Trump's Newest Drug Pricing Executive Order: Still Much More Bark Than Bite

September 16, 2020

On September 13, 2020, President Trump issued an Executive Order ("EO") addressing pricing for drugs covered by Medicare Part B and Part D. This EO directs the Department of Health and Human Service ("HHS") to pursue two rulemakings establishing "payment models" intended to limit the amount Medicare pays for selected drugs to the lowest price charged for that drug in certain developed economies. The EO glosses over the enormous difficulties associated with the restructuring of Medicare Part B and Part D operations in order to implement such models, making it unlikely that a final rule will be issued until after the election. If and when a final rule is issued, legal challenges are expected.

When the Trump Administration announced three EOs related to prescription drug prices on July 24, 2020, discussed here, President Trump threatened to release a fourth EO directing HHS to establish price controls for drugs paid for by Medicare Part B if the pharmaceutical industry did not voluntarily agree to price reductions. No such voluntary agreement has been reached, resulting in the issuance of this EO.

MEDICARE PART B

Medicare Part B pays for drugs (such as certain drugs for chemotherapy and dialysis) that are administered in outpatient clinical settings, such as doctor offices and hospital outpatient departments. Currently, Part B drugs are reimbursed at an effective rate equal to the Average Sales Price plus a 4.3% "add on" intended to cover the cost of processing the drug order, storage and handling. In November 2018, HHS released an Advance Notice of Proposed Rulemaking ("ANPRM"), addressed here, describing a proposal to implement price controls on Part B drugs based on a composite index of the prices charged for the drugs in other nations and change the process by which Part B drugs are distributed. No proposed rule, however, has been issued in response to the ANPRM.

The EO directs HHS to "immediately take appropriate steps to implement" rulemaking for a demonstration project under which Medicare Part B would pay only the "most-favored-nation price" for certain, unspecified "high-cost prescription drugs and

biological products." "Most-favored-nation" price is defined as the lowest price, after adjustments, for which the drug is sold in an Organisation for Economic Co-operation and Development country that has a per-capita gross domestic product comparable to the United States.

Implementing this proposal is likely to be politically and logistically challenging, however, and highly unlikely to occur this year. Under the current system, healthcare providers first purchase necessary drugs and only then are reimbursed by Medicare. Any cuts to Part B payments are in practice simply cuts to providers. The proposal may have the unintended effect of inducing providers to refuse to purchase and administer drugs that Medicare reimburses at an amount below cost.

While the EO is silent about how Part B drugs would be purchased and distributed, the ANPRM suggested solving this problem by restructuring the Part B system so that middlemen manage the distribution of these drugs and providers are paid only for the administration of the drugs. There appears, however, to be little industry interest in participating in such a program. And regardless, development of an entirely new distribution system for Part B drugs could take significant time. There would likely be a public outcry if the contemplated demonstration project interfered with the availability of life-saving drugs that are administered under the Part B program.

Further, as discussed in more detail here, the ANPRM proposed implementing this pricing model via a "demonstration project." HHS has the statutory authority to implement demonstration projects where certain Medicare requirements are waived in order to "test innovative payment and service delivery models." Approved projects must address a "defined population for which there are deficits in care," and typically involve a limited number of beneficiaries and a targeted change in provider practices or benefits. It is far from certain whether this statutory authority extends to the imposition of price controls. Therefore, the use of "demonstration project" authority to implement price controls would almost certainly result in a legal challenge by the pharmaceutical industry.

MEDICARE PART D

Medicare Part D covers the cost of prescription drugs (drugs patients typically obtain at the pharmacy) for enrolled beneficiaries. Part D plans operate similarly to commercial insurance, in that they set their own formularies (as long as they meet requirements established by Medicare) and negotiate with manufacturers through pharmacy benefit managers for discounts and rebates on covered drugs.

The EO also directs HHS to develop a payment model that would limit payments for unspecified Part D drugs where "insufficient competition exists" to the "most-favored-nation" price. The EO appears to contemplate the federal government purchasing certain Part D drugs itself at "most-favored-nation prices." The EO, however, does not specify the mechanism by which the federal government would purchase and distribute Part D drugs, although it references the same statutory authority for demonstration projects as discussed under Part B above. Nor does the EO provide details regarding how such a model would operate or any timeline for its development.

HHS would face serious complications if it seeks to quickly implement any new pricing mechanism. Medicare's contracts with Part D plans are already final for 2021, limiting HHS's ability to make any immediate changes. The EO also does not indicate what would happen in the event pharmaceutical companies refuse to sell drugs at prices mandated by the government. Further, the federal government is statutorily prohibited from "interfer[ing]" in negotiations between Part D plans and drug manufacturers. It is unclear what plan HHS could propose that would comply with the statute, and the pharmaceutical industry is again expected to file a legal challenge to any such plan.

In short, as with the EOs issued in July, this EO appears to amount to a statement of the Administration's policy goals rather than an announcement of any imminent changes to how Medicare pays for prescription drugs.

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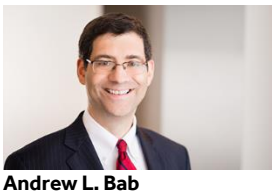

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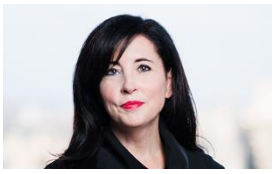

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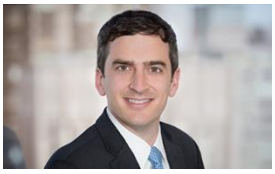

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