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Summary: Importation of Prescription Drugs; Final Rule

On September 25, 2020, the Food and Drug Administration (FDA) released a Final Rule titled "Importation of Prescription Drugs," allowing FDA-authorized programs to import specific drugs from Canada under certain conditions designed to ensure that the imported drugs pose no additional risk to health and safety as well as provide a "significant reduction" in costs to American consumers.

AMCP joined other national pharmacy organizations in sending comments on the proposed importation rule, stating our concerns with the potential safety issues associated with a drug importation program as well as our concerns that the potential cost savings are unknown and not sufficient to justify implementing an importation program.

The following is a summary of key sections in the final rule that may be of interest to AMCP members:

A. Section 804 Importation Programs

a. Authorizes the implementation of "Section 804 Importation Programs" (SIPs) authorized by the FDA and managed by a state, Indian Tribe, pharmacist, or wholesale distributor (collectively, SIP Sponsors).
   - SIPs will be approved initially for two years, but could be reauthorized for additional two year periods if the SIP Sponsor submits a proposal for reauthorization.

b. The SIP Sponsor will specify the eligible prescription drugs that would be included in the importation program.
   - To be included, any specified drug must be approved to be legally sold by the appropriate authorities in both the United States and Canada.
   - Controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery are prohibited by statute from being included in an importation program.

c. SIP proposals are required to identify the Foreign Seller in Canada that will purchase the drugs for importation directly from the manufacturer. The proposals must also specify the Importer in the United States that will buy the drug directly from the Foreign Seller.
   - The supply chain is initially limited to one manufacturer, one Foreign Seller, and one Importer, though if the SIP sponsor demonstrates that it is consistently importing drugs in accordance with the rules, it may submit a supplemental proposal to include additional Foreign Sellers and Importers.
   - The Foreign Seller must be licensed to wholesale drugs in Canada and registered with the FDA as a Foreign Seller. The Importer must be a pharmacist or wholesale distributor licensed to operate in the United States.

B. Supply Chain Security Requirements

a. The Foreign Seller must ensure that a section 804 serial identifier (SSI) is affixed to or imprinted on each package and homogenous case of an imported drug.
    - The SSI consists of an alphanumeric serial number unique to each package and homogenous case.

b. The Importer must ensure that a product identifier is then affixed or imprinted on each package or homogenous case of eligible prescriptions it receives from the Foreign Seller.
    - The product identifier must include a National Drug Code (NDC), a unique alphanumeric serial number, lot number, and expiration date in both human and machine-readable formatting.
    - Records must be maintained by both the Importer and the Foreign Seller to track shipments and receipts.

c. Once a SIP Proposal is authorized by the FDA, the Importer is required to submit a Pre-Import Request to the FDA at least 30 calendar days before the scheduled arrival or entry of for consumption of a shipment containing eligible prescriptions covered by the SIP Proposal.
    - Entry of and arrival of a shipment of eligible drugs is limited to the US Customs and Border Protection port of entry designated by the FDA.
    - If an Importer does not comply with the provisions regulating entry for consumption, the drug shipment is subject to refusal.

d. The final rule requires the manufacturer or Importer to conduct testing of eligible drugs for authenticity, degradation, and to ensure that imported drugs are in compliance with established specifications and standards.
    - Imported drugs must also be relabeled with the required US labeling.

C. Post-Importation Requirements

a. SIP Sponsors are required to report to the FDA cost savings to consumers realized from the SIP.

b. Sponsors must also submit adverse event, field alert, and other reports to both the drug manufacturer and the FDA.
    - SIP Sponsors are also required to effectuate any recalls as determined by the FDA or any SIP participant.

AMCP Position

a. AMCP has concerns with proposals that would allow the commercial importation of prescription drugs for sale in the United States and cannot support importation proposals until there are adequate resources to monitor the importation of prescription drugs, ensuring that their quality and safety have not been compromised.
    - AMCP is opposed to importation proposals until more conclusive data are available as to the likely impact of importation on the cost of drugs and the risks posed to the American citizens.

b. With respect to this final rule, AMCP has concerns that Canada's drug supply is wholly insufficient to supply the U.S. market and that should Canada increase its purchases to cover the demands of American consumers, manufacturers will likely be incentivized to increase prices to offset reduced American demand.
    - Additionally, Canadian pharmacists and other authorities have expressed opposition to US importation, in particular concerns with potential shortages for Canadian

consumers, indicating a lack of a willing partner in potential implementation programs.

c. Importation from Canada poses unacceptable risks to the US drug supply chain and will undermine the work pharmacists and other stakeholders have done to implement the closed supply chain that tracks and traces prescription drugs as they move from manufacturer to distributor to pharmacist that has been established in the US.
d. The largest drug wholesalers indicated that they would not participate in SIPs during the proposed rule stage, meaning that any SIP Proposals would need to rely on inexperienced or new wholesaler market entrants, increasing the risk to the supply chain and public safety.
e. Previous state estimates of drug importation programs concluded that savings from importation programs would not be significant.