

FIRST REGULAR SESSION

# HOUSE BILL NO. 1257

101ST GENERAL ASSEMBLY

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INTRODUCED BY REPRESENTATIVE DOLL.

2582H.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 wholesale prescription drug 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 ensure:**

**(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 imports only 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 dispensed imported 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 participating health plans keep their formularies and  
25 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 cost sharing  
28 on no more than the actual acquisition cost 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 Unites States branded products;

37 (13) That the program complies with the requirements of 21 U.S.C. Sections 360eee  
38 and 360eee-1, pertaining to the track and trace requirements as enacted in Title II of the  
39 Drug Quality and Security 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, of 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 dispensed imported product;
- 63 (i) The program is adequately financed to support all administrative 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, 2022.

2. Before February 1, 2022, 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, 2023, 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, 2021, 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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