PUBLICATION

Big Payment Changes Revealed In New Medicare Part B Drug Payment Test

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On March 8, 2016, the Centers for Medicare and Medicaid Services (CMS) unveiled a new Part B Drug Payment Model that, if implemented, would represent a radical change in Medicare reimbursement for outpatient drugs. The proposal, described as a "test" by the Center for Medicare and Medicaid Innovation, is likely to have a broad impact – affecting providers and suppliers, as well as drug manufacturers and beneficiaries. Comments are due to CMS by May 9, 2016.

Although labeled a test, it is perhaps more accurately described as a preview of the future. The two-phase model would run for five years, but CMS has stated its goal of having both phases of the model fully operational during the last three years. Absent data showing the test to be a failure, the proposed model would seem to represent CMS' payment program for the future.

Before the Affordable Care Act (ACA), a payment change of this magnitude would have required a legislative change. But through the newly created Center for Medicare and Medicaid Innovation, the ACA authorized Medicare to introduce pilot programs and demonstrations that could be expanded throughout the Medicare program if proven to reduce program expenditures while maintaining and enhancing the quality of care.

The proposal is designed to test (1) how the current reimbursement model drives the prescribing Part B drugs; and (2) whether alternate payment approaches could reduce Medicare expenditures while at the same time reward and improve Medicare beneficiary outcomes. CMS plans to use big data collected in a real-time claims monitoring program to track utilization, spending, and prescribing patterns and several other high-level claims-based measures. Success will be measured by whether it reduces net Medicare spending, without limiting coverage or benefits, while maintaining or improving patient care.

Current Law

Today, Medicare Part B generally pays physicians and hospital outpatient departments based on the Average Sales Price (ASP) plus a six percent add-on (ASP+6%). In its statement of need, CMS asserts that because the six (6) percent add-on generates more revenue for more expensive drugs the current payment methodology "encourages the use of more expensive drugs without reference to effectiveness of a particular drug, nor the cost of comparable drugs."

Proposed Part B Drug Pricing Model

The proposed model will test alternatives to the current six percent add-on methodology in a multi-phased, program beginning in Phase I, and will introduce value-based purchasing strategies in Phase II. Although all providers and suppliers furnishing and billing for Part B drugs in certain geographic areas would be required to participate in the model, not all would have their reimbursement altered during the test.

Phase I - ASP+X *(no earlier than 60 days from display of final rule -- Fall 2016)*	**Phase II - VBP** *(no earlier than January 2017)*

ASP+6% (control)	ASP+6% (control)
	ASP+6% with VBP tools
ASP+2.5% and Flat Fee	ASP+2.5% and Flat Fee
	ASP+2.5% and Flat Fee with VBP tools

As early as 60 days after the final rule is released to the public, CMS could begin to test the changes to Medicare Part B payments for drugs by creating a control group and a study group. In Phase I, reimbursement to providers in a ***control group*** will go unchanged; they will receive payment based on the current ASP+6 methodology.

Those in the ***test group*** will receive an alternative payment based on ASP plus a 2.5% add-on and a flat fee of $16.80. The flat fee, which is designed to be budget neutral, was determined based on the difference between total payments (using 2014 claims data) using the six percent add-on and total estimated payments using a 2.5 percent add-on, adjusted by the total number of encounters per day. The flat fee will be updated annually based on the CPI for Medical Care.

Providers and suppliers would be placed into a control or a study group based on Primary Care Service Areas (PCSAs), which are clusters of zip codes based upon patterns of Medicare Part B primary care services (excluding the state of Maryland where reimbursement operates under an all-payer model). CMS intends to use a stratified random design to assign PCSAs to the control group and test group. With limited exceptions, CMS is proposing to include all Part B drugs and biologicals in this model.

In Phase II, in addition to the payment-based testing, CMS would begin to test value-based purchasing (VBP) arrangements for selected Part B drugs for two of the test groups. Specifically, one test group will be paid based on ASP+6 with VBP tools; the other test group will be paid based on ASP+2.5% and flat fee with VBP tools. The VBP strategies will be more fully described in a separate proposed rule, but CMS currently proposes use of the following:

- *Reference pricing*. This VBP tool would test the practice of setting a standard payment rate – a benchmark – for a group of therapeutically similar drug products.
- *Indications-based pricing*. This VBP 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 VBP tool would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.
- *Discounting or eliminating patient co-insurance amounts*. This strategy would enable CMS to test how removing or reducing the 20% coinsurance obligation affects beneficiary behavior. It would not, however, enable providers and suppliers to waive or reduce coinsurance on their own.

In addition to the VBP tools, CMS proposes to roll out a new clinical decision support (CDS) tool in Phase II that would provide feedback based on drug utilization and prescribing patterns identified from regularly updated data from Medicare claims. In apparent anticipation of criticism that CMS is taking a very deep dive into clinical decision-making, CMS is seeking comments on the proposed CDS tool, including the approach to incorporating high quality evidence, the online format of the tool, the most effective method for physicians to access their reports on prescribing patterns, and the need for personalized reports and feedback to physicians.

Finally, as part of the test plan, CMS would also offer providers, suppliers, and beneficiaries the opportunity to dispute payments in Phase II both before a claim is submitted through a new Pre-Appeals Payment Exception Review process. After a claim is submitted, providers, suppliers, and beneficiaries can file an appeal through the current Part B administrative claims appeals process.

Looking Ahead

This proposal is controversial. Some critics consider this test to be too much too fast. Physician groups have objected that the assumptions underlying the proposal – that prescribing decisions are financially-motivated – are misplaced and that CMS has proposed a radical change that may ultimately result in higher costs from hospitalizations, readmissions, and suboptimal therapy. Others consider it a shot across the bow of the pharmaceutical industry, which has faced criticism from Congress and the Administration for rising drug costs.

CMS asserts that Phase I will be budget neutral in the aggregate, but will result in a redistribution of add-on payments between more and less expensive drugs. The overall effect, according to CMS, of Phase I will be to "modestly" shift money from hospitals and specialties that use higher cost drugs to specialties that use lower cost drugs. Phase II will not be budget neutral and the agency expects to realize savings-not currently quantifiable-in Medicare expenditures through the addition of value-based purchasing tools. The bottom line is that the impact of this test will be negative for some doctors, hospitals and patients, particularly for hospitals, pharmacies and certain physician practices where specialty medications, often more expensive, are the clinically-appropriate standard of practice.

CMS' proposal is a clear indication of the Administration's commitment to address drug pricing concerns and shift toward value-based payment and delivery models that align with delivery reform goals. Providers and suppliers should expect CMS to continue to build upon the value-based, episode-based, and bundled payment approaches proposed in this rule. It will be important for providers and suppliers to weigh-in on these proposals to help guide CMS' future rulemaking, which will result in further changes to Medicare drug reimbursement.

If you have any questions regarding the Part B Drug Payment Model being proposed by CMS or would like assistance with preparing comments, please contact the authors of this alert or a member of the Health Law Team or The Daschle Group.