MEDPAC Medicare Payment Advisory Commission

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October 7, 2004

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: File code CMS-1427-P

Submitted electronically

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the notice of proposed rulemaking (NPRM) entitled *Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates* (August 16, 2004). We appreciate the ongoing efforts of the CMS staff to administer and improve the outpatient prospective payment system (PPS), particularly considering competing demands on the agency.

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 composition of some APC groups and proposes changes to the relative weights based on analysis of claims and cost report data. The NPRM discusses new policies required by the Medicare Prescription Drug and Modernization Act (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 2005 update to the conversion factor.

Our comments on the proposed rule center on three issues: changes to the outlier policy; payment for drugs; and movement of items from new technology APCs to clinical APCs.

Outlier payments

Based on MedPAC analysis, CMS proposes to add a fixed dollar threshold to the outlier policy. Previously, the only threshold was relative to each APC's payment rate. Under the new proposal, in order for a hospital service to qualify for outlier payments in 2005, it must both cost more than 1.5 times

the APC payment amount AND cost more than the sum of the APC rate plus $625. The outlier payment will cover 50 percent of the costs above the threshold. Although MedPAC recommended eliminating the outlier policy, we appreciate that implementing a dollar threshold is the only regulatory action CMS can take. We agree with CMS's conclusion that the dollar threshold will allow for better targeting of outlier payments to the most expensive services.

Payments for drugs (drugs, biologicals, and radiopharmaceuticals non-pass-throughs)

The MMA required CMS to pay separately for all drugs costing $50 or more per administration. It set specific payment levels based on a reference average wholesale price (AWP) for most, but not all, drugs. Given the MMA provisions and other considerations, the proposed payment rates for drugs are more complex than ever. Payments for drugs are determined many different ways, depending on their cost, their treatment under the MMA, and their newness. One indicator of complexity is the number of APC codes for separately paid drugs: of a total of about 780 APCs, just under 40 percent are for separately paid drugs. MedPAC has concerns about the threshold for separate payment, payment methods for drugs not covered by the MMA, the proposed treatment of Aranesp and Procrit, and the implications of payments for new drugs for the pass-through provision.

We continue to be concerned about the use of an arbitrary cut-off ($50 per administration) for separate payment of drugs. The difficulties of this standard are highlighted in the proposed rule, where a class of drugs, anti-emetics, had some drugs fall above the threshold while others fell below. To ensure that payment rules do not impede access to a particular anti-emetic, CMS is proposing an exception to the packaging rules that would provide separate payment for all anti-emetics, including those falling below the threshold. While treating all anti-emetics similarly probably makes sense, the policy giving rise to this situation is problematic. MedPAC is concerned that separate payment for some, more expensive, drugs gives hospitals an incentive to use those drugs rather than those that are packaged into the payment rate for related services. The threshold also gives manufacturers an incentive to price their drugs to ensure that they are above $50 per administration. CMS should carefully analyze alternative thresholds or the creation of larger bundles to allow for alternative approaches once the MMA provision requiring a $50 threshold expires in 2007.

The MMA established payment methods for several categories of separately paid drugs. For two groups of drugs, CMS had discretion in how to set payment: those coming off the pass-through list this year; and the 41 drugs that have never been eligible for the pass-through, or that were historically packaged, but are now above the threshold for separately payment. The agency proposes to treat these groups differently, with the drugs coming off pass-through paid as if they were covered by the MMA (based on a reference AWP), and the older drugs paid based on the median cost data from claims. Given that one purpose of the pass-through payments is to allow time to accumulate data on costs, there seems to be no reason to believe that claims data are more accurate for one category of drugs than the other. The drugs coming off pass-through and the older drugs should be paid consistently. To help inform the decision of which approach to take, and to better understand the impact of the MMA, it would be useful to have a comparison of what the rates for separately paid drugs would be using the claims data with the rates in the proposed rule.

The MMA requires CMS to pay 95 percent of AWP for newly approved drugs and biologicals that do not have a HCPCS code. CMS also proposes to pay 106 percent of the average sales price (ASP) (as determined under the physician fee schedule) for drugs and biologicals newly approved by the FDA that have a HCPCS code. This class of drugs was not mentioned in the MMA. This proposal represents a

change in policy; previously, drugs of this nature were packaged until sufficient claims data were accumulated to calculate payment rates, unless they received pass-through status via an application process. With the change in policy, all newly approved drugs and biologicals with a HCPCS code will be paid the same, whether or not they meet the pass-through criteria of newness and costliness (MedPAC has recommended that clinical benefit also be a criterion). In addition, those newly approved drugs and biologicals that do not go through the pass-through payment mechanism will be added to the fee schedule without any control on spending. While the pass-through payments have a budget neutrality provision, the new policy does not. Given that the pass-through policy exists as a controlled mechanism for introducing new drugs into the PPS, these drugs should either be treated through the pass-through process or continue under the previous policy.

We note that the proposed rule sets payment for both Aranesp and Procrit according to the formulas in the MMA. Previously, functional equivalence was used to justify equivalent payment. As costs to the Medicare program continue to grow, the program will need to examine tools for obtaining value in its purchasing. We believe that, absent evidence that the previous policy denied beneficiaries' access to needed treatments, CMS should pursue value-based purchasing where possible.

Movement of items from new technology APCs

The outpatient PPS puts certain new technologies into separate APCs with payment based only on costs, as reported by those applying for new technology status. CMS proposes to move 24 services (as denoted by HCPCS codes) from new technology APCs to clinical APCs because the agency feels it has adequate claims experience on which to estimate costs. A number of PET scans are included in the services to be moved in 2005, for which the claims data indicate a significant reduction in payment. CMS is considering three approaches to setting payment for these services: a) use the claims data; b) keep the services in a new technology APC; or c) base payment on a blend of these two approaches. For example, payment for a PET scan used in diagnosing lung cancer (e.g., HCPCS G0210) would decline from $1,450 in 2004 to $899 in 2005, if payment were based on the hospital cost data. The blended payment approach would result in a payment of $1,150.

Services are placed in the new technology APCs based on data submitted by the applicant. One goal of the new technology APCs is to allow sufficient time for data on costs to accumulate. Barring convincing evidence that the cost data from hospitals are flawed and the resulting payment rates would limit beneficiary access to care, CMS should use hospital cost data to set payment rates for services moving from the new technology APCs. In this way, the same methodology will be used to set payment rates for services already in a clinical APC and those moving from a new technology APC to a clinical APC. MedPAC appreciates your consideration of our comments. If you have any questions, feel free to contact me or Mark Miller, Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman