The Trump Administration's Final Drug Pricing Hurrah—Will It Last?

November 24, 2020

On November 20, 2020, the Department of Health and Human Services ("HHS") issued two sets of rules addressing longstanding Trump administration proposals intended to reduce prescription drug prices.[1] HHS issued an Interim Final Rule that will result in "Most Favored Nation" ("MFN") pricing for certain Medicare Part B drugs, effectively subjecting them to a form of price control. HHS also issued a Final Rule that would repeal the regulatory safe harbor under the Anti-Kickback Statute ("AKS") for rebates from prescription drug manufacturers to pharmacy benefit managers ("PBMs") that administer Medicare Part D plans. As described in greater detail below, both rules are highly controversial and may be subject to legal challenge. The Biden administration could also decide to repeal these initiatives.

HHS' Interim Final Rule Implementing MFN Pricing for Certain Medicare Part B Drugs. The Medicare Part B program provides reimbursement for prescription drugs that are administered on an outpatient basis, *e.g.*, in physician offices and outpatient clinics. Currently, healthcare providers purchase these drugs for their patients and are reimbursed at an effective rate—set by statute—of the average sales price ("ASP"), plus a 4.3% add-on intended to cover the cost of processing the drug order, storage and handling.

HHS's Interim Final Rule would fundamentally restructure the method of reimbursement for 50 drugs that account for a significant percentage of Medicare Part B spending starting on January 1, 2021 and continuing through December 31, 2027.[2] HHS asserts that this model is authorized by a provision that allows HHS to test innovative payment and delivery models.

---

1 *See* Trump's Newest Drug Pricing Executive Order: Still Much More Bark than Bite (September 16, 2020); Trump's New Drug Pricing Executive Orders: Much More Bark Than Bite (July 29, 2020); CMS' Proposed Part B Price Controls: Hurdles and Unintended Consequences (November 5, 2018).

2 HHS has not yet identified which drugs will be included in the payment model for 2021. However, on the same day that HHS released the Interim Final Rule, it also issued a memorandum that lists the top 50 drugs, selected by Medicare Part B spending for 2018 (with certain exclusions). *See* https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf.

Under HHS' model, a MFN price would be determined using a formula that reflects the lowest price (with certain adjustments) that is paid by other wealthy countries. A potential consequence of the MFN price is that it could effectively "import" price controls set by government fiat in such countries. The MFN price will be phased in over four years: in the first year, applicable Part B drugs will be reimbursed at 75% of the applicable ASP and 25% MFN; in the second year, the reimbursements fall to 50% ASP and 50% MFN and by the fourth year, the reimbursements will be 100% MFN. HHS will also offer providers a fixed amount (about $150) for each drug administered as part of this model.

The MFN model will be applied to a variety of entities including physicians who treat Medicare beneficiaries, hospital outpatient departments and ambulatory surgical centers. The model does not apply to children's hospitals, certain cancer hospitals, critical access hospitals, Indian Health Service facilities and certain health centers and rural clinics.

The pharmaceutical industry has expressed strong opposition to MFN pricing models and is likely to file a lawsuit seeking to block implementation of the Interim Final Rule. Among other things, the drug companies are likely to argue that the Interim Final Rule is procedurally deficient because HHS did not comply with notice-and-comment rulemaking requirements pursuant to the Administrative Procedures Act. HHS argues that it is eligible for a "good cause" exception to the notice and comment requirement because of the "particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic." Courts, however, are frequently skeptical of agencies that seek to excuse themselves from the notice and comment requirement. That is particularly true here, because there seems to be no discernable connection between this seven-year model and the pandemic, and courts may question the decision to issue the Interim Final Rule at this stage of the pandemic. The pharmaceutical industry may also argue that HHS lacks statutory authority to impose price controls on certain drugs in the guise of a demonstration project. Further, any test model is required to "preserv[e] or enhance[e] the quality of care furnished to individuals," but HHS's proposal could have the opposite effect if it disrupts the provision of certain Part B drugs.

It is not known if the Biden administration will support the Interim Final Rule or will seek to abolish it by regulation or by letting it die should there be an adverse court ruling. Although many Democrats have supported various efforts to lower drug prices, the Biden administration may be concerned about the disruptive effects of this program. The Biden administration may instead attempt to pursue its objectives through legislation or its own regulatory initiatives.

If the Interim Final Rule goes into effect, there would likely be significant disruption in the Part B market for the drugs that are subject to the MFN program. Even HHS's commentary to the Interim Final Rule recognizes as much, anticipating that the

pharmaceutical industry may exhibit "strong resistance to the model" and may take a variety of steps including "(i) charging a lower price to providers and suppliers inside the model; (ii) refusing to adjust their price from the non-model amounts; or (iii) altering the availability and terms of their international prices."

HHS also recognizes that "[e]ligible providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs." In other words, if providers are being reimbursed at price-controlled rates by HHS but the amount they are being charged by pharmaceutical companies or wholesalers remains unchanged, the predictable result would be scarcity. Many providers may refuse to administer the drugs included in the model because doing so would not be economically feasible or may begin prescribing drugs that are not included in the payment model. This in turn may trigger litigation by Medicare beneficiaries, who may file suit against HHS arguing they have a statutory right to receive medically necessary drugs that are covered by the Part B program. It is difficult to predict how these problems will be addressed by HHS or the courts.

Final Rule Regarding PBM Rebates. The Trump administration has long argued that PBMs have contributed to rising drug costs for Medicare Part D (which covers prescription drugs that are typically obtained by senior citizens at pharmacies). In particular, the administration has criticized PBMs for conditioning the placement of a drug on a Part D formulary on the manufacturers' willingness to provide a significant rebate. PBMs typically either apply the rebate towards the reduction of the overall cost of the Part D plan or take a portion of the rebate as profits. Prior to the issuance of the Final Rule, such rebates were permitted under a regulatory AKS safe harbor for "discounts."

The Final Rule—scheduled to go into effect in January 2022—provides that rebates given by drug manufacturers to PBMs administering Part D plans will generally be prohibited. The Final Rule permits rebates from drug manufacturers only if certain requirements are satisfied: the rebates must be applied to reduce the price of the drug at issue at the time it is dispensed to the beneficiary (sometimes known as the "point of sale"). Further, the Final Rule permits pharmaceutical manufacturers to pay fees to PBMs for services that PBMs provide to pharmaceutical manufacturers related to services that the PBM furnishes to health plans, if, among other things, administer to health plans, provided that (among other things), the compensation is consistent with fair market value in an arm's length transaction, is fixed, and does not change based on volume of referrals.

The Final Rule has been strongly criticized by a variety of groups, including many PBMs and health insurers. Critics argue that eliminating the current rebate structure will

result in higher drug costs and more federal spending because PBMs currently use the "carrot" of favorable formulary placement as leverage for large rebates. These rebates reduce the overall cost of Part D plans and government spending since the federal government subsidizes Part D plans. Without these rebates, Part D premiums and government spending may rise.

It is not yet clear whether the Final Rule will be challenged in court. Additionally, because the Final Rule does not go into effect until 2022, the Biden administration will have an opportunity to decide whether to implement the Final Rule or to abolish it through new rulemaking.

* * *

Please do not hesitate to contact us with any questions.

NEW YORK

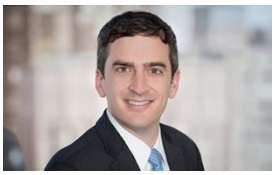
Andrew L. Bab
albab@debevoise.com

Jennifer L. Chu
jlchu@debevoise.com

Mark P. Goodman
mpgoodman@debevoise.com

Maura Kathleen Monaghan
mkmonaghan@debevoise.com

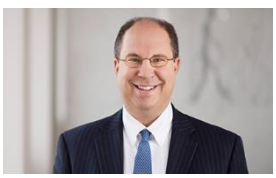
Kevin Rinker
karinker@debevoise.com



Jacob W. Stahl
jwstahl@debevoise.com

WASHINGTON, D.C.

Kim Le
kle@debevoise.com



Paul D. Rubin
pdrubin@debevoise.com

Melissa Runsten
mrunsten@debevoise.com