This paper, the last of 3 that discuss the reimbursement challenges facing new medical device technology in various issues of this journal, addresses the structural diversity of Medicare’s various payment systems. These systems vary widely in how they establish prices, how they incorporate new technologies and procedures, and the means by which they are updated and maintained. Their importance extends beyond Medicare because other payers use these payment rates as a basis for setting rates of their own. Device manufacturers and medical practitioners must often navigate several of these payment systems concurrently to ensure that technologies and procedures (that are already coded properly and covered) receive a fair payment rate. It is important to recognize that coverage can be undermined without adequate payment and that this situation will dampen further product innovation. The 3 papers, taken together, document the challenges posed by insurer reimbursement policies and show that a close working relationship between the manufacturers that develop new medical technologies and physician practitioners is needed if reimbursement hurdles are to be managed and medical innovation is to continue.

**Key Words:** Ambulatory payment classification, Centers for Medicare and Medicaid Services, diagnosis-related group


**INTRODUCTION**

In our previous papers, we discussed the incremental nature of medical device innovation and noted how these characteristics complicate the technology assessment process. We underscored the importance of procedure (or billing) codes for identifying new medical procedures and technologies and noted that clinical effectiveness data are used in both the coding and coverage processes. We also provided the time frames associated with the coding and coverage processes, cited developments that have made national Medicare coverage decision making more timely and open, and discussed the evidentiary hurdles that affect new services. In this paper, we turn to the challenges Medicare’s various payment processes pose for medical device adoption and use.

To be successful in planning for new products and procedures, manufacturers must not only work closely with medical specialty societies on coding and coverage matters, they also must understand the architecture of each of Medicare’s payment systems. They have to work to ensure that the rates assigned by Medicare for a given procedure are appropriate for each site of care in which it is offered. This is no easy task, given the number of distinct payment systems used in the Medicare program and the numerous technical changes that are made to these payment systems each year.

**MEDICARE PAYMENT**

Medicare is the largest purchaser of health care services in the United States. It provides health insurance coverage to more than 41 million beneficiaries, and it accounts for about 20% of all health care spending. Although the Medicare program reimbursed health care providers on
the basis of their reasonable costs and charges when it began in the mid-1960s, this health insurance program no longer “reimburses” costs incurred by health providers. It has evolved into a system whereby prices are set prospectively by the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program, through defined administrative and regulatory processes [1].

Over the years, one by one, Congress has authorized new prospective payment systems to replace inflationary retrospective cost reimbursement systems used when Medicare was launched in 1965. These new payment systems have had the desired effect of controlling per unit outlays. Other private payers in the United States use these Medicare prices as benchmarks in negotiating rates with health providers. Commercial purchasers typically pay a certain percentage above the Medicare price, and public purchasers, such as Medicaid, pay some percentage below it [1]. However, these payment systems have also had impacts on the adoption and use of new medical device procedures and technologies that may not have been fully anticipated by their architects.

The following sections of this paper examine how new medical device procedures and technologies are affected by several aspects of Medicare’s payment systems: their design and coordination with one another, the data used in setting payment rates, the ways they incorporate new procedures and technologies, how (and if) payment updates take place to account for inflation, and whether adjustments are made to correct errors that become apparent.

**Payment System Design**

Medicare currently makes use of more than a dozen distinct major payment systems to reimburse more than 1 million providers and suppliers for the care and services it furnishes [2]. See Table 1 for an inventory and brief overview of most of these payment systems. Each tends to vary in the way prices are established and adjusted, and each has its own approach toward incorporating new technology procedures and making year-to-year modifications.

The sheer size and scope of the Medicare program make it a challenge to grasp fully the intricacies of the payment machinery CMS has put into place. In addition, the variations that exist from payment system to payment system, and the fact that a single technology must often be recognized concurrently in several of these systems, add considerably to the complexity and uncertainty device manufacturers face in planning for new products.

For example, the costs hospitals incur in performing imaging procedures on an inpatient basis are not separately paid by Medicare. Instead, Medicare makes payments to hospitals for the inpatient services they provide using approximately 500 distinct diagnosis-related groups (DRGs) to categorize each discharge. A specific payment rate is set for each of these DRGs.

In contrast to this, imaging services performed on a hospital outpatient basis are paid by Medicare through a different prospective payment system, one based on groupings of clinically similar services with similar resource costs. Each hospital outpatient service is grouped into payment bundles called ambulatory payment classifications (APCs).

Physician who perform these imaging services in hospitals are reimbursed under the Medicare physician fee schedule for the professional component of the services, reflecting physician work associated with the procedures. Payments by Medicare under the DRG or APC system to hospitals serve, in effect, as payments for the technical component of the services. When these same imaging procedures are performed in physicians’ offices, or in independent diagnostic testing facilities, they are reimbursed under the Medicare physician fee schedule.

To further complicate this matter, Medicare DRG payments are based on International Classification of Diseases, 9th Rev (ICD-9), codes, whereas APC and physician fee schedule payments are based on Current Procedural Terminology® codes, and when imaging services are offered at other sites of care, such as rehabilitation or long-term care hospitals or ambulatory surgery centers (ASCs), other rules apply.

Because each of Medicare’s payment systems has a distinct method to set rates, these payments can vary, sometimes significantly, from one site of care to another, creating utilization incentives. We give 2 examples of this below.

**Example 1.** The Medicare hospital inpatient prospective payment system (the DRG system), established in the early 1980s, pays hospitals a fixed rate per discharge. This payment approach leads hospitals to make economical choices in the technologies and services provided during the course of an admission. Because payment is set in advance, hospitals have incentives to hold down the technology costs they incur for each admission and to limit lengths of stay.

However, DRGs also promoted the shift of many medical procedures from an inpatient site of care, where payment rates were “controlled,” to outpatient settings, where payment rates were not controlled through prospectively-set prices. At the time DRGs were established,
<table>
<thead>
<tr>
<th>Site of Care</th>
<th>Payment System, Characteristics, and Impact</th>
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<tbody>
<tr>
<td><strong>Inpatient/acute care</strong></td>
<td><strong>Acute care hospitals</strong></td>
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<tr>
<td></td>
<td>• Prospective payment since 1983/DRGs (per discharge payment for operating costs; separate prospective payment for capital)</td>
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<tr>
<td></td>
<td>• 3,900 acute care PPS hospitals</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $105 billion</td>
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<td></td>
<td><strong>Psychiatric facilities</strong></td>
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<td></td>
<td>• Prospective payment begun in 2005; 3-year transition/DRGs (per diem payment; includes both operating and capital costs)</td>
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<td></td>
<td>• 1,800 inpatient psychiatric facilities</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be about $4 billion</td>
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<td><strong>Ambulatory care</strong></td>
<td><strong>Physician services</strong></td>
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<td></td>
<td>• Physician fee schedule since 1992: based on CPT®, HCPCS codes (payment based on relative values)</td>
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<tr>
<td></td>
<td>• More than 875,000 physicians and other health care professionals</td>
</tr>
<tr>
<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $55.3 billion</td>
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<td></td>
<td><strong>Hospital outpatient services</strong></td>
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<tr>
<td></td>
<td>• Prospective payment since 2000/APCs (per service payment; includes both operating and capital costs)</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $16.6 billion</td>
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<tr>
<td><strong>Postacute care</strong></td>
<td><strong>Ambulatory surgical centers</strong></td>
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<tr>
<td></td>
<td>• Fee schedule since 1982: 9 payment groups based on CMS estimate of facility costs (top-paying group pays $1,339); covers both operating and capital costs</td>
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<td></td>
<td>• 2003 legislation requires a new prospective payment system to be implemented between 2006 and 2008; APCs being considered as basis for payment</td>
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<td></td>
<td><strong>Clinical laboratory services</strong></td>
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<tr>
<td></td>
<td>• Fee schedule since 1984: based on CPT®, HCPCS codes (national payment ceiling, or “NLA,” based on 74% of median of contractor fee schedules)</td>
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<td></td>
<td>• More than 1,000 CPT® and HCPCS codes assigned payment rates</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $6.3 billion</td>
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<td></td>
<td><strong>Skilled nursing facilities</strong></td>
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<td></td>
<td>• Prospective payment authorized in 1997/RUGs (per diem amount adjusted for case mix and area wages); covers both operating and capital costs</td>
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<td>• Total Medicare outlays in 2005 were projected to be $16 billion</td>
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<td><strong>Home health agencies</strong></td>
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<td></td>
<td>• Prospective payment since 2001/HHRGs (60-day episodes of care)</td>
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<td>• Total Medicare outlays in 2005 were projected to be $12 billion</td>
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<td><strong>LTC hospitals</strong></td>
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<td></td>
<td>• Prospective payment since 2002/LTC-DRGs (per discharge payment; currently being phased in); covers both operating and capital costs</td>
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<td></td>
<td>• 300 LTC hospitals</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $2.96 billion</td>
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<td></td>
<td><strong>Rehabilitation hospitals</strong></td>
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<td></td>
<td>• Prospective payment since 2002/CMGs with comorbidity tiers (per discharge payment); covers both operating and capital costs</td>
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<tr>
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<td>• 1,220 facilities (215 freestanding; 1,005 special units in acute care facilities)</td>
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<td></td>
<td>• Total Medicare outlays in 2005 were projected to be $5.7 billion</td>
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<tr>
<td><strong>Items and services</strong></td>
<td><strong>Ambulance services</strong></td>
</tr>
<tr>
<td></td>
<td>• Fee schedule begun in 2002; 5-year transition</td>
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Medicare reimbursed outpatient services on the basis of charges submitted by health providers. Some of the current controversy over the rate of increase in Medicare outlays for outpatient care is rooted in these clear incentives to move health services from more expensive inpatient settings to less expensive outpatient sites of care.

Example 2. In some instances, Medicare pays more for an imaging service performed in a physician office setting than in a hospital outpatient setting. For other imaging services, the situation is reversed. This is because these Medicare payment systems have differing payment methods: hospital APC payments are based on hospital charges submitted for the procedure, and Medicare payments for physicians’ services are based on relative value units established for each procedure [3,4].

The differing payment rates associated with these 2 payment systems recently drew the attention of Congress. The Deficit Reduction Act of 2005 requires Medicare to pay, effective in 2007, the APC payment rate for imaging services performed in physicians’ offices or at independent testing facilities when the APC payment rate is lower than the technical component rate calculated under the Medicare physician fee schedule.

Prospective payment systems also discourage the use of new, higher cost technologies that may increase quality or improve outcomes. For example, in the DRG system, the Medicare payment is based on patient discharges, and, as a result, the focus of hospitals is on holding down costs per admission. Hospitals have little financial incentive to make use of higher cost technologies that are more cost effective over a longer term than the patient admission [5]. For this reason, it is important that new technologies and procedures be carefully integrated into established prospective payment systems, a matter we address in the next section of this article.

Data Foundation for Rate Setting

If the data CMS uses to set Medicare prices do not accurately reflect per unit or per procedure costs, these prices can create incentives for providers to cut back, or drop, “under-reimbursed” services. At the very least, a rate set too low forces providers to cross-subsidize services, undercutting the rationale behind prospective payment. The recent transition in Medicare hospital outpatient payments from a system based on reasonable charges to one based on prospective rates illustrates this.

The implementation of the hospital outpatient prospective payment system (the APC system), which began in 2000, was marked by significant controversy concerning the adequacy of data CMS had available to set payment rates. Because CMS had insufficient information on hand to correctly price certain new technologies and procedures when it launched this new payment system, Congress directed the agency to make temporary additional “pass-through” payments for qualifying new med-

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Table 1. Continued

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<th>Site of Care</th>
<th>Payment System, Characteristics, and Impact</th>
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| **DME, prosthetics, orthotics, and supplies** | ● DME fee schedule since 1989; other items added in subsequent years based on HCPCS codes (national payment ceilings and floors on contractor-set rates)  
● Competitive bidding authorized in 2003 legislation  
● Total Medicare outlays in 2005 were projected to be $8 billion |
| **Hospice** | ● Prospectively set rates: 4 rates corresponding to level of care provided (per diem payment); covers both operating and capital costs; subject to a per beneficiary “cap amount”  
● Hospice benefit added to Medicare in 1983  
● 2,325 hospices in 2002 (1,074 freestanding)  
● In 2005, hospice services were expected to account for approximately $6 billion in Medicare payments |
| **Medicare Advantage Health Plans** | ● Monthly per person (capitated) county rates  
● 11% of Medicare beneficiaries have chosen this managed care option instead of fee-for-service |

Note: APC = ambulatory patient classification; CMG = case mix group; CMS = Centers for Medicare and Medicaid Services; CPT® = Current Procedural Terminology®; DME = durable medical equipment; DRG = diagnosis-related group; HCPCS = Healthcare Common Procedure Coding System; HHHRG = home health resource group; LTC = long-term care; NLA = national limitation amount; PPS = prospective payment system; RUG = resource utilization group.
ical technologies, including devices, drugs, biologicals, and radiopharmaceutical agents. Under this program, hospitals could receive pass-through reimbursement for the acquisition costs of eligible new technologies for a 2-year to 3-year period, along with the APC payments (which represented reimbursement for the procedure costs associated with the new technologies). At the end of this period, new technology costs would be folded into an appropriate clinical APC, pass-through payments would end, and full hospital payment would be provided through the APC rate. For expensive new products and procedures that did not meet the medical device eligibility requirements for pass-through payment (eg, services involving capital equipment, such as medical imaging procedures and nonimplantable products), CMS established a series of new technology APCs, organized on cost, not clinical, grounds, in which these new technology procedures could be temporarily assigned. During their assignment to new technology APCs, CMS studies hospital claims associated with these new technologies and procedures and uses this information as a basis for assigning them to clinical APCs.

The use of interim pass-through payments for eligible new technologies, as well as the temporary assignment of other new products and procedures to new technology APCs, was intended to integrate new products and procedures quickly into the new payment system while generating information CMS could use to construct new APC payments that reflected the costs of these new technologies. But even with this deliberate approach to gathering cost data for new technology procedures, problems arose as CMS made use of hospital claims data to set APC payment rates. During the first several years of the new APC system, Medicare rates were characterized by wide swings from year to year as CMS folded pass-through payment amounts for new technologies into clinical APC payment rates. In response, CMS took steps to “dampen” the impact of payment decreases and adjusted its methods for using hospital claims data for rate-setting purposes. In particular, CMS took steps to ensure that hospital claims were correctly coded to include device charges.

These measures helped ease the transition to the new prospective payment system. Large yearly swings in payment levels are more the exception than the rule today. However, this rate-setting process has illustrated more fundamental problems in establishing fair rates for medical services involving medical devices. One problem arises from the hospital data CMS uses to set APC rates.

Medicare uses hospital charge data to impute the costs hospitals incur in providing medical services. The CMS adjusts hospital charges for the procedures performed to “costs” by using hospital cost-to-charge ratios. However, accounting practices differ from hospital to hospital. Each hospital sets its own charges for particular services, and the charges hospitals set for procedures involving low-cost medical technologies are likely to be relatively higher than those using higher cost technologies. In effect, hospitals tend to “mark up” their costs less when expensive items are used. Because CMS deflates all hospital charges to costs by the same ratio, this differential markup situation results in a relative underpayment for the more costly procedures hospitals perform and a relative overpayment for procedures using lower cost supplies. This relative underpayment can be compounded when hospitals fail to account fully for technology charges in their bills for a procedure or when they do not correctly code (and charge for) the actual number of device units used in a medical procedure (eg, the number of catheters used in an interventional radiology procedure or the number of radioactive isotopes used in prostate brachytherapy procedures).

Given this, the medical device industry has proposed that Medicare use “external data” (ie, data documenting actual hospital acquisition costs for given technologies) as a reference point in price setting. CMS considered this type of data in setting prices for a limited number of APCs in the first years of the new hospital outpatient prospective payment system. However, the agency has stated that it does not plan to accept these data in the future.

Another cause of Medicare’s difficulty in setting fair rates in the hospital outpatient setting may be the newness and complexity of a procedure itself. The lack of an established method of accounting for a complex new procedure, combined with a relatively small number of hospitals filing claims for the procedure, can result in

2 Congress required CMS to establish the pass-through program in the Balanced Budget Refinement Act of 1999. The law and implementing regulations restricted eligible medical devices to significant-cost devices, integral to a medical procedure, that came into contact with human tissue and were either implanted or inserted.

3 The Medicare Payment Advisory Committee (MedPAC) contracted with the Lewin Group to survey hospitals about their practices in setting charges. Dr Chantal Worzala, a professional staff member with MedPAC, summarized the findings of the Lewin Group’s hospital survey for the committee at a 2004 MedPAC meeting. Concerning hospitals’ responses with respect to variations in markup practices, she said, “One of the most cited examples of variation would be that low-cost items have higher markups than high-cost items. Some of that has to do with sticker shock. If something is very expensive and you mark it up a lot, it becomes very, very expensive” [6].

4 A study commissioned by the medical device industry and conducted by the Moran Company [7] found that CMS’s approach to determining hospital service costs on the basis of submitted charges results in reimbursements for devices at only 72% of their acquisition costs.
hospital claims data that are not adequate to serve as a basis for rate setting. Fluoro-2-deoxyglucose (FDG) positron emission tomography (PET) imaging provides an example where it has been particularly difficult for Medicare to determine a fair price for a new procedure performed in the hospital outpatient setting. As a result, Medicare payments for these FDG PET imaging procedures have been the subject of considerable uncertainty in the medical device and health provider communities. Relatively few hospitals perform these imaging procedures, and the types of equipment used can range widely. In addition, changing market circumstances affect hospital costs, there is no uniformity in how hospitals allocate costs associated with these procedures, and the number of covered indications has grown. The situation has been further aggravated by changes in coding and variation in hospital practice concerning how to allocate the costs of capital expenses associated with medical imaging procedures.

Although FDG-PET has been consistently assigned to a new technology APC since the hospital outpatient prospective payment system began, the rate assigned to this procedure has provoked a good deal of controversy. Payment has ranged from more than $2,000 during the first 2 years of the hospital outpatient payment program to $1,150, the national rate today.

CMS has sought a lower rate, however, proposing (unsuccessfully) to reassign FDG-PET procedures from its new technology APC to a clinical APC paying a very low rate, $875, in 2002. The current (2006) payment rate was set in 2004 as a transition toward a lower rate that CMS stated was justified on the basis of hospital claims data. CMS did not cite any technical or data rationale for not assigning the lower rate to FDG-PET procedures, as it had intended, for 2006; rather, it stated that its decision was made “to ensure continuing beneficiary access to this technology” [8].

Medicare payment policy for FDG, the radiopharmaceutical used in these procedures, has also varied over the years. Hospital costs of acquiring FDG were passed through when the APC system began. It has had various defined payment rates, and a separate APC assignment, for several years, and it is currently paid on the basis of an individual hospital’s charge, adjusted to cost.

**Setting Rates for New Technologies and Procedures**

Medicare officials have considerable discretion in setting the initial payment rates for new technologies and procedures. However, if CMS assigns them to existing payment groups (eg, particular DRGs or APCs) with payment rates that are too low or establishes fee schedule rates that do not cover the costs of the new items or services, causing providers or suppliers to lose money, the use of the new technologies will be curtailed, and the incentive to innovate will be dampened.

Cochlear implant procedures represent an example of a new procedure assigned to a DRG (DRG 49) with too low a payment rate. When Medicare officials made this assignment, none of the other procedures in this DRG involved implanted devices, and the cochlear implant procedure was much more costly than these other procedures. This created a disincentive for hospitals to perform the procedure and may have severely limited the diffusion of this new medical technology.

After the procedure was assigned to DRG 49 in 1986, the Prospective Payment Assessment Commission recommended in 1987 that it be assigned to a temporary DRG of its own. However, Medicare officials chose not to follow this advice in 1988, or when requested to reconsider this assignment on several occasions through the mid-1990s [9, 10]. This DRG assignment meant that hospitals performing these implantations on Medicare patients in the mid-1980s lost approximately $3,000 to $5,000 per case. By 2000, the disparity in payment had grown to about $9,000 per implantation because of improvements in device technology and corresponding cost increases.

The establishment of the Medicare hospital outpatient prospective payment system in the late 1990s, and the difficulty Medicare officials had in factoring in new technology costs in setting the initial rates for this program, spurred the medical device industry to petition Congress for special methods to price new medical procedures. As discussed in the previous section of this paper, legislation enacted in 1999 established a program of interim pass-through payments for qualifying new hospital outpatient services. Medicare officials supplemented this program with a series of new technology APCs, into which new procedures could be assigned on a temporary basis until sufficient cost data were available for their assignment to clinical APCs.

Congress also responded to medical device industry requests for changes in how new technologies are incorporated into the hospital inpatient prospective payment system. In legislation enacted in 2000, Congress required CMS to report on potential methods to incorporate new procedures and technologies into the DRG system more rapidly, authorized additional payments for the approach, and required the agency to implement the

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5 The Prospective Payment Assessment Commission was established by legislation authorizing the DRG payment system. It was combined with another advisory group, the Physician Payment Review Commission, to form MedPAC.

6 This requirement was a part of the Balanced Budget Refinement Act of 1999.
method it preferred. As a result, CMS established temporary “add-on” payments for qualifying new technologies and procedures provided on an inpatient basis.

To receive either hospital outpatient pass-through payments or hospital inpatient add-on payments, a new technology or procedure must be found by CMS to provide a “substantial clinical improvement.” The standards for temporary add-on payments in the DRG system are quite stringent, and as of 2006, only 3 procedures qualify for these temporary additional payments. In the hospital outpatient setting, temporary pass-through payments are also difficult to come by: there were only 3 medical device categories receiving these payments in 2005, and one has been established for 2006.

Each of Medicare’s payment systems varies in how rates are set for new procedures and technologies. Some, like those mentioned above, have attracted congressional attention and engage the public through formal rule making and other processes. Others afford interested parties less interaction and opportunity to comment. The examples below illustrate this variety. For manufacturers who develop the affected products and the medical practitioners who use them, the uncertainty that accompanies these rate-setting processes has a chilling effect on innovation.

Example: Medical Clinical Laboratory Fee Schedule. After the American Medical Association’s CPT® Editorial Panel assigns new or revised codes to identify new clinical diagnostic tests, CMS either “cross-walks” the new test codes to existing codes (and payment amounts) on the clinical laboratory fee schedule or prices the new tests through a “gap-fill” methodology. Neither of these approaches is specified in law, and neither is governed by regulations that have been vetted with the public. The actions CMS takes can be arbitrary, and no mechanism exists to correct errors once they become apparent.

The clinical laboratory gap-fill approach is based on carriers’ advice to CMS on how to price new tests, but CMS provides no guidance on the methodology for contractors to use in doing so. The result is widely varying approaches and prices, that are used by CMS to set a price ceiling (or “national limitation amount”) for new test codes [12].

The CMS also incorporates some new tests by cross-walking them to tests already on the fee schedule. Not all cross-walks are straightforward, and the exercise can be quite subjective, resembling more an arbitrary price-setting exercise than a technical mapping of new codes to similar codes on the fee schedule. In response to manufacturers’ objections to the closed nature of this process (and its payment results), Congress acted in 2000 to require CMS to consult the public at an open meeting before making these decisions.

Example: Durable Medical Equipment (DME) Fee Schedule. New items added to the Medicare fee schedule for items of DME and other supplies are either cross-walked to existing codes (and prices) or priced through a gap-fill methodology. The method used to gap-fill new items of DME on this fee schedule involves deflating the price assigned to a new DME item (on the basis of inflation) back to the year the fee schedule began in the late 1980s and then reinflating the price of the new item using only the increases provided to the fee schedule. This results in a price set well below the market rate, because updates to this fee schedule have been constrained by a series of rate freezes and below-inflation increases since the fee schedule was established.

Updating Rates

The disincentive that exists in Medicare’s prospective payment programs toward acquiring new technology can be aggravated by the way Medicare updates these payment rates. Hospital prospective payment rates typically are set on the basis of the most recent claims data CMS has available. In the case of hospital inpatient and outpatient payments under the DRG and APC systems, for example, the data used to update hospital payment rates for any given year are 2 years old.

This underscores the need for methods to establish fair and appropriate payment rates for new procedures and technologies. The time lag associated with the availability of hospital data diminishes the incentive for new technology adoption and use. For hospitals that might have been prone to make errors in their coding and reporting before they became familiar with a new technology or procedure, it means that there is no immediate incentive or reward for them to take corrective action. Because the data used to set today’s hospital inpatient and outpatient rates do not reflect current hospital technology acquisition or procedure costs, hospital incentives to purchase new technologies or offer new services are dampened.

In the case of the fee schedules Medicare uses to pay suppliers for DME, supplies, and clinical laboratory tests, the situation could even be worse. There is no systematic, annual attempt to recalibrate rates to adjust them to actual provider costs after the rates have been set, a process that takes place each year in many of Medicare’s

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7 This requirement was a part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.
8 When CMS asks carriers to price new physician services for the Medicare physician fee schedule, carriers might use cross-walks to existing codes (and payment amounts) already on the physician fee schedule as a pricing method.

9 This was a requirement of section 531 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.
other payment systems, including the physician fee schedule. Instead, rates, once established, typically do not even keep pace with inflation, because of freezes in rates and below-inflation annual increases.

Payment System Maintenance

Some of the payment systems established by Medicare officials to replace inflationary retrospective cost or charge-based reimbursement approaches have been poorly maintained. These systems may not have been updated regularly to correct mistakes, they may not have been updated to incorporate new technologies and provider costs, or they may not have received needed revisions to keep pace with medical practice.

For example, the Medicare clinical laboratory fee schedule has no means to correct pricing errors that might have been made in establishing initial test payment rates. The CMS compounds these problems, time and again, as it cross-walks most new tests to existing tests on the fee schedule. The result is wide geographic variation in pricing for new tests being marketed by manufacturers because prices for new cross-walked tests are based on the historical accident of an initial carrier price set for the predicate test.

Medicare’s ASC payment system is another example. Established in 1980 to provide coverage and payment for surgical procedures that could be performed at less intensive and less expensive sites of care, this system has been only sporadically updated for inflation since Medicare officials surveyed ASC facility costs in 1986 and has been slow to incorporate new procedures that can be safely offered in settings other than hospitals. In particular, CMS’s list of procedures approved for ASCs has not kept pace with medical practice as the number of procedures offered in hospital outpatient settings has expanded greatly. Instead, only 9 ASC payment groups have been established, and the grouping with the highest rate pays only $1,339. Many procedures that might be offered at this less intensive and less costly site of care are not provided there because they do not fit within these limited payment groupings.

SUMMARY

This paper has addressed the structural diversity of Medicare’s various payment systems. These systems vary widely in how they were established, how they incorporate new technologies and procedures, and the means by which they are updated and maintained. Their importance extends beyond Medicare because other payers use these payment rates as a basis for setting rates of their own.

Product sponsors and medical practitioners must often navigate several of these payment systems concurrently to ensure that technologies and procedures receive fair payment rates. It is important to recognize that coverage can be undermined without adequate payment and that inadequate payment will dampen further product innovation.

CONCLUDING REMARKS

When manufacturers develop new medical technologies, they depend on physician practitioners for advice and direction. Without this close relationship, medical device innovation could not take place. The challenges posed by insurers’ reimbursement policies demand a similar close working relationship.

Coding, coverage, and payment processes—the components of reimbursement—present difficult challenges for those interested in making new medical services and technologies available to patients who need them. As we have pointed out in this paper, and the 2 that preceded it in this journal, these reimbursement processes are complicated and time consuming, and they shape medical practice. Our intent in these papers was to show just how complex they are, and to indicate that patients are best served when stakeholders work closely together to confront the hurdles that stand in the way of patient access and innovation.

Physicians and the medical specialty societies to which they belong have worked closely with manufacturers on these matters in the past to expand patient access to improved medical care. However, as health care outlays rise, the reimbursement landscape will continue to evolve and expose new challenges. Continued medical innovation will take place only if physicians remain actively involved in these reimbursement processes by advocating proper coding (where needed), timely coverage, and fair payment.

REFERENCES


8. Medicare program; changes to the hospital outpatient prospective payment system and calendar year 2006 payment rates; final rule. Fed Reg 2005;70:68580-1.


