CHAPTER 3

Accounting for new technology in hospital prospective payment systems

RECOMMENDATIONS

3A In the outpatient payment system, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies.

***YES: 13 • NO: 0 • NOT VOTING: 0 • ABSENT: 3**

3B In the outpatient payment system, pass-through payments for specific technologies should be made only when a technology is new or substantially improved and adds substantially to the cost of care in an ambulatory payment classification group.

YES: 13 • NO: 0 • NOT VOTING: 0 • ABSENT: 3

3C Pass-through payments in the outpatient payment system should be made on a budget-neutral basis and the costs of new or substantially improved technologies should be factored into the update to the outpatient conversion factor.

YES: 13 • NO: 0 • NOT VOTING: 0 • ABSENT: 3

3D For the inpatient payment system, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for patient classification changes to recognize the costs of new and substantially improved technologies.

YES: 14 • NO: 0 • NOT VOTING: 0 • ABSENT: 2

3E Additional payments in the inpatient payment system should be limited to new or substantially improved technologies that add significantly to the cost of care in a diagnosis related group and should be made on a budget-neutral basis.

YES: 14 • NO: 0 • NOT VOTING: 0 • ABSENT: 2

***COMMISSIONERS' VOTING RESULTS**

CHAPTER 3

Accounting for new technology in hospital prospective payment systems

In this chapter

In this chapter, the Medicare Payment Advisory Commission addresses questions about payment for new technology in hospital prospective payment systems. How should policymakers define "new technology"? Does the definition affect how a payment system treats a given technology? What payment principles should apply to new technology? These questions are discussed in light of recent legislative changes to the treatment of technology in the inpatient and outpatient prospective payment systems. The Commission presents a series of recommendations on these issues for the Congress and the Secretary aimed at making Medicare's payment systems responsive to technological innovation while minimizing exposure to cost-based payment. Chief among them are recommendations to the Secretary on assigning codes to new services and procedures, investigating the need for patient or service classification changes, updating relative weights, and implementing additional payments for new technologies. The preceding chapter (Chapter 2) addresses the related issue of methods for updating payments in traditional Medicare.

Most services provided in hospitals are now paid for prospectively. Recently, concerns have arisen regarding the treatment of new technology under prospective payment. Does Medicare recognize the introduction of new technologies quickly enough to ensure needed access for beneficiaries? Do payment rates adequately reflect the costs of new technologies? The Balanced Budget Refinement Act (BBRA) of 1999 addressed this issue for the outpatient prospective payment system (PPS) by establishing pass-through payments for certain types of new technology. The recently enacted Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) requires HCFA to develop new mechanisms to pay for technological advances under the inpatient PPS.

In considering the issue of payment for new technology at a conceptual level, the following questions must be addressed:

- How should we define "new technology"? Does that definition affect how a payment system treats a given technology?
- What payment principles should apply to the treatment of new technologies?
- How should prospective payment systems account for new technologies?

After this conceptual discussion, the chapter reviews how the outpatient and inpatient prospective payment systems treat new technology and recommends several policy changes.

Defining new technology

Technology has been the hallmark of modern medicine. Although technological advances have greatly improved the outcomes of medical care, they also have been a major element in increasing costs (Newhouse 1993). In considering how payment systems should treat new technology, the definition of "new technology" must be established. If, for example, a new technology applies to all services in a hospital, accounting for those costs in the payment system will require different mechanisms than a new technology that applies only to a specific service.

In the most basic sense, technology is the practical application of knowledge. In the health sector, this may include:

- drugs,
- devices, equipment, and supplies,
- medical and surgical procedures,
- support systems, and
- organizational and managerial systems (Goodman 1998).

Some of these technologies, such as drugs or surgical procedures, affect identifiable services and individual patients. Others, such as new diagnostic equipment, may be used for an array of services and multiple patients. Still others, such as information systems or improved management techniques, affect all services provided in a hospital. When defining a new technology, both brand new types of technology (such as digital imaging) and substantial improvements on older technologies may be considered. Within a payment system, a new technology may also be an adaptation of a technology previously used in another setting, such as movement of cholesystectomy from inpatient to ambulatory settings. Although the overall effect of technology has been to increase costs, specific new technologies may increase or decrease costs.

The mechanisms used to account for the costs of new technology in a payment system depend, in part, on the kind of technology considered. Recognition of the costs of a device used in a particular procedure, such as coronary stents used in angioplasty, may be reflected in the relative weight assigned that procedure or through an additional payment. The costs of broader technologies, such as capital equipment or information systems, however, are more easily treated through updates to the base payment rate. In some cases, such as the inpatient PPS, changes in relative weights are made in a budget-neutral fashion. In that case, the payment system still needs to account for the cost-increasing nature of technology through the update process.

Principles of payment system design and the treatment of new technology

Prospective payment was adopted by the Medicare program for hospital inpatient services to promote efficiency in provision of those services and thus protect taxpayers and beneficiaries from unnecessary treatments and expenditures. By setting payment rates in advance, the Medicare program gives hospitals a fixed payment that ideally reflects an efficient provider's costs. More generally, providers paid prospectively are placed at financial risk for costs above the payment amount and rewarded if they keep their costs below it. This contrasts with cost-based reimbursement, which has no built-in incentives for efficiency.

A prospective payment system provides financial incentives to adopt new technologies that lower costs; however, the payment system should also provide mechanisms to account for the costs of new technologies that enhance quality, even if they increase costs.

A PPS should maintain neutrality regarding clinical decisionmaking, including adoption of new technology. The payment system should not favor the use of one procedure or technology over clinically appropriate substitutes, but pay the costs of an efficient provider for all options, leaving medical personnel to choose what is clinically optimal given individual circumstances.[1] Payment rates

1 Payment policy is only one factor in the diffusion of technology. Many individuals participate in bringing new technology into use: basic and applied science, industry, marketers, providers, patients, government. The public role includes funding research, determining safety and efficacy, and setting coverage policy for the Medicare program. Setting Medicare payment rates is one of the final steps in that process.

are set for a given output, but the number and mix of inputs used to create the output is left to the clinical judgment of the provider. Payments that are too high place an unnecessary burden on both beneficiaries and taxpayers. If payments are too low, there is an incentive to withhold needed services. Correct payment rates are important both at the global level and for the distribution of payments among services.

A balancing process is needed to ensure that payments are sufficient to maintain access to needed services without spending more than necessary. The calculation of adequate payment rates must be administratively feasible, using the most reliable data sources available. Limited data and predictable variations in costs across providers also imply that payment adequacy be determined at a broad level, with payment adjustments such as those given to teaching hospitals used to account for predictable variations in costs among types of providers.

PPSs have certain common elements, including a patient or service classification system, a unit of payment, relative payments among services (payment weights), and a base payment rate (or conversion factor). All PPSs also have a process for updating both the relative payment weights and the base payment amount. The way these elements are treated has implications for the treatment of new technology under a given PPS.

Classification system

The classification system groups services for payment. It may be broad, as in the inpatient PPS, which groups hospital stays primarily by their leading diagnosis or significant procedure. Alternatively, it may be fairly narrow, as in the outpatient PPS, which groups services based on a single service or small bundle of services, such as a diagnostic test, an outpatient surgical procedure, or a clinic visit. The classification system may influence how technology is defined and how new technology is treated. A narrow payment system (such as the outpatient PPS) may target a specific device or drug by using additional payments or other directed mechanisms. Basing the classification system on diagnosis (as in the inpatient PPS) can make it more difficult to tie a specific technology to a given case.

Unit of payment

The unit of payment is related to the classification system and determines the scope of bundling within a payment. The inpatient PPS encompasses a broad bundle: payment is for all services provided during a hospital stay. In contrast, the outpatient PPS relies on a limited bundle: payment is for the inputs required for a narrowly defined procedure. Defining the unit of payment determines, in part, the extent of incentives for efficiency within a PPS: the broader the bundle, the more room for efficiency enhancements at the provider level, but the greater the opportunity for withholding services.

The payment unit also influences the mechanisms that can capture the cost of new technology. If the unit of payment incorporates a large bundle, increased costs in one area, such as a new-generation medical device, may decrease costs in another area, such as length of stay, causing total payment for the bundle to stay the same or decline. For a narrow bundle, however, there is less scope for offsetting efficiencies, and the costs of new technologies may need to be taken into account more explicitly.

Coding and relative weight updates

Updating codes and payment weights provides another avenue for considering how to treat new technology. Recalibrating relative weights for services takes into account the ways in which new technology, increased productivity, and other factors change the costs of services in relation to one another. This process also allows for the explicit introduction of new codes for innovative procedures. All PPSs provide for routine updating of codes and relative weights; both the inpatient and outpatient PPSs undergo annual revisions. The frequency with which codes and weights are revised does affect the length of time before appropriate payments may be made for new technologies. However, multiple priorities must be balanced, including the integrity of the coding and payment systems, disruption to providers from revising their billing processes to reflect new codes and new weights, data availability, and administrative requirements.

Payment updates

Finally, payment updates to base rates may also reflect the cost impacts of new technology. Some updating approaches—such as the update framework MedPAC developed for updates for the inpatient PPS and other fee-for-service settings—explicitly consider the effect of quality-enhancing but cost-increasing technologies on costs, and increase payments accordingly. Of course, when new technology increases efficiency and decreases costs, payment updates should also reflect those trends. For the inpatient PPS, the Congress legislates the update annually, with guidance from MedPAC and the Secretary of Health and Human Services. For the outpatient PPS, the Congress has set the update to the conversion factor through 2002. The updating process for future years has not been fully developed by the Health Care Financing Administration (HCFA). For the present, no explicit mechanism accounts for the cost impacts of new technology in updating the outpatient conversion factor.

Treatment of new technology in the outpatient payment system

The implementation of the outpatient PPS on August 1, 2000, marked a move away from primarily cost-based payment for services provided in hospital outpatient departments. This section describes the outpatient PPS and how it pays for new technology and makes recommendations for improving the system.

Structure of the outpatient payment system

The outpatient PPS classifies services based on their HCFA Common Procedure Coding System (HCPCS) code into ambulatory payment classification (APC) groups. There are two kinds of HCPCS codes. Level I codes are based on the Physicians' Current Procedural Terminology (CPT) coding system developed by the American Medical Association. Level II codes, which include many supplies, drugs and devices, are developed by HCFA. Services are classified to be similar clinically and with regard to resource use. The unit of payment for the outpatient PPS 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. Payment for a service in an APC group includes limited bundling of ancillary services and supplies considered incident to the primary service. The most extensive bundling occurs for outpatient surgery. Payment for outpatient surgery covers the hospital's costs for the operating and recovery rooms, anesthesia, most drugs, and most surgical supplies used during the surgery.

Responding to technology costs

The outpatient PPS explicitly addresses payment for new technologies by defining new technology APC groups and making pass-through payments that provide additional reimbursement for specific drugs, biologicals, and medical devices. The new technology APC groups aim to ensure timely payment for new technologies that represent new services, distinct from the existing APC groups. The pass-through payments aim to ensure adequate payment for new technologies that are inputs to an outpatient service, rather than a distinct service. A pass-through payment is a cost-based payment that supplements the standard APC payment when a specific technology is used. A major rationale for establishing these provisions was concern over the use of 1996 data as a baseline to establish payment rates, as the Congress believed that the 1996 data did not adequately reflect the costs of new technologies and could result in underpayments upon implementation in 2000. The rest of this section discusses coding and classification issues, the new technology APC groups, and the transitional pass-through payments.

Coding and classification issues

All of Medicare's payment systems include measures to accommodate the introduction of quality-enhancing technologies. Implementing them expeditiously ensures timely payment for new technologies.

RECOMMENDATION 3A

In the outpatient payment system, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies.

Industry has expressed concern that delays in the coding and classification processes hamper the diffusion of new technologies, although there is no clear evidence of access problems. In the outpatient PPS, the process for handling new technology includes assigning codes to new services and procedures, updating the classification (APC) weights, and investigating the need for new or restructured service classification groups.

Timely coding updates are especially important in the outpatient sector, where payment bundles are small and most procedures require a code for hospitals to be reimbursed. New outpatient codes are assigned by HCFA and/or the CPT Editorial Panel. In addition, to implement the outpatient technology provisions of the BBRA, HCFA has developed a system for assigning pass-through payment codes, including setting aside a block of temporary codes to be assigned quickly.[2] HCFA must also review the outpatient payment weights on an annual basis and restructure the APCs as needed, although the process for doing so has not been fully detailed beyond establishing an external advisory committee.

New technology ambulatory payment classification groups

In developing the outpatient PPS, HCFA created separate APC groups to classify new technology services that do not qualify for pass-through payments. These groups contain services that are similar in cost, but are not necessarily clinically similar. The agency established a total of 15 new technology groups, with cost ranges starting at $0 to $50 and ending at $5,000 to $6,000. The payment rate for all the services or items within a particular group will be the midpoint of the group's cost range.

To qualify for classification within a new technology APC, a service must be covered by Medicare, be underrepresented in the 1996 data used to set payment rates, have a HCPCS code, and be deemed reasonable and necessary for treating an illness or improving an impaired function. HCFA will group qualifying new technologies or services within new technology APC groups for two to three years before assigning the services to an existing or new standard APC group. This mechanism will allow HCFA to pay for new technologies shortly after they become available and qualify for Medicare payments. It will also allow HCFA to collect clinical and cost data to refine and update the APC classification system.

This approach to accounting for new technology is most applicable to a PPS with a narrow unit of payment and limited bundling. Given the narrow definition of a service in the outpatient PPS, new technologies may be appropriately defined separately from all the other APC groups. For example, under the outpatient PPS, new technology APC groups have been established for positron emission tomography (PET) scans for specific

2 As discussed later in this section, provisions of the Benefits Improvement and Protection Act of 2000 require HCFA to base pass- through payments on categories, which may also require additional changes in the coding system.

diagnostic purposes (for example, staging and characterization of lymphoma). One of the difficulties with this approach, however, is that it uses a temporary payment rate—the new technology APC group rate—while data on hospital costs are being collected to set a permanent rate. HCFA uses an application process to gather cost data to place services within the new technology APC groups, but data derived in this way are not easily verified and may not be representative of hospitals' operational costs.

Pass-through payments

Pass-through payments for certain drugs, biologicals, and medical devices were authorized under the BBRA to ensure that outpatient payments adequately accounted for the costs of new technologies (see text box, p. 40, regarding eligibility for pass-through payments). The policy responds to concerns that the 1996 data used to calculate payment rates did not adequately reflect the costs of certain new technologies. Pass-through payments are meant to supplement the standard payment rate when specific drugs, biologicals, and medical devices—the costs of which were not included in the 1996 data—are used as inputs to provide a service. They have the potential to be inflationary, however, because they re-introduce cost-based payment into the system.

By paying hospitals' incremental costs for new devices, pass-through payments encourage their adoption and diffusion. For drugs and biologicals, additional payments are set at 95 percent of average wholesale price. For medical devices, pass-through payments are based on each hospital's costs (as determined by adjusting charges using a cost-to-charge ratio). For all items, pass-through payments are made at the claim level. For example, when a pacemaker is implanted, the hospital receives a base payment for facility costs associated with performing the procedure (about $3,900 in 2001) and a pass-through payment based on costs for the device. In this example, the amount of the pass-through payment will be offset by subtracting the estimated cost of the device it replaces (about $2,850 in 2001) from the base payment rate.[3]

Pass-through payments will be paid for two to three years until standard payment rates can be modified to incorporate the costs of new devices. Data collected during the transition will be used to modify the standard payment rates. Total payments under the pass-through provision are limited to 2.5 percent of total program payments through 2003, and 2 percent thereafter. If this limit is exceeded, all pass-through payments are to be reduced. Additionally, total payments must remain budget neutral, meaning that the conversion factor will be decreased to account for the cost of the pass-through payments. In effect, the provision redistributes payments among services.

This approach to paying for new technologies targets inputs that are bundled into the APC payment, rather than new services that could have their own APC group. The provision is transitional in that additional payments are made for a set period of time (2-3 years) until sufficient data are available to set APC group rates. However, the provision will continue into the future as additional new technologies are introduced. As payment rates are updated to account for technologies not in the 1996 data, the need for pass-through payments may decline.

Experience implementing this policy to date has raised concerns about its effects on competition in the medical marketplace. HCFA interpreted the BBRA to require an item-specific approach. Critics contend that by approving items by trade name, HCFA has approved certain new devices within a class, but not competing products, potentially creating bias and an incentive for the favored manufacturer to price higher. This argument assumes that clinicians will decide which products to use based on their pass-through eligibility status. By identifying certain products but not their competitors as eligible for additional payment, this provision does not conform to the principle of maintaining neutrality in clinical decision-making. The effect on competition may be temporary, however. As the outpatient PPS becomes established, the process of approving items should be applied more evenly across products.

To address the issue of unfair competition, the BIPA requires HCFA to create categories of devices for the pass-through payments. Initial categories must be established by April 1, 2001. Additional categories will be established based on criteria to be developed by HCFA by July 1, 2001. The duration of a category will be two to three years; devices that enter a category after it has been established will be eligible for pass-through payments only for the remaining duration of the category. The BIPA also removes the criterion (established in the BBRA) that a technology be under-represented in the 1996 data. All medical devices described by a category will now receive pass-through payments, regardless of when they were first used in the outpatient setting. In effect, this provision will result in unbundling payments and providing cost-based pass-through payments for most medical devices.

In our June 2000 report, MedPAC noted that although transitional pass-through payments may help to ensure access to new and innovative technologies, they may also dilute the ability of the outpatient PPS to provide incentives for efficiency and cost control (MedPAC 2000). Introducing cost-based pass-through payments gives manufacturers and hospitals an incentive to increase prices for these items. Pass-through payments for drugs and biologicals will be based on average wholesale prices, which are also subject to manipulation. Inflationary trends in the pass-through payments will also increase future standard payment rates as the pass-through costs are incorporated into the base.

3 To date, HCFA has not been able to identify the cost of most devices in the underlying payment rates. Therefore, not all pass-through payments will be decreased to account for the costs of the older device in the base payment rate.

Eligibility for new technology pass-through payments under the outpatient payment system

The Balanced Budget Refinement Act (BBRA) specified the items and services that qualify for pass-through payments under the outpatient prospective payment system (PPS):

- drugs, biologicals, and brachytherapy[4] used in cancer therapy;
- orphan drugs;[5]
- radiopharmaceutical drugs and biological products used in diagnostic, monitoring, and therapeutic nuclear medicine procedures; and
- new medical devices, drugs, and biologicals[6] first paid as outpatient services after 1996.

The Health Care Financing Administration (HCFA) defines medical 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). To develop a per unit pass-through payment, a unit must be defined. To avoid paying for the same item multiple times, HCFA has decided that the device must be single use, although prorated payments might also be feasible. The restriction to implantable devices refers to a provision of the BBRA that shifts payment for some implantable devices from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule to the outpatient PPS. Other medical devices are paid under the DMEPOS fee schedule or are considered part of the bundled payment.

The following types of devices do not qualify for transitional pass-through payments: equipment, instruments, and items used for diagnostic or therapeutic purposes; devices that are not implanted; and those items used on more than one patient. Because these materials are included within supplies or capital expenses, HCFA maintains they are reflected in the ambulatory payment classification (APC) payments, updated to reflect inflation in outpatient costs. Indeed, the costs of supplies and capital equipment should be fairly well spread across services and would therefore have been captured in HCFA's process of increasing the conversion factor to account for increases in the costs of outpatient services between 1996 and 1999. This process works well for items used in many different services and thus unlikely to affect relative weights among services. For items with non-trivial costs that are inputs to a specific service, however, the use of old data may underestimate the relative weights, and hence payments, of specific services.

Devices must also be covered by Medicare and approved by the U.S. Food and Drug Administration. By law, the cost of a medical device must be "not insignificant" in relation to the portion of the payment rate associated with the technology. This provision limits pass-through payments to new technologies that are substantially more expensive than existing payments—so expensive that hospitals face incentives to limit the availability of the technologies. Although HCFA originally established three criteria related to cost, the interim final rule published on August 3, 2000, delayed implementation of two of them.[7] The interim final rule also reduced the threshold for the first criterion, which originally stated that the cost of the new technology must represent at least 25 percent of the total fee schedule amount for the related APC. The threshold was thought to be too restrictive and was lowered to 10 percent. ■

4 Brachytherapy is radiotherapy in which the radiation source is placed within the body.

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

6 Biologicals include items such as blood products, hormones, and antibodies.

7 The two criteria are: (i) the cost of a new technology must exceed the cost of the technology it replaces by 25 percent; and (ii) the difference between the cost of a new technology and the technology it replaces must exceed 10 percent of the related APC group rate. HCFA plans to implement these criteria on January 1, 2003.

The provision instituting a cap on total payments (2.5 percent of total program payments through 2003 and 2 percent thereafter) and proportional reductions of all pass-through payments if the cap is exceeded is meant to prevent increases in overall spending due to the pass-through payments. Due to political pressures and uncertainty regarding data, however, the cap will not be applied in 2000 and 2001, and program spending will increase despite the cap.

Whether or not the limit will be exceeded depends, in large measure, on the definition of what qualifies for pass-through payments. HCFA has expanded its definition numerous times since releasing the final rule; more than 1,000 items were eligible on January 1, 2001 (see text box, p. 40). Provisions of BIPA will lead to further expansions. For example, the BIPA will extend pass-through payments to medical devices that

had been in use before 1996 and the costs of which should already be included in the APC payment rates. As the list expands, the pass-through payments will make up a greater share of total outpatient payments. Based on cost data collected from applications for pass-through eligibility, HCFA estimated that pass-through payments for the existing list of technologies will exceed 5 percent of total outpatient spending in 2001. Changes introduced in the BIPA, such as expanding eligibility to older devices, will likely further increase these costs. However, HCFA will not implement proportional reductions in 2000 and 2001. Therefore, at least for 2001, the pass-through payments will exceed the cap and increase total costs significantly.

In considering pass-through payments, two principles should be kept in mind: minimizing interference with clinical decision-making, and ensuring that mechanisms are in place to limit the program's exposure to cost-based payment. Balancing these potentially conflicting notions requires consideration of the eligibility criteria for pass-through payments.

RECOMMENDATION 3B

In the outpatient payment system, pass-through payments for specific technologies should be made only when a technology is new or substantially improved and adds substantially to the cost of care in an ambulatory payment classification group.

Limiting pass-through payments to new and substantially improved technologies protects the program and beneficiaries against unnecessary exposure to cost-based payments. It also eliminates the potential to pay for technologies twice: once in setting the initial payment rates (which include older technologies) and again through a pass-through payment. For this reason, the definition of "new" should not include items whose costs were reflected in the 1996 data used to set payment rates. Limiting pass-through payments to those new or substantially improved technologies that add substantially to the cost of care limits the program's exposure to the administrative burden of special payment provisions and the introduction of cost-based payment for technologies that compose a small part of overall payment.

Another mechanism for protecting against the inflationary pressures of cost-based pass-through payments is the budget-neutrality provision. For interim payment adjustments for new technology to be maintained, they must be implemented on a budget-neutral basis to protect against excessive expenditures. However, HCFA will not do so for calendar year 2001 in the outpatient payment system.

RECOMMENDATION 3C

Pass-through payments in the outpatient payment system should be made on a budget-neutral basis and the costs of new or substantially improved technologies should be factored into the update to the outpatient conversion factor.

The budget-neutrality requirement lowers the conversion factor by 2.5 percent to fund the pass-through payments. This mechanism reimburses hospitals for the increased costs of these specific technologies when they are used, but does not account for the overall cost-increasing nature of new and substantially improved technologies. Budget-neutrality will also have distributional impacts. Since large urban and teaching hospitals are more likely to use new technologies, the redistribution of funds across services will also redistribute funds among hospital types.

Therefore, in a manner similar to the inpatient PPS, the costs of pass-through technologies should be brought into the system through the update to the conversion factor. This is one of the elements that MedPAC considers in its updating framework for inpatient care; a similar mechanism is needed in the outpatient PPS. However, any increase to the update for new technology should not include the costs of technologies in use prior to 1997 that are now eligible for pass-through payments because their costs are already accounted for in the base. Similarly, the update should not factor in the costs of new procedures that are part of the new technology APC groups. The costs of these services are covered directly as each unit is paid for, leading to increases in total spending.

Treatment of new technology in the inpatient payment system

Medicare's PPS for acute inpatient services has been in effect since 1984. The process for annually changing its payment rates already includes a set of largely informal procedures for responding to the costs of new technology. BIPA enacted a method to account directly for the costs of new services and technology, patterned somewhat after the outpatient technology pass-through provision discussed above. In this section, we briefly review the structure of the inpatient PPS and address both the existing and new treatments of technology costs.

Structure of the inpatient payment system

The unit of payment in the hospital inpatient payment system 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 APC system, encompassing all routine nursing, support service, and ancillary costs incurred in patients' stays. The payment system consists of three main components:

- operating and capital base payment rates, which reflect the average costliness of Medicare cases nationwide, adjusted for the relative input prices of the hospital's local area;
- the case weight, which accounts for the relative costliness of each DRG compared with the national average Medicare case; and
- special adjustments, which include outlier payments for unusually costly cases, an indirect medical education

adjustment that accounts for the higher costs of teaching facilities, and a disproportionate share adjustment providing additional funds to hospitals under financial pressure from caring for the poor.[8]

Responding to technology costs

The BIPA changed Medicare's method of paying for new technology in the inpatient PPS. In this section, we describe the procedures previously used to account for the costs of new technology and evaluate the new BIPA provisions. We conclude by recommending that HCFA formalize its procedures for responding to new and substantially improved technologies and offering guidelines for implementing the technology pass through mandated by the BIPA.

Previous methods

Technology has always been addressed in Medicare's inpatient PPS. The first component of HCFA's system is a technical advisory panel that assigns ICD-9-CM codes to new technologies and deletes codes for outdated procedures.[9] This group, known as the ICD-9-CM Coordination and Maintenance Committee, is jointly operated by HCFA and the National Center for Health Statistics. The process of assigning codes has no fixed timetable, but generally takes at least a year.

Second, HCFA staff analyze variation in the costliness of cases within DRGs, primarily in response to suggestions by industry representatives that the costs of certain types of cases are systematically higher than the applicable DRG average. Based on these analyses, HCFA periodically reassigns certain types of cases to a different DRG or splits DRGs into two or more new groupings and modifies the case weights accordingly.

The third way in which HCFA responds to new technology is by recalibrating the DRG case weights. Recalibration is done annually and reflects the relative costliness of cases (as determined by applying a hospital-specific cost-to-charge ratio to the charges of each case) in the most recent year's claims file. This process reflects any changes in the construct of DRGs that occurred in the previous year. Although annual recalibration plays an important role in maintaining accurate payment relatives, it can only reflect the current degree of dissemination. If only a few hospitals are using a new technology, their charges will have only a small effect on the DRG rate and they may continue to be underpaid pending the next recalibration.

The final mechanism for responding to technology changes is the annual update to the base payment rates. Since the early years of the inpatient PPS, Congress has legislated updates for operating payments, while HCFA has set the updates for capital payments (8.5 percent of the total) through an annual rulemaking process. Congress rarely indicates the factors it has taken into account in making an update decision, but both MedPAC and HCFA develop recommendations on the basis of an update framework. MedPAC's framework specifically addresses technology costs through a scientific and technological advancement factor, which is intended to account for the impact of quality-enhancing but cost-increasing new technologies and is offset at least partially by a negative productivity adjustment, which captures the effects of cost-decreasing new technologies.

During the 1980s, the Congress made its update decisions on an annual basis, after considering recommendations from the Prospective Payment Assessment Commission (ProPAC) and HCFA. More recently, Congress has legislated updates three to five years into the future, which means that several decisions must be made without input from either MedPAC or HCFA. Both MedPAC and HCFA, however, have continued to make update recommendations annually to guide the Congress on whether a change in the legislated updates might be warranted.

HCFA and ProPAC considered payment adjustments for specific technologies several times in the past, but few were implemented or even formally recommended. In 1989, ProPAC recommended covering the costs of providing blood clotting factor to Medicare patients with hemophilia, which had risen dramatically in 1987 and 1988. Congress enacted this recommendation for a two-year period in the Omnibus Budget Reconciliation Act of 1989. At the end of the two years, ProPAC recommended eliminating the adjustment because DRG recalibration had realigned payments appropriately and only a small number of patients distributed over several DRGs continued to have costs that markedly exceeded the applicable DRG average (ProPAC 1992).

ProPAC and HCFA were involved in an extensive debate over whether an adjustment was warranted for tissue plasminogen activator (TPA) and streptokinase, drug regimens for the follow-up treatment of heart attacks and stroke. Interest in a specific payment adjustment was generated by the unusually high cost of TPA, but the fact that TPA was much more expensive than streptokinase with little evidence of superior effectiveness emerged as a strong factor in ProPAC's and HCFA's decisions not to recommend an adjustment.

Provisions of the Benefits Improvement and Protection Act of 2000

The BIPA section addressing the treatment of new technology costs in the inpatient PPS contains three mandates for HCFA:

- Develop a process to incorporate new medical services and technologies expeditiously into the clinical coding system for inpatient hospital services, which is currently the ICD-9-CM system. The statute did not specifically identify drugs as new technologies, but it appears that HCFA could choose to include them.

8 A more detailed description of the inpatient PPS is provided in the introductory section of Chapter 5.

9 The ICD-9-CM acronym stands for International Classification of Diseases, 9th Revision, for Clinical Management.

HCFA is required to report to Congress on its proposed methods for adopting new technology codes, and then to implement the system by October 1, 2001.

- Collect data on the costs of new technologies (aided by the new clinical codes) for a period of 2 to 3 years, and then assign cases using the technologies into new or existing DRGs that have case weights derived from the data collected.

- Provide for additional payment to cover the costs of each new technology during the study period. This payment could be in the form of new technology groups with case weights reflecting the average costs of patients using the technologies, or it could be an add-on or adjustment to the normal DRG payment for cases where the technology is used.

The first two provisions serve to formalize, and perhaps expedite, most of the procedures that HCFA already uses. The third provision, implementing what amounts to an interim payment for specific new technologies, represents a sharp departure from current policy. Like the outpatient technology pass through, the Secretary is expected to implement the provision on a budget-neutral basis.[10] This means the effect of the additional payments for specific new technologies would be entirely distributional; the provision would not affect the need to account for the cost-increasing impact of new technology in annual payment updates.

The additional payments for new technologies are pass throughs in the sense that HCFA must establish rates that cover the estimated cost of each technology. Presumably, HCFA will update these amounts over time to keep them matched to current costs. However, the inpatient pass-through provision differs from the outpatient one in that it is based on the *average* cost of a technology rather than each hospital's costs. Thus, hospitals will benefit financially if they can negotiate a purchase price that is beneath the national average, and vice versa.

The reason for a technology pass through for acute inpatient care is to ensure that inadequate payment for specific DRGs or cases within DRGs does not prevent hospitals from adopting new services and technologies. When a new technology raises costs for most patients in a DRG, the payment rate may be too low relative to other DRGs until its weight is changed through recalibration. When a technology raises the costs of a subset of patients in a DRG, the payment rate for those patients may remain inadequate indefinitely unless HCFA believes that the problem is important enough to warrant a change in the DRG structure.

However, two reasons make this advantage less compelling for inpatient care than for outpatient services. First is the broader construct of DRGs, such that a new drug, device, or service is likely to make up a much smaller portion of overall costs. Consequently, there are more opportunities for decisionmaking on the mix of inputs used to produce the unit of payment—decisions on whether a technology is clinically necessary, how often a service should be used, and which competing technology is most cost-effective. A technology pass through would influence, and potentially distort, these decisions by ensuring that the costs of select new technologies will be covered in full and increase the total payment received, while the costs of other technologies and other types of inputs must be covered by the fixed case-level payment.

The second reason is that, unlike in the outpatient PPS, neither patients' DRG classification nor the process for recalibrating the DRG weights is dependent on HCFA assigning codes to new services or procedures. Similarly, recalibration is based on an accumulation of charges for all services provided, and ICD-9-CM codes are not needed for hospitals to provide services and record their charges. In fact, the DRG rates would likely have been recalibrated at least twice under current HCFA policy during the span of the time needed to assign a new procedure code, wait for a sufficient volume of claims reflecting the code to generate, and determine the appropriate payment system response as specified in BIPA. New codes serve only to facilitate analyses that might lead HCFA to restructure DRGs.

Several other problems cited above for the outpatient technology pass through will also likely apply to an inpatient pass through. These include:

- The lack of data for HCFA to determine an appropriate interim payment adjustment for a technology before hospitals have much experience in providing it. Setting payments early in the dissemination process would require reliance on either unverifiable cost or pricing data from technology manufacturers or on limited hospital charge data, collected at a time when the hospitals would have a strong incentive to set high charges.

- HCFA's difficulty predicting the frequency of new technology use and therefore the reduction in base payment rates needed to provide pass-through funding on a budget-neutral basis.

- The high staff-intensity of the process for HCFA and hospitals alike. Hospitals must submit more detailed claims and HCFA must process them, as well as manage systems for approving technologies for payment and establish appropriate rates for them.

Our recommendations envision a system for accounting for the costs of new technology that captures the best aspects of the previous system and the provisions of the BIPA. The first recommendation essentially endorses the first of three major BIPA provisions.

10 While the BIPA did not require budget neutrality, as was the case with the outpatient pass-through provision, the report of the Ways and Means Committee made clear that this was the Congress's intention.

RECOMMENDATION 3D

For the inpatient payment system, the Secretary should develop formalized procedures for expeditiously assigning codes, updating relative weights, and investigating the need for patient classification changes to recognize the costs of new and substantially improved technologies.

Although annual recalibration of inpatient payments has an established track record, the other two processes—code assignment and patient classification changes—are less formalized and perhaps not completed as quickly as they could be. For example, the ICD-9-CM Coordination and Maintenance Committee only meets twice per year to consider potential code changes. In addition, there are no established procedures for affected parties to request DRG restructuring, and no fixed process or timetable for HCFA staff to respond to such requests. Numerous complaints have been voiced regarding the lack of timeliness. For example, when cardiac surgeons began using stents during angioplasty procedures to improve and extend blood flow, it took five years for HCFA to ultimately decide that the applicable DRG should be split into two DRGs, for angioplasty with and without stent. MedPAC endorses the Congress' initiative via the BIPA to formalize and expedite HCFA's procedures.

With changes to formalize the system for assigning codes to new services and procedures and investigating the need for DRG changes, we believe the current inpatient payment system would have been capable of responding adequately to the costs of new technology. This conclusion rests on the premise that decisions regarding the adoption and use of technology are best made at the clinical level, and that a technology pass through may distort clinical decision making by removing all financial risk from the use of select technologies. The procedure-based system for outpatient payment makes it more difficult to respond to the introduction of new technologies without using pass-through payments. But the design of the inpatient PPS makes it easier to ensure an appropriate distribution of payments while accommodating technological advances.

The key reasons the system can allow the use of new technology to be governed by local decision making are that new technologies generally have a small impact on the broadly defined DRGs and that recalibration of DRG weights is already accomplished annually, without the need to assign new codes to new procedures and technologies. In addition, pass-through payments would inevitably lead to higher payments for the major teaching hospitals that lead the way in introducing new technologies, at the expense of hospitals that play a lesser role in technology dissemination. We believe that this is not necessary in light of the subsidy already built into the indirect medical education payments that teaching hospitals receive.

However, the payment system must ensure that the overall level of payments is sufficient to cover the costs of quality-enhancing new technology, in addition to providing for an appropriate distribution of payments. This job should fall primarily to the annual updating process.

While it is difficult to determine the appropriate increase in payments to accommodate new technology, we have mechanisms in place for attempting to do so. MedPAC's annual recommendation to the Congress on the inpatient payment update always includes a provision for cost-increasing new technologies, and we plan to sponsor research that will help to quantify this provision. The existing decisionmaking process has the advantage of flexibility in defining the scope of new technology (we have accounted for the costs of innovations in medical information technology, for example), and also allows simultaneous consideration of the impact of cost-decreasing technologies.

RECOMMENDATION 3E

Additional payments in the inpatient payment system should be limited to new or substantially improved technologies that add significantly to the cost of care in a diagnosis related group and should be made on a budget-neutral basis.

These parameters parallel those we specified earlier in the chapter for implementation of outpatient pass-through payments. The "substantial impact" provision would provide a temporary boost in payments when the impact of a new technology on its early users is the most severe, while minimizing interference with clinical decisionmaking at the local level. Budget neutrality would limit the pass through to influencing the distribution of payments, leaving decisions regarding changes in the overall level of payments to the annual updating process.

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