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International Reference Pricing for Medicare Drugs: New Lease on Life or Least Likely to Succeed?

On Sunday, September 13, 2020, President Donald Trump issued a long-anticipated [Executive Order](#) on international reference drug pricing (the “EO”), signaling that rulemaking on the prices that the Medicare program pays for drugs may be underway again. The EO introduces some new concepts for international reference drug pricing, including, significantly, application to Medicare Part D as well as Part B, and an even lower international reference price. However, like its predecessor pronouncements, the EO provides no specifics for implementation, leaving it unlikely that any changes to the Medicare program contemplated by the EO will go into effect, if ever, before the 2020 election, by the end of the year, or soon thereafter.

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This Alert discusses the specifics of the EO, as well as some of the substantial challenges that will at least delay, and possibly prevent, its implementation.

The Executive Order

The EO introduces a new option on the international reference drug pricing political menu, but is unlikely to trigger immediate legal change. In particular, the EO’s principal innovation is introducing a “most-favored-nation price,” which is designed to set the amount paid for designated Medicare Part B (physician-office) and Part D (pharmacy) prescription drugs to the *lowest price* at which the pharmaceutical manufacturer sells the drug to any other similarly developed nation. The EO provides the following definition of the “most-favored-nation price:”

...the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product.

The EO follows the Centers for Medicare and Medicaid Services’ (“CMS”) 2018 advance notice of proposed rulemaking (“ANPRM”). As we reported earlier this year, the ANPRM called for international reference pricing through a demonstration project that would reimburse vendors for select drugs at rates tied to the *average price* of the drugs in select countries. See our January 13, 2020 [Alert](#) for a full overview of this October 2018 ANPRM.¹ Thus, while the EO tracks in concept with the 2018 proposal, it departs on this material point.

Further, the EO—like the previous actions—provides little detail on the standards for determining the reference price. For example, the EO provides for no basis to determine which of the 37 OECD member countries have a “comparable” per-capita GDP, “after adjusting for volume and differences” in GDP. The EO also departs from the October 2018 proposal in that it applies to Medicare Parts B and D and not just Medicare Part B.

The EO directs the Secretary of Health and Human Services to implement rulemaking to test the most-favored-nation concept to determine whether it would improve outcomes and cut costs for Medicare Part B and Part D beneficiaries. However, the EO lacks substantial detail on how the Administration intends for this rulemaking to proceed. In particular, it does not describe a specific timetable or otherwise predict the timeline for future rulemaking.

In addition, numerous operational questions as to how such models would work remain unanswered. The ANPRM, for example, would replace the current physician buy-and-bill system—where a provider purchases the drug and is reimbursed by Medicare for the drug and its administration at its average sales price plus a defined markup—with a model where CMS instead would reimburse vendors that would bear the risk of acquiring drugs and distributing them to providers, who would receive fixed fees for the administration of such drugs. It is not necessarily clear how such a vendor-based system would operate in practice or how CMS would fulfill its pledge to hold providers harmless despite

such a fundamental change to how they are reimbursed. Incorporating international reference pricing into the Medicare Part D program poses even greater administrative challenges, because whereas Medicare currently reimburses individual drugs in Part B, Part D is administered by annually contracted private health plans that receive capitated rates not tied to the purchase of any single drug. The EO does not indicate how the framework of the Part D program and/or the mechanics of the supply chain would be resolved to allow these health plans to obtain the benefit of the most-favored-nation price for their enrolled Medicare beneficiaries.

Congressional Bills – By Comparison

International reference pricing has emerged as an unlikely policy option that is favored by both President Trump and House Democrats. The Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), introduced by Speaker Nancy Pelosi and passed in the House in December 2019, also relies heavily on its own international reference pricing mechanism whereby, for a minimum of 50 and up to 250 drugs each year, CMS would be required to negotiate drug prices directly with manufacturers, with the negotiated price not to exceed 120 percent of the average price paid in six reference countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). Though the bill passed the House and bears some similarities to the President's embrace of international reference pricing, the Trump administration opposed H.R. 3, which has virtually no chance of passing the current Republican-held Senate. Moreover, despite President Trump's support for his version of international reference pricing, congressional Republicans generally oppose such an approach in principle, likening the use of international prices to the importation of "socialist price controls." For example, the leading Senate bipartisan bill, the Prescription Drug Pricing Reduction Act, introduced by Senator Chuck Grassley (R-IA) (initially with the endorsement, later withdrawn, of Ranking Member Ron Wyden (D-OR) and other Senate democrats), does not incorporate international reference pricing. Instead, it adopts a less aggressive policy of requiring manufacturers to pay inflationary rebates to the Medicare program that has proven controversial with Senate Republicans.² And even congressional Democrats who found it easy to support international reference pricing when it stood no chance of passing the Senate would find themselves under extreme pressure to change course should the Congress flip.

Looking Ahead

While the EO signifies that the Administration is paying attention to drug pricing in the midst of a close presidential election campaign, it does not necessarily signal near-term large-scale changes in the drug-pricing regime, particularly given widespread political and industry opposition. In theory, the Administration may wish to finalize a proposal prior to the election—though such an action poses significant practical constraints and, in bypassing ordinary rulemaking, would almost certainly be subject to ready legal challenge. Moreover, given the operational complexities, development of such overhauls to the Medicare program will be time-consuming on the front end and will require additional time to obtain comments from the many stakeholders.

Finally, any final rule almost certainly will be subject to litigation on statutory, and potentially constitutional, bases. For instance, the 2018 ANPRM proposal indicated that the project would be implemented as a demonstration model by the Centers for Medicare & Medicaid Innovation under the Affordable Care Act—a construct that the EO appears to endorse. As such, a final rule could well be challenged in court as exceeding Medicare's demonstration authority, as well as inconsistent with the statutory payment amounts that Congress has set for Part B drugs and the design of the Part D program (which leaves price negotiation to the participating Part D plans).

If you have questions about this Alert, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. *Drug Pricing: What Happened in 2019 and What to Watch in 2020* (Jan. 13, 2020), available at <https://www.ropesgray.com/en/newsroom/alerts/2020/01/Drug-Pricing-What-Happened-in-2019-and-What-to-Watch-in-2020>.
2. *Id.*