ASSESSING THE IMPACT OF THE NEW DRUG PRICING EXECUTIVE ORDERS

On July 24, 2020, President Trump announced four Executive Orders ("Executive Orders") characterized as focusing on lowering drug prices via various mechanisms. These Executive Orders, described in more detail below, include: (1) Executive Order on Access to Affordable Life-saving Medications; (2) Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen; (3) Executive Order on Increasing Drug Importation to Lower Prices for American Patients; and (4) a proposed Executive Order that would require Medicare to pay the lowest price for Part B drugs among other advanced nations**.** If fully implemented, the Executive Orders would no doubt have wide-ranging and significant impacts on various health care industry stakeholders including hospitals, pharmacies, physician offices, drug manufacturers and pharmacy benefit managers ("PBMs"). However, the timing of the orders relative to the upcoming presidential election and processes governing administrative rulemaking together call into question the likelihood that the Executive Orders will actually be implemented as proposed or even at all.

It is important to remember that in spite of the clear statements contained in the Executive Orders, federal agencies remain bound by the statutory authority and agency law mandates related to advance publication and public comment regarding regulations or substantially similar guidance. The timing of this publication process, along with the timing of the relevant government deadlines and grant cycles, means that interested stakeholders, including Federally Qualified Health Centers ("FQHCs"), drug manufacturers and of course PBMs, will have some time to advocate for their positions and mitigate any potential financial impact these orders may have. This also means that any broad system impact wouldn't be materially seen or felt until sometime around or after the election.

Nevertheless, even if implemented by the affected agencies, it is highly likely that the Executive Orders would be challenged in court. In fact, the pharmaceutical industry has already stated that the proposed Executive Order that would require Medicare to pay the lowest price for Part B drugs among other advanced nations as currently structured is unconstitutional.

As such, the Executive Orders have been viewed by many as a last-ditch effort by the Administration to deliver on campaign promises to lower pharmaceutical prices before the November election. The Administration has introduced some of these concepts before. For example, some of these policies were introduced in a proposed rule in 2019 addressing safe harbor protection for prescription drug rebates paid by manufacturers to PBMs, Medicare Part D plans and Medicaid managed care organizations ("Proposed Rule"). Also, a notice of proposed rulemaking was published in 2018 addressing lowering the cost of Medicare Part B outpatient prescription drugs under an international price index model. We wrote about these policies previously here and here.

As noted above, the Executive Orders address the following drug pricing initiatives: (1) requiring FQHCs to pass 340B program pricing of EpiPens and insulin to patients; (2) requiring PBM-negotiated discounts to be directly passed on to patients; (3) allowing the importation of prescription drugs from other countries; and (4) requiring Medicare to pay the lowest price for Part B drugs among other advanced nations. The first three Executive Orders have been signed by the President and published in the Federal Register. The fourth has been signed, but the White House states it will not be released or go into effect until the pharmaceutical industry has devised an alternative plan to lower drug prices as explained below. Below we provide a brief overview of each Executive Order. Following each overview, we provide key considerations and practical takeaways for each before discussing broad takeaways regarding the Executive Orders as a whole.

OVERVIEW OF EXECUTIVE ORDERS AND KEY CONSIDERATIONS

1. ***Executive Order Requiring FQHCs to Pass 340B Pricing of Certain Drugs to Patients***

The first Executive Order (the "340B Executive Order") aims to lower the cost of injectable epinephrine (*i.e.*, EpiPens) and insulin for patients of FQHCs. FQHCs registered in the 340B Prescription Drug Program are able to purchase drugs at a discount from manufacturers. The 340B Executive Order requires that FQHCs pass the cost savings FQHCs received from manufacturers on to eligible patients for these drug purchases. To ensure cost savings are passed to such patients, the 340B Executive Order requires the Secretary of Health and Human Services ("HHS") to condition future grants to FQHCs on FQHCs having established practices to make insulin and injectable epinephrine available at the discounted 340B price paid by the FQHC (plus a minimal administration fee) to eligible patients at the point-of-sale. Eligible patients would be those with low incomes, as determined by HHS, who:

a. Have a high cost-sharing requirement for either insulin or injectable epinephrine;

b. Have a high unmet deductible; or

c. Have no health care insurance.

This Executive Order may not be as significant in the long term as it appears on its face since FQHCs typically have a high Medicaid-eligible population. Since fee-for-service Medicaid programs either require pass-through of 340B acquisition costs to state Medicaid agencies or prohibit prescriptions from being filled using 340B-discounted drugs, the actual scope of any acquisition cost pass-through may be limited.

2. ***Executive Order Requiring PBM-Negotiated Discounts to Be Passed Directly to Patients***

The second Executive Order ("EO on PBM-Negotiated Discounts") focuses on passing PBM-negotiated discounts directly to patients. Specifically, this Executive Order directs HHS to complete the rulemaking process related to the Proposed Rule to:

a. Eliminate Anti-Kickback Statute ("AKS") safe harbor protection for prescription drug rebates offered by drug manufacturers to PBMs, Medicare Part D plans and Medicaid managed care organizations; and

b. Establish new safe harbors to protect point-of-sale discounts and permit certain fixed-fee arrangements between PBMs and drug manufacturers.

In addition to ordering HHS to revive the Proposed Rule, the EO on PBM-Negotiated Discounts calls on HHS to first confirm that the rule will not increase federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs. Projections that the rebate rule would do precisely that is why the rule got pulled when originally proposed last summer. As referenced above, please visit our previous article for a detailed discussion of the Proposed Rule.

The EO on PBM-Negotiated Discounts also highlights the United States' goal of passing through rebates directly to the consumer; an objective that HHS emphasized in the Proposed Rule. The Executive Order characterizes PBM rebates as "the functional equivalent of kickbacks" and seeks to redirect them to Medicare beneficiaries by eliminating discounts to health plan sponsors and PBMs. The EO also dictates confirming that the Proposed Rule will not cause a spike in beneficiary premiums and suggests that narrowing the AKS Discount Safe Harbor will permit billions of dollars in rebates on Medicare Part D prescription drugs to flow directly to the patients. These statements align with HHS's projection in the Proposed Rule that moving away from the traditional rebate system and adopting the new safe harbors will lower Part D beneficiary spending as a whole.

Notably, the Proposed Rule originates from HHS's regulatory authority with respect to Federal Health Care Program rebates, while Congress regulates commercial insurance. Therefore, the Proposed Rule does not directly impact commercial insurance drug rebates. However, in the short term, PBMs and plans may increase premiums and patient co-pay obligations to supplement any lost revenues resulting from finalization of the Proposed Rule as directed by the EO on PBM-Negotiated Discounts. Moreover, if implemented, this policy would benefit pharmacies broadly including FQHC-operated pharmacies. As such, any implementation faces significant challenges.

3. ***Executive Order Allowing Importation of the Prescription Drugs from Other Countries***

The third Executive Order ("EO on Drug Importation") aims to lower prescription drug costs for American patients through the introduction of greater competition in the prescription drug marketplace. Specifically, the EO on Drug Importation permits the importation of safe prescription drugs from other countries with comparable regulatory frameworks and authorizes HHS to take the following Federal Food, Drug, and Cosmetic Act ("FDCA")-compliant actions to expand access to lower-cost imported prescription drugs:

a. Facilitate individual/personal use waivers of the prohibition against importation of prescription drugs, provided that such importation does not pose risk to public safety and results in lower drugs costs for Americans (essentially articulating the same requirement as set forth in section 804(j)(2) of the FDCA);

b. Authorize the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care under the FDCA; and

c. Permit importation of certain prescription drugs from Canada after completing the FDCA rulemaking process provided for under 21 U.S.C. 384(b)-(h).

This Executive Order's impact will not be immediate since HHS will have to engage in its customary, time-intensive rulemaking process. If implemented, the EO on Drug Importation would enable individual consumers to directly purchase prescription drugs from other countries (*i.e.*, personal use importation) deemed to have a safe drug manufacturing infrastructure. The American pharmaceutical industry will very likely resist this Executive Order citing public safety concerns and other potential adverse effects, which will need to be adequately addressed before any such importation occurs. If implemented, drug importation and Part B price negotiations would directly and indirectly benefit pharmacies, patients and the Medicare Part B trust fund.

4. ***Executive Order Requiring Medicare to Pay the Lowest Price for Part B Drugs Among Other Advanced Nations***

Regarding the proposed Executive Order that would require Medicare Part B to have access to "most favored nations" pricing, it is still unclear as to what will actually be put into place, if anything since the drug industry has pushed back on this proposal and there is a statutory prohibition on HHS's interference of negotiations between manufacturers and pharmacies and Prescription Drug Plan ("PDP") sponsors and instituting a price structure for Part D drugs. President Trump gave the drug industry one month (August 24, 2020) to find a "suitable alternative" to the plan, which would direct Medicare to tie Part B drug reimbursement to international prices. If the industry can come up with alternative measures for lowering drug costs, then the Administration may not implement the proposal to tie Part B pricing to international pricing. While the one month delay to allow for an alternative plan was meant as an olive branch to the pharmaceutical industry, negotiations have not gone smoothly. The White House scheduled meetings for July 27 and July 29, 2020 for stakeholders to discuss the proposal, although industry groups have stated they are still opposed to the proposal and have not yet met with the President.

Moreover, to promote competition in the industry, HHS is statutorily prohibited from directly negotiating or setting drug prices for Part D drugs. Thus, HHS's role in negotiation price structures for Medicare drugs is limited. Although bills with bipartisan support have been introduced in the House and Senate with the goal of lowering Part D drug prices by allowing HHS to negotiate prices with drug manufacturers, they have not gained enough traction. It is also unclear if a law will pass to lift this prohibition before the November election.

The Trump Administration has said that the proposed Executive Order that would tie Medicare Part B drug reimbursement to international prices will not be issued if the pharmaceutical industry comes up with an alternative plan. However, negotiations for an alternative plan have been bumpy due to the drug industry's resistance to the proposal and have been limited due to the prohibition on the government's negotiation of drug prices for Part D drugs.

PRACTICAL TAKEAWAYS

Although these Executive Orders appear significant at first glance, it is unclear how quickly the Trump Administration will be able to implement these policies due to required notice and comment rulemaking procedures and the likelihood that the pharmaceutical industry will challenge certain policies in court. As such, interested stakeholders should closely monitor developments but avoid taking any significant action in reliance on the implementation of the Executive Orders.

If you have any questions on the issues discussed in or related to this article, please contact:

- Todd Nova at (414) 721-0464 or tnova@hallrender.com;
- Abby Kaericher at (202) 780-2989 or akaericher@hallrender.com;
- Lindsey Croasdale at (414) 721-0443 or lcroasdale@hallrender.com;
- Adele Merenstein at (317) 752-4427 or amerenstein@hallrender.com;
- Amy Poe at (919) 228-2404 or apoe@hallrender.com;
- Andrew Harrison at (414) 721-0467 or aharrison@hallrender.com;
- Katherine Schwartz at (317) 977-1486 or kschwartz@hallrender.com; or
- Your regular Hall Render attorney.

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