Research

The Part B Demo

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On March 8, 2016, the Center for Medicare and Medicaid Innovation (CMMI) proposed a new five-year Medicare Part B payment demonstration program aimed at lowering Medicare spending on outpatient prescription drugs.[1] Currently, traditional Medicare reimburses physicians for drugs administered in an outpatient setting by paying the Average Sales Price (ASP) plus 6 percent to cover the cost of administering the drugs. The new demonstration will have two phases where adjustments will be made to this payment formula.

PHASE I

Phase I of the demonstration will do away with the ASP + 6 percent formula and replace it with ASP + 2.5 percent + a flat rate of $16.80. For example, under the current system, a drug that costs $5.00 would be reimbursed at $5.30 while a drug that costs $1,000 would be reimbursed at $1,060. Under the new system, however, the $5.00 drug would be reimbursed at $21.93, and the $1,000 drug would only receive $1,041.20 in compensation.

This calculation will apply to all outpatient prescription drugs in the demo group except most biologics and biosimilars, non-infused drugs, drugs in short supply, specific vaccines, end-stage renal disease treatments, and blood products.

Because of continued sequestration, the effective payment rate in this phase will be ASP + 0.5 percent + $16.80. This change in payment rate will make it more profitable for physicians to prescribe the least expensive drugs (typically primary care treatments), while creating a financial disincentive to prescribe the more expensive (typically specialty) treatments.

There is concern that this low payment rate overshoots the mark of discouraging doctors from always prescribing the most expensive drugs and instead creates a strong financial incentive for providers to stop offering services involving expensive prescription medications—such as cancer treatments—if the provider will be unable to recover the costs of purchasing the drugs and providing the service. Some have argued that no physician would refuse to prescribe life-saving drugs just because there was no profit to be made; however, what this argument fails to consider is whether physicians, especially those in rural or remote areas, would continue offering any services at all if they are unable to recover costs. Instead, perhaps, they may work in more urban areas, or there may be a trend away from physicians specializing in areas of medicine or diseases whose treatments are particularly expensive.

PHASE II

Phase II of the demonstration would introduce Value-Based Purchasing (VBP) tools to the Part B reimbursement system. It is not clear, however, which of the VBP tools mentioned by CMMI will actually be used.

One VBP option is reference pricing, wherein a provider is paid a specific amount for a given health care service, and providers are then able to retain any savings they are able to generate by providing care at less than that amount. Some industry experts have raised concerns that this type of model would ignore the complex and often individual-specific nature of diseases treated by many Part B medications, and may make it difficult for patients to access the most appropriate treatments because of the financial disincentive for providers to prescribe more expensive care.

Another VBP model is indication-based pricing, which ties the price of prescription drugs to their ability to treat a number of different conditions. This VBP tool raises similar problems to reference pricing, in that health care providers are given an incentive to prescribe the drug that has the best reimbursement rate, rather than focusing only on which drugs are most likely to have positive outcomes for the patient.

Outcome-based risk sharing, like indication-based pricing, ties the price of the drug to its efficaciousness. However, in outcome-based pricing, the price is tied to the drug's effectiveness in treating the specific condition that the patient has been diagnosed with, rather than its general effectiveness across different indications. This model is one of the most commonly mentioned value based purchasing models, but it is rarely used because of the substantial amount of clinical data that would be needed to support pricing decisions.

THE DEMONSTRATION

The demonstration will be implemented in two waves and will be applied to four test groups. Together these four test groups will encompass 100 percent of Medicare providers who bill for Part B services.

The first phase of the demonstration will implement Phase I's alternative add-on payment rates beginning in late 2016, and will be applied to half of the test groups. Phase II will go into effect no later than January 1, 2017. Phase II will also apply to two of the four test groups.

Test groups will be determined by the Dartmouth Atlas' Primary Care Service Areas (PCSAs), which are drawn along boundaries following those of local zip codes. The first PCSA group will participate only in Phase I of the demo and will continue to receive ASP + 2.5 percent + $16.80 throughout the entire five-year demonstration.

The second test group will begin participation later and will only participate in Phase II of the demo, receiving VBP reimbursement—whatever that turns out to be. Group three will participate in both Phase I and Phase II of the trial. The final control group will not participate in either Phase I or II and will continue to receive the current reimbursement rate.

CONCERNS

Many have raised legitimate concerns over this proposed rule, which should be addressed by CMMI before finalizing this program.

One major issue that has been raised is whether a demonstration project that requires the participation of every Part B provider in the country[2] is really a demonstration at all. The sheer scope and scale of this project looks more like a substantial change by regulators without legislative direction.

The concern about regulatory overreach is only compounded by the fear that a program that could place severe restrictions on patients' access to necessary, life-saving prescription drugs may be impossible to repeal through normal legislative channels. Any Congress that attempted to repeal the program would have to pay for the lost savings generated by the decrease in prescriptions written for expensive drugs.

CONCLUSION

The proposed demonstration project demonstrates that CMMI has listened to stakeholders' ideas regarding things like VBP arrangements and the difficulties presented by ASP+6, but it seems that this is where the investigation ended. Before moving forward with this (or perhaps any) demonstration, CMMI should invest more time in understanding not only the problems that currently exist, but what problems may be caused by these approaches to modifying the Part B reimbursement system. The regulatory body should further consider which path forward will prove best for the Medicare's fiscal health and beneficiaries in the short and long term.

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[1] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html

[2] With the exception of those in Maryland, which has its own alternative payment model