

## PRESIDENT TRUMP SIGNS DRUG PRICING EXECUTIVE ORDERS REINFORCING THE ADMINISTRATION'S PRIORITIES

Date: 27 July 2020

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On July 24, 2020, President Trump issued four executive orders aimed at lowering drug prices. The executive orders direct the Secretary of the Department of Health and Human Services (HHS) to:

- Increase access to insulin and injectable epinephrine by having federally qualified health centers (FQHCs) pass their 340B Drug Pricing Program (340B Program) discounts to individuals who have a high cost-sharing requirement, a high unmet deductible, or no health insurance;
- Allow the importation of certain drugs from other countries by facilitating waivers of the prohibition of importation of prescription drugs, authorizing the reimportation of insulin products, and finalizing the proposed rule on the importation of prescription drugs from Canada;
- Exclude from safe harbor protections under the Anti-Kickback Statute certain retrospective reductions in price that are not applied at the point of sale that drug manufacturers provide to health plan sponsors or Pharmacy Benefit Managers (PBMs) in operating Medicare Part D; and
- Depending on negotiations with pharmaceutical companies, ensure that the Medicare program pay no more for costly Medicare Part B drugs than other economically comparable countries.

Although the drug pricing executive orders are unlikely to be implemented before the 2020 election, they reinforce the administration's priorities on drug pricing. As stakeholders plan for the years ahead, they should be mindful of their potential impact on their operations. This client alert provides an overview of the President's drug pricing executive orders and describes their scope and potential impact.

### INCREASING ACCESS TO LIFE-SAVING MEDICATIONS

President Trump's executive order on "Access to Affordable Life-saving Medications" directs the Secretary of HHS to condition future federal grants available to FQHCs under section 330(e) of the Public Health Service Act upon making insulin and injectable epinephrine available at the discounted price paid by the FQHCs for the drugs through the 340B Program to low-income individuals who have a high cost-sharing requirement for either insulin or injectable epinephrine, a high unmet deductible, or no health insurance.<sup>1</sup>

FQHCs receive discounted prices on prescription drugs through the 340B Program.<sup>2</sup> According to the executive order, these "steep discounts, however, are not always passed through to low-income Americans at the point of sale."<sup>3</sup> The executive order argues that individuals with low incomes are exposed to high prices for medications such as insulin and injectable epinephrine, adding that such individuals often do not benefit from discounts negotiated by insurers or federal or state governments.<sup>4</sup>

The administration's targeting of FQHCs was surprising, given the bipartisan support FQHCs receive from Congress and HHS. In response to the executive order, the National Association of Community Health Centers highlighted the support FQHCs have received to date as "excellent stewards of the 340B Program," stressing that they do not charge low-income patients "massive, full prices" for drugs.<sup>5</sup>

## **PERMITTING THE IMPORTATION OF DRUGS FROM OTHER COUNTRIES**

President Trump's executive order on "Increasing Drug Importation to Lower Prices for American Patients" is aimed at expanding access to low-cost imported drugs. Pursuant to sections 801 and 804 of the Food, Drug, and Cosmetic Act (FDCA), the executive order directs the Secretary of HHS to facilitate waivers of the prohibition of importation of prescription drugs, authorize the reimportation of insulin products as required for emergency medical care, and finalize the proposed rule on the importation of prescription drugs from Canada that has been under review at the Office of Management and Budget.<sup>6</sup>

In regard to the latter, HHS and the Food and Drug Administration (FDA) issued last year their Safe Importation Action Plan, which described potential pathways to allow entities to import certain drugs from abroad in an effort to bring down drug prices.<sup>7</sup> As part of the administration's Safe Importation Action Plan, the FDA would use its authority under the FDCA to propose rules authorizing demonstration projects developed by states, wholesalers, or pharmacists to allow importation of drugs from Canada.<sup>8</sup>

To this end, a number of states, including Florida, Maine, Vermont, and Colorado, have enacted legislation to allow them to import certain drugs from Canada. Officials from Canada, however, have signaled concern about the potential diversion of the country's drug supply and responsibility for assuring safety.<sup>9</sup> The pharmaceutical industry, and in particular the Pharmaceutical Research and Manufacturers of America (PhRMA), has opposed the administration's proposal and increased its advocacy to block it.<sup>10</sup>

The executive order would build on the Administration's Safe Importation Action Plan by also allowing for individual waivers to import drugs as long as the importation does not pose a risk to public safety and by allowing the reimportation of insulin.<sup>11</sup> The latter has been of particular interest, given that states, wholesalers, and pharmacies cannot import biologics under the Safe Importation Action Plan.<sup>12</sup> Earlier this year, the Secretary of HHS indicated that he was open to allowing the importation of insulin.<sup>13</sup>

## **ELIMINATING REBATES TO HEALTH PLAN SPONSORS AND PBMS**

President Trump's executive order on "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen" would direct the Secretary of HHS to finalize its proposed rule entitled, "Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," which is commonly referred to as HHS' "rebate rule."<sup>14</sup>

By doing so, the Secretary would (i) exclude from safe harbor protections under the Anti-Kickback Statute certain retrospective reductions in price that are not applied at the point of sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program and (ii) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point of sale in order to lower patient out-of-pocket costs.<sup>15</sup>

Notably, the executive order contains a restriction which reduces the likelihood that it will be finalized. The order directs the Secretary to confirm, prior to finalizing the proposed rule, that the proposal will not increase federal spending, Medicare beneficiary premiums, or patients' out-of-pocket costs.<sup>16</sup> Last year, HHS withdrew the rebate rule after the Congressional Budget Office found that it was expected to cost taxpayers \$177 billion over the next decade and would have raised premiums for seniors in Part D.<sup>17</sup>

Congressional leaders also withdrew some attempts to include the administration's rebate proposal last year as part of a bipartisan legislative package due to the same concerns. Senate Health, Education, Labor, and Pensions Committee Chair Lamar Alexander (R-TN), for example, had indicated that the committee was considering including the proposal as part of the Lower Health Care Costs Act (S. 1895).<sup>18</sup> However, the proposal was not included because it was expected to increase premiums and taxpayer costs.

## IMPLEMENTING A MOST FAVORED NATION APPROACH

Finally, in announcing the executive orders, President Trump also announced he would be taking steps to “ensure that the Medicare program and seniors pay no more for the most costly Medicare Part B drugs than any economically comparable OECD country.”<sup>19</sup> Touted as the President's “most significant [drug pricing] executive order,” the “most favored nation” order would build on his International Pricing Index (IPI) model, which the administration announced in 2018, but has also failed to implement to date.

As discussed in our alert here, under the IPI model, the federal government would pay certain vendors directly for Part B drugs at rates that are benchmarked to align with prices paid in economically similar countries.<sup>20</sup> The model would pay physicians and hospitals a per-month or per-dispense administration fee that would not be tied to the cost of the drug administered.<sup>21</sup> HHS proposed to test the approach with sole-source Part B drugs in certain areas for five years.<sup>22</sup> Stakeholders and policymakers raised concerns about imposing foreign price controls on U.S. markets and how the IPI model would work in practice.

Despite such concerns, HHS sent a proposed rule to the White House Office of Management and Budget, which has been reviewing the proposal since June 2019. The administration has delayed release of the proposed rule several times since then, with the administration's Spring 2020 Regulatory Agenda most recently noting that the proposal would be issued in June of this year.<sup>23</sup> HHS has informally indicated that it has revised the proposal multiple times following feedback from President Trump and the White House.

In announcing the most favored nation order, President Trump said that he would hold off on beginning to implement the order until August 24 in order to give the pharmaceutical industry an opportunity to “come up with something that will substantially reduce drug prices.”<sup>24</sup> President Trump noted that he would be meeting with major drug companies on Tuesday, July 28, to discuss the executive order, although there have been several reports that the meeting was postponed. PhRMA said the executive order is a “reckless distraction that impedes our ability to respond to the current pandemic.”<sup>25</sup>

## CONCLUSION

Although President Trump's drug pricing executive orders largely serve to highlight the administration's actions on drug pricing ahead of the 2020 election, they reinforce the administration's priorities for the years ahead. As stakeholders assess the financial landscape post COVID-19, they should be mindful of the potential impact of these orders on their operations. K&L Gates will continue to monitor the status of these proposals. K&L Gates'

health care and FDA practice and public policy and law practice regularly advise stakeholders on pharmacy matters, including 340B Program implementation and compliance, and facilitate stakeholder engagement with Congress and the administration can assist in this regard.

## FOOTNOTES

<sup>1</sup> See White House, *Executive Order on Increasing Drug Importation to Lower Prices for American Patients*, Executive Orders (July 24, 2020).

<sup>2</sup> Federally qualified health centers are eligible to participate in the 340B Program, which allows eligible covered entities to access covered outpatient drugs at discounted prices. See 42 U.S.C. §256b(a)(4)(A).

<sup>3</sup> See White House, *supra* note 1.

<sup>4</sup> *Id.*

<sup>5</sup> See Press Release, National Ass'n of Cmty. Health Centers, *The White House Executive Order Regarding Health Centers and the 340B Drug Pricing Program* (July 24, 2020).

<sup>6</sup> See White House, *supra* note 1.

<sup>7</sup> See Food & Drug Admin., *Safe Importation Action Plan* (July 31, 2019).

<sup>8</sup> *Id.*

<sup>9</sup> See, e.g., Jessie Hellmann, *Trump's Drug Importation Plan Faces Resistance in US, Canada*, *The Hill* (Dec. 1, 2019).

<sup>10</sup> See PhRMA, *Medicine Safety: Drug Importation*, (last visited July 26, 2020).

<sup>11</sup> See White House, *supra* note 1.

<sup>12</sup> See Food & Drug Admin., *supra* note 7.

<sup>13</sup> See John Wilkerson, *Azar Open To Allowing Imports Of Insulin, Despite Being A Biologic*, *Inside Health Policy* (Feb. 26, 2020).

<sup>14</sup> See 84 Fed. Reg. 2340 (Feb. 6, 2019).

<sup>15</sup> See White House, *Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen*, Executive Orders (July 24, 2020).

<sup>16</sup> *Id.*

<sup>17</sup> See Congressional Budget Off., *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections - Updated Budget Projections: 2019 TO 2029* (May 2, 2019).

<sup>18</sup> See Rachel Cohrs, *Alexander's Draft Bill Stops Short Of Expanding Trump's Rebate Plan*, *Inside Health Policy* (May 23, 2019).

<sup>19</sup> See White House, *Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices*,

Remarks (July 24, 2020).

<sup>20</sup> See 83 Fed. Reg. 54,546 (Oct. 30, 2018).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> See Office of Mgmt. & Budget, Spring 2020 Unified Agenda of Regulatory and Deregulatory Actions, (last visited July 26, 2020).

<sup>24</sup> See White House, *supra* note 19.

<sup>25</sup> See Press Release, PhRMA, Statement on Drug Pricing Executive Orders (July 24, 2020).

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