State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-1727/P1
TJD:kjf

DOA:.....Ames, BB0243 – Drug importation program

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

AN ACT ***to create*** 250.048 of the statutes; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND HUMAN SERVICES

GENERAL HEALTH AND HUMAN SERVICES

1. Prescription drug importation program

This bill requires DHS, in consultation with persons interested in the sale and pricing of prescription drugs and federal officials and agencies, to design and implement a prescription drug importation program for the benefit of and that generates savings for Wisconsin residents. The bill establishes requirements for the program including all of the following: DHS must designate a state agency to become or contract with a licensed wholesale distributor and seek federal certification and approval to import prescription drugs; the importation program must comply with certain federal regulations and import from Canadian suppliers only prescription drugs that are not brand-name drugs, have fewer than four competitor drugs in this country, and for which importation creates substantial savings; DHS must ensure that prescription drugs imported under the program are not distributed, dispensed, or sold outside of Wisconsin; and the importation program must have an audit procedure to ensure the program complies with certain requirements specified in the bill. Before submitting the proposed implementation program to the federal government for certification, DHS must submit the proposed importation to JCF for its approval.

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 250.048 of the statutes is created to read:

250.048 Prescription drug importation program. (1) IMPORTATION PROGRAM REQUIREMENTS. The department, in consultation with persons interested in the sale and pricing of prescription drugs and appropriate officials and agencies of the federal government, shall design and implement a prescription drug importation program for the benefit of residents of this state, that generates savings for residents, and that satisfies all of the following:

(a) The department shall designate a state agency to become a licensed wholesale distributor or to contract with a licensed wholesale distributor and shall seek federal certification and approval to import prescription drugs.

(b) The prescription drug importation program under this section shall comply with relevant requirements of 21 USC 384, including safety and cost savings requirements.

(c) The prescription drug importation program under this section shall import prescription drugs from Canadian suppliers regulated under any appropriate Canadian or provincial laws.

(d) The prescription drug importation program under this section shall have a process to sample the purity, chemical composition, and potency of imported prescription drugs.

(e) The prescription drug importation program under this section shall import only those prescription drugs for which importation creates substantial savings for

residents of the state and only those prescription drugs that are not brand–name drugs and that have fewer than 4 competitor prescription drugs in the United States.

(f) The department shall ensure that prescription drugs imported under the program under this section are not distributed, dispensed, or sold outside of the state.

(g) The prescription drug importation program under this section shall ensure all of the following:

1. Participation by any pharmacy or health care provider in the program is voluntary.

2. Any pharmacy or health care provider participating in the program has the appropriate license or other credential in this state.

3. Any pharmacy or health care provider participating in the program charges a consumer or health plan the actual acquisition cost of the imported prescription drug that is dispensed.

(h) The prescription drug importation program under this section shall ensure that a payment by a health plan or health insurance policy for a prescription drug imported under the program reimburses no more than the actual acquisition cost of the imported prescription drug that is dispensed.

(i) The prescription drug importation program under this section shall ensure that any health plan or health insurance policy participating in the program does all of the following:

1. Maintains a formulary and claims payment system with current information on prescription drugs imported under the program.

2. Bases cost-sharing amounts for participants or insureds under the plan or policy on no more than the actual acquisition cost of the prescription drug imported under the program that is dispensed to the participant or insured.

3. Demonstrates to the department or a state agency designated by the department how premiums under the policy or plan are affected by savings on prescription drugs imported under the program.

(j) Any wholesale distributor importing prescription drugs under the program under this section shall limit its profit margin to the amount established by the department or a state agency designated by the department.

(k) The prescription drug importation program under this section may not import any generic prescription drug that would violate federal patent laws on branded products in this country.

(L) The prescription drug importation program under this section shall comply to the extent practical and feasible before the prescription drug to be imported comes into possession of the state's wholesale distributor and fully after the prescription drug to be imported is in possession of the state's wholesale distributor with tracking and tracing requirements of 21 USC 360eee to 360eee-1.

(m) The prescription drug importation program under this section shall establish a fee or other approach to finance the program that does not jeopardize significant savings to residents of the state.

(n) The prescription drug importation program under this section shall have an audit function that ensures all of the following:

1. The department has a sound methodology to determine the most cost-effective prescription drugs to include in the importation program under this section.

2. The department has a process in place to select Canadian suppliers that are high quality, high performing, and in full compliance with Canadian laws.

****NOTE: I am unsure what exactly "high performing" means in this context. You may want to select more specific terms to reflect cost consciousness, efficiency, supplying a variety of prescription drugs, or whatever you would like "high performing" to mean.

3. Prescription drugs imported under the program are pure, unadulterated, potent, and safe.

4. The prescription drug importation program is complying with the requirements of this subsection.

5. The prescription drug importation program under this section is adequately financed to support administrative functions of the program while generating significant cost savings to residents of the state.

6. The prescription drug importation program under this section does not put residents of the state at a higher risk than if the program did not exist.

7. The prescription drug importation program under this section provides and is projected to continue to provide substantial cost savings to residents of the state.

(2) ANTICOMPETITIVE BEHAVIOR. The department, in consultation with the attorney general, shall identify the potential for and monitor anticompetitive behavior in industries affected by a prescription drug importation program.

(3) APPROVAL OF PROGRAM DESIGN; CERTIFICATION. No later than the first day of the 7th month beginning after the effective date of this subsection .... [LRB inserts date], the department shall submit to the joint committee on finance a report that includes the design of the prescription drug importation program in accordance with this section. The department may not submit the proposed prescription drug importation program to the federal department of health and human services unless the joint committee on finance approves the proposed prescription drug

implementation program. Within 14 days of the date of approval by the joint committee on finance of the proposed prescription drug importation program, the department shall submit to the federal department of health and human services a request for certification of the approved prescription drug importation program.

(4) IMPLEMENTATION OF CERTIFIED PROGRAM. After the federal department of health and human services certifies the prescription drug importation program submitted under sub. (3), the department shall begin implementation of the program and the program shall be fully operational by 180 days after the date of certification by the federal department of health and human services. The department shall do all of the following to implement the prescription drug importation program to the extent the action is in accordance with other state laws and the certification by the federal department of health and human services:

(a) Become a licensed wholesale distributor, designate another state agency to become a licensed wholesale distributor, or contract with a licensed wholesale distributor.

(b) Contract with one or more Canadian suppliers that meet the criteria in sub. (1) (c).

(c) Create an outreach and marketing plan to communicate with and provide information to health plans and health insurance policies, employers, pharmacies, health care providers, and residents of the state on participating in the prescription drug importation program.

(d) Develop and implement a registration process for health plans and health insurance policies, pharmacies, and health care providers interested in participating in the prescription drug importation program.

(e) Create a publicly accessible source for listing prices of prescription drugs imported under the program.

(f) Create, publicize, and implement a method of communication to promptly answer questions from and address the needs of persons affected by the implementation of the program before the program is fully operational.

(g) Establish the audit functions under sub. (1) (n) with a timeline to complete each audit function every 2 years.

(h) Conduct any other activities determined by the department to be important to successful implementation of the prescription drug importation program under this section.

(5) REPORT. By January 1 and July 1 of each year, the department shall submit to the joint committee on finance a report including all of the following:

(a) A list of prescription drugs included in the importation program under this section.

(b) The number of pharmacies, health care providers, and health plans and health insurance policies participating in the prescription drug importation program under this section.

(c) The estimated amount of savings to residents of the state, health plans and health insurance policies, and employers resulting from the implementation of the prescription drug importation program under this section reported from the date of the previous report under this subsection and from the date the program was fully operational.

(d) Findings of any audit functions under sub. (1) (n) completed since the date of the previous report under this subsection.

SECTION 9119. Nonstatutory provisions; Health Services.

(1) PRESCRIPTION DRUG IMPORTATION PROGRAM. The department of health services shall submit the first report required under s. 250.048 (5) by the next January 1 or July 1, whichever is earliest, that is at least 180 days after the date the prescription drug importation program is fully operational under s. 250.048 (4). The department of health services shall include in the first 3 reports submitted under s. 250.048 (5) information on the implementation of the audit functions under s. 250.048 (1) (n).

(END)