



## **An Act to Permit the Wholesale Importation of Prescription Drugs into [State]**

*Whereas:* United States citizens pay some of the very highest prices for prescription drugs in the world and the Canadian government estimated that U.S. consumers pay twice as much as Canadians for patented prescription drugs and 20 percent more for generics.

*Whereas:* Under FDA discretion not to enforce the law, individual patients may import a 90 day supply of prescription drugs from Canada that are less expensive than drugs licensed by the FDA in the United States.

*Whereas:* Individual importation via the internet increases consumer health and safety risks because many internet pharmacies are not licensed in Canada and it is difficult to verify the validity, reputation, actual identity and pharmacy practices of ex-U.S., on-line pharmacies.

*Whereas:* The U.S. allows patients to go to other countries for surgeries and other high-risk medical treatments without regulating that consumer purchasing activity and insurers sometimes facilitate and pay for ex-US treatments.

*Whereas:* FDA estimates that currently 40 percent of finished prescription drug products are produced outside the U.S. and 80 percent of raw product for U.S. pharmaceutical manufacturing comes from outside the U.S.

*Whereas:* The FDA has just signed reciprocity agreements with EU regulators to accept the results of EU inspections pharmaceutical manufacturing plants. The FDA has a Memorandum of Understanding for regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities since 1973.

*Whereas:* Canada has a rigorous regulatory system to license prescription drugs that is considered to be on par with the U.S. licensing system.

*Whereas:* Title II of the federal Drug Quality and Security Act (P.L. 113 -54 ), Drug Supply Chain Security, has resulted in improvements in drug security and safety through a system of pharmaceutical track and trace that can be leveraged for safe importation.

*Whereas:* The Secretary of the U.S. Department of Health and Human Services may certify a prescription drug reimportation program that is safe and saves consumers money.

*Whereas:* [State] can assure that wholesale importation of prescription drugs from Canada into our State will be safe and cost-saving for [State] consumers.

*Therefore:* [State agency] is directed to implement a wholesale drug importation program for the exclusive benefit of residents of the State of [name].

### **General Description**

This Act directs the [State agency] to work with relevant State stakeholders, as well as federal offices and agencies, to develop and implement a prescription drug wholesale importation program that is safe for

[State] consumers and generates substantial savings for [State] consumers.

## **Section 1. Definition**

Importation Program: A State-administered wholesale importation program where the State is the licensed wholesaler, importing drugs from a licensed, regulated Canadian supplier, solely for distribution to voluntarily participating, state-licensed, in-state, pharmacies and administering providers for the exclusive purpose of dispensing to state residents with a valid prescription.

## **Section 2. Directive to Develop the Wholesale Importation Program Design that Complies with the Following Administrative Specifications**

The [State agency] is directed to design a wholesale prescription drug importation program in consultation with relevant State stakeholders and federal offices and agencies that will meet relevant requirements of 21 U.S.C. 384, including safety and cost savings. In developing a prescription drug importation program for federal certification, the [State agency] shall address the following issues:

1. That a State agency either becomes a licensed wholesaler or licenses an entity to become a wholesaler for the purpose of seeking federal certification and approval to import safe prescription drugs that will provide savings to [State] consumers;
2. That the program uses Canadian suppliers regulated under the appropriate Canadian and/or provincial laws;
3. That the program has a process to sample the purity, chemical composition, and potency of imported products;
4. That the program only imports those prescription pharmaceuticals expected to generate substantial savings for [State] consumers;
5. That the program ensures imported products will not be distributed, dispensed, or sold outside of [State] borders;
6. That the program ensures voluntary participant, state-licensed, pharmacies and administering providers charge individual consumers and health plans the actual acquisition cost of the imported, dispensed product;
7. That the program ensures health plan payment of the product component of pharmacy and provider billing reimburses no more than the actual acquisition cost of the dispensed, imported product;
8. That the program ensures participating health plans keep their formularies and claims payment systems up to date with the prescription drugs provided through the wholesale importation program;
9. That the program ensures participating health plans base patient cost sharing on no more than the actual acquisition cost of the dispensed, imported product;
10. That the program require participating health plans to demonstrate to the [State agency] how savings on imported drugs are reflected in premiums.
11. That profit margin of any participating wholesaler and/or distributor(s) of imported pharmaceutical products is limited to a specified amount established by the [State agency];
12. That the program does not import generic products that would violate U.S. patent laws on U.S. branded products;
13. That the program complies with the requirements of 21 U.S.C. 581-582, pertaining to the track and trace requirements as enacted in Title II of the Drug Security and Quality Act (P.L. 113-54) to the extent practical and feasible before imported drugs come into possession of the State

- wholesaler and complies fully after imported drugs are in the possession of the State wholesaler;
14. That the program is adequately financed through a fee on each prescription or other appropriate approach, but the size of the fee cannot jeopardize significant consumer savings;
  15. That the program includes an audit function to ensure that:
    - (1) The [State agency] has a sound methodology by which to determine the most cost-effective products to include in the importation program on an ongoing basis;
    - (2) The [State agency] has processes in place to select Canadian suppliers of high quality, high performance, and in full compliance with Canadian law and regulation [and at the option of the Sponsor, state pharmacy or wholesaler laws];
    - (3) Imported drugs under the State program are not shipped, sold, or dispensed outside the State once in the possession of the State;
    - (4) Imported products are pure, unadulterated, potent, and safe;
    - (5) Participating pharmacies and administering providers are not charging more than actual acquisition cost to any consumer or any participating health plan;
    - (6) Participating health plan formularies and claims processing systems remain up to date with all relevant aspects of the importation program;
    - (7) Participating health plans base patient coinsurance and other cost sharing on the actual acquisition cost of covered, imported drugs;
    - (8) Participating health plans reimburse participating pharmacies and administering providers actual acquisition cost for imported, dispensed product;
    - (9) The program is adequately financed to support all administrative functions while generating significant consumer savings;
    - (10) The program does not put consumers at higher risk than if the program did not exist; and
    - (11) The program continues to provide [State] consumers with substantial savings on prescription drugs.

### **Section 3. Monitoring for Anti-Competitive Behavior**

The [State Agency] shall enlist the assistance of the Attorney General to identify the potential for anticompetitive behavior in industries that would be affected by a program of importation.

### **Section 4. Report Back to Authorizing Committee**

The [State agency] is directed to report back to Committee of jurisdiction by [6 months from date of enactment] on the final State wholesale importation program design that takes into consideration at least the items in Section 2 above.

### **Section 5. Submission of Request for Federal Certification and Approval**

Upon the approval of the Committee, the [State agency] shall submit a formal request to the Secretary of the U.S. Department of Health and Human Services for certification of the State's wholesale drug importation program. The [State agency] shall submit the request within two weeks of obtaining the Committee's approval.

### **Section 6. Implementation/Additional Administrative Requirements**

Upon certification and approval by the Secretary of the US Department of Health and Human Services, the [State agency] shall begin implementation of the wholesale importation program and have the

program operational within six months of the date of the Secretary's certification. As part of the implementation process the [State agency] shall, in accordance with State procurement and contracting laws and rules as appropriate:

- (1) Become licensed as a wholesaler or license an entity to become a wholesaler;
- (2) Contract with a state-licensed distributor or distributors;
- (3) Contract with a licensed, regulated, Canadian supplier or suppliers;
- (4) Engage health plans, employers, pharmacies, providers, and consumers;
- (5) Develop a registration process health plans, pharmacies, and administering providers willing to participate;
- (6) Create a publicly available source for listing prices of imported products that will be available to all participating entities and consumers;
- (7) Create an outreach and marketing plan to generate program awareness;
- (8) Create and staff a hotline to answer questions from any affected sector starting in the weeks before the program becomes operational that can address the needs and questions of consumers, employers, plans, pharmacies, and providers, among others;
- (9) Establish the audit function and a two year audit work plan cycle; and
- (10) Conduct any other activities determined to be important to successful implementation as determined by the [State agency].

#### **Section 7. Ongoing Oversight of Program Administration**

The [State agency] shall report to this Committee biannually, commencing with either the first June or December after implementation, whichever is the nearest date to the date that is six months after program implementation. The report to the Committee shall include:

- (1) The drugs covered in the wholesale importation program;
- (2) The number of participating pharmacies, providers and health plans;
- (3) The number of prescriptions dispensed under the program in the period;
- (4) The estimated savings to consumers, health plans, and employers that resulted from the program in the reporting period and to date;
- (5) In the first three reporting periods, information on the implementation of the audit plan and, on an on-going basis, audit findings for the reporting period; and
- (6) Any other information of importance as determined by the [State agency].

### Contact Us

State officials interested in this model legislation can have access to a legislator's guide and additional background materials as they become available. If you have questions about the model act or are interested in technical assistance, please contact NASHP Executive Director Trish Riley ([triley@nashp.org](mailto:triley@nashp.org)).

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