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September 16, 2005

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

Re: File code CMS-1501-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit comments on CMS's proposed rule entitled: *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates*, Vol. 70, No. 141, pages 42673-43011 (July 25, 2005). We appreciate your staff's ongoing efforts to administer and improve the payment system for hospital outpatient services, particularly considering the agency's competing demands. We have comments on several of the issues addressed in the proposed rule, and where applicable we have included the captions specified in the rule.

As you know, the outpatient prospective payment system (OPPS) classifies services provided in outpatient departments into ambulatory payment classification (APC) groups. Each APC group has a relative weight, and the OPPS determines payments as the product of the relative weights and a conversion factor. The proposed rule documents changes in the composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. It also discusses new policies required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), payment for drugs, parameters for outlier payments, and the movement of some services from new technology APCs to clinical APCs. Finally, the rule estimates the calendar year 2006 update to the conversion factor.

Our comments on the proposed rule center on three issues: the proposed adjustment of payments to sole community hospitals (SCHs) located in rural areas, payments for nonpass-through drugs, and discounted payments for certain imaging services when a hospital performs multiple imaging services in a single session.

Rural hospital adjustment

The MMA requires the Secretary to study whether rural hospitals incur greater costs than urban hospitals under the OPSS. If the Secretary finds a cost discrepancy, the MMA directs the Secretary to adjust OPSS payments to reflect the higher costs of rural hospitals.

The proposed rule includes an analysis by CMS of hospitals' outpatient costs per unit. Based on results of that analysis, CMS proposes to pay rural SCHs 6.6 percent above the standard APC payment rates.

CMS's analysis consists of a series of regressions that have the hospital as the unit of observation. The dependent variable in the first regression discussed in the proposed rule is hospitals' cost per unit from furnishing OPSS services. This regression has several explanatory variables, but the text in the proposed rule focuses on one: an indicator of whether a hospital is located in a rural area. Statistical tests show this variable has only marginal significance (p-value = .058), so CMS could have concluded that rural hospitals do not have higher costs than urban hospitals. Indeed, the proposed rule states that the "evidence is weak." CMS pursued the issue further, performing additional regressions that have hospitals' costs per unit as the dependent variable and that separate rural hospitals into several groups, including rural SCHs.

Results from these additional regressions show rural SCHs have statistically significant higher costs than urban hospitals. Based on this finding, CMS proposes to increase OPSS payments for rural SCHs.

We have three concerns about CMS's analysis:

- Model specification.
- Whether it is appropriate policy to focus payment adjustments on SCHs.
- The additional payments do not focus on assuring beneficiaries' access to care.

Model specification issues

We believe the regression model excluded some important variables that would have more completely identified whether a rural location has a significant effect on hospital costs. Conceptually, the kinds of variables that should be added reflect the financial pressures hospitals face and the structure of the hospitals' markets. The rationale for measures of financial pressure is that financial pressure can affect a hospital's incentive to hold down costs. The rationale for measures of market structure is that market structure can affect the competitive pressure on a hospital, which can affect their costs.

Focusing payment adjustments on SCHs may not be appropriate

Hospitals should not receive additional payments for relatively high costs if those high costs are due to inefficiency. It is plausible that the high costs experienced by SCHs are due to inefficiency because SCHs have special payment status under both the inpatient PPS (IPPS) and OPSS. Under the IPPS,

Medicare pays SCHs the greater of the IPPS amounts or amounts based on their historical costs updated to the current year. Under the OPSS, SCHs have had “hold harmless” status in 2004 and 2005, getting paid the greater of their PPS amounts or the amounts they would have been paid under the cost-based system that preceded the outpatient PPS. Under both PPSs, SCHs may be under less financial pressure than hospitals that are paid strictly their PPS amounts. CMS should investigate whether the higher costliness of SCHs is due to less financial pressure or to factors that are beyond their control.

Payment adjustments should focus on access to care

The central objective of any payment policy should be to ensure beneficiaries’ access to care. Many SCHs are near other hospitals that have opened since the SCHs were granted their status. Others are near critical access hospitals, which are excluded when CMS considers whether a hospital meets the criteria for being an SCH. Because they are often near other hospitals, many SCHs are not essential to beneficiaries’ access to care. Consequently, we believe payment adjustments should not focus on SCHs in rural areas.

We acknowledge that CMS is legally required to make this payment adjustment based on whether a hospital has a rural location. However, we believe a more appropriate policy would adjust payments to hospitals with relatively high costs for factors beyond the hospital’s control, such as a relatively small scale of operation. Consequently, we encourage the Secretary to offer a legislative proposal to the Congress that would allow adjustments to OPSS payments to small-scale hospitals. Small scale could be measured by a hospital’s volume of outpatient services provided. Of course, it is possible that a hospital has a small scale because of poor performance or because it is in a market with excess capacity. Therefore, payment adjustments should be directed only to hospitals that are at least a specified number of miles from other hospitals.

Payments for nonpass-through drugs

Our comments on payments for nonpass-through drugs include sections on payments for specified covered outpatient drugs (SCODs), overhead and handling costs for SCODs, and the issue of packaging drugs with related procedures for payment purposes.

Payment for specified covered outpatient drugs

The MMA directs Medicare to pay for SCODs provided in outpatient departments at the drugs’ average acquisition costs beginning in 2006. But, if the data on acquisition costs are not available, the MMA allows Medicare to use alternative rates. The Government Accountability Office (GAO) has collected data on the purchase price of drugs that comprise most of the Medicare spending on SCODs, with the intent that Medicare could use them as acquisition costs. However, CMS has proposed to use 106 percent of manufacturers’ average sales price (ASP), citing three problems with the purchase prices from GAO:

- The purchase prices do not fully account for manufacturer rebates or payments from group purchasing organizations.

- It would be difficult to update the purchase prices during 2006 and subsequent years.
- The purchase prices are from a less recent time period than the ASP data, and the purchase prices could have increased during the intervening period.

In cases where ASP data are not available, CMS will base payments on charge data from claims, adjusted to costs.

We acknowledge the problems presented by the purchase price data, and we recognize use of ASP data as a viable alternative. The ASPs are based on prices that manufacturers report to CMS every quarter and are net of discounts and rebates. However, a limitation of ASP data is that CMS derives ASPs from manufacturers' sales to all distribution channels—wholesalers, group purchasing organizations, hospitals and other providers such as physicians. Furthermore, reporting may not be consistent across manufacturers, and CMS may need to verify the accuracy of ASP data through confidential audits.

Although we support CMS's proposed use of ASPs, we are concerned about the proposal to pay most SCODs at a rate of 108 percent of ASP—106 percent of ASP for the drug and an additional 2 percent for handling costs. CMS's analysis in the proposed rule suggests that, for drugs covered by GAO's survey, hospitals' mean purchase price was equivalent to 103 percent of ASP. Given that average ASP values have declined in recent quarters and that GAO's data do not fully reflect rebates, we believe that the proposed payment rates may be too high.

Overhead and handling costs for specified covered outpatient drugs

The MMA directed MedPAC to submit a report to the Secretary on whether the payments for SCODs should have an adjustment to cover the costs of overhead and handling expenses. Our analysis suggests that these costs are not negligible. This is an important finding because of the MMA's requirement that CMS begin paying hospitals for SCODs on the basis of acquisition costs in 2006. Payments that equal the true acquisition cost of the drug do not compensate hospitals for overhead and handling costs.

We included the mandated study as part of our June 2005 Report to the Congress. We recommended that the Secretary establish separate, budget neutral payments to cover the costs hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals. We also recommended that the Secretary:

- define a set of handling-cost APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes that affect handling costs;
- instruct hospitals to submit charges for these APCs; and
- base payment rates for the handling-cost APCs on submitted charges, adjusted to costs.

We are, in general, pleased that CMS's proposed method to pay for overhead and handling costs beginning in 2008 reflects our recommendations. The method would establish three HCPCS codes and three corresponding APC groups that are differentiated by characteristics affecting overhead and handling costs. Further, CMS proposes to instruct hospitals to submit charges for overhead costs to the appropriate HCPCS for each drug administration. CMS would collect these charges for two years (2006

and 2007) and consider basing payments for the three handling-cost APCs in 2008 on these charges adjusted to costs. This is similar to the method CMS uses to set payment rates for procedural APCs.

However, we are concerned about CMS's proposed method for paying overhead and handling costs in 2006, when the charge data necessary to set payments under the proposed method for 2008 are not yet available. For 2006, CMS proposes to pay hospitals 2 percent of ASP on each drug administration. We are concerned about the proportional nature of this method. We recognize that this is a difficult problem with no easy solution because of lack of data. But, CMS should consider another alternative because the proposed method ties reimbursement for handling costs directly to the acquisition cost of a drug, even though a high acquisition cost does not imply high handling costs. A potential consequence is that payments for the handling costs of a particular drug could differ sharply from the handling costs hospitals actually incur. In addition, CMS's proposed approach could become permanent rather than temporary. Finally, we are concerned that this method could result in higher prices paid by hospitals because it gives manufacturers an incentive to increase prices.

In place of the proposed method, we suggest that CMS estimate the total dollars that should be dedicated to paying handling costs—additional to the amount for acquisition costs—and determine how much of the total should be allocated to groups of drugs that are similar with respect to their handling costs. The following is an outline of a method CMS could use. Note that within this approach, hospitals would receive the same payment for handling costs for different SCODs within the same category of handling costs, no matter the drugs' acquisition costs.

- *Estimate pool of total handling costs.* CMS has proposed to pay handling costs for each SCOD in 2006 at a rate of 2 percent of the drug's ASP. Irrespective of the rate CMS chooses to use for acquisition costs (CMS has proposed 106 percent of ASP, but we speculate a lower rate may be justified), 2 percent of ASP is a viable basis for creating a pool of total handling costs for all SCODs. For each SCOD, CMS can calculate the product of an estimate of the drug's total volume and 2 percent of the drug's ASP. The total pool would be the sum of these products.
- *Collect SCODs into categories.* Collect the SCODs into the three handling-cost APCs discussed above.
- *Estimate handling costs for each category.* CMS can determine how much of the total pool should be allocated to each handling-cost APC using estimates of the relative handling costs and volume for the drugs in each APC. Our analysis of handling costs shows that handling costs per drug administration are about 15 times greater for drugs with the greatest handling costs relative to the drugs with the smallest handling costs. CMS could use this range of relative handling costs or handling cost data from other interested parties to determine how much to allocate to each APC. Within each APC, the handling-costs should be divided equally among drug administrations. Note that the range of relative costs we cited excludes radiopharmaceuticals, for which we have no data.

A final issue concerning drug handling costs is CMS's decision to collapse the seven handling-cost categories we developed in our June 2005 Report to the Congress into the three handling-cost APCs. We acknowledge that CMS's stated rationale is justifiable: Some drugs can fall into more than one of our categories, usually because different hospitals use different forms of the same drug. However, after

CMS collects the charge data necessary to set rates for the handling-cost APCs, we encourage CMS to explore whether it would be reasonable to expand the number of handling-cost APCs beyond three. We also encourage CMS to further research how to best construct categories of handling-cost APCs for radiopharmaceuticals, which are likely to require greater resources than drugs and biologicals

Packaging drugs with related services

Separate payments for the handling costs of SCODs will increase the degree of unpackaging in the OPSS. Under the OPSS, the unit of payment is the APC. Some APCs have extensive packaging, but every drug that costs at least \$50 per administration has its own APC as well as a separate payment for drug administration. We have long been concerned about the incentives created by the unpackaging that exists in the OPSS.

When a payment system packages some products and pays separately for others, providers have an incentive to use the products paid separately, if they are more profitable than packaged items. In an October 2003 Report to the Congress, we documented considerable increases in program spending on drugs that are used in dialysis treatment and billed separately from the composite rate. In the OPSS, providers have an incentive to use a higher-cost drug that is paid separately in place of a lower-cost drug that is packaged into the APC payment of the applicable service. If hospitals act on this incentive, it could raise beneficiaries' overall cost sharing, Part B premiums, and program spending.

In addition, setting payment rates for small packages is likely to be less accurate than setting rates for larger packages. Isolating a single input requires great precision in setting rates. With greater packaging, variations in charging practices are more likely to balance out, leading to payment rates that, on average, are closer to costs.

Finally, we believe incentives to use separately paid products may be exacerbated if CMS implements its proposal to apply budget neutrality for SCODs by reducing payment rates in all APCs except for the SCODs. For example, the financial incentive of using a SCOD instead of a packaged drug would be increased by the proposed method of budget neutrality. Moreover, it would create higher payments for hospitals that are relatively high users of SCODs and reduce payments for low users.

Discount for multiple diagnostic imaging procedures

Under the OPSS, hospitals receive full APC rates for each diagnostic imaging service on a claim, even though hospitals can save costs when they perform multiple services using the same imaging modality on contiguous body parts in the same session. We recommended in our March 2005 Report to the Congress that the Secretary improve coding edits that detect unpackaged diagnostic imaging services and reduce payments for multiple imaging services performed on contiguous body parts.

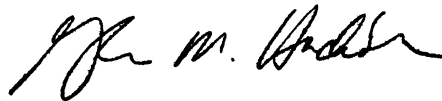
The proposed rule acknowledges that the OPSS currently discounts payments for multiple surgical procedures performed on the same patient in the same operative session. CMS believes a similar policy for diagnostic imaging services would be more appropriate than the current policy.

Table 32 of the proposed rule groups imaging services into 11 “families” by imaging modality and contiguous body area. Analysis by CMS shows that many claims report more than one imaging service within the same family provided on the same day. Further analysis shows that many costs incurred for an initial imaging service are not incurred in subsequent services. The proposed rule concludes that excluding the costs that are not incurred in subsequent services justifies a 50 percent reduction in payments for subsequent services provided in hospital outpatient departments. Therefore, CMS is proposing to reduce by 50 percent OPPS payments for multiple imaging services within the same family performed in the same session. Full payment would be made for the service with the highest APC rate, and the 50 percent discount would be applied to the APC rate for each additional service in the same family performed in the same session.

We support the direction that CMS proposes to take on this issue. However, CMS proposes to make these discounts budget neutral, preventing potential budgetary savings and lower cost sharing for beneficiaries. We acknowledge that CMS is legally required to make this budget neutral adjustment, but we encourage the Secretary to offer a legislative proposal to the Congress in order to capture the potential savings.

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

Sincerely,



Glenn M. Hackbarth
Chairman