payment rate at ASP plus 6 percent, the Secretary will account for the variation in the purchase price for dialysis injectables across different types of providers. Our analysis of data from the OIG and IMS—and our survey of smaller providers—suggests that some providers can negotiate larger discounts for drugs than others. Together, these data sources suggest that the four largest freestanding dialysis chains obtain the lowest purchase price for injectable drugs, followed by hospital-based and smaller freestanding providers.

Over the long term, the Secretary should set a payment rate that reflects efficient providers' costs. In the next section, we recommend that the Secretary periodically collect acquisition cost data from a sample of providers and compare it to the ASP data. By periodically collecting data on providers' costs, the Secretary can make adjustments as necessary in the ASP level.

Improving data on paying for drugs

Although the Commission recommends using ASP data to pay for all dialysis drugs, we caution that these data do have some limitations. ASP data may deviate from AAP data because:

- The Secretary derives ASP on pricing data that manufacturers submit for all “channels” (that is, types of purchasers of a particular dialysis drug, not just dialysis providers). Thus, ASP reflects the purchase price of dialysis providers as well as that of other providers, such as physicians, nursing facilities,

hospitals, and home health providers. The Secretary's calculation of ASP includes all sales except those that are exempt from Medicaid's best price calculations.

However, the effect of basing the ASP calculation on nearly all sales may not be large. According to stakeholders, medical professionals use the top 10 dialysis drugs, except for vancomycin, primarily to care for renal patients.

- ASP may, in fact, understate the price that providers pay because ASP does not include wholesalers' service fees.

Because ASP and AAP might deviate over time, MedPAC recommends that the Secretary periodically collect acquisition cost data from both freestanding and hospital-based dialysis providers and compare it to ASP data. In doing so, the Secretary will better understand the effect of including nearly all sales in the calculation of ASP data. By monitoring the comparability of both data sources over time, the Secretary will be able to set the payment rate to reflect efficient dialysis providers' costs.

The Secretary will need additional data to assess the impact of using ASP data for hospitals. Such an assessment is necessary in order to carry out the MMA's intent—that is, to modify the composite rate so that it accounts for any profit associated with the previous payment method and to maintain budget neutrality with pre-MMA payment levels.

To conduct the assessment, the Secretary will need to obtain data to estimate hospitals' costs and Medicare's payment per unit for these drugs. No published source identifies the unit payment for these drugs because Medicare pays hospitals their reasonable costs. We attempted to calculate the unit payment from 2003 claims data, but the accuracy of the data fields we needed to make this calculation was unclear, particularly the number of units furnished and Medicare's payment to the hospital.

As mentioned earlier, the OIG will be conducting a second study on the difference between (a) the Medicare payment amount for separately billable dialysis drugs for which a billing code did not exist prior to January 1, 2004, and (b) the acquisition costs of such drugs. The OIG could also collect hospitals' payment and cost data for the top 10 dialysis injectables (other than erythropoietin). The Secretary also might collect data on hospitals' cost and payment per unit for drugs in the agency's demonstration study of a broader bundle, which will begin in 2006.

RECOMMENDATION 4C

The Congress should give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare it with average sales price data. The Secretary should collect data on the acquisition cost and payment per unit for drugs—other than erythropoietin—that hospital-based providers furnish.

RATIONALE 4C

By collecting data on dialysis providers' acquisition cost, the Secretary will be able to assess that data's comparability, over time, to ASP data.

IMPLICATIONS 4C

Spending

- This recommendation will not increase federal program spending relative to current law.

Beneficiary and provider

- Some facilities could receive higher payments or lower payments. We do not expect this recommendation to affect providers' willingness and ability to provide quality care to Medicare beneficiaries.

Smaller facilities that are not affiliated with a dialysis chain cannot purchase drugs as inexpensively as the largest chain providers. To protect beneficiaries' access to these smaller facilities, policymakers might consider extending to dialysis providers the competitive acquisition program for outpatient drugs and biologicals. Beginning in 2006, the MMA gives physicians the choice of either obtaining certain Part B injectables from contractors (who would then bill Medicare) or continuing to purchase the drugs and receive ASP plus 6 percent from Medicare.

Impact of implementing MedPAC's recommendations

We assessed the impact of implementing our recommendations that refine payment policies for composite rate services and dialysis injectables by modeling 2006 spending under pre-MMA policies and under MedPAC's recommendations (Table 4-3). This analysis also includes our recommendation to update the payment for composite rate services in 2006 (MedPAC 2005). This analysis serves illustrative purposes only. If the Congress and the Secretary adopt MedPAC's recommendations, the Secretary will need to determine

TABLE 4-3

Estimated impact of MedPAC's recommendations to refine outpatient dialysis payment policies, 2006

Service	Freestanding			Hospital-based			Total		
	Payments in millions			Payments in millions			Payments in millions		
	Pre-MMA	Post-MMA	Percent change	Pre-MMA	Post-MMA	Percent change	Pre-MMA	Post-MMA	Percent change
EPO	\$2,229	\$2,146	-4	\$216	\$208	-4	\$2,445	\$2,354	-4
All other drugs	1,022	648	-37	157	157	0	1,179	805	-32
Total: Drugs	3,251	2,794	-14	372	364	-2	3,624	3,158	-13
Composite rate	4,239	4,626		634	670		4,872	5,296	
B-N factor	0	36		0	5		0	41	
Total: Composite rate	4,239	4,662	10	634	675	6	4,872	5,338	10
Drugs and composite rate	7,490	7,456	-0.5	1,006	1,040	3	8,496	8,496	0

Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act), EPO (erythropoietin), B-N (budget neutrality). The column titled "Post-MMA" reflects MedPAC's recommendations to change payment policies in 2006. MedPAC's recommendations are estimated based on the average sales price plus 6 percent reported by CMS in April 2005 and inflated to 2006 prices. The aggregate composite rate represents the base rate and the add-on adjustment as implemented in CMS's final rule, updated by 2.5 percent, which was MedPAC's most recent recommendation for composite rate services (MedPAC 2005). Spending for aggregate composite rate services includes a budget-neutral factor of \$41 million in order for MedPAC's recommendations to maintain budget neutrality with pre-MMA spending levels. See text box for a complete description of the methods. Sums may not total correctly due to rounding.

Source: MedPAC analysis of 2003 claims data submitted by freestanding and hospital-based providers.

Impact analysis of MedPAC's recommendations to refine outpatient dialysis payment

Our impact analysis illustrates payments under pre-Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) policies and payments under MedPAC's recommendations, the latter of which (a) eliminate differences in composite rate and drug payment policies between the two provider types and (b) combine the base composite rate and add-on adjustment. To the extent possible, we used methods similar to those that the Secretary used in the Part B final rule.

As we show in Table 4-3, all spending is expressed in terms of 2006 dollars. For both scenarios, we applied MedPAC's most recent update recommendation (2.5 percent) for composite rate services. For the pre-MMA scenario, we applied the update factor to the base composite rate. For the scenario modeling MedPAC's recommendations, we applied the update factor to the base composite rate and add-on adjustment.

We could not model the impact of changing drug payment policies for injectables other than erythropoietin provided by hospitals. Thus, payment for these drugs remains unchanged when we modeled the impact of our recommendations. Because hospitals receive reasonable cost for these drugs, the Secretary has no data source from which to obtain the per-unit payment for these drugs. By contrast, the Secretary used the Single Drug Pricer for January 2004 to derive freestanding providers' pre-MMA per-unit payment.

MedPAC attempted to derive the payment per unit data from 2003 claims that hospital-based providers submitted. However, after thoroughly reviewing these data, we were unsure of their accuracy because Medicare does not pay according to the number of units reported on the claim. Validating the claims data to data reported on patients' medical records would demand more resources and time than available. Thus, we took a conservative approach: When modeling the effect of our recommendations, we maintained pre-MMA spending levels for these drugs.

To put this omission in perspective, Medicare's payments for drugs other than erythropoietin to hospital-based providers account for a small proportion of total payments for dialysis drugs. In 2003, payments for these drugs accounted for 2 percent of all payments and 5 percent of all drug payments to freestanding and hospital-based providers.

Lastly, our impact analysis does not reflect the case-mix adjustment implemented by CMS on April 1, 2005. Although this adjustment might affect the two types of providers differently, it would not affect overall spending because the MMA mandated that the Secretary implement the case-mix adjustment budget neutral. ■

the impact of these changes on different provider types using the most current data available.

For the pre-MMA payment scenario, we updated the base composite rate by 2.5 percent—MedPAC's most recent update recommendation for composite rate services. To model the effect of our recommendations, we set the payment rate for dialysis injectables at ASP plus 6 percent and updated the aggregate composite rate by 2.5 percent. The text box contains a complete description of the methods.

Through these recommendations, we intend to maintain overall budget neutrality with pre-MMA spending levels.

We do so by including a budget neutrality factor with spending for composite rate services. Using the most current data available and updating it to represent 2006 spending and prices, we estimate a budget neutrality factor of about \$41 million. Total 2006 spending estimates for composite rate services and for drugs under both scenarios adds to \$8.5 billion.

The impact on aggregate spending for composite rate services under MedPAC's recommendations reflects:

- ***The Secretary implementing the single add-on adjustment.*** This action, mandated by the MMA, resulted in transferring dollars from freestanding to hospital-based facilities. The Secretary estimates that

total payments for freestanding facilities decreased by 0.6 percent and payments for hospital-based providers increased by 5.2 percent.

- ***The Congress eliminating the \$4 difference between freestanding and hospital-based providers.*** This action, recommended by MedPAC, would result in an estimated aggregate composite rate of \$143.58 in 2006. If the Congress does not eliminate the \$4 difference, we estimate the aggregate composite rate would be \$143.00 and \$147.53 for freestanding and hospital-based providers, respectively. Thus, by eliminating the \$4 difference, Medicare would increase the composite rate by 0.4 percent for freestanding providers and decrease the rate for hospital-based providers by 2.7 percent. This impact stems from the fact that freestanding providers furnish a much larger share of all dialysis treatments than do hospital-based providers (87 percent versus 13 percent, respectively).
- ***The Congress requiring that the Secretary implement the Commission’s recommendations so that aggregate payments in 2006 are equal to what payments would have been under pre-MMA policies.*** In doing so, Medicare would increase the aggregate composite rate by 0.8 percent to \$144.70 for both facility types.

Compared with pre-MMA payments, we estimate that aggregate erythropoietin payments will decrease by 3.7 percent for both provider types under MedPAC’s recommendations. This decline reflects the difference in the payment rate under pre-MMA policies and the ASP plus 6 percent that MedPAC estimated in 2006.¹²

For freestanding providers, we estimate that aggregate payments under MedPAC’s recommendations for all other drugs will decrease by more than one-third compared to pre-MMA levels. This decrease reflects the pre-MMA policy of paying 95 percent of the AWP. We estimate that payments for freestanding providers for all dialysis injectables will decrease by 14 percent.

Because of data limitations, our analysis assumes that hospitals are receiving constant payments for drugs other than erythropoietin. Consequently, we estimate that hospitals’ total payments for all drugs will decrease by 2 percent.

Considering spending for both composite rate services and drugs together, we estimate that freestanding providers’ payments will decline slightly (by 0.45 percent) and that hospital’s payments will increase (by 3.4 percent).

Modernizing the outpatient dialysis payment system

Improving current payment for composite rate services and dialysis injectables serves only as an interim solution; the Congress should also broaden the payment bundle in order to modernize this payment system. Medicare could provide incentives for controlling costs and promoting quality care by broadening the payment bundle to include dialysis injectables and laboratory services that are not separately billable and by linking payment to quality.

Facilities have stronger incentives to control the costs of services included in the payment bundle compared with services that fall outside it—that is, services that are separately billable. Under pre-MMA payment policy, drug spending per patient varied among different provider types, perhaps reflecting providers’ differing incentives to furnish drugs under different payment systems. For example, per patient per month spending varied from \$453 to \$530 for erythropoietin, \$69 to \$93 for injectable iron, and \$67 to \$166 for vitamin D analogues across the four major for-profit chains and hospital-based facilities (USRDS 2004). In addition, an earlier MedPAC analysis showed that dialysis quality of care (a) did not significantly differ among facilities with lower and higher costs for composite rate services and (b) was poorer for facilities with higher-than-average costs for composite rate services and for injectable drugs (MedPAC 2003). Differences in case mix may also partly account for these findings. Together, these findings suggest that certain facilities might less efficiently furnish injectable drugs than other facilities, and this inefficiency may in turn reflect less than optimal patient care.

The new law creates incentives for facilities to more appropriately use dialysis injectables, because Medicare pays acquisition cost for most drugs. However, because some providers can negotiate steeper discounts than the acquisition cost and because the payment system pays on a per-unit basis, the new law does not eliminate the incentive for inappropriate use.

Both facility types showed substantial spending for dialysis injectables—\$2.8 billion for drugs compared with \$4.2 billion for composite rate services in 2003. Spending for drugs accounts for a similar proportion of all dialysis spending for both facility types—39 percent of all spending for hospital-based providers and 41 percent of all spending for freestanding providers in 2003. If the Congress had not implemented the MMA, we estimate that drug spending would have increased to about 44 percent of all spending in 2006.

Spending for laboratory services outside the payment bundle may also be significant. Researchers at the University of Michigan recently estimated that spending for laboratories outside the composite rate was \$249 million in 2003. The Government Accountability Office (GAO) previously found that clinically similar ESRD patients received laboratory tests at widely disparate rates. The GAO also concluded that at one extreme, Medicare may be paying for an excessive number of tests; at the other, patients may not be receiving the tests needed to adequately monitor their condition (GAO 1997).

MedPAC has recommended that the Congress should—as soon as possible—refine the outpatient dialysis payment system by broadening the dialysis payment bundle to include commonly furnished services that Medicare currently excludes. The Congress should also account for factors that affect providers' costs, including dialysis method, dose, and patient case mix (MedPAC 2001). MedPAC has also recommended that the Congress implement pay-for-performance for both facilities and physicians who treat dialysis patients (MedPAC 2004). In addition, to promote the delivery of clinically appropriate care, the Secretary needs to continue to develop quality measures and to monitor and improve dialysis care. Together, these recommendations should improve the efficiency of the payment system, better align incentives for providing cost-effective care, and reward providers and physicians for providing high-quality care.

The new law begins to consider expanding the payment bundle. Starting on January 1, 2006, the Secretary must conduct a three-year demonstration of a sample of dialysis providers to test a broader payment bundle.

Future MedPAC issues

MedPAC plans to continue analyzing the following outpatient dialysis payment issues:

- **Wage index adjustment to the composite rate.** In the MMA, the Congress gave the Secretary discretionary authority to revise the wage index that the Secretary currently uses in the dialysis payment system. When CMS implemented other changes to dialysis payment required by the MMA, the agency chose not to make changes to the wage index. The agency argued that (a) new statistical area definitions recently published by the Office of Management and Budget will affect payment distribution and (b) the evaluations of the impact of these new statistical areas are necessary before changes to the wage index are made. MedPAC is exploring the implications of more current wage indexes on providers' spending.
- **Payment for home dialysis.** One issue for the Congress to consider when modernizing the payment system is whether to maintain the same payment rate for in-center and home dialysis. Currently, the composite rate is the same for in-center hemodialysis and dialysis that is administered in patients' homes—that is, peritoneal dialysis and hemodialysis. In 1981, the Congress mandated that payment not differ in order to encourage patients' use of home dialysis. Historically, providers incurred lower costs for providing home dialysis than in-center dialysis. Despite this cost difference, the use of home dialysis has declined during the past 10 years. Issues that remain to be explored include a comparison of the current use of dialysis injectables by at-home and in-center patients, the impact of the pre-MMA payment system on the use of home dialysis, the impact of pre-ESRD care on the use of home dialysis, and the use of quality incentives to promote home dialysis.
- **Case-mix adjustment.** As we mentioned earlier, CMS has recently adjusted the composite rate for age and body mass. Some stakeholders are concerned that this adjustment results in payments that are greater for younger adult patients than for older patients. MedPAC's preliminary analysis confirms CMS's findings. The association between patients' age and providers' cost is "U"-shaped, with pediatric patients, young adults (18 to 44 years of age), and elderly patients (greater than 80 years of age)

incurring higher costs than those of other age groups (patients who are 45 to 59 and 70 to 79 years of age). MedPAC plans to explore factors that may be affecting providers' costs, such as patient compliance and dialysis time. We also plan to evaluate different ways in which the Secretary can case-mix adjust a broader payment bundle.

- ***Part B and Part D coverage for drugs.*** CMS may be considering paying for dialysis injectables under both the Part B and Part D payment systems. MedPAC will be following this issue closely because it can affect beneficiaries' cost sharing under the current payment system of paying separately for dialysis injectables, and because this issue would also complicate the implementation of a broader payment bundle. ■

Endnotes

- 1 To qualify for the ESRD program, individuals must be insured under the Social Security or Railroad Retirement program, be entitled to monthly benefits under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary.
- 2 As of April 2005, CMS uses the following measures to adjust the composite rate for differences in case mix:
 - age (<18, 18–44, 45–59, 60–69, 70–79, >80 years), and
 - two body measurement variables—body surface area and body mass index—calculated from patients’ height and weight when they develop ESRD. As of January 2005, CMS requires that dialysis facilities report patients’ height and weight on dialysis claims.

CMS does not use the body measurement variables to calculate payments for patients under age 18.
- 3 In 1981, the Congress mandated that the composite rate include all nursing services, supplies, equipment, and selected drugs associated with a single dialysis session.
- 4 Although the Secretary has not rebased the composite rate, the Congress updated it twice during the past five years (in 2000 and 2005).
- 5 Under pre-MMA policies, the payment rate for erythropoietin was the same for freestanding and hospital-based facilities—\$10 per 1,000 units. For drugs other than erythropoietin, Medicare paid freestanding facilities 95 percent of the AWP; by contrast, Medicare paid hospital-based facilities reasonable cost for these drugs.
- 6 The top 10 drugs are erythropoietin, calcitriol, doxercalciferol, iron dextran, iron sucrose, levocarnitine, paricalcitol, sodium ferric gluconate complex, alteplase recombinant, and vancomycin.
- 7 The OIG is mandated to conduct two studies on the pricing of dialysis drugs. The first study, published in May 2004, examined the pricing of drugs that had a billing code before 2004. The second study, due to the Congress by April 2006, will examine the pricing of drugs that did not have a billing code in 2004.
- 8 The three leading drugs—in terms of Medicare payments in 2003—for freestanding facilities were erythropoietin (\$1.7 billion), paricalcitol (\$323 million), and iron sucrose (\$153 million).
- 9 IMS Health collects purchase price data from manufacturers and drug wholesalers.
- 10 The Secretary derives ASP from sales data that manufacturers submit to the agency no later than 30 days after the close of each quarter. The term manufacturer means any entity engaged in the following activities: (1) production, preparation, propagation, compounding, conversion, or processing of prescription drug products, or (2) packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. The ASP for a given product is the volume-weighted average of the manufacturers’ average sales prices reported to the Secretary across all drugs assigned to a HCPCS code. ASP is the net of all price concessions, including volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates. The Secretary estimates total price concessions using a 12-month rolling price concession. Medicare payment allowances for the first quarter of 2005 are based on submissions from the third quarter of 2004.
- 11 CMS has not announced any changes to the ASP values for the second quarter of 2005. The agency did revise the ASP values of a few drugs for the first quarter of 2005 to correct technical errors.
- 12 MedPAC estimated the 2006 average sales price plus 6 percent for erythropoietin by inflating the rate used by CMS in the second quarter of 2005 by an update factor of 4.1 percent. We derived this factor using a combination of historical data on producer prices for prescription drugs and CMS’s projections of future growth in nationwide drug spending per person.

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CHAPTER

5

Payment for post-acute care

Payment for post-acute care

Providers should base their decisions about where beneficiaries receive post-acute care services on patient characteristics and resource needs, not on Medicare payments. Given the potential overlap in services and lack of criteria delineating the appropriate treatment setting, post-acute care decisions are sensitive to payment system incentives. Where overlap exists, the tradeoffs between cost and quality often are unknown. In this chapter, we report on the results of one study comparing patient characteristics, outcomes, and spending in different post-acute settings for beneficiaries who had a hip or knee replaced. Next, to examine how well policymakers and researchers could compare patients across settings, we report on the various patient assessment tools currently required in three post-acute settings. Finally, we discuss the reasons that the payment systems for skilled nursing facilities and home health services may not be paying appropriately for all types of patients. We discuss ways to correct problems with payments in these settings to ensure that payments better track the resource needs of different patients.

In this chapter

- Comparing outcomes and spending for beneficiaries who have had a hip or knee replaced
- Comparing the patient assessment tools used in post-acute care settings
- Assessing the skilled nursing facility PPS
- Assessing the home health PPS

Post-acute care generally follows an acute hospitalization and is provided in four settings—skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), and the home. Post-acute care includes services such as physical or speech therapy, wound care, skilled nursing care for chronic conditions, and care for patients who use ventilators. Eligible beneficiaries who are referred from the community and who use home health services without a prior hospitalization also use post-acute care.

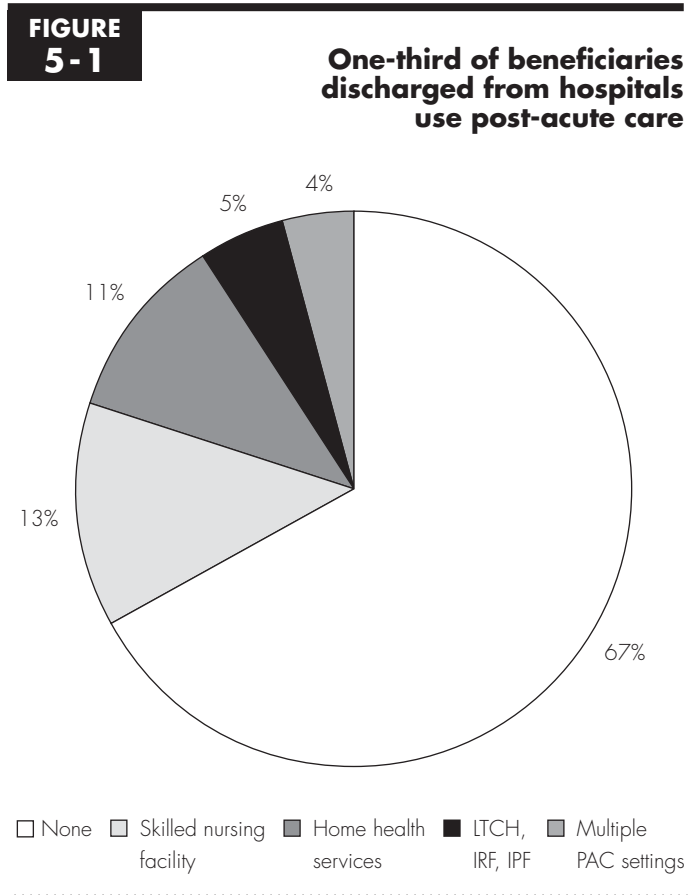
In 2002, one-third of Medicare beneficiaries discharged from acute hospitals used post-acute care within one day of leaving the hospital (Figure 5-1). SNFs are the most frequently used setting, with home health the next most frequently used.

Services provided in the four post-acute settings are often similar, but coverage rules, service intensity, and payments differ for the four post-acute settings. Medicare’s eligibility criteria for beneficiaries using post-acute care vary by setting. The program’s conditions of participation (COPs) for providers, staffing ratios, and even types of staff differ by setting. Medicare pays for care in each setting using a distinct payment system. The differences among the settings in COPs, staffing ratios, and intensity of care have contributed to the historical costs on which the payment system in each setting is based. Pronounced geographic differences in the supply of post-acute services also exist.

Some observers maintain that beneficiaries can use post-acute care as a continuum of care, where patients use multiple types of post-acute care consecutively as their need for care decreases. Evidence indicates that although it may be a continuum for some, relatively few beneficiaries use more than one post-acute setting: In 2002, 4 percent of the beneficiaries discharged from the hospital used more than one post-acute setting. Most beneficiaries who used more than one setting used home health services after a SNF stay (97 percent).

Several studies have explored whether care in one setting can be appropriately substituted for care in another by looking at whether similar patients have experienced similar outcomes in different settings. In one study, researchers found that the potential for substitution varied by diagnosis, with little potential for substitution among stroke patients but more potential for congestive heart failure patients (Gage 1999). Other studies provided

mixed evidence of substitution, which sometimes varied by diagnosis (Deutsch et al. 2005, Kane et al. 2000, Keith et al. 1995, Kramer et al. 2000, Kramer et al. 1997, Manton et al. 1994). For example, Kramer (1997) found that SNFs and IRFs had equivalent functional outcomes for hip fracture patients, but Kane (2000) found that hip fracture patients experienced better outcomes in IRFs and at home compared with SNFs. In the only study that used data collected after the SNF and IRF prospective payment systems (PPSs) began, researchers found that hip fracture patients who used IRFs experienced better functional outcomes than patients who used SNFs (Munin et al. 2005).



Note: LTCH (long-term care hospital), IRF (inpatient rehabilitation facility), IPF (inpatient psychiatric facility), PAC (post-acute care). "None" indicates patients who used no post-acute care following their hospital stay. This chart shows the share of patients who used post-acute care within one day of discharge from the hospital.

Source: Hogan 2004.

Comparing outcomes and spending for beneficiaries who have had a hip or knee replaced

One criterion that distinguishes IRFs from acute hospitals is the so-called 75 percent rule. This rule requires that an IRF admit 75 percent of patients for one or more conditions from a list of conditions that CMS specifies, such as stroke or hip fracture. In 2004, after several years of not enforcing the rule, CMS revised the list of conditions for the first time since 1983. Specifically, CMS eliminated “polyarthritis”—the most frequent diagnosis for beneficiaries who used IRFs in 2002—from the list and replaced it with four arthritis-related conditions. These conditions include (a) patients with polyarthritis who have bilateral joints replaced, are aged 85+, or have a body mass index (BMI) of 50+; (b) patients who have two major weight-bearing joints with severe osteoarthritis (not counting replaced joints); (c) rheumatoid arthritis; and (d) systemic vasculidities with joint inflammation. The last three conditions must not have improved after an appropriate, aggressive, and sustained course of outpatient therapy services (or services in less intensive rehabilitation settings) immediately preceding the IRF admission or must result from a systemic disease activation immediately before admission. CMS is phasing in the changes in the 75 percent rule, beginning in July 2005, over a period of four years—50 percent the first year, 60 percent the second year, 65 percent the third year, and 75 percent in successive years. CMS maintains that polyarthritis—the diagnosis for hip and knee replacement patients—does not require the intense rehabilitation provided by IRFs, except in select cases.

In effect, the change in the 75 percent rule means that fewer beneficiaries with a single hip or knee replacement will likely use IRF care. IRFs that previously have admitted a substantial proportion of joint replacement patients are expected to change their behavior in order to comply with the new rule as it phases in. As a result, under the new 75 percent rule, some beneficiaries with a hip or knee replacement who need rehabilitation but do not meet the new criteria will not go to an IRF but instead will have a longer acute hospital stay, be referred to SNFs, or be sent home with home health or outpatient therapy. Other such beneficiaries may continue to use IRFs; the rule provides for 25 percent of IRF patients to have conditions not on the list. The research we discuss in this section is the first

study comparing outcomes and spending for joint replacement patients across settings.

To determine the potential effect of the change in the 75 percent rule, we convened a physician panel of orthopedic surgeons and specialists in physical medicine and rehabilitation in which they could discuss their views of differences among patients that influence the setting beneficiaries use. We also contracted with RAND to compare outcomes and Medicare spending across settings for beneficiaries who have had a hip or knee replaced. This information can help policymakers better understand the impact of the new 75 percent rule on beneficiaries and Medicare’s costs.

Physician panel

We convened a panel of six orthopedic surgeons who perform many hip and knee replacements and five specialists in physical medicine and rehabilitation who are familiar with the rehabilitation of these types of patients. Generally our panelists were affiliated with large academically oriented health care institutions located in various parts of the nation. We asked this panel to discuss where beneficiaries who have had a hip or knee replaced should be rehabilitated after surgery. We also asked the panel to discuss whether they had observed any change in practice or referral patterns since the publication of the new 75 percent rule.

The orthopedic surgeons told us that patients who have had a hip or knee replaced ideally should go home with either home health care or outpatient therapy services—between 50 percent and 85 percent of their Medicare patients go home from the hospital in two to four days following surgery. (These estimates are higher than the national rate [Table 5-1, p. 109].) The panel said that characteristics of patients who require rehabilitation in an institutional setting (IRF or SNF) are those who:

- are limited in weight-bearing ability or cannot walk 100 feet,
- are obese,
- have impairment of one or more joints (other than the one replaced),
- have diminished presurgery functioning,
- have comorbidities, such as congestive heart failure or post-operative dementia,

- have architectural barriers at home, or
- have no informal caregiver.

Weight-bearing ability is an important predictor of how fast patients recover after surgery, and it may even determine whether the patient makes progress. Obesity also affects a patient's ability to bear weight. The panel unanimously questioned the appropriateness of a BMI of 50 as a criterion for joint replacement patients who are obese to be counted in the 75 percent rule. The panelists thought that beneficiaries with a BMI of 50 or more would not be able to tolerate the intense rehabilitation provided in IRFs. Thus, in the panelists' opinion, the standard excluded all obese persons who might benefit from IRF care. Some panelists thought a BMI of 38 was a more appropriate standard.

Regarding the question of whether patients with the need for rehabilitation in an institutional setting should go to an IRF or a SNF, the orthopedic surgeons felt that joint replacement patients could go to SNFs, although SNFs would not rehabilitate patients as quickly as IRFs. The panelists also agreed that certain circumstances cause IRFs to be more appropriate. For example, when a patient has comorbidities, he may benefit from the extra medical attention that an IRF provides. However, if a patient cannot stand the intense therapy provided at an IRF, or if he has a weight-bearing constraint, the convalescent care of a SNF may be more appropriate.

Orthopedic surgeons in some communities decide on an IRF versus a SNF based on the characteristics of the specific facilities available. The surgeons suggested that their comfort level with facilities may reflect the level and type of staffing at the facility, whether the facility follows protocols, or even the surgeon's convenience. For example, because physicians in SNFs are usually not involved in frequent supervision of patients while physicians in IRFs are integrally involved with patients, orthopedic surgeons may prefer IRFs because they can hand off patients to an IRF's physicians with confidence that those patients would continue to receive close monitoring. One surgeon said that his practice area had neither SNFs nor IRFs. In general, surgeons said that they did not know the outcomes of patients being rehabilitated in SNFs.

The panelists maintain that the publication of the new rule defining IRFs has already affected referral patterns. They reported that some IRFs will no longer accept joint

replacement patients and that acute hospital lengths of stay (LOSs) have increased slightly as a result. Panelists told us that IRFs with a large referral base would have fewer problems meeting the new criteria, but IRFs with a smaller referral base may have greater difficulty complying. Some orthopedic surgeons also reported having developed protocols for home health agencies, so that these agencies could provide more intensive rehabilitation services to patients after hip or knee replacement.

Results from the empirical study

We contracted with researchers to study outcomes and Medicare spending for all beneficiaries who had hip or knee replacements and who were discharged from an acute hospital between January 2002 and June 2003 (see text box on p. 113 for study methods) (Beeuwkes Buntin et al. 2005).¹

The research questions in this study were:

- What are the differences among hip or knee replacement patients who use IRFs, SNFs, or go home following surgery?
- What are the differences in outcomes for these patients?
 - What are the differences in functional status?
 - What are the differences in patients residing in the community at 120 days?
- What are the differences in Medicare spending for these patients?

Differences in patient characteristics

The study found:

- About 30 percent of patients who had hip or knee replacements used SNF care following surgery, 35 percent used IRF care, and the remaining 35 percent returned home (with home health care, outpatient therapy, or no care) (Table 5-1).
- On average, patients who go home following surgery are younger, have fewer comorbidities and complications, and are less likely to be eligible for both Medicare and Medicaid than IRF patients. Compared with IRF patients, SNF patients are significantly older, have more comorbidities and complications, and are more likely to be eligible for both Medicare and Medicaid (Table 5-1).

**TABLE
5-1**

Selected characteristics of patients with hip or knee replacement

Characteristics	Site of care after surgery		
	Home	IRF	SNF
Number of observations	149,000	149,000	128,000
Percentage	35%	35%	30%
Demographic characteristics			
Age (years)	72.7	75.0	76.3**
Female	54.3%	70.2%	72.2%**
White	94.2	89.9	93.3**
Black	3.3	6.8**	4.1
Medicaid coverage	5.2	9.2	10.1**
Complications			
Postoperative pulmonary compromise	0.3	0.5	0.8**
Postoperative GI hemorrhage or ulceration	0.2	0.2	0.3**
Cellulitis or decubitus ulcer	0.3	0.5	0.8**
Septicemia	0.0	0.0	0.1**
Mechanical complications due to device or implant	0.9	1.2	1.7**
Shock or cardiorespiratory arrest	0.1	0.1	0.2**
Postoperative heart attack	0.3	0.4	0.6**
Venous thrombosis or pulmonary embolism	0.5	0.7**	0.6
Iatrogenic complications	3.4	4.0	4.7**
Comorbidities			
Acute renal failure	0.3	0.7	0.8**
Delirium	0.7	1.4	2.0**
Chronic pulmonary disease	9.1	11.2	11.8**
Congestive heart failure	3.4	5.8	7.1**
Chronic renal failure	0.1	0.2	0.2**
Nutritional deficiencies	0.1	0.2	0.4**
Dementia	0.5	0.9	2.3**
Pneumonia	0.6	0.8	1.2**
Type of joint replacement			
Hip replacement	31.2	36.1	40.0**
Total	25.8	30.1	31.0**
Partial	0.6	1.3	2.7**
Hip revision	4.8	4.8	6.3**
Knee replacement	68.5	63.9**	60.0
Total	62.5	60.0**	55.8
Bilateral procedure	1.8	6.2**	4.0

Note: IRF (inpatient rehabilitation facility), SNF (skilled nursing facility), GI (gastrointestinal). Patients who were in a custodial nursing home before or after their acute stay, who used acute rehabilitation (DRG 462), used long-term care hospitals, or died in the first 30 days after their acute discharge are excluded from this analysis. This excludes < 3% of the sample. Patients in the sample were hospitalized from January 2002 through June 2003.

** Indicates significant t-test for differences between IRF and SNF values at the 0.0001 level.

Asterisks are placed next to the higher of the values for SNF and IRF.

Source: Beeuwkes Buntin et al. 2005.

- Of beneficiaries who use institutional settings, those who have had hip replacements are more likely to go to a SNF, while beneficiaries who have had knee replacements are more likely to go to an IRF (Table 5-1, p. 109).

TABLE 5-2

Characteristics of discharging hospitals and proximity to facilities for patients with hip or knee replacement

	Site of care after surgery		
	Home	IRF	SNF
Number of observations	149,000	149,000	128,000
Percentage	35%	35%	30%
Discharging hospital's characteristics			
Nonprofit hospital	78%	76%	79% **
Government hospital	10	9	10 **
Percentage of:			
Low-income patients	12	13 **	12
Medicare days	47	47	49 **
Hospital's ADC	204	235 **	191
Resident-to-ADC ratio	0.118	0.144 **	0.110
Case-mix index	1.532	1.548 **	1.469
Patient's proximity to facility			
Average number of			
IRFs within travel radius	11	13 **	11
SNFs within travel radius	39	43	46 **
No SNFs within travel radius	0.001	0.001 **	0.001
Distance to nearest			
SNF in miles	3	2	2 **
Distance to nearest			
IRF in miles	18	11	18 **

Note: IRF (inpatient rehabilitation facility), SNF (skilled nursing facility), ADC (average daily census). Patients who were in a custodial nursing home before or after their acute stay, used acute rehab (DRG 462), used long-term care hospitals, or died in the first 30 days after their acute discharge are excluded from this analysis. This excludes < 3% of the sample. Patients in the sample were hospitalized from January 2002 through June 2003.
 ** Indicates significant t-test for differences between IRF and SNF values at the 0.0001 level.
 Asterisks are placed next to the higher of the values for SNF and IRF.
 Travel radius is defined as the 90th percentile of the distance traveled to a type of provider by beneficiaries living in that type of area.

Source: Beeuwkes Buntin et al. 2005.

- On average, IRF patients come from acute hospitals that are larger, have a higher case-mix index, and are more likely to be teaching hospitals (Table 5-2).
- Distance to a facility may be a factor in determining site of care. On average, patients who use an IRF have one that is relatively close to their residence (Table 5-2).

Differences in outcomes

In this section, we discuss differences in functional status for SNF and IRF patients, mortality, and residence in the community. IRFs and SNFs measure functional status close to or at admission for their patients. Patients who go home with outpatient therapy or with no care do not have their functional status assessed.

The preferred outcome—improvement in functional status—is not assessed for most SNF patients. Because SNFs do not assess patients' functional status at discharge, researchers compared functional status at admission and discharge (or at 14 days) for patients who stayed in the IRF or the SNF at least 14 days.² Researchers created a measure of functional status similar to the Barthel Index (Mahoney and Barthel 1965) and mapped from the SNFs and IRFs assessment tools to the index. As discussed in the section on patient assessment instruments, clinicians use these tools to ask different questions and assess patients at different times during their post-acute stay, so the quasi-Barthel Index may not be comparable. As a result, researchers also examined patients' independence in walking and in transfer (for example, from a bed to a chair).

Descriptive analysis Based on descriptive statistics that do not control for differences in patient characteristics and potentially measure IRF and SNF patients at different points in their stay, SNF patients have a higher functional status score at admission than IRF patients. But SNF patients with a 14-day or longer stay have lower functional status scores than IRF patients discharged from the facility at 14+ days (Table 5-3).

Walking—Of patients who were discharged at 14+ days after admission, 1 percent of IRF patients were walking independently at admission but 76 percent were walking independently at discharge. For SNF patients in the facility at 14+ days after admission, 9 percent were walking independently at admission but 31 percent were walking independently at 14 days (Table 5-3).

**TABLE
5-3**

**Functional status outcomes
for patients with hip or
knee replacement**

Site of care after surgery

	IRF	SNF
Functional status for all patients		
Mean score on Barthel Index at admission (0–90)	46	55 **
Percentage of patients:		
Walking independently at admission	10 %	20 %**
Transferring independently at admission	11	16 **
Functional status for patients with 14+ day stay†		
Mean score on Barthel Index (0–90):		
at admission	35	47 **
at discharge	65 **	58
Percentage of patients:		
Walking independently at admission	1 %	9%**
Walking independently at discharge/14+ days	76 **	31
Transferring independently at admission	2	8 **
Transferring independently at discharge/14+ days	79 **	30

Note: IRF (inpatient rehabilitation facility), SNF (skilled nursing facility). Patients who were in a custodial nursing home before or after their acute stay, used acute rehabilitation (DRG 462), used long-term care hospitals, or died in the first 30 days after their acute discharge are excluded from this analysis. This excludes < 3% of the sample. Patients in the sample were hospitalized from January 2002 through June 2003. ** Indicates significant test for differences between IRF and SNF values at the 0.0001 level. Asterisks are placed next to the higher of the two values. Barthel Index (Mahoney and Barthel 1965) created by mapping functional status items from assessment instruments used in SNFs and IRFs. Higher scores on Barthel Index mean greater independence in functional status. † Indicates discharge from IRFs; 14+ days means SNF patients assessed at 14 days.

Source: Beeuwkes Buntin et al. 2005.

Transferring—Of patients who were discharged at 14+ days after admission, 2 percent of IRF patients were transferring independently at admission but 79 percent were transferring independently at discharge. For SNF patients in the facility at 14+ days after admission, 8 percent were transferring independently at admission but 30 percent were transferring independently at 14 days (Table 5-3).

Multivariate analysis As noted in the descriptive analyses, there is a great deal of selection of patients into the three settings (IRF, SNF, and home). Thus it is critically important to control for both observed and unobserved selection. The importance of controlling for selection effects is demonstrated by the results from an unadjusted regression model that shows that SNF patients are 2.7 percentage points more likely to be dead or institutionalized at 120 days after discharge from an acute hospital as compared with patients going home (Table 5-4, p. 112). The difference declines to 1.2 percentage points in the model adjusted for observable patient characteristics. The difference declines further to 0.46 percentage points in an instrumental variable (IV) model that is designed to capture unobserved selection effects.

Using IV models, researchers found that compared with patients who went home after surgery, patients who used IRFs and SNFs are more likely to be dead or institutionalized 120 days after discharge from an acute hospital by 0.18 and 0.46 percentage points, respectively (Table 5-4, p. 112). It is important to note that neither IRFs nor SNFs have a significant statistical effect when mortality by itself is the outcome; therefore, the effect appears to be operating through institutionalization alone.

The IV models provide the best estimates of the causal effect of post-acute care on outcomes, but the researchers were unable to rule out the possibility that some selection remains in these estimates. Outcomes depend on many factors, including patients’ physical and cognitive abilities, underlying medical conditions, sensory and emotional factors, willingness to participate in care, and supportive environments. No risk adjustment approach can control for every factor affecting outcomes of care (Iezzoni 2003). The choice of IVs was carefully considered to address this problem, but the estimates could be biased if the instruments are invalid. Another limitation of the study is that the outcomes analyzed are not the ideal outcomes for patients who have had hip or knee replacements. The preferred outcomes analysis would examine changes in patients’ functional status, but the data are not available for all patients.

Differences in Medicare payments

Instrumental variable analyses show that IRF patients cost Medicare more than patients who go home and more than patients who use SNFs. Patients who use IRFs cost about \$8,000 more in Part A spending than those who go home after surgery, and patients who use SNFs cost about

**TABLE
5-4**

Outcomes for patients with hip or knee replacement

Outcome	Unadjusted model	Adjusted for patient characteristics			Instrumental variable model		
	Marginal effect	Marginal effect	Standard error	P-value	Marginal effect	Standard error	P-value
Dead or institutionalized at 120 days after discharge							
IRF vs. home after surgery	0.0058	0.0043	0.0004	0.00**	0.0018	0.0009	0.04*
SNF vs. home after surgery	0.0267	0.0120	0.0005	0.00**	0.0046	0.0008	0.00**
Dead at 120 days after discharge							
IRF vs. home after surgery	0.0030	0.0020	0.0003	0.00**	0.0016	0.0012	0.18
SNF vs. home after surgery	0.0089	0.0038	0.0003	0.00**	0.0023	0.0012	0.06
Part A PAC payments							
IRF vs. home after surgery	\$9,959	\$9,050	\$31	0.00**	\$8,298	\$68	0.00**
SNF vs. home after surgery	6,028	4,685	33	0.00**	3,704	61	0.00**
Part A payments (PAC payments + acute stay)							
IRF vs. home after surgery	\$10,204	\$8,871	\$33	0.00**	\$8,023	\$70	0.00**
SNF vs. home after surgery	6,116	4,590	35	0.00**	3,578	63	0.00**

Notes: IRF (inpatient rehabilitation facility), SNF (skilled nursing facility), PAC (post-acute care). Marginal effect is the change in predicted probability associated with changes in the explanatory variables. Post-acute payments are accumulated for 120 days after discharge from the acute hospital. Patients in the sample were hospitalized from January 2002 through June 2003.

* Indicates significance at the 0.05 level. ** Indicates significance at the 0.0001 level.

Source: Beeuwkes Buntin et al. 2005.

\$3,600 more in Part A spending than those who go home after surgery (Table 5-4).³ Payment rates differ widely for patients who are rehabilitated in IRFs versus SNFs. Medicare pays IRFs on a per-case basis but pays SNFs on a per-diem basis. Because of these different payment units, it is not straightforward to compare, but in general, Medicare pays IRFs more. The costs reported here are incomplete because we do not include payments to physicians or payments for outpatient therapy in the spending comparisons. These results also highlight the importance of controlling for selection effects, although controlling for selection had a small effect in the payment models compared with the outcome models.

Discussion

We undertook this study to determine the impact the new 75 percent rule might have on beneficiaries and the

Medicare program. The evidence is not definitive. Some descriptive and multivariate results suggest that marginal patients may be institutionalized more frequently when they use SNFs rather than IRFs, and more frequently in both of these settings compared with those going home. But the fact that patients going home after surgery do better than those in either SNFs or IRFs suggests that patient selection is strongly present in these data and we cannot fully discount its effects. (See text box for a description of study methods.)

In general, the results from the models show that in terms of Part A costs, episodes in an IRF or SNF are much more costly for Medicare than for episodes of care among patients going home. The results also show that payments for episodes of care involving IRF care are much higher than episodes of care involving SNF care, even after controlling for characteristics of patients and discharging acute hospitals.

Study methods for multivariate analyses

In this study sample, RAND included all elderly Medicare beneficiaries who underwent a hip or knee replacement with no preceding hip fracture and who were discharged from an acute hospital between January 2002 and June 2003 (Beeuwkes Buntin et al. 2005). Researchers defined “post-acute location” as the first Medicare-covered site in which the patient received care within 30 days of discharge from an acute hospital. Excluded from the sample were the following types of patients, who made up less than 3 percent of the total:

- patients who died in the hospital or within 30 days of discharge (<1 percent);
- patients who received custodial care in nursing homes before or after their admission to the acute hospital;
- patients discharged to long-term care hospitals from acute hospitals;
- beneficiaries who enrolled in HMOs within four months of discharge; and
- patients who had incomplete personal information or missing discharge hospital characteristics.

Independent variables

Researchers at RAND included a wide array of independent variables that they expected would affect beneficiaries’ choice of post-acute care. Examples of individual predictors are age, gender, race, Medicaid enrollment, and place of residence. To capture the complexity of patients at the time of hospital discharge, researchers included a large set of comorbidities and complications tailored to joint replacement patients. To capture factors that may influence post-acute use, researchers used variables from the acute hospital, such as average daily census, teaching status, ownership, Medicare share, case-mix index, and low-income patient percentage. Researchers defined availability of post-acute care based on how close inpatient rehabilitation facilities (IRFs) and skilled nursing

facilities (SNFs) were to patients’ homes and how many of each type of facility were located within reasonable distances of patients’ homes.

Outcomes

Researchers examined descriptive statistics on health outcomes: residency in a nursing home at 60 days and 120 days; and death within 60 days and 120 days of their acute hospital discharge. Researchers combined the institutionalization and mortality variables into composite measures to avoid the bias associated with using variables for survivors only.

Payments

Researchers adjusted payments for area wage differences. They created summary variables for total post-acute care payments and total episode payments. The total episode payments combined payments for the acute hospital stay and total post-acute payments.

Multivariate analyses

Researchers used multivariate analyses to estimate how the site of care affected outcome measures. Multivariate analysis controls for observable differences in the patient population at each site of care—differences that might confound estimates of the site’s effect on outcomes. In all models, researchers control for the individual predictors, clinical predictors, and characteristics of discharging hospitals.

Instrumental variables analyses

Researchers frequently use instrumental variable (IV) methods to remove the estimates of confounding due to unobservable characteristics. RAND used measures of post-acute care availability as instruments. Because these factors are not correlated with beneficiaries’ clinical needs, researchers use them to predict use of IRFs and SNFs, and thus to infer the effect on outcomes for a marginal patient. Researchers typically use IV methods to control for the effects of selection bias, but these methods do not always capture all these effects. Beeuwkes Buntin and colleagues (2005) provide more information on methods. ■

As discussed above, functional status is the ideal measure of outcomes for patients who have had a hip or knee replaced. To determine the effect—on beneficiaries and on the program—of using different sites of care for rehabilitation after hip or knee replacement, we would need to compare functional status, walking, and transfer across settings. One major problem in comparing these measures is that SNFs do not assess patients' functional status at admission and discharge. For this and other reasons, we recommended in our March 2005 *Report to the Congress* that CMS collect information on functional status at admission and discharge.

Comparing the patient assessment tools used in post-acute care settings

Policymakers need uniform data to monitor and evaluate the quality of care and patient outcomes across post-acute settings. Comparing post-acute patients across settings will likely require CMS to construct a new assessment tool that includes valid and reliable measures that use consistent definitions, timeframes, and scales across the post-acute settings.

Common information across the post-acute sites is currently not available. Medicare requires three of the four settings—home health agencies (HHAs), SNFs, and IRFs—to use tools to assess patients, but each setting uses a different tool. LTCHs are not required to use a tool to assess patients. Because the information gathered by clinicians differs across settings, it is not possible for CMS to (a) compare the care needs or outcomes of patients who are treated by different types of providers or (b) consider this information when designing an integrated post-acute care payment system.

In this section, we compare the information gathered by clinicians using each patient assessment tool. For dimensions that are similar, we assess the aspects and definitions of the care that the tools evaluate, the time periods that the tools cover, and the measurement scales that the tools use. We found that although the tools have four aspects of care in common, the definitions of care included in the measures, the timeframes covered, and the scales used to differentiate patients vary considerably. The differences among the tools limit how easily and meaningfully we can consolidate these data and whether we can evaluate patient outcomes across settings.

Conducting the patient assessments

Medicare requires that clinicians in three post-acute settings evaluate patients using specific assessment tools (Table 5-5):

- The Minimum Data Set (MDS) must be used in SNFs.
- The Outcome and Assessment Information Set (OASIS) must be used in HHAs.
- The IRF–Patient Assessment Instrument (IRF–PAI) must be used in IRFs.

Medicare does not require LTCHs to use a patient assessment tool. However, many LTCHs assess their patients' care needs using the Acute Physiology and Chronic Health Evaluation (APACHE) and the Functional Independence Measure (FIM™). Last year, the Commission discussed the need for all LTCHs to use the same patient assessment tool as part of a review process for all admissions (MedPAC 2004).

CMS developed the three instruments independently and for different purposes. The IRF–PAI, the shortest instrument, was designed to evaluate and monitor outcomes of rehabilitation. The OASIS was originally a quality measurement instrument. Because clinicians furnish home health care in a noninstitutional setting, the OASIS also assesses a patient's ability to function at home. CMS developed the MDS to ensure that each beneficiary regularly received a comprehensive assessment and care plan designed specifically for him or her. Originally designed as a care-planning tool for long-stay patients, many of MDS's elements are not useful for classifying and assessing short-stay SNF patients (MedPAC 2003).

Partly reflecting these different purposes, the tools vary considerably in how frequently clinicians administer them and the time period that the assessment covers; the type of clinician who conducts the assessment, the method they use, and how long the assessment takes; and the scales that the tools use to differentiate patients.

Assessment timeframes vary

The tools differ in terms of when a clinician conducts the assessment during a patient's course of treatment. SNFs conduct patient assessments within five days of admission and at specific intervals thereafter, but not necessarily on the day of admission or discharge. In contrast, clinicians

in HHAs and IRFs conduct the assessments primarily at admission and discharge. SNFs' lack of assessments at admission and discharge poses particular problems for evaluating these patients' outcomes. Most SNF patients do not stay long enough (14 days minimum) to be assessed a second time, making it impossible to measure patient outcomes. In March, MedPAC recommended that CMS collect information about activities of daily living (such as the ability to walk)—one of the common measures used to assess patients—at admission and discharge in SNFs (MedPAC 2005).

The period of time reflected in the measures varies considerably across the instruments. The time period covered by many of the functional status measures in the MDS is the previous seven days, compared with a single point in time captured in the IRF-PAI and the OASIS. As a result, even identical aspects of a patient could reflect differing patient characteristics or abilities at a given point

in time. For example, an assessment of a wound infection in a beneficiary at a SNF could mean that the patient had a wound infection within the past seven days, whereas in an IRF, this assessment would mean that the infection was present at time of admission.

Assessment methods vary

The tools also differ in terms of the types of caregivers who may conduct the patient assessments and how the assessor gathers the information. As a result, clinicians may assess similar patients differently. In the MDS, clinicians may gather information from direct observation, interviews with multiple caregivers (including nurses, aides, and therapists), and review of patient care documentation. Direct patient observation is the preferred method of gathering information for the OASIS and IRF-PAI, but both instruments allow a combination of direct observation and reported performance (including

TABLE 5-5

Frequency, time period covered, and measurement scales differ across post-acute patient assessment tools required by Medicare

Dimension	Skilled nursing facilities	Home health agencies	Inpatient rehabilitation facilities	Long-term care hospitals
Tool	MDS	OASIS	IRF-PAI	None
Frequency of assessments	Initial (day 1–8); day 14; day 30; and every 30 days, up to day 100.	Initial at admission; every 60 days thereafter; and at discharge.	At admission and discharge.	
Time period covered	Generally 7-day look-back.	Status of patient on day of assessment.	Status on day 3 (for admission) and at discharge.	
Method of assessment	Information gathered from multiple caregivers' descriptions and documentation. Direct observation not required.	Direct observation preferred, but also often used interviews with patient, in-home caregiver.	Direct observation preferred but can be combined with reported performance.	
Minutes to complete	90 minutes ^a	90 minutes ^b	25 minutes ^c	

Note: MDS (Minimum Data Set), OASIS (Outcome and Assessment Information Set), IRF-PAI (Inpatient Rehabilitation Facility–Patient Assessment Instrument).

^a CMS 2002.

^b St. Pierre 2005.

^c Buchanan et al. 2003.

Source: MedPAC analysis of patient assessment tools.

patient interviews). The IRF–PAI requires that facilities train their assessors to use the instrument; this training may increase the reliability of different assessors’ ratings.

The tools also require very different amounts of staff time to complete. The IRF–PAI is the shortest form (taking an estimated 25 minutes), while the OASIS and the MDS take an estimated 90 minutes.⁴ A shortened version of the MDS can be submitted to update a beneficiary’s condition, but a full MDS must be completed within 14 days of admission.

Assessment scales differ

The measurement scales used by the different tools vary in several ways, making it difficult to compare the information gathered with the tools. First, the number of points on the scales varies, thus resulting in differing distinctions between patients. For example, the MDS uses a four-point scale to evaluate many aspects of functional status, whereas the IRF–PAI uses a seven-point scale. Even for a task such as bathing, which is relatively similar in definition across settings, each tool codes the degree of assistance that patients require differently. For example, the MDS defines “independent” patients as those who use assistive devices without help while walking or eating. In contrast, the OASIS instrument distinguishes between “complete” and “modified” independence. If categories were collapsed, some of the detail currently collected would be lost.

Second, the scales can measure different aspects of a task, such as independence in performing an activity. For example, in the task of dressing, the gradations in the IRF–PAI scale refer to the share of the individual tasks

that the patient performs, whereas the MDS scale measures the number of times a patient needs assistance and whether assistance involves any weight bearing.

Third, the scorings across settings do not always distinguish between verbal cues (such as encouragements or reminders) and physical assistance (such as guided maneuvers or weight-bearing support needed to accomplish a task). The MDS and the IRF–PAI generally differentiate the types of help needed, but the OASIS typically does not.

Only one of the tools—the MDS—separately records (a) the typical amount of help that patients need and (b) the most help that patients need in their most dependent state. In contrast, the IRF–PAI and OASIS instruments capture a patient’s status at one point in time, which neither MDS measure captures.

Common dimensions of care assessed differ across tools

The tools that Medicare requires have four common dimensions that clinicians assess for every patient: (1) diagnoses, (2) comorbidities, (3) functional status, and (4) cognitive status. But within each dimension, the aspects of care that clinicians evaluate vary considerably across the three tools.

Diagnoses and comorbidities

Of the four dimensions, researchers generally find diagnoses and comorbidities the simplest to compare across settings. Yet little consistency exists in the recording of diagnostic information. MDS currently does not gather International Classification of Diseases,

**TABLE
5-6**

Patient assessment tools do not consistently use diagnosis codes

Dimension	MDS	OASIS	IRF–PAI
ICD–9–CM codes	Not used	3 digits	5 digits
Number of diagnoses reported	Unlimited items can be checked off a set list	Primary +5 secondary diagnoses	Impairment category +10 comorbidities

Note: ICD–9–CM (International Classification of Diseases, Ninth Revision, Clinical Modification), MDS (Minimum Data Set), OASIS (Outcome and Assessment Information Set), IRF–PAI (Inpatient Rehabilitation Facility–Patient Assessment Instrument). Impairment categories are broad clinical categories used by the prospective payment system for inpatient rehabilitation facilities. Examples include traumatic and nontraumatic spinal cord injuries, stroke, and traumatic and nontraumatic brain injuries.

Source: MedPAC analysis of patient assessment tools.

Ninth Revision, Clinical Modification (ICD–9–CM) codes and instead uses checkoff lists for diagnoses and health problems (Table 5-6). The OASIS requires that only three of the five digits of the ICD–9–CM codes be completed (where the first three digits refer to a broad condition and the last two digits add specificity), thus limiting patient comparisons. In administering the IRF–PAI, clinicians may collect up to 10 comorbid conditions using ICD–9–CM codes, but the basic patient classification system requires a special “look-up” table to match “impairment groups” to ICD–9–CM codes. Before patients treated in IRFs can be compared with patients treated in other settings, the impairment group for each IRF patient needs to be mapped to an ICD–9–CM code.

The lack of uniform ICD–9–CM coding also limits the comparison of the severity of patients treated in different settings. Severity measurement systems, such as the all patient refined diagnosis related group (APR–DRG), require five-digit ICD–9–CM coding to differentiate among patients. Because SNFs do not gather ICD–9–CM codes, the severity of their patients’ diseases cannot be assessed. Furthermore, although the OASIS does not gather complete ICD–9–CM code information, it asks clinicians to rate each diagnosis on a four-point severity scale. While these ratings can assess the severity of patients within HHAs, they do not help with comparisons across settings.

Functional status

Despite many similarities in the aspects of functional status that are assessed by the tools, the definitions of the activities vary considerably. All three tools assess a patient’s ability to walk, transfer (e.g., the ability to move between bed and chair), eat, dress, use a toilet, and do personal grooming. Yet within each category of care, the definition of the care the clinician evaluates varies across the tools—this variation could translate into meaningful differences in the patient’s care needs (Table 5-7). For example, in assessing a patient’s ability to walk, the IRF–PAI rates the distances the patient walks, whereas the MDS evaluates the amount of assistance the patient needs to walk within his or her room, down the hall, or to a different part of the facility. In assessing toilet use, one tool considers only the patient’s ability to get to and from the toilet, while another considers other aspects of toilet use but specifically excludes this one. The OASIS is the only tool that assesses the beneficiary’s ability to perform instrumental activities of daily living (such as housekeeping and meal preparation), reflecting the noninstitutional setting of this care.

Researchers who compared the functional status dimensions of MDS, OASIS and the FIM™ (which formed the basis of the IRF–PAI) found that although each measure was well suited for measuring patient status within its setting, none was well equipped to monitor the quality and outcomes across post-acute settings (Jette et al. 2003).

TABLE 5-7

Examples of the differences in functional status measures included in post-acute patient assessment tools required by Medicare

Dimension	MDS	OASIS	IRF-PAI
Walking	Amount and type (e.g., weight bearing or encouragement) of assistance required.	Ability to walk or to use a wheelchair on a variety of surfaces.	Distance walked.
Toilet use	Various aspects of toileting including transfer on and off toilet. No mention of getting to/from toilet.	Ability to get to and from toilet.	Various aspects of toileting but excludes transfer on and off toilet. No mention of getting to and from toilet.

Note: MDS (Minimum Data Set), OASIS (Outcome and Assessment Information Set), IRF–PAI (Inpatient Rehabilitation Facility–Patient Assessment Instrument).

Source: MedPAC analysis of patient assessment tools.

Cognitive status

The cognitive status of patients is the assessment item that varies most across the three tools. Not only does the range of measures vary considerably, but measures of the same dimension of cognitive ability are also quite different (Table 5-8). For example, the MDS evaluates 13 aspects of cognitive status, including 6 measures for delirium and 16 for depression. The OASIS records information about 5 indicators of depression, while the IRF–PAI does not directly ask about it. The tools do not consistently require clinicians to separately record behaviors (such as wandering, or physically or verbally disruptive behavior) that may influence the amount of staff assistance required. Three measures in the IRF–PAI—short-term memory, social interaction, and problem solving—are broad and

could span considerable differences in patients and their resource requirements.

In addition to differences in measurement, differences in the definitions of cognitive status across the tools also exist. Although each tool evaluates the patient’s ability to make decisions, examples of the types of decisions patients should be able to make to be considered “independent” vary widely across the tools. For example, the MDS assesses a patient as independent if she can make decisions to organize her daily routine (such as knowing when to go to lunch and picking out clothing). By comparison, the IRF–PAI distinguishes between complex and routine decisions. The IRF–PAI assesses a patient as independent if she can solve complex problems such as managing a checking account.

**TABLE
5-8**

Wide range in cognitive status measures evaluated by patient assessment tools

MDS	OASIS	IRF-PAI
<p>Comatose</p> <ul style="list-style-type: none"> Comatose (yes/no) 	<ul style="list-style-type: none"> Comatose not reported 	<ul style="list-style-type: none"> Comatose (yes/no)
<p>Memory</p> <ul style="list-style-type: none"> Memory: short- and long-term Memory recall ability Cognitive skills for daily decision making Indicators of delirium (6 elements) 	<ul style="list-style-type: none"> Cognitive functioning (includes alertness, orientation, concentration, and immediate memory for simple commands) Frequency of confusion 	<ul style="list-style-type: none"> Short-term memory Problem solving Delirium (yes/no)
<p>Communication</p> <ul style="list-style-type: none"> Making oneself understood Ability to understand others 	<ul style="list-style-type: none"> Ability to express oneself Ability to hear and understand spoken language 	<ul style="list-style-type: none"> Expression Comprehension
<p>Depression</p> <ul style="list-style-type: none"> Indicators of depression, anxiety, sad mood (16 elements) Mood persistence Behavioral symptoms (such as wandering, or verbally or physically abusive behavior) 	<ul style="list-style-type: none"> Depressive feelings reported or observed (5 elements) Frequency of anxiety Behavior demonstrated (includes verbal disruption, physical aggression, socially inappropriate behavior) and frequency. 	<ul style="list-style-type: none"> Social interaction
<p>Other</p> <ul style="list-style-type: none"> Sense of involvement Unsettled relationships Past roles 		

Note: MDS (Minimum Data Set), OASIS (Outcome and Assessment Information Set), IRF–PAI (Inpatient Rehabilitation Facility–Patient Assessment Instrument).

Source: MedPAC analysis of patient assessment tools.

Extensive data collection required to classify patients in Medicare's post-acute PPSs

Medicare's four prospective payment systems (PPSs) for post-acute care use many data elements to classify patients into payment groups.

Diagnoses and clinical characteristics

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes; rehabilitation impairment codes; change in weight; urinary and bowel incontinence; impaired vision; frequency of pain; skin condition (surgical wounds/lesions, number and stage of pressure ulcers); age; sex

Functional status

Activities of daily living—dressing, bathing, transferring, toileting, ambulation and locomotion, bed mobility, grooming, bladder and bowel control

Cognitive status

Comatose, memory, decision making, comprehension, communication, social interaction, depression, verbal/physically abusive or disruptive behavior, hallucinatory/delusional/paranoid

Services provided

Rehabilitation therapy, intravenous/infusion therapy, total parenteral nutrition, intravenous feeding, daily injections for diabetes, chemotherapy, dialysis, respirator/ventilator support, tracheostomy care, oxygen therapy, suctioning, transfusions, radiation therapy, amputation and prosthesis care, range of motion, physician visits

Other

Preceding inpatient hospital, rehabilitation facility, or skilled nursing facility stay; total charges; discharge status ■

Building a uniform patient assessment tool

MedPAC's analysis shows that the current assessment tools that Medicare requires do not collect information that is easily and meaningfully integrated. If CMS were to build on the existing patient assessment tools, the data would still not be consistent due to the large differences in timeframes, scales, and many of the definitions. Furthermore, the current post-acute PPSs together require considerable information to establish payments (see text box).

In designing a new patient assessment tool, data elements should be selected so that CMS can establish payments and evaluate patient outcomes across all four post-acute settings. CMS has started this process (see text box, p. 120). Data elements need to predict resource use; capture relevant clinical data; be reliable, valid, and well accepted; and minimize the burden to providers and CMS. In addition to evaluating elements of the patient assessment tools currently required by Medicare, the merits of other assessment tools (such as the Mini-Mental

State Examination, the APACHE, and the Nursing Severity Index) should be considered.

Ideally, hospital discharge planners would use a uniform patient assessment tool to assess patients (and whether they can go home safely) prior to discharge from the acute hospital, identify the most appropriate post-acute setting(s), and discuss the placement option(s) with the beneficiary. Until a uniform tool is routinely collected, the Commission will consider the idea of using site-specific admission criteria to place patients in the most appropriate post-acute settings. In 2004, MedPAC recommended that CMS develop patient and facility criteria to ensure that patients treated in LTCHs are medically complex and have a good chance of improvement (MedPAC 2004). In 2005, the Government Accountability Office (GAO) recommended that CMS develop more specific descriptions of the patients appropriate for IRFs (GAO 2005). Expanding on these ideas, establishing setting-specific criteria could delineate the service capabilities and staffing levels for the provider, and could identify the clinical characteristics (including functional status) and resource needs of the patients.

Assessing the skilled nursing facility PPS

In this section, we review concerns with the resource utilization group, version III (RUG–III) system. We begin by explaining how the classification system functions as a case-mix system to adjust SNF payments for patients with higher- and lower-than-average resource use. We then discuss problems with the payment system that stem from how the case-mix system (1) does not adequately distribute payment for nontherapy ancillary (NTA) services and (2) categorizes patients based on the amount of services SNFs provide or expect to provide. Next, we discuss payment system concepts that may address each of these problems. We conclude with a description of possible directions for future work to improve the SNF payment system.

How does the current PPS buy SNF services?

Medicare’s SNF benefit covers SNF care for beneficiaries who, following an inpatient hospital stay of three or more days in the month preceding the SNF admission, need skilled nursing care. The SNF payment system pays hospital-based and freestanding SNFs a case-mix adjusted daily rate for up to 100 days of care per beneficiary. However, almost 60 percent of SNF stays lasted just 20 or fewer days in 2001, and only about 9 percent of covered SNF stays were longer than 60 days (Figure 5-2). The mean covered LOS for all Medicare-covered SNF stays was about 24 days. In 2003, Medicare paid \$14 billion for about 57 million days of SNF care.

CMS activities to develop a uniform assessment tool

The Medicare, Medicaid, and State Children’s Health Insurance Program Benefits Improvement & Protection Act of 2000 (BIPA) instructed the Secretary to report by January 2005 on the development of an instrument to assess the health and functional status of beneficiaries who use post-acute services. BIPA required developers to create an instrument that would collect data that are readily comparable and to gather only the information necessary to meet program objectives. To date, CMS has not developed the instrument.

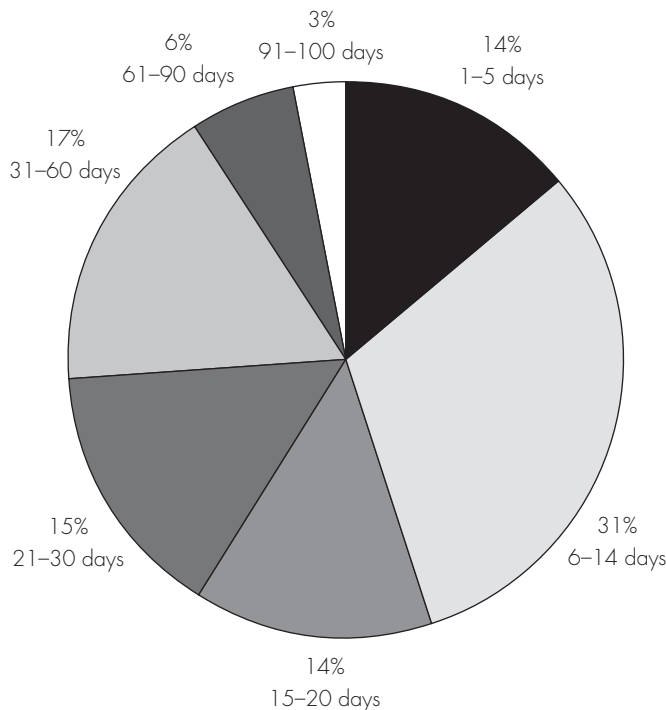
Although CMS has not focused on the development of an assessment tool, it has pursued the more fundamental task of examining the consistency of the definitions and terms used to evaluate the quality of post-acute care. With an eye toward adopting standard terminology to encourage the use of clinical information technology, CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the Department of Health and Human Services have collaborated to examine the consistency of vocabulary terms and definitions that describe key aspects of patient condition, such as “functional status.” In a recent study, ASPE found that one medical terminology system—Systematized Nomenclature of Medicine—included many of the terms experts said were needed to assess the quality in nursing homes in three domains:

pain management, incontinence, and pressure ulcers (ASPE 2003). However, this study also found that the Minimum Data Set (MDS)—the only tool examined—did not adequately gather the data elements the experts said were necessary to evaluate these aspects of care. In addition, the researchers of the study reported that most of the information the MDS gathered was not covered by any of the three medical terminology languages examined—this lack of coverage would seriously limit the meaningful integration or exchange of these data. An ASPE-led group of federal agencies involved with disability (such as the Veterans Administration and the Social Security Administration) also concluded that no standardized terminology provided sufficient coverage of the functional status concepts needed by the federal government, including the functional status concepts reflected in the three post-acute assessment instruments.

In a separate study, ASPE also examined the use of advanced electronic health records (EHRs) in skilled nursing facilities (SNFs). In a set of site visits to SNFs that have state-of-the-art electronic health records, ASPE found that SNFs typically did not integrate information stored in the EHR and the patient assessment tools. As a result, the detailed clinical information housed in the EHR was not available to the patient assessment tool, and vice versa. ■

FIGURE 5-2

Distribution of SNF stays, by length of stay, in 2001



Note: SNF (skilled nursing facility).

Source: MedPAC analysis of SNF stay file for SNF admissions in 2001.

The SNF daily rate consists of two component base rates—one for nursing and one for therapy—that are case-mix adjusted up or down depending on the patient’s relative resource use. Under a PPS, adjusting the base payment rates for case mix gives providers equal incentives to treat patients who require different levels of resources. CMS developed the nursing and therapy base rates from 1995 SNF costs inflated to 1998 (the first year of the PPS phase-in for SNFs) according to rules prescribed in the Balanced Budget Act of 1997 (BBA).

Medicare’s payment system adjusts SNF nursing and therapy base rates for expected resource use employing weights associated with the each of 44 RUG–III categories. The 44 groups fall into 7 major categories: (1) rehabilitation, (2) extensive services, (3) special care, (4) clinically complex, (5) impaired cognition, (6) behavior only, and (7) reduced physical function. For rehabilitation groups, the payment system applies associated nursing and therapy indexes to the nursing and therapy base payment rates to adjust for relative resource

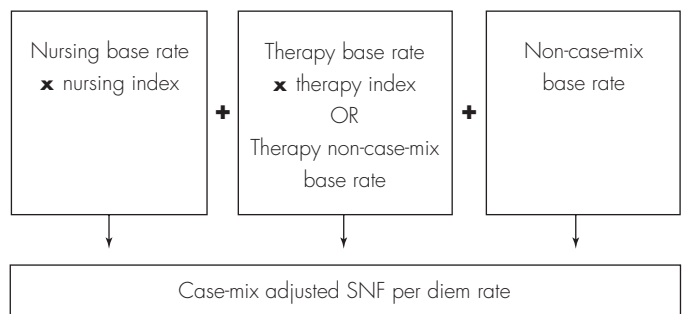
use of each category (Figure 5-3). The nonrehabilitation groups have a constant component for therapy instead of an adjusted therapy base rate. All RUG–III also have a constant “non-case-mix component” to cover costs that the payment system considered to be uniform across all patients, such as room and board. Once the base rates have been adjusted for case mix, the payment system adjusts a portion of the payment for geographic differences in labor costs using the hospital wage index.

The payment system’s assignment of a beneficiary to a RUG–III category is based on the number of minutes of therapy (physical, occupational, or speech) that the patient has used or is expected to use; the need for certain services (e.g., respiratory therapy or specialized feeding); the presence of certain conditions (e.g., pneumonia or dehydration); an index based on the patient’s ability to perform independently four activities of daily living (ADLs) (eating, toileting, bed mobility, and transferring); and in some cases, signs of depression. As we discussed earlier in this chapter, the payment system’s assignments of SNF patients to case-mix groups are determined by the SNFs’ required periodic patient assessments using the MDS. SNF staff assess patients using the MDS at the 5th, 14th, 30th, 60th, and 90th day of their stay. The assessment at day 5 determines Medicare payment for days 1 through 14 of the stay; assessment at day 14 determines Medicare payment for days 15 through 30 of the stay, and so on.

The first decision that determines a patient’s RUG–III assignment is whether that patient receives or is expected to receive at least 45 minutes of therapy per week (Figure 5-4, p. 122). If patients meet this therapy

FIGURE 5-3

Determining case-mix adjusted SNF payment rate



Note: SNF (skilled nursing facility).

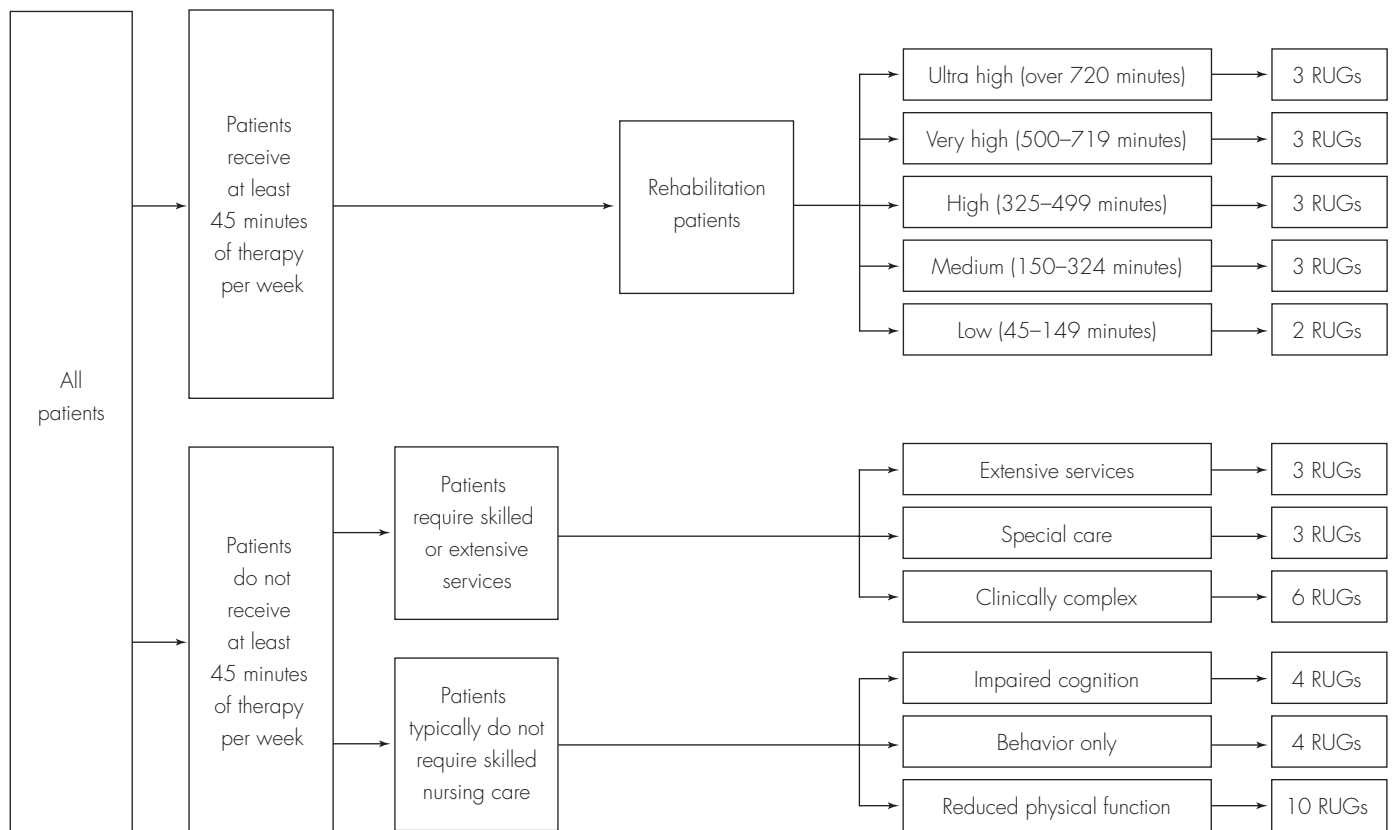
threshold, the classification system places them into one of 14 rehabilitation RUG–IIIs based on the number of therapy minutes per week, types of therapy, and ADL score. On the first MDS assessment, a patient can be categorized into a high, medium, or low rehabilitation group using an estimate of the amount of therapy that will be provided, rather than the actual amount provided, during the first two weeks. To be classified into one of the ultra high or very high rehabilitation groups on the first MDS assessment, patients must actually have received the minimum amount of therapy for a given group at the time that the SNF completes the patient assessment. For all subsequent assessments, the beneficiary must have already received the minimum amount of therapy that defines a group in order to be categorized in that group (GAO 2002).

The classification system categorizes patients who do not receive 45 minutes of therapy per week—but who have certain characteristics and still require skilled care—into the extensive services, special care, or clinically complex groups. Medicare typically does not reimburse SNFs for patients in the bottom three RUG–III categories because they usually do not require skilled care. CMS decides to reimburse for patients in these categories on a case-by-case basis.

The RUG–III system is hierarchical; beneficiaries may qualify for multiple categories, but the classification system assigns them to the highest payment category for which they qualify. For example, a patient could meet the criteria for being classified in an extensive-care RUG–III but could also receive enough therapy to be classified into

FIGURE 5-4

RUG–III classification scheme



Note: RUG–III (resource utilization group, version III).

Source: Figure adapted from GAO 2002.

a high-rehabilitation RUG–III.⁵ In such a case, the patient would be categorized into the high-rehabilitation RUG–III that corresponded to his or her score on an ADL index, and Medicare would pay the SNF the high rehabilitation RUG–III rate.

A review of SNF PPS problems and potential improvements

MedPAC, GAO, CMS, and the SNF industry have identified and discussed several shortcomings of the classification system since the implementation of the SNF PPS (CMS 2000a; Fries et al. 2000; GAO 1999; Kramer et al. 1999; MedPAC 2000, 2001, 2002; White 2003; White et al. 2002). Among the problems researchers have identified for improvements are the system’s payment for nontherapy ancillary services and payment for rehabilitation services according to the amount of service provided rather than patient characteristics. Various revisions to the PPS potentially can address current problems, but additional research is needed to assess the merits of any payment system alternative.

Payments for nontherapy ancillary services not adequately addressed by case-mix system

The BBA required that Medicare’s prospective payment bundle for SNFs include payment for NTAs, such as prescription drugs and respiratory therapy. In compliance with this mandate, CMS included the cost of NTAs as part of the total costs used to develop Medicare’s SNF base payment rates. However, NTA costs were not used to develop the RUG–III case-mix indexes that adjust the base payment rates according to patients’ resource use. Instead, the payment system distributes payments for NTAs using the weights that are used to allocate payment for nursing care. As a result, the payment system does not distribute payments for NTAs according to variation in expected NTA costs across different patient types.

The dispensing of medications is one service that illustrates the possible disconnect between staff time to provide a service and the cost of that service. For example, two medications may differ substantially in cost, but the staff time it takes to dispense the expensive drug and the inexpensive drug may be the same. In this case, the payment system does not adjust payments to the SNF dispensing the expensive drug to reflect the higher cost of the medication; instead payments are distributed equally according to staff time. SNFs that treat a higher-than-average share of patients with higher-than-average NTAs

will be disadvantaged by the payment system relative to facilities that treat a lower-than-average share of these patients. In addition, facilities may have an incentive to systematically avoid patients expected to have high NTA use or to stint on the provision of NTA services.

The current classification system may exacerbate the problem of the lack of case-mix adjustment for NTA resource use by assigning patients to the highest category for which they qualify in the RUG–III hierarchy. This classification method categorizes SNF patients with heterogeneous resource needs into the same groups and pays the same rate for them. For example, the classification system classifies patients with extensive service needs who also qualify for a rehabilitation RUG–III into a rehabilitation group. Similar to patients in the extensive services category, these extensive service/rehabilitation patients have, on average, higher staff time costs and much higher NTA and total costs than rehabilitation patients who do not also qualify for an extensive services category (White et al. 2002). However, the current SNF case-mix system does not recognize this variation because it does not adjust for case mix based on these NTA-related patient differences within payment groups. Failure to adequately differentiate among patients with varying resource needs means that Medicare is not paying accurately for patients, causing some patients to be more or less profitable for facilities than others.

Since CMS implemented the SNF PPS, researchers and CMS have given considerable attention to the failure of the case-mix system to account for variations in NTA costs (CMS 2000a). Researchers estimate that NTA costs represent, on average, about 16 percent of total costs (GAO 2000, White et al. 2002), but these NTA costs vary widely across patients (White et al. 2002). Researchers using 1995 data found that the RUG–IIIs predict approximately 40 percent of the variance in staff time but only 4 percent of the variance in per diem ancillary charges (Fries et al. 2000).⁶ They also found that the RUG–IIIs accounted for 10 percent of the variance in total costs.

Current payment system allows higher payments for providing additional services

Another criticism of the SNF PPS is that it determines the payment rate based on the amount of services the patient uses, or is expected to receive, rather than on patient characteristics and clinical appropriateness (MedPAC 2004, GAO 2002). However, those in favor of this feature

of the SNF PPS assert that categorizing and paying for the amount of therapy provided counters incentives in the PPS for SNFs to stint on therapies. The system has two incentives related to the provision of therapy. The first incentive is for SNFs to provide additional therapy to achieve a higher payment category even though the patient may not benefit from additional therapy. Second, because the payment system pays a fixed rate for ranges of therapy minutes provided—45 to 149 minutes (low), 150 to 324 minutes (medium), 325 to 499 minutes (high), 500 to 719 minutes (very high), and more than 720 minutes (ultra high)—providers face an incentive to provide the fewest number of minutes in the highest achievable payment category because therapy times at the bottom of the categories have the lowest cost relative to revenue (Wodchis 2004, White 2003).

Several studies have found evidence that SNFs may have responded to therapy-related payment incentives in the PPS. Consistent with the incentive to classify patients into rehabilitation groups since implementation of the PPS, more patients were categorized into high and medium rehabilitation groups and fewer into the highest and lowest categories at patients' initial assessments (GAO 2002, OIG 2003). Providers' payments for these high and medium rehabilitation groups reportedly had the highest payment relative to costs (GAO 2002, White 2003). White also found that the proportion of residents receiving no rehabilitation therapy also declined between 1997 and 2000. Consistent with incentives to provide minutes of therapy at the low end of the range for a given payment category, patients in the medium and high rehabilitation categories—upon their initial assessment—received at least 30 fewer minutes of therapy per week in 2001 than in 1999; half of the patients initially categorized into these two groups did not actually receive the minimum minutes to be classified in these groups (GAO 2002). GAO explained this latter finding, in part, by more patients being classified using estimated rather than actual therapy minutes (GAO 2002). Changes in patient characteristics could have contributed to these changes, but the Office of Inspector General (OIG) did not find substantial shifts in the gender, race, age, or reason for eligibility of Medicare beneficiaries who used SNFs from January 1999 to December 2002 (OIG 2003).

Refining the RUG-III system to address NTA payment

Recognizing the problem of the payment system's failure to properly distribute payments for NTAs, CMS undertook

research “to review the RUG-III classification system with particular emphasis on the care needs of medically complex Medicare beneficiaries and the variation in nontherapy ancillary services within RUG-III categories” (CMS 2000a). To evaluate potential improvements to, but not replacement of, the RUG-III system, CMS awarded a contract to Abt Associates, Brown University Center for Gerontology and Health Care Research, and the University of Michigan's Institute of Gerontology in 1999 (Fries et al. 2000). These researchers found, among other things, that patients in the extensive services category had higher NTA costs than patients in other categories.

In their final report in 2000, the contractors recommended that CMS consider adding 14 new groups to the top of the RUG-III hierarchy for SNF patients who qualify for the rehabilitation and extensive services category. This proposal was called the “RUG-III+ model,” which had 58 payment groups instead of 44. However, this change alone did not directly address the NTA payment issue. To address the failure of the case-mix system to distribute payment for NTA costs, the contractors also proposed applying a weighted or unweighted nontherapy ancillary index model to the new RUG-III+. Researchers developed these indexes from MDS items (e.g., suctioning, tracheostomy care, IV medication) that were found to be significantly related to per diem nontherapy ancillary (drug, respiratory therapy, and other ancillaries) costs. The index would determine an additional payment for nontherapy ancillary care for each day of SNF care.

Based on the contractors' findings that this refined case-mix system had improved ability to predict variance in total and NTA costs, CMS issued a proposed rule in April 2000 to refine the case-mix system using the RUG-III+ and the unweighted index model (CMS 2000a). But in the July final rule, CMS announced the results of testing the models on post-PPS national-level data (CMS 2000b). CMS found that these models did not improve the ability of the case-mix system to explain cost variance enough to warrant changing the SNF payment system. Therefore, CMS did not implement the refinements in the proposed rule.

Although this specific model proved less successful when tested on later, national-level data, an index that is similar in concept could again be developed from national-level data to explain NTA costs. Additional research to identify variables that better predict NTA costs would be required.

Outlier policy may not be optimal way to address NTA payments

Some have suggested that the Medicare PPS for SNFs should have an outlier policy to pay for high-cost patients. Many Medicare PPSs for other settings include an outlier policy that recognizes the extraordinary costs of certain cases and defrays some of these costs that exceed certain cost thresholds. Ideally, such a policy does not undercut incentives to be efficient but at the same time encourages providers not to avoid especially costly cases and protects providers from unpredictable and unavoidable financial risks. An outlier payment can be a desirable policy in a PPS to prevent a provider from trying to avoid excessively costly patients and to protect providers from extreme financial losses. But the problem of consistent underallocation of payment for certain types of costs—such as NTAs in the SNF PPS—may argue more strongly for fundamentally refining the case-mix system to better distribute payments according to these costs rather than imposing an outlier policy.

Another feature of the SNF PPS—although not an outlier policy per se—may diminish the need for a SNF outlier policy. Certain high-cost, infrequently provided services such as ambulatory surgery performed in operating rooms, certain chemotherapy agents, and customized prosthetic devices are currently excluded from the SNF payment bundle and paid for separately (GAO 2001). This policy mitigates for providers the financial risk of treating patients who need these excluded services. By excluding high-cost, infrequently provided services from the payment bundle, CMS may reduce the number of cost outlier cases that might otherwise occur if these services were included in the per diem rate.

Alternative classification system using SNF patient characteristics

One potential option that CMS could explore to improve the SNF PPS is replacing the RUG–III classification system with an entirely different classification scheme based on patient characteristics that are correlated with all SNF resource use. Before CMS implemented the SNF PPS, Cotterill tested the ability of a diagnosis related group (DRG)–based case-mix index to predict Medicare SNF patient resource use at the facility level (Cotterill 1986). Because a SNF stay follows a hospitalization, using the same classification method used to pay hospitals was appealing because, at the time, this method would not have required the development of a SNF-specific case-mix measure.

However, Cotterill also noted that DRGs may not be good predictors of care needs for SNF patients because of evidence that “diagnosis is not a strong predictor of differential use of nursing home resources for Medicare SNF patients.” A significantly positive relationship existed between SNF costs and the SNF diagnosis-based index, but the explanatory power in the SNF setting was weaker than the relationship between hospital costs and the hospital index. However, the diagnosis-based index was a better predictor of costs in SNFs that had a high share of Medicare patients than in facilities that had a low share of Medicare patients. One explanation for the DRGs’ relatively weak prediction of SNF patients’ resource use is that DRGs do not measure functional status, which researchers have found to be an important factor predicting post-acute resource use (Clauser and Bierman 2003).

A DRG-based case-mix index or a similar diagnosis-based case-mix system may hold some promise and appeal as an alternative payment classification system to RUG–III. A classification system based on patient characteristics may be less influenced by provider behavior than a classification system based on the amount of services provided. Similar to what Abt and colleagues proposed in their RUG refinement research, other variables such as measures of SNF patients’ functional status could possibly be added to a diagnosis-based system to predict SNF patients’ resource use. Again, additional research is needed to determine what variables explain cost variation in SNF patients and whether valid data are currently available to develop these variables. Such research could explore whether distinct, identifiable subgroups of patients exist in SNFs—subgroups that the current payment classification system does not capture. Examples of these subgroups include patients who have short stays and are recovering from acute conditions versus those who have longer SNF stays and become (or resume being) a nursing home resident.

SNF PPS revisions should address current shortcomings

CMS should improve the PPS for SNFs to better distribute payments for patients with different resource needs. To accomplish this task, CMS would need to address the current shortcomings of the SNF PPS by better distributing payment for NTA costs and paying for care based on patients’ needs and characteristics rather than on the services SNFs provide.

CMS's report on the study—mandated in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2002—of “the different payment systems for categorizing patients in Medicare skilled nursing facilities in a manner that accounts for the relative resource utilization of different patient types” should evaluate potential alternative systems for classifying patients and how those alternatives compare to the current system. The report on this study was due to the Congress on January 1, 2005, but as this MedPAC report was going to press, CMS had not provided their report to the Congress. It is not clear when CMS will release their report. However, MedPAC expects CMS to release a proposed rule that addresses potential payment system refinements in May 2005, and MedPAC will comment on any proposed payment system changes. We will also pursue analyses of different SNF payment system options—including refinements to the current RUG-III case-mix system, alternative patient classification systems, and various state-level nursing home payment systems—to determine the potential for any of these options to improve the SNF payment system.

Assessing the home health PPS

CMS implemented the home health PPS on October 1, 2000. We began our assessment of the home health PPS in 2004 with an analysis of the PPS outlier provision. Our findings from that analysis, combined with other evidence, suggest that the current PPS may not be working optimally. This section expands upon that analysis. We briefly describe the current PPS, focusing on how the case-mix classification works; review some of the current problems with the PPS; and conclude with plans to further investigate the PPS.

How does the current PPS buy home health services?

Medicare pays for home health service in 60-day units called episodes. Episodes begin when home health agencies admit patients to home health care. Most patients complete their course of care, and agencies discharge them, before 60 days have passed. If agencies do not complete patients' care within 60 days, another episode of payment may start without a break in their care.

Agencies receive a base payment of \$2,268 per episode for home health services in 2005. The base payment is

case-mix adjusted to account for differences in patients' expected resource needs, as reflected by their clinical and functional severity, recent use of other health services, and therapy use. Nurses or therapists record patients' conditions using OASIS, a standardized home health patient assessment tool, to score patients' health on admission. Figure 5-5 illustrates the OASIS items that describe the patient and the possible scores. The 80 case-mix groups—called home health resource groups (HHRGs)—in the home health PPS represent all combinations of the scores in the three domains (4 clinical \times 5 functional \times 4 service = 80 case-mix groups).

Payment also is adjusted for differences in local prices by the hospital wage index. Adjustments for several other special circumstances, such as unusually high costs or very short episodes, can also modify the payment.

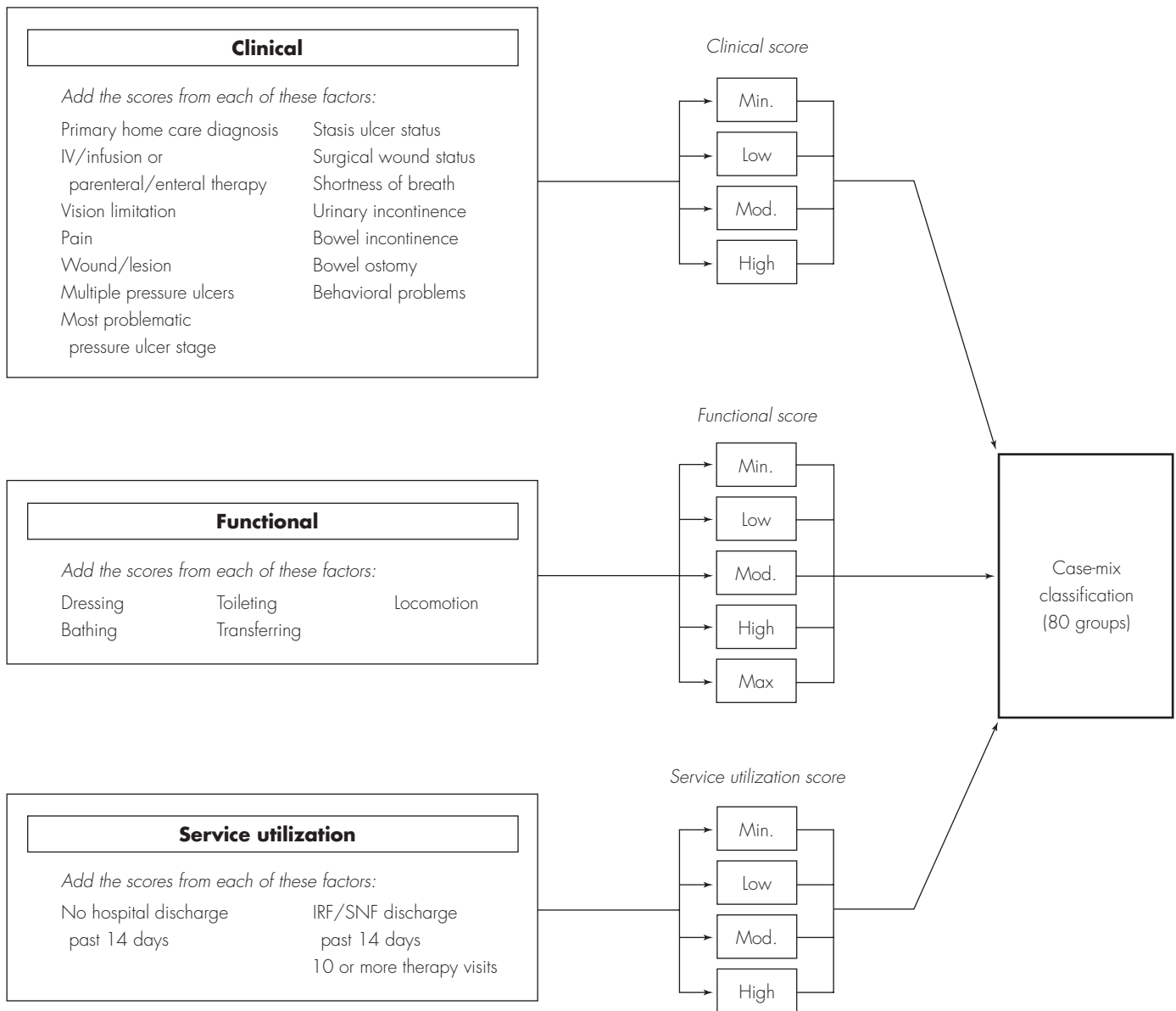
Some problems with the home health PPS

All PPSs are likely to suffer from several “pathologies” (Newhouse 2002). Among them is the failure to account for economies of scale. Also, if small providers draw an unfavorable mix of patients, they may be disadvantaged by a system that depends on relatively more profitable patients “subsidizing” the costs of relatively less-profitable ones to pay appropriately on average. Furthermore, the case-mix system within a PPS frequently fails to account for variations within case-mix groups. These problems lead to a mismatch of payments and costs at the patient and agency level. Evidence suggests that the home health PPS shows symptoms of each of these pathologies. Finally, Medicare's PPSs pay the same amounts regardless of quality.

The PPS does not account for economies of scale; smaller agencies have higher per-episode costs because they spread their overhead costs over fewer episodes. The GAO found evidence that fixed overhead costs had a significant impact on agencies' performance under the PPS (GAO 2004). Home health agencies' overhead includes legal, accounting, and data processing services; taxes; malpractice insurance; and office and equipment rental. Agencies with poor financial performance spent more than twice as much as well-performing agencies on overhead, and poorly-performing agencies had 25 percent fewer visits. GAO concluded that agencies' small size caused some of the difference in overhead costs per visit; however, additional factors appeared to be at work because nearly 20 percent of well-performing agencies were also small in size.

FIGURE 5-5

Clinical, functional, and service information from OASIS determines patients' home health case-mix classification



Note: OASIS (Outcome and Assessment Information Set), IV (intravenous), IRF (inpatient rehabilitation facility), SNF (skilled nursing facility).

Source: CMS 2000c.

Small agencies could also have more difficulty with a PPS because it pays on the basis of averages. The greater the number of cases an agency has in a given case-mix group, the more likely the agency's average cost for that case-mix group will equal the national standard upon which the

payment for the case-mix group is based. If a small agency has only one or two cases in a given case-mix group, then the agency's average costs for that group will likely be higher or lower than the national standard. If agencies do not have enough patients with lower-than-average costs in

some case-mix groups to offset the patients with higher-than-average costs in others, then they could be underpaid. Researchers noted the potential for difficulties for small agencies (Phillips et al. 1992). When testing several case-mix models for the PPS, the developers found that small agencies (ones with 200 or fewer episodes in a year) under a PPS would be somewhat more likely than medium agencies to be under- or overpaid in a given year by at least 5 percent. Furthermore, small agencies would be more than twice as likely to be under- or over-paid than large agencies (ones with more than 925 episodes).

Another PPS pathology is the failure to account for large variations of costs within case-mix groups. In the March 2005 report, MedPAC noted the wide variation in the number of minutes that nurses, therapists, aides, or social workers spent with patients during an episode in the same case-mix groups. We measured the average number of minutes of service per episode for each case-mix group, as well as the amount of variation around each of those averages. In more than half of the 80 case-mix groups in this system, the coefficient of variation for minutes per episode was greater than 1. A coefficient of variation of 1 or greater implies that the standard deviation is equal to or greater than the average, indicating very wide variation. Although the congruence between costs and minutes of service may not be one-for-one, the weak relationship between minutes and case mix suggests that the home health PPS case-mix system may fail to fully account for variation in costs within payment groups.

The handful of HHRGs with very small numbers of patients may compound the problem. As noted earlier, the 80 HHRGs represent every combination of each level of clinical and functional severity and service use; the HHRGs for maximum clinical severity and minimum functional limitation are populated only by a few patients each year (one such HHRG had only 45 patients nationwide in 2001; another had only 100 patients). Such small numbers of patients contribute to inconsistency in the average service use and cost of care for the HHRG. Perhaps CMS should consider merging these small HHRGs into larger, similar HHRGs.

The home health PPS pays the same amount for high- and low-quality care, as do all of Medicare's payment systems. MedPAC recommended in March 2005 that CMS should align the incentives of payment systems with incentives for quality (MedPAC 2005). We found that the home

health setting was ready for pay for performance and that a portion of the payments should be linked to achieving a high level of patient outcomes or improving the proportion of patients who achieve good outcomes. Pay for performance is especially important in the home health setting because the product definition is not strong; under pay for performance, some dollars are linked directly to what Medicare truly wants to buy: better health for beneficiaries.

Home health product has changed since CMS designed the case-mix system

Substantial changes in the home health care product that have occurred since the system was designed could limit the system's ability to account for current differences among agencies and for differences among case-mix groups. Abt Associates designed the case-mix system under contract with CMS in 1999 (Goldberg et al.) using claims from October 1997 through April 1998. At that time, the payment system was cost based; agencies could generate more revenue by providing more visits. HHAs had an incentive to deliver more visits and were responding to that incentive in 1996 and 1997, admitting more beneficiaries and providing more visits than ever before.

Since the contractors developed the case-mix system, the PPS has substantially changed agencies' incentives. First, the prospective payment limits an agency's ability to increase revenue by increasing visits because payment is *mostly* determined by patients' conditions rather than the amount of service delivered. The case-mix system has reversed the incentive for more visits. Second, the portion of the PPS payment that is not based strictly on patients' conditions is the additional payment for delivering at least 10 therapy visits. Meeting the therapy threshold produces substantially higher payments for otherwise similar patients. For example, an episode for a patient with moderate clinical severity and moderate functional limitation would be paid \$2,440 (base payment \times case weight 1.08) if the episode did not meet the therapy threshold and \$4,420 (base payment \times case weight 1.95) if the patient did meet the therapy threshold. In this example, the difference between the two patients could be minimal; they may have the same diagnosis and the same level of functional limitation, but one patient may have received 9 therapy visits and the other may have received 10. This may be a strong incentive to shift the mix of visits toward therapy to meet the 10-visit threshold for higher payment.

Agencies have decreased the number of visits per episode and increased the amount of therapy delivered as a proportion of those services, thus substantially changing the product of home care from the one that Abt used to calculate the case-mix weights. These changes are fairly substantial: Visits declined 47 percent, minutes declined 37 percent, and therapy increased as a proportion of all visits by 17 percentage points (Table 5-9). The relative resource needs calculated for each HHRG in 1999 are probably not correct today because it seems unlikely that these substantial changes to the home health product occurred evenly in each HHRG. Some HHRGs probably changed more than others, which could affect their resource intensity relative to those HHRGs that were less affected.

These changes in the product have led many to wonder whether quality of care has declined as a result. Older studies found small but significant benefits from higher numbers of visits; newer results seem to challenge that conclusion. The text box on the next page discusses some evidence on this point.

Plans for future research

The evidence we have cited in this chapter suggests problems with the home health PPS. To accurately identify the source of the problem, we need to conduct more research. If the case-mix system is not working well, we may be able to detect patterns in the costs and claims data. MedPAC will pursue the following questions in future research:

- How well do the relative weights match the minutes of service in each HHRG?
- How well do the relative weights match the reported costs of care in each HHRG? We will explore several different models for cost.
- Does the case-mix adjustment work better for some types of beneficiaries than others? Specifically, are there subgroups of beneficiaries whose care needs are not well anticipated by the current case-mix system? We will explore groups of users who are post-hospital and non-post-hospital, who are with and without an informal caregiver, who are qualified for both Medicare and Medicaid, who have multiple markers of frailty, who have cognitive disabilities, or who are young and have disabilities.

**TABLE
5-9**

The home health product changed between 1997 and 2002

	1997	2002
Average visits per episode	36	19
Average minutes per episode	1,500	940
Percentage of therapy visits	9%	26%

Source: Goldberg, H. B., D. Delargy, R. J. Schmitz, et al. 1999; MedPAC analysis of 20 percent of CMS Datalink file; and MedPAC analysis of 5 percent Standard Analytic File of home health claims.

CMS may wish to consider a recalibration of the weights as the first step in improving the current PPS. CMS recalibrates the weights of the inpatient acute-care hospital PPS on a regular basis to maintain their accuracy. Alternatively, more substantial changes to the system could be considered, such as mixing prospective payment with retrospective payment or limiting agencies' profits and losses or paying differently for different types of care. ■

Is more home health service better?

Early research suggested small but significant differences between the quality of outcomes for patients who received more home health care and patients who received less. However, more recent studies appear to challenge that conclusion. Research by Baker, Gill, and others links inactivity and decline in older adults; perhaps too much care, especially aide care, for homebound patients may promote inactivity on the part of the patient and thereby worsen the patient's condition (Gill et al. 2002).

Schlenker, Shaughnessy, and Hittle (1995) found fee-for-service beneficiaries received more visits, had higher costs, and achieved better functional outcomes than beneficiaries in managed care plans. This would suggest that more home health care is better for patient outcomes.

More recent evidence is mixed. Hadley and colleagues (2000) used an instrumental variable approach to estimate a very small but statistically significant difference between the functional outcomes of home health users and nonusers in the six months following hospitalizations. After controlling for the differences between users and nonusers, they found that home health users improved their functional status by 219 points on a 5,363-point scale, compared to nonusers (all patients had an average score of 875 points). The authors note that more research is needed about home health care that does not follow a hospitalization and home health care that is long term; it may not be appropriate to generalize the results to those populations.

In their study of eight states, 44 HHAs, and more than 700 episodes, Brega and colleagues (2002) conclude: "Patients receiving more frequent visits experienced

marginally better outcomes of home care than did patients with less frequent visits." Their outcomes included 27 measures of improvement in activities of daily living.

An examination of the relationship between the amount of home health service and patient satisfaction found that decreasing amounts of home health service did not decrease beneficiaries' satisfaction with the agency, their discharge, or nursing or therapist care (McCall et al. 2004). The researchers did find a decrease in satisfaction with fewer personal care services, though they note that "there was concern [before the decrease in services] that the benefit was increasingly being used to provide personal care services for beneficiaries having no skilled care need."

Since the implementation of the PPS and the attendant decline in the average number of visits, patient outcomes of care have shown a slight improvement, as measured by CMS's Home Health Compare (MedPAC 2005). More home health patients have improved their ability to dress themselves, walk, and conduct other activities of daily living even though they are receiving a lower number of visits than they did in the past. Also, Hogan (2004) found that from 1996 to 2002, "there was a statistically significant decline in re-admission and an increase in percent of episodes ending in return to the community." The Hogan study made some adjustments to account for changes in the patient population; the Home Health Compare data do not. The latter study also found that potentially avoidable hospitalizations as a fraction of all readmissions also declined, further suggesting that quality of care did not decline as the number of visits per episode fell. ■

Endnotes

- 1 A small number of patients (about 17,000 out of 426,000) included in the study sample had bilateral (both knees or both hips) replacements.
- 2 Fourteen percent of IRF patients are discharged at 14+ days; 31 percent of SNF patients have a 14-day assessment.
- 3 RAND standardized the rates for IRFs and SNFs to remove the effect of differences in area wages.
- 4 The MDS estimate was made by CMS (2002). One study found that the MDS for Post-Acute Care, a tool that is similar to the MDS, took an average of 85 minutes to complete once 10 or more assessments had been done (Buchanan et al. 2003). The OASIS estimate was made by the National Association for Home Care (St. Pierre 2005). The IRF-PAI estimate was done by researchers at Harvard University (Buchanan et al. 2003).
- 5 To qualify for the extensive services category, patients must have, in the past 14 days, received IV medications, received tracheostomy care, required a ventilator/respirator, required suctioning, or must have received IV feeding in the past 7 days. In addition, the patients assigned to this category must have a minimum ADL score of 7.
- 6 The study conducted by Fries and colleagues used staff time data from CMS Staff Time Measurement studies as a measure of staff time costs (Fries et al. 2000). Studies that attempt to measure the variance in costs explained by the RUG-III case-mix system must define the dependent variable (cost) using available, but limited, administrative data. Specifically, facility-level nursing and other cost data are not directly available from the Medicare cost reports, and data are not available for determining costs at the individual beneficiary level.

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CHAPTER

6

**Payment for pharmacy
handling costs in hospital
outpatient departments**

R E C O M M E N D A T I O N S

6A The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals.

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

.....
6B The Secretary should:

- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

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

Payment for pharmacy handling costs in hospital outpatient departments

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 mandates that MedPAC report on whether the Secretary should adjust payments in the outpatient prospective payment system (PPS) for pharmacy and nuclear medicine handling costs. The issue arises because Medicare will begin to pay for certain drugs, biologicals, and radiopharmaceuticals based on acquisition costs in 2006. Previously, the payment rates for these items were higher, providing hospitals with resources to cover handling costs. The Commission concludes that handling costs are nontrivial and an adjustment is warranted. However, any adjustment should be budget neutral because when CMS established the outpatient PPS, payments were based on hospital charges that reflected these handling costs. This chapter closes with a discussion of the significant unbundling that has occurred within the outpatient PPS. The current granular approach to paying for drugs undermines incentives for efficient use of services in broader payment bundles. The Commission suggests that, in the future, CMS identify larger payment bundles.

In this chapter

- Is a payment adjustment needed?
- How should a payment adjustment be structured?
- How should handling costs be measured?
- What are the options for collecting data?
- A longer term agenda: Broader payment bundles in the outpatient PPS

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 changed the way in which Medicare will pay hospitals for certain drugs, biologicals, and radiopharmaceuticals delivered in their outpatient departments and covered under the outpatient prospective payment system (PPS). The law affects radiopharmaceuticals and products that Medicare reimbursed under the outpatient PPS's pass-through mechanism as of December 2002 (called specified covered outpatient drugs). The pass-through mechanism enables additional payment for those technologies for a period of two to three years, after which CMS incorporates them into the payment system.

Providers use many, but not all, of the drugs and biologicals on the pass-through list in cancer treatment.

Other pass-through drugs and biologicals treat rheumatoid arthritis, diseases of immune deficiency, and additional conditions. Table 6-1 lists the drugs and biologicals receiving the highest total payments under the outpatient PPS in 2002; Table 6-2 lists the top radiopharmaceuticals. In general, hospital pharmacies handle drugs and biologicals. Radiopharmaceuticals are radioactive agents used for diagnostic or therapeutic purposes. Many providers use radiopharmaceuticals in nuclear imaging procedures; others target drugs and radioisotopes in certain cancer treatments. Radiopharmaceuticals may be handled by hospital pharmacies, radiopharmacies or, more typically, nuclear medicine departments.

When these drugs, biologicals, and radiopharmaceuticals (hereafter referred to as "products") were on the pass-through list, CMS paid hospitals 95 percent of average wholesale price (AWP), a benchmark price that researchers and auditors have found to be well above acquisition cost (MedPAC 2003, GAO 2001, OIG 2001). After CMS moved these products off the pass-through list, the agency set payment rates using the general approach of the outpatient PPS: calculating the median value of hospital charges reduced to costs using adjustment factors from hospital cost report data. Manufacturers believe that these payment rates are too low (PhRMA 2002).¹

In the MMA, the Congress directed CMS to pay hospitals for specified covered outpatient drugs in different ways than before. Beginning in 2006, the MMA mandates that CMS set payment equal to average acquisition cost, taking into account data collected by the Government Accountability Office (GAO) through a survey of hospitals. GAO surveyed hospitals from fall 2004 to spring 2005. It provided CMS with data on acquisition costs in spring 2005.

The MMA also required MedPAC to determine whether the outpatient PPS should have a payment adjustment to cover services provided by hospital pharmacies or nuclear medicine departments when they handle these products. The law directed MedPAC to suggest a method for making such an adjustment, if needed. (Relevant excerpts from the MMA language requesting the study can be found at the end of this chapter, p. 152.)

MedPAC's study focuses on the handling costs that pharmacy and nuclear medicine departments incur for storing, preparing, transporting, and disposing of the products. The study excludes the acquisition costs of the products themselves, which GAO is studying. The study

TABLE 6-1 Study drugs and biologicals with highest payments in 2002, ranked highest to lowest

APC in 2002	APC title in 2002	Brand name(s)
0733	Non-ESRD epoetin alpha injection	Epogen, Procrit
0849	Rituximab	Rituxan
7043	Infliximab injection	Remicade
0863	Paclitaxel injection	Taxol
0811	Carboplatin injection	Paraplatin
0823	Docetaxel	Taxotere
0828	Gemcitabine HCL	Gemzar
0830	Irinotecan injection	Camptosar
9115	Zoledronic acid injection	Zometa
9217	Leuprolide acetate suspension	Lupron, Eligard
0730	Pamidronate disodium	Aredia
0728	Filgrastim injection	Neupogen
7049	Filgrastim injection	Neupogen
1613	Trastuzumab	Herceptin
0768	Ondansetron HCL injection	Zofran
7046	Doxorubicin HCL liposome injection	Doxil
9005	Retepase injection	Retavase
9119	Pegfilgrastim injection	Neulasta
0852	Topotecan	Hycamtin
0810	Goserelin acetate implant	Zoladex
1203	Verteporfin for injection	Visudyne
7031	Octreotide acetate injection	Sandostatatin
0855	Vinorelbine tartrate	Navelbine
9002	Tenecteplase	TNKase
0905	Immune globulin	*

Note: APC (ambulatory payment classification), ESRD (end-stage renal disease), HCL (hydrochloride).
* Various manufacturers.

Source: MedPAC analysis of 2002 outpatient claims file from CMS.

also excludes costs associated with administering the product to the patient—such as preparing the patient for chemotherapy, monitoring the patient during an infusion, or treating side effects—because Medicare pays separately for administration of chemotherapy and other drugs, as well as for nuclear medicine procedures. MedPAC’s analysis considers broader issues that this study raises, namely the design of payment rates.

In considering the question of pharmacy handling costs in hospitals, a review of the literature revealed little relevant research or data. MedPAC consulted widely with stakeholders, including numerous hospital pharmacy directors and administrators, representatives of hospital associations (including cancer hospitals), pharmaceutical distributors, representatives of product manufacturers, and CMS staff. We also coordinated our work with that of GAO. To better understand how hospital pharmacies operate, MedPAC staff conducted a site visit to a cancer center in the Washington, DC, area. We then developed a conceptual framework with assistance from a contractor, a technical advisory panel, and four facilities that agreed to serve as case studies.

Is a payment adjustment needed?

MedPAC’s analysis indicates that handling costs for these products are not insignificant. CMS built the existing outpatient PPS payment pool using hospital charges that reflected handling costs. Consequently, the Commission concludes that CMS should make a payment adjustment, but it should be budget neutral. In other words, total payments for all services would remain the same, and the resources for an adjustment would come from a redistribution of payments from other categories of services.

Background

Determining whether the outpatient PPS needs a payment adjustment requires an understanding of previous payment policies. Historically, hospitals generally charged only for the drug provided; they did not routinely develop separate charges for their pharmacy services. In a recent survey of hospital charging practices, most respondents indicated that this practice continues today (Worzala and Ashby 2004). In our discussions with hospitals, officials indicated that they set charges for drugs and radiopharmaceuticals high enough to reflect the products’ handling costs as well

**TABLE
6-2**

Study radiopharmaceuticals with highest payments in 2002, ranked highest to lowest

APC in 2002	APC title in 2002
1600	Technetium-99m sestamibi
0705	Technetium-99m tetrofosmin
1603	Thallium-201
1775	FDG
1601	Technetium-99m medronate
1622	Technetium Tc-99m mertiatide
1604	In-111 capromab pendetide
1627	Technetium-99m labeled RBCs
1348	I-131 solution
1188	I-131 capsule

Note: APC (ambulatory payment classification), FDG (fluorodeoxyglucose F18), Tc (technetium), In (indium), RBCs (red blood cells).

Source: MedPAC analysis of 2002 outpatient claims file from CMS.

as their acquisition costs. Historically, Medicare payments were sufficient to cover both.

Under the outpatient PPS, CMS generally sets payments based on hospitals’ charges, which the agency reduces to estimated costs using a cost-to-charge ratio from Medicare cost report data. Using this methodology, CMS incorporates handling costs into the payment rates because handling costs are built into hospitals’ charges. Many observers have voiced concerns about the completeness of the data available to CMS and the accuracy of this methodology when setting rates for specific items (see more detailed discussion in the section about broader payment bundles on p. 150). Nevertheless, CMS included handling costs as a component of hospital-wide expenses when it set up the outpatient PPS. Thus, the current payment system incorporates handling costs in the total payment pool.

The MMA requires GAO to collect acquisition cost data that CMS then will use to set payment rates for these products in 2006. If the acquisition cost data are not available, the MMA allows CMS to use the drug price data collected in order to pay physicians for Part B drugs—that is, average sales price or prices from competitive acquisition arrangements. Under either of these approaches, the payment for the product would no longer include handling costs.

Our conversations with stakeholders and analysis of data from Maryland hospitals and from Medicare cost reports

suggest that handling costs are not negligible. However, because most hospitals do not develop charges for pharmacy handling costs today, they do not have precise information about the magnitude of these expenses.² The fact that hospitals typically prepare inpatient and outpatient drug and biological products within the same pharmacy complicates the measurement of handling costs. In interviews that MedPAC staff conducted for this research, hospital pharmacy directors stated that the types of medications that providers administer more frequently in outpatient departments generally require more pharmacy preparation time than do those for inpatients. Although data are not available to make a comparison, the pharmacy directors believed that inpatients generally received more medications as pills, injections, or as simple intravenous (IV) solutions, while outpatients generally had a larger proportion of complex infusion therapies that pharmacists needed to reconstitute or compound. Radiopharmacists or pharmacy technicians usually prepare radiopharmaceuticals in a separate nuclear medicine department, or commercial nuclear pharmacies under contract with the hospital deliver near-ready unit doses.

One study of 1996 Medicare hospital cost report data found that labor and costs other than the acquisition cost of drugs accounted for about one-third of expenses associated with pharmacy-related cost centers—where hospitals state the costs of drugs and of operating the pharmacy department (Kathpal Technologies 1999). However, it is unclear whether available data are comparable across hospitals. The Kathpal study relied on a sample of 55 hospitals. MedPAC analyzed recent Medicare cost report data for more than 3,300 hospitals and found that hospitals are not consistent in their reporting of pharmacy costs. This inconsistency makes it difficult to separate drug acquisition costs from pharmacy handling costs. MedPAC found that in nearly 1,200 hospitals in which reporting appears to be comparable, wages, salaries, and fringe benefits make up 25 percent, on average, of pharmacy-related direct costs. The cost of purchasing pharmacy supplies and acquiring drugs and biologicals account for the remaining 75 percent of direct costs. Radiopharmaceutical handling costs are typically an expense of running a nuclear medicine department, and we were unable to estimate the relative magnitude of these costs from Medicare cost report data.

MedPAC also analyzed cost data for about 40 hospital pharmacy departments in Maryland from 2001 to 2003—nearly all the hospitals in that state (see text box).³ Those data show that pharmacy department wages and

salaries, fringe benefits, and supplies made up 26 percent to 28 percent of pharmacy departments' direct costs (defined as the cost of labor, benefits, and supplies plus the acquisition cost of drugs).

Moving to a payment system based on acquisition cost for separately paid drugs means that the system will no longer compensate hospitals for handling costs as part of the payment for the drug itself.⁴ Yet handling costs are not negligible. In addition, some hospitals provide more of these services than others (for example, hospitals that specialize in cancer care, or teaching hospitals that provide more new technology services). Therefore, the move to reimburse for these products based on acquisition cost could have redistributive effects among facilities. For the reasons mentioned above, the payment system should include an adjustment for handling products when Medicare pays for the products at acquisition cost.

A budget-neutral payment adjustment

A payment adjustment for handling costs should be budget neutral because when CMS established the outpatient PPS, it based payments on hospital charges that reflected these handling costs. A payment adjustment would ensure that Medicare reimburses hospitals for the costs of these services more directly than before, but payments should come from the redistribution of resources already within the outpatient PPS payment base.

Prospective payment systems comprise three basic parts:

- a classification system to define the services for which Medicare is paying (called ambulatory payment classification [APC] groups in the outpatient PPS);
- relative weights to determine the relative payments among services; and
- a conversion factor Medicare uses to set the level of payments.

Together with volume, these three factors determine the size of the payment pool.

MedPAC's study primarily focuses on the classification system and the relative weights. A payment adjustment may require creating new APCs, which would change the classification system. Setting appropriate payment rates for new APCs would require establishing relative weights.

Current law generally requires that changes to the classification system and relative weights be made in a budget-neutral fashion. MedPAC's study does not address

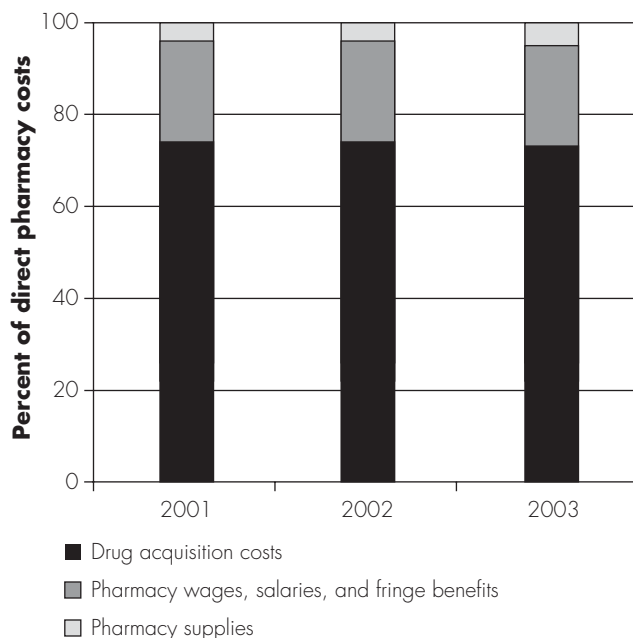
Hospital pharmacy costs in Maryland

In order to measure handling costs for drugs and radiopharmaceuticals delivered in hospital outpatient departments, MedPAC analyzed data from the Maryland Health Services Cost Review Commission (HSCRC). Maryland regulates hospitals' charges; all payers base their payments on those charges. Maryland established the HSCRC in 1971 to

set the rates that hospitals charge for the all-payer system. Due to the nature of its work, the HSCRC possesses comprehensive hospital accounting data that helped us understand the types of costs that hospitals incur for outpatient pass-through drugs. MedPAC analyzed HSCRC hospital pharmacy accounting data from approximately 40 Maryland hospitals for 2001 to 2003. The data include the following types of hospital pharmacy costs: acquisition cost of drugs, the pharmacy department's other direct costs, capital costs, payment adjustments, and an allowance for profit. We call the sum of these costs "total direct drug expenses."

FIGURE 6-1

Labor and supplies components of direct pharmacy expenses are stable



Source: MedPAC analysis of hospital cost report data from the Maryland Health Services Cost Review Commission.

MedPAC analyzed three components of direct drug expenses: (a) drug acquisition costs, (b) pharmacy wages, and (c) pharmacy supplies. In all three years, the nondrug elements of direct costs made up 26 percent to 28 percent of the total (Figure 6-1).

As these data illustrate, nondrug costs make up a nontrivial proportion of costs. Figure 6-1 also shows that the average proportions did not change much from year to year. Overall, these data demonstrate that the handling costs hospital pharmacies incur are not negligible; thus, Medicare payments should account for these costs.

Limitations of the data

Although these data can inform the relationship between cost categories within the pharmacy, they do not include information on the types or volume of drugs prepared in the pharmacy—nor do they separate the products delivered in outpatient departments from those used by inpatient departments. Finally, these data exclude radiopharmaceuticals. ■

the level of payments—this task is done through the annual updates to the conversion factor, which the Congress determines based on guidance from MedPAC.⁵

In addition to the outpatient PPS's structure, other factors support a budget-neutral payment adjustment:

- Hospital officials and others told MedPAC staff that hospitals build handling costs for drugs, biologicals,

and radiopharmaceuticals into the charges for the products themselves as part of the markup over costs. Therefore, the original payment pool that CMS based on hospital charges (reduced to costs) reflected handling costs. In recent years, relative weights derived from charges (reduced to costs) also reflect handling costs.

- In setting up pass-through payments in the Balanced Budget Refinement Act of 1999, the Congress designed the policy to be budget neutral (MedPAC 2002).⁶
- Through the MMA, the Congress legislated interim payment rates in 2004 and 2005 for the products in this study based on AWP. Because AWP are benchmark prices well above acquisition costs, that policy provided additional resources within the system to cover pharmacy handling expenses. By law, increased payments resulting from the interim payment rates were made with new money—that is, the policy was not budget neutral.⁷ Medicare has subsequently built this increased spending into the total payment pool.

How should a payment adjustment be structured?

Hospitals appear to incur nontrivial costs in handling separately paid drugs and radiopharmaceuticals. Thus, as the outpatient PPS moves toward reimbursing hospitals for drugs at their acquisition cost, it should also provide some payment for handling costs.

To cover reasonable pharmacy and nuclear medicine handling costs, a payment adjustment could take one of several forms:

- a percentage markup on acquisition costs,
- a handling fee tied to each administration to a patient, or
- inclusion of handling costs in a larger payment bundle.

Markup on acquisition costs

Medicare could link payment for handling costs to the acquisition cost of products. Indeed, some stakeholders interpret the Kathpal study’s findings (1999) as follows: A payment methodology to reimburse hospitals for pharmacy department costs should provide, on average, a 50 percent markup over the acquisition cost of products (ACCC 2004). Under that logic, if handling costs make up one-third of the sum of handling costs plus acquisition costs, Medicare would need to pay 1.5 times the acquisition cost to cover both costs.

This approach would be administratively straightforward, provided that Medicare can collect reliable data on acquisition costs. However, handling costs may not be directly proportional to a product’s acquisition costs. Prices that hospitals pay to purchase the products depend on a number of factors, such as the availability of generic or therapeutic substitutes, the volume that each hospital (or each hospital system) buys, and the abundance or scarcity of the products. Some drug therapies with lower acquisition costs have relatively high handling costs because these therapies require that a pharmacist reconstitute them over a lengthy period or prepare them for infusion using specialized safety equipment. Other products carry relatively high price tags because they are single-source drugs, but some are manufactured in a form that requires less pharmacy handling (for example, prepackaged unit doses, or liquids rather than powders).

Handling fee per administration

A second way to structure an outpatient PPS payment for handling costs is to reimburse hospital pharmacies for each preparation of a product that is administered to a patient. Unlike providing a markup over the product’s acquisition cost, a per administration handling fee could provide a more direct link between Medicare’s payment and the resources required to carry out pharmacy and nuclear medicine departments’ tasks. This approach is similar to the way in which Medicaid and private payers reimburse retail pharmacies for the dispensing costs of outpatient prescription drugs.

MedPAC staff’s discussions with hospital pharmacy directors and other stakeholders revealed wide variation in the processes and resources required to handle drug therapies in hospital outpatient departments. For example, a hospital pharmacy may require the ability to dispense not only simple pills but also highly toxic chemotherapy agents for intravenous infusion. Some patients may receive a single drug; others receive a combination therapy that requires the pharmacies to mix products before administering them. Therefore, CMS may want to classify products into broad categories, with each group requiring similar levels of pharmacy resources. The agency would then set a fixed payment to cover the handling costs for each category of drugs and radiopharmaceuticals.⁸

This classification approach is preferable to a markup over acquisition cost because it links payment more closely to actual resource use. On the other hand, it is more administratively complex. However, these complexities do

not appear to be insurmountable and should diminish over time. To institute this approach, CMS would have to create categories of handling costs, establish Healthcare Common Procedures Coding System (HCPCS) codes for them, and set payment rates. Hospitals would have to bill Medicare for their handling costs using the new HCPCS codes. Once Medicare began receiving such charges, it could set payment rates for handling costs in each category in the same manner that it does for other APCs within the outpatient PPS—by evaluating the median level of costs among submitted charges (reduced to costs). Hospitals would need advance notice of the new codes as well as time to collect appropriate cost information, develop the charges, and modify their billing operations.

Can hospitals set charges for their handling services? Although most hospitals do not currently charge for their handling costs, they set charges for many different services and should be able to develop charges for handling costs as they have done for other costs. In fact, one hospital official with whom MedPAC spoke stated that his facility had already developed charges for pharmacy services. Other hospitals indicated that if required, they could do so.⁹ Through four case studies (described on p. 147), MedPAC assessed whether hospitals could estimate their handling costs, which could provide valuable information for setting charges. The case-study facilities successfully estimated costs, although they found the process time consuming. Hospitals may need a transition period before CMS deems that the charge data submitted are reliable enough to set payment rates. CMS also would need to develop a process for evaluating the handling costs of new products and categorizing them within appropriate APCs.

Other payers also often reimburse hospitals for handling costs through payment for the product itself. If Medicare reimbursed handling costs through separate APCs, that approach could conflict with hospitals' method of obtaining payment from other payers. However, it seems likely that once Medicare begins paying for these products based on acquisition costs, other payers would want to follow suit. Under that scenario, developing standard charges would help hospitals ensure more direct payment for handling costs from all payers.

Larger payment bundles

Alternatively, CMS could create larger bundles of services within the outpatient PPS that include pharmacy and nuclear medicine handling costs. In order to ensure that

Medicare reimburses hospitals for handling costs, hospitals would still need to develop charges for pharmacy services. CMS would reimburse hospitals for bundles that include not only the acquisition cost of clinically similar products but also their handling costs. This approach is consistent with the original intent behind the outpatient PPS—to provide a predetermined level of payment for clinically similar services (APCs), thereby giving hospitals an incentive to control costs (MedPAC 2000).

Over time, CMS has expanded the number of APCs, narrowing certain bundles of services, to the point of providing separate payment for many individual products. The Congress required CMS to set up separate payments for the products covered in MedPAC's study because these products are newer technologies that generally have higher costs than other therapies. Proponents were concerned that if these products were bundled within broader APCs that also included less costly therapies, reimbursement would be too low for hospitals that chose to provide newer products. Broad bundles, proponents believe, could adversely affect patient care if newer therapies represent significant advances in treatment that are disadvantaged by the design of APCs.

Yet arguably, in cases where older and newer agents are therapeutically equivalent, it is appropriate for CMS to include both older and newer agents within the same APC. This approach would give hospitals a greater incentive to decide whether the clinical outcomes of newer therapies justify their higher acquisition costs. Moreover, not all new products constitute significant advances in therapy.

How should handling costs be measured?

Measuring handling costs is primarily a cost accounting exercise. However, after a literature review and conversations with stakeholders, MedPAC concluded that no systematic, consensus-based approach exists for identifying or measuring handling costs for these products. To break down the process of measuring handling costs, we took three steps:

- Developed a framework to identify and define the handling costs.
- Classified the study products into categories according to characteristics related to the level of resources used

in handling, including radioactivity, toxicity, mode of administration, and special-handling considerations.

- Conducted case studies in four facilities to test the validity of the framework and classification system, as well as to assess hospitals' ability to estimate the relative handling costs across categories by resource use.

Framework

In order to measure handling costs, one must first define them. With the help of a contractor, MedPAC developed a framework that lays out the categories of costs (Figure 6-2). The framework and definitions are sufficiently broad to span the range of products covered by this study and to apply to both pharmacy and nuclear medicine departments. MedPAC asked a technical advisory panel of experts in pharmacy, nuclear medicine, hospital finance, and cost accounting to evaluate the framework. We then modified the groupings based on the panel's input. (A list of the members of the advisory group is available from MedPAC upon request.) The dimensions of handling costs that MedPAC considered include:

- pharmacy or nuclear medicine management, including regulatory compliance;
- storage, including inventory management;

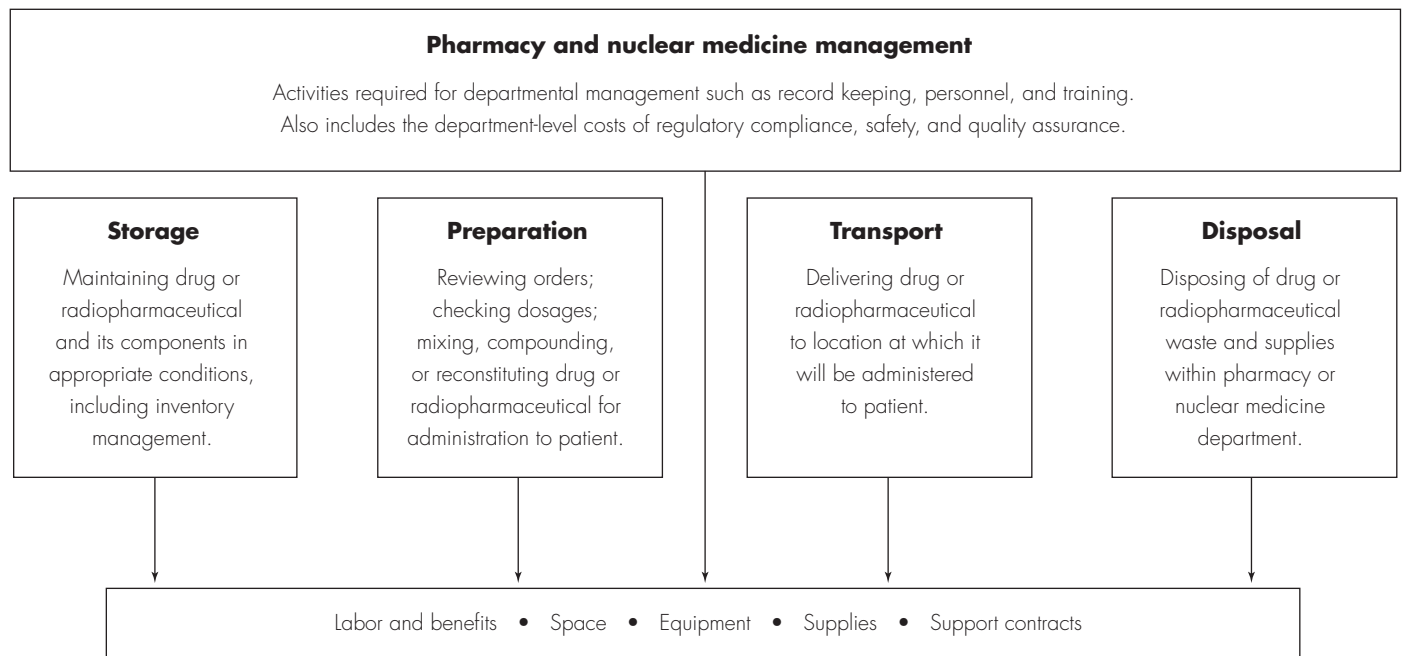
- preparation, including review of drug orders and dosage calculations;
- transport within the hospital (such as from the pharmacy to the infusion suite); and
- disposal of products from the pharmacy or nuclear medicine department.

Costs for specific products will vary across these categories. Some products may have significant storage requirements (such as extremely low temperatures to maintain product integrity or shielded containers to protect workers from contamination); others may have extensive preparation costs (such as lengthy reconstitution times or complex dosage calculations and verifications). In some cases, management of inventory for high-cost products can be a significant expense. In concept, all handling costs should fit into at least one of the categories. Within each category, the kinds of costs to measure include:

- labor and benefits,
- space,
- equipment and supplies, and
- support contracts for other organizations to provide certain services (such as waste disposal contracts).

FIGURE 6-2

Pharmacy and nuclear medicine functions and handling costs covered by this study



Activities such as regulatory compliance and quality improvement can affect the costs in these categories. For example, studies have shown that individuals preparing toxic agents can be exposed to these agents through their skin or through breathing aerosolized particles (Morris 2005). Consequently, the National Institute for Occupational Safety and Health (NIOSH) has issued guidelines to protect workers who come in contact with antineoplastics and other drugs (NIOSH 2004). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) assesses hospitals' compliance with quality and safety standards that include guidelines for preparing products in hospital pharmacies. Accrediting bodies such as JCAHO and some state pharmacy boards have also adopted recent revisions to sterile compounding standards issued in Chapter 797 of the U.S. Pharmacopeia (USP) (U.S. Pharmacopeial Convention, Inc. 2004). In addition, many hospitals institute their own quality safeguards, such as multiple reviews of orders, to prevent medication errors. The Nuclear Regulatory Commission (NRC) and individual states regulate and license institutions that use radioactive materials. All hospitals must follow stringent NRC and state guidelines on how those materials are stored, transported, and disposed of (CORAR 2004). All of these activities should be reflected in cost elements such as the storage space required, the supplies and equipment used, or the labor involved. The costs that hospitals incur to manage and document their compliance with NRC and state guidelines fall under pharmacy and nuclear medicine management.

Categorizing products

Users of any payment adjustment for handling costs will need to group products according to the level of resources used. The study products vary considerably, from radioactive injections and chemotherapy infusions to simple oral tablets. In discussions with stakeholders and the technical advisory panel, MedPAC identified four characteristics that correlate with the level of resources needed for handling: (1) radioactivity, (2) toxicity, (3) mode of administration, and (4) special handling needs. Initially, the pharmacists in MedPAC's advisory group used these characteristics to group the study products into nine categories. After reviewing information collected by the contractor from the case studies, panel members reduced the number of categories to seven in order to collapse those with similar handling costs (Table 6-3 and the glossary of terms, p. 146). The technical advisory panel ranked categories, with

**TABLE
6-3**

Categories for drugs, biologicals, and radiopharmaceuticals and their relative handling costs

Category	Description	Relative handling cost*
1	Orals (oral tablets, capsules, solutions)	0.36
2	Injection/sterile preparations	1.00
3	Single IV solution/sterile preparations (drawing up a drug for administration)	1.28
4	Single IV solution/sterile preparations (adding a drug or drugs to a sterile IV solution) or controlled substances	1.61
5	Compounded/reconstituted IV preparations (requiring calculations performed correctly and then compounded correctly)	2.70
6	Specialty IV or agents requiring special handling in order to preserve their therapeutic value or oral cytotoxic agents (chemotherapeutic, teratogenic, or toxic) requiring personal protective equipment	5.33
7+	Cytotoxic agents (chemotherapeutic, teratogenic, or toxic) in all formulations except oral requiring personal protective equipment	N/A
	Radiopharmaceuticals: basic and complex diagnostic agents (including PET), therapeutic agents, and radioimmunoconjugates	N/A

Note: IV (intravenous), PET (positron emission tomography), N/A (not available). Due to insufficient cost data and handling information on radiopharmaceuticals from case-study sites, the expert panel did not provide final recommendations for categorizing these products.

*Relative handling costs are calculated as follows: MedPAC's expert panel selected at least one product from each category—generally those with the largest volume within 2002 Medicare claims under the outpatient prospective payment system. The Lewin Group calculated median handling costs for each drug selected across four case-study facilities that conducted microcosting exercises, where the median is the average of the middle two observations ranked by cost. Lewin divided each category's median cost by the median cost for Category 2. For categories in which cost information was available for more than one product, the values reflect relative costs weighted by volume.

Source: The Lewin Group for MedPAC, 2005.

radiopharmaceuticals requiring the greatest resources and oral preparations requiring the least.

In general, radioactive materials require greater handling resources than drugs. First, their additional safety requirements affect every component of handling costs. These measures include, for example, lead-lined storage, special protection during preparation, and disposal in accordance with strict regulations. Next, because the level of radioactivity changes over time according to the product's half-life, radiopharmacies need to make

Glossary of terms

Drugs: Any chemical compound used in the prevention, diagnosis, treatment, or cure of disease, for the relief of pain, or to control or improve any physiological or pathological disorder.

Biologicals: Products derived from living material—human, plant, animal, or microorganism—applicable to the prevention, treatment, or cure of diseases or injuries.

Cytotoxic agents: Substances that have toxic effects on certain cells. They are capable of causing injury or death if handled without proper personal protective equipment or if used inappropriately.

Teratogenic agents: Substances that can cause developmental malformations if handled without proper protection or if used inappropriately.

Radiopharmaceuticals: A drug or biological product that contains a radioactive entity. They are used in medicine for diagnostic and therapeutic purposes.

Diagnostic radiopharmaceuticals: Radioactive drugs or biological products that contain a radionuclide that typically is used with planar imaging, single photon emission computed tomography, positron emission tomography (PET), or other radiation detection probes.

Therapeutic radiopharmaceuticals: Agents intended to exert a cytotoxic effect on certain targeted tissues.

Radioimmunoconjugates: Agents that contain combinations of diagnostic or therapeutic substances linked with specific immune substances such as immunoglobulins, monoclonal antibodies, or antigens. They are used for specific targeting of drugs and radioisotopes in treating certain cancers. ■

additional checks and coordinate with providers and patients to ensure a therapeutic dose and to minimize wastage. These requirements, in turn, lead to management costs as hospitals must ensure and document compliance.

Toxic products, such as chemotherapy drugs, generally require greater handling costs than nontoxic drugs because of the need to protect both pharmacy workers and patients. Pharmacists must carefully check dosages and sometimes lab results to ensure that patients can tolerate the drugs. Pharmacists and technicians must prepare certain products under laminar flow hoods and use personal protective equipment. Disposal of toxic waste can be a considerable expense, and some toxic products require special storage considerations, such as extremely low temperatures. These costs accrue regardless of how the drug is administered.

The mode of administration can also influence handling costs due to the time pharmacists and technicians spend in preparing the materials. In general, stakeholders and technical advisory group members said that IV preparations require more resources than simple injections. For example, pharmacists or technicians might combine multiple drugs into a single infusion. They also may reconstitute powders into liquid form, a practice that

can require significant amounts of time. By contrast, injections generally require that the pharmacist or technician draw a measured dose into a syringe. Oral drugs generally require the fewest resources for handling.¹⁰

Special handling means some products require particular care in their preparation, storage, and transport in order to retain their therapeutic value. For example, some products should not be transferred from the hospital pharmacy to the point of administration through pneumatic tubes because they can become denatured if shaken too vigorously. MedPAC's panel of experts believed that this need for special handling was associated with greater handling costs, even if the product itself was not radioactive or highly toxic. A significant number of new agents under development are protein-based antibodies that may require special handling.

Understanding the handling costs associated with radiopharmaceuticals requires additional study because hospitals procure these products in two distinct ways: (1) either already prepared, or (2) as inputs to be prepared on site.¹¹ Handling costs vary according to the form in which hospitals order the product. This form may depend

on factors that are specific to the patient's plan of care and the product's availability. One recent survey suggests that 80 percent of hospital-based nuclear medicine facilities purchase their radiopharmaceuticals as commercially prepared patient doses from radiopharmacies (Merlino 2004). In these cases, the invoice for the product combines handling costs with acquisition costs and delivery fees. Some hospitals create their own radiopharmaceuticals on site in their nuclear medicine departments. In this case, the handling costs will be much higher but the acquisition costs will be much lower, because the hospitals purchase only component ingredients. Hospitals that prepare radioactive materials on site may have less wastage but significantly higher costs for shielding and equipment. The "make versus buy" decisions of nuclear medicine departments constitute a dimension of complexity that CMS will need to consider. Given its limited case-study approach, MedPAC could not adequately determine the relative costliness of one approach versus the other, or the circumstances in which compounding radiopharmaceuticals in house would be more appropriate.

The technical advisory panel initially discussed at least two categories for radiopharmaceutical handling costs. These two categories are based on whether products are basic diagnostic agents or one of three other types: (1) complex diagnostic agents, (2) therapeutic agents, or (3) radioimmunoconjugates. These three types of products likely have higher handling costs because they require personnel with more specialized training to prepare them, more shielding and protective equipment, and additional regulatory compliance programs (Callahan 2005). If a facility conducts its own compounding, handling costs could also include shielded storage areas for radioactive generators, additional equipment for measuring radionuclidic purity, and other supplies. Although MedPAC presents radiopharmaceuticals as one category in Table 6-3 (p. 145), the topic deserves further study to better understand how handling costs for these products differ. Based on interviews with radiopharmacists, the range of handling costs within a single category of radiopharmaceuticals can be greater than the range within any of the other product categories. Thus, CMS may want to consider establishing multiple categories for radiopharmaceuticals.

Case studies

In order to validate the proposed framework and classification of products, MedPAC contracted with

The Lewin Group to conduct four case studies of hospital outpatient pharmacy and nuclear medicine department handling costs. A case-study approach helped to ensure that we employ common definitions and have a more thorough understanding of participating facilities' handling costs.¹² Lewin asked each hospital or hospital system to categorize the study products using the proposed classification system to determine whether the facility put products into the same categories as the pharmacists on our advisory panel. Lewin also asked the case-study sites to estimate handling costs for at least one product in each category, using the proposed framework to identify handling costs.

MedPAC does not claim that one can generalize from estimates of handling costs provided by four case-study facilities to all hospitals. Consequently, MedPAC asked Lewin to report on relative costs across categories of products rather than reveal specific dollar-value estimates. This confidential approach not only helped secure hospitals' participation but also allowed for comparison of relative costs across hospitals without having the results confounded by the level of costs.¹³

To check the reliability of the classification developed by the pharmacists on the technical advisory panel, the contractor asked each case-study facility to put about 230 products covered by this study into one of nine initial categories.¹⁴ By comparing responses across facilities, Lewin could then assess whether the categories were clear and well-understood and whether different pharmacists put drugs into the same categories (a reliability test). The contractor asked case-study facilities if the categories correlate well with the resources they devote to pharmacy handling costs. Preliminary responses from those interviews suggested that most of the categories were clear, with pharmacists placing 83 percent of the products into the same categories.¹⁵ After reviewing case-study results, the advisory panel reassigned a small number of products to other categories, which raised the rate of correspondence to 89 percent. Both the advisory panel and participating sites reported that the categories were consistent and reflected increasing levels of handling costs. One caveat to this analysis, however, is that only one of the case-study hospitals compounds its own radiopharmaceuticals.

Four facilities undertook microcosting analyses of handling costs for unit doses of six to nine products, one from each category that they could cost (three facilities could not cost radiopharmaceutical products because they

contract out nuclear medicine services). The four facilities' cost analyses followed MedPAC's framework for defining handling costs. The result was a detailed costing of the functions shown in Figure 6-2 (p. 144): pharmacy and nuclear medicine management, storage, preparation, transport, and disposal. The pharmacists in the advisory group selected specific products in each category that generally reflect the highest volume products typifying the categories' characteristics. Lewin asked all of the facilities to cost out the same product for seven categories; in two categories, one hospital costed a different product because it did not use the product selected by the advisory group.

Facilities reported that the costing exercise was feasible and that they could isolate the inputs of handling costs. However, they also reported that the exercise was time consuming, requiring between 16 and 40 hours to complete. In addition, the contractor made follow-up phone calls with case-study facilities to ensure that the components of cost were comparable to one another. Nevertheless, the exercise showed that it is possible for hospitals to measure handling costs as they do routinely for other services. This exercise would allow hospitals to develop charges for pharmacy services.

The results of the microcosting exercise show that handling costs generally increase across the categories (Table 6-3, p. 145). The expert panel arrived at these seven categories after reviewing results of the microcosting exercise using nine categories and then collapsing them.¹⁶ To calculate the relative values, Lewin first took the median of estimated costs for each category across case-study sites.¹⁷ Then, Lewin divided each category's median cost by the median for Category 2, injections/sterile preparations. Thus, the median handling costs for Category 3, simple IV solutions/sterile preparations (where a single drug is added to an IV) or controlled substances, are about 1.3 times those for Category 2. The costs for Category 4, complex IV solutions in which the pharmacist must perform calculations correctly to compound the preparation, are 1.6 times those of Category 2. Similarly, Category 6, cytotoxic agents in all formulations except oral, which require the pharmacist or technician to use personal protective equipment, have handling costs that are approximately 5.3 times those of Category 2. Note that since Lewin could not collect sufficient information about the handling costs of radiopharmaceuticals, these products were presented as one category and without a

relative value. However, the data that Lewin was able to collect suggest that these handling costs could vary widely and relative values are likely to be considerably higher than those shown for Categories 1 through 6. For this reason, radiopharmaceuticals may require several categories of handling costs.

Of course, uncertainty exists behind each set of cost estimates from the case studies. For example, analysts at one facility initially estimated labor costs assuming that pharmacists and pharmacy technicians “multitask”—that is, work to prepare several products at the same time. Because the other case-study sites did not use a similar approach, the contractor asked that facility to reestimate labor costs without its multitasking assumption. If multitasking is common when handling these products, the level of “true” handling costs would be lower than those collected for this study, although relative costs might not be affected.

Other costs are likely understated. For example, many hospitals are only in the initial phases of carrying out new regulatory guidelines, such as USP's Chapter 797, Standards on Compounding Sterile Preparations. Compliance with those standards would likely raise estimates of handling costs for some categories of products. However, full compliance will take time, because some hospitals will need to make capital expenditures that hospital administrators may not have already built into their plans.

Given resource constraints, Lewin generally asked case-study sites to provide information for the handling costs of just a single product in each category. Clearly, however, many products would fall within each category. Although variation undoubtedly exists in handling costs among the products that fall within a given category, MedPAC relied on the expert judgment of its technical advisory panel and the informed opinions of pharmacists and finance officials at case-study sites to devise categories of products that reasonably capture gradations of resource use.

The case-study analysis demonstrates that it is feasible for hospitals to collect data that would help them establish charges for handling services.

RECOMMENDATION 6A

The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals.

RATIONALE 6A

When CMS begins to pay hospitals for drugs, biologicals, and radiopharmaceuticals based on their acquisition costs, the payment system will no longer directly reimburse hospitals for their costs in storing, preparing, and disposing of these products. Pharmacy handling costs are a nontrivial expense for hospital outpatient departments and thus, a payment adjustment seems appropriate. Since CMS previously built handling costs into the outpatient PPS payment pool (by basing payment on hospital charges), any adjustment should be budget neutral.

IMPLICATIONS 6A

Spending

- Given budget-neutral implementation, this recommendation will have no impact on program spending.

Beneficiary and provider

- In general, any effects on beneficiaries and providers are likely to be small. This recommendation may help ensure beneficiary access to care by more directly linking payment to handling costs. Hospitals may receive higher or lower payments based on the mix of drugs they use, but such distributional impacts are likely to be minimal.

What are the options for collecting data?

To implement a payment adjustment for handling costs, CMS would need data to set payment rates. MedPAC considered three means of collecting data: (1) surveying hospitals periodically, (2) conducting a series of microcosting analyses, and (3) requiring hospitals to submit charges. Each approach has limitations, but requiring hospitals to submit charges has the advantage of providing data in the same form that CMS uses to set payment rates for all other services under the outpatient PPS.

One approach to collecting data for setting payment rates is to survey hospitals in much the same way that the MMA directed GAO to survey hospitals on the acquisition cost of specified covered outpatient drugs, and then set payment rates based on periodic survey results. However, a survey approach might be less successful for collecting data on pharmacy handling costs than for product acquisition costs. In the case of the latter, GAO asked hospitals to provide data from product invoices—a

relatively unambiguous if tedious task for the more than 1,000 national drug codes involved. For handling costs, each hospital might use its own definitions and accounting approach for enumerating the costs of pharmacy and nuclear medicine departments, then allocate those costs across other cost centers. Previous MedPAC work on hospital charging practices suggests that these different accounting approaches would confound attempts to collect data on handling costs through surveys.

Alternatively, CMS could periodically conduct a series of microcosting analyses, in much the same way that MedPAC's case-study facilities did. However, CMS would need a larger sample of hospitals estimating costs for more products in order to develop a more representative and stable set of cost estimates. CMS could use those analyses to establish payment rates in certain benchmark years, with indexes of cost growth used to update costs in other years. For example, one recent study of pharmacy costs for preparing chemotherapy infusions used a microcosting approach (Pharmacotherapy Outcomes Research Center 2005).¹⁸ Time-and-motion studies are a common part of such exercises, in which cost analysts measure directly the amount of pharmacist and pharmacy technician time and other resources that pharmacies use to prepare specific products. Although this approach offers the most promise for measuring resource use accurately, CMS would likely find it prohibitively expensive to conduct such studies for a representative sample of hospitals and for a wide variety of drug, biological, and radiopharmaceutical products.

Under a third approach, CMS would require hospitals to submit charges for pharmacy handling costs under a limited number of separately paid APCs. Those APCs would be designed to reflect categories of pharmacy handling costs in much the same way as the seven categories of products devised by MedPAC's technical advisory panel. Hospitals would submit charges based on their handling costs for each administration delivered to a patient. If CMS needs to set payment rates before they begin to collect hospital charge data, the agency could conduct a limited number of microcosting analyses for a set of products to set initial payments. Ultimately, however, CMS would set payments in the same manner as for other APCs: by calculating the median of hospitals' charges reduced to costs for those services, thereby limiting the burden on CMS.

Requiring hospitals to set charges for handling costs has disadvantages and advantages. CMS has no control over

the level of sophistication that hospitals would use to develop charges for handling costs. While some hospitals might conduct “time and motion” studies or detailed cost analyses, other hospitals might use cruder approaches. Nevertheless, CMS would use the charges that hospitals developed from both more and less sophisticated methods to set payment rates. An advantage of requiring hospitals to set charges is that this process automatically would provide CMS with updated information about handling costs. In comparison, CMS would need to repeat surveys or microcosting analyses periodically in order to keep information current.

RECOMMENDATION 6B

The Secretary should:

- **define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;**
- **instruct hospitals to submit charges for those APCs; and**
- **base payment rates for the handling fee APCs on submitted charges, reduced to costs.**

RATIONALE 6B

In order to set more accurate payment rates for pharmacy department services, CMS should base handling fees on handling costs for preparing a drug administration or nuclear medicine procedure, rather than making these handling fees proportional to the acquisition cost of the product. CMS could use MedPAC’s framework to develop separate payments for hospital pharmacy handling costs. Our contractor conducted categorization and microcosting exercises at four case-study sites to test whether hospitals could understand the framework and collect information about handling costs in order to set charges for handling services provided by pharmacy and nuclear medicine departments. MedPAC’s analysis suggests that developing charges for handling costs is feasible.

IMPLICATIONS 6B

Spending

- This recommendation will have no impact on program spending.

Beneficiary and provider

- In general, any effects on beneficiaries and providers are likely to be small. This recommendation may help ensure beneficiary access to care by making more

direct payment for handling costs. Some hospitals may incur costs to develop charges for handling costs; however, those costs are likely to be relatively small compared with similar efforts that hospitals undertake to develop charges for all other services that they provide. For hospitals that deliver a larger volume of this study’s products, developing charges for handling costs could be worthwhile because under this recommendation, Medicare would pay hospitals directly for pharmacy department services.

A longer term agenda: Broader payment bundles in the outpatient PPS

MedPAC’s study question falls within the context of the Congress’s changes to payment rates beginning in 2006, when Medicare will pay hospitals based on the hospitals’ average acquisition costs for the study products. Therefore, our analysis focused on the need for—and design of—a payment adjustment for handling costs. However, for the longer term, a broader question is whether the current approach to paying for drugs in the outpatient PPS provides incentives for delivering those hospital services efficiently.

Under the outpatient PPS, the unit of payment is the ambulatory payment classification, or APC. The breadth or narrowness of a bundle within the outpatient PPS varies tremendously by APC. For some services, such as outpatient surgery, considerable packaging takes place. The APC includes all costs incurred by the hospital to admit and prepare the patient, staff and equip the operating room, supply products needed during the procedure (including inexpensive drugs), and observe the patient after the procedure. (Medicare pays for physician services separately.) In contrast, the outpatient PPS includes separate APCs for every drug that costs at least \$50 per administration, as well as separate payments for drug administration, and—if CMS adopts MedPAC’s recommendation—a separate handling fee.

If CMS adopts a handling fee, the outpatient PPS will have a greater degree of unbundling for drugs than other Part B payment systems. In physician offices, Medicare makes one payment for the drug, while handling costs are built into the payment for drug administration. For dialysis facilities, Medicare bundles payment for many of the drugs, their handling, and administration costs into the composite rate for dialysis services.

One can see the disproportionate unbundling of drugs in the number of APCs. All clinic visits, procedures, and diagnostic tests paid for under the outpatient PPS are described by about 450 APCs. In comparison, some 300 APCs exist for separately paid drugs, which account for a small share of payment.¹⁹

Initially, CMS proposed packaging many drugs with related procedures. It determined payments using the same process as for other items: charges from the claims reduced to costs using cost-to-charge ratios (CCRs) from cost reports. Manufacturers' concerns about the accuracy of hospital coding and methods that CMS used to set payment rates led to gradual unbundling of payments for drugs and radiopharmaceuticals as well as to the use of alternative data sources for setting payment rates.

Manufacturers and others worry that bundling would make hospitals less willing to supply expensive drugs if CMS calculated the payment rates as the median costs among claims that included lower cost products as well. They argue that newer agents provide significant advances in therapy, and thus the design of payment bundles could adversely affect patient care. Manufacturers and others also argue that the standard approach to setting payments is inadequate for expensive drugs, due to the poor quality of coding for claims and to practices that underestimate costs for more expensive items and overestimate costs for less expensive ones.

Historically, hospitals did not need to code individual drugs using HCPCS codes, nor did they need to accurately record the number of units because payment was based on total charges. Today, however, hospitals must bill separately paid drugs with a HCPCS code and must ensure that the units are accurate in order for CMS to set reasonably accurate payment rates. As experience with the outpatient PPS builds, hospitals' coding should become more accurate. But the payment system is complex, and some hospitals use antiquated billing systems. For these reasons, hospitals continue to struggle with their coding.

Charge compression results from the interaction of hospitals' methods of setting charges and CMS's method of converting those charges to costs. Generally, CMS uses a single CCR to convert the charges for all services in a single revenue center, such as pharmacy, into costs. Within a revenue center, however, some hospitals mark up inexpensive products more than they do expensive products, which leads to charge compression. For example, when setting charges for a generic antibiotic, a hospital may mark up its acquisition cost by a factor

of six, while it marks up an expensive chemotherapy drug by a factor of two. If CMS uses a single CCR that covers all pharmaceuticals to estimate costs from the resulting charges, the approach will tend to overestimate the costs of inexpensive items while generally underestimating the costs of expensive items. MedPAC's survey of hospital charge-setting practices confirmed that hospitals often use smaller markups on more expensive items. Other researchers have found similar results (GAO 2004).

Although this phenomenon may lead to inaccurate estimates of costs for individual products, the global estimate of costs for pharmacy products should not change: Any overestimate of lower cost items should generally balance out any underestimate of higher cost items. This balancing out may be one reason why concern over charge compression is greater among manufacturers of drugs, biologicals, and medical devices than among hospitals.

When some items are bundled and others are not, the payment system provides an incentive to use those products paid separately, if they are more profitable than the bundled items. MedPAC has documented considerable problems in payment for dialysis treatment—such as rapid increases in use of separately paid items—when CMS bundles payment for some services and bills separately for other services, notably drugs. CMS is conducting a demonstration to broaden the dialysis bundle and counter those problems. In the outpatient PPS, providers have an incentive to substitute a high-cost drug that is separately payable for a lower cost drug that would be bundled into the APC payment for the service. If hospitals act on this incentive, it could raise beneficiaries' overall cost sharing, Part B premiums, and Medicare's program spending.

In addition, setting payment rates for small bundles is likely to be less accurate than setting rates for larger bundles. Isolating a single input requires great precision in setting payment rates. Given the tools available to CMS, that precision may not be possible. Relying on outside data sources, such as the GAO study of acquisition costs, is administratively cumbersome. It also requires considerable administrative resources that CMS might better spend elsewhere.

With broader payment bundles, variations in charging practices across inputs are more likely to balance out, leading to payment rates that, on average, are close to costs. Furthermore, greater bundling of hospital outpatient department services could work in tandem with payment approaches that take into account quality and efficiency.

For example, rather than paying for each administration of chemotherapy, CMS may be able to identify episodes of chemotherapy treatment. Ideally, both payment and performance measurement would span entire episodes. Currently, broader bundles do not exist, but additional

research could result in a more streamlined payment system that offers better incentives. As MedPAC continues to pursue its agenda on refinements to the outpatient PPS, we will investigate this topic. ■

Mandate for this study (excerpts from Section 621 of the MMA)

Sec. 621. Hospital outpatient department (HOPD) payment reform.

(a) Payment for Drugs.

(1) Special rules for certain drugs and biologicals. Section 1833(t) (42 U.S.C. 13951(t)), as amended by section 411(b), is amended by inserting after paragraph (13) the following new paragraphs:

“(14) Drug APC payment rates.

...

“(B) Specified covered outpatient drug defined.

“(i) In general. In this paragraph, the term ‘specified covered outpatient drug’ means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

“(I) a radiopharmaceutical; or

“(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

“(ii) Exception. Such term does not include—

“(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

“(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

...

“(E) Adjustment in payment rates for overhead costs.

“(i) MedPAC report on drug APC design. The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

“(I) a description and analysis of the data available with regard to such expenses;

“(II) a recommendation as to whether such a payment adjustment should be made; and

“(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

“(ii) ADJUSTMENT AUTHORIZED. The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i). ■

Endnotes

- 1 Specifically, manufacturers believe that hospitals set their charges for higher cost drugs with smaller markups than for lower cost drugs and services. Manufacturers are concerned that if hospitals adjust drug charges to costs using a single department-wide cost-to-charge ratio, estimated costs will be too low for high-cost drugs and too high for lower cost items (PhRMA 2003). See the section on broader payment bundles later in this chapter for a more detailed discussion.
- 2 Some of the few available sources are annual national surveys of pharmacy practices in hospital settings conducted by the American Society of Health-System Pharmacists (ASHP). Although these surveys provide useful insights, they focus on the role of pharmacists in managing the medication-use process rather than tracking the cost of all resources needed to perform pharmacy services. The ASHP also conducts an annual pharmacy staffing survey to gauge the supply of and demand for pharmacists and pharmacy technicians.
- 3 Maryland uses a regulatory process to set the rates that hospitals charge. Because of its regulatory approach, the state collects detailed cost information from hospitals, including the acquisition cost of drugs, salaries and fringe benefits, and other supplies used in hospital pharmacy departments.
- 4 Given budget-neutral recalibration of the relative weights, any decrease in the relative weights for drugs, biologicals, and radiopharmaceuticals that results from moving to acquisition cost would result in slightly increased relative weights for other services. Total payments for all services would remain the same.
- 5 The outpatient PPS experienced a full market basket update in 2001, 2003, 2004, and 2005.
- 6 Despite the law, pass-through payments from August 2001 through April 2002 were not adjusted to ensure budget neutrality.
- 7 The interim payment rates depend on the type of drug and are based on AWP as of May 1, 2003. Sole-source drugs were paid between 88 percent and 95 percent of the reference AWP in 2004 and are paid between 83 percent and 95 percent of the reference AWP in 2005. Innovator multiple-source drugs are paid up to 68 percent of the reference AWP. Noninnovator multiple source drugs are paid up to 46 percent of the reference AWP.
- 8 CMS would need to consider how to pay hospitals for handling combination therapies. Options include paying a handling fee for each individual product, paying one handling fee for the more resource-intensive product of the combination, or paying one handling fee for the first product listed when they are billed for concurrent handling and a smaller percentage for each subsequent product.
- 9 Although most hospitals do not set separate charges for their handling costs, a small number do. Some hospitals also bill separately under evaluation and management codes for the time that pharmacists spend educating individual patients about their drug regimens and answering their questions.
- 10 Controlled substances constitute an exception.
- 11 Some hospitals make decisions daily about whether to prepare radiopharmaceuticals in house or to purchase commercially prepared unit doses, depending on the hospital's expected caseload of patients.
- 12 MedPAC initially considered conducting a representative survey (as GAO is doing for its study on acquisition costs) but concluded that it would be difficult to ensure the comparability of any data collected. We based that decision on the lack of common definitions for these costs and on observations from hospital pharmacy and finance directors that hospitals account for their pharmacy costs in very different ways.
- 13 Four hospitals or hospital systems committed to participating in both parts of the case-study analysis (categorizing drugs and providing estimates of handling costs). All four hospitals or hospital systems are located on the East Coast and range in size from 100 to more than 700 beds. Three are located in large urban areas (population greater than one million), and one is located in a smaller urban area. One of the facilities is an outpatient cancer center associated with a major teaching hospital. For each case study, directors of finance, pharmacists, and cost analysts generously shared their time and expertise. Two additional hospital systems—one in the South and another in the East—agreed to conduct the categorization but not the costing exercise.
- 14 Lewin did not require hospitals to categorize products that they do not dispense.
- 15 The majority of cases in which categorizations differed involved situations in which hospitals used different forms of the same product—for example, a prepackaged liquid versus a powder form that requires reconstituting.

- 16 This study's technical advisory panel initially used separate categories for oral cytotoxic agents and specialty IV agents that require special handling, but then they later grouped both within Category 5 because both agents' handling costs were of a similar magnitude. One external reviewer of this study suggested splitting those two types of agents because they believe that changes in therapy, handling procedures, and the need to track utilization warrant separate groupings.
- 17 Because there was an even number of sites (four), the median was calculated as the simple average of the two middle values. Although there was substantial variation in estimated costs for any one product across case-study sites, the cost data demonstrate that the categories reflected increasing levels of handling costs.
- 18 This study evaluated handling costs at two academic medical outpatient infusion centers and two community cancer centers. The study focused on facilities that provide only chemotherapy, rather than a mixture of medication therapies as most U.S. hospitals provide.
- 19 Given the changing definitions, it is difficult to compare the number of APCs to the share of spending. However, pass-through drugs, separately paid drugs, and blood products accounted for about 7 percent of spending in 2002.

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CHAPTER

7

Critical access hospitals

Critical access hospitals

The Congress mandated that MedPAC study the effect of the critical access hospital (CAH) provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The CAH program increases Medicare payments to small hospitals whose Medicare costs exceed prospective payment system (PPS) rates. The program has increased Medicare payments and the profitability of many small rural hospitals. Cost-based payments for those CAHs will total about \$5 billion in 2006, roughly \$1.3 billion more than under the PPS. The MMA changes will cause a few more hospitals to convert to CAH status this year but will also effectively stop conversions after 2005.

Some CAHs are quite close to other providers. In 2003, approximately 17 percent of cost-based Medicare payments went to CAHs that were 15 or fewer miles from another hospital. This raises an issue of competition between CAHs and providers paid under Medicare PPS. For example, Medicare payments to CAHs for post-acute patients in swing beds are higher than rates paid to competing SNFs. Payment modifications and other adjustments may be needed for fair competition.

In this chapter

- Congressional mandate and background
- How does conversion to CAH status affect hospitals?
- Is quality of care at low-volume rural hospitals comparable to that of higher volume rural hospitals?
- MMA changes to the CAH program
- Summary of findings

Congressional mandate and background

The Congress mandated that MedPAC “analyze the effect on total payments, growth in costs, capital spending, and such other payment effects” of a broad range of rural provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This rural report is due in December 2006. As an interim step, the Congress also mandated that “The Commission shall submit to Congress an interim report on the matters...with respect to changes to the Critical Access Hospital provisions under section 405” of the MMA (see text box, p. 174). In this report, we describe the current state of the critical access hospital (CAH) program and then evaluate the current and future implications of the following four key aspects of section 405:

- removing states’ ability to waive the requirement that a CAH be located 35 miles by primary road and at least 15 miles by secondary road from another provider starting in 2006;
- increasing the maximum daily acute census from 15 to 25;
- allowing CAHs to operate PPS psychiatric and rehabilitation units, which do not count toward the 25-bed limit; and
- increasing CAH payments to 101 percent of costs.

History

In 1988, the Montana Hospital Research and Education Foundation (an affiliate of the Montana Hospital Association) designed a demonstration of a type of hospital called a medical assistance facility (MAF) that received cost-based reimbursement from Medicare. MAFs were isolated, limited-service hospitals that could admit patients for up to a four-day length of stay. In 1989, the Congress authorized the Rural Primary Care Hospital (RPCH) program, a second demonstration program whereby small, rural hospitals would receive cost-based payments from Medicare. The Balanced Budget Act of 1997 (BBA) merged the MAF and RPCH programs into a new category of hospitals called critical access hospitals (CAHs). CAHs would receive cost-based inpatient and outpatient payments from Medicare. To qualify for the CAH program, a hospital had to be 15 miles by secondary

road and 35 miles by primary road from the nearest hospital or be declared a “necessary provider” by the state. Because states can waive the distance requirement, the CAH program became an option that could help almost all small rural hospitals, as opposed to being limited to helping isolated hospitals.

Following the BBA, the Congress approved a series of legislative and regulatory changes that made the program more beneficial for rural hospitals (Table 7-1). In 2000, the Congress categorized on-call payments to physicians as a reimbursable expense and provided CAHs with cost-based reimbursement for post-acute services in swing beds. Swing beds can be used for acute or post-acute care. The MMA reduced restrictions on CAHs by allowing them to treat up to 25 (rather than up to 15) acute patients at one time, and to operate psychiatric or rehabilitation units. The MMA also increased inpatient and outpatient payments to CAHs from 100 percent of costs to 101 percent of costs. Advocates have argued that CAHs need Medicare payments to be greater than costs so they can build reserves to replace buildings and equipment that continue to become more expensive. CMS restrained the program’s growth somewhat in 2004 when it clarified that observation beds that could also be used as inpatient beds would count toward the 25-bed limit. As a result, some hospitals that have a peak census above 25 patients may have decided not to convert to CAH status. Given current CAH payment policies, most rural hospitals that have a peak census of 25 or fewer patients will benefit from conversion to CAH status if they expect their Medicare prospective payments to be less than 101 percent of allowed Medicare costs.

CAH regulations also require that patients’ length of stay in CAHs be limited to an average of four or fewer days. If a CAH fails to meet the four-day rule (a rare case), CMS requires that the CAH develop and implement a plan of correction. The flexibility provided by swing beds makes it easier for CAHs to meet the four-day rule. Physicians can discharge their patients to post-acute status after three days of acute care if the patient meets the clinical requirements for being discharged to post-acute care. The patient can stay in the same swing bed and the CAH receives the same cost-based payment. The average Medicare acute length of stay at hospitals that converted to CAH status fell from 3.8 days in 1998 to 3.2 days in 2003. The sum of Medicare acute and post-acute days in swing beds per Medicare discharge increased from 6.0 days in 1998 to 6.4 days in 2003 for hospitals with swing beds.

TABLE 7-1

Legislation and changes in regulation make CAH conversions easier and increase payments

Legislation	Key aspects of CAH legislation and regulations
BBA (1997)	<p>The CAH program is enacted. It allows rural hospitals to choose cost-based payments for outpatient and acute inpatient services if the hospitals agree to the following limitations:</p> <ul style="list-style-type: none"> • 15 acute patients. • 25 total patients (including swing beds, excluding observation beds). • All patients' length of stay is limited to 4 days. • States can declare rural hospitals "necessary providers," removing the requirement that hospitals be isolated from other providers.
BBRA (1999)	<ul style="list-style-type: none"> • Length-of-stay restriction is changed to an average of 4 days. • States can declare hospitals "rural," allowing CAHs to exist in MSAs.
BIPA (2000)	<ul style="list-style-type: none"> • Medicare pays cost-based reimbursement of "on-call" payments to physicians. PPS hospitals do not receive this type of payment. • CAHs receive cost-based reimbursement for Medicare post-acute patients in swing beds.
Cost accounting regulations (2001)	<ul style="list-style-type: none"> • CMS increases CAH Medicare post-acute payments in rules regarding CAHs' swing-bed cost accounting methodology.
MMA (2003)	<ul style="list-style-type: none"> • Inpatient limit is expanded from 15 to 25 acute patients. • Rehabilitation and psychiatric units are allowed and do not count toward the 25-bed limit. They are still paid PPS rates. • Payments increased to 101 percent of costs. • Starting in 2006, new CAHs must be 35 miles by primary road or 15 miles by secondary road from another provider. States can no longer waive this requirement.
CMS interpretive guidelines (2004)	<ul style="list-style-type: none"> • CMS will count observation beds that could be used as acute beds toward the 25-bed limit.

Note: CAH (critical access hospital), BBA (Balanced Budget Act of 1997), BBRA (Balanced Budget Refinement Act of 1999), MSA (metropolitan statistical area), BIPA (Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000), PPS (prospective payment system), MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003).

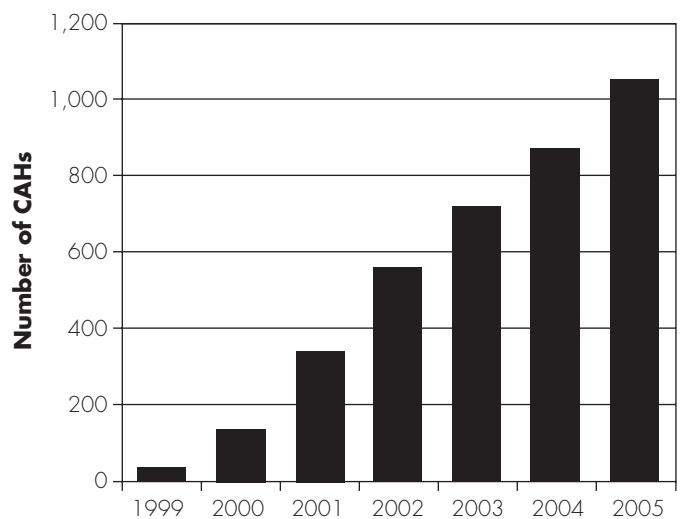
The increase in post-acute days per discharge may reflect longer post-acute stays at the CAH and an increase in patients transferred to the CAH for post-acute care.¹

The number of CAHs has grown rapidly

As the series of legislative changes shown in Table 7-1 made CAH status more attractive, the CAH program grew from 41 hospitals on January 1, 1999, to 1,055 hospitals on January 1, 2005 (Figure 7-1). Most CAHs failed to meet the 35-mile criteria for being considered an isolated provider and entered the program based on state criteria that declared them necessary providers. A state can declare hospitals necessary providers only if it has an approved rural health plan that lists the criteria used to determine which hospitals are necessary providers. States have set the criteria so that most (and in some cases, all) of their small rural hospitals are declared necessary providers, and therefore are eligible to be helped by the CAH program. Criteria do not have to be closely related to access to care. For example, some states give necessary provider status to all rural hospitals in counties with an above-average percentage of people over age 65. One state declares hospitals necessary providers if they have a high risk of closure based on several considerations such as having a low occupancy rate and being located in an area with local

FIGURE 7-1

The CAH program is growing rapidly

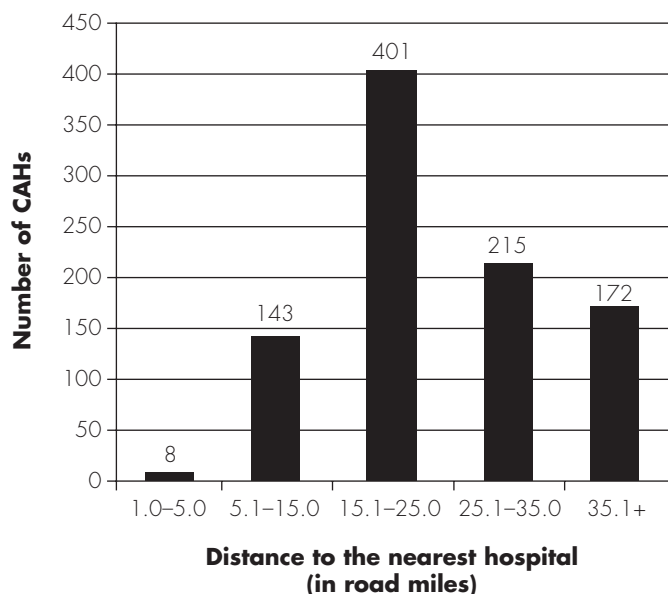


Note: CAH (critical access hospital). Number is as of January 1 of each year.

Source: The Rural Hospital Flexibility Tracking Project, 2003, and additional data from CMS.

**FIGURE
7-2**

Most CAHs are 15 to 35 miles from other hospitals



Note: CAH (critical access hospital). Distances from 939 CAHs that were operating in fall 2004 are to the closest hospital, which may be another CAH. Indian Health Service CAHs and hospitals located closest to Indian Health Service hospitals are excluded from this analysis.

Source: MedPAC analysis of Medicare Cost Report file from CMS.

competition (Gale 2002). CMS gave states great flexibility in setting necessary provider criteria because CMS believed that the Congress intended to give the states almost total control over this issue.

In addition to the “necessary provider rule,” states can declare hospitals rural, even those within metropolitan statistical areas (MSAs). Due to the flexibility in the “necessary provider” and rural requirements, only 18 percent of CAHs are more than 35 road miles from another provider (Figure 7-2). We identified 151 hospitals that were located 15 or fewer road miles from another provider and 616 that were located 15 to 35 road miles from another provider.

How does conversion to CAH status affect hospitals?

The CAH program is designed to increase Medicare payments to low-volume hospitals whose Medicare costs

exceed PPS payment rates. Hospitals project whether their costs (under CAH cost accounting) will exceed PPS payment rates by hiring consultants. The Federal Office of Rural Health Policy provides hospitals with grant funds to pay these consultants through the Rural Hospital Flexibility Grant program.² CAHs receive four key types of cost-based Medicare payments: (1) inpatient, (2) general outpatient, (3) post-acute (swing-bed), and (4) laboratory payments.³ To estimate how the four types of payment changed following conversion, we examine changes in Medicare payments from 1998 (preconversion) to 2003 (postconversion) for hospitals that converted between 1999 and 2002. To control for industry-wide changes in the volume of services, we compare changes in Medicare payments for converting hospitals with changes in Medicare payments for a comparison group of similar hospitals that remained PPS hospitals during that timeframe.

Because all CAHs had 1,900 or fewer discharges in 2003, we limit the comparison group to hospitals that either became CAHs in 2004 or had fewer than 1,900 discharges in 2003. Because most CAHs are located in rural locations, we also limit the comparison group to hospitals outside core metropolitan areas, as defined by Rural-Urban Commuting Areas (RUCAs), which use census tracts (rather than counties) to evaluate the degree to which various areas are rural (Morrill et al. 1999). We further restricted CAHs and the comparison hospital sample to hospitals that filed a 12-month (as opposed to a partial-year) cost report in 1998 and 2003. The result is a set of 498 CAHs that converted to CAH status between 1999 and 2002 and 551 comparison hospitals that retained their PPS status through 2003. The 551 comparison hospitals are larger than the average existing CAHs, but they still fall within the size range for CAHs.⁴ In fact, during the first nine months of 2004, 141 of the 551 comparison hospitals converted to CAH status. We expect that roughly half of the comparison hospitals will convert to CAH status by the end of 2005.

In the subsections below, we first discuss the benefits of cost-based inpatient, outpatient, and post-acute (swing-bed) payments. We then turn to the more difficult issue of laboratory payments.

Inpatient Payments Medicare cost reports indicate that converting CAHs had reported inpatient costs that exceeded PPS payments by an average of \$10,000 before conversion—indicating that for most hospitals, cost-based

inpatient reimbursement was a small incentive to convert. Following conversion, inpatient payments per CAH discharge increased from \$3,868 in 1998 to \$4,704 in 2003, a 4 percent annual rate of increase. This change exceeded the 2.3 percent annual increase at the comparison hospitals. The net annual average increase in inpatient payments was \$81,000 per hospital (Table 7-2, p. 164). Total inpatient payments to CAHs rose slower than the rate of cost growth per discharge due to a decline in the average number of Medicare acute discharges from 575 in 1998 to 499 in 2003 (Table 7-3, p. 166).

Outpatient Payments Converting hospitals reported total Medicare outpatient costs that exceeded Medicare payments by roughly \$100,000 in 1998 (before conversion). CAH conversion allowed these hospitals to eliminate the reported losses. In addition, conversion to CAH status allows on-call payments to physicians and other on-call providers to become a reimbursable outpatient cost. Elimination of losses on outpatient

services and higher outpatient volume contributed to CAHs increasing their outpatient payments more than comparison hospitals (an annualized rate of 15 percent compared with 5.7 percent per year [Table 7-2, p. 164]). Over five years, outpatient payments increased by an aggregate of 69 percentage points faster than at comparison hospitals. The one-time shift to cost-based reimbursement accounts for much of this jump in outpatient payments.

Post-acute payments When a hospital converts to CAH status, it qualifies for cost-based reimbursement for post-acute patients in swing-beds. The shift from receiving SNF rates for post-acute patients to receiving estimated costs (which assume post-acute routine costs equal acute routine costs) resulted in a dramatic increase in post-acute care payments from \$259 per day before conversion to \$1,016 per day after conversion (Table 7-2, p. 164). This compares to an increase from \$262 to \$270 at comparison hospitals that operated swing beds in 1998

Swing-bed cost accounting rules result in higher post-acute payments

In fiscal years starting before December 21, 2000, Medicare paid critical access hospitals (CAHs) a fixed payment for the costs associated with routine care provided to post-acute patients in swing beds. This fixed payment equaled the average cost of routine care for post-acute patients in freestanding skilled nursing facilities (SNFs). Due to the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, CMS now uses a new method to calculate payments for routine services (HCFA 2001).

Under this new method, CMS pays for routine care based on hospitals' reported costs, averaged over acute and skilled nursing patients. To calculate the cost of a post-acute patient's routine care, CMS divides the hospitals' total inpatient routine costs (acute and post-acute) by the sum of acute and post-acute days to obtain an estimated routine cost per day. Because hospitals' routine costs per day exceed freestanding SNFs' routine costs per day, this change in payment methodology causes a significant increase in payments for post-acute care. In our sample of CAHs, payments for post-acute care (including ancillary services) rose from \$259 per

day before conversion to \$1,016 per day after conversion (Table 7-2, p. 164).

Relative to the old method, the new payment methodology increases payments for post-acute care and decreases payments for acute care. The changes reflect a shift in cost allocation from acute to post-acute care. To compute the routine costs allocated to acute patients, CMS starts with total inpatient routine costs and then "carves out" the payments for Medicare post-acute patients. CMS then allocates the remaining costs to acute patients. When post-acute payments increase, the amount that CMS carves out increases, and the costs remaining to be allocated to acute patients decrease. Although CAHs receive roughly \$1,000 in Medicare payments for every post-acute day, some of that gain is offset by a reduction in costs allocated to acute patients. For the marginal post-acute day, the net increase in Medicare payments may be only \$400 to \$500 rather than the full \$1,000. Net revenue per post-acute day of \$400 to \$500 is about \$100 to \$200 more than SNF payment rates of roughly \$300 per day. ■

and 2003. The increased payment rates—not utilization—were the primary reason that payments to converting hospitals increased by an average of \$463,000 per hospital (Table 7-2).

Most of the increased swing-bed revenue is offset by a decline in payments for Medicare acute patient days. Financial consultants to CAHs have informed us that some hospital administrators do not fully appreciate how this offset works. A more transparent pricing system may improve hospital administrators' ability to understand exactly how much their Medicare revenue will increase when they serve more Medicare post-acute patients in swing beds. We discuss the details of swing-bed cost accounting in the text box (p. 163).

The sum of inpatient, outpatient, and post-acute (swing-bed) payments rose by 9.5 percent per year at hospitals that converted to CAH status, compared with a 3.3 percent rise at the comparison group hospitals (Table 7-2). If the CAHs' Medicare revenues had grown at the comparison group's annual rate (3.3 percent) rather than at their actual rate (9.5 percent), Medicare payments per hospital for inpatient, outpatient, and post-acute services would have been approximately \$750,000 lower in 2003. It should be noted that the rate of cost growth at the comparison hospitals was roughly 1 percent above the rate of increase in PPS payments. Therefore, the difference between the 9.5 percent payment increase for CAHs and the 3.3 percent payment increase at PPS hospitals partially

**TABLE
7-2**

CAHs benefit from large increases in outpatient and swing-bed payments

	Medicare payments 1998	Medicare payments 2003	Change	Annualized growth rate
Total payments per hospital				
CAHs that converted after 1998 and before 2003				
Inpatient	\$1,240,000	\$1,321,000	\$81,000	1.0 %
Outpatient	528,000	1,061,000	533,000	15.0
Post-acute (swing-bed)	+ 117,000	+ 580,000	+ 463,000	37.7
Total payments	1,885,000	2,962,000	1,077,000	9.5
Comparison hospitals that did not convert				
Inpatient	\$2,363,000	\$2,695,000	\$332,000	2.7 %
Outpatient	786,000	1,038,000	252,000	5.7
Post-acute (swing-bed)	+ 134,000	+ 122,000	+ -12,000	-1.9
Total payments	3,283,000	3,855,000	572,000	3.3
Payments per unit of service				
CAHs that converted after 1998 and before 2003				
Per acute discharge	\$3,868	\$4,704	\$836	4.0%
Per post-acute day	259	1,016	757	31.4
Comparison hospitals that did not convert				
Per acute discharge	\$4,166	\$4,670	\$504	2.3%
Per post-acute day	262	270	8	0.6

Note: CAH (critical access hospital). In this table, outpatient revenue in 1998 and 2003 does not include outpatient lab costs because fee schedule data were not readily available. The Medicare payments also do not include skilled nursing facility, home health, rehabilitation, or psychiatric unit payments, which are all paid based on prospective payment systems.

Source: MedPAC analysis of Medicare Cost Report file from CMS.

reflects the fact that updates in PPS payments were lower than increases in hospital costs from 1998 through 2003.

Laboratory payments Traditional hospitals receive payments for outpatient laboratory services based on a fee schedule. CAHs receive cost-based payments. We cannot precisely compute how much larger CAHs' cost-based laboratory payments are because we lack preconversion Medicare cost data on laboratory services. However, our discussions with CAH accountants, analysis of postconversion laboratory payments, and examination of total lab costs before conversion suggest that, on average, cost-based laboratory payments increase CAH payments by roughly \$100,000 per CAH.

Net increase in Medicare payments Converting hospitals reported over \$3 million per hospital in cost-based Medicare payments in 2003, which is roughly \$850,000 more per hospital than CAHs would have received if payments had risen at the same rate as that of the comparison hospitals. The \$850,000 consists of the estimated \$100,000 in additional laboratory payments plus the \$750,000 figure representing above-average growth in inpatient, outpatient, and post-acute (swing-bed) payments.

The difference in PPS payment rates and cost-based payment rates How much of the \$850,000 represents an increase in the payment rate, and how much represents an above-average increase in patient volume? To answer this question, we used patient-level claims data to model the payments that hospitals would have received under PPS in 2003 and compared those payments with the payments that CAHs actually received under cost-based reimbursement in 2003. We modeled outpatient payments by calculating ambulatory payment classification (APC) and hold-harmless payments based on Medicare claims and cost report data submitted by the hospitals. The difference between CAH payment rates and PPS payment rates provides a rough estimate of increased Medicare spending. In addition to modeling outpatient PPS payments, we modeled inpatient payments and swing-bed payments. Inpatient payments were modeled using the hospitals' 2003 case mix index derived from claims data using a 2003 diagnosis related group (DRG) grouper and any special payment status the hospital had, such as sole community hospital status prior to converting to CAH status. We modeled PPS swing-bed payments using the per diem rate received by the comparison group hospitals.

We found that roughly all of the \$850,000 represented increased payment rates to CAHs rather than volume increases.⁵ While CAHs increased their volume of outpatient services and post-acute days following conversion, these increases were roughly offset by decreases in inpatient volume.⁶ Averaging across inpatient and outpatient service lines, volume growth appears to be about equal in the two hospital groups from 1998 to 2003.

If the difference between CAH payments and PPS payment rates per hospital was roughly \$850,000 in 2003, what will the difference be in 2006? To answer this question, we needed to make four adjustments to the \$850,000 figure. First, we adjusted for the increases to PPS payment rates that were enacted as part of the MMA, including increases in disproportionate share payments, a lower labor share for hospitals with a below-average wage index, and a low-volume adjustment for isolated rural hospitals that will be in effect in 2006. Second, we accounted for the fact that CAHs will receive 101 percent of Medicare costs in 2006 rather than the 100 percent of costs received in 2003. Third, we modeled PPS payments with the hold-harmless provision extended and a second time assuming the hold harmless is allowed to expire prior to 2006. Fourth, we examined a range of potential cost increases at CAHs.

We found that if CAHs can restrain their cost growth to a level equal to increases in PPS payment rates and if the outpatient hold-harmless provision is extended, the net difference between CAH payment rates and PPS payment rates would grow from roughly \$850,000 in 2003 to slightly below \$1 million per CAH in 2006. However, if Medicare payments to CAHs continue to rise at historical rates or if the hold-harmless provision is allowed to expire, the difference between CAH payments and PPS payments would rise to over \$1 million per year in 2006. Given the range of potential differences between CAH payment rates and PPS payment rates, we estimate that 2006 payments per CAH will be roughly \$1 million higher under cost-based reimbursement than they would have been under PPS payment rates.

The hospital doors stay open

One goal of the CAH program is to preserve access to care in isolated areas by improving the financial condition of isolated hospitals and preventing closures. The program has accomplished that mission. By converting to CAH status, converting hospitals have dramatically increased

their Medicare payments and improved their all-payer profit margins from -1.2 percent in 1998 to 2.2 percent in 2003.⁷ This increase can be compared to the comparison hospitals' decline in all-payer margins from 2.2 percent in 1998 to -0.2 percent in 2003. As CAHs improved their profitability, CAH closures almost ceased. CMS reported that 15 CAHs closed from 1999 through 2003, and we have identified one additional closure in 2004. The hospital that closed in 2004 was approximately six miles away from two competing hospitals. A for-profit corporation is considering reopening the closed CAH.⁸

Many of the CAHs that are helped by the program are critical for beneficiaries' access to care. Some are in isolated areas of the West; others are located on islands (e.g., Martha's Vineyard; Kodiak, Alaska). In these isolated areas, the CAH may serve as the only source of care—not only for local citizens but also for individuals visiting the area or driving through on local highways. About 20 percent of CAHs (172 of the approximately 939) for which we have data are located more than 35 road miles from the closest hospital.

Why did some small hospitals choose not to convert?

In most cases, hospitals do not convert to CAH status for one of two reasons:

- They do not want to be limited to 25 acute-care beds.
- They expect their Medicare PPS payment rates to be higher than their reported costs under CAH cost accounting.

Hospitals with above-average Medicare PPS payment rates are less likely to convert. The comparison hospitals received an average of \$298 more in payments per discharge in 1998 than converters (\$4,166 versus \$3,868, Table 7-2, p. 164). Payments differ in part because comparison hospitals were more likely to be Sole Community Hospitals and more likely to receive significant disproportionate share (DSH) payments. Sole Community Hospitals receive inpatient payment rates based on their historical costs when these cost-based payments exceed current payment rates. (DSH payments go to PPS hospitals with high shares of Medicaid and low-income Medicare patients.) Hospitals that did not convert received an average of \$113,000 in DSH payments in 2003; they would have lost these payments if they had converted.

Hospitals with below-average costs are also less likely to convert. After adjusting for case mix and wage levels, comparison hospitals tended to have lower costs per discharge (\$4,013 versus \$4,429 for CAHs in 1998).

Changes in service offerings follow national trends and financial incentives

Following conversions, CAHs exhibited a change in their service mix and in their patient mix. Services shifted from acute inpatient services to post-acute care and outpatient

TABLE 7-3

Changes in service volumes per hospital following conversion to CAH status

	1998	2003	Change
Total acute discharges			
Converters (n=498)	575	499	-76*
Comparison group (n=551)	1,097	1,121	24*
Medicare acute discharges			
CAH converters	320	288	-32*
Comparison group	568	586	18*
Medicare acute and swing-bed days			
Converters' Medicare acute days	1,229	939	-290*
Comparison Medicare acute days	2,368	2,209	-159*
Converters' swing days	461	651	190*
Comparison swing days	537	461	-76*
Medicaid acute days			
Converters' Medicaid acute days	159	127	-32*
Comparison Medicaid acute days	401	427	26*
Total acute and swing-bed days (all payers)			
Converters	2,764	2,439	-325
Comparison group	4,563	4,314	-249
Medicare percentage of all days (acute and swing-bed)			
Converters	61%	65%	4%*
Comparison group	62%	62%	0%*

Note: CAH (critical access hospital). Values presented are unweighted means. An evaluation of medians found similar changes over time and similar differences between CAHs and comparison hospitals.
* Indicates changes are significant using a p<.01 criterion and a standard t-test.

Source: MedPAC analysis of Medicare Cost Report file from CMS.

services. The hospitals' inpatient payer mix shifted toward post-acute Medicare patients and slightly away from acute Medicare and Medicaid patients (Table 7-3). The increased payment rates for post-acute services in swing beds may have contributed to the decision by an additional 10 percent of CAHs to initiate swing-bed services (Table 7-4).

In contrast with swing beds, the profitability of operating home health and hospital-based SNFs is expected to decline slightly following conversion to CAH status. Home health and SNF profitability decline slightly because Medicare pays for these types of care on a prospective basis. Retaining these services causes some hospital overhead to be allocated to these services, resulting in less hospital overhead eligible for cost-based reimbursement. Cost-based reimbursement can slightly distort the decision to close a home health agency or a SNF by reducing the profitability of the services due to the allocation of overhead to these services. CAHs were only slightly more likely to close their SNFs (4 percent versus 3 percent) and their home health agencies (11 percent versus 9 percent) than comparison hospitals (Table 7-4). The differences are not statistically significant, suggesting that the small shift in incentives is not having a large effect on decisions to close services.

The Federal Office of Rural Health Policy has funded a multiyear study by a team of academic researchers to track conversions to CAH status as well as CAHs' activities and successes. The Flex Tracking Team found that between 2002 and 2004, 40 percent of CAHs significantly expanded radiology services and 20 percent expanded laboratory services (Casey and Klingner 2004). Nineteen percent of CAHs expanded their rehabilitation services and 12 percent expanded their emergency services. In contrast, 6 percent of CAHs dropped their obstetric services.

Distribution of payments, by distance to other hospitals

Although the CAH program has helped preserve access to emergency and inpatient care in isolated areas, it may not have accomplished this goal in an efficient manner. In some cases, Medicare pays cost-based reimbursement to CAHs that are not critical for patients' access to care. In our sample of 623 CAHs (which includes hospitals with partial-year cost reports), 15 percent of cost-based payments (\$289 million) went to providers that were located more than 35 miles from another provider, and 17 percent of payments (\$320 million) went to hospitals that were located within 15 miles of another provider (Figure 7-3, p. 168). The remainder of the \$1.9 billion in payments went to hospitals that were located 15 to 35 miles from another provider.

Consultants who work with CAHs have noted a flurry of activity among hospitals that are deciding whether to convert to CAH status before the states lose their ability to declare necessary providers on January 1, 2006. Based on these conversations and an examination of cost-report data, we estimate that roughly 1,300 CAHs will exist by the start of 2006. Given recent cost growth trends and the projected number of CAHs, we expect Medicare's cost-based payments to CAHs to total roughly \$5 billion in 2006. We estimate that this \$5 billion in payments will represent between 3 and 4 percent of all Medicare inpatient and outpatient payments to hospitals in 2006. We expect the \$5 billion in cost-based payments to be roughly \$1.3 billion above PPS payment rates for those services.

Will CAH costs continue to grow rapidly?

The PPS was implemented in the early 1980s to increase hospitals' incentive to control costs. Now that CAHs have reverted back to cost-based reimbursement, there is a concern that CAHs will have a reduced incentive to

TABLE 7-4

Changes in service offerings

	1998	2003	Change
Swing-bed services are offered			
Converters	85%	95%	10%*
Comparison group	74	77	3*
SNF services are in a distinct-part unit			
Converters	32	28	-4
Comparison group	26	23	-3
Home health agency services are offered			
Converters	49	38	-11
Comparison group	56	47	-9

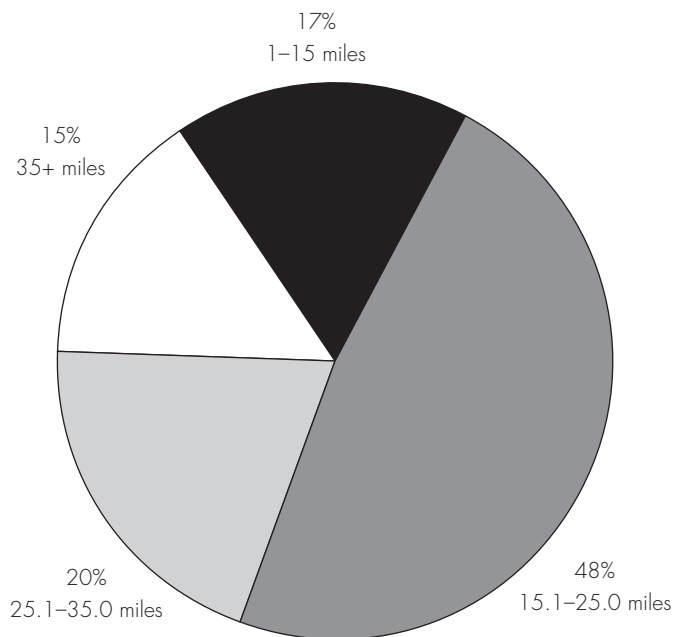
Note: SNF (skilled nursing facility).

* Indicates changes are significant using a p<.01 criterion and a standard t-test.

Source: MedPAC analysis of Medicare Cost Report file from CMS.

**FIGURE
7-3**

**CAH payments, by distance
from the nearest hospital**



Note: CAH (critical access hospital).

Source: MedPAC analysis of Medicare Cost Report file from CMS.

control costs. Although cost-based reimbursement does reduce hospitals' incentive to control costs, it does not eliminate that incentive. Three important points frame our thinking about CAHs' incentives to cost control costs:

- All hospitals have some incentive to control costs.
- The incentive is weaker under cost-based reimbursement.
- Factors other than cost-based reimbursement affect the hospitals' incentive to control costs.

Non-Medicare patients represent 35 percent of CAHs' inpatient days, and CAHs need to keep their costs below the rates they receive from private payers to remain profitable. Technically, CAHs need to keep their costs per unit of service on all non-Medicare patients (including indigent patients) lower than their income per unit of service, including nonoperating income such as government support, investment income, and charitable contributions. Although the need to make money on private-payer patients gives CAHs some incentive to

control costs, CAHs can increase spending more easily than similar PPS hospitals can, all else being equal. When a PPS hospital purchases additional labor or equipment, it must pay for those inputs with cash flow from existing sources or through increased patient volume. In contrast, when a CAH purchases additional labor or equipment, its Medicare payment per unit of service increases (assuming that volume does not change). For example, assume Medicare patients account for 50 percent of a CAH's charges. If that CAH hires a full-time pharmacist for a total cost of \$100,000 per year, the hospital must absorb \$50,000 of the cost, but increased Medicare reimbursements will pay for the remaining \$50,000. The effective price of the pharmacist drops from \$100,000 to \$50,000. If the employee's value to the community exceeds 50 percent of his or her cost, the hospital would hire that individual.

So why do some CAHs choose not to hire full-time pharmacists? Some CAH administrators may feel that they cannot afford the 50 percent of the cost that Medicare does not cover. Factors such as uncompensated care costs can place pressure on hospitals to control costs, making the hospitals more reluctant to make expenditures with a negative return on investment. In summary, cost-based reimbursement reduces hospitals' incentive to control costs, but it does not eliminate that incentive.

Costs per unit of service grow at CAHs

To test for differences in cost growth between CAHs and our comparison group of similar small hospitals, we examined costs per inpatient day. We focus on inpatient days because this unit of output covers both Medicare acute-care days and post-acute (swing-bed) days. We have to combine acute-care and post-acute costs because the cost accounting rules for allocating costs between the two categories change when hospitals convert to CAH status.

From 1998 to 2003, costs at converting hospitals rose by an average of \$461 per day, from \$869 to \$1,330 per day (a 53 percent increase) compared to a \$318 per day increase (37 percent) for the comparison group (Figure 7-4). This measure should be viewed with caution for three reasons. First, this measure is influenced by changes in total patient days and the ratio of post-acute days to acute days from 1998 to 2003. As we noted above, CAHs had a larger reduction in total days and a shift toward post-acute swing-bed patients. CAHs' reduction in total inpatient days will push costs per day upward, while the shift toward post-acute days may slightly push costs per day downward. Second, this cost increase may be a one-

time phenomenon associated with the conversion to CAH status. For example, if a hospital closes its SNF and home health agency, overhead costs may be allocated back to inpatient and outpatient services—therefore, the shift upward in costs may be a one-time event. Third, we cannot be sure about causation. Hospitals that experienced (or expect to experience) an increase in costs are more likely to convert because cost-based reimbursement is more advantageous for high-cost hospitals. Causation is likely flowing both ways: Cost growth can drive conversion and conversion can drive cost growth.

When we looked at cost growth of CAHs that had converted by 2001, we found that older CAHs actually reported lower cost growth per inpatient day from 2002 to 2003. These older CAHs showed an increase in costs per inpatient day of 7 percent (\$84) from 2002 to 2003, while the comparison hospitals reported cost increases of 9 percent (\$101) per day. The lower cost growth per day at CAHs could partially reflect the steady increase in post-acute Medicare days without an increase in Medicare acute discharges. The lower cost growth could also reflect a moderation in cost growth at CAHs following an initial jump in costs associated with conversion to CAH status.

After conversion, Medicare payments to CAHs continue to grow

To get an idea of how fast payments will continue to grow in years after conversion has been completed, we examined changes in payments to CAHs that converted by 2001. We found that Medicare payments for inpatient, outpatient, and post-acute services at CAHs increased by 16 percent from 2001 to 2002 and by 12 percent from 2002 to 2003—compared with 4 percent and 1 percent, respectively, for hospitals in the comparison group. The payment increases result from increases in costs and increases in the volume of services at CAHs.

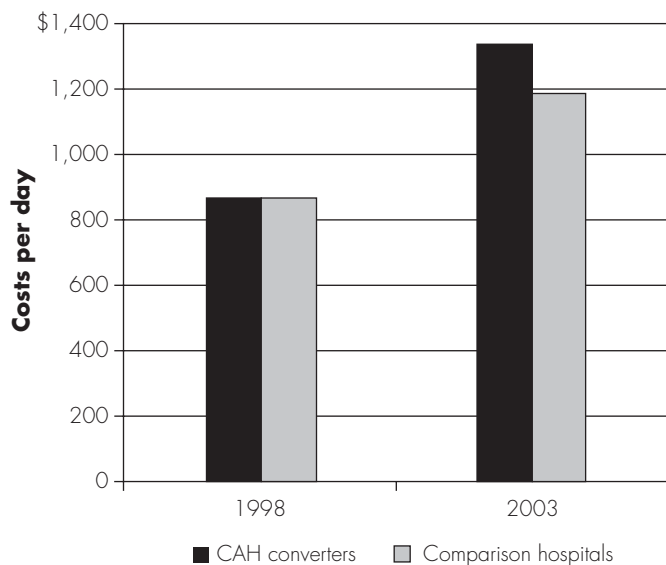
Is quality of care at low-volume rural hospitals comparable to that of higher volume rural hospitals?

The CAH program helps small hospitals remain financially viable, even when they are located in close proximity to other small hospitals. A key policy issue is whether patients are better served by two small hospitals located in close proximity to one another or by one merged hospital. On the one hand, low-volume hospitals have limited resources. For example, a recent survey found that most CAHs do not employ a full-time pharmacist; 40 percent have a pharmacist on site for 10 or fewer hours per week (Casey et al. 2004). A lack of resources and a lack of experience seeing patients with similar conditions could affect outcomes at low-volume hospitals. On the other hand, patients at low-volume hospitals may receive more personal attention. The combination of less sophisticated resources and more personalized attention may affect outcomes differently, depending on the type of services that a hospital provides.

We have limited information on the quality of care in low-volume rural hospitals. The Institute of Medicine (IOM) notes a general absence of studies on patient safety in rural settings (IOM 2005). The Agency for Healthcare Research and Quality (AHRQ) reports patient safety indicator (PSI) rates for all-payer discharges in national, metropolitan, and micropolitan areas; however, it does not report PSI measures at small rural hospitals (AHRQ 2004). Romano and colleagues studied all-payer data for 1.1 million hospitalizations in 14 states in 2000. They found that rural hospitals reported fewer patient safety problems on 12 of 19 PSIs than urban nonteaching hospitals (Romano et al.

FIGURE 7-4

CAH costs per inpatient day rose faster than those of comparison hospitals



Note: CAH (critical access hospital). Days includes both acute and postacute days.

Source: MedPAC analysis of Medicare Cost Report file from CMS.

2003). Coburn and colleagues compared reported PSI rates for rural hospitals by size. Rural hospitals with fewer than 50 beds reported lower rates of postoperative hip fracture and postoperative hemorrhage or hematoma compared with rural hospitals with 50 to 99 beds. The hospitals with under 50 beds also reported lower rates of iatrogenic pneumothorax, infection due to medical care, and postoperative hemorrhage or hematoma, compared with rural hospitals with 100 or more beds (Coburn et al. 2004). This limited literature suggests that the smaller hospitals report fewer patient safety problems.

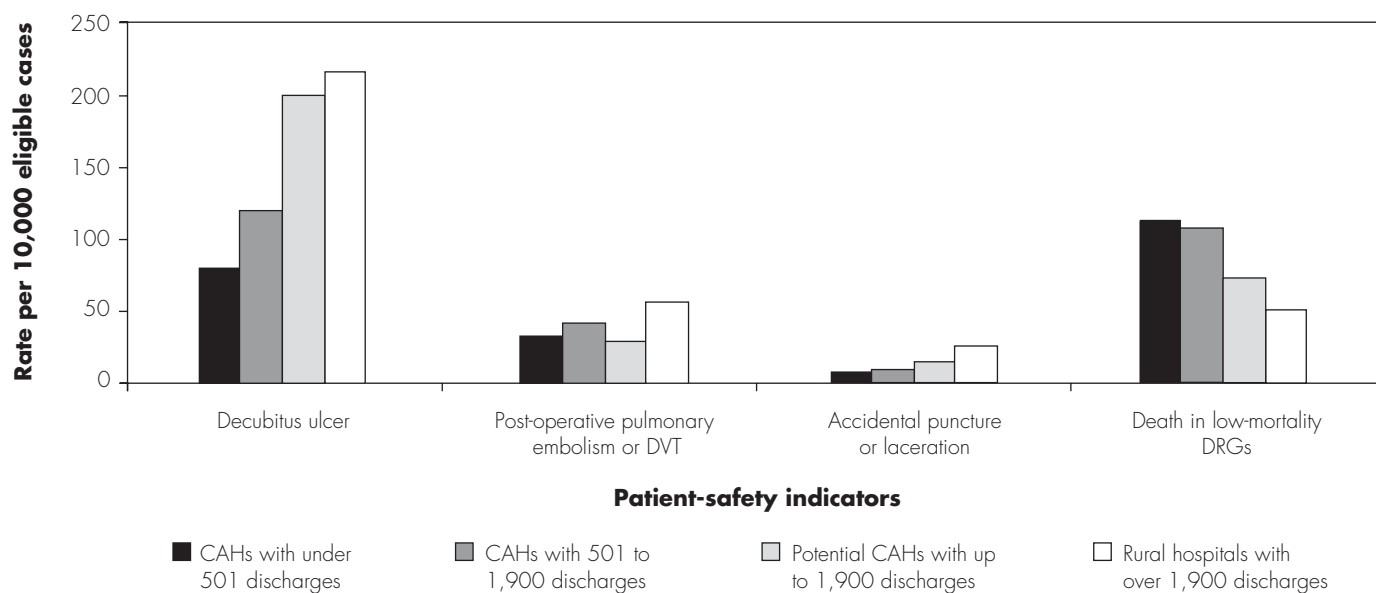
MedPAC presented information on hospitals' patient safety indicators and risk-adjusted mortality in our last two March reports (MedPAC 2004, MedPAC 2005). Due to the small number of discharges at CAHs, we limited our examination to the five most common patient safety issues at rural hospitals and the five DRGs with the largest number of deaths in rural hospitals. The small number of discharges at each individual CAH prevented us from accurately commenting on the quality of individual CAHs or even commenting on the variance in quality across

CAHs. We were limited to examining the average quality of care at different categories of hospitals. We compared small CAHs (500 or fewer discharges per year), larger CAHs (more than 500 discharges per year), our list of 551 potential CAHs (our comparison hospitals), and all other rural hospitals. We split CAHs into two categories—hospitals with more than 500 discharges and hospitals with fewer than 500 discharges—because prior research has indicated that the smaller CAHs are less likely to be accredited by the Joint Commission on Accreditation of Healthcare Organizations and less likely to employ a pharmacist for 40 or more hours per week (Casey et al. 2004).

We examined risk-adjusted rates of patient safety indicators for the most common adverse events in rural hospitals in 2003 (Figure 7-5). We risk adjust rates for age, sex, modified DRG, and comorbidity using AHRQ's methods (AHRQ, 2005). Although small CAHs reported higher mortality in low-mortality DRGs than other rural hospitals, these small CAHs (with 500 or fewer discharges) reported better rates than larger hospitals

FIGURE 7-5

Patient-safety scores, other than death in low-mortality DRGs, are better in smaller rural hospitals

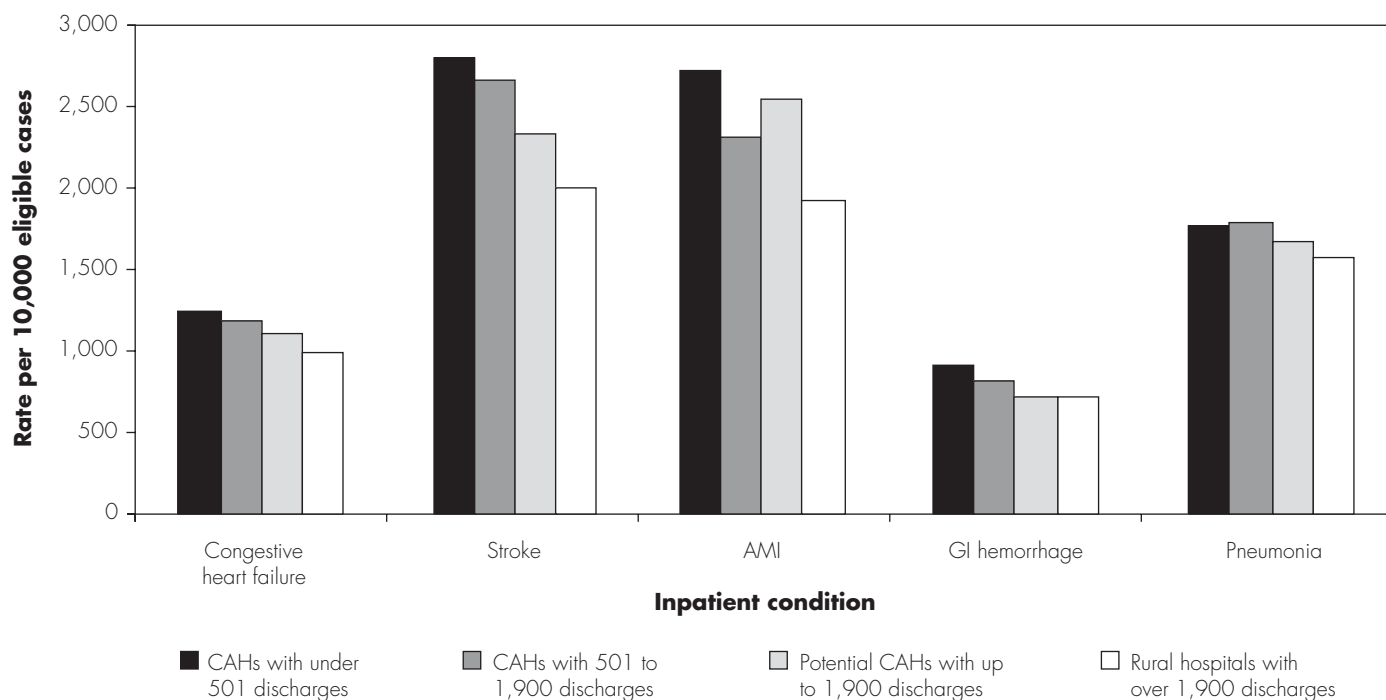


Note: DRG (diagnosis related group), DVT (deep vein thrombosis), CAH (critical access hospital). Rate is risk adjusted per 10,000 eligible cases by hospital size using 2003 data. Differences between rates for CAHs and rural hospitals with more than 1,900 discharges are statistically significant using a $p < .5$ criterion.

Source: MedPAC analysis of 100 percent MedPAR data using Agency for Healthcare Research and Quality indicators and methods.

FIGURE 7-6

Mortality rates are higher in smaller rural hospitals



Note: AMI (acute myocardial infarction), GI (gastrointestinal), CAH (critical access hospital). The total number of eligible cases at CAHs ranges from 1,946 for AMI to 17,180 for pneumonia. The number of eligible cases at potential CAHs ranges from 4,739 for AMI to 35,645 for pneumonia. Rate is risk adjusted per 10,000 eligible cases by hospital size using 2003 data. Differences between rates for CAHs and rural hospitals with more than 1,900 discharges are statistically significant using a $p < .5$ criterion.

Source: MedPAC analysis of 100 percent MedPAR data using Agency for Healthcare Research and Quality indicators and methods.

for failure to rescue, accidental puncture or laceration, postoperative pulmonary embolism or deep vein thrombosis, and decubitus ulcer.

The limited literature on risk-adjusted mortality at rural hospitals is dated, reports mixed findings, and fails to separately examine hospitals as small as CAHs (Schlenker et al. 1996; Keeler et al. 1992). Our analysis of risk-adjusted mortality may be the first national study that compares risk-adjusted mortality in hospitals with 25 or fewer beds to that of other rural hospitals. We examined all Medicare inpatient claims (the 100 percent MedPAR file) and risk-adjusted rates for age, sex, and severity of patients' conditions based on all patient refined diagnosis related groups (APR-DRGs). Smaller CAHs reported higher risk-adjusted 30-day mortality rates than larger CAHs, potential CAHs, and all rural hospitals for congestive heart failure, stroke, acute myocardial infarction (AMI), and gastrointestinal hemorrhage.

Other than for pneumonia, the 30-day risk-adjusted mortality rates generally declined as hospital volume increased (Figure 7-6). We examined the risk of death for the 30 days following admission to control for the fact that CAHs may be more likely to transfer patients that develop complications and need more intensive services. Studies examining in-hospital mortality (as opposed to 30-day mortality) or that focus on non-Medicare patients may yield different findings.

Why do patient safety measures look better at smaller hospitals and risk-adjusted mortality measures look worse? One possibility is that small hospitals perform well with some aspects of quality and not as well with other aspects of quality. It is also possible that small hospitals do not fully code the complications that patients experience. Once Medicare pays a hospital based on costs, that hospital may lack an incentive to code complications that do not affect charges and payments. When hospitals

code poorly, they may not report complications that in turn make their patient mix look less sick and increase their risk-adjusted mortality. To gain some insight into whether poor coding and hence poor risk adjustment is driving higher risk-adjusted mortality rates at smaller hospitals, we also examined 30-day mortality without risk adjustment. The raw mortality data tell a similar story. Other than for pneumonia, unadjusted mortality tends to fall as patient volume increases.

Without reviewing the patients' charts, we will not know whether this higher mortality reflects poorer quality of care at CAHs, or if the CAHs have patients with a higher risk of mortality and that risk is not picked up in our administrative data. It is possible that patients with a high risk of mortality—due to factors not detected by our risk-adjustment model—might choose the local CAH over a distant hospital if they thought they were too ill to be assisted by a larger hospital. In other words, CAHs may attract Medicare beneficiaries who expect to die if the patients see the CAH as a more comforting environment than a larger hospital. CAHs may thus have a higher quality of care than is indicated purely by the mortality statistics shown in Figure 7-6 (p. 171).

In our June 2001 report on Medicare issues in rural areas, we noted that peer review organizations—now known as quality improvement organizations (QIOs)—faced incentives to target quality improvement efforts to large and usually urban providers. We recommended that the Secretary require peer review organizations to work with more rural providers when carrying out their quality improvement activities (MedPAC 2001). In the eighth scope of work for the QIOs—which begins in 2005—the Secretary requires that QIOs recruit CAHs to participate in reporting 13 quality improvement measures specified for CAHs. The QIOs will be evaluated based on CAH reporting of the CAH quality measures and CAH conduct of local quality improvement projects (CMS 2005). This changes the incentives faced by QIOs and may lead to increased efforts to measure and improve the quality of care in CAHs.

One tool for monitoring quality of care at CAHs that is currently missing is the Minimum Data Set (MDS) patient assessment instrument for post-acute patients. While the MDS is an imperfect instrument, the Secretary could consider requiring CAHs to assess patients using the MDS or developing an alternative assessment instrument that could be used for post-acute patients in SNFs and swing beds.

MMA changes to the CAH program

Now we turn to looking at a series of changes in the MMA that affected CAHs. We are often limited to projecting the effects of these MMA changes, because some of the changes have not yet become effective and we do not yet have 2004 financial data from hospitals.

States lose their ability to declare new “necessary providers”

The most important recent change to the CAH program is the elimination of states' ability to declare additional hospitals “necessary providers” starting in 2006. As a result, the CAH program will essentially cease to add additional hospitals at the start of 2006. Almost all hospitals that would meet the criteria of being 15 miles by secondary road and 35 miles by primary road have already converted to CAH status. The Congress grandfathered existing CAHs into the program.

How will this 2006 change affect Medicare beneficiaries? Because most hospitals have already converted, the impact will be limited. However, a few hospitals may be forced to close or merge with neighboring facilities when their patient volume declines, if they do not meet the distance criteria for the CAH program. Closures can result in increased travel times for patients and increased volumes at the remaining hospitals in the market. The net effect on patients is unclear. Although the general belief is that shorter travel times will improve outcomes, the magnitude of that travel-time effect is not clear from the limited literature on the topic (Lerner et al. 2003). There is also the question of whether hospital consolidation will improve quality. Although patient mortality is lower in larger hospitals, it is not clear that the AHRQ risk-adjustment model adequately adjusts for the health status of patients who choose to go to very small hospitals. Given that the law will affect very few existing hospitals and that each closure is expected to have a limited effect on patient travel times, this new provision of the MMA should have a small impact on Medicare beneficiaries.

There is a question of whether Congress went far enough to restore the focus of the CAH program on isolated hospitals. If having two neighboring providers is not clearly better than having one provider with higher volumes, then it may not be justified to continue providing cost-based payments to the two providers when they are

within 15 miles from one another. If all CAHs were required to be 15 miles from another provider to maintain their necessary provider status, neighboring low-volume hospitals would face financial pressure to consolidate. It may be difficult to overcome local political tensions between two communities and merge hospitals, but the mergers could result in having a higher volume facility with more resources.

There is also a concern that Medicare will have roughly 1,300 hospitals that receive higher payment rates than PPS hospitals and SNFs that compete with them. The PPS hospitals may feel they should receive the same payment rates as a CAH if they compete in the same market for employees, physician loyalties, and patients. The problem of a nonlevel playing field exists primarily because CAHs are allowed to be in close proximity to other hospitals.

Limit on acute patients increases from 15 to 25

Prior to the MMA, CAHs could use only 15 of their 25 beds for acute care. When CAHs operated under this constraint in 2003, the largest number of discharges at a CAH was 1,900. Will this legislative change result in significantly more conversions to CAH status or significantly more discharges at existing CAHs?

Even with the option of using all 25 beds for acute care, it will be difficult for a hospital to have significantly more than 1,900 discharges. A hospital with 2,000 discharges would have an 88 percent occupancy rate if its patients stayed four days on average and a 66 percent occupancy rate if its patients stayed three days (acute plus post-acute). It may be difficult for CAHs to reduce patients' lengths of stay (acute plus post-acute) below four days. After examining Medicare margins for hospitals with close to 2,000 discharges, we believe that allowing CAHs to have up to 25 acute-care patients will generate less than 100 additional conversions to CAH status.

Will admissions per CAH and the cost (to Medicare) of CAH conversions increase? Hospitals that downsized to become CAHs may slightly increase their inpatient admissions. However, the payment rates for acute inpatient care at CAHs tend to be only slightly higher than payment rates at PPS hospitals. It is the payment rates for outpatient and post-acute services at CAHs that are significantly higher than PPS payment rates. Raising the limit on acute patients from 15 to 25 does not affect the number of post-acute patients or the volume of outpatient services a CAH can provide. Therefore, we

do not expect this provision to have a major effect on the average cost (to Medicare) of each CAH conversion. The average conversion is still expected to result in Medicare payments that are roughly \$1 million more than PPS rates per hospital in 2006.

CAHs can have distinct-part psychiatric and rehabilitation units with up to 10 beds

Prior to the passage of the MMA, the Government Accountability Office (GAO) studied the potential impact of allowing CAHs to have distinct-part units. The GAO suggested that the provision may result in an additional 47 conversions. As of January 1, 2005 (12 months after Congress passed the MMA), 15 CAHs have distinct-part psychiatric units and 4 CAHs have distinct-part rehabilitation units. Among our list of 551 comparison hospitals, 74 had distinct-part psychiatric or rehabilitation units. Given our review of the data, the GAO's prediction of roughly 50 additional conversions due to allowing distinct-part units appears to be correct.

The shortage of mental health professionals in rural areas is well documented (IOM 2005). The distinct-part psychiatric units in CAHs may allow some mental health patients to stay closer to home and may help in the retention of mental health professionals in rural areas. Little research exists regarding how well the mental health services provided by these distinct-part units match rural communities' needs. The Maine Rural Health Research Center is planning to conduct a study of mental health services at small rural hospitals in 2006 and should be able to shed some light on the degree to which the services provided at these distinct-part units meet the needs of rural communities.

The cost of this MMA provision has been modest. Medicare pays prospective payment rates for services provided in distinct-part units, and fewer than 50 CAHs are expected to have distinct-part units.

Payments rise to 101 percent of costs

The MMA increased payments to CAHs from 100 percent of allowable costs to 101 percent of allowable costs. The average CAH allocated roughly \$3 million of costs to cost-based Medicare services in 2003. The net impact of allowing a 1 percent profit margin is roughly \$30,000 per hospital in 2003. By the time conversions cease in 2006, we expect that average costs per CAH will have grown by slightly more than 12 percent annually due to historical

rates of growth in payments to CAHs and larger CAHs entering the program. In 2006, we expect that a 1 percent increase in Medicare payments will be roughly \$40,000 to \$50,000 per hospital, equivalent to between \$52 million and \$65 million total for the projected 1,300 CAHs.

Summary of findings

The CAH program has successfully helped low-volume hospitals remain financially viable. In 2003, Medicare payments grew by roughly \$850,000 per CAH more than they would have if payments had grown at the rate of competing hospitals. Higher Medicare revenues led to improved profit margins, and CAH closures have almost ceased.

Although it is important to have a program that provides isolated rural hospitals with enough funding to cover the cost of efficiently delivering high-quality care, there are several drawbacks to the current system of cost-based Medicare payments:

- Cost-based payments can distort the financial incentives to close services and reduce hospitals' incentives to control costs.
- Cost-based payments can differ from the prospective payment rates Medicare pays to nearby competitors for similar or identical services. For example, the current system pays much higher rates for post-acute care in CAHs than it does for post-acute care in competing SNFs.

- Some low-volume hospitals are receiving cost-based reimbursement when they are not critical for beneficiaries' access to care.

These three troubling aspects of the CAH program need further research. MedPAC will continue to track cost growth at CAHs to see whether cost-based reimbursement leads to above-average cost growth.

There may also be a need for research that evaluates whether CAHs are gaining market share in services where their payment rates are substantially above the rates paid to competitors. For example, if CAHs are gaining market share in post-acute services due to being paid significantly higher rates than SNFs, paying CAHs a fixed payment rate for post-acute care that is closer to the rate paid to their competitors might be appropriate. In the case of hospitals, there is a need to evaluate whether paying CAHs higher payment rates than competing PPS hospitals creates an unlevel playing field when hospitals compete for employees, physician loyalties, and patients.

In addition, given the CAH program's ability to preserve hospitals with low patient volumes, there is a need for further research that examines whether Medicare beneficiaries are better served by (a) having two low-volume hospitals in close proximity to each other or (b) having those neighboring hospitals merge into one larger hospital. Policy makers may wish to balance the desire to keep care local with the goals of improving the quality of care and restraining cost growth. ■

Section 433 of the MMA

(a) In General.—The Medicare Payment Advisory Commission shall conduct a study of the impact of sections 401 through 406, 411, 416, and 505. The Commission shall analyze the effect on total payments, growth in costs, capital spending, and such other payment effects under those sections.

(b) Reports.—

(1) Interim Report. —Not later than 18 months

after the date of the enactment of the Act, the Commission shall submit to Congress an interim report on the matters studied under subsection (a) with respect only to changes in the critical access hospital provisions under section 405.

(2) Final Report.—Not later than 3 years after the date of enactment of this Act, the Commission shall submit to Congress a final report on all matters studied under subsection (a). ■

Endnotes

- 1 In the case of certain DRGs, Medicare pays a reduced PPS payment rate if the patient is discharged to a SNF for post-acute care and had an unusually short hospital stay. However, Medicare does not reduce payments if the patient is discharged to a CAH's swing bed (Schoenman 2004).
- 2 The Rural Hospital Flexibility Grant program gives states grants that can be used for the following purposes: to assist rural hospitals in assessing conversion to Critical Access Hospital status, network development, and integration of emergency medical services. The program is authorized under section 1820 of the Social Security Act.
- 3 CAHs also benefit from being paid 115 percent of the physician fee schedule if physicians assign their billing rights to the CAH. This benefit was not included in our estimate of the benefits of conversion to CAH status.
- 4 CAH conversion is not a random event. Hospitals choose to convert. Therefore, any comparison group will differ from converting hospitals. Almost all of the smallest rural hospitals (fewer than 500 discharges) have chosen to convert to CAH status. Therefore, our comparison hospitals tend to be the size of larger CAHs (500 to 1,900 discharges). While all CAHs had 1,900 or fewer discharges after conversion, it should be noted that some hospitals had more than 1,900 discharges prior to conversion, but were willing to downsize to 25 beds to obtain higher payment rates as a CAH. Some hospitals have more discharges prior to conversion than they do after conversion.
- 5 The actual difference between cost-based payments and payment under PPS rates could range anywhere between \$800,000 and \$900,000 in 2003. We can only present a rough estimate (\$850,000) of the difference due to our inability to precisely estimate what outpatient therapy payments and outpatient hold harmless payments would have been if the CAHs had been paid fee schedule rates for therapy services and had reported their outpatient costs using PPS cost-accounting rules.
- 6 Consultants have informed us that the projected benefits of conversion are usually lower than \$850,000 per hospital. However, most consultants project benefits of conversion based on preconversion service volumes. We examine the difference between PPS payments and cost-based payments using hospitals' postconversion service volumes. Following conversion, CAHs have tended to expand their volume of services in areas where they received substantially higher payments than neighboring PPS hospitals, specifically outpatient services and post-acute care in swing beds.
- 7 We report all-payer margins because they are not affected by the changes in Medicare cost accounting rules that occur when a hospital converts to CAH status. In contrast, overall Medicare margins are affected by the differences between CAH cost accounting rules and PPS cost accounting rules.
- 8 In our sample of 498 CAHs, 18 are for-profit hospitals.

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CHAPTER

8

**Using clinical and cost
effectiveness in Medicare**

Using clinical and cost effectiveness in Medicare

Policymakers are looking for ways to use Medicare's resources more efficiently. One way Medicare has done so is by using information about the clinical effectiveness of a service when making coverage decisions and setting payment rates. MedPAC supports CMS's recent effort in linking coverage with a requirement for collecting clinical effectiveness data. By contrast, Medicare does not explicitly consider the cost effectiveness of a service in either the coverage or payment process. Nonetheless, cost effectiveness potentially can promote care that is more cost efficient and higher quality. Before Medicare can routinely use cost effectiveness, policymakers will need to address valid concerns about its methods. The Secretary could play an important role in standardizing the methods used in these analyses. Medicare can begin considering cost effectiveness by collecting this type of information from manufacturers when making coverage decisions (when available), sponsoring cost-effectiveness studies, and using such studies to prioritize pay-for-performance and disease management initiatives.

In this chapter

- Medicare's coverage and payment processes consider clinical effectiveness
- Understanding cost-effectiveness analysis
- Medicare's coverage and payment processes do not explicitly use cost-effectiveness analysis
- The future of cost-effectiveness analysis in Medicare

Considering evidence about the clinical effectiveness and cost effectiveness of alternative health services might be another way to increase the return on society's investment in health care. Cost effectiveness evaluates the clinical effectiveness and resource costs of two or more alternative services, including drugs, medical devices, surgical and diagnostic procedures, and medical treatment strategies. The central function of cost-effectiveness analysis is to assess the relative value of alternative services for improving health. Currently, Medicare does not explicitly consider a service's cost effectiveness when making coverage decisions or setting payment rates. Medicare does, however, consider a service's clinical effectiveness when making coverage decisions and when making payments for certain services.

The first section of this chapter outlines how Medicare uses clinical information when making coverage decisions and setting payment rates. We find that CMS uses an open, evidence-based process when making coverage decisions and considers clinical effectiveness information in the rate-setting process for certain services. MedPAC supports CMS's recent effort in linking coverage with a requirement for prospective data collection.

Next, MedPAC begins to consider the use of cost-effectiveness information by Medicare. Cost-effectiveness analyses can potentially improve Medicare's ability to maximize beneficiaries' health and well-being and might enable the program to achieve better value for its expenditures. Medicare cannot use the dollars that it spends on services that are not cost effective for other important purposes—purposes such as providing other health benefits within and outside Medicare. Medicare, together with other payers and purchasers, is in a strong position to consider such information because it represents the interest of large populations.

Medicare could begin to consider cost-effectiveness analysis in the following specific ways:

- standardizing the methods used to conduct such studies,
- collecting cost-effectiveness information from manufacturers and providers in the coverage process (when available),
- sponsoring cost-effectiveness studies,

- providing cost-effectiveness analyses to beneficiaries and health professionals, and
- using available cost-effectiveness analysis to prioritize pay-for-performance and disease management initiatives.

However, before Medicare can routinely begin to use cost-effectiveness analysis, policymakers will need to address valid concerns about the methods that researchers use in current analyses. Policymakers and other stakeholders cite the lack of a common set of techniques in cost-effectiveness analysis as one reason for their limited use of such a method. The Secretary could play an important role in advancing the field of cost effectiveness by helping to standardize the methods in these analyses. In addition, the Secretary could develop the methods in an open process similar to the current process of making national coverage decisions.

Medicare's coverage and payment processes consider clinical effectiveness

Although Medicare's coverage process does not explicitly consider cost effectiveness, it does consider value by assessing the clinical effectiveness of new services. Medicare also considers clinical effectiveness when determining payment for new services paid through under certain prospective payment systems (PPSs) and for some services not paid through PPSs. However, the Congress recently limited the agency's use of such information when paying for certain services furnished in the hospital outpatient setting.

Making coverage decisions and using clinical effectiveness information

Medicare covers health care services when adequate evidence shows that these services improve health outcomes, regardless of the unit or aggregate cost. In practice, services that are high cost will receive greater scrutiny than other services (Tunis 2005).

Historically, CMS based its coverage determinations on descriptive information as well as scientific and clinical evidence. A general notice that the agency published in 1999 formalized the evidence-based process for making coverage decisions and made the process more transparent and understandable to the public. Using such an evidence-

based approach, CMS assesses whether a given service is reasonable and necessary by determining: (1) if it is safe and effective per the Food and Drug Administration (FDA) regulatory process; and (2) if adequate evidence leads CMS to conclude that the service improves net health outcome.

CMS may limit coverage to specified circumstances based on scientific evidence. For example, in a decision concerning carotid artery stenting, CMS extended coverage to patients who were at high risk of stroke and complications during surgery. To better ensure that patients receive care most appropriate for their needs, the coverage decision also delineated minimum standards that facilities must meet to treat high-risk patients—such as providing necessary imaging equipment, advanced physiologic monitoring equipment, and emergency management equipment and systems.

Recently, CMS is also linking national coverage with participation in comparative clinical trials and data registries in order to determine the effectiveness of new services for Medicare beneficiaries. The agency refers to these comparative clinical trials as “coverage with evidence development” or practical clinical trials.¹ CMS collects the data to ensure patient safety, evaluate the benefit of the service, and improve physician decision making. Ultimately, these data should improve the quality of the available scientific evidence because the current FDA regulatory process provides some but not all information needed for CMS to make evidence-based decisions. These trials can potentially enhance Medicare’s ability to assess the effectiveness of new services while providing beneficiaries with access to these services. Information that CMS derives from these trials may enable the agency to refine coverage decisions based on high-quality evidence.

The characteristic features of practical clinical trials are that they: (1) select clinically relevant alternative services to compare; (2) include a diverse population; (3) recruit participants from heterogeneous practice settings; and (4) collect data on a broad range of health outcomes (Tunis et al. 2003). Recent examples of these trials include:

- ***FDG-PET (2-deoxy-2- [F-18] fluoro-D-glucose positron emission tomography) scans for the diagnosis of patients who have mild cognitive impairment or shows signs of early dementia.*** CMS will collaborate with the National Institute on Aging, the Agency for Healthcare Research and

Quality (AHRQ), the Alzheimer’s Association, manufacturers, and other experts to develop a large practical clinical trial.

- ***Percutaneous transluminal angioplasty of the carotid artery with stenting.*** CMS will cover this technology when medical providers furnish it in accordance with FDA-approved protocols that govern postapproval studies.
- ***Off-label uses of four anticancer drugs: xaliplatin (Eloxatin[®]), irinotecan (Camptosar[®]), bevacizumab (Avastin[®]), and cetuximab (Erbix[®]).*** CMS will cover these drugs for beneficiaries in certain clinical trials sponsored by the National Cancer Institute.

What do these services have in common? They are either new or a new use of an existing service, they are costly, they have the potential for high use, and current scientific evidence is inadequate for certain populations of interest. For example, the four anticancer drugs are costly. One of the new drugs to treat colorectal cancer costs about \$30,000 when used with other agents for an eight-week course of treatment (Schrag 2004).

Finally, paying for the costs of routine care for patients in FDA clinical trials—which began in September 2000—is another way in which Medicare has strengthened its clinical evidence base. CMS pays the routine costs of care for patients who enroll in trials that meet certain criteria.² From the information collected in clinical trials, Medicare can begin to learn about the effectiveness of new services. In addition, the MMA authorizes the AHRQ to conduct and support research studying the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services.

Setting payment rates and use of clinical effectiveness information

Some of Medicare’s PPSs consider the clinical effectiveness of new technologies in the rate-setting process. For example, for a new technology to be eligible to receive a pass-through payment in the inpatient PPS, it must represent an advance in medical technology that substantially improves (relative to services previously available) diagnosis or treatment. For new-technology pass-through payments under the hospital outpatient PPS, medical devices must meet the same criteria.

For services not covered under PPSs, CMS has set a new service’s payment rate the same as that of an existing service after concluding that both services are clinically

comparable. In 2003, CMS set the payment rate for a new service (a biological) at the same rate as that of an existing service after concluding that both services were functionally equivalent. The new service was darbopoetin alfa (Aranesp[®]), and the existing service was erythropoietin (Procrit[®] and Epogen[®]). Specifically, the agency concluded that both products were functionally equivalent because they used the same biological mechanism to produce the same clinical result—stimulation of the bone marrow to produce red blood cells.

Section 622 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) limits the use of the functional equivalence standard. The Congress prohibited the use of this standard for drugs and biologicals in the hospital outpatient setting. However, the MMA did not preclude the agency from setting the payment rate the same for other clinically comparable services in other settings. Under the “least costly alternative” policy, Medicare’s contractors (carriers and fiscal intermediaries) may deny coverage for the additional cost of a more expensive service if a clinically comparable service costs less.³

Carrier policies related to two drugs illustrate how this policy works. During the last several years, many carriers have implemented a least costly alternative for two drugs used to treat prostate cancer—leuprolide acetate (Lupron[®]) and goserelin acetate (Zoladex[®])—administered in physicians’ offices. Current payment for Lupron is \$226.66 versus \$192.68 for Zoladex. According to the Office of Inspector General (OIG), carriers implemented a least costly alternative in 47 of 57 jurisdictions in 2003 (OIG 2004). Thus, in these jurisdictions, contractors paid physicians the payment amount for Zoladex when they furnished Lupron. In some instances, contractors paid the higher payment amount if the physician documented why the more costly treatment option was medically necessary. The OIG recommended that all carriers apply a least costly alternative for Lupron.

Understanding cost-effectiveness analysis

For more than 25 years, researchers have used cost-effectiveness analysis as a technique for economic evaluation in health care. This tool is used by some commercial health plans and purchasers, most frequently for understanding the value of new drugs. Many medical

directors believe that cost-effectiveness analysis can and should play a greater role. Nonetheless, some stakeholders fear that the explicit use of cost effectiveness by public and private payers could harm patients’ access to care, negatively affect the innovation of new services, and lead to the rationing of care.

What is cost-effectiveness analysis?

Cost-effectiveness analysis involves estimating the costs and health outcomes of a service and its alternatives. Researchers usually summarize their results in a series of cost-effectiveness ratios that show the cost of achieving one unit of health outcome for different kinds of patients and alternative services.

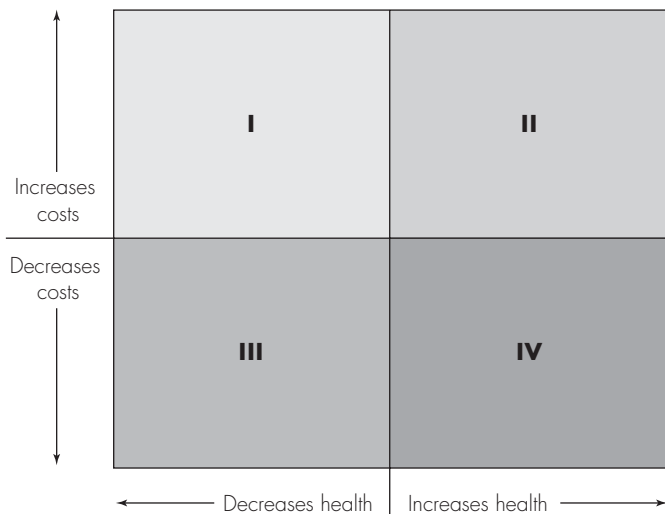
Cost-effectiveness analysis is closely related to cost-benefit analysis. Although both types of analyses consider costs and benefits, the key difference is how researchers measure benefits. In cost-benefit analysis, researchers express benefits in monetary terms, whereas cost-effectiveness analysis presents benefits in terms of health outcomes.

Researchers often measure health outcomes in terms of years of life gained, cases of a particular disease prevented, or improvements in functional status. Researchers also commonly use improvements in health-related quality-of-life years as a measure. The quality-adjusted life year (QALY) is a measure of health outcome that assigns to each time period a weight (ranging from 0 to 1) that corresponds to the quality of life during that period. It is the arithmetic product of life expectancy and a measure of the quality of the remaining life years. QALYs provide a common currency to assess the extent of the benefits that patients gain from a variety of services in terms of health-related quality of life and survival. Although use of QALYs in cost-effectiveness analysis is widespread, some researchers are concerned that these measures do not adequately reflect societal values (Nord et al. 1999).

By providing estimates of outcomes and costs, cost-effectiveness analysis shows the tradeoffs involved in choosing among services. That is, the analysis provides information about the opportunity cost of each service. We can think of the value of services—in terms of their net costs and net outcomes—as a grid, with four quadrants showing the impact of services as either increasing or decreasing health and either increasing or decreasing costs (Figure 8-1).

FIGURE 8-1

The impact of services on outcomes and costs



Note: This figure shows the impact of services in terms of their net costs and net outcomes as a grid, with four quadrants showing the impact of services as either increasing or decreasing health and either increasing or decreasing costs.

Researchers refer to a service that is more effective and less costly than its alternatives as “dominant.” In Figure 8-1, dominant services fall into the lower right quadrant (IV). A service that is more costly and more effective than its alternatives falls into the upper right quadrant (II). Table 8-1 presents the cost-effectiveness ratios of selected services that beneficiaries use; we present this table for illustrative purposes only. Among the selected services we include in the table, influenza vaccination is “dominant.” The remainder of the services fall into quadrant II—they improve health but increase costs. The cost-effectiveness ratios range from less than \$10,000 per QALY for beta blocker after acute myocardial infarction to over \$500,000 per QALY for left ventricular assist devices and positron emission tomography (PET) for Alzheimer’s disease (Gillick 2004, Neumann 2005a).

How have cost-effectiveness analyses evolved in health care?

In the 1960s and early 1970s, policymakers applied cost-effectiveness analysis to a variety of health issues, including kidney disease and maternal and child health programs. Beginning in the 1970s, cost-effectiveness analyses of health issues began to appear in major medical

journals. Since then, researchers have developed models to compare costs and outcomes for services ranging from:

- **drugs**—(e.g., those used in combination antiretroviral therapy for HIV disease);
- **preventive services**—(e.g., vaccination against pneumococcal pneumonia);
- **screening**—(e.g., for HIV and different types of cancers and chronic diseases, such as chronic kidney disease);
- **services**—(e.g., early hospital discharge after uncomplicated acute myocardial infarction and smoking-cessation services); and
- **procedures**—(e.g., bypass surgery for coronary artery disease and lung-volume-reduction surgery (Boulware et al. 2003, Eddy 1989, Paltiel et al. 2005, Willems et al. 1980).

The number of cost-effectiveness analyses has grown steadily (Elixhauser 1998). General medical, medical specialty, public health, and policy journals publish more than 100 studies per year (Gold et al. 1996). Neumann (2005b) reported that about 40 percent of all published cost-effectiveness studies assess the value of pharmaceuticals (Neumann 2005b). This investigator found that fewer studies are published assessing the cost

TABLE 8-1

Cost effectiveness of selected services in the Medicare population

Technology	Cost-effectiveness ratio (2002\$/QALY)
Influenza vaccine	Cost saving
Beta blocker after acute myocardial infarction	Under \$10,000
Cholesterol management, secondary prevention	\$1,000–\$50,000
Dialysis for ESRD	\$50,000–\$100,000
Lung volume reduction surgery	\$100,000–\$300,000
Left ventricular assist devices	\$500,000+
PET for Alzheimer's disease	\$500,000+

Note: QALY (quality-adjusted life year), ESRD (end-stage renal disease), PET (positron emission tomography). The cost-effectiveness ratio is expressed in 2002 dollars spent for each additional year of life at full quality gained.

Source: Gillick 2004, Neumann 2005a.

effectiveness of other types of services, such as surgical interventions, screening services, and medical and diagnostic procedures. The availability of efficacy data on drugs from FDA clinical trials partly accounts for the higher proportion of published studies assessing drugs. In addition, manufacturers' need to show the value of a new drug to formulary committees and other purchasers may also play a role, as discussed below. Manufacturers also use cost-effectiveness analysis to predict the price that purchasers will be willing to pay for a new drug (Neumann 2005b).

Over the years, pharmaceutical manufacturers have sponsored an increasing proportion of cost-effectiveness analyses. Neumann (2005b) estimates that their share increased from 14 percent between 1976 and 1997 to 20 percent between 1998 and 2001, while government- and foundation-sponsored studies decreased from 54 percent to 43 percent. About one-third of all studies did not report the funding source during each time period.

Designing cost-effectiveness analysis

When measuring the clinical effectiveness, outcomes, and costs of alternative services, researchers must construct a conceptual model. Such models range from the simple (such as decision trees) to the complex (such as Markov models).⁴ A cost-effectiveness analysis typically addresses the following methodological issues:

- **The perspective of the analysis.** The findings of a cost-effectiveness analysis vary depending on the viewpoint of interest to the researcher—society, purchaser, insurer, or another party. A cost-effectiveness analysis from a societal perspective includes everyone who is affected by the service; it also includes all associated health outcomes and costs (Gold et al. 1996). By contrast, a cost-effectiveness analysis from an insurer's perspective would include only those outcomes and costs that affect that particular insurer.
- **The sources of clinical effectiveness and outcomes data.** Researchers can use data from numerous sources, including FDA clinical trials and practical clinical trials, patients' medical records, health care claims submitted to insurers, and health surveys.
- **The method of defining costs.** Costs include direct medical (e.g., cost of medical services), direct nonmedical (e.g., transportation costs), and indirect

(e.g., value of lost productivity). For example, lost productivity measures the costs associated with lost or impaired ability to work or to engage in leisure activities, and lost economic productivity due to death.

- **The selection of comparison services.** Comparative groups can include pharmaceutical, medical, and surgical services, or no treatment.
- **The time horizon.** Researchers must choose the period of time to measure a service's costs and outcomes.
- **The discounting of costs and outcomes.** When the time horizon of cost-effectiveness analyses extends into the future, researchers must convert future costs and future health outcomes to their present value. In doing so, researchers appropriately adjust the cost-effectiveness ratios for the different timing of cost and outcomes. The discount rates that researchers use to convert health outcomes and costs to a present value can differ.
- **The uncertainty of the clinical events and costs.** Sensitivity analysis varies the assumptions of the clinical and cost data.
- **The measurement of outcomes.** As we mentioned earlier, researchers measure outcomes in terms of QALYs, cases of a particular disease prevented, or improvements made in functional status.

Recognizing the complexity of cost-effectiveness analysis, several groups have published guidelines designed to ensure and improve the quality of such analyses. In 1993, the Public Health Service convened the U.S. Panel on Cost Effectiveness in Health and Medicine to address methodological concerns about cost effectiveness. The panel reviewed the state of the health and medicine field and developed recommendations to improve the quality and comparability of these types of studies.⁵ In addition to this panel, some peer-reviewed journals have also developed publication standards for cost-effectiveness studies.⁶

One study shows that more recently published cost-effective analyses are adhering to the guidelines of the panel (Neumann 2005c). Comparing studies published in 1998 to 2001 with those published in 1976 to 1997, studies improved in almost all categories, including: clearly presenting the study perspective (73 percent versus 52 percent, respectively); discounting both costs

and outcomes (82 percent versus 73 percent, respectively); and reporting incremental cost-effectiveness ratios (69 percent versus 46 percent, respectively).

Who uses cost-effectiveness analysis?

The experience of public and private entities regarding cost-effectiveness analysis varies. Cost-effectiveness analysis is not explicitly used by Medicare, and is used by some organizations to develop clinical guidelines and—on a limited basis—by health plans and purchasers. Other countries use cost-effectiveness analysis more widely than the United States.

Use of cost-effectiveness analysis by public and nonprofit entities

At least two organizations consider cost-effectiveness analysis when developing guidelines—the recent recommendations of the third U.S. Preventive Services Task Force (USPSTF) and the *U.S. Guide to Community Preventive Services*.⁷ USPSTF, an independent panel of private-sector experts in primary care and prevention, considered cost-effectiveness studies in its recommendation concerning screening for abdominal aortic aneurysms, coronary heart disease, and bacteriuria. The *U.S. Guide to Community Preventive Services* examines population-based health promotion and disease prevention services. This group considered selected economic evaluations, including cost-effectiveness analysis, for the following topics: diabetes, oral health, physical activity, and tobacco. The task force used these analyses to make the case that the intervention was valuable and should be incorporated routinely into primary medical care.

The National Committee for Quality Assurance (NCQA) has recognized the importance of cost-effectiveness information. In selecting a measure for a particular clinical condition, the committee considers cost-effectiveness information. For example, in its *State of Health Care Quality Report*, it includes estimates of the incremental cost effectiveness of conducting conventional pap screening every three years, compared with conducting no pap screening (NCQA 2004). This effort shows how policymakers can use cost-effectiveness analysis in prioritizing which measures to use in pay-for-performance programs and how frequently providers should furnish these services to patients.

One state—Oregon—experimented with using cost-effectiveness analysis to help reform its Medicaid program. The state attempted to rank different services

based on their cost effectiveness and cover only those services that fell above a line established by the state's budgetary resources. Ultimately, policymakers considered information on cost effectiveness less formally in the plan Oregon eventually adopted because of disputes surrounding its use. Specifically, stakeholders criticized the initial priority list that ranked services based on their cost effectiveness as being counterintuitive, assigning higher priorities to some services that seemed less important than other lower ranked services (Eddy 1991).

Use of cost effectiveness by commercial health plans and purchasers

Health plans, pharmacy benefit managers (PBMs), and hospitals have used cost-effectiveness analysis, along with other types of pharmacoeconomic analysis, for the past two decades (Neumann 2005b). Pharmacoeconomic data include cost-effectiveness analysis and other types of health economic analyses, such as cost-benefit, cost-of-illness, and cost-of-care studies.

The 1997 Food and Drug Administration Modernization Act codified rules governing the health economic information that manufacturers can disseminate to plans and purchasers. The act permits manufacturers to disseminate health economic information, provided that this information directly relates to an approved indication of a service and results from reliable scientific evidence.

Commercial plans and purchasers frequently consider evidence about a new service's cost rather than its cost effectiveness when making coverage decisions. Cost information supplements the clinical effectiveness information that plans use in making these decisions (Project HOPE 2002). A survey of medical directors of 228 managed care plans in 2001 indicates that 90 percent of the plans consider the cost of a new service (Garber 2004). The survey results also indicate that:

- Nearly all plans (93 percent) will cover a more effective service, even if it is more costly.
- Plans use cost information the most frequently (58 percent) to design policies that require the use of less costly (but equally effective) services first.

By contrast, plans consider formal cost-effectiveness analyses to assess new services less frequently. In one survey, only 40 percent of the plans reported using cost-effectiveness analysis (Garber 2004). Another survey found that 51 percent of private payers used either cost-effective or cost-benefit analysis (Bloom 2004).

The Blue Cross Blue Shield Evaluation Center, which provides technology assessments to subscribing commercial health plans and provider groups, uses an evidence-based process for assessing services but generally excludes explicit considerations of cost and cost effectiveness (Garber 2001). Instead, the center relies primarily on clinical evidence.⁸

Purchasers more frequently consider cost-effectiveness information to inform coverage decisions about drugs than about other services. To consider such information appropriately, formulary managers have increasingly adopted the Academy of Managed Care Pharmacy's (AMCP's) new evidence-based formulary guidelines, which call for drug manufacturers to submit clinical and economic evidence about their products to support the listing of new pharmaceuticals (AMCP 2005). These guidelines, the *Principles of a Sound Drug Formulary System*, were developed by a coalition of national organizations and lay out the essential components of a drug formulary system. AMCP supports the consideration of pharmacoeconomic factors when making formulary decisions, after establishing a drug's safety, efficacy, and therapeutic need.

Why do commercial health plans not use cost-effectiveness analysis more widely? Concerns about potential litigation may discourage them from explicitly using such analysis in coverage decisions. In one survey of health plan officials, most respondents said that they would cover equally effective but costlier treatments for fear of litigation or backlash (Singer et al. 1999). To date, very little litigation has directly raised or challenged the use of cost-effectiveness analysis (Jacobson and Kanna 2001). Researchers also note that if the medical profession begins to accept cost-effectiveness analysis underlying its standards of care, the courts could incorporate the information by deferring to professional custom.

Lack of understanding about the value and applicability of cost-effective analysis may also limit its use. Issues surrounding the methods used to conduct studies may be another factor. We discuss some of these issues later in this chapter. Prosser and colleagues (2000) report that plans may not use cost-effectiveness analysis because their members may view such analysis as a tool to ration care.

Use of cost effectiveness internationally

The international experience sharply contrasts with that of the United States. For a number of years, health systems in Australia, the United Kingdom, and other countries have

incorporated cost-effectiveness considerations explicitly into their processes for making coverage and pricing decisions about drugs and other services.⁹ For example:

- Since 1992, Australia requires drug companies to submit evidence on the comparative cost effectiveness of new pharmaceuticals before listing them on the national formulary, and this information guides the government's decisions on paying for new drugs. Companies cannot list new drugs on the national formulary unless an independent statutory body (the Pharmaceutical Benefits Advisory Committee) recommends it. Between 1993 and 2000, the pharmaceutical industry in Australia submitted more than 300 studies (Hill et al. 2000).
- In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) provides nonbinding guidance to the National Health Service (NHS) on treatments and care for people who use the NHS in England and Wales. NICE develops technology assessments on the use of new and existing services and clinical guidelines on the appropriate treatment of specific diseases and conditions. NICE's technology assessments consider both clinical effectiveness and cost-effectiveness information.

However, the consideration of clinical effectiveness and cost-effectiveness information internationally has not proceeded without some disputes. For example, some patient groups and manufacturers have raised concerns about a January 2005 preliminary recommendation by NICE that did not support the use of three drugs for treating mild to moderate Alzheimer's disease (NICE 2005). NICE will release its final guidance in July 2005.

Some concerns surrounding Medicare's use of cost-effectiveness analysis

Numerous stakeholders—drug and device manufacturers, providers, beneficiaries, and health economists—have raised issues and concerns about Medicare's use of cost-effectiveness information in the coverage process. Stakeholders have also raised some of these same concerns about the use of such information by other public and private payers and purchasers.

- *Use of cost effectiveness might impair beneficiaries' access to certain services and will lead to rationing.* For example, a policy that covers only those services that have cost-effectiveness ratios below a specific threshold would result in beneficiaries not having

access to all services. Critics are concerned that Medicare will use cost-effectiveness information for cost containment purposes only, not for promoting appropriate care.

- ***Some policymakers, providers, and beneficiaries may not understand cost-effectiveness methods.*** Cost-effectiveness analysis requires a kind of abstract thinking that might be counterintuitive to some individuals because it ranks treatments by their cost-effectiveness ratios instead of by their benefits (Eddy 1992).
- ***Some policymakers, providers, and beneficiaries may mistrust the methods used to conduct cost-effectiveness analysis.*** Researchers have noted that the methodological approach varies from study to study. Evaluations of the same services and diseases can show different results. In assessing the cost effectiveness of treating patients with diabetes, Eddy (2005) compared five models that used the same quality weights and cost per treatment. He found that cost-effectiveness ratios varied from about –\$10,000 per QALY to nearly \$40,000 per QALY.

Although the U.S. Panel on Cost Effectiveness in Health and Medicine recommended that published studies include a reference case that uses a standard set of methods, many published analyses do not do so. The lack of clear reporting on methods has led to concerns from some stakeholders that cost-effectiveness analysis is not transparent and that analyses are “black boxes.” Finally, some stakeholders are concerned that analyses contain the biases of the sponsors who fund the studies and the researchers who conduct them.

- ***Cost-effectiveness analysis might slow innovation.*** Medicare’s coverage policies strongly influence the medical care that beneficiaries receive for services not covered under PPSs. (For services paid through PPSs, providers serve as the purchaser and make decisions about which services to furnish to beneficiaries.) Because Medicare covers more than 40 million beneficiaries, a negative coverage decision could have an enormous effect on manufacturers’ revenues. Manufacturers have noted that a noncoverage decision by Medicare has a much greater impact on them than the coverage decisions of individual commercial health plans. In addition, other payers—including commercial health plans and Medicaid—often follow Medicare’s policies.

- ***CMS may not have the statutory authority to consider costs.*** Section 1862 of the Social Security Act gives the Secretary the authority to cover items or services that are “reasonable and necessary” for the diagnosis or treatment of illness or injury or that improve the functioning of a malformed body member. Some stakeholders question whether the Secretary has the authority to consider the value of a service—in terms of its costs or cost effectiveness—when making a determination of reasonable and necessary.
- ***Cost effectiveness may not capture public preferences for allocating limited resources.*** Some stakeholders contend that cost effectiveness might be an aid to decision making, but it is not a complete procedure for making resource allocation decisions because it cannot incorporate all the values relevant to such decisions.

Medicare’s coverage and payment processes do not explicitly use cost-effectiveness analysis

Although the national coverage process considers clinical effectiveness, it generally does not consider clinical and cost information together—that is, cost effectiveness. Only in one instance—for a colorectal screening test—has CMS explicitly considered the cost effectiveness of a service when making a national coverage decision and setting the payment rate (see text box, p. 188).

On several occasions, CMS tried to interpret the statute’s requirement that Medicare only pay for services that are reasonable and necessary by including either cost effectiveness or added value considerations. In 1989, the agency published a proposed regulation stating that for purposes of coverage, the medical community would have to accept a technology as safe, effective, noninvestigational, and appropriate. CMS also included cost effectiveness as an explicit criterion. Stakeholders criticized the proposal, particularly for its cost-effectiveness provision, and the agency withdrew the proposal in 1999.

Later, in 2000, CMS published a notice of intent outlining the criteria the agency would use when making national coverage decisions. The criteria considered the cost only for services that provided equivalent benefits to an

CMS's use of cost effectiveness for a new service

The Balanced Budget Act of 1997 extended coverage of colorectal screening tests to Medicare beneficiaries. To carry out the law, CMS first asked the Agency for Healthcare Research and Quality (AHRQ) to conduct a technology assessment of immunochemical fecal occult blood tests (iFOBTs) to:

- compare iFOBT to guaiac-based fecal occult blood test (gFOBT) in terms of cancers detected, cancer deaths averted, and costs;
- assess cost effectiveness; and

- estimate payment levels of iFOBT at which cost effectiveness would equal that of gFOBT at current Medicare payment.

Based on information from this technology assessment and other sources, CMS concluded that there was adequate evidence for Medicare to cover iFOBT. The results of this analysis demonstrate that CMS can use cost-effectiveness information in developing payment rates. ■

existing covered alternative but that were more costly (Figure 8-2). Again, because of strong opposition, CMS never issued a proposed regulation. Foote (2002) noted that resistance by affected interest groups was one element that delayed action.

The future of cost-effectiveness analysis in Medicare

In recent years, Medicare is using its resources more efficiently by assessing the clinical effectiveness of services when making coverage decisions and when setting payment rates for certain services. MedPAC supports CMS's efforts in using an evidence-based, transparent process when making coverage decisions and, more recently, in implementing practical clinical trials and data registries as a means to obtain better scientific evidence.

Might cost-effectiveness analysis also improve Medicare's ability to obtain better value for its expenditures? Cost effectiveness has the potential to favor medical services that are more likely to improve patient outcomes and to discourage the use of services with fewer benefits. Cost-effectiveness analysis may not save the Medicare program money. Wider use of cost-effective, underutilized services might result in increasing Medicare spending, which might not be offset with savings elsewhere.

On the other hand, cost effectiveness could save the Medicare program money in the long run if its use by the program encourages manufacturers to develop services that are more cost effective than current ones. Manufacturers might bring more cost-effective products to the market, if doing so could allow them to increase their share of Medicare's market.

Medicare could begin to consider cost-effectiveness analysis in four ways. First, the program could begin to collect cost-effectiveness information during the coverage process. If feasible, CMS could collect the data via data registries and practical clinical trials after the agency agrees to cover a service. In addition, manufacturers that have already prepared cost-effectiveness analyses could share these analyses with the agency. Such analyses could help the agency better understand the value of a new service. Almost all large drug and medical device companies have formalized the conduct of cost-effectiveness analysis within their firms (DiMasi et al. 2001).

Second, the Secretary could sponsor cost-effectiveness studies—but these studies will be successful only if the research is independent. The Secretary could conduct the studies or could sponsor other organizations—such as quasi-public entities or independent private organizations—to do so. AHRQ has already conducted cost-effectiveness studies and technology assessments

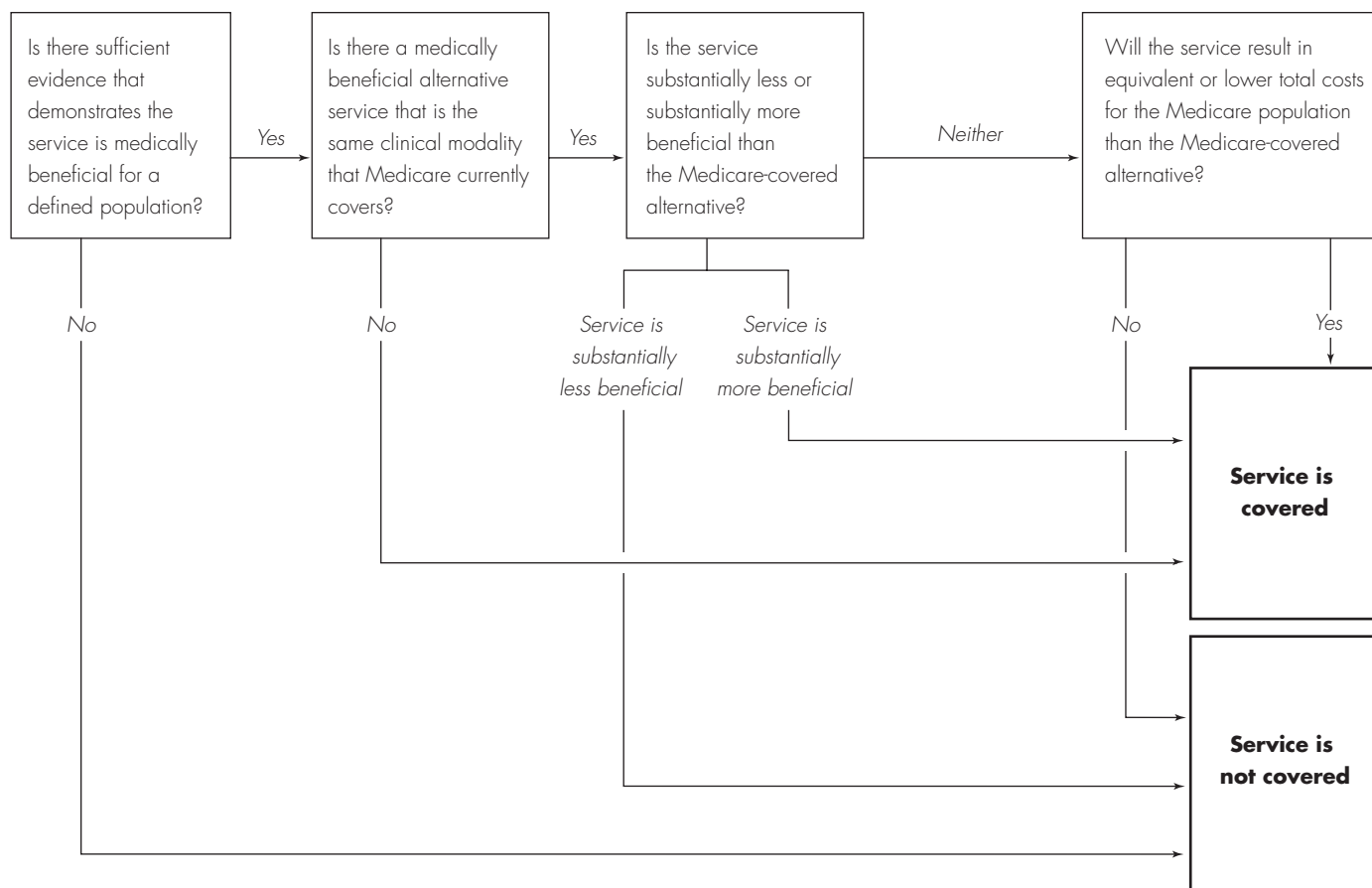
for CMS to use in the national coverage process. In addition, AHRQ—along with its predecessor agency, the National Center for Health Services Research—has sponsored methodological work in this field (Power and Eisenberg 1998). The National Institutes of Health have also sponsored internal and external research on cost effectiveness. Neumann (2004) raises the possibility of contracting with quasi-public entities, such as the Institute of Medicine, to conduct such studies. Alternatively, Reinhardt (2001, 2004) suggests that independent research institutes conduct cost-benefit analyses on drug therapies. The Secretary would also need to determine the services on which to focus—for example, services with high costs

and the potential for high use versus services for which little cost-effectiveness information is available (such as surgical and diagnostic procedures and medical devices).

Third, Medicare could provide cost-effectiveness analysis to beneficiaries and health professionals. Both are potential audiences for information about the relative value of treatment alternatives that cost-effectiveness analysis can provide. The traditional Medicare program does not encourage providers and beneficiaries to weigh the costs and benefits of a service when making health care decisions. Medicare does provide some clinical effectiveness information about certain providers—

FIGURE 8-2

Proposed criteria for making coverage decisions



Note: CMS never officially implemented this set of criteria, which was issued in a notice of intent.

Source: CMS 2000.

dialysis facilities, hospitals, home health agencies, and nursing homes—but not cost-effectiveness information.

A consortium of health-related organizations conducted a project in which consumers participated in discussion groups and physicians responded to a survey and participated in discussion groups on the use of cost effectiveness. The results suggest that the former are interested in obtaining better information and that the latter consider cost effectiveness when making clinical decisions (Ginsburg 2004; Sacramento Healthcare Decisions 2001). This project included the following key findings:

- Physicians vary in how often they discuss cost effectiveness with their patients: 50 percent do so occasionally, 30 percent do so frequently or always, and 20 percent report that they never do.
- Most physicians (90 percent) either agreed strongly or agreed somewhat that it is appropriate for them to consider cost effectiveness when making clinical decisions.
- Many consumers accept cost effectiveness as a reasonable criterion when doctors consider treatment alternatives for individual patients.
- Consumers also indicated that they need to take more responsibility in their role as health care recipients, to improve their individual well-being as well as to reduce costs.

This research shows that patients and providers can—and sometimes do—consider cost-effectiveness information. Nonetheless, Medicare, together with other payers and purchasers, is in a strong position to disseminate such information because it represents the interest of large populations.

By using cost-effectiveness analysis, Medicare might promote other organizations' use of this analysis. For example, more commercial health plans might begin to consider cost-effectiveness analysis; as mentioned earlier, less than half of the surveyed plans consider cost-effectiveness analysis. Medical organizations and federal agencies might also consider using cost-effectiveness analysis to develop clinical guidelines.

Fourth, Medicare could begin to use available cost-effectiveness analysis to prioritize pay-for-performance and disease management initiatives. Consider the screening of chronic kidney disease among the Medicare population: Cost-effectiveness analyses could help inform policymakers about which subpopulations (such as beneficiaries who have diabetes) would generate the most favorable ratios of health gain to spending. USPSTF has demonstrated the usefulness of cost-effectiveness analysis to determine optimal interventions for screening and to identify the different target populations or risk groups who might be suitable for preventive services (Saha et al. 2001).

Before Medicare can routinely use cost-effectiveness analysis for any of these purposes, it will need to address valid concerns about the methods used in current analyses. The measurement of costs and outcomes differ from study to study. As we mentioned earlier, evaluations of the same services and diseases can show different results. The lack of a standardized method of cost-effectiveness analysis has limited its use by policymakers (Gold et al. 1996).

The Secretary could play an important role in advancing the field of cost effectiveness. As mentioned earlier, the U.S. Panel on Cost Effectiveness in Health and Medicine made important contributions in addressing methodological concerns. The Secretary could help standardize the methods used to conduct these analyses in an open process similar to the current national coverage process. This action will improve the quality of cost-effectiveness studies, in turn increasing their usefulness to patients, private and public payers, policymakers, and health professionals.

As the field of cost effectiveness evolves and as Medicare and researchers address methodological issues, Medicare could begin to apply cost-effectiveness analysis in its rate-setting process. This method might augment the tools that Medicare now uses in the rate-setting process, such as the “least costly alternative” policy. ■

Endnotes

- 1 Practical clinical trials address questions about a service's risks, benefits, and costs as they would occur in routine clinical practice (Tunis et al. 2003). In practical clinical trials, researchers select clinically relevant interventions to compare, include a diverse population of study participants, recruit participants from a variety of practice settings, and collect data on a broad range of health outcomes. Researchers conduct these trials in "real-world settings" with minimal intrusion on care.
- 2 CMS will pay for beneficiaries' routine costs in clinical trials for those trials that: (1) evaluate a service included in a Medicare benefit category; (2) assess the clinical efficacy of a service; and (3) enroll patients with a diagnosed disease rather than healthy volunteers.
- 3 CMS contracts with companies, known as fiscal intermediaries and carriers, to process and reimburse Part A and Part B claims.
- 4 Decision-tree models represent the sequence of chance events and decisions over time for an intervention and each comparative service. A Markov model is a special type of state-transition model in which the transition probabilities depend only on the current state, not on the previous states.
- 5 Among the panel's recommendations is one regarding the use of a reference case, in which researchers should use a standard set of methods. For example, the reference case analysis should compare the proposed service of interest to existing practice.
- 6 For example, the *New England Journal of Medicine* developed a policy for the review of cost-effectiveness analyses intended to preclude financial conflicts of interest that might affect the choice of methods or data that researchers use in an analysis (Kassirer and Angell 1994). The journal announced that it would not publish cost-effectiveness analyses if an author has a financial relationship with a sponsoring company.
- 7 The USPSTF, convened by the Public Health Service, evaluates clinical research to assess the merits of preventive measures, including screening tests, counseling, immunizations, and preventive medications.
- 8 The Blue Cross Blue Shield Technology Evaluation Center uses five criteria for evaluating services: (1) the technology must receive final approval from the appropriate government regulatory bodies; (2) the scientific evidence must permit conclusions by the Commission concerning the technology's effect on health outcomes; (3) the technology must improve the net health outcome; (4) the technology must be as beneficial as any established alternatives; and (5) the improvement must be attainable outside the investigational settings.
- 9 Other countries that consider cost-effectiveness information include Canada, Denmark, Finland, France, Hungary, Ireland, Italy, New Zealand, the Netherlands, Norway, Portugal, Spain, and Switzerland.

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CHAPTER

9

**Review of CMS's preliminary
estimate of the physician
update for 2006**

Review of CMS's preliminary estimate of the physician update for 2006

CMS has an annual requirement to use a statutory formula and calculate a preliminary estimate of the next payment update for physician services and to send the estimate to MedPAC. MedPAC must then include a review of the estimate in its

In this chapter

- Spending growth in 2004
- Preliminary estimate of the physician update for 2006
- Making the case for change

June report to the Congress. For 2006, CMS's estimate is an update of -4.3 percent. In general, we find that in calculating the update, CMS used estimates that are consistent with recent trends. In sending MedPAC this estimate, CMS raises a second issue: rapid growth in spending for physician services in 2004 (Kuhn 2005). CMS's preliminary analysis shows that increases in the volume of a broad range of services—office visits, minor procedures, imaging, laboratory and other tests, and drugs administered in physician offices—explain the vast majority of the increase in spending. Increases of this magnitude raise technical and policy questions and may argue for changes in the way Medicare pays for physician services, consistent with MedPAC's recommendations on paying for performance, measuring resource use, reforming the payment update for physician services, and developing quality standards for imaging providers. Future recommendations could come from planned Commission work on laboratory services, physical therapy, and possible mispricing of payments under the physician fee schedule.

Physicians are central to the delivery of health care. They evaluate and manage patients, decide when hospitalization is necessary, perform surgery in hospitals and ambulatory settings, prescribe drugs, and direct nurses and other professionals in various settings, including nursing homes, home health agencies, and dialysis facilities.

CMS's preliminary estimate is that Medicare spending for physician services rose sharply by 15.2 percent in 2004 (Kuhn 2005). Its preliminary estimate of the physician update for 2006 is -4.3 percent. The spending increase and the update are linked: A statutory formula adjusts the update if spending differs from a target based on growth in the national economy.

We expected a negative update for 2006. A large difference has accumulated between actual spending and the target. In addition, the Congress prevented negative updates that would have occurred in 2004 and 2005 in the absence of intervention. The spending increase in this preliminary estimate is large and requires further study because it has implications for the financing of Medicare and beneficiaries' out-of-pocket spending. In addition, such a large one-year increase would raise technical and policy questions about why the increase occurred and how much of it is due to better diagnosis and care versus spending that is not necessary and not contributing to the quality of care.

In this chapter, we discuss the implications of the spending growth in 2004. We also review the preliminary estimate of the 2006 physician update. CMS is required to submit such an estimate to MedPAC in accordance with a provision in the Balanced Budget Refinement Act of 1999 (BBRA). The BBRA also requires a MedPAC review of the estimate as part of the Commission's June report. In reviewing CMS's estimate, MedPAC's purpose is not to assess the adequacy of the update. Our analysis of the update for 2006 can be found in our March 2005 report to the Congress (MedPAC 2005). Instead, we limit our review to the technical issues involved in CMS's use of the statutory formula to calculate the update.

Spending growth in 2004

CMS states that the surge in spending occurred across a broad range of services (Table 9-1). The highest growth occurred in two categories—minor procedures and imaging, with spending for each category growing by 22 percent in one year. CMS attributes much of the increase in minor procedures to spending for chemotherapy administration and physical therapy. The increase in spending for chemotherapy administration is at least partly due to an increase in payments for the services required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Spending growth was also high for Part B drugs and for laboratory and other tests, with spending for each category growing by 17 percent.¹

CMS attributes most of the overall rise in spending to growth in the volume of services. Growth in the number of beneficiaries accounts for only a small fraction of the increase, and CMS estimates that legislative changes—namely, provisions in the MMA—account for only about one-fifth of the increase. To understand more about the volume growth, CMS plans to work further on this issue and to discuss the results with the physician community and other stakeholders. Indeed, referring to MedPAC recommendations on measuring quality and resource use, CMS is exploring ways to confidentially share information with individual physicians about how their practices compare with those of their peers (MedPAC 2005).

In the meantime, MedPAC has analyzed 2004 volume growth for services that it has studied previously—

**TABLE
9-1**

**Spending growth varies by
type of service, 2003-2004**

Type of service	Percent of spending	Spending increase
Visits	38%	11%
Minor procedures	20	22
Imaging	14	22
Laboratory and other tests	12	17
Part B drugs	10	17
Major procedures	6	8
Other	1	13
Total	100	15

Note: In the first column of numbers, percentages may not necessarily add to the total, due to rounding. The total spending increase is a weighted average, so the spending increases by type of service do not add to the total.

Source: Kuhn 2005 and unpublished data from CMS.

services that Medicare pays for under the physician fee schedule. To conduct this analysis, we decomposed CMS spending growth rates into their components: enrollment growth, the physician update for 2004, and a change in law concerning the geographic practice cost indexes (GPCIs) in the fee schedule.² This decomposition left a residual spending increase that we can interpret as growth in the volume of services (Boards of Trustees 2005).³ We then compared that measure of 2004 volume growth with estimates of volume growth from 1999 to 2003 (MedPAC 2005). The results agree with CMS’s conclusions about volume growth: For the services studied, growth in the volume of physician services in 2004 was considerably higher than it was from 1999 to 2003 (Figure 9-1). The biggest difference (12 percentage points) was in minor procedures, which increased 18 percent in 2004 compared with average annual growth of 6 percent from 1999 to 2003. Growth in the volume of imaging was also much higher in 2004: Eighteen percent in 2004 compared with 10 percent annually from 1999 to 2003.

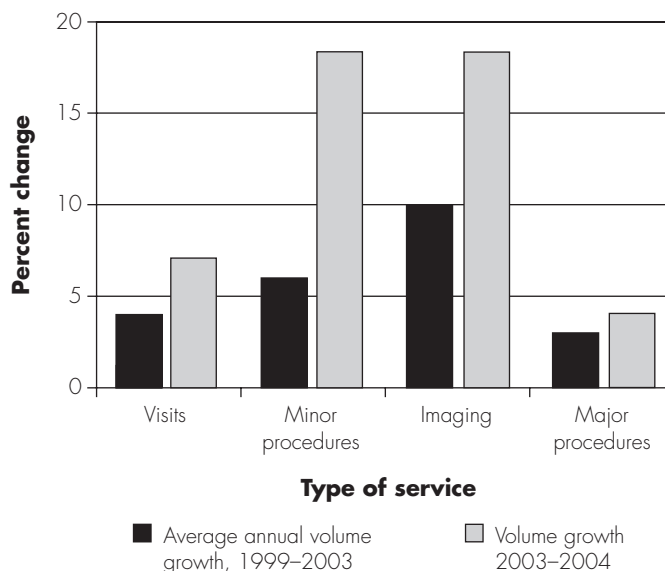
Did all of the increases in 2004 represent services that beneficiaries need? It is possible that some of the increases are due to factors often cited as reasons for growth in spending and use of services: technological innovation, defensive medicine, direct-to-consumer advertising, shifts in the site of care, and adherence to clinical guidelines that call for more intensive treatment of chronic illness. These factors, however, are not likely the whole story because all of them have been at work for at least several years. Referring to one component of the growth in spending—a 25 percent increase in spending for advanced imaging—the CMS administrator said during a press briefing that nothing suggests that such an increase is appropriate (Precht 2005).

One consequence of the spending increase is that CMS now expects the monthly Medicare Part B premium to rise higher than previously expected—perhaps by another \$1.50. This increase would be on top of the \$9.50 increase already contemplated for 2006 by the trustees of the Medicare trust funds and would result in a net 14 percent increase in the premium. The increase would follow the large 17 percent increase for 2005 (Boards of Trustees 2005).

Another effect of the spending increase is a larger Part B claim on the general revenues of the U. S. Treasury. Not only does this claim impose a burden on taxpayers, but it also increases the likelihood that spending will reach a

FIGURE 9-1

Volume grew more rapidly in 2004 than in previous years



Note: For minor procedures, volume growth from 2003 to 2004 includes changes in the structure of payments for chemotherapy administration.

Source: MedPAC analysis.

trigger in the MMA. This trigger requires legislative action if general revenues exceed 45 percent of total outlays for the Medicare program.

The jump in spending and the associated increase in use of services also raise concerns about the quality of care. By the Institute of Medicine’s definition, quality problems include not just misuse and underuse of services but also overuse (Institute of Medicine 2001). If some of the increase represents overuse of services, it may have negatively affected the quality of care.

The magnitude of the spending increase in 2004 and its effects argue for change; the question is, how can the payment system for physician services be part of that change? As MedPAC has stated previously, the physician fee schedule—indeed, all of Medicare’s payment systems—is neutral or negative toward quality. The Commission has also said that the update formula for physician services is inequitable because it treats all physicians and regions of the country alike regardless of their individual efficiency in furnishing care. And we further suspect that payments and costs for imaging

**TABLE
9-2**

Preliminary sustainable growth rate, 2006

Factor	Percent
Change in:	
input prices	2.8%
traditional Medicare enrollment	-2.5
real GDP per capita	2.3
Change due to law and regulations	0.0
 Sustainable growth rate	 2.5

Note: GDP (gross domestic product). Percents are converted to ratios and multiplied, not added, to produce the sustainable growth rate.

Source: Kuhn 2005.

services are misaligned because CMS bases the payments for practice expense on historical charges instead of relative resource use.⁴ There are likely other examples of mispriced services.

These and other problems have prompted MedPAC to make a series of recommendations on paying for performance, measuring resource use, reforming the payment update for physician services, and developing quality standards for imaging providers (MedPAC 2005). More recommendations may come from work we have planned on laboratory services and physical therapy. As we discuss in more detail later in this chapter, other issues concern the physician fee schedule and possible mispricing of services, which could have an effect on the volume of services. We plan to address such issues in the context of reviewing Medicare’s experience with the physician fee schedule now that it has been in place for over a decade. However, before we discuss these plans, we fulfill our statutory requirement to review CMS’s estimate of the physician update for 2006. In general, we find that in calculating the update, CMS used estimates that are consistent with recent trends.

Preliminary estimate of the physician update for 2006

Medicare pays for physician services according to a fee schedule that assigns relative value units (RVUs) to services, reflecting resource requirements. These RVUs

are adjusted for geographic differences in practice costs and multiplied by a dollar amount—the conversion factor—to determine payments. Thus, the conversion factor is a key element of the payment system. Changes in the conversion factor trigger proportional changes in the payment rates for all of the more than 7,000 services represented in the physician fee schedule.

CMS updates the conversion factor annually, based on a formula in law that is designed to control spending while accounting for factors that affect the cost of physician services. CMS issues a final rule on the update in November of each year and implements the update on January 1 of the following year. To help the Congress and others anticipate the update, the BBRA requires CMS to prepare, by March 1 of each year, a preliminary estimate of the next year’s update. The BBRA also requires MedPAC to review that estimate in the Commission’s June report. This chapter fulfills that requirement for the 2006 update.

Calculating the update

Calculating the update is a two-step process. First, CMS estimates the sustainable growth rate (SGR). The SGR is the target rate of growth in spending for physician services and is a function of projected changes in:

- input prices for physician services;⁵
- real gross domestic product (GDP) per capita, an allowance for growth in the volume of services;⁶
- enrollment in traditional fee-for-service Medicare; and
- spending attributable to changes in law and regulation.

For 2006, CMS’s preliminary estimate of the SGR is 2.5 percent (Table 9-2).

Second, CMS calculates the update, which is a function of:

- the change in input prices for physician services,⁷ and
- an update adjustment factor that increases or decreases the update as needed to align actual spending, cumulated over time, with target spending determined by the SGR.

The estimate of the change in input prices for 2006 is 2.9 percent (Table 9-3). The more important part of the update calculation, however, is the update adjustment factor,

which CMS estimates at -7.0 percent, the maximum negative adjustment permitted under current law. When we combine this adjustment with the estimated change in input prices, the result is an update of -4.3 percent.

The update adjustment factor is the link mentioned earlier between spending and the update. The factor is negative because actual spending for physician services started to exceed the target in 2000 and has since remained above the target (Figure 9-2). Indeed, the update adjustment factor would be -21.1 percent if not for the -7.0 percent limit.

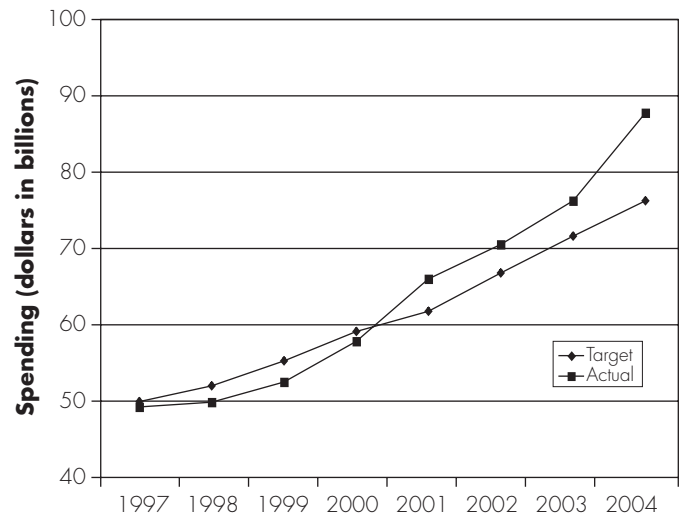
Reviewing CMS's estimate

Because the update adjustment factor is well beyond the statutory limit, MedPAC anticipates no changes in CMS's estimates that would change the update. In the 2006 SGR, the estimate of the change in input prices, as measured by the Medicare Economic Index (MEI), is similar to changes in the MEI for earlier years.⁸ The change in real GDP per capita of 2.3 percent equals the 10-year moving average of real GDP estimates from the Bureau of Economic Analysis (BEA), adjusted for population growth (BEA 2005).

CMS expects no measurable changes in spending due to law and regulation for 2006.⁹ Provisions in the MMA will expire then (e.g., floors on the GPCIs for Alaska), but CMS anticipates that the drop in spending will be very small—less than 0.1 percent. CMS also considered implementation of the Medicare Part D drug benefit and the possible effects of the benefit on the use of physician services. The agency chose not to include a specific spending change in the SGR related to the Part D benefit, relying on a recommendation of the Technical Review

FIGURE 9-2

Through 2004, actual spending for physician services exceeded target



Source: Office of the Actuary 2005.

Panel on the Medicare Trustees Report (2004). The panel concluded that Part D could lead to higher or lower use of other health services, and the panel agreed with an assumption of no effect on utilization or costs in Part A or Part B. However, the panel recommended further research on the topic to take advantage of the natural experiment offered by implementation of Part D. Depending on the results of this research, CMS could revise the SGR's law and regulation factor in the future.

The remaining factor in the SGR estimate for 2006—the change in fee-for-service enrollment—is also uncertain. CMS assumes a decrease in fee-for-service enrollment of 2.5 percent (Table 9-2). This figure differs from the Congressional Budget Office's (CBO's) enrollment projection, which is an increase in fee-for-service enrollment of 0.5 percent for fiscal year 2006. A decrease would occur if some enrollment shifts from Medicare fee-for-service to Medicare Advantage (MA). The magnitude of such a shift (if it occurs) remains unclear, but CMS will know more in June 2005 when MA plans submit bids and identify market areas. CMS can then revise the enrollment projection, if necessary, before the update becomes final in November 2005. Even then, CMS will have limited information on changes in enrollment in 2006, but the agency will have another two years to revise

TABLE 9-3

Estimate of the update for physician services, 2006

Factor	Percent
Change in input prices	2.9%
Change in adjustment factor	-7.0
Update	-4.3

Note: Percents are converted to ratios and multiplied, not added, to produce the update.

Source: Kuhn 2005.

**TABLE
9-4**

Impact of the practice expense GPCI on the payment rate for an equipment-intensive service

Example: MRI of lumbar spine without contrast material performed in a physician's office or IDTF, 2005

Locality with lowest practice expense GPCI: Missouri, excluding Kansas City and St. Louis

	RVU		GPCI	=	Adjusted RVU
Physician work	1.48	x	1.000	=	1.48
Practice expense	12.93	x	0.813	=	10.51
PLI	0.71	x	0.892	=	+ 0.63
					12.63
			Conversion factor	x	\$37.90
			Payment rate		\$478.47

Locality with highest practice expense GPCI: San Francisco

	RVU		GPCI	=	Adjusted RVU
Physician work	1.48	x	1.064	=	1.57
Practice expense	12.93	x	1.501	=	19.41
PLI	0.71	x	0.651	=	+ 0.46
					21.44
			Conversion factor	x	\$37.90
			Payment rate		\$812.71

Note: GPCI (geographic practice cost index), MRI (magnetic resonance imaging), IDTF (independent diagnostic testing facility), RVU (relative value unit), PLI (professional liability insurance). Results may not equal numbers shown due to rounding. Localities considered are those in the continental United States.

Source: CMS 2004.

the enrollment estimate if better data become available, just as the agency does with changes in spending due to law and regulation.

Regardless of what happens with enrollment, CMS's calculation of the update for 2006 is very unlikely to change. To see the effect of an enrollment change, MedPAC substituted CBO's projection for CMS's projection, then calculated an update adjustment factor of -21.0 percent, almost the same as CMS's calculation of -21.1 percent based on its own estimate of enrollment growth.

The only remaining issue concerns CMS's estimates of actual spending for 2004 and 2005. Data on actual spending are nearly complete through the first three quarters of 2004 but are less complete for the last quarter of that year. Therefore, the estimate of actual spending in 2004 may increase or decrease somewhat before CMS issues a final rule on the update in November 2005. Of course, the uncertainty regarding 2005 estimates is greater than for 2004 because CMS currently has very little information on actual spending for 2005.

To address these uncertainties, the agency has used stochastic projection techniques to analyze variation in the update adjustment factor (Office of the Actuary 2005). Under a range of possible scenarios for growth in real GDP per capita and growth in the volume of physician services, the analysis shows a 100 percent probability that the update adjustment factor will equal the maximum negative adjustment of -7.0 percent.

A maximum negative adjustment has such a high probability because a different outcome would require an uncharacteristic decrease in spending for physician services in 2005. An update of 1.5 percent for 2005 has already occurred. Therefore, the only way in which spending could fall is through a substantial decrease in the volume of physician services per beneficiary. However, this decrease is very unlikely based on historical trends. From 1999 to 2003, for example, volume increased at an average annual rate of about 5 percent per year. As we discussed earlier, volume grew at an even higher rate in 2004. For this reason, MedPAC anticipates that CMS's update calculations (to be published in November 2005) will show the maximum reduction that the statute permits.

Making the case for change

Previously, the Commission has recommended policies that could work in tandem with the physician fee schedule, such as paying for performance, measuring resource use, and developing quality standards for imaging providers. Additional issues have emerged that are internal to the fee schedule. As such, they represent instances of possible mispricing. If mispricing includes Medicare overpaying for services, that mispricing could contribute to overuse of services—one of the concerns with the spending increase in 2004.

Adjusting payments geographically for input prices

Under the physician fee schedule, GPCIs adjust payment rates to account for differences in the price of inputs used in furnishing physician services. Three separate GPCIs correspond to each of three components of the fee schedule's relative value scale: physician work, practice expense, and professional liability insurance.

MedPAC's concern is with the practice expense GPCI. Current policy stipulates that the prices of some inputs—namely, equipment and supplies—do not vary geographically because physicians purchase those inputs in a national market, not locally. When constructing the GPCI, CMS accounts somewhat for this fact by holding constant the price of equipment and supplies. The problem is that the GPCI applies to the entire practice expense payment for all services, even though the cost of equipment and supplies, as a proportion of practice expense, varies by service. Therefore, for equipment- and supply-intensive services, payments are too high, relative to costs, in high-GPCI areas and too low, relative to costs, in low-GPCI areas.

The effect of the GPCI adjustment can be significant. The most frequently billed magnetic resonance imaging (MRI) study—MRI of the spine—is an example. In the locality with the lowest practice expense GPCI (areas of Missouri outside Kansas City and St. Louis), the payment rate for MRI of the spine is \$478 (Table 9-4, p. 202). By contrast, the payment rate is \$813—70 percent higher—in San Francisco, the locality with the highest practice expense GPCI.¹⁰ The main reason for the difference is that the practice expense GPCI is 0.813 in the areas of Missouri. In San Francisco, it is 1.501. This difference prevails even though most of the direct costs of furnishing the service originate from the equipment, which physicians purchase in a national market.¹¹

The problem with the practice expense GPCI varies, depending on the service. Across all services, equipment and supplies represented about 32 percent of direct costs, on average, in 2003 (Figure 9-3). For imaging services, however, equipment and supplies represented an average of 76 percent of direct costs. For other services—such as major procedures and evaluation and management (E&M)—equipment and supplies make up a lower-than-average share of direct costs. Within this latter group of services, the practice expense GPCI causes payments to be

too low, relative to costs, in high-GPCI areas and too high, relative to costs, in low-GPCI areas.

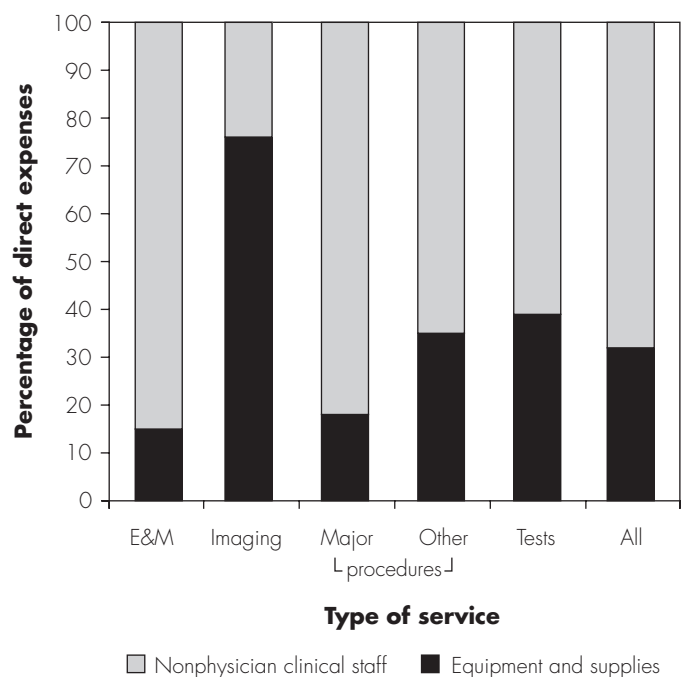
To assess the magnitude of this problem, MedPAC plans to analyze the correlation between the volume of the affected services—such as imaging—and the practice expense GPCI. To assess possible solutions, we plan to replicate CMS's practice expense methodology and to calculate the portion of each service's practice expense RVUs that we can attribute to equipment and supplies. In addition to illustrating the methods required, we can then model the payment effects of a policy change.

Revisiting the boundaries of payment localities

The GPCIs vary by geographic areas called payment localities. Of the 89 total payment localities, 34 consist of entire states (Figure 9-4). Initially, Medicare accepted the localities established by the contractors who process claims for Medicare. To set boundaries for the localities, the contractors used their knowledge of patterns in physician charges for services.

FIGURE 9-3

Direct expenses in practice expense RVUs, 2003



Note: RVU (relative value unit), E&M (evaluation and management).

Source: MedPAC analysis of practice expense input file from CMS, 2003; Medicare claims data for 100% of beneficiaries.

**FIGURE
9-4**

Physician fee schedule payment localities



Note: States with no shaded regions have one payment locality. Additional payment localities in the other states are indicated by variation in area shading.

Source: MedPAC analysis.

As another possible instance of mispricing of services, it may be time to revisit the boundaries of payment localities, at least in those states that do not have statewide localities. CMS has not revised the boundaries since 1997, when it consolidated 210 localities to the current 89 to simplify administration and reduce payment differences among adjacent geographic areas. In addition, physicians can initiate a change in the locality boundaries of their state. Some physicians are working toward such a change. For instance, the California Medical Association has proposed an increase in the number of localities in the state from 9 to 19.

Given that CMS has not reconfigured the localities in at least 8 years (and, in some cases, 40 years), the localities likely do not correspond to market boundaries for the inputs physicians use in furnishing services. As a result, Medicare is probably overpaying in some geographic areas and underpaying in others.

To revisit the locality boundaries, MedPAC plans to use data on input prices by county and identify cases in which the boundaries are inconsistent with variation in input prices beyond a predefined threshold. We can then model the effects of alternative locality configurations. The Commission could recommend alternative locality boundaries as appropriate.

Valuing services in the physician fee schedule

The fee schedule's RVUs are a key element of the payment system because the RVUs determine how payment rates vary, one service relative to another. Initially, research at Harvard University led to the RVUs that were implemented with the fee schedule in 1992. The expectation was that payment rates would rise for E&M services relative to other services, such as surgery and other procedural services. Analyses by the Physician Payment Review Commission (PPRC) and others showed that such changes in payment rates occurred (PPRC 1997, Iglehart 2002).

In addition to the changes in payment rates anticipated with implementation of the fee schedule, other factors have affected payments for physician services. CMS has reviewed and modified the RVUs for selected services after receiving recommendations from the RVS Update Committee (RUC).¹² CMS has established RVUs for new services using a similar process of receiving recommendations from the RUC. The volume of services has changed.

To understand the effects of these other factors affecting payments, MedPAC contracted with The Urban Institute for analyses of changes in RVUs over time and how those changes interact with growth in the volume of services. To measure these effects, the contractor developed a measure of RVU volume, which comprises units of service weighted by each service's RVU.

Preliminary findings from this work describe the effects of periodic RVU review,¹³ the interaction between changes in RVUs and growth in the volume of services, and the effects of introducing new services—all during the first 10 years of experience with the physician fee schedule (Maxwell, Zuckerman, and Berenson 2005). In general, the findings highlight the importance of new services and the importance of the choices that CMS and the RUC make about the services whose RVUs are reviewed. The following specific findings are of particular interest to MedPAC:

- By 2002, CMS had not reviewed or revised the RVUs for about 50 percent of services, but those services accounted for only 16 percent of volume. For the services that accounted for the remaining 84 percent of volume, CMS had established the RVUs with recommendations from the RUC.
- CMS's review of RVUs has led to substantially more increases than decreases in RVUs because the process by which CMS and the RUC consider potentially misvalued services has given priority to services that may be undervalued rather than services that may be overvalued. The reviews have yielded this result even though the factors that can lead to a service becoming misvalued—technology diffusion, learning by doing, technology substitution, personnel substitution, reengineering, patient severity, and mandatory documentation—suggest that both undervalued and overvalued services are an issue.¹⁴
- Growth in units of service has driven growth in RVU volume for some services; however, for other services, growth in RVUs per unit of service was the more important factor underlying growth in volume.
- In addition to volume growth, the introduction of new services has shifted the distribution of total RVU volume among services. For E&M services, the result has been an offset of the gains in RVU volume that the services experienced because of increased RVUs.

MedPAC plans further work on the process for valuing services in the fee schedule. An initial step will be to continue the work on RVU volume, looking at the effects of volume growth and changes in RVUs on the distribution of payments by service and also by physician specialty. Next, we plan to consider the process for selecting services for review to determine whether this process adequately identifies services whose RVUs may need to decrease. This effort will include monitoring the next review of RVUs for physician work, scheduled for completion in 2007, so we can assess whether the process is becoming more successful in identifying both undervalued and overvalued services. We also plan to consider the process that CMS uses to establish RVUs for new services. In doing so, we will explore ways to ensure further review of the RVUs after physicians have gained some familiarity and become more efficient in furnishing new services. In addition, to ensure that RVUs account for the cost of an efficient physician's services, we plan to examine the RVUs for practice expense and the extent to which the RVUs represent the marginal cost (not just the average cost) of furnishing a given service.¹⁵ We also plan to explore how CMS might distinguish the marginal costs incurred by physicians who demonstrate superior productive efficiency per unit of service.

Determining practice expense RVUs

On average, payments for practice expense account for about 44 percent of spending under the physician fee schedule. As discussed in MedPAC's *Report to the Congress: Impact of Resource-Based Practice Expense Payments for Physician Services* (2004b), CMS derived resource-based practice expense RVUs for the physician schedule with the best data available at the time. However, some of those data are becoming out of date—for instance, much of the data on physicians' aggregate practice costs date back to the mid- to late- 1990s. Although CMS has received supplemental data from some physician specialties, the accuracy of practice expense payments is becoming more of an issue as time passes. MedPAC plans to continue analyzing the data that CMS uses to establish practice expense payments and the methods that it uses to derive these payments.

Changing the unit of payment

Compared to other payment systems, the unit of payment in the physician fee schedule is very small. The fee schedule includes payment rates for many of the discrete services that a physician furnishes—visits, imaging studies, laboratory and other diagnostic tests, and procedures. In some cases, the physician furnishes the services during a single encounter with a patient. In other cases, the physician furnishes the services during multiple encounters over a period of time. Such a small unit of payment raises a long-standing concern about whether it gives physicians a financial incentive to increase the volume of services (MedPAC 1999). To address this concern, MedPAC could explore options for increasing the size of the unit of payment to include bundles of services that physicians often furnish together or during the same episode of care. MedPAC's work would address procedures for identifying the relevant services, determining payment methods for the services, and analyzing the implications for quality of care. ■

Endnotes

- 1 The 17 percent increase in spending for Part B drugs must include a large increase in the volume of the drugs because spending increased despite a drop in payment rates for the drugs. In 2004, CMS implemented a statutory reduction in the payment formula for the drugs, which reduced payment rates for them by 10 percentage points.
- 2 The Congress established floors under geographic practice cost indexes (GPCIs) as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Effective for the first time in 2004, the floors raised payments in Alaska for physician work, practice expense, and professional liability insurance (PLI). Elsewhere, payments went up for practice expense only. To analyze the effects of the GPCI floors, we used 2003 claims data from 100 percent of beneficiaries to determine how spending in that year would have changed if the floors had been in effect in that year. We conducted this analysis by payment locality and procedure code and then aggregated the results by type of service. The results were that the GPCI floors increased spending as follows: visits, 1.0 percent; minor procedures, 0.8 percent; imaging, 0.5 percent; and major procedures, 1.0 percent.
- 3 For minor procedures, the residual also includes a change in the structure of payments for chemotherapy administration. Although 2004 data are not yet available on the effect of this change, the 2003 data show that chemotherapy administration accounted for about 3 percent of spending for minor procedures.
- 4 In CMS's methodology for determining relative value units (RVUs) for practice expense, the technical components of imaging services and other diagnostic tests are in a category called the nonphysician work pool. The practice expense RVUs for those technical component services are not yet resource based. CMS plans to propose resource-based RVUs for those services in 2005.
- 5 For the SGR, physician services include services commonly performed by a physician or performed in a physician's office. In addition to physician fee schedule services, these services include diagnostic laboratory tests and most of the drugs covered under Medicare Part B. To estimate this factor, CMS uses a weighted average of the Medicare Economic Index (MEI), a measure of changes in input prices for physician services, the change in payment rates for laboratory services legislated by the Congress, and a weighted average of the change in payment rates for Part B-covered drugs.
- 6 As required by the MMA, the real GDP per capita factor in the SGR is a 10-year moving average.
- 7 For the update, physician services include only those services in the physician fee schedule.
- 8 Historical changes in the MEI are published by the CMS Office of the Actuary (2005).
- 9 For further discussion of changes in spending due to law and regulation, see MedPAC's *Report to the Congress: Growth in the Volume of Physician Services* (2004a).
- 10 For purposes of this discussion, we include localities in the continental United States (i.e., excluding Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands).
- 11 In the methodology for determining practice expense RVUs, CMS defines two types of costs: direct and indirect. Direct costs are costs attributable to specific services, such as the earnings of nonphysician clinical personnel, equipment, and supplies. Indirect costs are not as readily assigned to services and include the earnings of administrative personnel, rent, and utilities.
- 12 The RVS Update Committee is a committee involving the American Medical Association and national medical specialty societies.
- 13 By law, RVUs are reviewed every five years.
- 14 The list of sources of changes in physician work is from CMS. It was prepared for the review of physician work RVUs that was completed in 2002 (CMS 2000).
- 15 MedPAC has discussed the goal of basing payment rates on a provider's marginal cost in a previous report (MedPAC 2001).

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A P P E N D I X

A

**Commissioners' voting
on recommendations**



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: Monitoring the implementation of Part D

The Secretary should have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Raphael, Wakefield

Chapter 2: Medicare Advantage payment areas and risk adjustment

2A The Congress should establish payment areas for Medicare Advantage local plans that have the following characteristics:

- Among counties in metropolitan statistical areas, payment areas should be collections of counties that are located in the same state and the same metropolitan statistical area.
- Among counties outside metropolitan statistical areas, 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.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

2B The Secretary should update health service areas before using them as payment areas in the Medicare Advantage program. In addition, the Secretary should make periodic updates to health service areas to reflect changes in health care market areas that occur over time.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

Chapter 3: The Medicare Advantage program

3A The Congress should eliminate the stabilization fund for regional preferred provider organizations.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Smith, Stowers, Wolter

No: Scanlon

Absent: Wakefield

3B The Secretary should calculate clinical measures for the fee-for-service program that would permit CMS to compare the fee-for-service program to Medicare Advantage plans.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

3C The Congress should clarify that regional plans should submit bids that are standardized for the region's Medicare Advantage-eligible population.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

3D The Congress should remove the effect of payments for indirect medical education from the Medicare Advantage plan benchmarks.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

3E a) The Congress should set the benchmarks that CMS uses to evaluate Medicare Advantage plan bids at 100 percent of the fee-for-service costs.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

b) At the same time, the Congress should also redirect Medicare's share of savings from bids below the benchmarks to a fund that would redistribute the savings back to Medicare Advantage plans based on quality measures.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

3F The Congress should put into law the scheduled phase-out of the hold-harmless policy that offsets the impact of risk adjustment on aggregate payments through 2010.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

Chapter 4: Payment for dialysis

4A The Congress should direct the Secretary to:

- eliminate differences in paying for composite rate services between hospital-based and freestanding dialysis facilities; and
- combine the base composite rate and the add-on adjustment.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

4B The Secretary should:

- eliminate differences in paying for injectable drugs between hospital-based and freestanding dialysis facilities; and
- use average sales price data to base payment for all injectable dialysis drugs that are separately billable in 2006.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

4C The Congress should give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare it with average sales price data. The Secretary should collect data on the acquisition cost and payment per unit for drugs—other than erythropoietin—that hospital-based providers furnish.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

Chapter 5: Payment for post-acute care

No recommendations

Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments

6A The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

6B The Secretary should:

- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

Yes: Bertko, Burke, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Milstein, Muller, Nelson, Raphael, Reischauer, Scanlon, Smith, Stowers, Wolter

Absent: Wakefield

Chapter 7: Critical access hospitals

No recommendations

Chapter 8: Using clinical and cost effectiveness in Medicare

No recommendations

Chapter 9: Review of CMS's preliminary estimate of the physician update for 2006

No recommendations

Acronyms

Acronyms

AAP	average acquisition payment	DME	durable medical equipment
AAPCC	adjusted average per capita cost	DoD	Department of Defense
ACCC	Association of Community Cancer Centers	DRG	diagnosis related group
ACR	adjusted community rate	DSH	disproportionate share
ADC	average daily census	DUR	drug utilization review
ADL	activity of daily living	DVT	deep vein thrombosis
AHA	American Hospital Association	E&M	evaluation and management
AIDS	acquired immunodeficiency syndrome	EHR	electronic health record
AMCP	Academy of Managed Care Pharmacy	EPO	erythropoietin
AMI	acute myocardial infarction	ESRD	end-stage renal disease
AHRQ	Agency for Healthcare Research and Quality	ER	emergency room
APACHE	Acute Physiology and Chronic Health Evaluation	FDA	Food and Drug Administration
APC	ambulatory payment classification	FDG	fluorodeoxyglucose F18
APR-DRG	all patient refined diagnosis related group	FDG-PET	(18)F-fluorodeoxyglucose and positron emission tomography
ARC	Actuarial Research Corporation	FEHB	Federal Employees Health Benefits [Program]
ASHP	American Society of Health-System Pharmacists	FFS	fee-for-service
ASP	average sales price	FIM™	Functional Independence Measure
ASPE	Assistant Secretary for Planning and Evaluation	FPL	federal poverty level
AWP	average wholesale price	GAF	geographic adjustment factor
BBA	Balanced Budget Act of 1997	GAO	Government Accountability Office [formerly General Accounting Office]
BBRA	Balanced Budget Refinement Act of 1999	GDP	gross domestic product
BEA	Bureau of Economic Analysis	gFOBT	guaiac-based fecal occult blood test
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000	GI	gastrointestinal
BMI	body mass index	GME	graduate medical education
B-N	budget neutrality	GPCI	geographic practice cost index
CAH	critical access hospital	GPO	group purchasing organization
CAHPS	Consumer Assessment of Health Plans Survey	HbA1c	hemoglobin A1c
CBA	cost-benefit analysis	HCC	hierarchical coexisting condition
CBO	Congressional Budget Office	HCC	hierarchical condition category
CCR	cost-to-charge ratio	HCCA	health care commuting area
CEA	cost-effectiveness analysis	HCFA	Health Care Financing Administration
CEO	chief executive officer	HCPCS	Healthcare Common Procedures Coding System
CMS	Centers for Medicare & Medicaid Services	HCPP	health care prepayment plan
CMS-HCC	CMS-hierarchical condition category	HCL	hydrochloride
COP	condition of participation	HEDIS	Health Plan Employer Data and Information Set
COPD	chronic obstructive pulmonary disease	HIV	human immunodeficiency virus
CORAR	Council on Radionuclides and Radiopharmaceuticals	HHA	home health agency
COX-2	cyclo-oxygenase-2	HHRG	home health resource group
CY	calendar year	HHS	Department of Health and Human Services
DCG	diagnostic cost group	HMO	health maintenance organization

HOS	Health Outcomes Survey	NDC	national drug code
HOPD	hospital outpatient department	NHS	National Health Service
HRR	hospital referral region	NICE	National Institute for Health and Clinical Excellence (United Kingdom)
HSA	health savings account	NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
HSA	health service area	NIOSH	National Institute for Occupational Safety and Health
HSCRC	Health Services Cost Review Commission	NORC	National Opinion Research Center
HWI	hospital wage index	NRC	Nuclear Regulatory Commission
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification	NRHA	National Rural Health Association
ID	identification	NTA	nontherapy ancillary
IDTF	independent diagnostic testing facility	OASDI	Old-Age, Survivors, and Disability Insurance
iFOBT	immunochemical fecal occult blood test	OASIS	Outcome and Assessment Information Set
IHS	Indian Health Service	OIG	Office of Inspector General
IME	indirect medical education	OMB	Office of Management and Budget
IN	indium	P&T	pharmacy and therapeutics
IOM	Institute of Medicine	PAC	post-acute care
IPF	inpatient psychiatric facility	PACE	Program of All-Inclusive Care for the Elderly
IPPS	inpatient prospective payment system	PAI	patient assessment instrument
IRF	inpatient rehabilitation facility	PBM	pharmacy benefit manager
IRF-PAI	Inpatient Rehabilitation Facility–Patient Assessment Instrument	PCT	pragmatic, or practical, clinical trial
IV	instrumental variable	PDA	personal digital assistant
IV	intravenous	PDP	prescription drug plan
JCAHO	Joint Commission on Accreditation of Healthcare Organizations	PET	positron emission tomography
LOS	length of stay	PFFS	private fee-for-service
LTCH	long-term care hospital	PhRMA	Pharmaceutical Research and Manufacturers of America
M+C	Medicare+Choice	PIP-DCG	principal inpatient diagnostic cost group
MA	Medicare Advantage	PLI	professional liability insurance
MA-PD	Medicare Advantage–Prescription Drug [plan]	POS	point of service
MAF	medical assistance facility	PPE	personal protective equipment
MCBS	Medicare Current Beneficiary Survey	PPI	producer price index
MDS	Minimum Data Set	PPO	preferred provider organization
MedPAC	Medicare Payment Advisory Commission	PPRC	Physician Payment Review Commission
MedPAR	Medicare Provider Analysis and Review file	PPS	prospective payment system
MEI	Medicare Economic Index	PRO	peer review organization
MEPS	Medical Expenditure Panel Survey	PSI	patient safety indicator
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003	QALY	quality-adjusted life year
MRI	magnetic resonance imaging	QIO	quality improvement organization
MSA	metropolitan statistical area	QMB	Qualified Medicare Beneficiary
MSA	medical savings account	RBC	red blood cell
MTMP	medication therapy management program	RPCH	rural primary care hospital
N/A	not applicable, not available	RUC	Relative Value Scale Update Committee
NCQA	National Committee for Quality Assurance	RUCA	Rural–Urban Commuting Area

RUG	resource utilization group	SPAP	State Pharmacy Assistance Program
RUG-III	resource utilization group, version III	SSA	Social Security Administration
RVS	relative value scale	Tc	technetium
RVU	relative value unit	TPN	total parenteral nutrition
SCHIP	State Children’s Health Insurance Program	U.S.	United States
S/HMO	social health maintenance organization	U.S.C.	United States Code
SGR	sustainable growth rate	USP	the U.S. Pharmacopeia
SHIP	State Health Insurance Assistance Program	USPSTF	U.S. Preventive Services Task Force
SLMB	Specified Low-Income Medicare Beneficiary	USRDS	United States Renal Data System
SNF	skilled nursing facility	VA	Department of Veterans Affairs
SNOMED	Systematized Nomenclature of Medicine	WWAMI	Washington, Wyoming, Alaska, Montana, and Idaho
SNP	special needs plan		

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Sheila P. Burke, M.P.A., R.N., F.A.A.N., is the Smithsonian Institution's deputy secretary and chief operating officer. Before joining the Smithsonian, she was executive dean and lecturer in public policy at the John F. Kennedy School of Government, Harvard University, Cambridge. From 1986 to 1996, Ms. Burke was chief of staff for former Senate Majority Leader Bob Dole and was elected secretary of the Senate in 1995. She currently serves as a board member of the Kaiser Family Foundation, the Kaiser Commission on Medicaid and the Uninsured, the Academy for Health Services Research and Health Policy, the American Board of Internal Medicine Foundation, WellPoint Health Networks, Chubb Insurance, and the University of San Francisco. She is a member of the Institute of Medicine and the National Academy of Public Administration. She also sits on the national advisory council at the Center for State Health Policy and has chaired the National Academy of Social Insurance's project on Restructuring Medicare for the Long-Term. Ms. Burke holds a B.S. in nursing from the University of San Francisco and an M.P.A. from Harvard University.

Francis J. Crosson, M.D., is executive director of the Permanente Federation of medical groups that make up the physician component of Kaiser Permanente. He also cochairs the Kaiser Permanente Partnership Group, the organization's management committee. He joined Kaiser Permanente in 1977. In 1988 he was appointed associate executive director of the Permanente Medical Group and served in that position until his current appointment. 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 currently is chair-elect of the Board of Directors of the American Medical Group Association. Dr. Crosson received his undergraduate degree in political science from Georgetown University and his M.D. degree from Georgetown's School of Medicine.

Autry O. V. "Pete" DeBusk is chairman, chief executive officer, and founder of DeRoyal, a global supplier of medical products and services in the acute care, patient care, wound care, and original equipment manufacturing markets. Mr. DeBusk formed his first company in 1970 with a patent he received on an orthopedic product. In 1976 he consolidated his many product lines into one company, DeRoyal Industries. A member of several community organizations, Mr. DeBusk is also chairman of the Board of Trustees at Lincoln Memorial University in Harrogate, TN, as well as a founder of the Autry O. V. DeBusk facility, Boys and Girls Club, Powell, TN. As an innovative leader in the medical industry, he received a prestigious award from Duke University in 2000 recognizing his original contributions to orthopedic surgery. He received his B.S. degree from Lincoln Memorial University and attended graduate school at the University of Georgia.

Nancy-Ann DeParle, J.D., is a senior adviser to JPMorgan Partners, LLC, and adjunct professor of health care systems at the Wharton School of the University of Pennsylvania. From 1997 to 2000, she served as administrator of the Health Care Financing Administration (HCFA), which is now the Centers for Medicare & Medicaid Services. Before joining HCFA, Ms. DeParle was associate director for health and personnel at the White House Office of Management and Budget. From 1987 to 1989, she served as the Tennessee Commissioner of Human Services. She has also worked as a lawyer in private practice in Nashville, TN, and Washington, DC. She is a trustee of the Robert Wood Johnson Foundation and a board member of Accredo Health, Cerner Corporation, DaVita, Guidant Corporation, Triad Hospitals, and the National Quality Forum. Ms. DeParle received a B.A. degree from the University of Tennessee; B.A. and M.A. degrees from Oxford University, where she was a Rhodes Scholar; and a J.D. degree from Harvard Law School.

David F. Durenberger, J.D., is president of Policy Insight, LLC; senior health policy fellow at the University of St. Thomas in Minneapolis, MN; and chairman of the National Institute of Health Policy. He is also president of the Medical Technology Leadership Forum and a member of the Kaiser Foundation Commission on Medicaid and the Uninsured, the Board of the National Committee for Quality Assurance, and the National Commission for Quality Long Term Care. From 1978 to 1995, he served as the senior U.S. Senator from Minnesota, as a member of the Senate Finance Committee and chairman of its health subcommittee. He was a member of the Senate Environment Committee; Government Affairs Committee; and the committee now known as the Health, Education, Labor, and Pensions Committee. He chaired the Senate Select Committee on Intelligence. Senator Durenberger is a graduate of St. John's University, received his J.D. degree from the University of Minnesota, and served as an officer in the U.S. Army.

Glenn M. Hackbarth, J.D., is chairman of the Commission and an independent consultant living 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. Harvard Vanguard was created from the staff-model delivery system that was the original core of Harvard Community Health Plan. Mr. Hackbarth previously served as senior vice president of Harvard Community Health Plan. From 1981 to 1988, he held positions at the U.S. Department of Health and Human Services, including deputy administrator of the Health Care Financing Administration. Mr. Hackbarth received his B.A. from Pennsylvania State University and his M.A. and J.D. from Duke University.

Arnold Milstein, M.D., M.P.H., is medical director of the Pacific Business Group on Health (PBGH) and U.S. health care thought leader at Mercer Human Resource Consulting. PBGH is the largest health care purchasers coalition in the United States. Dr. Milstein focuses on performance improvement methods for large health care purchasers and providers, clinical performance measurement, and the psychology of clinical performance failure. He cofounded both the Leapfrog Group and the Consumer Purchaser Disclosure Project, and heads clinical standards setting for both initiatives. He is an associate clinical professor at the University of California at San Francisco. Dr. Milstein has a B.A. in economics from Harvard, an M.P.H. in health services planning from the University of California at Berkeley, and an M.D. degree from Tufts University.

Ralph W. Muller, M.A., is chief executive officer of the University of Pennsylvania Health System, one of the largest academic health systems in the country. Most recently he served as managing director of Stockamp & Associates, a hospital consulting firm, and as a visiting fellow at the King's Fund in London. From 1985 to 2001, he was president and chief executive officer of the University of Chicago Hospitals and Health Systems. Before joining the hospital, he held senior positions with the Commonwealth of Massachusetts, including deputy commissioner of the Department of Public Welfare. Mr. Muller is past chairman of the Association of American Medical Colleges, past chairman of the Council of Teaching Hospitals and Health Systems, and past vice chairman of the University Health System Consortium. He is past chairman of the National Opinion Research Center, a social service research organization, and serves on the board of the National Committee for Quality Assurance. Mr. Muller received his B.A. in economics from Syracuse University and his M.A. in government from Harvard University.

Alan R. Nelson, M.D., is an internist–endocrinologist who was in private practice in Salt Lake City until he became chief executive officer of the American Society of Internal Medicine (ASIM) in 1992. After the merger of ASIM with the American College of Physicians (ACP) in 1998, Dr. Nelson headed the

Washington office of ACP–ASIM until his semi-retirement in January 2000 and now serves as special adviser to the executive vice president and chief executive officer of ACP. He was president of the American Medical Association from 1989 to 1990. Dr. Nelson also serves on the Board of Trustees of Intermountain HealthCare, a large integrated health system whose headquarters are in Salt Lake City. A member of the Institute of Medicine (IOM) of the National Academy of Sciences, he serves on the IOM Roundtable on Environmental Health Sciences Research and Medicine and was chairman of the study committee on Racial and Ethnic Disparities in Health Care. Dr. Nelson received his M.D. from Northwestern University.

Carol Raphael is president and chief executive officer of the Visiting Nurse Service (VNS) of New York, the country's largest voluntary home health care organization. VNS programs include post-acute and long-term care, rehabilitation, hospice, mental health services, and a managed care plan for dually eligible Medicare and Medicaid beneficiaries. Ms. Raphael developed the Center for Home Care Policy and Research, which studies the management, cost, quality, and outcomes of home- and community-based services. Previously, Ms. Raphael served as the executive deputy commissioner of the Human Resources Administration in charge of the Medicaid and public assistance programs in New York City. Ms. Raphael has served on several Robert Wood Johnson Foundation advisory committees and New York State panels, including the New York State Hospital Review and Planning Council and the Medicaid Reform Task Force. She is on the boards of Lifetime Healthcare, Future Health, and the American Foundation for the Blind and is a member of the Pfizer Hispanic Advisory Board and the Kaiser Permanente Planning Group for Geriatric Care. She was a Visiting Fellow at the King's Fund in London and is a fellow of the New York Academy of Medicine. She has an M.P.A. from Harvard University's Kennedy School of Government.

Robert D. Reischauer, Ph.D., is vice chairman of the Commission and president of The Urban Institute. Previously, he was a senior fellow with the Brookings Institution, and from 1989 to 1995 he was the director of the Congressional Budget Office. Dr. Reischauer currently serves on the boards of the Academy of Political Sciences, the Center on Budget and Policy Priorities, and the Committee for a Responsible Federal Budget. He also is a member of the Institute of Medicine, the National Academy of Public Administration, and Harvard Corporation. Dr. Reischauer received his A.B. degree from Harvard College and his M.I.A. and Ph.D. from Columbia University.

William J. Scanlon, Ph.D., is a health policy consultant. Until April 2004, he was managing director of health care issues at the General Accounting Office (now the Government Accountability Office [GAO]). At GAO, he oversaw congressionally requested studies of Medicare, Medicaid, the private insurance market and health delivery systems, public health, and the military and veterans' health care systems. Before joining GAO in 1993, 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 had been a principal research associate in health policy at The Urban Institute. His research at Georgetown and The Urban Institute focused on the Medicare and Medicaid programs, especially provider payment policies, and the provision and financing of long-term care services. He has been engaged in health services research since 1975. Dr. Scanlon has published extensively and has served as a frequent consultant to federal agencies, state Medicaid programs, and private foundations. He has a Ph.D. in economics from the University of Wisconsin at Madison.

David A. Smith, M.Ed., is a senior fellow at Demos, a New York-based public policy research center. He previously served as director of the Public Policy Department at the AFL–CIO. Prior to joining the AFL–CIO, he served as senior deputy budget director and as commissioner of economic development for the City of New York. Mr. Smith spent most of the 1980s in Washington as an aide to Massachusetts Senator Edward M. Kennedy and as a senior economist at the Joint Economic Committee. Mr. Smith has taught economics and public policy at the University of Massachusetts and the New School for Social Research and is a senior fellow at the Century Foundation. He is a member of the Board of Directors of Public Campaign and a fellow of the National Academy of Social Insurance. Mr. Smith attended Tufts University and received an M.Ed. from Harvard University.

Ray E. Stowers, D.O., is director of the Oklahoma Rural Health Policy and Research Center as well as associate dean of rural health in the Department of Family Medicine at Oklahoma State University Center for Health Sciences. He was in private rural practice for 25 years at Family Medicine Clinics, Inc., in Medford, OK, and serves on the Policy Board of the National Rural Health Association. Dr. Stowers is a member of the Board of Trustees of the American Osteopathic Association and has served that organization in many capacities, including several related to physician coding and reimbursement issues. He has

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Mary K. Wakefield, Ph.D., R.N., F.A.A.N., is director of and professor at the Center for Rural Health at the University of North Dakota. Dr. Wakefield has held administrative and legislative staff positions in the U.S. Senate and served on many public and private health-related advisory boards. Dr. Wakefield is a member of the Institute of Medicine of the National Academy of Sciences and serves on the Committee on Quality Health Care in America. She is a fellow of the American Academy of Nursing. She has served on a number of rural health–related committees, including the National Advisory Committee on Rural Health, Office of Rural Health Policy, and Health Resources and Services Administration. Dr. Wakefield received her B.S. in nursing from the University of Mary, Bismarck, North Dakota, and her M.S. and Ph.D. from the University of Texas at Austin.

Nicholas J. Wolter, M.D., is a pulmonary and critical care physician who serves as chief executive officer for Deaconess Billings Clinic (DBC) in Billings, Montana. DBC is a regional, not-for-profit medical foundation consisting of a multispecialty group practice, tertiary hospital, critical access hospital affiliates, health maintenance organization, research division, and long-term care facility serving a vast rural area in the northern Rockies. Dr. Wolter began his Billings Clinic practice in 1982 and served as medical director of the hospital’s intensive care unit from 1987 to 1993. He began his leadership role with the successful merger of the clinic and hospital in 1993. Dr. Wolter is a diplomate of the American Board of Internal Medicine and serves on the boards of many regional and national health care organizations. He has a B.A. degree from Carleton College, an M.A. degree from the University of Michigan, and an M.D. degree from the University of Michigan Medical School.

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*Special assistant to the
executive director*

.....
Annissa McDonald

Administrative staff

.....
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Wylene Carlyle
Mathew Chase
Diane E. Ellison
Donna M. Fletcher
Tina Jennings, MTESL
Plinie (Ann) Johnson
Cynthia Wilson

