MEDPAC Medicare Payment Advisory Commission

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October 4, 2002

Thomas Scully, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Re: File code CMS-1206-P

Dear Mr. Scully:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the notice of proposed rulemaking (NPRM) entitled *Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports* (August 9, 2002). MedPAC commends the Centers for Medicare & Medicaid Services (CMS) for their efforts in further developing the outpatient prospective payment system (PPS). We also appreciate the attention given to recommendations from the Commission's March 2002 Report to the Congress in the rule.

As you know, services provided in the hospital outpatient department are classified into ambulatory payment classification (APC) groups for payment. Each APC group is given a relative weight. Payment is determined by multiplying the relative weight by a conversion factor. The proposed rule documents changes in the definition of APC groups, including identification of a new APC code for payment for implantation of drug-eluting coronary artery stents. The rule also proposes changes to the relative weights, which are based, for the first time, on data from hospitals operating under the outpatient PPS. The NPRM also provides a description of the process used to incorporate medical devices, drugs, and biologicals previously eligible for transitional pass-through payments into the base APC structure and estimates the calendar year (CY) 2003 update to the conversion factor.

Our comments on the proposed rule will center on five issues: the new codes established for payment of drug-eluting stents; the transition of devices, drugs, and biologicals from pass-through payment status to base APCs; payments for Part B drugs in other settings; the update to the conversion factor; and distributional impacts of the proposed changes.

Payment for drug-eluting coronary artery stents

The NPRM establishes a new APC code and payment rate for insertion of drug-eluting coronary artery stents, even though this technology has not yet been approved by the Food and Drug Administration (FDA). Payment will not take place before FDA approval, but creation of the code allows for payment upon FDA approval and accelerates payment for the technology. This step mirrors the creation of new payment categories for drug-eluting stents in the inpatient PPS for fiscal year 2003. For both payment systems, this is the first time that a code and payment amount have been set for a new technology prior to FDA approval.

As explained in the NPRM, the pass-through mechanism meant to facilitate payment for new technologies could not be used in this instance because a category, one that will expire at the end of 2002, was previously established for coated stents. According to the law, a new category cannot be established for a device if it could fit into a previously existing category.

As noted in the NPRM, the temporary APCs were created to ensure beneficiary access to a technology that many believe will "revolutionize" the provision of cardiac care. This step illustrates that CMS can respond rapidly to ensure adequate payment for technologies that are thought to be of a breakthrough nature. It also demonstrates that CMS can set a national payment rate for a new device, even in the absence of hospital claims and cost data, by relying on data from other countries where it is being used and information from manufacturers. While these sources are less reliable than hospital cost data, they appear adequate in the absence of hospital data, at least in this case. Of course, more general use of data from other countries would raise long term issues regarding the impact of this approach on manufacturers' investment and pricing strategies, both abroad and in the U.S. The Commission has begun to consider these issues in more depth, and would encourage CMS to do so as well. Given the use of outside data, use of these APCs and associated costs reported by hospitals should be carefully monitored and compared to the payment that was set.

In setting payment rates for drug-eluting stents, CMS has acted in a manner analogous to a recommendation in our March 2002 Report to the Congress. In that report, we recommended that CMS should be given authority to set national payment rates for pass-through devices. This mechanism would avoid the incentives to inflate charges for new technologies that exist in the current pass-through payment mechanism for new medical devices, which pays hospitals their costs, based on charges.

The new codes and payment rates for drug-eluting stents set a precedent. As noted in the NPRM, the agency will need to resist pressure to create new temporary codes for non-breakthrough technologies, rather than following the standard process, in the future. We encourage you to maintain highly selective criteria when creating new codes for new technologies.

Integration of pass-through devices, drugs, and biologicals into base payment rates

On January 1, 2003, the vast majority of medical devices, drugs, and biologicals previously eligible for pass-through payments will lose that special payment status. Integrating these items into the payment system will make it less complicated and reduce the potential for overpayments by eliminating cost-based payments (for medical devices) or payments based on 95 percent of the average wholesale price (for drugs and biologicals). On the whole, integrating pass-through items into the base APC is the most appropriate course of action. Beginning in 2003, the pass-through mechanism will be reserved for truly new technologies that have passed the stringent criteria set forth by CMS for eligibility for pass-through status. Minimizing the number of pass-through items limits the likelihood of surpassing the cap on pass-through payments, set at 2.5 percent of total spending in 2003 ($457 million). You have yet to estimate whether or not the cap will be exceeded, leading to a pro rata reduction in all pass-through payments. Even if a modest pro rata reduction is required, however, we do not anticipate serious consequences for access to new technology services for several reasons. First, the payment methods used to calculate pass-through payments have the potential to overcompensate for these services. Second, physicians and hospitals are still likely to use these items, both to improve care and to maintain reputations for excellence. Third, there is little evidence that we are aware of that demonstrates access problems due to the large pro rata reduction made in 2002. Fourth, asking hospitals to share in the costs of new technologies gives them an incentive to assess their value before adopting them.

Medical devices. The rule notes that the proposed 2003 payments for many services that include medical devices previously eligible for pass-through payments are considerably different, and often lower, than the 2002 payments. You explain that you established the 2003 rates using your standard approach of taking hospitals' charges for these items and reducing them to costs by applying hospital-specific, department-specific cost-to-charge ratios. In contrast, the 2002 rates incorporated an estimated 75 percent of the costs of pass-through medical devices, using information from manufacturers as the basis for estimating costs.

The Medicare program has historically based its payments on hospital charge and cost data, rather than supplier information, because it strives to pay the costs of an efficient provider. Basing payments on hospital data is the preferred approach because it reflects, albeit imperfectly, the operation of the market.

In general, this method of calculating payment rates is adequate. We also recognize, however, that the outpatient PPS is extraordinarily complex and poses significant challenges to hospitals in determining appropriate coding for pass-through items. Therefore, we believe that CMS should work with stakeholders who can present credible evidence that coding issues may have led to inaccurate payment rates for services that include medical devices previously eligible for pass-through payments. We do not believe, however, that an extension of pass-through eligibility is warranted, or that data

other than hospital cost data should be used to set payment rates when reliable hospital data are available. It will also be important to monitor beneficiaries' access to procedures that include medical devices previously eligible for pass-through payments if payments for those procedures are cut significantly.

Drugs and biologicals. The incorporation of drugs and biologicals previously eligible for pass-through payments poses difficult issues. As with medical devices, basing payments on hospital-reported cost data is the appropriate approach. However, CMS proposes to bundle low-cost drugs into the base APC they are associated with while paying separately for high-cost drugs. The rule arbitrarily chooses $150 as the dividing line between high and low-cost drugs. This means that approximately 40 percent of the drugs previously eligible for pass-through payments will continue to be paid separately.

Paying separately for high-cost drugs poses significant problems. When some items are bundled and others are not, the payment system provides an incentive to use those paid separately, if these items are more profitable than the bundled items. MedPAC has documented considerable problems in payment for dialysis treatment, where some services are bundled and other services – notably drugs – are billed separately (MedPAC reports to Congress in March 2001 and March 2002). We have recommended, and CMS is currently undertaking a study, to expand the services included in the bundled dialysis payment to avoid these incentives. In the case of the proposed outpatient PPS payments, there is the additional incentive to substitute a high-cost drug that is separately payable for a lower-cost drug that is bundled into the APC payment for the service. If hospitals act on this incentive, it could have consequences for patients, the program, and the pharmaceutical industry.

We appreciate the difficulty you face in incorporating drugs into the standard APC rates, given that many drugs are an input to numerous services. We also agree with the need to ensure adequate payment so that beneficiaries are guaranteed access to needed treatments. However, paying separately for high-cost drugs has the potential to distort the payment system. Therefore, we urge you to limit the amount of time that this policy is followed and work to move more drugs into the base APCs. We look forward to learning more about the steps CMS will take to further that aim.

The methodology used to set payment rates for drugs relies on hospital's, reported costs, as determined by the 2001 claims and the latest available cost reports. It will, in many cases, result in lower payments for drugs in 2003 than in 2002, when pass-through payments were received. The rule notes, however, that the previous payment rates were established based on average wholesale prices (AWPs) set by manufacturers. Many observers have noted that AWP is generally much higher than hospitals' acquisition costs for drugs. As with the medical devices, we believe that hospital cost data is preferred for setting payment rates. However, given the newness of the payment system and the coding challenges it presents to hospitals, careful consideration should be given to stakeholder comments on payment for specific items. It will also be important to monitor beneficiaries' access to drugs and biologicals that experience significant cuts in payment.

We are concerned that many of the drugs previously eligible for pass-through payments will now be reimbursed at a higher rate in other settings, such as physicians' offices, where CMS will continue to pay 95 percent of AWP. These payment differences may result in decisions regarding the setting of care that are based on financial, rather than clinical, criteria. This difference in payment rates across settings is not a sufficient reason to change payments for these drugs in the hospital outpatient setting, but requires a new approach to paying for Part B drugs.

Payment for Part B drugs in other settings

A series of studies by the GAO and the Office of the Inspector General have provided ample evidence that Medicare pays far more than market price for the outpatient prescription drugs that it covers under Part B. Overpayments not only cost the program money but lead to inflated coinsurance payments for beneficiaries. The Commission recognizes that changes in the drug payment method may have implications for other parts of the payment system, for example, if inadequate payments for some services are cross-subsidized by overpayments for drugs. We think this cross subsidization, when it exists, is bad public policy. We understand that Congress and CMS are considering ways of reforming the current system. If Congress or CMS implements a new system this year, the Commission will monitor the impact of payment changes and their implications for beneficiary access. We will recommend refinements if necessary. If Congress does not act on the issue this session, we will focus our efforts on analyzing options for change.

Update to the conversion factor

The conversion factor for CY 2003 will be updated by the hospital market basket, which is now estimated to be 3.5 percent. CMS has authority under statute to modify updates in response to unnecessary increases in the volume of services provided. While CMS indicated its intentions to assess alternative volume control mechanisms for future implementation in its proposed rule for the outpatient PPS (1999), no additional plans have been discussed. Given the incentives for increased volume that are inherent in a fee schedule like the outpatient PPS, CMS must carefully track changes in the volume of services delivered and develop appropriate mechanisms to respond to excessive increases in volume. In a similar vein, we urge CMS to be vigilant in tracking increases in coding intensity and looking for patterns of upcoding. The agency has the authority to use the update as a mechanism to correct for upcoding.

Distributional impacts of the proposed changes

As noted above, the proposed payments for APCs that include technologies coming off the pass-through list are generally lower than the 2002 payments. The proposed rule notes that the incorporation of pass-through items into the base APC payment rates, and the associated reduction in payments for high-technology services, has distinct distributional impacts for hospitals. These impacts arise because changes to the relative weights are made in a budget neutral manner. In particular, large urban and teaching hospitals are expected to receive a smaller increase in payments than smaller and rural

hospitals because they have a service mix that includes more services that incorporate technologies previously eligible for pass-through payments. In contrast, large urban and teaching hospitals benefitted from the changes in the relative weights made in 2002 to incorporate some of the costs of pass-through devices into the base payment rates, while smaller and rural hospitals saw payments decline. Therefore, the distributional shifts expected in 2003 offset those experienced in 2002 to some extent.

In addition to the gains in payment expected in 2003, small rural hospitals (those with 100 or fewer beds) will continue to be held harmless from losses under the outpatient PPS. In 2004, however, they will no longer receive those additional payments. We urge CMS to carefully study the performance of small rural hospitals and evaluate the impact of ending their hold harmless status.

MedPAC appreciates your consideration of our comments. If you have any questions, feel free to contact me or Mark Miller at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

GMH/cw/w