PUBLICATION

CMS Issues Proposed Medicare Part B Drug Payment Model [Ober|Kaler]

2016

On March 11, 2016, CMS published in the Federal Register [PDF] its proposed new Medicare Part B Drug Payment Model. Comments are due by May 9, 2016. Below are some highlights of the proposed rule.

Current Medicare Part B Reimbursement Model

Medicare Part B provides prescription drug coverage to Medicare beneficiaries for drugs that are administered in a physician's office or a hospital outpatient department (such as cancer medications, antibiotic injections, and eye care treatments). Currently, Medicare Part B pays physicians and outpatient departments the average sales price (ASP) of the drug plus a 6-percent add-on.

According to CMS, the current payment model can penalize doctors for prescribing inexpensive, yet more effective drugs, as the 6-percent add-on generates more revenue for more expensive drugs. Therefore, the proposed payment model will test whether lowering the add-on percentage to 2.5 percent but adding a flat fee payment of 16.80 per drug per day will change prescribing incentives and lead to improving quality and value.

CMS says its intent is to "encourage better care, smarter spending, and healthier people by paying providers for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality." 81 Fed. Reg. 13,230, 13,231 (March 11, 2016).

The Proposed Model

CMS will test its proposed model in two phases by placing all providers and suppliers billing for Part B drugs in control or study groups based on selected geographic areas (Primary Care Service Areas). Phase 1 will focus on testing changes to Medicare Part B ASP payments, and Phase 2 will later introduce value-based pricing strategies to further evaluate changes and to collect additional data. This complete evaluation will be conducted over the course of five years, with the goal of having Phase 2 fully operational during the last three years.

Phase 1: Average Sales Price Payments

Beginning no earlier than 60 days after the final rule is published, CMS will test the changes to Medicare Part B ASP payments for drugs by creating the two groups: (1) a control group of physicians and outpatient departments that will be reimbursed under the current 6-percent add-on payment model; and (2) a study group, consisting of different physicians and outpatient departments, that will be reimbursed under the proposed payment model – 2.5 percent of ASP of the drug plus a $16.80 flat payment per drug per day.

Phase 2: Incentive and Value-Based Purchasing Tests

No earlier than January 2017, CMS will begin to test value-based purchasing arrangements, similar to those used by commercial health plans, pharmacy benefit managers, and hospitals, by further dividing the average sales price study and control groups and introducing value-based purchasing tools into the study groups. By introducing these value-based pricing strategies, CMS seeks to test approaches for transition from a volume-

based payment system into one that "encourages or even rewards providers and suppliers who maintain or achieve better patient outcomes while lowering Part B expenditures." 81 Fed. Reg. at 13,243.

The proposed value-based pricing strategies/tests include:

1. *Discounting or eliminating patient cost-sharing*, which will decrease or eliminate cost sharing for products determined to be high in value.
2. *Feedback on prescribing patterns and online decision support tools*, which will create evidence-based clinical decision support tools as a resource for providers.
3. *Indications-based pricing*, which will vary the payment for a drug based on its clinical effectiveness for different conditions.
4. *Reference pricing*, which will test the practice of setting a standard rate for a group of therapeutically similar drug products.
5. *Risk-sharing agreements based on outcomes*, which will allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with payment. This method is sometimes used in the private sector when there are limited published studies about a drug's long-term value with regard to patient health outcomes.

CMS will determine whether the proposed model will reduce Medicare spending, without limiting coverage or benefits, while maintaining or improving patient care. It will do this, in part, by utilizing a concurrent real-time claims monitoring program to track utilization, spending, and prescribing patterns while providing Medicare beneficiaries with access to the same drugs and choice of providers.

Proposed Pre-Appeals Payment Exception

The proposed model introduces a new pre-appeals payment exceptions review process for Phase II that would allow a physician, supplier, or beneficiary to seek an exception from this pricing approach by explaining why Medicare's value pricing policy is not appropriate for the beneficiary.

Additional Comments Solicited

In addition to soliciting comments associated with Phase I and Phase II, CMS is also soliciting comments on (1) how to create value-based purchasing arrangements with manufacturers under Medicare fee-for-service (FFS) payment for drugs; (2) whether CMS should consider updating the Competitive Acquisition Program; and (3) whether CMS should move from a FFS structure to a more bundled or episode-based approach. These additional comments will be considered for future rulemaking.

Ober|Kaler's Comments

By shifting Medicare payments from hospitals and specialties that use higher cost drugs to those that use lower cost drugs, the proposed change will unquestionably be controversial. Providers and suppliers should submit comments to the extent they believe CMS failed to consider important factors in its analysis.