

CHAPTER

4

**Payment for new technologies
in Medicare's prospective
payment systems**

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

The Secretary should introduce clinical criteria for eligibility of drugs and biologicals to receive pass-through payments under the outpatient prospective payment system.

***YES: 16 • NO: 0 • NOT VOTING: 0 • ABSENT: 1**

***COMMISSIONERS' VOTING RESULTS**

Payment for new technologies in Medicare's prospective payment systems

Medicare has a responsibility to pay enough for beneficial new technologies to ensure beneficiaries' access to care, but must also be a prudent purchaser. The hospital inpatient and outpatient prospective payment systems currently incorporate the costs of new technologies through an annual review of payment rates, as well as through special payment mechanisms for specific new technologies. The details of these new technology payments—such as the criteria technologies must meet to be eligible for them—are the mechanisms through which Medicare balances the goals of ensuring adequate payment for beneficial new technologies and being a prudent purchaser. To increase the program's ability to be a prudent purchaser and to ensure fair treatment across technologies and payment systems, MedPAC recommends that the clinical criteria currently applied to all new technology applicants under the inpatient PPS, and to new medical device applicants under the outpatient PPS, be extended to applications for new outpatient drugs and biologicals. Finally, our review of how other private and public sector payers deal with the issue of paying for new technologies suggests that many of their approaches—such as negotiation and competitive bidding—may not easily be adopted into Medicare's current administered pricing systems, but point to value-based purchasing as a concept to pursue.

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 - Hospital inpatient services
 - Hospital outpatient services
 - Lessons from other health care purchasers
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New medical technologies can improve clinical outcomes and quality of care. They are also considered a major source of escalating health care costs. Since the implementation of Medicare's prospective payment system (PPS) for inpatient hospital services in 1983, questions have arisen about how to pay for beneficial new technologies (Garrison and Wilensky 1986).

Medicare has a responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, but must also be a prudent purchaser. Achieving these two goals is technically challenging and often involves tradeoffs. Paying prudently and adequately for beneficial new technologies requires, at a minimum, the ability to determine a technology's merit, accurate and verifiable information on which to base a price, and a payment system that can incorporate new technologies in a timely fashion. However, the evidence on the value of a technology is not always clear. Furthermore, information on the market price of new technologies and their effect on the costs of providing services is often not available. Also, it takes time for Medicare's administered pricing mechanisms to reflect the costs of new technologies.

For the purposes of this chapter, we define new technologies as those that have been on the market for a short period of time. They may be true innovations, significant incremental improvements on existing technologies, or expanded uses of an old technology for a new indication.¹ We do not include those that provide no or insignificant incremental improvements on existing technology. Some are new drugs or medical devices, others are new surgical techniques or imaging devices.

Although the need to incorporate new technologies applies to all prospective payments, the topic may be more relevant to hospital payment systems because new technologies are often first adopted in that setting. In addition, in the past several years, Medicare has integrated new technology payments into the hospital inpatient and outpatient prospective payment systems through specific payment mechanisms applied when a claim is submitted. Therefore, this chapter provides a brief review of those systems. The chapter then presents information on how other large purchasers of health care pay for new technologies and considers the relevance of those approaches for Medicare. Though the chapter focuses primarily on payment, it notes that payment for new technologies often relates closely to coverage decisions (see Appendix B).

Payment for new technologies in prospective payment systems: an overview

The incentives built into PPSs promote the use of new technologies that reduce costs, but they may slow the adoption of new technologies that increase costs. In response to those concerned about delays in the incorporation of new technologies into Medicare's payment systems, the Congress implemented special payments for new technologies used in the hospital inpatient and outpatient settings.

Prospective payment systems define a fixed payment for a bundled service. That is, CMS establishes a set payment for treating a case or providing a service meant to cover all the costs of providing

the service. Clinicians and providers decide how the service will be delivered, including decisions regarding the use of specific technologies. This system provides an incentive for providers to adopt technologies that decrease costs. It can also fairly easily accommodate most incremental technologies that increase costs only modestly.²

In considering how payment systems deal with technology, it is useful to distinguish between new technologies that are inputs to an existing service and new technologies that result in a new service:

- **Technologies that are inputs to an existing service.** In the case of new technologies that are inputs to an existing service (e.g., monoclonal antibodies for treatment of cancer or drug-eluting coronary artery stents used in angioplasty), Medicare pays providers using the payment category for that service. Most new technologies fall into this category. Technologies that decrease costs or raise them only modestly can enter the payment system without additional decision making. For technologies that are very expensive, additional decisions may be required. The Centers for Medicare & Medicaid Services (CMS) might revisit how the service is classified or pay for the technology through a special payment mechanism.
- **Technologies that result in a new service.** In the case of new technologies that result in new services (e.g., laser angioplasty, positron emission tomography (PET) scanning, or digital mammography), the appropriate coding group must first assign it a code (e.g., an

1 This definition applies primarily to new technologies that are involved in clinical care. As discussed later, each payment system has criteria that define the new technologies to be covered by a specific new technology payment provision. Additional forms of new technology, such as information systems, might affect the entire organization of a hospital.

2 This section provides an overview of the process through which new technologies are incorporated into the payment system. A more detailed discussion can be found in Chapter 3 of MedPAC's March 2001 Report to the Congress.

ICD-9-CM³ code or a HCPCS⁴ code). The coding process takes time because the code sets must be reviewed by medical professionals, with public input, and updated in a manner that preserves the integrity of the system. Medicare uses multiple coding systems and is only one of many players involved in maintaining and updating the code sets. After a code is assigned, CMS must incorporate the technology into the payment system and set a payment rate.

Prospective payment systems classify services and set a unit of payment that incorporates all of the inputs needed to provide the service.⁵ Relative weights apply to each service, reflecting the relative resource costs of providing that service compared with the others in the classification system. Generally, these relative weights are recalibrated annually to reflect changes in the relative costs of one service versus another, using the most recent cost and claims data. The combination of the coding and recalibration processes generally takes at least two years because of the multiple parties involved and the open process that must be followed.

Some critics of prospective payment argue that the pace of technology adoption, the time required to make code assignments, and the time needed to collect and process cost data can make it difficult to reflect the costs of new technologies immediately and may, therefore, slow diffusion. New technologies enter the marketplace continuously. Between 1995 and 2001, for example, the Food and Drug Administration (FDA) approved about 950 new drugs, biologicals, and medical devices (American Hospital Association and The Lewin Group 2002). However,

the process of placing a new technology in the payment system also gives CMS an opportunity to better understand its clinical merits and obtain accurate information about its costs. In addition to the incremental cost of the technology itself, using a new technology may lead to efficiency gains that lower the total costs of providing the service. Conversely, use of a new technology may result in additional requirements that increase the total costs of providing a service beyond the cost of the technology itself. Finally, any dampening effect these payment systems might have on technological diffusion is often balanced by the competitive and clinical forces encouraging physicians and hospitals to use new technologies.

The general prospective payment approach described above works especially well when the unit of payment covers a broad bundle of services, as with the inpatient PPS, but less so with narrow bundles, for which technology can represent a large share of the total payment. For example, a new scalpel may not represent a large share of the payment for a surgical stay on the inpatient side, but the costs of a new cancer drug could dominate payment for outpatient chemotherapy administration. In addition, this approach does not immediately capture the rapid decline in prices that often occurs shortly after the introduction of a new technology or when competitors enter the market. Payments are set annually using hospital charge data. Price changes during the course of the year, therefore, are not built into the payments until the next payment review. In addition, it is unclear whether or not hospitals decrease their charges, which Medicare uses to approximate costs, as quickly as input prices decline.

At least partly in response to those arguing that Medicare's prospective payment systems have not adequately incorporated the costs of new technologies, the Congress introduced specific payment mechanisms for hospital outpatient services (Balanced Budget Refinement Act of 1999 and Benefits Improvement and Protection Act of 2000) and hospital inpatient services (Benefits Improvement and Protection Act of 2000).

Providing separate payment promotes adoption of new technologies (as long as the payment is sufficient), thereby helping to ensure beneficiary access to them. However, the process involves the government heavily in determining which items receive separate payment and which do not. These choices may influence both the marketplace for technologies and clinical decision making. Separate payment unbundles the unit of service, diminishing the efficiency incentives of prospective payment. It may also accelerate unnecessary use of expensive technologies, leading to increased costs for Medicare beneficiaries and taxpayers. From a systems administration perspective, separate payment streams also put a burden on both CMS and hospitals to incorporate new codes into their billing systems. There is a tension between timely inclusion of separate payment for new technologies that requires frequent system changes and the stability of the payment system. Finally, if the separate payments are financed in a budget-neutral manner, they will direct resources away from other inputs, such as nursing, to fund new technologies.

Given the potential drawbacks of introducing separate payment mechanisms for new technologies, it is important to target them to technologies that are truly new, costly, and beneficial. It is through the details of the new technology payment

3 ICD-9-CM refers to the International Classification of Diseases, Ninth Revision, Clinical Modification. This is a two-part system of coding patient information used in abstracting systems and for classifying patients into diagnosis-related groups (DRGs) for Medicare. The first part of the ICD-9-CM is a list of diseases; the second part contains procedure codes, independent of disease codes.

4 HCPCS refers to the Healthcare Common Procedure Coding System. There are three kinds of HCPCS codes. Level I codes are based on the Current Procedural Terminology coding system developed by the American Medical Association. Level II and III codes, which include many supplies, drugs, and devices, are developed by CMS in collaboration with the Health Insurance Association of America and the Blue Cross Blue Shield Association.

5 In some payment systems, Medicare pays separately for certain inputs. For example, blood products are paid separately under the outpatient PPS.

mechanisms that Medicare balances the goals of ensuring adequate payment for beneficial new technologies and being a prudent purchaser.

Hospital inpatient services

Medicare incorporates the costs of new technologies into the inpatient PPS through the standard systems used to code services and set payment rates, as well as through the recently implemented add-on payments for new technologies.

Medicare's standard system for coding and setting payment rates for inpatient hospital services

The unit of payment in the hospital inpatient PPS is the inpatient discharge, as classified by diagnosis related group (DRG).⁶ The DRG system provides for a broad patient classification, encompassing all routine nursing, support service, and ancillary costs incurred in patients' stays. Most technologies are bundled into the DRG payment system. The standard system incorporates new technology costs through three processes.

First, a technical advisory panel assigns codes to new technologies using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). In response to criticism about delays in the recognition of the costs of new technologies, CMS recently shortened the coding process to speed the entry of new technologies (CMS 2001).⁷

Second, CMS responds to requests for refinements in the classification of costs within DRGs and analyzes variation in the costliness of cases within DRGs.

Reassignment to a higher-paying DRG may occur if certain cases are considered to be systematically more costly, perhaps because of the use of a new technology. For example, for fiscal year (FY) 2003, CMS established new DRGs and higher payment rates for angioplasty that involves the use of drug-eluting coronary artery stents, a new technology expected to be widely adopted once approved by the FDA.

Third, the annual recalibration of DRG case weights corrects relative payments by looking at the most recent year's claims.

Medicare's add-on payments for new technologies used in inpatient settings

The Congress authorized add-on payments for new technologies, which CMS began to make in fiscal year 2003. The add-on payments described below are summarized and contrasted with the new technology provisions of the outpatient PPS in Table 4-1.

A team of clinical experts within CMS evaluates applications for technologies that may raise the cost of a case so much that it merits additional payment beyond the base DRG payment. The eligibility criteria for these payments, set forth in regulation, are considered to be fairly stringent, encompassing the newness, clinical benefit, and cost of a new technology.

The newness criterion states that a given technology will be eligible for add-on payments until data reflecting its costs are used to recalibrate the DRG weights, generally two to three years from market entry.

Clinical considerations require that the technology substantially improve—relative to technologies previously available—the diagnosis or treatment of beneficiaries (see text box, p. 182).

Cost considerations require the applicant to provide data showing that the technology is expensive relative to the cost of the entire case. The applicant must demonstrate that the average charge for a case using the technology is one standard deviation above the geometric mean of the standardized charges for all cases in the relevant DRG.⁸ Since the charges per case vary considerably for any given DRG, the standard deviation is generally large, and technologies that meet the cost criteria will be relatively unusual. These criteria bring together payment issues (How much does it cost?) and those generally considered part of the coverage process (Is it better than technologies previously available?). Only one technology (a biologic to treat severe sepsis) has met these criteria to date (CMS 2001, CMS 2002b).

Some critics contend that these criteria set the bar too high. However, strict criteria provide a mechanism for ensuring that limited funds for new technologies are directed to those with clinical benefit and high costs. They are one tool for balancing Medicare's need to be a prudent purchaser with quicker recognition of the costs of new technologies.

When a technology is eligible for additional payment, CMS will not automatically make an additional payment each time it is used. Instead, CMS bases the payment on the costs incurred for the whole case, as determined by the fiscal intermediary that processes the claim. In order for additional payment to be made, the costs of the case must be above the

6 For a more detailed description of the inpatient PPS, see Appendix A. Regarding the standard process for responding to technology costs under the inpatient PPS, see Chapter 3 of MedPAC's March 2001 Report to the Congress.

7 The process was shortened by moving the twice-yearly meetings of the ICD-9-CM coordinating committee from May and November to April and December and allowing some new codes to be incorporated into the final rule without first appearing in the proposed rule. The revised schedule allows more new codes to take effect under the October 1 start of the fiscal year, but restricts the time for public comment on some new codes.

8 Hospitals' reported charges are standardized through use of the hospital wage index to remove the effects of regional differences in medical costs. To obtain the geometric mean, the standardized charges are first transformed onto a logarithmic scale before the average is taken. This mathematical approach provides a better estimate of the average because the distribution is highly skewed and bounded by zero.

**TABLE
4-1**

Design of the hospital inpatient and outpatient new technology payment mechanisms

| Design element | Inpatient add-on payments | Outpatient pass-through payments | | Outpatient new technology APCs |
|---|--|---|--|--|
| | | Medical devices | Drugs and biologicals | |
| What kinds of new technologies can receive additional new technology payments? | New technologies that represent a new procedure or are an input to an existing diagnosis-related group. | New technologies that are an input to an existing service. | New technologies that are an input to an existing service. | New technologies that represent a new service. |
| Which specific technologies receive additional new technology payments (criteria applied by CMS)? | Eligibility based on clinical benefit, newness, and cost. | Eligibility based on clinical benefit, newness, and cost. | Eligibility based on newness and cost. | Eligibility based on newness. |
| How are payments financed? | Budget neutral financing. | Budget neutral financing. | Budget neutral financing. | New expenditures. |
| What is the unit of payment? | Payment based on the additional costs of treating a case using the new technology. | Payment based on the cost of the new technology. | Payment based on the cost of the new technology. | Payment based on the cost of providing the service. |
| How are payments determined? | Payment equal to 50 percent of the additional costs, capped at 50 percent of the estimated cost of the new technology. | Payment equal to 100 percent of reported costs minus device costs already built into the base payment rate. | Payment equal to 95 percent of average wholesale price. | Payment equal to the midpoint of the payment range for the new technology APC group. For example, payment for a service in the \$1,000 to \$2,000 new technology APC is \$1,500. |

Note: APC (ambulatory payment classification).

Source: MedPAC analysis.

standard DRG payment. To preserve incentives for judicious use of technologies, Medicare does not pay the full extra costs of a case using the new technology. Rather, the additional payment covers only 50 percent of a hospital's costs above the standard DRG payment, up to a maximum of 50 percent of the estimated cost of the new technology. Some argue that partial payment is not great enough to ensure beneficiary access to new technologies. However, this method also provides an

incentive for hospitals to weigh carefully the benefits of a technology against its costs. Countervailing competitive and clinical forces also push technology diffusion.

The add-on payment mechanism is budget neutral, meaning that CMS lowers the base payment rate prospectively by the same percentage for all services to finance the add-on payments. This introduces the need to balance the impact of the payment mechanism on payments for all services

against the need for additional payments for new technologies. Expenditures for the add-on payments are capped at 1 percent of total operating payments.

Hospital outpatient services

Medicare's hospital outpatient PPS incorporates costs of new technologies through the standard systems used to code

Clinical criteria for new technology add-on payments for inpatient services and the establishment of outpatient pass-through categories for new devices

To be eligible for new technology add-on payments under Medicare's prospective payment system (PPS) for inpatient hospital services, a new technology must, among other characteristics, substantially improve the diagnosis or treatment of beneficiaries. To be eligible for new-technology pass-through payments under the hospital outpatient PPS, medical devices must meet the same clinical criteria. CMS has established the following examples of how a technology can meet these criteria:

- It offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- It offers the ability to diagnose a medical condition in a patient population in which their medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the technology to make a diagnosis

affects the management of the patient.

- Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. For example, improvements might include:
 - Reduced mortality rate
 - Reduced rate of complications
 - Decreased rate of subsequent diagnostic or therapeutic interventions (e.g., due to reduced rate of recurrence of the disease process)
 - Decreased number of future hospitalizations or physician visits
 - More rapid beneficial resolution of the disease process
 - Decreased pain, bleeding, or other quantifiable symptom
 - Reduced recovery time

Extracted from CMS 2001. ■

mixes fairly broad bundles of inputs used to provide a service such as ambulatory surgery, with fairly narrow bundles of inputs to provide an ancillary service such as an X-ray. In cases where the bundle is narrow, a specific technology can represent a fairly large share of the costs for providing an outpatient service. Therefore, the outpatient PPS includes two mechanisms targeted specifically to new technologies, as well as a standard approach for maintaining the payment system, similar to that described for the inpatient sector.

Services are classified into APC groups based on their Healthcare Common Procedure Coding System (HCPCS) codes. There are three kinds of HCPCS codes. Level I codes are based on the Current Procedural Terminology coding system developed by the American Medical Association. Level II and Level III codes, which include many supplies, drugs, and devices, are developed by CMS in coordination with the Health Insurance Association of America and the Blue Cross Blue Shield Association. Both coding systems accept applications for new codes. In the case of new technologies, CMS has assigned temporary codes on an expedited basis to facilitate payments.

As with the inpatient PPS, CMS responds to requests for refinements in the classification of services within the APC system. The outpatient PPS is unique in that it also has an external advisory body, composed of hospital representatives, that is charged with aiding the agency in defining the APCs. The advisory committee also serves as a public forum for considering requests for changes in APC groupings.

Finally, the annual recalibration process should reflect the costs of new technologies as reported by hospitals. The recalibration process undertaken to set the calendar year 2003¹⁰ payment rates led to significant swings in payment, particularly

services and set payment rates, as well as through two mechanisms that specifically target new technologies: new technology ambulatory payment classification (APC) groups and pass-through payments. The two new technology payment mechanisms described in this section are summarized and contrasted with the inpatient add-on payments in Table 4-1 (p. 181).

Medicare's standard system for coding and setting payment rates for outpatient services

The unit of payment in the hospital outpatient PPS is the service provided, as classified by ambulatory payment classification groups.⁹ The APC system

⁹ For a more detailed description of the outpatient PPS, see Appendix A. Regarding the standard process for responding to technology costs under the outpatient PPS, see Chapter 3 of MedPAC's March 2001 Report to the Congress.

¹⁰ The hospital inpatient PPS runs on a fiscal year, while the hospital outpatient PPS runs on a calendar year.

for services incorporating new technologies. These problems may be transitional, in that this was the first year CMS used data from hospitals operating under the PPS to set the payment rates, and hospitals reported significant difficulties in coding for technologies.¹¹ However, the small bundles used in the classification system may make payment rates inherently less stable.

New technology APC groups for technologies used in outpatient settings

To be placed in a new technology APC, a technology must be a complete service or procedure that cannot be adequately described by an existing payment category. In addition, it must be a covered service that is new and does not meet the criteria for pass-through payments (described below). For example, PET scans—a newly covered service that does not fall into any existing payment category—currently fall in the new technology APCs. The new technology APCs are grouped into heterogeneous categories by cost (for example, \$0–50, or \$5,000–6,000), with payment at the midpoint of the range. No cap or budget neutrality provision governs the new technology APCs. In addition, since the categories are defined solely by cost ranges, CMS does not include these APC groups when recalibrating payment rates. Therefore, each service results in additional payment. CMS moves services out of the new technology APCs and into the standard system during the annual review of the APC classification and recalibration process, when sufficient data on hospitals' costs for the technology have accumulated.

The lack of a budget-neutrality constraint for new technology APCs means that payments for new technologies could increase dramatically. Currently, 75 services (as denoted by discreet HCPCS codes) fall into new technology APCs. CMS also has five applications pending review. In 2001, services in new technology APCs accounted for about 1 percent of total payments (MedPAC analysis of 2001 outpatient claims from CMS).

Medicare's transitional pass-through payments for technologies used in outpatient settings

Transitional pass-through payments cover technologies that are an input to an existing service. They are limited to medical devices, drugs, and biologicals.¹² For example, alemtuzumab is a monoclonal antibody used in the treatment of breast cancer and is paid under the transitional pass-through mechanism. There are already codes governing chemotherapy administration, but they do not reflect the cost of this new technology. In this case, the pass-through payment supplements the base payment for chemotherapy.

Pass-through eligibility criteria are somewhat different for drugs and devices. Eligibility for devices has been tightened recently to introduce clinical criteria in addition to newness and cost. The clinical criteria are essentially the same as those for the inpatient add-on payments and require that the technology under consideration substantially improve, relative to technologies previously available, the diagnosis or treatment of beneficiaries (see text box on p. 182). Including clinical considerations for

establishing new categories of medical devices raises concerns by some manufacturers that the bar has now been set too high, whereas it was previously thought to be too low by most observers. The cost considerations require CMS to assess the cost of the technology in relation to the base APC payment rate and compare its cost to that of similar technologies it replaces.¹³

The treatment of drugs and devices is inconsistent, in that only newness and cost criteria are applied to pass-through drugs. This difference in the criteria represents unequal treatment between types of technology within the outpatient payment system. It also leads to a discrepancy between the treatment of drugs under the inpatient and outpatient payment systems, since the clinical criteria are applied to all technologies, including drugs, on the inpatient side. Furthermore, without considering clinical benefit, the criteria applied to pass-through drugs may over-emphasize the goal of paying adequately for new technologies at the expense of prudent purchasing.

Payment for pass-through items is tied to use of the technology itself, without considering the impact on total costs of providing the service, such as efficiency gains or additional incremental costs associated with use of the technology. That is, each use of a pass-through item results in the hospital receiving additional payment, whether or not total costs for the entire service actually rose or fell. For medical devices, the pass-through payment is based on 100 percent of charges reduced to costs through use of a hospital-specific cost-to-charge ratio. For drugs or biologicals, payment is based on 95 percent of average wholesale price.¹⁴

11 In revising payments for 2003, CMS for the first time used claims and cost reports from hospitals operating under the outpatient PPS. Previously, CMS relied on pre-PPS claims data and information from manufacturers on the costs of technologies to set the payments. For 2002, manufacturers' price data were used to incorporate 75 percent of medical device pass-through costs into the base APC rates. Using these data led to much higher payment rates in 2002 for services using medical devices than the rates calculated for 2003 using cost data reported by hospitals. In addition, it appears that some hospitals did not code accurately for pass-through items, particularly in the beginning of the outpatient PPS. CMS modified the rates for 2003 to limit changes in payment from 2002 (CMS 2002c).

12 Until recently, radiopharmaceuticals could also be considered for pass-through eligibility. However, beginning in January 2003, CMS will no longer consider radiopharmaceuticals (CMS 2002c).

13 The three cost considerations are that the device represent at least 25 percent of the related APC rate, that it be at least 25 percent more expensive than a device it replaces, and that the increase in cost associated with using the device represents at least 10 percent of the related APC rate.

14 Payments for all pass-through items may be reduced if estimated total payments exceed a statutory cap discussed below.

These payment mechanisms provide an incentive to manufacturers and hospitals to overstate prices and charges to increase payments. Analysis of the 2001 claims indicates that hospitals initially had trouble billing for pass-through devices; however, over time both the share of hospitals billing for these items and their reported costs increased (CMS 2002c).

The pass-through payment provision is budget neutral, meaning that payments for all services are reduced by the same percentage to finance these payments. Budget neutrality redistributes funds to services or cases that include new technologies and away from those that do not. This mechanism can have distributional effects across types of hospitals depending on the service mix of a given provider. The text box on p. 185 discusses the distribution of pass-through payments among providers.

The Congress capped spending on pass-through items at 2.5 percent of total outpatient PPS payments (both program and beneficiary).¹⁵ However, the cap was not enforced until the last nine months of 2002. Because of congressional and administrative actions, the number and costs of pass-through items far exceeded original expectations in the early years of implementation. In 2001, pass-through items accounted for over 8 percent of total payments (MedPAC analysis of 2001 claims). The number of pass-through items has subsequently slowed and should continue at a modest pace, at least in the near term. The 2003 final rule includes about two dozen drugs and five device categories (CMS 2002c). CMS currently has fewer than 10 applications pending review (personal contact with CMS staff).

Despite this modest growth in the number of pass-through items in the near term, continued medical advances are likely, perhaps leading to pressures to relax eligibility criteria or increase payments.

For example, a recent review of Wall Street analyses states that medical device and supply manufacturers are in good financial health and have increased spending on research and development, indicating that the pipeline of new products will continue (CMS 2002a). In addition, the recent passage of legislation authorizing user fees for FDA review of medical devices will likely accelerate approval of additional technologies.

MedPAC has documented a number of problems with the pass-through mechanism, some of which relate to the eligibility criteria, whereas others involve payment. The Commission has recommended that pass-through payments be selectively targeted to technologies that are truly new (MedPAC 2001, MedPAC 2002). The changes to the criteria for new categories of medical devices are a step in that direction. Though CMS has moved to tighten the criteria for pass-through devices, it is likely that the agency and the Congress will face pressures to relax them in the future. However, MedPAC believes that it is appropriate to reserve additional payments for technologies that provide clinical benefit and do not have clinical substitutes. It may even be appropriate to limit payments to technologies that provide additional benefits commensurate with their costs. At a minimum, clinical criteria should apply to all new technologies.

RECOMMENDATION:

The Secretary should introduce clinical criteria for eligibility of drugs and biologicals to receive pass-through payments under the outpatient PPS.

IMPLICATIONS:

Spending

- This recommendation would have no impact on spending because the pass-through payments are budget neutral.

Beneficiary and provider

- The clinical criteria would apply only to eligibility for additional payment. New drugs and biologicals not meeting the criteria may still be used and be paid for at the base APC rate. Therefore, the recommendation should not affect beneficiaries' access to care.
- The recommendation should have no impact on providers' payments because the pass-through payments are budget neutral. Limiting additional payments to drugs and biologicals that have clinical benefit will marginally reduce hospitals' administrative burden.

MedPAC has previously noted that payments for devices are based on hospitals' charges (reduced to costs by applying a cost-to-charge ratio), providing incentives for manufacturers and hospitals to raise their prices and charges, potentially resulting in overpayments. CMS calculates payments for drugs based on average wholesale price (AWP). A number of studies by the General Accounting Office and the Office of Inspector General have provided ample evidence that payment based on AWP generally results in Medicare paying far more than market price.¹⁶ Incorporating data based on inflated costs will lead to distortions in the relative weights (MedPAC 2002). The problems we have noted previously with the payment formulas continue and merit further study.

Lessons from other health care purchasers

Various private and public sector payers other than Medicare deal with the issue of paying for new technologies. To assist deliberations on how best to pay for new technologies in Medicare, MedPAC contracted with Project HOPE to conduct

¹⁵ The cap falls to 2.0 percent in 2004 and subsequently.

¹⁶ As indicated in MedPAC's comment letter on the proposed rule for the outpatient PPS, the Commission is concerned about all Part B payments for drugs that are based on AWP, not just the outpatient pass-through payments. The Commission understands that the Congress and CMS are considering ways of reforming the current system. If the Congress or CMS implements a new system this year, the Commission will monitor the impact of payment changes and their implications for beneficiary access. We will recommend refinements if necessary. If the Congress does not act on the issue this session, we will focus our efforts on analyzing options for change.

Distribution of new technology payments among providers

One issue raised by new technology payments is distributional: Which providers will receive them? The question is even more salient in a budget-neutral system, where payments for all other services go down while those for new technologies increase. Generally, hospitals will benefit or not depending on their service mix. Hospitals that provide many technology-driven services will benefit whereas those providing more basic services will not. Given that the outpatient prospective payment system (PPS) pass-through payments represent the first new technology provision to be implemented under a Medicare PPS, the breakdown of payments under that mechanism illustrates the distributional effects of new technology payments.

The outpatient PPS pass-through payments were not evenly distributed in 2001 (Table 4-2). Some of the results are to be expected. For example, though teaching hospitals received about 50 percent of total outpatient PPS payments, they received 56 percent of pass-through payments. Similarly, cancer hospitals, which received only 1 percent of total outpatient PPS payments, received 4.3 percent of the pass-through payments and 5.5 percent of payments for pass-through drugs. However, other results are more

TABLE 4-2

Outpatient PPS payments by service type and hospital group, 2001

| Hospital group | Share of payments by service type | | | | |
|----------------|-----------------------------------|--------------------------|-----------------------|--------------------|----------------------|
| | Total payments | Nonpass-through payments | Pass-through payments | Pass-through drugs | Pass-through devices |
| Urban | 80.7% | 80.8% | 79.8% | 76.9% | 90.6% |
| Rural | 19.3 | 19.2 | 20.2 | 23.1 | 9.4 |
| 1-100 beds | 9.5 | 9.5 | 9.5 | 11.5 | 2.5 |
| 101+ beds | 9.8 | 9.7 | 10.6 | 11.7 | 6.9 |
| Cancer | 1.0 | 0.7 | 4.3 | 5.5 | 0.0 |
| Teaching | 50.2 | 49.7 | 55.9 | 54.2 | 62.1 |
| Nonteaching | 49.7 | 50.2 | 44.1 | 45.8 | 38.0 |

Note: PPS (prospective payment system). Numbers may not sum to 100 due to rounding.

Source: MedPAC analysis of the 100 percent Special Analytical File of 2001 outpatient PPS claims from CMS.

surprising. For example, urban hospitals did not receive a disproportionate share of pass-through payments. Urban hospitals received a similar share of total payments (81 percent) and pass-through payments (80 percent); however, they received a higher share of payments for pass-through devices (91 percent). Rural hospitals, in contrast, received proportionate shares of total payments (19 percent) and pass-through payments (20 percent) but had a

somewhat higher share of payments for pass-through drugs (23.1 percent). The distribution of payments was similar for smaller rural hospitals (less than 100 beds). One reason the distributional impact was not as marked as might be expected could be the large number of items, many of which were not truly new, that received pass-through payments in 2001. In addition, many cancer drugs that are often provided in rural hospitals were eligible for pass-through payments. ■

a survey of large public and private sector purchasers to learn what strategies they use to get the best possible prices for new technologies. The interviewees included well-informed representatives of health care insurers, group purchasing organizations (GPOs), pharmaceutical benefit management organizations (PBMs), large integrated delivery systems, the Department of Defense, the Department of Veterans Affairs (VA), the New York Medicaid program, the United

Kingdom (UK), and Australia (Mohr et al. 2002). We also convened an expert panel with representatives from hospitals, manufacturers, insurers and other payers, academia, and CMS (Mohr 2002). The panel discussed the following three questions:

- What principles should Medicare follow in paying for new medical technologies?

- What constraints does Medicare face in paying for new technologies?
- What options might Medicare consider for paying for new medical technologies?

As described below, MedPAC's structured interviews found that the approaches used by other payers include negotiation, competitive bidding, and other strategies that incorporate value into

decisions about covering and paying for new technologies. The expert panel convened by MedPAC suggested that although other payers' approaches may not easily be adopted into Medicare's administered pricing systems, the program should pursue the concept of value-based purchasing.

Other payers' approaches to paying for new technologies

Evidence from the interviews and other analysis by MedPAC suggest that large purchasers other than Medicare use several strategies to ensure prudent purchasing of new technologies:

- **Staying informed.** All respondents reported that they invest considerable resources in tracking new technologies and understanding the medical evidence regarding their benefits to bolster their position in negotiations with manufacturers. They monitor the clinical trials being performed to obtain FDA approval, plus technology hotlines developed by commercial technology assessment organizations, and they may have their own internal capabilities as well. Price information may be obtained from industry analysts, commercial databases, European experience, or information gathered from within an integrated delivery system or health plan, such as purchase contracts of member hospitals or claims data for affiliate health plans.
- **Direct negotiation and contracting with manufacturers.** Some large integrated health care systems (including military health care), GPOs, and PBMs negotiate and contract directly with the manufacturers of new technologies. They use information about a technology's clinical effectiveness and costs during their negotiations. If a product is a "blockbuster" technology that has great clinical benefit and no competitors, the manufacturer is at an advantage in setting its price. Purchasers then try

to limit the length of a contract and introduce competition clauses to renegotiate prices if a competing product enters the market.

- **Use of coverage policies and other tools to limit exposure to high prices.** Early in the diffusion of a new technology, other payers and purchasers use various tools to restrict use of new technologies to the most appropriate cases. Examples include tiered copayments, dissemination of guidelines for the use of a technology, step therapy, in which use of a new technology is approved only if existing technologies have been tried and failed, and prior authorization.
 - **Competitive bidding.** Competitive bidding is used when similar, or therapeutically equivalent, products are available. It is especially successful in closed systems like integrated delivery systems or the military health services that can limit procurement. Insurers are less likely to use competitive bidding. If purchasers know that a new product offers similar clinical outcomes to existing or other new therapies, then they can offer guaranteed volume to a manufacturer in exchange for a lower price. This process generally results in lower prices but also limits the choice of products to be used. Interviewees representing closed systems suggested that involving end-users of technologies (usually physicians) in the development of product specifications and guidelines for a product's use makes competitive bidding more viable and successful.
 - **Invoice submission.** When insurers decide to cover a new technology that is not already built into the payment rates they have negotiated with providers, they may require providers to submit an invoice showing their costs. This approach is most effective for technologies like medical devices. The insurer will then pay the invoice
- cost plus a percentage to cover overhead. Using this approach, the insurer avoids the need to pay billed charges—which often reflect a considerable mark-up—and can benefit from any reductions in price that may occur over time. However, invoices generally do not reflect any rebates that a purchaser has received and may, therefore, overstate acquisition costs.
- **Cost-effectiveness analysis.** Many payers, both public and private, invest substantial resources in determining the cost-effectiveness of new and existing technologies. This work supports coverage decisions and plays into payment decisions. For example, in Australia, manufacturers wishing to place a pharmaceutical on the national schedule for the national health insurance system must submit an application that includes cost-effectiveness information. Pricing data are considered, and if the costs are considered too high, the government may restrict use of the drug or negotiate with the manufacturer to reduce the price. The Australian health care system also applies cost-effectiveness analysis to other health care interventions, including devices, procedures, diagnostics, and blood products, although the link to pricing is less clear. In the United Kingdom, the National Institute for Clinical Excellence (NICE) provides guidance to the National Health Service (NHS) about the use of individual health technologies. Although NICE is not directly involved in establishing prices for new technologies, it does influence manufacturers' pricing decisions indirectly by examining cost-effectiveness analyses when making their recommendations. If a technology exceeds a threshold that is loosely set at 30,000 pounds (almost \$50,000 given current exchange rates) per quality-adjusted life year, NICE is less likely to recommend the product.

- Return on equity.** In the United Kingdom, prices for pharmaceuticals are subject to a cap based on a reasonable return on equity. Manufacturers may set any price they wish at product launch, subject to the constraint that the total rate of return on capital invested in the UK on all their products reimbursed by the NHS does not exceed a pre-set limit. The return on equity is limited to a range of 17–21 percent. If the rate of return exceeds these targeted rates, the manufacturer must grant the NHS a rebate or reduce the price of the drug. Manufacturers must submit audited financial returns detailing their investment in the UK. The return on equity approach applies only to companies based in the UK.

Applicability of other purchasers' strategies to Medicare

Evidence from the expert panel discussion and other analysis by MedPAC suggest that other payers' approaches may not easily be adopted into Medicare's administered pricing program, but point to value-based purchasing as a future direction to pursue.

Constraints unique to Medicare

Medicare faces constraints that other payers do not and that may limit its ability to use the alternative strategies outlined above. These constraints have to do with the size and national scope of the Medicare program, its role as an insurer, and program issues like public disclosure requirements and limited administrative capacity.

Medicare covers more than 40 million Americans. This large market means that decisions made by the Medicare program can have a large impact. In the area of new technologies, Medicare's decisions can greatly affect the financial status of a manufacturer and also have an impact on future innovation. Restricting Medicare's purchasing to one or two suppliers, as is

generally done under the competitive bidding arrangements of the organizations we interviewed, could determine which suppliers flourish and which do not. Of course, Medicare could structure competitive bidding to involve more players. In addition, other payers often follow Medicare in setting payment rates, leading to an even greater influence on the market. Furthermore, the Medicare program is national in scope. Under current law, payments are set nationally. This makes it difficult for Medicare to take advantage of local market conditions, such as market share, that might allow the program to negotiate better prices in one area as compared to another.

The Medicare program acts as an insurer, reimbursing hospitals and physicians for their services using administered pricing systems required under law. Consequently, the program has no direct role in negotiating with manufacturers or distributors. It also has little control over the choices made by providers serving Medicare beneficiaries. Of the strategies listed above, both negotiation strategies and competitive bidding are done best by closed delivery systems, such as the VA or an integrated delivery system, which do have the ability to negotiate prices and to influence the delivery of care to enrollees. However, the Medicare competitive bidding demonstration project for purchase of durable medical equipment may provide lessons that can be applied to other parts of the program.

Administrative issues also constrain the program. For instance, Medicare must follow rule-making processes that involve public comment unless there is a specific exception in law, such as the Medicaid prescription drug rebate program. Public disclosure requirements limit the program's ability to obtain and use proprietary information. For example, Medicare would be less successful in negotiating the best price for an item if that price then becomes public because manufacturers would face pressure to offer that price to all purchasers. Even if

the program had authority to negotiate prices in confidence, administration of the payment system currently requires the program to publish payment rates for use by the fiscal intermediaries and hospitals. The rule-making process also adds time to any decision-making as time must be allowed for comment by interest groups and response from CMS.

Finally, Medicare has limited administrative capacity to implement the alternative strategies noted above. Most private payers devote considerable resources to monitoring the new technology pipeline and conducting technology assessments. Large systems, such as the VA, even conduct clinical trials to evaluate technologies. Given current resources, CMS may not be able to make the same level of investment in these activities as other organizations have done.

Other environmental considerations

In addition to the system constraints noted above, other factors prevent the Medicare program from engaging in the strategies used by many other large payers and purchasers. Since Medicare is an entitlement program, beneficiaries and the general public have expectations about access and choice, making decisions about limiting access to specific items controversial. Similarly, Medicare as a public sector payer is expected to ensure a level playing field among competing manufacturers, which limits its ability to be selective, a major tool used by other payers. Selectivity also runs afoul of the law stating that Medicare will not interfere with the practice of medicine.¹⁷

One strategy that Medicare might consider despite these constraints is limiting return on equity, as done in the UK. This approach does not limit the number of suppliers or establish a specific price, but regulates the return to the manufacturer, and is one factor that must be taken into account when setting a product's price. One advantage of this approach is that it

¹⁷ The Medicare+Choice program and the competitive bidding demonstrations are governed by separate statutory provisions that allow some level of selectivity.

operates directly on the manufacturer. Since manufacturers of new technologies are generally at an advantage in price negotiations, this approach provides incentives to limit the price to the most appropriate actor.

The use of return on equity in the UK, however, is based on a number of factors that may not be applicable to Medicare. The UK limits this approach to a single industry, pharmaceuticals, and conducts its return-on-equity calculations based on the whole portfolio of products that a manufacturer sells to the National Health Service, including both existing and new technologies. Therefore, there is no need to allocate investments to a specific product. By contrast, Medicare serves a limited population (the NHS covers the whole population), and would only want to use the return on equity approach to set payments for new technology.

Consequently, Medicare would want to determine a return on equity for a specific product, or, alternatively, all of the manufacturer's products used in providing Medicare services. This would require substantial review of manufacturers' finances and sophisticated accounting to separate out expenses and revenue streams for a subset of products. A return on equity calculation might also need to take into account some share of firms' investments in unsuccessful products. Given the large number of unsuccessful products manufacturers pursue in addition to the successful ones, this calculation could prove complex.

Furthermore, since the UK establishes a return for all products, manufacturers are free to price new drugs well above the established range of return to take advantage of market position as a monopoly provider of a new product. Applying return on equity to a subset of products would limit a manufacturer's ability to do this. Another wrinkle is that the return-on-equity approach is used only for firms based in the UK and applies only to investments made in the UK. If

Medicare were to adopt this approach, the program would need to decide how to treat investments overseas and firms not based in the United States. CMS has also noted that it does not have the administrative capacity or legal authority to develop a return-on-equity approach and doubts that the resources needed to develop one are warranted given that new technology payments are meant to be limited to a small number of technologies (CMS 2002d). Despite these complexities, return on equity may be a reasonable approach for setting payment rates in certain situations, such as when there is a single producer of a technology with clear clinical benefits and no substitutes, and Medicare is the predominant purchaser of the technology. It would, however, signal a major break with Medicare payment policy, which generally avoids regulating profits.

Another possibility is the use of third-party purchasers. Can Medicare contract with multiple GPOs and PBMs to negotiate better prices for these items? It seems clear that the limited volume of new technology items makes this approach less viable. However, the use of third-party purchasers by Medicare has been discussed in the context of paying for Part B drugs and outpatient pharmaceuticals under a Medicare drug benefit. If these strategies are pursued, third-party purchasing of new technologies might be considered as an additional role.

Value-based purchasing as a future direction

Although the specific techniques used by other payers seem to have limited applicability in an administered pricing program that is national in scope, like Medicare's prospective payment systems, together they embody a concept that could prove useful to the program. In paying for new technologies, other payers strive for value-based purchasing. That is, they try to limit coverage to those technologies

that provide a demonstrated clinical benefit, and assess the level of additional benefits over existing technologies against the additional costs for the new technologies. For example, cost-effectiveness information is used in negotiations with manufacturers, and establishment of therapeutic equivalence is key to competitive bidding. Most participants in the expert panel on how Medicare should pay for new technologies agreed that the program should pursue value-based purchasing, although they did not agree on specific approaches for doing so.

Value-based purchasing involves making judgments about the benefit of a new technology compared to other available therapies and considering the value of the additional costs associated with use of the new technology. Under value-based purchasing, additional payments would be less likely for a new technology that has existing substitutes, even if the new technology is substantially more costly. If the same clinical outcome is achieved, is it necessary to pay more than is paid for the existing technology? If there are modest clinical gains at a great increase in price, should the program pay?

The clinical criteria introduced for add-on payments under the inpatient PPS and for medical devices under the outpatient PPS move in the direction of value-based purchasing by having Medicare determine the clinical benefit of a new technology before it receives additional payment. The next step, however, of assessing the value of that clinical benefit, or the relationship of the clinical benefit to the extra cost, has not been taken systematically.¹⁸

Several methodological issues surround value-based purchasing. These include, among others: establishing the level of evidence needed to assess value; specifying a measure for assessing benefit, such as quality-adjusted life-years; and defining the scope of the costs and benefits to be included in assessing value,

18 While value-based judgments are not made systematically within the Medicare program, they have been used in at least one case. In the November 1 final rule for the outpatient PPS (CMS 2002c), CMS did declare a new anemia treatment, darbepoetin alpha, "functionally equivalent" to an existing treatment, epoetin alpha, and reduced the pass-through payment for the new biologic to \$0. The agency used its authority to ensure equity of payments in taking this step, which was novel.

such as impact on future wage earnings or cost-savings because of a reduced need for future medical interventions. In addition, the choice of a threshold value that a technology must exceed to receive additional payment would likely become a political issue, leading to extensive debate among manufacturers, clinicians, beneficiaries, and other interested parties. In fact, previous attempts by Medicare to introduce cost-effectiveness analysis into the coverage process have been blocked. For example, in 1989 CMS (then the Health Care Financing Administration) put forth a notice of proposed rule-making

that included cost-effectiveness as a coverage criterion. The rule was never finalized. Later, in 2000, CMS published a notice of intent of proposed rule-making that outlined a four-step process for considering the value of an item or service when making national coverage decisions. The agency has yet to follow up on this issue. In both instances, resistance by affected interest groups was considered one element in delaying action (Foote 2002).

Despite methodological and other challenges to its development, value-based purchasing provides a framework for deciding where to spend scarce dollars. Expanding its ability to pursue value-based purchasing would allow Medicare to better balance the goals of paying enough for beneficial new technologies to ensure beneficiary access to appropriate care, and being a prudent purchaser. ■

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