HDA
Healthcare Distribution Alliance

PATIENTS MOVE US.

June 25, 2019

Crystal Demott
Procurement Director
State of Florida
Agency for Healthcare Administration
2727 Mahan Drive
Tallahassee, FL 32308

Re: Request for Information (RFI), Canadian Prescription Drug Importation Program (HB 19)

Ms. Demott,

The Healthcare Distribution Alliance (HDA) offers this response to communicate our concern with the State of Florida regarding the Canadian Prescription Drug Importation Program as enacted by House Bill 19. Specifically, HDA is seeking clarity and a better understanding of the role of vendors in the Program.

HDA is the national trade association representing primary pharmaceutical wholesale distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies and other healthcare settings nationwide. Specific to Florida, our members operate thirteen facilities in the state and employ nearly 3,000 residents.

On behalf of the industry, HDA engaged throughout the legislative process, outlining the complex issues associated with HB 19. We remain concerned that the Canadian Prescription Drug Importation Program portion to the State of Florida's Agency for Healthcare Administration (AHCA) will negatively impact the pharmaceutical supply chain and jeopardize patient safety.

The U.S. pharmaceutical supply chain is the most sophisticated, efficient and secure drug supply chain system in the world. The highly secure nature of the supply chain was further strengthened in 2013 by the passage of the federal Drug Supply Chain Security Act (DSCSA). This law outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. DSCSA enhances the Food and Drug Administration's (FDA) ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The system also improves detection and removal of potentially dangerous drugs from the pharmaceutical supply chain.

Under the confines of DSCSA, any drug distributed in the U.S. must be distributed to and from an authorized trading partner. Further, any drug distributed within the U.S. must also be a serialized product, incorporating the National Drug Code, Serial Number, Lot Number and expiration date. Medications that are sold or designated for sale in Canada as well as other countries do not conform

with these U.S. traceability regulations and do not have the necessary data to align with DCSCA requirements, increasing the risk of illegitimate or counterfeit medications entering the U.S. market and putting patient safety at risk. As the FDA continues to finalize its regulatory guidance for the second phase of DSCSA implementation, it is counterproductive to introduce foreign pharmaceuticals—that would need repackaging, relabeling and serialization as well as screening for counterfeiting—before the current supply chain is able to conform and comply with new DSCSA standards.

Drug approval by the FDA is contingent upon the strictest guidelines for product integrity, good manufacturing practices, scientific data analysis and public safety. At this point, the FDA cannot guarantee to American consumers that a drug sold or designated for sale in foreign countries will be the same product his or her physician prescribed, nor can it fully attest to its safety. [1] Further, the four most recent FDA Commissioners wrote an open letter to Congress in March 2017 expressing their continued concerns with any drug importation program.[2]

Both branded and generic drugs are susceptible to counterfeiting, sometimes containing insufficient or too much of an active ingredient or being contaminated by unsanitary manufacturing conditions. The U.S. supply chain, regulated by the FDA, devotes significant resources to ensure safe manufacturing, product authenticity and the secure distribution of drugs through authorized parties from the point of manufacture to the point of dispensing. HDA members are an essential part of this closed distribution system, working daily with supply chain partners, law enforcement and government regulators to help ensure prescription medicines are safely delivered to licensed pharmacies within the U.S.

HDA appreciates the inclusion of HHS approval requirements for safety and DSCSA traceability standards in the law. However, these provisions are moot under current federal law. When comparing the current structure and standards of the U.S. pharmaceutical supply chain with international standards, HDA does not see how meeting such requirements is possible. Verifying and tracking foreign product in the U.S. pharmaceutical supply chain to ensure patient safety and prevent diversion by the strict standards put forth within current federal law would be impossible.

In moving forward with this Request for Information, the Agency for Healthcare Administration must understand the risks associated with establishing a Canadian Prescription Drug Importation Program, specifically the risks it is asking potential vendors contracted under the Program to assume with the inherent uncertainty that exists. HDA submits the following and requests clarification on the below sections which are organized sequentially as they appear in the law.

[1] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi, Esq., The Kullman Firm https://www.crowell.com/pdf/FDALetter.pdf

[2] Open letter to Congress authored by four FDA commissioners opposing drug importation, (March 2017)https://www.documentcloud.org/documents/3519007-FDA-Commissioners-Drug-Reimportation.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals

Comments & Questions:

1. It is not clear from the definition of "vendor" in the law, Section 381.02035 (l), if vendors are meant to engage in the act of distributing the medications between supplier and importer or intended to oversee such activity by other entities. HDA asks that this be clarified.
    a. Are the vendors facilitating the Wholesale Importation Program meant to be primary wholesale distributors?
    b. Are other entities going to be considered for this role and if so, what kind of entities would they be?
    c. How many vendors does the AHCA expect will manage the importation program or will there only be one vendor?

2. It is the opinion of the primary wholesale distribution industry that having systems in place to compile the list identifying the prescription drugs that have the highest potential for cost savings to state programs by the December 1, 2019 is not a reasonably achievable timeframe. HDA believes this does not leave sufficient time for any forthcoming competitive solicitation process that would need to occur before vendors are selected and required to submit such a list.

3. How does the state intend to deal with preemptive requirements under the DSCSA and broader Food Drug and Cosmetic Act for products, data exchange, and supply chain partners?

Sincerely,

Elizabeth Gallenagh
Senior Vice President, Government Affairs
Healthcare Distribution Alliance