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MEMORANDUM

SUBJECT: PRESIDENTIAL EXECUTIVE ORDERS TO ADDRESS DRUG PRICING
DATE: JULY 28TH, 2020

On Friday, July 24th, President Donald Trump released three Executive Orders (EOs) aimed at reducing the price of prescription drugs – and indicated that a fourth has been signed and would be released in the near future. In general, it remains an open question as to whether any of these orders can be implemented before the end of 2020.

Below is a summary of each EO, as well as key policy and political considerations.

1) **Importation of Prescription Drugs –** The President's first EO resurfaces a Notice of Proposed Rule Making that was issued by the FDA in December of 2019 that would permit States/Tribal governments to establish programs for the importation of certain drugs from Canada. That NPRM was largely in response to proposed importation programs by the State of Florida that were submitted to the Administration in 2019, pursuant to Florida State Statute). A summary of the FDA's NPRM can be found here.

   This EO also contains other components that direct the Secretary to establish the following: (1) a program/process for granting individuals the ability to import prescription drugs, contingent on importation waivers that would have to be approved by the FDA; and (2) a process/mechanism for authorizing the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d).

   - **Policy Perspective:** The drug importation program outlined by the FDA in December of 2019 was limited in scope. The proposed program would exclude the following drugs: controlled substances; biological products (this would include insulin); infused drugs; intravenously injected drugs; drugs inhaled during surgery; intrathecally or intraocularly injected drugs; drugs that are subject to a risk evaluation and mitigation strategy (REMS); and, drugs that are not a "product" for purposes of section 582 as defined in section 581(13) of the Act. Many of the products excluded are the most expensive drug products in the U.S., which limits the impact of the proposed policy on the overall cost of prescription drugs.

     Nevertheless, drug importation of non-injectable, non-specialty drugs may still have a relevant impact on drug spend for the majority population. This said, Canada is likely to limit drug exports and drug makers could limit sales to Canada to minimize the proposal's impact. In 2017, CBO estimated that a somewhat broader legislative proposal (S. 469) could save the federal government $7 billion over 10 years.

   - **Political Outlook**: Since Florida submitted its proposal, Drug Importation Programs have been considered and/or formally proposed by multiple states. It is likely that the Administration will promulgate something to this effect in the coming months.

2) **Mandate 340B Discount Passthrough –** The President's second EO directs the Secretary of HHS to withhold certain operating grants available to Federally Qualified Health Centers (FQHCs) if they fail to set prices for insulin and injectable epinephrine equal to the discounted prices paid to acquire such products – in particular,

by the FQHC grantee or sub-grantee for such products under the 340B Prescription Drug Discount Program. Those prices are essentially equal to Medicaid's net prices, which incorporate large statutory discounts. Naturally aligned with the target populations of FQHCs, the EO states that this is specific to the purchase of insulin and injectable epinephrine by low-income individuals who: "have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or, have no health care insurance."

- **Policy Perspective:** This policy directly affects only the ~1,362 Health Center program grantees active in the U.S., as well as connected providers to an extent. (In 2017, there were 16,842 federal grantee sites participating in 340B, as well as 21,554 hospital-affiliated sites.) However, it could place pressure on other 340B participants to pass on those discounts as well.

- **Political Outlook:** 340B loopholes have remained a significant policy challenge for both Republican and Democratic parties. While there may be pushback given the impact this policy may have on safety net providers during the COVID-19 pandemic, if timed appropriately, this policy could be relatively less partisan than the other proposals. HHS had sought through regulation to reduce Medicare payments to hospitals obtaining drugs through the 340B program, but that action was blocked in court.

3) **Mandated Rebate Passthrough and Point-of-Sale Discounts in Part D –** The President's third EO directs the Secretary of HHS to finalize the proposed rule issued by the Administration in 2018 but withdrawn in 2019. That proposal required health plan sponsors, pharmacies, and/or PBMs to pass all rebates collected from drug manufacturers to Medicare Part D patients in the form point-of-sale discounts at the pharmacy counter. Specifically, the Proposed Rule (as reinforced in the EO), would eliminate safe harbor protections for rebates provided post-sale that are not passed through, and would establish new safe harbors that would permit plan sponsors, pharmacies, and PBMs to apply discounts at the point-of-sale.

   Importantly, Section 4 of the relevant EO language states that "prior to taking action under section 3 of this order, the Secretary of Health and Human Services shall confirm — and make public such confirmation — that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."

   - **Policy Perspective:** The original Part D proposed rule was scored by CBO as potentially costing the federal government $177 billion over a 10-year period due to Medicare premium increases that would be experienced across the program. CBO did not provide an estimate of the effect on beneficiary premiums, but the CMS Actuary produced a similar estimate – finding that federal costs would increase by $196 billion and beneficiary premiums would rise by $50 billion. It remains to be seen whether or how this policy can be altered in a way that eliminates or reverses this budget impact, while also maintaining the essence of the proposal (i.e., eliminating rebates in Part D). Without appropriate policy changes, the proposal is likely to violate the Section 4 language of the EO – which was reportedly put in by CMS Administrator Seema Verma, who has consistently been against the policy. In the short run, however, the announcement allows the Administration to assert that it is forcing rebates to be passed through – thus lowering point-of-sale prices – without raising beneficiary premiums or federal costs.

   - **Political Outlook:** The rebate "bubble" and "rebate wall" issues have been labeled by both political parties as key contributors to rising drug prices, as well as inhibitors to market entry for new generic-drug and/or biosimilar manufacturers. Nonetheless, since the CBO score was released, many democratic lawmakers have abandoned the notion of eliminating rebates in Part D due to the potential of premium increases and have turned to more drastic policies such as direct Medicare "negotiation" or price regulation. Furthermore, Wall Street stakeholders, and other key figures of the investment community, have opposingly voiced that the President should stop focusing on rebates and price control policies entirely, and instead pivot to policies that improve research & development and regulatory approval pathways. Given the pushback to this policy (from multiple angles), and considering the budgetary restriction instilled in Section 4, it is unlikely that the Administration will

finalize anything that drastically alters the rebate landscape in Part D—at least at the magnitude proposed under the original proposed rule.

4) **'Most Favored Nations' Policy** – The President and his Administration have yet to reveal the text of the fourth EO because he has asked to first meet and negotiate with pharmaceutical executives on the matter. It remains to be seen how similar this 'Most Favored Nation' (MFN) policy will be to its predecessor – the International Pricing Index (IPI) proposed rule released in 2018. For reference, the IPI proposed rule looked to establish a CMMI demo covering 50% of the U.S., and would instill a CAP-like system for the purchase of most Part B drugs at a pricing index that reflects the prices paid by other OECD countries. Under the IPI, these prices would be gradually phased down (over a 5-year period) to reflect 125% of the International Pricing Index price established. The original notion was that, due to the 25% markup, manufacturers would still prioritize the U.S. market over international markets.

   The MFN policy seems to be a somewhat broader proposal than the IPI. While this has not been confirmed, in the President's speech it seems as though the Administration is pursing a policy that would price the most expensive Part B drugs at the most favorable price offered to any given nation. This would contrast with the IPI model, which would price drugs based on the average market-basket price experienced among a group of defined OECD countries. However, without the text of the EO or a corresponding rule, this cannot be confirmed.

   What ***is*** known about the MFN proposal is that it will remain focused on Part B drugs. Notably, the President will not implement this EO officially until August 25th. In his announcement, the President stated that he will provide the pharmaceutical industry one month to present an alternative proposal that will yield similar price reductions. The President and his team were scheduled to meet with a team of pharmaceutical executives on Tuesday, July 28th, to begin these discussions—but that meeting has been cancelled because the executives refused to meet with the President.

   Whether and how this proposal will proceed is unclear. The IPI proposal faced strong resistance from the drug industry as well as some beneficiary advocates – and was not popular with Republicans in Congress, who viewed it as a form of price controls. And whether such an initiative can proceed at the same time as the drug industry is focusing on developing vaccines and treatments for COVID-19 – another argument advanced by the drug industry – is also uncertain.