HB4362

LRB10115908CPF65265b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB4362

Introduced 1/29/2020, by Rep. Anna Moeller

SYNOPSIS AS INTRODUCED:

New Act

Creates the Wholesale Importation of Prescription Drugs Act. Requires the Department of Public Health to design an importation program where the State is the licensed wholesaler of imported drugs from licensed, regulated Canadian suppliers. Requires the program to address specified issues, including billing issues, cost savings issues, and safety and regulatory issues. Contains auditing and reporting requirements. Provides that the Department shall enlist the assistance of the Attorney General to identify the potential for anti-competitive behavior in industries that would be affected by an importation program. Requires the Department to submit a formal request to the Secretary of the United States Department of Health and Human Services for certification of the importation program. Requires the Department to have the program operational within 6 months after receiving the certification. Contains provisions concerning implementation requirements.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning regulation.

WHEREAS, United States citizens pay some of the highest prices for prescription drugs in the world, and the Canadian government estimated that United States consumers pay twice as much as Canadians for patented prescription drugs and 20% more for generics; and

WHEREAS, Under the Food and Drug Administration's 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 Food and Drug Administration in the United States; and

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 online pharmacies outside the United States; and

WHEREAS, The United States 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 treatments outside the United States; and

WHEREAS, The Food and Drug Administration estimates that currently 40% of finished prescription drug products are produced outside the United States and 80% of raw products for United States pharmaceutical manufacturing come from outside the United States; and

WHEREAS, The Food and Drug Administration recently signed reciprocity agreements with European Union regulators to accept the results of European Union inspections of pharmaceutical manufacturing plants. The Food and Drug Administration has a Memorandum of Understanding for regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities since 1973; and

WHEREAS, Canada has a rigorous regulatory system to license prescription drugs that is considered to be on par with the United States licensing system; and

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; and

WHEREAS, The Secretary of the United States Department of Health and Human Services may certify a prescription drug reimportation program that is safe and saves consumers money; and

WHEREAS, The State can ensure that wholesale importation of prescription drugs from Canada into the State will be safe and cost-saving for State consumers; therefore

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Wholesale Importation of Prescription Drugs Act.

Section 5. Definitions. As used in this Act:

"Department" means the Department of Public Health.

"Importation program" means 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, and in-state pharmacies and administering providers for the exclusive purpose of dispensing to State residents with a valid prescription.

Section 10. Importation program. The Department shall design an importation program in consultation with relevant State stakeholders and federal offices and agencies that meets the relevant requirements of 21 U.S.C. 384, including requirements concerning safety and cost savings. In developing an importation program for federal certification, the Department shall address the following issues:

(1) That the program requires the Department to become a licensed 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 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 this State's borders.

(6) That the program ensures that voluntary participants, 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 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 Department how savings on imported drugs are reflected in premiums.

(11) That the profit margin of any participating wholesaler or distributor of imported pharmaceutical products is limited to a specified amount established by the Department.

(12) That the program does not import generic products that would violate United States patent laws on United States branded products.

(13) That the program complies with the requirements of 21 U.S.C. 581 through 21 U.S.C. 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 amount of the fee may not jeopardize significant consumer savings.

(15) That the program includes an audit function to ensure that:

(A) the Department has a sound methodology by which to determine the most cost-effective products to include in the importation program on an ongoing basis;

(B) the Department has processes in place to select Canadian suppliers of high quality, of high performance, and in full compliance with Canadian law and regulation and State pharmacy or wholesaler laws;

(C) imported drugs under the importation program are not shipped, sold, or dispensed outside the State once in the possession of the State;

(D) imported products are pure, unadulterated, potent, and safe;

(E) participating pharmacies and administering providers are not charging more than the actual acquisition cost to any consumer or any participating health plan;

(F) participating health plan formularies and claims processing systems remain up to date with all relevant aspects of the importation program;

(G) participating health plans base patient coinsurance and other cost sharing on the actual acquisition cost of covered, imported drugs;

(H) participating health plans reimburse participating pharmacies and administering providers the actual acquisition cost for imported, dispensed product;

(I) the program is adequately financed to support all administrative functions while generating significant consumer savings;

(J) the program does not put consumers at higher risk than if the program did not exist; and

(K) the program continues to provide State consumers with substantial savings on prescription drugs.

Section 15. Monitoring for anti-competitive behavior. The Department shall enlist the assistance of the Attorney General to identify the potential for anti-competitive behavior in industries that would be affected by an importation program.

Section 20. Report to the General Assembly. The Department shall report to the General Assembly no later than 6 months after the effective date of this Act on the final importation program design that takes into consideration at least the items in Section 10. The report to the General Assembly shall be filed with the Clerk of the House of Representatives and the Secretary of the Senate in electronic form only, in the manner that the Clerk and the Secretary shall direct.

Section 25. Submission of request for federal certification and approval. No later than 2 weeks after the Department submits the report required under Section 20, the Department shall submit a formal request to the Secretary of the United States Department of Health and Human Services for certification of the importation program.

Section 30. Implementation and additional administrative requirements. Upon certification and approval by the Secretary of the United States Department of Health and Human Services, the Department shall begin implementation of the importation program and have the program operational within 6 months after the date of the Secretary's certification. As part of the implementation process, the Department shall, in accordance with State procurement and contracting laws and rules as appropriate:

(1) Become licensed as a wholesaler.

(2) Contract with a State-licensed distributor or distributors.

(3) Contract with licensed, regulated Canadian suppliers.

(4) Engage health plans, employers, pharmacies, providers, and consumers.

(5) Develop a registration process for health plans, pharmacies, and administering providers that are willing to participate.

(6) Create a publicly available source for listing prices of imported products that shall 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 2-year audit work plan cycle.

(10) Conduct any other activities determined to be important to successful implementation, as determined by the Department.

Section 35. Ongoing oversight of program administration. The Department shall report to the General Assembly every 6 months, commencing with either the first June or December after implementation, whichever is the nearest date to the date that is 6 months after implementation of the importation program. The report to the General Assembly shall include the following:

(1) The drugs covered in the 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 3 reporting periods, information on the implementation of the audit plan and, on an ongoing

basis, audit findings for the reporting period.

(6) Any other information of importance, as determined by the Department.

The report to the General Assembly shall be filed with the Clerk of the House of Representatives and the Secretary of the Senate in electronic form only, in the manner that the Clerk and the Secretary shall direct.