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CLIENT ALERT

President Trump Signs Executive Orders on Drug Pricing and Domestic Supply Chain Reform

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August 2020

On August 6, 2020, President Donald Trump signed an executive order directing federal agencies to increase domestic procurement and identify supply chain vulnerabilities of certain essential medicine and products. This "Buy American" executive order[1] is the latest in a series of recent executive orders aimed at tackling issues within the pharmaceutical industry.

On July 24, 2020, President Trump signed four executive orders of sweeping breadth that address prescription drug prices. The orders were designed to reduce insulin and injectable epinephrine out-of-pocket expenses for certain individuals, permit drug importation from Canada or through individual waivers, limit prescription drug rebates, and recommence efforts to use external benchmarking to set prices of certain drugs at the level paid by other countries.[2] These executive orders largely attempt to resurrect drug pricing reform initiatives originally mentioned in the Trump administration's 2018 "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."

Although these executive orders could be viewed as far-reaching proposals that may attract attention during this presidential election year, they have no immediate legal effect. The executive orders direct Alex Azar, the Secretary of the U.S. Department of Health & Human Services ("HHS"), to implement the four policies through federal rulemaking procedures; however, these executive orders do not address some of the underlying barriers that hindered progress on similar proposals.

[1] Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 Fed. Reg. 49929 (Aug. 14, 2020), https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential.

[2] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, the White House, (July 24, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices/.

340B Discounts for Insulin and Injectable Epinephrine

The first executive order directs the Secretary of HHS to require Federally Qualified Health Centers ("FQHCs") to make insulin and injectable epinephrine available to certain low-income individuals at the price paid by the FQHC under the 340B Prescription Drug Program ("340B Program").[3] FQHCs—community-based health providers that provide primary care services in underserved areas and meet specific requirements—are funded through federal grant money from HHS's Health Resources and Services Administration ("HRSA").[4] To participate in Medicaid, manufacturers must agree to comply with the 340B Program's requirement to sell certain outpatient drugs at statutorily determined discounted prices to statutorily defined "Covered Entities," such as FQHCs, that provide care to low-income and uninsured patients.[5] Under this executive order, the Secretary would condition an FQHC's future operating FQHC federal grants upon having the FQHC make insulin and injectable epinephrine available at the 340B discounted price it paid—plus a minimal administration fee—to certain low-income patients who have a high cost-sharing requirement for either insulin or injectable epinephrine, a high unmet deductible, or no health insurance.[6] According to President Trump, this executive order would cause FQHCs to pass along "the giant discounts they receive from drug companies on insulin and EpiPens directly to their patients."[7]

The 340B Program generally allows 340B Covered Entities, including FQHCs, to utilize the cost savings from 340B discounted drugs to stretch scarce resources without specific limitations on how the 340B savings are to be used by these Covered Entities. Similarly, the FQHC federal grant requirements merely require FQHCs to use 340B Program savings for purposes that generally advance the FQHC's HRSA-federal grant-approved scope of project. The executive order, although benefiting FQHC patients eligible to receive the discount, would be the first instance where FQHCs or any other 340B Covered Entity would be ***required*** to pass on the 340B discounted price to the patient rather than giving the Covered Entity the discretion to reinvest the savings generated from the 340B discounted price into other activities that may benefit the FQHC's patient population.

The limited nature of this executive order raises questions as to whether it will have any broad meaningful impact on drug pricing. Not only is its scope limited to two drugs, but the executive order also addresses the dispensing of those drugs only by 340B FQHCs, and only to certain 340B eligible patients of the FQHC Covered Entities. Beyond those

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[3] Access to Affordable Life-Saving Medications, Exec. Order No. 13,937, 85 Fed. Reg. 45755 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16623/access-to-affordable-life-saving-medications.

[4] HRSA, Federally Qualified Health Centers (May 2018), https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html; 42 U.S.C. § 1395x(aa)(3).

[5] Public Health Service Act § 340B, 42 U.S. Code § 256b.

[6] Public Health Service Act § 330(e), 42 U.S. Code § 254(e); Access to Affordable Life-Saving Medications, Exec. Order No. 13,937, 85 Fed. Reg. 45755 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16623/access-to-affordable-life-saving-medications.

[7] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, the White House, (July 24, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices/.

specific 340B eligible patients, it is unclear how this executive order will have a broader impact on drug pricing.[8]

Drug Importation

The second executive order is designed to "minimize international disparities" in the prices of drugs[9] by directing the Secretary of HHS to take three actions to safely expand access to lower-cost, imported prescription drugs. First, the executive order directs the Secretary to grant individual waivers of the prohibition of prescription drug importation if importation poses no additional risk to public safety and if importation would result in lower costs to patients. In his remarks, President Trump stated that the executive order would apply to "states, wholesalers, and pharmacies."[10] Second, the Secretary must authorize the re-importation of insulin products that the Secretary deems necessary for emergency medical care. Finally, this executive order directs the Secretary to complete the federal rulemaking process for the previously released proposed rule to allow importation of certain prescription drugs from Canada.

Although the executive order's first directive to permit waivers does not limit the countries from which waiver recipients might import drugs, several states have already passed statutes authorizing the importation of drugs from Canada, and, as of the beginning of August 2020, 43 drug-importation bills have been introduced at the state level in 2020.[11] However, those state statutes and proposals are nonoperational and have no effect without federal authorization of drug importation. Accordingly, on December 18, 2019, the Trump administration began the process to approve state-based efforts to authorize drug importation by issuing a notice of proposed rulemaking and draft guidance on prescription drug importation.[12] The first directive of the executive order is aimed at speeding up this process, as well as expanding its scope.

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[8] CMS recently introduced the Part D Senior Savings Model, effective for the 2021 plan year, to address high insulin prices in the Medicare program. Under the model, participating Part D sponsors would offer Part D drug plans that include supplemental benefits to cover insulin during the coverage gap phase of the Part D benefit, and the 70 percent discount paid by participating pharmaceutical manufacturers in the coverage gap would be calculated before the application of supplemental benefits to reduce out-of-pocket spending for consumers. Press Release, Ctr. for Medicare & Medicaid Servs., President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors, CMS (May 26, 2020), https://www.cms.gov/newsroom/press-releases/president-trump-announces-lower-out-pocket-insulin-costs-medicares-seniors; CMS, Part D Senior Savings Model (updated July 27, 2020), https://innovation.cms.gov/innovation-models/part-d-savings-model.

[9] Increasing Drug Importation to Lower Prices for American Patients, Exec. Order No. 13,938, 85 Fed. Reg. 45757 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16624/increasing-drug-importation-to-lower-prices-for-american-patients.

[10] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, the White House, (July 24, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices/.

[11] National Academy for State Health Policy, 2020 State Legislative Action to Lower Pharmaceutical Costs (July 28, 2020), https://www.nashp.org/rx-legislative-tracker/.

[12] Press Release, U.S. Dep't of Health & Human Servs., Trump Administration Takes Historic Steps to Lower U.S. Prescription Drug Prices (Dec. 18, 2019), https://www.hhs.gov/about/news/2019/12/18/trump-administration-takes-historic-steps-to-lower-us-prescription-drug-prices.html; U.S. Dep't of Health & Human Servs., Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological

The executive order's provisions relating to individual waivers and insulin largely appear to be reiterations of existing law.[13] The executive order, however, also imposes an additional requirement, not required under 21 U.S.C. § 384(j)(2), that the imported drug not only be safe, but also result in lower costs to American patients. The insulin provision, which authorizes re-importation upon an HHS finding of its need for emergency medical care, reflects the same standard for insulin re-importation that already exists under 21 U.S.C. § 381(d)(2).[14]

Generally, drug importation policies, such as the three outlined in the executive order, face obstacles in implementation. Of utmost concern is whether a drug importation program can ensure that Americans receive only safe and effective imported drugs. Beyond safety concerns, questions remain as to whether legalized importation actually could produce savings. A state legislative study of recent Vermont drug importation legislation raised doubts, finding that Vermont Medicaid would generate no savings through an importation program and that the cost of upfront investment, appropriations, and other costs may offset any other savings.[15]

Finally, a drug importation program would face logistical obstacles. For example, Canada has expressed fears that a U.S. drug importation program could result in drug shortages in Canada and "has promised to circumvent any plan that hurts Canadians' supplies."[16] Furthermore, the Drug Supply Chain Security Act ("DSCSA"), a federal law governing wholesaler licensure and the tracking and tracing of prescription drugs, does not easily apply to a U.S. drug supply chain that allows for imported drugs.[17] Congress would need to either modify the DSCSA to accommodate a drug importation program or carve out such a program from the DSCSA. The latter likely would undermine the DSCSA. By undermining the DSCSA, which is intended to track and trace drugs to prohibit counterfeit drugs from entering into the U.S. supply chain, this executive order would also negate its own stated requirement that imported drugs be safe.

Narrowing the Drug Rebate Safe Harbor

The third executive order addresses the disparity between drug prices that patients see at the point-of-sale and prices paid by health plans and pharmacy benefit managers ("PBMs").[18] The federal Anti-Kickback Statute ("AKS") prohibits knowingly and willfully offering, paying, soliciting, or receiving "remuneration" in return for or to induce the

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Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry (Dec. 2019), https://www.hhs.gov/sites/default/files/importation-of-certain-fda-approved-human-presciption-drugs-including-biological-products.pdf.

[13] See 21 U.S.C. § 384(j)(2) (addressing individual waivers).

[14] See 21 U.S.C. § 381(d)(2) (addressing re-importation of insulin).

[15] AGENCY OF HUMAN SERV., WHOLESALE IMPORTATION PROGRAM FOR PRESCRIPTION DRUGS LEGISLATIVE REPORT (2018).

[16] Sarah Karlin-Smith and Sarah Owermohle, 4 Reasons Trump's Drug Importation Plan Won't Work, Politico, December 18, 2019.

[17] 21 U.S.C. § 360eee, *et seq.*

[18] Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Exec. Order No. 13,938, 85 Fed. Reg. 45759 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16625/lowering-prices-for-patients-by-eliminating-kickbacks-to-middlemen.

purchase of federally reimbursable items or services unless the arrangement satisfies the requirements of a safe harbor.[19] Certain discounts and rebates, including rebates paid by drug manufacturers to health plans or PBMs for formulary placement, may be protected if they satisfy the elements of an available safe harbor.[20] The executive order directs the Secretary of HHS to complete the federal rulemaking process he commenced in February 2019 to exclude from AKS safe harbor protection certain rebates that are not applied at the point-of-sale or other remuneration pharmaceutical manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program.[21] The Secretary of HHS also must establish two new safe harbors that would (i) permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale and (ii) permit the payment of certain *bona fide* PBM service fees.

This executive order would revive the Trump administration's February 2019 attempt to exclude certain rebates on pharmaceutical products from safe harbor protection, with some alterations. Most significantly, this executive order requires the Secretary of HHS to confirm, prior to federal rulemaking, that the action will not increase federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs. This directive likely will be difficult to satisfy, as both CMS's Office of the Actuary and two independent actuarial firms, hired to assess the February 2019 proposed rule's potential effects on premiums and out-of-pocket expenses under various assumptions, projected that the proposed rule would cause beneficiary premiums to increase.[22] The Trump administration withdrew the proposal in July 2019 due to the impact it would have on beneficiaries' premiums and the Congressional Budget Office's projection that the proposal would increase federal spending by $177 billion between 2020 and 2029.[23]

Even if the Secretary of HHS could demonstrate that completing the federal rulemaking process would not increase federal spending or beneficiaries' premiums, it is unclear that this executive order's directive to complete that rulemaking process would have the desired effect of eliminating rebates. The February 2019 proposed rule did not propose any modifications to the group purchasing organization ("GPO") safe harbor, which

[19] 42 U.S.C. § 1320a–7b(b)(3)(A).
[20] Fraud and Abuse; 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, 84 Fed. Reg. 2340 (Feb. 6, 2019), https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0001&contentType=pdf.
[21] Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Exec. Order No. 13,938, 85 Fed. Reg. 45759 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16625/lowering-prices-for-patients-by-eliminating-kickbacks-to-middlemen.
[22] Fraud and Abuse; 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, 84 Fed. Reg. 2340 (Feb. 6, 2019), https://www.regulations.gov/contentStreamer?documentId=HHSIG-2019-0001-0001&contentType=pdf.
[23] *Id.*; Peter Sullivan, White House withdraws controversial rule to eliminate drug rebates (July 11, 2019), https://thehill.com/policy/healthcare/452561-white-house-withdraws-controversial-rule-to-eliminate-drug-rebates; Cong. Budget Off., Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029 (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

remains available to protect manufacturer rebates retained by PBMs. Modifying the GPO safe harbor to prohibit PBMs' retention of such rebates through regulation would be challenging, because the AKS includes a statutory exception protecting payments to GPOs that may not be narrowed through regulation. Consequently, congressional action likely would be required to achieve the goal of eliminating rebates.

The International Pricing Index / "Most Favored Nation" Approach

The final drug pricing executive order—referred to by President Trump as the "granddaddy" of the executive orders—would advance a "most favored nation" policy that is similar to the international pricing index ("IPI") model for Medicare Part B introduced in 2018.[24] Unlike the other drug pricing executive orders President Trump signed on July 24, 2020, which became effective immediately, President Trump stated that this "very tough" executive order would not go into effect until August 24, 2020. The purported reason for the delay was to provide pharmaceutical companies with an additional month to propose an alternative solution to this executive order that would "substantially reduce drug prices."[25]

During the press conference announcing this executive order, President Trump cited the much higher prices the United States pays for certain drugs as compared to other nations and stated that, under the executive order, Medicare would be "required to purchase drugs at the same prices as other countries."[26] When describing the executive order's proposed methodology, President Trump stated that his administration "will determine what other medically advanced nations pay for the most expensive drugs, and instead of paying the highest price, Medicare will pay the lowest price and so will lots of other U.S. buyers."[27] Further, under the "favored nation" proposal, President Trump emphasized that Americans would "get the lowest price anywhere in the world."[28]

The "most favored nation" approach would differ somewhat from the IPI model CMS proposed in 2018. Whereas the executive order reportedly states that the Medicare program "should not pay more for costly Part B prescription drugs or biological products than the most-favored-nation price,"[29] under the proposed IPI model, Medicare Part B reimbursement for certain drugs would be based on the average prices paid by

[24] Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Dec. 31, 2018), https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.
[25] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, the White House, (July 24, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices/.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] Avik Roy, How Trump's Prescription Drug Executive Orders Reduce Costs For Seniors & Taxpayers, FORBES (July 24, 2020), https://www.forbes.com/sites/avikroy/2020/07/24/trumps-most-favored-nation-prescription-drug-executive-order-will-reduce-costs-for-seniors--taxpayers/#6903fe291860.

economically comparable countries.[30] It is unclear whether this executive order would limit the most-favored-nation price to the Medicare program or whether President Trump's reference to its impact on "lots of other U.S. buyers" means that the executive order also would apply in circumstances where drug pricing is indexed to a Medicare reference price. CMS was expected to release a proposed rule on the IPI model in the spring of 2019 following the fall 2018 release of the advanced notice of proposed rulemaking.[31] However, the IPI model received significant opposition, and, despite President Trump referencing the proposal during a July 2019 speech, Secretary Azar stated that the Trump administration was still making changes to the IPI proposal as of November 2019.[32] The proposed rule has been under review at the Office of Management and Budget since June 20, 2019.[33]

The "Buy American" Executive Order

President Trump's most recent executive order addressing pharmaceutical issues focuses on the supply chain rather than drug pricing. Under the "Buy American" executive order, executive departments and agencies involved in the procurement of certain Essential Medicines, Medical Countermeasures, and Critical Inputs (collectively "Products") must consider actions to increase domestic procurement.[34] Among other directives, the executive order directs the Food and Drug Administration ("FDA") Commissioner to take action to accelerate FDA approval or clearance for domestic producers of Products and to issue guidance regarding the development of advanced manufacturing techniques. The FDA Commissioner must also—in consultation with the Director of the Office of Management and Budget, the Assistant Secretary for

[30] Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Dec. 31, 2018), https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.

[31] CMS, International Pricing Index (IPI) Model (updated Apr. 9, 2020), https://innovation.cms.gov/innovation-models/ipi-model#:~:text=CMS%20is%20considering%20issuing%20a,until%20the%20spring%20of%202025; Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Dec. 31, 2018), https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs.

[32] Kyle Blankenship, Trump seeks 'favored-nation' order on drug prices—but what would that even look like?, FIERCE PHARMA (July 8, 2020), https://www.fiercepharma.com/pharma/trump-seeks-order-for-favored-nation-clause-drug-prices-but-what-would-even-look-like; Peter Sullivan, Trump officials making changes to signature drug pricing proposal, Azar says, THE HILL (Nov. 13, 2019), https://thehill.com/policy/healthcare/470230-trump-officials-making-changes-to-signature-drug-pricing-proposal-azar-says.

[33] Off. of Mgmt. & Budget, List of Regulatory Actions Currently Under Review (n.d.), https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp.

[34] The executive order defines "Essential Medicines" are medicines "medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms." "Critical Inputs" are Active Pharmaceutical Ingredients (API), API Starting Material, "and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures." Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 Fed. Reg. 49929 (Aug. 14, 2020), https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential.

Preparedness and Response, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy—identify the list of Products that are "medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms."[35] Several other provisions are included to increase domestic procurement and to identify supply chain vulnerabilities. It is possible that this most recent executive order could result in increases in drug production costs, and therefore drug prices, as overseas manufacturing of key materials or products has been an important mechanism for cost reductions.

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[35] *Id.*