

CHAPTER

3

**Paying for new technology in
the outpatient prospective
payment system**

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

3A The Congress should:

- Replace hospital-specific payments for pass-through devices with national rates.
- Give the Secretary authority to consider alternatives to average wholesale price when determining payments for pass-through drugs and biologicals.

*YES: 14 • NO: 0 • NOT VOTING: 0 • ABSENT: 3

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3B The Secretary should:

- Ensure additional payments are made only for new or substantially improved technologies that are expensive in relation to the applicable ambulatory payment classification payment rate.
- Avoid basing national rates only on reported costs.
- Ensure that the same broad principles guide payments for new technologies in the inpatient and outpatient payment systems.

YES: 14 • NO: 0 • NOT VOTING: 0 • ABSENT: 3

*COMMISSIONERS' VOTING RESULTS

Paying for new technology in the outpatient prospective payment system

Medicare continues to struggle to find the optimal methods to pay for new technology. Medicare adopted a special payment provision for hospital outpatient services to ensure adequate payment for new technology—the so-called pass-through payments. Implementation of the pass-through payments, however, has been fraught with difficulties. While the Commission believes that Medicare must ensure adequate payment for new technology, we see systemic flaws in the pass-through payment mechanism. As currently structured, the pass-through payments provide manufacturers and hospitals with incentives to raise their prices and charges, potentially resulting in overpayments. The overstated charges also cause a second-order problem of incorrect relative payments among services when the costs of new technology are incorporated into the base payment rates at the end of pass-through eligibility. To correct this problem, MedPAC recommends that the Congress replace hospital-specific payments for pass-through devices with national rates to be set by the Secretary. The Congress also should give the Secretary authority to consider alternatives to average wholesale price when determining payments for pass-through drugs and biologicals.

In this chapter:

- Development of the outpatient payment system
- Approaches to paying for new technology
- How technology is paid for under the outpatient payment system
- Systemic problems with the pass-through payments
- Alternatives for paying for technology used in outpatient departments
- Improving the pass-through system

This chapter first reviews the development of the outpatient prospective payment system (PPS) and provides a conceptual discussion of alternative approaches to paying for new technology. It discusses the existing payment mechanism under the outpatient PPS—the so-called pass-through payments—and highlights its problems. Finally, the chapter discusses ways to address shortcomings in the system and recommends an alternative approach.

Development of the outpatient payment system

The Balanced Budget Act of 1997 (BBA) mandated the use of a PPS for services provided in hospital outpatient departments. The law required that the Centers for Medicare & Medicaid Services (CMS) use claims data from 1996 and the most recent available hospital cost reports to develop the PPS, which was implemented in August 2000.

The PPS groups services into ambulatory payment classifications (APCs) based on clinical and cost similarity. All services in an APC have the same base payment rate; the unit of payment is the individual service. If a patient receives multiple services during an encounter, such as a clinic visit and a diagnostic x-ray, the hospital will receive separate payment for each service. The payment system also has an outlier policy that partially reimburses hospitals for extraordinarily high-cost services (see Chapter 1 for a description of the outpatient PPS, including the outlier policy).

Payment for a service in an APC includes limited bundling of ancillary services and supplies, including drugs, biologicals, and medical devices (hereafter called technology).¹ The most extensive bundling occurs for outpatient surgery, but

even that is limited. Payment for outpatient surgery covers hospitals' costs for the operating and recovery rooms, anesthesia, most drugs, and most surgical supplies used during the surgery. Given the limited bundling in the PPS, a specific input, such as a medical device, can represent a fairly large share of the total cost of the service. For example, in the 2002 final rule for the outpatient PPS (CMS 2001a), the national payment rate for pacemaker implantation (APC 0089) is about \$7,600, of which CMS estimates device costs at about \$6,400, or 84 percent of the total payment. By contrast, the pacemaker itself represents about 64 percent of the total inpatient payment for a pacemaker implantation with no complications, reflecting the broader bundle under the inpatient PPS.²

Approaches to paying for new technology

Making bundled payments for services has a number of goals. First, it gives hospitals an incentive to provide services efficiently because they can control the allocation of spending among inputs. Second, it avoids incentives to increase the use of inputs inherent in payment systems that pay for services on a line-item basis or on costs. Third, it obviates the need for CMS to set prices for individual items, an administratively cumbersome task that is likely to result in errors. If item-level prices are wrong, some items will be overpaid and others will be underpaid, providing incentives for providers to choose some technologies and avoid others for financial, rather than clinical reasons.

Although bundled payments are generally thought to enhance efficiency, unbundling may be appropriate in some cases. With regard to the outpatient PPS, unbundling payment for some technologies may be appropriate to the extent that the payment

rates are, in fact, too low for the covered technology, which may discourage use of the most clinically appropriate technologies. In the case of costly new technology, bundled payments are likely to be insufficient until payment weights are recalibrated to take into account the incremental costs of the new technology, which generally takes two years.

The way Medicare pays for new technology may influence technological diffusion, access to new technologies for Medicare beneficiaries, and the level of trust fund spending. Medicare needs to balance the incentives to avoid costly new technology inherent in bundled payment with the incentives to use—and perhaps overuse—new technology paid for on a fee schedule or cost basis.

Impact on diffusion

A fully bundled payment will not cover the incremental costs of an expensive new technology unless use of the technology is also accompanied by savings in other areas. If losses associated with the use of new items are significant, hospitals may ask physicians to avoid using them or refuse to stock them, thereby hampering diffusion of technology. However, hospitals must balance financial incentives against the clinical merits of the technology and the desire of physicians to use it, which may lead them to use the technology even if payments are below cost. In addition, competitive pressures to keep abreast of changes in technology and pressure from physicians to use new technology may lead hospitals to accept short-term losses on some items. The clinical importance of a particular new technology, its incremental cost, and the relationship of the incremental cost to the base payment all factor into decisions about whether or not to use an item under a fully bundled payment.

In contrast to a fully bundled payment, a fee schedule or cost-based approach to paying for new technology provides

1 As described below, special payment rules have been put into place for new drugs, biologicals, and medical devices under the outpatient PPS. Biologicals include items such as blood products, hormones, and antibodies.

2 This comparison assumes that the estimated device cost is the same in each setting. For the inpatient calculation, we assume diagnosis related group 116 performed in a non-teaching, large urban hospital with a wage index of 1.0.

incentives to increase use of these items as long as the extra payment exceeds the extra costs to the hospital of treating the case. Depending on the level of payment, such an approach can provide strong incentives favoring diffusion. In fact, given the reliance on technology in medicine and the role technology plays in competition between providers, this approach to paying for new technology may accelerate technological diffusion unnecessarily, which could affect both costs and the quality of patient care.

Impact on access and quality

Medicare has a responsibility to ensure that its payment systems provide beneficiaries with access to needed care, including access to new technologies that will bring significant clinical benefits. As mentioned above, a bundled payment might impede access to new technologies. For example, inadequate payment for cochlear implants under the inpatient PPS appears to have reduced access to this technology (Lewin Group 2000). In some instances, however, new technologies turn out to be less advantageous than originally thought. For example, in the late 1980s, CMS debated whether an adjustment to the inpatient PPS was warranted for tissue plasminogen activator (tPA), a thrombolytic agent used in treating blockages in coronary arteries. Interest in a specific payment adjustment was generated by the unusually high cost of tPA. Additional experience with the drug, however, suggested it was not as widely beneficial as anticipated. The agency decided not to implement a payment adjustment, and the costs of the drug were offset by shorter lengths of stay and decreased costs per case (CMS 2001c).

Impact on spending

In comparing the impact of a bundled payment mechanism with a separate payment for new technology, a bundled payment is more likely to save trust fund

dollars by paying less than the full cost for a new technology, and by providing a financial incentive to avoid costly new technology altogether.³ In contrast, a fee schedule that pays at least adequately or cost-based payments are more likely to increase spending by paying the full cost of technology and by providing incentives to increase use. Of course, other factors such as patient preferences or physician practice patterns also affect spending.

To balance the desire to promote efficiency with the need to pay enough to ensure beneficiaries' access to quality-enhancing new technologies, the Congress directed CMS to maintain a bundled payment for the outpatient PPS, but make additional pass-through payments for new technologies that have high incremental costs. Additional payments are made until payment weights can be recalibrated to accurately capture the costs of new technologies. Important characteristics of the system include the eligibility criteria for additional payment, the approach used to set the additional payment amounts, and the impact of the payment mechanism on the data used to recalibrate relative weights. Unfortunately, both the eligibility criteria and the approach used to set the additional payment amounts led to undesirable effects, as will be discussed below.

How technology is paid for under the outpatient payment system

For a number of reasons, including the age of the data and poor coding of claims, critics were concerned that the payment rates set by CMS under the outpatient PPS did not accurately account for the costs of technology, and particularly recently developed technology. In response, the Congress established pass-through payments for certain classes of technology in the Balanced Budget Refinement Act of

1999 (BBRA). A pass-through payment is a cost-based payment that supplements the standard APC rate when a specific technology is used. It covers inputs to outpatient services and is meant to pay the incremental costs of technologies with costs that exceed the technology costs included in base payment rates.⁴ In general, the new technologies replace existing items that have costs already included in the bundled payment amount. The pass-through payments are to be made for two to three years, and data collected during that period are to be used to modify the relative weights for APCs that use these technologies. The two goals of the pass-through payments are to ensure adequate payment for new technology and to obtain accurate data on the costs of the new technology that can then be incorporated into the base APC rates.

The law and regulations establish eligibility criteria to define those drugs, biologicals, and medical devices that are to receive pass-through payments. When hospitals bill for a service using one of these items, they receive: (1) the base APC payment, and (2) the gross payment for the item minus an amount representing the costs of similar items already included in the base (the pass-through payment). Payments for drugs and biologicals are based on 95 percent of average wholesale price (AWP). Payments for devices are based on reported costs, defined as the product of hospital charges and a hospital-specific cost-to-charge ratio for all outpatient services.

To clarify how CMS determines pass-through payments, we need to look at devices separately from drugs and biologicals. First, suppose a hospital uses a pass-through device and charges \$15,000 for it. The hospital has a cost-to-charge ratio of 0.5, so CMS estimates the cost of this device at \$7,500 (0.5 x \$15,000). CMS also estimates that the cost of the device being replaced in the

3 Although this is true for technologies that increase costs, in the case of technologies that decrease costs, a bundled payment may prove more expensive if payments are not adjusted in a timely manner.

4 Completely new services are handled through new technology APC groups.

associated APC is \$5,000. The pass-through payment is then \$2,500 (\$7,500 minus \$5,000).⁵

The method of determining pass-through payments for drugs and biologicals is a little different because payment is based on AWP (and CMS has given each pass-through drug its own APC). To estimate the payment for pass-through drugs and biologicals already included in the base, CMS imputes the acquisition cost, usually at 68 percent of AWP. The additional pass-through payment is calculated as the difference between 95 percent of AWP and the estimated acquisition cost. For example, suppose a hospital uses a pass-through drug with an AWP of \$100. Total allowed payment is \$95, or 95 percent of \$100, and CMS imputes the acquisition cost of the drug at \$68. The pass-through payment is then \$27 (\$95 minus \$68).

To protect beneficiaries and taxpayers against the payment system's incentives to overuse technologies, the Congress made pass-through payments budget neutral. This means the base payment rates for all services are reduced to cover pass-through costs. The Congress further protected beneficiaries and taxpayers by limiting pass-through payments to 2.5 percent of total payments in the outpatient PPS (2.0 percent in 2004 and later). If CMS estimates that the cap will be exceeded in the coming year, a pro rata reduction in all pass-through payments must be made to maintain the cap. For 2002, CMS estimates that total payments for services covered by the outpatient PPS will be \$17.5 billion. Therefore, the limit on pass-through spending should be about \$435 million. Due to political pressures and uncertainty regarding data, however, during 2000, 2001, and the first three months of 2002 (at least), the pass-through payments were not reduced, even though total spending on these items was likely to greatly exceed the cap, at least in 2001 and 2002.⁶

A major reason payments are expected to exceed the cap in 2002 is that administrative and legislative actions significantly expanded the number of items eligible for pass-through payments after the initial law was passed. In August 2000, CMS softened one cost-based criterion for device pass-through eligibility and delayed two others. Through the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), the Congress made pass-through payments possible for many items whose costs were included in the data used to set base rates (see text box, opposite, for a description of the pass-through eligibility criteria).

The likelihood of pass-through payments exceeding the cap should diminish substantially in the future, and, therefore, so should the need for large pro rata reductions in pass-through payments. The number of items eligible for pass-through payments should be lower in 2003 and beyond, because nearly all current items will exhaust their eligibility for pass-through payments on December 31, 2002.⁷ In addition, CMS has created more stringent eligibility criteria for new categories of medical devices. Representatives of device manufacturers and CMS predict a substantially reduced pool of pass-through items in the future, with fewer than 15 applications for new device categories and less than 5 applications for new drugs and biologicals currently in the pipeline.

Although the volume of pass-through items will decrease, the pass-through payment mechanism continues to have some systemic flaws, relating mainly to setting payment rates, that should be addressed.

Systemic problems with the pass-through payments

The pass-through payment mechanism suffers from a number of flaws that will persist, even as the number of pass-through items declines.

- The pass-through payment mechanism, which relies on reported costs and AWP, provides an incentive for manufacturers and hospitals to increase their prices and charges for pass-through items. Studies have shown that Medicare overpays for drugs when payments are based on AWP (GAO 2001, OIG 2001). In addition, the mechanism CMS uses to determine hospitals' costs for devices—the product of charges and a cost-to-charge ratio—can be manipulated because the cost-to-charge ratio is determined for all outpatient services, not for a specific device, and is known in advance.
- The pass-through payment system effectively unbundles APCs. It provides an incentive to use pass-through items rather than comparable technologies because a separate payment is made for these items but not for other technologies that may be clinically appropriate but not eligible for special payment. If the separate payment covered only hospitals' actual incremental costs, there would be no incentive for overuse. However, the pricing mechanism provides an opportunity to receive payments that exceed incremental costs.
- The incentive to raise charges also makes the goal of collecting reliable cost data on new technology difficult

5 CMS was not initially able to estimate the cost of most devices in the underlying payment rates other than pacemakers and neurostimulators. Therefore, to date, most pass-through payments for devices have not been decreased to account for the cost of devices in the associated base rates, resulting in overpayments. When the 2002 payment rates are implemented, the agency will have estimates of the costs of devices in all base rates.

6 The estimate for 2002 was \$1.3 billion in pass-through spending, requiring a pro rata reduction in pass-through payments of almost 70 percent to maintain budget neutrality (CMS 2001a).

7 CMS will incorporate the costs of the over 1,000 pass-through items into base APC payments at that time.

Eligibility for pass-through status

The eligibility criteria for pass-through payments are complex, and include both clinical and cost criteria.

Clinical criteria

Initially, the Balanced Budget Refinement Act of 1999 (BBRA) required that to be eligible for pass-through payments drugs, biologicals, and devices had to be in one of these groups:

- drugs, biologicals, and brachytherapy used in cancer therapy;
- orphan drugs;¹
- radiopharmaceutical drugs and biological products used in diagnostic, monitoring, and therapeutic nuclear medicine procedures; or
- medical devices, drugs, and biologicals first covered by Medicare as outpatient services after 1996—which is a requirement that these items be “new”—and have costs “not insignificant” in relation to the base rate of the applicable ambulatory payment classification (APC).

The Centers for Medicare & Medicaid Services (CMS) further specified devices eligible for pass-through payments as those that “are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted in a patient during a procedure but may also be removed during the procedure so that the patient leaves the hospital without the device” (HCFA 2000). Also, devices must be covered by Medicare and approved by the Food and Drug Administration.

Provisions in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) expanded the number of eligible items in several ways. First, contrast agents used in imaging procedures were added to the pass-through list. Second, the law made possible pass-through payments for devices that do not meet the BBRA criterion for being new. One provision required that CMS approve categories of devices that serve a similar purpose rather than individual devices. These categories are eligible for additional payments for two to three years. The BIPA also required that the initial set of categories consist of devices already approved, which would seem to imply they must meet the BBRA definition of new. However, another BIPA provision allowed for devices not specified in the initial set of categories that do essentially the same thing as one of the categories to also be eligible. The latter provision makes it possible for devices already in use for decades to be eligible, potentially increasing the number of eligible items significantly.

The BIPA also required CMS to establish guidelines for categories of pass-through devices not defined in the initial set. Devices included in the new categories:

- cannot be described by any of the existing or previously existing categories;
- were not paid for as an outpatient service as of December 31, 1996;
- must have demonstrated they will achieve substantial clinical improvement over devices in previously established categories or other available treatments, such as reduced mortality, reduced rate of

complications, lesser symptoms, or reduced recovery time; and

- must meet more stringent cost criteria (see below).

Once established, the new device categories are eligible for pass-through payments for two to three years.

Cost criteria

The BBRA stated that pass-through items “must add substantially to the cost of care.” In interpreting the statute, CMS put forth the following cost criteria for devices:²

- the estimated average reasonable cost of devices in a category must exceed 25 percent of the payment amount in the applicable APC;
- the estimated average reasonable cost of devices in a category must exceed the cost of the device it replaces by at least 25 percent; and
- the difference between the average cost of a new category of devices and the cost of the device it replaces must be greater than 10 percent of the payment rate in the applicable APC.

In an August 2000 interim final rule, CMS lowered the first of these cost criteria for medical devices so that a device’s expected reasonable costs needed to exceed 10 percent of the applicable APC payment. A recent interim final rule increased the threshold back to 25 percent because the lower threshold greatly expanded the pool of eligible devices (CMS 2001b). All of these cost criteria are relative; there are no dollar amount thresholds for pass-through eligibility. ■

1 Orphan drugs are products used to treat diseases affecting fewer than 200,000 Americans.

2 The initial regulations applied to specific devices. To conform with the BIPA, they were changed to apply to categories of medical devices.

to achieve. In general, CMS relies on hospital charge data to estimate costs. While the agency has methods to estimate overall charge inflation, it cannot measure inflation for specific items.

- Overpayment and overuse of pass-through items will distort relative weights when CMS incorporates the costs of pass-through items in the relative weights. Including the pass-through items in the costs of related services will increase the relative weights for the APCs associated with pass-through technologies. To maintain budget neutrality during the recalibration of relative weights, CMS must reduce the relative weights for all APCs when pass-through costs are incorporated into the relative weights associated with the pass-through items. If pass-through items are overused and overpaid, APCs that include these technologies will be relatively overpaid while APCs that do not will be underpaid. This process also will have inappropriate distributional effects among hospitals if some hospitals provide more services that use pass-through technologies than others.
- The pass-through payment system is administratively burdensome for hospitals and CMS. It requires that eligible technologies be separately coded, and that costs be calculated at the hospital level. In the 2002 final rule, there were about 400 APC codes for outpatient services and around 350 codes covering over 1,000 pass-through items. The system also increases the burden of monitoring claim accuracy—including coding edits and fraud and abuse measures—because of the additional payments for unbundled items.
- The pass-through payment mechanism in the outpatient PPS also creates an additional difference in the way services are paid across sites of care: inpatient, outpatient, ambulatory surgical centers, and

Paying for new technology in the inpatient payment system

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 required the Centers for Medicare & Medicaid Services (CMS) to establish additional payments for new technologies that are inputs to services covered by the inpatient prospective payment system (PPS) for a period of two to three years while data on the costs of new technologies were being collected. The final regulations outlining the process to be used were released in September (CMS 2001c); payments under the new process will be made beginning in October 2002.

The unit of payment in the hospital inpatient PPS is the case, or inpatient discharge, as classified by diagnosis related group (DRG). The DRG system provides for much broader patient classifications than the outpatient ambulatory payment classification system, encompassing all routine nursing, support service, and ancillary costs incurred in patients' stays. The payment

provision for new technology has the following elements:

- Eligibility criteria include requirements for clinical improvement similar to those governing outpatient pass-through device categories.
- On average, cases using new technology must exceed the average cost of all cases in the DRG by a specified amount.
- Payment is made for individual cases, based on hospitals' reported costs.
- Payment covers only 50 percent of the increased costs for cases using eligible new technology.
- Payment is limited by the average national price of the new technology, as determined by CMS based on information obtained from manufacturers on their applications for eligibility. ■

physicians' offices. This payment differential creates incentives to provide services in the setting that receives the most favorable payment, which may not be best suited to the patient and may result in increased costs for the program. The inpatient PPS also has a system for making additional payments for new technologies (described in text box, above), which differs somewhat from the outpatient pass-through mechanism.

Given the flaws in the current payment system, movement to a different means of paying for technology used in providing outpatient services may be appropriate. The next section evaluates two alternative approaches against a number of criteria.

Alternatives for paying for technology used in outpatient departments

The Congress established pass-through payments because data were not available to reflect the costs of new technology in base payment rates; the intent was to provide adequate payments for new technology while CMS collected meaningful cost data. Because the pass-through mechanism has several flaws, as discussed above, an alternative system may be appropriate.

We have identified two viable possibilities:

- Phase out the pass-through payments so that APC base rates are the only reimbursements for all technologies.

- Continue to use pass-through payments, but change the mechanism that gives manufacturers and hospitals an incentive to increase prices. For devices, base payments on a fee schedule, which would replace the hospital-specific payments for pass-through devices with pre-set national rates. For drugs and biologicals, consider alternatives to AWP as the basis for pass-through payments.

When assessing these alternatives, three criteria should be considered. First, what are the efficiency incentives in the payment system: are there incentives to inflate prices to maximize payment? Second, how does the payment system affect the use of technology: does it inappropriately hinder or help the diffusion of specific technology items? Third, what is the administrative burden for CMS and hospitals?

Phasing out pass-through payments

Phasing out pass-through payments would fare well against two of our criteria. First, a phase-out would avoid the incentive in the pass-through system for manufacturers and hospitals to increase prices and charges for new technologies. This would allow hospitals to determine whether or not a new technology is clinically appropriate and cost-effective without the bias in favor of using new technology embedded in the current system. Also, relative payments would not be distorted in favor of services that use new technologies.

A phase-out also would reduce administrative burden. CMS and hospitals would not have to identify eligible items or process the data necessary for pass-through payments.

A phase-out compares less favorably against the criterion of diffusion of new technology, however. Base rates might not adequately cover the cost of expensive new technologies, giving hospitals a disincentive to use them. In cases in which the cost of a new technology substantially

exceeds the cost of the technology it replaces, we believe underpayment would slow diffusion and therefore impair beneficiaries' access. Quality of care also could be affected.

Continue the pass-through system with modifications

Under this option, CMS would continue to make pass-through payments, but use a fee schedule as the basis for calculating pass-through payments for devices. CMS should establish this fee schedule with national rates that reflect adequate payments for hospitals to make pass-through devices available. Also, the Secretary should have authority to consider alternatives to AWP when determining payments for pass-through drugs and biologicals. These changes would require Congressional action.

A fee schedule would address the criterion of eliminating the incentive for hospitals to increase profits on pass-through devices by raising charges. Also, payments for drugs and biologicals could be based on measures below AWP, which has been shown to substantially exceed hospitals' acquisition costs in many cases (GAO 2001). Consequently, there would be less financial incentive for hospitals to inappropriately use pass-through technology or avoid other comparable technology. CMS also would acquire more meaningful data to incorporate the costs of new technology into the base rates because payment for devices would no longer depend on hospitals' charges. Therefore, relative weights would be less distorted.

Manufacturers, however, would have an incentive to persuade CMS that fee schedule rates should be higher than necessary. CMS would have to address this when setting rates.

A fee schedule also would fare well against the criterion of diffusion of new technology. If rates are set adequately, hospitals would be paid enough to ensure that high-cost new technologies are used in outpatient departments. Consequently, new technology would diffuse quickly,

and beneficiaries would have access to new technology that improves their quality of care.

Relative to the phase-out, a fee schedule does not perform well on the criterion of administrative burden for CMS and hospitals. A fee schedule would impose on hospitals and CMS most of the burdens of the current system, except CMS would not have to calculate hospitals' cost-to-charge ratios. However, CMS would have the additional burden of setting rates for the fee schedule.

Improving the pass-through system

In terms of our criteria, both options have comparative advantages and disadvantages. The comparative disadvantage that concerns the Commission the most is the incentive for hospitals to avoid high-cost new technology under a phase-out, which could adversely affect beneficiaries' access to quality-improving technology. A fee schedule would assure beneficiaries' access to new technology, if rates are adequate. Therefore, although a fee schedule would be more burdensome for CMS, the Commission recommends that the Congress base payments for new technology on a fee schedule that uses national rates.

RECOMMENDATION 3A

The Congress should:

- **Replace hospital-specific payments for pass-through devices with national rates.**
- **Give the Secretary authority to consider alternatives to average wholesale price when determining payments for pass-through drugs and biologicals.**

To further improve the pass-through system, we also recommend the following:

RECOMMENDATION 3 B

The Secretary should:

- **Ensure additional payments are made only for new or substantially improved technologies that are expensive in relation to the applicable ambulatory payment classification payment rate.**
- **Avoid basing national rates only on reported costs.**
- **Ensure that the same broad principles guide payments for new technologies in the inpatient and outpatient payment systems.**

The first directive for the Secretary reflects the Commission's belief that pass-through payments should be targeted to technologies with costs that are not adequately reflected in the base rates; these costs should be sufficiently high in relation to the applicable payment rate that diffusion would be impeded without additional payment to hospitals.

We applaud CMS's recent efforts to base pass-through eligibility for new device categories on more restrictive cost criteria and new clinical criteria and encourage the agency to be diligent in applying these criteria to avoid unnecessary pass-through payments. Limiting pass-through payments to high-cost technologies that are new or substantially improved has several benefits. It limits the burden of the pass-through system on hospitals and CMS because special payments would be made for fewer items; it reduces the likelihood of exceeding the statutory cap on pass-through payments; and given budget neutrality requirements, it limits the redistribution of funds across hospitals that are high versus low users of pass-through technology.

The second directive—to avoid basing payment rates only on reported costs—reflects the Commission's concern that manufacturers and hospitals have an incentive to inflate reported costs if

payments are tied too closely to them. Finally, the Commission believes that outpatient and inpatient payments for new technology should be based on the same broad principles to help ensure that decisions about where to provide care are based on clinical criteria as opposed to financial criteria. This does not imply that identical methods must be used. However, introducing national payment rates would make the two systems more consistent. The Secretary could also make the cost criteria more consistent.

Setting fee schedule rates for devices

Setting appropriate rates for a fee schedule would be a difficult task for CMS. Good data are the biggest concern; one of the reasons pass-through payments exist is because CMS did not have adequate data on new technology to incorporate their costs into the base APC rates.⁸ The Commission believes strongly that basing payments on manufacturers' prices or hospitals' reported costs gives incentives to inflate these measures. We discuss a number of alternatives for setting rates below, but recognize that future work is needed to devise an adequate mechanism.

Conceptually, one possibility is to set fee schedule rates for devices at levels that, if paid to manufacturers, would give them adequate but not excessive return on equity to supply the devices. This would avoid incentives for hospitals to inflate charges, but establishing rates for devices would be burdensome for CMS. The agency would have to obtain access to manufacturers' financial information, perhaps having to obtain legal rights to do so. Also, CMS would have to determine manufacturers' equity used to produce pass-through items. For manufacturers with many products, CMS would have to disentangle equity used to produce pass-through items from the equity associated with other products. Moreover, debate would occur over what represents an adequate rate of return.

Although this return on equity approach would present a burden for CMS, the concept has been used in the United Kingdom (UK) to regulate profits on new drugs. Manufacturers are allowed to set any price they wish, subject to the constraint that the total rate of return on capital invested in the UK on all their products reimbursed by the National Health Service does not exceed a pre-set limit. Manufacturers negotiate their limits with the government. Manufacturers who exceed their limits may retain part of the excess and either return the remainder or decrease their prices (Danzon 1997).

A second possibility for fee schedule rates is competitive bidding, which has successfully reduced program payments for durable medical equipment in demonstration projects. An advantage of competitive bidding is that there would be no debate over whether manufacturers are being paid adequately. However, competitive bidding could not be used for those pass-through devices that have only one manufacturer, which will probably be true of most pass-through devices in the future.

Although we have not presented a convincing alternative to payments based on cost, the Commission intends to further investigate the options discussed here and others we identify later. We urge CMS to join us in that effort because establishing an appropriate fee schedule is vital for paying adequately for new technology until quality data become available for incorporating new technologies into base payment rates.

Because we have yet to identify a satisfactory alternative, CMS may need to base fee schedule rates partially and temporarily on cost data from manufacturers or hospitals. We believe the best option is to use manufacturers' estimates of prices paid by hospitals, net of discounts and other reductions. Even though manufacturers would have an incentive to inflate reported prices, CMS could mitigate this problem through

8 An additional problem is that payment codes for devices represent categories rather than specific products. The devices in a category can have a range of costs, making precise payments difficult in some cases. However, we do not think relatively small inaccuracies in an add-on payment will affect hospitals' use of new devices.

auditing. Also, this approach would be relatively efficient because manufacturers already must include this information on applications for pass-through eligibility. Finally, using this data source would increase consistency between sites of care because payments for pass-through technology used in inpatient departments are limited by the prices paid by hospitals as reported by manufacturers on applications for pass-through eligibility.

Setting payments for drugs and biologicals

Pass-through drugs and biologicals are essentially already on a fee schedule with national rates because payments are based on AWP, which are fixed national rates. AWP, however, typically exceed

hospitals' acquisition costs by a wide margin. The U.S. General Accounting Office has argued that Medicare could reduce payments for drugs if it used either of two pricing systems used by other public programs (GAO 2001). One system is the federal supply schedule (FSS) administered by the Veterans' Administration, which is intended to equal or better the price that manufacturers offer to their most-favored non-federal customer. The other is average manufacturer price (AMP) used by Medicaid, which is the average price—net of discounts and other reductions—paid to drug manufacturers by wholesalers. The application of a system similar to either FSS or AMP would be limited, however. Pass-through payments will be restricted

to new products, so the necessary market-based prices would not be available for many pass-through drugs and biologicals.

Another possibility is to set payments at levels that would give an adequate return on equity to manufacturers, as we suggested earlier for devices. We reiterate that this would present an administrative burden to CMS, especially in cases where manufacturers produce many products. As with medical devices, we recognize that finding an appropriate mechanism for setting prices will require additional work. In the interim, CMS could rely on information included in manufacturers' applications for pass-through status that estimates the prices paid by hospitals, net of discounts and other reductions. ■

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare program; changes to the hospital outpatient prospective payment system for calendar year 2002; final rule, Federal Register. November 30, 2001a, Vol. 66, No. 231, p. 59856–60125.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare program; prospective payment system for hospital outpatient services: criteria for establishing additional pass-through categories for medical devices, Federal Register. November 2, 2001b, Vol. 66, No. 213, p. 55850–55857.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare program; payments for new medical services and new technologies under the acute care hospital inpatient prospective payment system; final rule, Federal Register. September 7, 2001c, Vol. 66, No. 174, p. 46902–46925.

Danzon PM. Pharmaceutical price regulation: national policies versus global interests. Washington (DC), the AEI Press. 1997.

General Accounting Office. Medicare: payments for covered outpatient drugs exceed providers' cost, No. GAO-01-1118. Washington (DC), GAO. September 2001.

Health Care Financing Administration, Department of Health and Human Services. Medicare program; prospective payment system for hospital outpatient services; interim final rule with comment period, Federal Register. November 13, 2000, Vol. 65, No. 219, p. 67798–68019.

Lewin Group. Outlook for medical technology innovation: will patients get the care they need? The Medicare payment process and patient access to technology. Washington (DC), AdvaMed. July 21, 2000.

Office of Inspector General, Department of Health and Human Services. Medicare reimbursement of prescription drugs, No. OEI-03-00-00310. Washington (DC), HHS/OIG. January 2001.