

2019 DRAFTING REQUEST

Bill

For: Administration-Budget

Drafter: tdodge

By: Ames

Secondary Drafters:

Date: 1/31/2019

May Contact:

Same as LRB:

Submit via email: YES

Requester's email:

Carbon copy (CC) to: doasbostatlanguage@wisconsin.gov
tamara.dodge@legis.wisconsin.gov

Pre Topic:

DOA:.....Ames, BB0243 -

Topic:

Drug importation program

Instructions:

See attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	tdodge 2/1/2019	kfollett 2/1/2019			
/P1			lparisi 2/1/2019		State

FE Sent For:

<END>

Dodge, Tamara

From: Cathlene Hanaman <cathleneh@gmail.com>
Sent: Thursday, January 31, 2019 10:16 AM
To: Dodge, Tamara; Walkenhorst Barber, Sarah
Subject: Fwd: Statutory Language Drafting Request - 2019-21

Sent from my iPhone

Begin forwarded message:

Biennial Budget: 2019-21

Topic: Drug Importation Program

Tracking Code: BB0243

SBO Team: HSI

SBO Analyst: Ames, Kyle
Phone: 608-266-2214
E-mail: kyle.ames@wisconsin.gov

Agency Acronym: 435

Agency Number: 435

Priority: Low

Intent:

The current drafted language regarding the drug importation program should consist of language that defines imported prescription drugs to be generic or off-brand name drugs that have less than four competitors in the U.S.

Attachments: False

Please send completed drafts to SBOSatlanguage@spsmail.enterprise.wistate.us



State of Wisconsin
2019 - 2020 LEGISLATURE

1727/P1
LRB-0944/P1
TJD:kjf

DOA:.....Ames, BB0118 - Prescription drug importation program

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

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

Insert Analysis

Analysis by the Legislative Reference Bureau

HEALTH AND HUMAN SERVICES

GENERAL HEALTH AND HUMAN SERVICES

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

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:

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

3 **250.048 Prescription drug importation program. (1) IMPORTATION**
4 PROGRAM REQUIREMENTS. The department, in consultation with persons interested in
5 the sale and pricing of prescription drugs and appropriate officials and agencies of
6 the federal government, shall design and implement a prescription drug importation

1 program for the benefit of residents of this state, that generates savings for residents,
2 and that satisfies all of the following:

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

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

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

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

15 (e) The prescription drug importation program under this section shall import
16 only those prescription drugs for which importation creates substantial savings for
17 residents of the state. ^{Insert 2-17}
18

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 2. The department has a process in place to select Canadian suppliers that are
18 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.

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

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

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

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

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

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

11 **(3) APPROVAL OF PROGRAM DESIGN; CERTIFICATION.** No later than the first day of
12 the 7th month beginning after the effective date of this subsection [LRB inserts
13 date], the department shall submit to the joint committee on finance a report that
14 includes the design of the prescription drug importation program in accordance with
15 this section. The department may not submit the ^{proposed} prescription drug importation
16 program to the federal department of health and human services unless the joint
17 committee on finance approves the proposed prescription drug implementation
18 program. Within 14 days of the date of approval by the joint committee on finance
19 of the proposed prescription drug importation program, the department shall submit
20 to the federal department of health and human services a request for certification of
21 the approved prescription drug importation program.

22 **(4) IMPLEMENTATION OF CERTIFIED PROGRAM.** After the federal department of
23 health and human services certifies the prescription drug importation program
24 submitted under sub. (3), the department shall begin implementation of the program
25 and the program shall be fully operational by 180 days after the date of certification

1 by the federal department of health and human services. The department shall do
2 all of the following to implement the prescription drug importation program to the
3 extent the action is in accordance with other state laws and the certification by the
4 federal department of health and human services:

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

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

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

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

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

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

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

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

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

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

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

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

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

18 **SECTION 9119. Nonstatutory provisions; Health Services.**

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

25 (END)

2019-2020 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1727/P1ins
TJD:...

1 INSERT ANALYSIS

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.

2 END INSERT ANALYSIS

3 INSERT 2-17

4 and only those prescription drugs that are not brand-name drugs and that have
5 fewer than 4 competitor prescription drugs in the U.S. ^{the United States}

6 END INSERT 2-17



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

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19 prescription drugs.

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7

(END)