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Part B drugs revisited—yet again

Part B drugs are making news, again, despite the decision of the Centers for Medicare & Medicaid Services (CMS) to withdraw its planned pilot projects for Part B Medicare—or perhaps because of that decision.

The Medicare Payment Advisory Commission (MedPAC) included a chapter on Part B drugs in its June 2016 report, but the chapter was primarily informational and provided only a single recommendation: that Part B dispensing and supplying fees should be reduced to rates similar to those paid by other payers. That recommendation was not acted on before the end of the Obama administration.

Part B Drug Pricing

The history of pricing for Part B drugs—i.e., drugs that are administered by infusion or injection, either in physician offices or in outpatient departments—has differed from that of other pricing in Medicare. Before the Medicare Modernization Act (MMA) was passed in 2003, Part B drugs were paid at 95 percent of the average wholesale price (AWP). The problem, at least in part, was that the AWP was a reported manufacturing price that was never defined in law or regulation. It was such an unreliable indicator of what was actually paid that it was commonly known in Washington as "ain't what's paid."

Since the MMA, Part B drugs have been paid on the basis of the average sales price (ASP), plus 6 percent for administration. The switch to the ASP has been associated with a sharp decline in spending relative to the pre-MMA period: 6 percent annual growth versus 21 percent before the MMA, although the annual growth rate has been 9 percent since 2009. Although switching from the AWP to the ASP as a basis for payment produces a closer representation of the actual average acquisition cost of the drugs, the policy of making the administrative fee a fixed percentage of the ASP encourages the use of higher-priced drugs, especially if different drugs are available for treating given conditions—as is frequently the case for Part B drugs.

CMS's Proposed Part B Demonstrations

In early 2016, CMS proposed a series of Part B models that it wanted to test. One model would have used an add-on payment of 2.5 percent plus a flat fee of $16.80 per drug administration per day. These numbers were expected to be budget-neutral in the aggregate, but they also were expected to change the prescribing incentives.

Other proposed variations included the following:

- Discounted or eliminated patient cost-sharing
- Creation of an evidenced-based clinical decision support tool for clinicians to use in selecting drugs
- Use of reference pricing, involving a standard payment rate for therapeutically similar drugs, indications-based pricing that would cause the payment to vary based on drugs' clinical effectiveness for various indications, and risk-sharing arrangements based on outcomes

The reference-pricing approach would have allowed CMS to enter voluntary agreements with manufacturers linking price adjustments to patient outcomes.

The models, which were based on strategies already in use within the private sector, were

supposed to run for five years, with an evaluation performed after that time. They were to be mandatory, although only for the physicians designated to participate in each test.

Opposition to the Demonstrations—and Alternatives

Physician groups as well as patient groups vigorously opposed these mandatory demonstrations and lobbied Congress to have CMS withdraw them or to legislate against allowing them to be implemented. CMS withdrew the proposed demonstrations after Democrats lost the election.

In April, MedPAC commissioners unanimously voted for a new series of recommendations about Part B drugs for their June 2017 report. The most interesting recommendation to me—because it both advances value-based pricing and leverages market forces—is a proposed drug value program, which is being offered on a voluntary basis. Under the program, private vendors would negotiate prices for Part B drugs, and could use formularies and value-based protocols, just as they do in the private sector. The clinicians would buy the drugs at the negotiated rates, and CMS would pay that rate plus an administrative fee. Clinicians would be able to share in any savings produced through the program.

Another interesting recommendation proposes common billing codes for reference biologics and biosimilars, but it raises some complex issues, including one similar to an issue still being debated by the Food and Drug Administration (FDA): whether *biosimilars* should be called by the same name as the biologic or by a different name.[a] This debate is more complicated than the FDA's debate about generics, which are biochemically equivalent to small-molecule branded products. Biosimilars must demonstrate a functional or clinical equivalence to the branded biologic, but there is no direct comparability to the biochemical as exists with small molecules. Using the same name or a common billing code will affect the extent to which biosimilars are likely to exert competitive pressure on the pricing of biologics, and it also would leverage market forces.

The other recommendations—requiring the reporting of the ASP, reducing the payment for new drugs from wholesale acquisition price (WAP) plus 6 percent to WAP plus 3 percent, and requiring a rebate if the ASP exceeds an inflation benchmark—are all administrative pricing mechanisms aimed at reducing government spending rather than encouraging value-based pricing or leveraging market forces.

What is disappointing is that, as with the 2016 CMS mandatory demonstrations, MedPAC ignores the most obvious option: making Part B a part of Part D and allowing private drug plans to use formularies and negotiate prices so long as they have a minimum number of drugs in a class. It is easy to forget that a separate Part B program would never have existed at all but for the historical accident that the Medicare program's drug coverage was limited to Part B drugs when the program was launched in 1965, and it did not start covering outpatient prescription drugs until 2003—years after most private insurers began including outpatient prescription drug coverage in their health plans for the working population.

Private-sector plans routinely include specialty drugs in their pharmacy benefit management contracts for the under-65 population. There is no obvious reason such coverage could not also be provided for the Medicare population. However, given what we saw with the mandatory demonstration projects, the pushback from clinicians, hospitals, patients, and, of course, the drug companies is likely to be fierce. ■

a. The FDA defines a *biosimilar product* as "a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product." See FDA, "Information on Biosimilars," May 10, 2016.

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