Legislative Analysis

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PRESCRIPTION DRUG IMPORTATION PROGRAMS

House Bill 4978 as introduced
Sponsor: Rep. Tommy Brann

House Bill 4979 as introduced
Sponsor: Rep. Steven Johnson

Committee: Health Policy
Complete to 12-5-19

SUMMARY:

House Bills 4978 and 4979 would create a Prescription Drug Importation Act and an International Prescription Drug Importation Act, respectively, with accompanying programs to effect the goals of those acts.

House Bill 4978 would require the Department of Health and Human Services (DHHS) to establish and promulgate rules for a prescription drug importation program for the purposes of importing safe and effective drugs from Canada.

Request for approval

By January 1, 2021, DHHS would have to submit a request to the U.S. Department of Health and Human Services for approval of the program. If approved, DHHS would have to notify the Senate Majority Leader, the Speaker of the House of Representatives, and each health policy standing committee and begin operating the program within 180 days of notice of the approval.

The request would have to contain all of the following:

- A description of DHHS's plan for operating the program.
- An explanation of how each prescription drug imported under the program would meet state and federal standards for safety and effectiveness, as well as tracking-and-tracing requirements.
- A list of proposed prescription drugs with the highest potential for cost savings to Michigan through importation at the time the request was submitted.
- An estimate of the total cost savings attributable to the program.
- The cost to Michigan of implementing the program.
- A list of each potential Canadian supplier from which Michigan may import drugs and documentation demonstrating that each potential supplier is in compliance with applicable federal and state laws and Canadian federal and provincial laws.

Vendor requirements

If approved by the U.S. Department of Health and Human Services, DHHS would have to contract with a vendor to manage and provide services under the program. The vendor would have to comply with the following:

- By January 1, 2021, and each year thereafter, develop in consultation with DHHS a wholesale prescription drug importation list that identifies each prescription drug that can be imported into Michigan under the program. The vendor would have to consider which prescription drugs are less expensive in Canada and able to provide Michigan savings. DHHS would have to review the list every three months to ensure that it meets the program's requirements and could direct the vendor to revise the list if necessary.
- Develop and maintain a list identifying each eligible Canadian supplier.
- Contract with one or more eligible Canadian suppliers to import prescription drugs under the program or facilitate contracts between eligible importers and eligible Canadian suppliers to import prescription drugs under the program.
- Ensure that, as a condition of participation, each eligible supplier and importer complies with the program's requirements and applicable laws and requirements and does not distribute, dispense, or sell prescription drugs imported under the program outside of Michigan.
- Assist DHHS in preparing the required report and provide DHHS with relevant information.
- Provide an annual financial audit of the vendor's operations and a quarterly financial report on the program to DHHS. The quarterly report would have to include information on the performance of any of the vendors' subcontractors.

DHHS would have to require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance or fraudulent or dishonest acts committed by the vendor or an employee or subcontractor of the vendor.

Requirements for importation

In order to import a prescription drug into Michigan under the program, the importation could not violate federal patent laws; would have to be expected to generate a cost savings to Michigan and meet the U.S. Food and Drug Administration's standards for safety, effectiveness, misbranding, and adulteration; and could not be a controlled substance, biological product, infused drug, drug that is intravenously injected, drug that is inhaled during surgery, or parenteral drug whose importation poses a threat to public health.

Eligibility for Canadian suppliers

A Canadian supplier would be eligible to participate in the program if the vendor determined that the supplier was in compliance with relevant U.S. and Canadian laws and the requirements of the program, the supplier has agreed to export the allowable drug at a cost savings to Michigan, and the supplier submitted an attestation of a named registered agent in the United States.

Safety and quality checks

Under the bill, the vendor would have to ensure the safety and quality of each imported prescription drug by complying with the following:

- For an initial shipment of a specific prescription drug, ensuring that each batch was statistically sampled and tested for authenticity and degradation, and for subsequent shipments ensuring that a statistically valid sample was tested.
- Certifying that the prescription drug was approved for marketing in the United States, was not adulterated or misbranded, and met the labeling requirements in federal law.
- Ensuring that each required test be conducted in a laboratory that meets standards for drug testing and maintaining documentation.
- Maintaining laboratory records.

Documentation and reporting requirements

A participating importer would have to submit to the vendor all of the following for each prescription drug:

- The name and quantity of the active ingredient of the drug.
- A description of the dosage form of the drug.
- The date on which the drug was shipped.
- The quantity of the drug that was shipped.
- The point of origin and destination of the drug.
- The price paid by the eligible importer.
- Any other information that DHHS considered necessary for the protection of the public health.

A participating Canadian supplier also would have to submit to the vendor the shipping information, as well as certain information regarding the manufacture and lot or control and batch numbers and any other information DHHS considered necessary for the protection of the public health.

Violation

The bill would require DHHS to suspend immediately the importation of a specific prescription drug or of a specific prescription drug by an eligible importer if it determined that the drug or activity was in violation of a requirement of the program or a federal or state law. DHHS could revoke the suspension if, after conducting an investigation, it determined that the public was adequately protected from counterfeit or unsafe prescription drugs being imported into Michigan.

Report

By October 1, 2021, and annually after that, DHHS would have to submit a report to the governor, Senate Majority Leader, and Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report would have to include a list of prescription drugs imported and dispensed under the program, participating suppliers and importers, estimated cost savings, a description of the methodology for determining eligible drugs, and documentation on the program.

The bill would take effect 90 days after enactment.

House Bill 4979 would require DHHS, by January 1, 2021, and subject to approval or authorization under federal law, to develop and implement an international wholesale prescription drug importation program in order to import drugs from countries with which the U.S. has an agreement on good manufacturing practice regulations. DHHS would also have to promulgate rules to implement the proposed act.

Drug importation list

DHHS would have to create and maintain a wholesale prescription drug importation list that identified each drug able to be imported under the program, review the list every six months, and revise it as necessary. Drugs on the list would have to meet the following requirements:

- Be identified by DHHS as retailing for less in a foreign nation, thus providing a cost savings to Michigan if imported. (This section would be reviewed every January and revised as necessary.)
- Be determined by DHHS to meet the standards for safety, effectiveness, misbranding, and adulteration of the U.S. Food and Drug Administration.
- Not violate federal patent laws.
- Not be a controlled substance, biological product, infused drug, drug that is intravenously injected, drug that is inhaled during surgery, or parenteral drug whose importation poses a threat to public health.

An importer or exporter registered with DHHS could import or export a prescription drug on the list as long as he or she did not distribute, sell, or dispense a drug imported under to program to anyone outside of Michigan or violate the act or any rules promulgated under the act.

Documentation and reporting

An eligible importer that imported prescription drugs under the program would have to submit the following to DHHS for each drug:

- The name and quantity of the active ingredient of the drug.
- A description of the dosage form of the drug.
- The date on which the drug was shipped.
- The quantity of the drug that was shipped.
- The point of origin and destination of the drug.
- The price paid by the eligible importer.
- Documentation from the exporter specifying the original source of the drug and the quantity of each lot of the prescription drug originally received and the source of the lot.
- The lot or control number assigned to the drug by its manufacturer.
- The name, address, telephone number, and license number of the importer.
- If shipped directly by a foreign recipient, documentation of the shipping process, quantity of the drug, and sampling and testing for authenticity and degradation.
- If not shipped directly by a foreign recipient, documentation of sampling and testing for authenticity and degradation.

- A statement certifying that the drug was approved for marketing in the U.S., was not adulterated or misbranded, and met the labeling requirements in federal law.
- Any other information that DHHS considered necessary for the protection of the public health.

An eligible exporter under the program also would have to submit to DHHS the shipping information, as well as certain information regarding the manufacture and lot or control and batch numbers and any other information DHHS considered necessary for the protection of the public health.

Safety and quality checks

DHHS would have to create and maintain a list of each laboratory that met standards under the federal act and any other applicable federal and state law governing laboratory qualifications for drug testing.

Additionally, DHHS would have to ensure that each batch was statistically sampled and tested for authenticity and degradation by an approved laboratory. (DHHS could enter into one or more contractual agreements for the administration of this task.)

DHHS would have to maintain information described in "Documentation and reporting," above, for at least seven years.

The bill requires DHHS to suspend immediately the importation of a specific prescription drug or the importation of a drug by an eligible importer if it determined that either were in violation of the act or a rule promulgated under the act. DHHS could revoke the suspension if, after conducting an investigation, it determined that the public was adequately protected from counterfeit or unsafe prescription drugs being imported into Michigan.

FISCAL IMPACT:

House Bills 4978 and 4979 would create indeterminate administrative costs for DHHS resulting from the requirement to develop and submit importation plans for purchasing wholesale prescription drugs from Canada specifically, and from foreign countries generally, to the U.S. Department of Health and Human Services for approval or denial. Additional administrative costs would be incurred if the plan is approved, resulting from implementation of the plan, contracting with Canadian, or other, vendors, and providing oversight of the contracted vendors.

The State of Florida has previously implemented similar legislation, and has assessed the costs of implementing and administering the programs, if approved by the U.S. Department of Health and Human Services.[1] The assessed administrative costs to the state derive from the requirement to hire 6.0 additional FTE positions to manage the programs. Specifically, the State of Florida required 1.0 additional administrative FTE position and 5.0 additional

[1] Florida House of Representatives, *CS/HB 19 Staff Analysis Final Bill Analysis*, https://www.flsenate.gov/Session/Bill/2019/19/Analyses/h0019z1.HQS.PDF

analyst FTE positions. Additionally, Florida estimated that the state would require 3.0 FTE regulatory positions, to include pharmacists and drug inspectors.

If the State of Michigan faced similar implementation and administrative requirements as the State of Florida, estimated costs incurred by DHHS would be approximately $985,000 per year.

Pending approval by the U.S. Department of Health and Human Services, the importation plans developed by DHHS under House Bills 4978 and 4979 could result in indeterminate, but likely minor, decreases in some prescription drug prices. Multiple factors influence prescription drug prices in the U.S., Canada, and elsewhere, including, but not limited to, proprietary rights to drugs developed by companies through research and development—including price setting, government regulations on prescription drug costs, and available prescription drug supply, which would have an impact on any potential reduction in prices resulting from an expansion in prescription drug markets.[2]

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.

[2] Congressional Budget Office, *Would Prescription Drug Importation Reduce U.S. Drug Spending*, April 29, 2004, https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf