U.S. Medicare Payment Advisory Commission Report Addresses Part B Drug Payment Policy

The Medicare Payment Advisory Commission (MedPAC or the Commission) has released its June 2017 report to Congress on Medicare and the healthcare delivery system. The report details a number of reform proposals, including a chapter devoted to the commission’s recommendations regarding Medicare payment for Part B drugs.

MedPAC is an independent congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program. In its June 2017 report, MedPAC described a number of challenges facing Medicare and offered proposals and recommendations designed to address many of those challenges. With respect to Part B drugs — which include drugs and biologicals administered by infusion or injection in physician offices and hospital outpatient departments, as well as certain drugs furnished by suppliers — MedPAC noted that since 2009, Medicare’s spending on Part B drugs has grown at an average of about nine percent per year. In 2015, MedPAC notes, Medicare and its beneficiaries paid about US$26 billion for drugs and biologics covered under Part B; biologics accounted for two-thirds of that.

The report reflects MedPAC’s concerns about the overall price that Medicare pays for Part B drugs, the lack of price competition among drugs with similar health effects and the rapid growth in Part B drug spending over recent years. Medicare pays for most Part B drugs based on a covered product’s average sales price (ASP) plus six percent. According to MedPAC, the six percent add-on to ASP may create incentives for providers to choose higher-priced drugs over lower-priced drugs.

In its report, MedPAC makes a number of recommendations to Congress intended to improve the current ASP-based reimbursement system for Part B drugs. For example, MedPAC recommends reforming the current system by implementing an inflation rebate to be triggered by price increases on drugs that outpace the rate of inflation. MedPAC also recommends that Congress gradually reduce the ASP add-on payment and consolidate reference biologic and biosimilar drugs into a single billing code.

In addition, MedPAC recommends that within the next five years, Medicare should develop a market-based program referred to as the Part B Drug Value Program (DVP). The DVP would allow providers to voluntarily...
enroll and would use private vendors to negotiate drug prices with manufacturers. The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools, such as formularies, to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities.

The specific recommendations for Medicare’s payment for Part B drugs and biologicals, as stated in MedPAC’s report, are that Congress should take these steps.

1. Modify the ASP system in 2018 to:
   - require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report;
   - reduce wholesale acquisition cost (WAC)-based payment to WAC plus three percent;
   - require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark and tie beneficiary cost sharing and the ASP add-on to the inflation-adjusted ASP; and
   - require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

2. No later than 2022, create and phase in a voluntary DVP that must have the following elements:
   - Medicare contracts with a small number of private vendors to negotiate prices for Part B products.
   - Providers purchase all DVP products at the price negotiated by their selected DVP vendor.
   - Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with opportunities for shared savings.
   - Beneficiaries pay lower cost sharing.
   - Medicare payments under the DVP cannot exceed 100 percent of ASP.
   - Vendors use tools, including a formulary, and, for products meeting selected criteria, binding arbitration.

3. Upon implementation of the DVP or no later than 2022, reduce the ASP add-on under the ASP system.

MedPAC’s report reflects recommendations only; the proposals are advisory in nature and cannot be implemented without congressional action. It remains to be seen whether or to what extent Congress will take up MedPAC’s recommendations or other proposals relating to prescription drug pricing and reimbursement.

In the meantime, the Trump administration has signaled that it may seek to advance policy changes relating to prescription drug pricing through an executive order (EO). While the EO would not be able to change current statutes or regulations, early reports indicate that it could include provisions designed to promote value-based arrangements, encourage re-evaluation of trade agreements to seek greater intellectual property protection and competition in the global market, address regulations that are perceived as contributing to
higher prices or cost-sharing for medical products and scale back the 340B drug discount program. It remains unclear whether or to what extent the final EO might include these potential policies if and when it is released. The timing for the EO remains unclear at this time as well.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

**Stephanie P. Hales**  
Partner  
shales@sidley.com  
+1 202 736 8349

**Heath Ingram**  
Associate  
hingram@sidley.com  
+1 202 736 8556

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