1	STATE OF OKLAHOMA
2	2nd Session of the 56th Legislature (2018)
3	SENATE BILL 1381 By: Standridge
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6	AS INTRODUCED
7	An Act relating to prescription drugs; creating the Prescription Drug Safety and Cost Reduction Pilot
8	Program Act; providing short title; providing definitions; requiring Oklahoma Health Care Authority
9	to submit certain application by certain date; specifying criteria for application; directing
10	Authority to conduct certain study; specifying criteria for study; requiring Authority to consult
11 12	with State Board of Pharmacy and certain individuals; requiring Authority to submit certain report;
13	directing establishment of certain program; specifying program requirements; prohibiting pharmaceutical manufacturers from engaging in certain
14	activities; authorizing Attorney General to take certain civil action; providing for codification;
15	providing an effective date; and declaring an emergency.
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18	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
19	SECTION 1. NEW LAW A new section of law to be codified
20	in the Oklahoma Statutes as Section 3092 of Title 63, unless there
21	is created a duplication in numbering, reads as follows:
22	This act shall be known and may be cited as the "Prescription
23	Drug Safety and Cost Reduction Pilot Program Act".
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SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3092.1 of Title 63, unless there is created a duplication in numbering, reads as follows:

For the purposes of this act:

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- 1. "Health insurer" means an insurer who offers health insurance as defined in Section 4522 of Title 36 of the Oklahoma Statutes.
- 2. "Secretary" means the Secretary of the United States
 Department of Health and Human Services.
- SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3092.2 of Title 63, unless there is created a duplication in numbering, reads as follows:
 - A. There is hereby created the Prescription Drug Safety and Cost Reduction Pilot Program.
 - B. The Oklahoma Health Care Authority shall submit to the Secretary no later than August 30, 2018, an application for:
 - 1. The approval of a program to allow for the importation of prescription drugs from Canada into the state under the provisions of 21 U.S.C., Section 384 (1938); and
- 2. Certification by the Secretary to the United States
 2. Congress, in accordance with 21 U.S.C., Section 384, that
 2. importation of Canadian prescription drugs will:
 - a. pose no additional risk to the public's health and safety, and

- b. result in a significant reduction in the cost of covered products to the American consumer.
- C. The application described in this section shall contain the findings of the prescription drug importation study described in subsection D of this section and a description of the prescription drug importation program designed by the Authority in accordance with the provisions of this act, including measures that will be taken to:
 - 1. Comply with existing state and federal law; and
 - 2. Reduce the risk to the public's health and safety.

The application shall also include an estimate of the reduction in the cost of covered products and health insurance premiums to Oklahoma consumers.

- D. 1. The Oklahoma Health Care Authority shall study how to gain approval by the Secretary for the state to import a limited number of prescription drugs from Canada for the purpose of implementing a pilot to reduce prescription drug costs for Oklahoma consumers and state agencies.
 - 2. The study shall include:

- a. a plan for operating the prescription drug program,
- b. a plan to ensure that prescription drugs imported into the state under the prescription drug importation program meet applicable United States federal and state standards for safety and effectiveness,

c. examples of five to seven highly prescribed drugs with
a large cost differential between Canadian and U.S.

average prices whose importation will create
significant consumer savings,

- d. an estimate of the total potential consumer and state agency savings through importation at the time of the study,
- e. potential wholesalers with whom the state could contract to distribute imported prescription drugs to participating Oklahoma licensed pharmacies,
- f. proposed amendments to state law to facilitate importation by the state, and
- g. in coordination with the Office of the Attorney

 General, proposed amendments to state law to inhibit

 pharmaceutical manufacturers from manipulating the

 pharmaceutical market in this state or adversely

 affecting consumer access to pharmaceuticals under the

 prescription drug program.
- 3. The Oklahoma Health Care Authority shall consult with the Oklahoma Board of Pharmacy, representatives of the pharmaceutical industry, patient advocates and others representing persons who could be affected by the prescription drug importation program, in conducting the study in this subsection.

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4. No later than November 1, 2019, the Oklahoma Health Care Authority shall submit a written report on the findings and recommendations of the study described in this subsection to the President Pro Tempore of the Senate, the Speaker of the House of Representatives and the Governor.

- E. The Oklahoma Health Care authority shall establish a Canadian prescription drug importation pilot program in accordance with the provisions of this section. The prescription drug importation pilot program shall:
- 1. Identify and only allow for the importation of five (5) to seven (7) highly prescribed drugs with a large cost differential between Canadian and U.S. average prices whose importation will create significant consumer savings. Prescription drugs identified:
 - a. shall be legally importable from Canada under applicable United States federal and state law,
 - b. shall not include a controlled dangerous substance,
 - c. shall not include a biological product,
 - d. shall not include an infused drug, including a peritoneal dialysis solution, and
 - e. shall not include an intravenously injected drug;
- 2. Monitor consumer prices to ensure that market competition and routine health plan administration provide significant savings for Oklahoma consumers and state agencies;

3. Only use Canadian suppliers regulated under relevant Canadian federal or provincial laws;

- 4. If required by the Secretary, establish a process to sample the purity, chemical composition and potency of imported products;
- 5. Ensure that imported prescription drugs are not distributed, dispensed or sold outside of this state;
- 6. Ensure that all participating health insurers keep formularies and claims payment systems up to date with the prescription drugs provided through the prescription drug importation program;
- 7. Ensure that all participating health insurers base patient cost sharing on a reasonable commercial price for imported prescription drugs;
- 8. Work in conjunction with the Insurance Department to establish a requirement that all participating health insurers demonstrate how savings on imported prescription drugs are reflected in premiums;
- 9. Ensure that health insurers and the state Medicaid program work only with pharmacies which are licensed and located in this state;
- 10. Ensure that the program does not import any generic prescription drug that would violate United State patent laws;
- 23 11. Ensure that participating pharmacies may still be
 24 reimbursed a fair markup over the wholesale cost for the equivalent

1 drug in the United States due to patient or prescriber demand or for 2 lack of availability;

- 12. Comply with the requirements of 21 U.S.C., Section 360eee-1 (2014), pertaining to the track and trace requirements in Title II of the Drug Security and Quality Act, before imported prescription drugs come into possession of the wholesaler;
- 13. Ensure that the supply and distribution chain is in compliance with the applicable United States federal and state law after imported prescription drugs are in the possession of the wholesaler;
- 14. Establish a nominal fee-per-unit of imported pharmaceutical drug to cover only costs necessary to efficiently administer the importation program and not jeopardize consumer savings;
- 15. Reimburse participating pharmacies at the wholesale cost plus a dollar amount equal to or not significantly more than the margin dollars paid for each drug's equivalent in the United States; and
- 16. Upon approval from the Secretary, issue a request for proposal to contract with a private entity to carry out the provisions of this act.
- F. In conjunction with this act, pharmaceutical manufacturers shall be prohibited from engaging in the following activities:
- 1. Taking any action, by agreement, unilaterally or otherwise, that has the effect of fixing or otherwise controlling the price

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    that a pharmaceutical supplier, distributor or dispenser charges or
    advertises from pharmaceuticals in the prescription importation
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    program; and
        2. Discriminating against a pharmaceutical supplier,
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    distributor or dispenser based on whether the supplier, distributor
    or dispenser participates in the prescription drug importation
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    program.
        G. The Office of the Attorney General is authorized pursuant to
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    this section to bring a civil action or seek an injunction against
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    any person who violates a provision of this section.
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        SECTION 4. This act shall become effective July 1, 2018.
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        SECTION 5. It being immediately necessary for the preservation
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    of the public peace, health or safety, an emergency is hereby
    declared to exist, by reason whereof this act shall take effect and
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    be in full force from and after its passage and approval.
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