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# HHS Drug Import Proposal Is Unlikely To Succeed

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In late December 2019, the U.S. Food and Drug Administration, an agency operating within the U.S. Department of Health and Human Services, issued two documents — a proposed rule and a draft guidance — intended to establish two pathways for drug importation. The U.S. Department of Health and Human Services previewed these approaches in its Safe Importation Action Plan last July.

These proposed pathways are broadly, if not necessarily effectively, aimed at reducing U.S. drug prices in two different ways.

The proposed rule sets out a means by which states and certain other nonfederal governmental entities would be permitted to import certain drugs (notably excluding biologics and many specialty pharmaceuticals) from Canada. Manufacturer consent is not required for importation under this Pathway 1, but many manufacturer obligations and risks flow from it.

The draft guidance creates a framework under which manufacturers could choose to bring their drugs that are manufactured and intended for sale outside the U.S. into the U.S. market. This Pathway 2 would permit both domestic national drug codes, or NDCs, and imported NDCs of the same product to be marketed simultaneously.

**Summaries of Pathways 1 and 2**

Under Pathway 1, the FDA would implement much of Section 804 of the Food, Drug and Cosmetic Act, establishing a regulatory mechanism to oversee the importation of certain prescription drugs from Canada (and Canada only). The proposed rule would permit states and other governmental entities — working with wholesalers, pharmacies and other cosponsors — to submit drug importation plans to HHS for review and approval.

Approved importers would be subject to supply chain security, testing and relabeling requirements. Manufacturers of drugs subject to the importation plans would be required to provide importers with the information necessary to conduct required FDA testing and relabeling. Personal importation is not implemented in the proposed rule. A few key provisions follow.

***Prescription Drug Eligibility***

For a prescription drug to be eligible for importation under a Section 804 importation program, or SIP, it must (1) be approved by Health Canada, (2) meet the conditions in an FDA-approved drug application, other than the labeling requirements, such that the drug could be sold legally in the U.S. with appropriate labeling, and (3) meet the definition of "product" for the purposes of the Drug Supply Chain Security Act (i.e., any prescription drug in finished dosage form, subject to certain exceptions).

Pursuant to statutory exclusions under Section 804, the proposed rule would exclude: (1) controlled substances, (2) biological products, (3) infused drugs, (4) intravenously injected drugs, (5) drugs that are inhaled during surgery and (6) drugs that are subject to risk evaluation and mitigation strategies. In addition, the proposed rule proposes to categorically exclude intrathecally injected drugs and intraocularly injected drugs.

***Foreign Sellers and U.S. Importers***

Under the proposed rule, an initial SIP proposal must identify (1) one foreign seller — the entity in Canada that will purchase the eligible prescription drug directly from the manufacturer, and (2) one importer — the entity in the U.S. that will buy the drug directly from the foreign seller. To qualify as a foreign seller, an entity must be licensed by Health Canada as a wholesaler and registered with the FDA.

To qualify as an importer, an entity must be a wholesaler or pharmacist licensed to operate in the U.S. Both the foreign seller and the importer would be subject to supply chain security requirements from the DSCSA, as well as additional requirements imposed by the proposed rule, if finalized.

***Testing Requirements***

Once the FDA has authorized a SIP, Section 804 of the FDCA requires importers to provide documentation to the FDA demonstrating that "each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation."[1] Under the proposed rule, importers can meet that requirement by (1) requesting that the manufacturer agree to conduct the necessary testing, or (2) conducting the testing themselves, after the manufacturer provides the requisite information.

Notably, if the manufacturer fails to provide such information in a timely fashion, the manufacturer would be committing a prohibited act under Section 301(aa) of the FDCA. In that circumstance, the FDA could provide such information directly to an importer, to the extent it is contained in an NDA or an abbreviated new drug application.

***Enhanced Penalties Against Manufacturers for Noncompliance***

Section 804 of the FDCA has a built-in statutory enforcement mechanism. Section 301(aa) of the FDCA establishes that noncompliance with Section 804, or the implementing regulations, is a prohibited act. The FDCA also establishes enhanced criminal fines and imprisonment for manufacturers or importers that violate Section 804(e), the provision that requires manufacturers to share testing information with importers.

The standard felony provision under the FDCA authorizes three years imprisonment and a $10,000 fine, but the enhanced penalty is 10 years imprisonment and a $250,000 fine. Notably, the proposed rule

explicitly emphasizes that the obligations on manufacturers are enforceable under Section 301(aa).

Pathway 2 would allow manufacturers to import their own FDA-approved drugs that are also manufactured, approved and intended for distribution in foreign markets (including but not limited to Canada) — into the U.S. The drugs subject to Pathway 2 are referred to as multimarket-approved products or MMA products.

Under this pathway, a manufacturer would market the imported version of its drug under a different NDC number than the domestic version, which might (consistent with the policy hopes of the administration) allow the manufacturer to introduce it to the U.S. market at a lower price. HHS has noted that this pathway would offer manufacturers who are locked into contracts with other parties in the supply chain with an opportunity to import lower-cost versions of their drugs.

The FDA's draft guidance addresses the steps that drug manufacturers would need to take to obtain a new NDC to import MMA products — should drug manufacturers want to do so. Those steps include:

1. Labeling: MMA products, like all FDA-approved prescription drugs, must be accompanied by FDA-approved labeling. Therefore, a manufacturer seeking to market an MMA product under an NDA or biologics license application must submit a labeling supplement. The supplements, among other things, must include an attestation by the manufacturer that the MMA product has the same quality and characteristics as the FDA-approved products.

2. Registering, listing and proposing an NDC: The FDA recommends that drug manufacturers propose a new NDC for the MMA product by following the procedures set forth in Title 21 of the Code of Regulations Section 207.33. The procedures for registration and listing are the same for MMA products as for all FDA-approved drugs.

3. Drug Supply Chain Security Act: Section 582 of the FDCA (added by the DSCSA) requires, among other things, product tracing and verification and product identification. It also establishes authorized trading partner requirements for manufacturers, repackagers, wholesale distributors and dispensers to facilitate the tracing of certain prescription drugs through the supply chain. Any MMA product that meets the definition of a "product" under the DSCSA,[2] will be subject to all the applicable requirements for such products under Section 582.

4. Importation of MMA products: The FDA encourages the filing of an electronic entry in the automated commercial environment, and notes that international mail is not appropriate for the importation of MMA products. In addition, the FDA encourages manufacturers to submit a report via the electronic submissions gateway that includes (1) the drug name, dosage form and quantity of the drug, (2) the name, address and telephone number of the authorized importer, and (3) any temporal or other limitations the manufacturer has placed on the authorized importation.

**Key Takeaways Regarding the Proposed Importation Pathways**

Our key takeaways from the FDA's drug importation proposals are as follows:

***The Legality of the Proposed Rule Is In Question***

We have significant concerns that the FDA does not have statutory authority to implement the proposed rule as written because HHS cannot make the required cost reduction certification. The FDA can only

implement Section 804 of the FDCA if HHS certifies that the implementation of the law will (1) pose no additional risk to the public health, and (2) result in a significant reduction in the cost of covered products to the American consumer.[3] Based on our initial read of the proposed rule, however, we do not believe that the FDA provided a sufficient factual basis for HHS to certify that the implementation of the rule will satisfy the second prong.

Indeed, at the very start of the proposed rule, the FDA concedes that it is "unable to estimate the volume or value of drugs that may be imported under the SIPs or the savings to U.S. consumers who may participate in such programs."[4] We have serious doubts that cost savings — let alone significant cost savings — will materialize because the importation program only applies to Health Canada-approved drugs.

The Canadian government has already made clear that it will not allow U.S. demand to create drug shortages for Canadians, and thus, the volume of drugs that Canadians can spare, at least in the short-term until manufacturers are able to ramp up operations, may be limited. Further, the testing and relabeling requirements will increase the cost of the drugs being imported.

***The Testing Requirements for Manufacturers Are Vague and Could Subject Them to Significant Legal Exposure***

The proposed rule would require importers to provide documentation to the FDA demonstrating that each batch of imported drug was statistically sampled and tested for authenticity and degradation, and it would require manufacturers to either do the testing themselves or provide importers with the necessary information required to do the testing.

The proposed rule does not explain what such necessary information may include. We can envision disputes between manufacturers and importers over the scope of information to be produced and the timing of the production, and the importers would have considerable leverage in these disputes given that manufacturers are exposed to criminal enforcement if they fail to comply.

***Government Price Reporting and Federal Reimbursement Implications***

Neither the proposed rule nor the draft guidance addresses how the importation pathways would affect price reporting or federal reimbursement. This is not surprising, given that the proposed rule and draft guidance were issued by the FDA, not CMS. Nevertheless, manufacturers should consider how Pathways 1 and 2 would affect the sale, use, reimbursement and rebating of imported medications. A few initial thoughts:

*Manufacturer Price Reporting Implications of Pathway 1*

Presumably, initial ex-U.S. drug sales under Pathway 1 would remain excluded from price reporting requirements, even if the drugs were subsequently reimported into the U.S. (particularly if the imported units bear unique NDCs). Sales to entities in foreign countries (including Canada) have been excluded for Medicaid, Medicare and VA/FSS price points for decades.

This might change if the manufacturer is itself a party to an indirect importation sales agreement through a Canadian foreign seller that generates a chargeback to the manufacturer. The existing pricing rules do not contemplate a foreign direct sale, domestic indirect sale situation. In addition, unless imported products bear a labeler code different from that of the manufacturer, U.S. dispenses of

Canadian-sourced drugs may generate government and commercial insurance rebates payable by the manufacturer that will affect price reporting and revenue.

Manufacturers should consider the gross-to-net effects of being pulled into a Pathway 1 importation scheme (low priced sales generating rebatable utilization in a way not contemplated when contracted-for).

*Importer Price Reporting Implications of Pathway 1*

Query (1) whether importers under Pathway 1 that relabel with their own labeler codes would need to sign National Rebate Agreements for the products to be covered by Medicaid, (2) whether Medicaid price reporting and rebate liability under that situation would flow to the importer, (3) whether the importer also would be required to extend 340B discounts, and (4) whether any importer would be willing to undertake those expensive obligations? These issues need clarification.

*Price Reporting Implications of Pathway 2*

The price reporting implications of Pathway 2 are also potentially problematic. The FDA might not care if the same dosage form and strength of a single drug has multiple NDCs, but CMS certainly does. The Medicaid rules and guidance regarding blending across NDC-9s are muddy at best; they are at times mandatory, and at other times permissive. The administration's promises of a low-price second pathway via importation may be illusory if CMS requires best price blending across the NDCs.

*Reimbursement Implications*

Query whether (1) government program reimbursement will treat domestic and foreign NDCs of the same product separately, with separate reimbursement calculations, or as the same product, with a common or blended reimbursement, and (2) whether imported products will be able to be priced separately (and lower) than their domestic counterparts in the Medicare Part D and Medicaid programs, and how that will affect rebate and discount negotiations between plans, pharmacy benefit management and manufacturers.

Arguably, importing pharmacies may be able to offer lower-cost drugs at the point of purchase to Medicare and Medicaid beneficiaries, but it is unclear whether such products would be covered by Part D plans or states. These issues need clarification.

*The Utility of Pathway 2 Remains Unclear*

In our benchmarking and informal conversations in the industry, we have not encountered a lot of enthusiasm about Pathway 2, and we do not anticipate that the guidance will create much momentum for manufacturer-lead importation.

Although some have theorized the pathway would permit manufacturers to circumvent pharmacy benefit management rebates and contractual arrangements, it is unclear how such products could actually be covered by a health plan on formulary, or how they would effectively be carved out of PBM rebate utilization. We will have to await further clarification from the CMS to see if this pathway is even viable from a business operations and government price reporting perspective.

Given that drug manufacturers may not embrace the manufacturer-led importation envisioned under Pathway 2, the existence of the pathway may ultimately serve more as a mechanism to shift the blame for high drug prices from the government to drug manufacturers, than as a true mechanism for meaningful change.

Indeed, we suspect that Pathway 2 might simply be a shaming tool that would allow HHS to say that the government gave industry the opportunity to import their own drugs at a lower cost and industry failed to seize it.

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[1] See 21 U.S.C. § 384(d)(1)(J).

[2] See 21 U.S.C. § 360eee (defining "product" as any prescription drug in finished dosage form, subject to certain exceptions).

[3] 21 U.S.C. § 384(l)(1)(A), (B).

[4] 84 Fed. Reg. 70796, 70798, (Dec. 23, 2019).