ENGROSSED SENATE
BILL NO. 940

By: Standridge of the Senate

and

McEntire of the House

[Prescription Drug Safety and Cost Reduction Importation Pilot Program Act - application - criteria for drugs – identification number – eligibility of pharmacies – fee – contract – reimbursement – prohibited acts – requirements - advisory council – codification - ~~effective date~~ - ~~emergency~~]

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3092 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. This section shall be known and may be cited as the "Prescription Drug Safety and Cost Reduction Importation Pilot Program Act".

B. The Oklahoma Health Care Authority shall submit an application to the United States Secretary of Health and Human Services for the purpose of establishing a prescription drug importation pilot program for the state Medicaid program to import pharmaceutical drugs from one or more countries approved by the United States Food and Drug Administration (FDA). The importation pilot program shall comply with the applicable requirements of 21

U.S.C., Section 384 including, but not limited to, the requirements pertaining to safety and cost savings.

C. The Authority shall identify the top twenty (20) most frequently prescribed drugs through the state Medicaid program that have a large cost differential between Canadian and United States average prices whose importation will create significant cost savings in the state Medicaid program. Not less than six (6) months following approval of the application described in subsection B of this section, the Authority shall make available the top twenty (20) highly prescribed drugs as provided in this paragraph to pharmacies willing to participate. Prescription drugs identified:

1. Shall be legally importable under applicable federal and state law;

2. Shall not include a controlled dangerous substance;

3. Shall not include a biological product;

4. Shall not include an infused drug, including a peritoneal dialysis solution;

5. Shall not include marijuana, medical marijuana, cannabidiol or related derivatives;

6. Shall not include an intravenously injected drug; and

7. Shall be in compliance with applicable state and federal standards for safety and effectiveness.

D. The Authority shall purchase drugs only from suppliers approved by FDA in countries approved by FDA. Except for drugs to

which FDA issues a National Drug Code number, the Authority shall issue a unique identification number to each drug in the importation pilot program for the purposes of tracking and submitting claims to the Authority.

E. Only a retail pharmacy located in this state that has a valid license issued by the State Board of Pharmacy may participate in the importation pilot program. The Authority shall create a simple application for applying pharmacies which shall include a field for the pharmacy's license number. The application shall be made available on the website of the Authority. Upon receipt of a completed application, the Authority shall verify the license with the Board and issue a permit to the pharmacy within thirty (30) calendar days authorizing the pharmacy to purchase drugs through the importation pilot program.

F. The Authority shall establish a nominal fee-per-unit of imported pharmaceutical drugs, not to exceed three percent (3%) of the cost of the unit, to cover the costs of administration, warehousing and distribution in addition to the absolute cost of importation.

G. The Authority shall contract with the entity currently tasked with administering pharmacy benefits for the state Medicaid program on the effective date of this act for the purpose of administering the importation pilot program. A pharmacy benefit manager shall not be used for the importation pilot program.

H. 1. A pharmacy participating in the importation pilot program shall submit claims to the Authority or the Authority's contracted third-party administrator, and shall be reimbursed through the state Medicaid program as provided in this subsection.

2. The pharmacy shall be reimbursed in an amount equal to:

a. for a brand-name drug, the cost to the pharmacy of the drug, plus fifteen percent (15%), plus Fifteen Dollars ($15.00), or

b. for a generic drug, the cost to the pharmacy of the drug, plus thirty percent (30%), plus Fifteen Dollars ($15.00).

3. No pharmacy shall be reimbursed in an amount more or less than as provided in this subsection. If a pharmacy is reimbursed less than as provided in this subsection, the pharmacy shall, upon proof of purchase, be reimbursed the difference of the amount provided in this subsection and the amount of the actual reimbursement within thirty (30) days of an appeal and subsequent decision by the Authority in favor of the pharmacy. Any adjustments not reimbursed to the pharmacy within thirty (30) days of the favorable decision shall be assessed interest with an annual percentage rate of twenty-five percent (25%) of the owed adjustment compounded daily until the payment is sent to the pharmacy. The accrued interest shall be paid to the pharmacy. No fees or other charges shall be assessed to a pharmacy in relation to the

importation pilot program or any purchases executed pursuant to the importation pilot program.

I. 1. A pharmaceutical manufacturer, supplier or any other entity shall not:

a. give or receive kickbacks or rebates, or participate in any other scheme that interferes with the transparency of the importation pilot program or interferes with pharmacies obtaining the lowest possible prices on drugs purchased through the importation pilot program,

b. take any action, by agreement, unilaterally or otherwise, that has the effect of fixing or otherwise controlling the price that a pharmaceutical supplier, distributor or dispenser charges or advertises from pharmaceuticals in the importation pilot program,

c. discriminate against a pharmaceutical supplier, distributor or dispenser based on whether the supplier, distributor or dispenser participates in the importation pilot program, or

d. manipulate the pharmaceutical market in this state or adversely affect consumer access to pharmaceuticals under the importation pilot program;

2. The Authority shall:

a. ensure that savings are passed to consumers and not recouped or clawed back, retroactively or otherwise, by pharmaceutical manufacturers or any other entity,

b. ensure that the importation pilot program complies with the requirements of 21 U.S.C, Section 360eee and 360eee-1, 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, and

c. establish a process for seeking all appropriate federal approvals, waivers, exemptions or agreements, or a combination thereof, as needed to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the importation pilot program to the fullest extent possible without jeopardizing eligibility in the 340B Program.

J. Upon approval of the application described in subsection A of this section, the Authority shall form an advisory council that consists of key stakeholders including, but not limited to, consumer and patient advocates, pharmacists, contracted providers under the state Medicaid program and governmental agencies necessary to propose rules and changes in law to enable the Authority to implement the provisions of this section.

K. Upon approval of the application described in subsection A of this section, the Oklahoma Health Care Authority Board shall promulgate rules to implement the provisions of this section.

~~SECTION 2. This act shall become effective July 1, 2020.~~

~~SECTION 3. It being immediately necessary for the preservation of the public peace, health or safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.~~

Passed the Senate the 12th day of March, 2020.

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Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2020.

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Presiding Officer of the House of Representatives