American Hospital Association

Special Bulletin

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CMS Issues Proposed Medicare Part B Prescription Drug Payment Model

This bulletin is 5 pages.

On March 8, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to test new models for how Medicare Part B pays for prescription drugs provided in physician offices and hospital outpatient departments (HOPDs), and by durable medical equipment (DME) suppliers.

Medicare currently pays physicians and HOPDs for Part B drugs at the rate of the average sales price (ASP) plus 6 percent. This ASP-based payment for drugs is in addition to a separate payment made in physician offices and HOPDs for administering the drug. CMS and others, including the Medicare Payment Advisory Commission, have noted that, under this methodology, costly drugs receive higher add-on payment amounts, that payment does not vary based on the effectiveness of a particular drug, and that payment does not take into consideration the cost of clinically comparable drugs that may be priced differently. The agency postulates that the ASP methodology may encourage the use of more costly drugs because the 6 percent add-on generates more revenue for these drugs. Therefore, it proposes a two-phase model – the Part B Drug Payment Model – that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries.

Like the Medicare program and other insurers, hospitals and their patients also bear the burden of out-of-control drug costs. As such, the AHA supports finding ways to rein in these skyrocketing drug prices. However, it is critical that proposed solutions do not unfairly penalize hospitals or physicians. The AHA is analyzing the proposed rule, and we look forward to working with CMS to find policy solutions that focus on the core problem of unrestrained pricing by drug companies.

Highlights of the proposed rule follow.

HIGHLIGHTS

Model Overview. CMS proposes two phases for the Part B Drug Payment Model. In Phase I, the agency proposes to implement an alternative to the add-on component of the Part B payment methodology in different geographic areas of the country. CMS would test whether the proposed alternative approach would strengthen the financial incentive for providers to choose less costly drugs. Specifically, it would change the add-on payment from 6 percent to 2.5 percent plus a flat fee payment of $16.80 per drug per day. CMS proposes to implement the first phase no earlier than 60 days following the issuance of the final rule. The flat fee would be updated at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period.

In Phase II, which would be implemented no sooner than January 2017, CMS would apply value-based purchasing (VBP) tools similar to those employed by commercial health plans, pharmacy benefit managers and other entities that manage health benefits and drug utilization. The proposed VBP strategies include:

- *Reference Pricing*. This policy would set a standard payment rate, a benchmark, for a group of therapeutically similar drug products.
- *Indications-based Pricing*. This tool would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time.
- *Risk-sharing Agreements Based on Outcomes*. This policy would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.
- *Discounting or Eliminating Patient Cost-sharing*. This policy would decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.
- *Feedback on Prescribing Patterns and Online Decision Support Tools*. This tool would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications. Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.

This group of tools would serve as a framework for interventions for selected Part B drugs. The agency would gather additional information on the proposed tools, including which tools should apply to which specific drugs. CMS would finalize the implementation of specific tools for specific drug codes after soliciting public input on each through a sub-regulatory process prior to implementation.

Other Approaches for Comment. CMS also solicits feedback on a number of other approaches it is considering including:

- how to create other VBP arrangements with manufacturers for Medicare fee-for-service (FFS) payment for drugs;
- whether it should consider implementing an updated version of the Competitive Acquisition Program; and
- whether it should pursue a more bundled or episode-based approach that moves beyond an FFS payment structure.

The agency would consider all comments on these approaches in future rulemaking.

Model Scope. Under the proposed model, providers and suppliers in a selected geographic area who are furnishing Part B drugs included in this model would receive alternative Part B drug payments. To eliminate selection bias, the agency would require participation for all HOPDs, physicians and other suppliers furnishing the relevant drugs in the geographic areas that are selected for inclusion.

CMS proposes to use Primary Care Service Areas (PCSAs), which are clusters of ZIP codes that reflect primary care service delivery, as the geographic unit for testing. It would determine a provider or supplier's specific geographic location based on the ZIP code for the address associated with its CMS certification number for hospital outpatient claims; the service location ZIP code for physician drug claims; and the beneficiary ZIP code for DME supply claims. **All PCSAs would be randomly assigned to one of four groups, but this would not be done until the final rule.** The four groups would be for those:

1. being paid a modified ASP add-on amount;
2. implementing VBP tools;
3. using both modified ASP add-on and VBP tools at the same time; or
4. serving as a control group that would have no change in payment and no use of VBP tools.

CMS would include the majority of drugs paid under Part B in the model, which, in general are those drugs that appear on the quarterly ASP Price Files. Some categories of drugs are proposed to be excluded from the model, including:

- contractor-priced drugs;
- influenza, pneumococcal and hepatitis B vaccines;
- drugs infused with a covered item of DME in Phase I;
- drugs separately billed by End-Stage Renal Disease facilities;
- blood and blood products; and

- drugs that are reported by the Food and Drug Administration as being in short supply.

Timing. CMS proposes that the model run for five years. Phase I would begin in the fall of 2016 (no earlier than 60 days after the rule is finalized). During Phase I, providers and suppliers that participate in the model would receive payments with either the existing statutory add-on amount or payments with the modified add-on amount. Phase II would begin no sooner than Jan. 1, 2017. When Phase II begins, providers and suppliers selected to participate in the VBP policies would begin receiving VBP-based payments for certain drugs and would participate in other VBP activities, such as feedback on prescribing patterns. CMS notes that Phase II could take several years to fully implement. However, the goal is to have both phases of the model in full operation during the last three years of the proposed five-year duration to fully evaluate changes and collect sufficient data.

TABLE 1: Summary of the Proposed Model

Phase I – ASP+X (no earlier than 60 days after display of final rule, Fall 2016)	Phase II – VBP (no earlier than January 2017)
ASP+6 percent (control)	ASP+6 percent (control)
	ASP+6 percent with VBP tools
ASP+2.5 percent and $16.80 flat fee drug payment	ASP+2.5 percent and $16.80 flat fee drug payment
	ASP+2.5 percent and $16.80 flat fee drug payment with VBP tools

Impact. As noted previously, under Phase I, the modified ASP add-on amount is proposed to be 2.5 percent plus a flat fee of $16.80. CMS asserts that the amount of the flat fee is calculated to ensure that total estimated payments under this model are budget neutral to aggregate Part B drug spending across hospitals, physician offices and other suppliers using the most recent year of available claims data.

However, although budget neutral in aggregate, CMS's proposed policies would redistribute Part B drug payment among practitioners and hospitals, with the overall effect of shifting money from hospitals and specialties that use higher-cost drugs, such as ophthalmology, to specialties that use lower-cost drugs, including primary care, pain management and orthopedic specialties.

CMS estimates that under the alternate drug payment model in Phase I, hospitals will see a decline of 2.3 percent in Part B drug payments, an estimated overall cut to hospital spending of about 0.3 percent. In aggregate, rural hospitals are estimated to experience smaller reductions than urban hospitals. Overall, spending on drugs

furnished in the physician office setting would increase, but the impact varies widely by specialty.

CMS notes that it intends to achieve savings through behavioral responses to the revised pricing. The agency believes that removing the financial incentive that may be associated with higher add-on payments will lead to some reduction in expenditures during Phase I of the proposed model through changes in physician prescribing behavior. CMS says it cannot provide an exact estimate of the amount of savings that might be achieved through behavioral responses.

In Phase II, the model would not be budget neutral, and the agency intends to achieve savings. Again, CMS does not believe that it has enough detail on the structure of the final VBP component to quantify potential savings at this time.

NEXT STEPS

Comments on the proposed rule will be accepted through May 9. Watch for a more detailed analysis in the coming weeks. The AHA will reach out to members potentially impacted by the proposed rule to seek their input to inform our feedback to CMS on their behalf.

If you have further questions, contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org.