Changes to Part B Drug Pricing in the 2019 Medicare Physician Fee Schedule Proposed Rule

On July 12, the Centers for Medicare & Medicaid Services (CMS) published its 2019 Medicare Physician Fee Schedule Proposed Rule (Proposed Rule) covering a wide range of topics. In our series of articles, we have summarized and offered our insights on several key provisions. Note that comments on the Proposed Rule were due to CMS by September 10, 2018, and we expect CMS to publish the Final Rule later this fall. Of the 15,313 comments CMS received on the Proposed Rule, 1,212 of them included the acronym MIPS. You can review all the comments here.

On May 11, President Trump announced his administration was “launching the most sweeping action in history to lower the price of prescription drugs for the American people.” The following week, the Department of Health and Human Services (HHS) published its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

The Blueprint includes several proposed changes to Medicare Part B drug policies. Part B covers drugs administered in physician offices and hospital outpatient departments by infusion or injection—such as drugs to treat cancer, macular degeneration, and rheumatoid arthritis. From 2011 to 2016, per capita spending on Part B drugs has increased 54%, from $532 to $818. Most of this growth is the result of increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs.

While most of the Blueprint’s proposed changes require congressional action, in the
Proposed Rule CMS pursues the one change that can be accomplished by regulation, namely pricing for new drugs. Presently, Medicare reimbursement for most Part B drugs is based on the drug’s average sales price (ASP) plus 6%. (Due to the sequestration cuts, the actual mark-up amount is 4.3%.) ASP is computed using manufacturers’ actual sales, i.e., list price minus all price concessions (e.g., volume discounts, prompt pay discounts, cash discounts, free goods, chargebacks, rebates).

When ASP data is not available for a specific drug, CMS reimburses 106% of the manufacturer-reported wholesale acquisition cost (WAC) for that drug (i.e., the manufacturer’s list price for the drug paid by wholesalers or direct purchasers in the U.S.). For a new drug, CMS uses WAC until there is a full quarter of ASP data available, with a two-quarter lag. Thus, Medicare reimbursement for a new drug may remain at WAC plus 6% for up to nine months following the initial release of that drug.

Last year, the Medicare Payment Advisory Commission (MedPAC) compared the WACs and ASPs for several new, high-expenditure Part B drugs and found that these drugs’ ASPs were lower due to WACs not accounting for price concessions. MedPAC noted these findings were consistent with those in a 2014 report by the Office of Inspector General regarding manufacturers’ reporting of ASP data. Based on these findings, MedPAC recommended reducing the payment rate from “WAC plus 6%” to “WAC plus 3%.”

In the Proposed Rule, CMS adopts this recommendation, noting its intent to reduce the payment rate from WAC plus 6% to WAC plus 3%. CMS notes this change would not impact WAC-based payments for single source drugs, as Section 1847(b) of the Social Security Act specifies that payment for these drugs is 106% of the lesser of ASP or WAC.

CMS reiterates its belief that “it is desirable to have fair reimbursement in a healthy marketplace that encourages product development” and “provide(s) more options to patients and physicians.” However, given the steep increases in drug prices in the recent past, CMS concludes the change in reimbursement “will improve Medicare payment rates by better aligning payments with drug acquisition costs,” especially for drugs with “high launch prices where single doses can cost tens or even
hundreds of thousands of dollars.”

In the Regulatory Impact Analysis accompanying the Proposed Rule, CMS admits it cannot quantify the savings from reducing reimbursement for new drugs. The agency, however, “do[es] not anticipate this change will result in payment amounts that are below acquisition cost or that the proposals will impact providers’ or patients’ access to Part B drugs.”

Assuming the proposal takes effect January 1, 2019, a physician administering a drug previously reimbursed at WAC plus 6% would see an immediate decrease in reimbursement. Once reimbursement for that drug moves to ASP plus 6% (which would happen in no more than nine months from the first full quarter ASP data is available for the drug), there would be no further reimbursement impact to the provider. While CMS states its intent to reduce the incentive for physicians to prescribe more expensive drugs, the move to WAC plus 3% also will disincentivize physicians’ prescribing of new drugs. Whether this will have a broader impact on the market remains to be seen.

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