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Via Electronic Mail: ***jhorvath@nashp.org***

Jane Horvath, Senior Policy Fellow
National Academy of State Health Policy
1233 20th Street NW, Suite 303
Washington DC 20036

Re*: *Importation of Prescription Drugs from Canada for use within State Healthcare Systems

Dear Jane,

You asked us to review and evaluate a proposed program whereby prescription drugs can be legally imported from Canada under Title 21 United States Code ("USC") § 384 exclusively by or under the direct control of a State authority. The U.S. Food and Drug Administration ("FDA") regulates and enforces the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) including the importation of prescription drugs from Canada. You requested that we provide our initial assessment regarding the legality and feasibility the proposed program. You also asked us to participate in a teleconference and answer questions from attending representatives from one or more States and other associations who may be stakeholders interested in the proposed importation program. The following outlines our review and evaluation and summarizes our opinions based upon the preceding.

The Applicable Law

Under 21 USC § 384 (Section 804 of the FFDCA), Congress directed FDA to establish and implement by regulation a drug importation program whereby a "pharmacist" or a "wholesaler" can legally import drugs from Canada provided that certain safeguards are in place to ensure that each prescription drug imported under this regulation complies with section 505 of the FFDCA (including with respect to being safe and effective for the intended use of the prescription drug), with section 501 (adulteration) and section 502 (misbranding), and with other applicable requirements of the FFDCA. Section 804 includes a "poison-pill," which has left the authority dormant since its enactment. Specifically, section 804(l)(1) states that the commencement of this program shall become effective only if the Secretary of the U.S. Department of Health and Human Services ("HHS") certifies to the Congress that the implementation of this section will (A) pose no additional risk to the public's health and safety; and (B) will result in a significant reduction in the cost of covered products to the American consumer. After this certification to the Congress, the Secretary of HHS may promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada only after consultation with the United States Trade Representative and the Commissioner or Customs (CBP).

Section 804(k) states, that as provided in this section, the authority of the Secretary concerning section 801(d)(1) concerning re-importation of prescription drugs is limited. Therefore, prescription drugs that were exported from the United States can be re-imported from Canada. Because of the conditions in the bill, no HHS Secretary has made the required certification to the Congress – thus, the provision has never gone into effect.

The Proposal

NASHP has proposed, in short form, to initiate a regime established and maintained by various States under their own authorities (1) permitting and regulating the importation from Canada of qualified prescription drugs into the State under the §384 protocol, and (2) restricting distribution of such drugs to qualified facilities within the state.

In our view, there is no legal impediment to such a program. We discuss specific questions posed by stakeholders below, along with some additional commentary that may prove helpful in developing a program that the current Secretary of HHS can certify that it meets the statutory limitations criteria.

A. What would the Supply and Distribution Chains look like under such a program?

The Supply and Distribution Chains under such a program would look much like every other supply chain. Wholesale distribution of prescription drugs is governed now by the Drug Supply Chain Security Act of 2013 ("DSCSA"), which supplemented the Prescription Drug Marketing Act ("PDMA") and amended the Federal Food Drug and Cosmetic Act ("FFDCA"). The DSCSA states that all parties in the prescription Rx only) drug distribution chain including drug manufacturers, wholesale distributors, repackers/relabelers, and pharmacies that do business in the State are required to hold various registrations or permits from each State authority and maintain certain records establishing a pedigree for each lot of drug received, stored and distributed. As an initial caveat, the first foreign recipient of an FDA-approved drug (from an authorized drug manufacturer – whether foreign or domestic) must be able to document having purchased the qualifying drug from an FDA-authorized manufacturer and that the drug was lawful in the first purchaser's foreign country. Further, under the DSCSA, the foreign (Canadian) seller of Rx drugs imported to the States under this program is required to register with FDA as such and to appoint a U.S. Agent for FDA purposes.

Where the first foreign purchaser is in Canada and is the foreign seller to the US, importation of the qualifying drug would follow the same basic supply chain as other Rx drugs imported into the USA, except, there will need to be a repacking step prior to export from Canada.

The foreign seller's registration would be connected to FDA's (and to the extent required) DEA's registrations. The repacker/relabeler would also be an FDA-registered entity. The foreign seller and foreign repacker/relabeler do not have to be the same entity (that is, the repacker/relabeler can operate under contract); however, the foreign seller must be the Canadian exporter. The qualified drugs would then pass through the border via international carrier/courier to the U.S. Distributor/Wholesaler or Pharmacist. Section 384 now contemplates the importer of a qualified drug will be a wholesaler or pharmacist. Under the current provision, there is nothing in the federal law that prevents the State from requiring participating importers to be partly or wholly owned by

the State, which would thereby increase the chance of satisfying FDA and HHS that the State can maintain secure distribution of the imported drugs. control of the

In situations where the first foreign purchaser is not the Canadian foreign seller to the US, additional steps are necessary to ensure the authenticity and integrity of the qualifying drug, but the supply chain will be similar. We recommend considering restricting the number of commercial entities between the manufacturer and the first foreign seller and requiring documentation from the foreign seller demonstrating the purchased drug is traced back to the manufacturer of the FDA-approved drug.

Under the DSCSA, all Rx drug wholesalers are required to be licensed or permitted in the states in which they operate. Some states require foreign (non-US) wholesalers, repackers/relabelers and manufacturers (even though they do not operate in the state) to hold certain licenses or permits to distribute Rx drugs into their jurisdictions. The applicable state law will have to be satisfied or amended before qualified drugs may be legally imported into the state.

The critical element for monitoring and maintaining the integrity of the program's supply chain is governed primarily by the track and trace methods used for the drugs within a supply chain. Through the tracking (pedigree) requirements and the advancement of Block Chain technology, we see no significant hurdle to presenting adequate evidence to FDA that a State program is no less secure than the supply chain of the manufacturer.

B. How/When/Where in the Supply Chain can imported or reimported drugs be relabeled for the U.S. market?

As intimated in the answer to Question A, the imported or reimported drugs must be relabeled and, as needed, repackaged, prior to importation into the USA. This reduces the likelihood that FDA will successfully refuse admission to an entry of drugs imported under the program. FDA has the authority to detain and refuse admission to imported drugs that merely "appear" to be violative under applicable provisions of the FFDCA. In the case of a § 384 program, the importer is already required to certify to the Secretary of HHS that the drugs are FDA-approved, are not adulterated, and/or misbranded. We contemplate propsing use of an FDA Code to be transmitted to FDA informing the whether a particular imported drug shipment qualifies for admission under the proposed program. This will reduce unnecessary delays during the importation process.

C. How can the FDA National Drug Code (NDC) number be placed on the product to allow billing of U.S. payers?

Solution to this question remains open for a number of reasons, though we expect it can be answered during the proposal and proposal review process.

Under current law, the initial five digits of the NDC code are the "labeler code" and represent the specific drug establishment that labeled the finished drug product. Consequently, using the drug manufacturer's NDC code is not feasible.

Implementation of a § 384 program requires review and acceptance by the Secretary of HHS. The Secretary is also obligated to establish by regulation those provisions dictated by law. The statute clarifies that these regulations must:

> (1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of the prescription drug), with sections 351 and 352 of this title, and with other applicable requirements of this chapter;
>
> (2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and
>
> (3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health *or as a means to facilitate the importation of prescription drugs*.

See 21 U.S.C. § 384(c) (*emphasis added*).

Among the regulations to facilitate importation of qualifying drugs would be those ensuring that § 384 importers or foreign sellers (whether or not repackers/relabelers) could list the drugs with FDA as required and obtain NDC numbers from for exportation to the USA under the approved program. Because FDA and Centers for Medicare and Medicaid Services ("CMMS") are agencies within HHS, the Secretary clearly has the authority to ensure third party billing for qualified drugs.

Second, we anticipate ensuring through the § 384 proposal process that importers or foreign sellers are able to obtain NDC numbers for relabeled/repackaged drugs. The NDC numbers for such qualifying drugs could be cross-linked to existing NDC numbers for the manufacturers' products for the purposes of third party billing.

In our opinion, this question should be an essential part of any § 384 program proposed by a State. Because the lot numbers for qualified drugs imported under the program must already be tracked, it can be relatively simple to incorporate into the billing systems the appropriate NDC numbers to enable third paying billing. However, we expect there to be technical gaps that would need to be filled to implement the program.

D. How can an imported drug be identified for tracking for safety and U.S. billing purposes?

The existing supply chain track-and-trace technology, pedigree requirements under DSCSA and state laws, and the power of the evolving Block Chain technology are fully capable of managing the risk of an unqualified drug slipping into the pipeline and ensuring the imported prescription drug was handled to ensure its safety and efficacy. U.S. billing questions primarily revolve around the approval status of a prescription drug, and compliance with that requirement is already presumed in a § 384 evaluation.

E. Any recommendations for Canadian suppliers to approach for this program?

We have not contacted any potential suppliers at this point because the details of the program are still too vague. As part of any discussion with Canadian companies, the matter of drug shortages

and price increases for Canadian citizens will surely become part of the discussion. We have spoken with various companies interested in similar arrangements, without having a State filing the proposal with HHS. The combination of the two elements (State support and action and the commercial interest of international companies) is likely to produce powerful alliances. At this stage, the States must consider the roles they will play in the process (as mere regulator/oversight, as partner-participant, or as the importer/distributor). The suppliers' interest levels will change depending upon the role the State decides to ultimately pursue.

Conclusion

We have attempted to provide enough detail to provide an appropriate level of confidence that a State-sponsored program could obtain Secretary certification. In our view, importation and re-importation of qualified prescription drugs exported from Canada could be accomplished in a manner and with adequate safeguards to ensure at least the same level of safety, efficacy, authenticity and integrity contemplated by § 384. In our opinion, the existing federal and state regulatory structures and the supply chain technologies already exist to implement the program, though certain modifications would be required. The question of U.S. billing will require some regulatory modification by CMMS.

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If you have any question regarding the above, please do not hesitate to contact me at 410-220-2800 or blengland@fdaimports.com.

Sincerely,

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