

SECOND REGULAR SESSION

# HOUSE BILL NO. 2652

100TH GENERAL ASSEMBLY

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INTRODUCED BY REPRESENTATIVE LAVENDER.

5689H.011

DANA RADEMAN MILLER, Chief Clerk

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## AN ACT

To amend chapter 192, RSMo, by adding thereto seven new sections relating to prescription drug wholesale importation.

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*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Chapter 192, RSMo, is amended by adding thereto seven new sections, to be known as sections 192.3000, 192.3002, 192.3004, 192.3006, 192.3008, 192.3010, and 192.3012, to read as follows:

**192.3000. 1. The department of health and senior services shall design a wholesale prescription drug importation program in consultation with the United States Department of Health and Human Services that meets the relevant requirements of 21 U.S.C. Section 384.**

**2. In developing the program, the department of health and senior services shall address the following issues:**

**(1) That a state agency becomes a licensed wholesaler for the purpose of seeking federal certification and approval to import safe prescription drugs that will provide savings to Missouri consumers;**

**(2) That the program uses Canadian suppliers regulated under the appropriate Canadian 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 drugs expected to generate substantial savings for Missouri consumers;**

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

16           **(5) That the program ensures imported products will not be distributed, dispensed,**  
17 **or sold outside of the state;**

18           **(6) That the program ensures that voluntary participants, state-licensed**  
19 **pharmacies, and administering providers charge individual consumers and health plans**  
20 **the actual acquisition cost of the imported, dispensed product;**

21           **(7) That the program ensures health plan payment of the product component of**  
22 **pharmacy and provider billing reimburses no more than the actual acquisition cost of the**  
23 **dispensed, imported product;**

24           **(8) That the program ensures that participating health plans keep their formularies**  
25 **and claims payment systems up to date with the prescription drugs provided through the**  
26 **wholesale prescription drug importation program;**

27           **(9) That the program ensures participating health plans base patient costs sharing**  
28 **on no more than the actual acquisition costs of the dispensed, imported product;**

29           **(10) That the program requires participating health plans to demonstrate to the**  
30 **department of health and senior services how savings on imported drugs are reflected in**  
31 **premiums;**

32           **(11) That the profit margin of any participating wholesaler or distributor of**  
33 **imported pharmaceutical products is limited to a specified amount established by the**  
34 **department of health and senior services;**

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

37           **(13) That the program complies with the requirements of 21 U.S.C. Sections 581**  
38 **to 582, pertaining to the track and trace requirements as enacted in Title II of the Drug**  
39 **Security and Quality Act, Pub. L. 113-54, to the extent practical and feasible before**  
40 **imported drugs come into the possession of the state wholesaler and complies fully after**  
41 **imported drugs are in the possession of the state wholesaler;**

42           **(14) That the program is adequately financed through a fee on each prescription**  
43 **or other appropriate approach, but the size of the fee shall not jeopardize significant**  
44 **consumer savings; and**

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

46           **(a) The department of health and senior services has a sound methodology by**  
47 **which to determine the most cost-effective products to include in the prescription drug**  
48 **importation program on an ongoing basis;**

49           **(b) The department of health and senior services has a process in place to select**  
50 **Canadian suppliers of high quality, high performance, and in full compliance with**  
51 **Canadian laws and regulations;**

- 52 (c) Imported drugs under the state program are not shipped, sold, or dispensed  
53 outside of the state once in possession of the state;
- 54 (d) Imported products are pure, unadulterated, potent, and safe;
- 55 (e) Participating pharmacies and administering providers are not charging more  
56 than actual acquisition cost to any consumer or any participating health plan;
- 57 (f) Participating health plan formularies and claims processing systems remain up  
58 to date with all relevant aspects of the importation program;
- 59 (g) Participating health plans base patient coinsurance and other cost sharing on  
60 the actual acquisition cost of covered, imported drugs;
- 61 (h) Participating health plans reimburse participating pharmacies and  
62 administering providers actual acquisition cost for imported, dispensed product;
- 63 (i) The program is adequately financed to support all administration functions  
64 while generating significant consumer savings;
- 65 (j) The program does not put consumers at higher risk than if the program did not  
66 exist; and
- 67 (k) The program continues to provide Missouri consumers with substantial savings  
68 on prescription drugs.

192.3002. The department of health and senior services shall enlist the assistance  
2 of the state attorney general to identify the potential for anticompetitive behavior in  
3 industries that would be affected by a wholesale prescription drug importation program.

192.3004. 1. The department of health and senior services shall complete its plan  
2 for implementation of the wholesale prescription drug importation program before  
3 January 1, 2021.

4 2. Before February 1, 2021, the department of health and senior services shall  
5 submit a formal request to the Secretary of Health and Human Services for certification  
6 of the wholesale prescription drug importation program.

192.3006. Upon certification and approval by the Secretary of Health and Human  
2 Services, the department of health and senior services shall begin implementation of the  
3 wholesale prescription drug importation program, and such program shall be operational  
4 within six months of the date of the Secretary's certification. As part of the  
5 implementation process, the department of health and senior services shall, in accordance  
6 with state procurement and contracting laws and rules, as applicable:

- 7 (1) Become licensed as a wholesaler;
- 8 (2) Contract with a state-licensed distributor or distributors;
- 9 (3) Contract with a licensed, regulated Canadian supplier or suppliers;
- 10 (4) Engage health plans, employers, pharmacies, providers, and consumers;

- 11           **(5) Develop a registration process for health plans, pharmacies, and administering**  
12 **providers who wish to participate;**
- 13           **(6) Create a publicly available source for listing prices of imported products that**  
14 **will be available to all participating entities and consumers;**
- 15           **(7) Create an outreach and marketing plan to generate program awareness;**
- 16           **(8) Create and staff a hotline to answer questions from any affected sector starting**  
17 **in the weeks before the program becomes operational that addresses the needs and**  
18 **questions of consumers, employers, plans, pharmacies, and providers;**
- 19           **(9) Establish the audit function and a two-year audit work plan cycle; and**
- 20           **(10) Conduct any other activities determined to be important to successful**  
21 **implementation as determined by the department of health and senior services.**

**192.3008. Before January 1, 2022, and annually thereafter, the department of**  
2 **health and senior services shall submit a report to the general assembly on the status of the**  
3 **wholesale prescription drug importation program, including:**

- 4           **(1) The drugs covered in the wholesale prescription drug importation program;**  
5           **(2) The number of participating pharmacies, providers, and health plans;**  
6           **(3) The number of prescriptions dispensed under the program in the reporting**  
7 **period;**
- 8           **(4) The estimated savings to consumers, health plans, and employers that result**  
9 **from the program in the reporting period;**
- 10           **(5) In the first three reporting periods, information on the implementation of the**  
11 **audit plan and audit findings for the reporting period; and**
- 12           **(6) Any other information of importance as determined by the department.**

**192.3010. The director of the department of health and senior services may**  
2 **promulgate all necessary rules and regulations for the administration of this section. Any**  
3 **rule or portion of a rule, as that term is defined in section 536.010, that is created under**  
4 **the authority delegated in this section shall become effective only if it complies with and**  
5 **is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This**  
6 **section and chapter 536 are nonseverable, and if any of the powers vested with the general**  
7 **assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove**  
8 **and annul a rule are subsequently held unconstitutional, then the grant of rulemaking**  
9 **authority and any rule proposed or adopted after August 28, 2020, shall be invalid and**  
10 **void.**

**192.3012. Under section 23.253 of the Missouri sunset act:**

2           **(1) The provisions of the new program authorized under sections 192.3000 to**  
3 **192.3012 shall automatically sunset six years after the effective date of sections 192.3000**  
4 **to 192.3012 unless reauthorized by an act of the general assembly;**

5           **(2) If such program is reauthorized, the program authorized under sections**  
6 **192.3000 to 192.3012 shall automatically sunset twelve years after the effective date of the**  
7 **reauthorization of sections 192.3000 to 192.3012; and**

8           **(3) Sections 192.3000 to 192.3012 shall terminate on September first of the calendar**  
9 **year immediately following the calendar year in which the program authorized under**  
10 **sections 192.3000 to 192.3012 is sunset.**

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