MEDPAC Medicare Payment Advisory Commission

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October 14, 2003

Thomas Scully, 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-1229-P

Dear Mr. Scully:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the notice of proposed rulemaking (NPRM) entitled *Medicare Program; Payment Reform for Part B Drugs* (August 20, 2003). We appreciate your staff's ongoing efforts to improve the way Medicare pays for drugs covered under Part B, particularly considering the competing demands on the agency. We have comments on several issues addressed in the proposed rule.

As you know, MedPAC addressed the issue of Medicare payments for outpatient drugs under Part B in our June 2003 *Report to the Congress: Variation and Innovation in Medicare.* We found that Medicare payments for drugs far exceed provider acquisition costs and we analyzed the advantages and disadvantages of a number of different options to reform the payment system. At that time, we did not recommend any one particular approach but argued that each of the alternatives reviewed in the report would be a significant improvement over the current payment system. We also stated that drug administration fees do not reflect the true costs of providing drugs to beneficiaries.

In the proposed rule, the agency does not indicate a preferred approach, but asks for comments on four possible payment methods: lowering payments for specific drugs based on comparability of prices paid by private purchasers; basing payments on an average of widely available discounts from average wholesale prices (AWPs); basing payments on prices derived from market monitoring; and establishing a competitive acquisition program and average sales price (ASP) system. In our June 2003 report, we analyzed three of these approaches, but did not address the first alternative - basing payments on prices comparable to those paid by private purchasers. After commenting on this alternative, we briefly summarize our analysis from June 2003 on the three other approaches. The full discussion is available at www.medpac.gov.

Payments based on comparability

MedPAC is concerned that payments based on comparability could result in increased regional variation in Medicare payment rates, without any evidence of underlying differences in acquisition costs. In addition, this method would not provide savings comparable to the other identified approaches.

This proposal, based on section 1842(b)(3)(B) of the Social Security Act, limits Medicare payments for a drug to what Medicare contractors pay when the same drug is provided to their private policyholders and subscribers under comparable circumstances. Individual Medicare carriers, including Durable Medicare Equipment Regional Carriers (DMERCs), would report pertinent information to CMS. If the agency determined that a carrier's lower private payment for a drug has comparability in a particular location, the lower private payment limit would apply in that single locality.

Permitting payment rates to vary for some drugs in some local areas would make it harder to implement a payment system in which Medicare pays appropriately for all drugs. Further, this approach runs counter to the CMS policy, initiated in January 2003, of choosing a single drug pricer (SDP) to determine AWPs for Part B carriers[1] to ensure that all providers would be paid at the same rate for identical products. At the time, CMS noted that implementation of a single drug pricer would create the infrastructure for further changes, including permitting the carrier to use market surveys to calculate payment rates based on what physicians and other providers pay for drugs.

In addition, the potential savings that could be achieved with this approach are limited. Most private payers use payment methods similar to Medicare's to pay for physician-administered drugs. Physicians purchase drugs from suppliers and manufacturers and bill payers at a rate based on AWP. However, payers often pay less for drugs used with durable medical equipment, so Medicare might save money applying the comparability approach for these drugs. Payments for drugs used with durable medical equipment represent about 20 percent of total Medicare spending for Part B drugs.

Payments based on average discount from AWP

Under this approach, the Medicare payment limit would be set between 80 and 90 percent of listed AWPs as of April 1, 2003. Prices would be updated annually based on increases in the consumer price index for medical care. Medicare payments for new drugs would be based upon information supplied by each manufacturer on the anticipated widely available market price for their product.

MedPAC believes this method would lower the price Medicare pays for existing covered drugs but might provide some incentive for manufacturers to set prices for new drugs at AWPs higher than might otherwise be the case. As in the current system, providers would

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[1]The DMERCs also have a system to ensure a single drug price for each HCPCS drug code for the claims they process.

have the incentive to switch from an existing drug to an equally effective new drug priced with a higher AWP to maximize revenue. In recent years, there has been rapid diffusion of new covered drugs under Part B.

Payments based on market monitoring

Medicare payments would be based upon widely available market prices as reported in data collected by the General Accounting Office and the HHS Office of the Inspector General. Payment rates for drugs without market based price information would be based upon the average discount off AWP. In cases where the market price was less than 80 percent of AWP, transition to the market based price would be made in increments of 15 percentage points annually. CMS would also develop additional sources for market based prices.

Like the previous approach, we believe this method would result in lower payments for existing drugs but could lead to higher prices for new products. In addition, since market surveys would not capture rebates and private discounts provided by manufacturers to their best customers, this method could result in wider variation in prices, with providers with lower market shares paying higher prices.

Payments based on a competitive acquisition and average sales price (ASP) system

Under this approach, entities within a designated area would bid to supply physicians with covered drugs within categories determined by the Secretary. Bids would be evaluated on the basis of price, ability to ensure product integrity, customer service, and prior experience. Physicians would be able to make an annual selection to obtain drugs through a winning bidder or purchase drugs directly and bill Medicare. Physicians who billed Medicare would be paid based on the ASP for the drug. Payments would be set at a rate between 101 and 112 percent of the ASP.

We believe that both a competitive acquisition method and an average sales price system would allow Medicare to pay more accurately for drugs. However, policymakers would have to address a number of design issues. The structure of the bidding process, the size of service areas, and the type of drugs subject to the bidding process would affect the feasibility and savings potential of the competitive acquisition system. The proposed rule does not provide enough detail to determine how this system would work. CMS should provide an opportunity for comment on a more detailed proposal before implementing a new payment system based on this approach.

Finally, we believe that the approaches proposed in the NPRM should result in Medicare paying more appropriately for drugs. However, insuffic ient detail is provided to fully understand how the proposed new payment systems would be implemented.

Payments for separately billable ESRD drugs

Medicare pays dialysis facilities a prospective payment— the composite rate—for each dialysis treatment they provide in dialysis facilities (in-center) or in patients' homes. In addition, providers receive a separate payment for furnishing certain injectable drugs during dialysis that are currently excluded from the composite rate payment bundle. Providers receive 95 percent of the AWP for separately billable injectable medications other than erythropoietin administered during in-center dialysis. The Congress has set the payment for erythropoietin at $10 per 1,000 units.

CMS believes that it is important to pay appropriately for the composite rate and separately billable drugs and not have payments for one cross-subsidize the other. Therefore, CMS proposes to include ESRD separately billable drugs for which providers are paid 95 percent of the AWP when reforming payments for Part B drugs. Based on MedPAC's recent analysis that suggests that the profitability of the separately billable drugs is subsidizing the lower margins under the composite rate, the agency is proposing to increase providers' payments to offset the savings that will occur when reforming drug payments. This would result in the same amount of money being paid to dialysis providers in 2004, but with more accurate payment for separately billable drugs. CMS prefers to increase providers' payments by increasing the composite rate and is requesting that the Congress give them the authority to do so. However, even without explicit authority from the Congress, CMS indicates that the agency can make additional payments to providers for the administration, handling, and storage of drugs and biologicals. The agency's proposal does not include erythropoietin, the costliest of these drugs in terms of spending by Medicare and beneficiaries, because its payment rate is statutorily set by the Congress.

MedPAC supports the agency's efforts to refine payments for ESRD drugs. However, the Commission is concerned that CMS's proposal does not address how the agency plans to monitor the effect of such a change on dialysis quality. If aggregate payments for composite rate services and separately billable drugs are not adequate in the future, patients' access to high-quality care may be affected. Since 1993, CMS's annual survey of dialysis quality has reported on key aspects of the dialysis process, such as dialysis adequacy and outcomes associated with certain injectable drugs, such as erythropoietin and intravenous iron. We commend CMS's commitment to improving dialysis quality and urge the agency to expand its effort to include use of and outcomes associated with other key injectable drugs, such as vitamin D analogues and antibiotics. Doing so will further ensure the delivery of clinically appropriate care to dialysis patients.

Finally, the Commission is concerned that CMS's proposal neither provides incentives for providers to be efficient in furnishing these drugs nor addresses the deficiencies in the content of the composite rate bundle. Providers have strong incentives to control the costs of services included in the composite rate payment bundle. However, they have few incentives to control the costs of commonly furnished drugs billed outside the composite rate. To address these deficiencies, MedPAC believes that CMS should, as soon as possible, broaden the dialysis payment bundle to include commonly furnished injectable drugs and other services that are currently excluded from it and account for factors that affect providers' costs, including patient case mix. Modernizing the outpatient dialysis payment system and monitoring quality will better enable Medicare to achieve its objectives of providing incentives for controlling costs and promoting access to quality services. Although MedPAC supports paying appropriately for drugs furnished to ESRD patients, CMS must devote the resources necessary to assure that the implementation of a broader bundle is not delayed.

Increases in payments related to furnishing or administering drugs

In conjunction with reform of the payment system, the agency proposes to raise the practice expense for administration of chemotherapy. Practice expense RVUs are calculated based on data from the American Medical Association (AMA) Socioeconomic Monitoring System (SMS), along with data collected through expert panels. The most recent SMS data on practice expense are from 1999. Because of questions raised about the adequacy and timeliness of SMS data, the Congress[2] directed the agency to establish a process to incorporate supplemental survey data collected by other organizations. In this NPRM, the agency proposes to adjust the practice expense for administration of chemotherapy based upon the results of a supplemental survey submitted by the American Society of Clinical Oncology (ASCO) in 2002. Although it met the criteria established by the agency, CMS notes that practice expenses calculated on the basis of this survey are more than 174 percent higher than the all physician average and 45 percent higher than those for the next highest specialty. These adjustments to physician payments would not be budget neutral. The agency intends to continue investigating why these expenses should be so far above other specialties.

We do not disagree with the direction taken by CMS and recognize the difficulty faced by the agency in determining the proper level for practice expense. But MedPAC is concerned about the use of individual supplemental surveys alone to address practice expense issues. As we stated in our June 2003 Report, if the agency continues to use the current methodology to determine practice expense values, a data source to replace the SMS must be assured. One option for collecting such data would be for the agency to pursue a collaborative approach, perhaps involving the AMA, physician specialty societies, and the federal government.

[2]Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA).

MedPAC appreciates the opportunity to comment on this important policy issue. The Commission also values the willingness of the CMS staff to provide relevant data and to consult with us concerning technical policy issues. We look forward to continuing this productive relationship.

If you have any questions or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

JS/wc