

1 STATE OF OKLAHOMA

2 1st Session of the 58th Legislature (2021)

3 SENATE BILL 589

By: Hicks

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5
6 AS INTRODUCED

7 An Act relating to prescription drugs; defining
8 terms; requiring drug manufacturer to notify
9 Insurance Department of price increases of certain
10 drugs by certain amount and introduction of certain
11 new drugs; establishing timeline for notification;
12 specifying what data notification shall include;
13 applying certain protections to data; requiring
14 pharmacy benefit managers and wholesale drug
15 distributors to report certain data after
16 notification by Department; requiring certain
17 insurers to report spending on certain prescription
18 drugs and drug groups; specifying information
19 required to be reported; requiring insurers to report
20 certain data on drugs and drug groups; requiring
21 certain entities to register with the Department by
22 certain date; requiring certain entities to pay
23 annual assessment to Department; directing assessment
24 to cover certain activities; establishing procedures
for determining assessment; specifying procedures for
sending requests for payment of assessment; directing
monies to certain fund; requiring certain entities
certify required reporting; establishing civil
penalty for violation of act; authorizing Department
to audit reported data; authorizing Department to
require certain entities submit corrective action
plans; authorizing Department to hold public hearings
and subpoena certain entities; requiring Department
to prepare and post report on prescription drug
prices on website; requiring Department to hold
public hearing on report data; specifying required
data in report; requiring Department to keep certain
information confidential; authorizing Department to
promulgate rules; providing for codification; and
providing an effective date.

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

2 SECTION 1. NEW LAW A new section of law to be codified
3 in the Oklahoma Statutes as Section 6730 of Title 36, unless there
4 is created a duplication in numbering, reads as follows:

5 As used in this act:

6 1. "Brand-name drug" means a prescription drug approved under
7 21 U.S. Code Section 355(b), as amended or 42 U.S Code Section 262,
8 as amended;

9 2. "Drug group" is as defined by the Insurance Department for
10 the purpose of facilitating revenue and cost reporting by
11 manufacturers;

12 3. "Insurer" means any entity or insurer authorized to provide
13 health insurance or health benefits pursuant to the laws of this
14 state and any entity or person engaged in the business of making
15 contracts for accident or health insurance;

16 4. "Manufacturer" means any person or entity that holds the
17 national drug code for a prescription drug and is either engaged in
18 the production, preparation, propagation, compounding, conversion or
19 processing of drug products in this state. It shall also include
20 any person or entity that is engaged in the packaging, repackaging,
21 labeling, relabeling or distribution of drug products in this state,
22 or any person or entity that causes the drug products to be
23 compounded, packaged or transported in this state, that is not a
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1 wholesale distributor of drugs or a retail pharmacy licensed by the
2 Board of Pharmacy;

3 5. "Market introduction" means the month and year in which the
4 manufacturer acquired or first marketed the drug for sale in the
5 United States;

6 6. "National drug code" means the numerical code maintained by
7 the Food and Drug Administration that includes the labeler code,
8 product code and package code;

9 7. "Pharmacy benefits manager" means a person, business or
10 entity, and any partially or wholly owned subsidiary of an entity,
11 doing business in this state which contracts to administer or manage
12 prescription drug benefits on behalf of a managed-care company,
13 nonprofit hospital, medical service organization, insurance company,
14 third-party payor or a health program administered by a department
15 of this state;

16 8. "Reporting entity" means any manufacturer, insurer, pharmacy
17 benefits manager, wholesale drug distributor or any other entity
18 required to report to the Insurance Department under the provisions
19 of this act;

20 9. "Wholesale acquisition cost" means the list price of the
21 manufacturer charged to wholesalers or direct purchasers in the
22 United States on December 31 of the reference year, as reported in
23 wholesale price guides or other publications of drug or biological
24 pricing data. This does not include prompt pay or other discounts,

1 rebates or reductions in price. The current or proposed wholesale
2 acquisition cost is the amount that requires reporting under the
3 provisions of this act;

4 10. "Wholesale acquisition cost unit" means the lowest
5 identifiable quantity of a drug or biological that is dispensed,
6 exclusive of any diluent without reference to volume measures
7 pertaining to liquids. If reporting by drug group as indicated by
8 the Insurance Department, it is the total number of wholesale
9 acquisition cost units in the drug group; and

10 11. "Wholesale drug distributor" means a person or entity
11 engaged in the sale of prescription drugs to persons other than a
12 consumer or patient and licensed by the Oklahoma State Board of
13 Pharmacy.

14 SECTION 2. NEW LAW A new section of law to be codified
15 in the Oklahoma Statutes as Section 6731 of Title 36, unless there
16 is created a duplication in numbering, reads as follows:

17 A. A manufacturer shall notify the Insurance Department if it
18 is increasing the wholesale acquisition cost of a brand-name drug by
19 more than twenty percent (20%) per wholesale acquisition cost unit
20 during any twelve-month period, or if it is increasing the wholesale
21 acquisition cost of a generic drug priced at Ten Dollars (\$10.00) or
22 more per wholesale acquisition cost unit by more than twenty percent
23 (20%) during any twelve-month period. The notice shall be provided,
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1 in writing, at least sixty (60) days prior to the planned effective
2 date of the increase.

3 B. A manufacturer shall notify the Insurance Department if it
4 intends to introduce a new drug in the United States that has a
5 wholesale acquisition cost of more than Six Hundred Seventy Dollars
6 (\$670.00) per wholesale acquisition cost unit. The notice shall be
7 provided, in writing, at least sixty (60) days prior to market
8 introduction.

9 C. A manufacturer that is required to notify the Insurance
10 Department under subsection A of this section shall report to the
11 Insurance Department all data elements specified in the National
12 Academy for State Health Policy Model Act report template at least
13 thirty (30) days before the price increase.

14 D. A manufacturer that is required to notify the Insurance
15 Department under subsection B of this section shall report to the
16 Insurance Department all data elements specified in the National
17 Academy for State Health Policy Model Act report template at least
18 sixty (60) days before the date of market introduction.

19 E. Disclosure of all information reported under this section is
20 subject to protections defined in Section 8 of this act.

21 SECTION 3. NEW LAW A new section of law to be codified
22 in the Oklahoma Statutes as Section 6732 of Title 36, unless there
23 is created a duplication in numbering, reads as follows:

1 A. Each pharmacy benefit manager shall, to the extent allowed
2 by law, report annually to the Insurance Department all data
3 elements specified in the National Academy for State Health Policy
4 Model Act report template within sixty (60) days after receiving
5 notification by the Insurance Department indicating the specific
6 drugs for which reporting is required.

7 B. Disclosure of all information reported under this Section is
8 subject to protections defined in Section 8 of this act.

9 SECTION 4. NEW LAW A new section of law to be codified
10 in the Oklahoma Statutes as Section 6733 of Title 36, unless there
11 is created a duplication in numbering, reads as follows:

12 A. Each wholesale drug distributor shall report annually to the
13 Insurance Department all data elements specified in the National
14 Academy for State Health Policy Model Act report template within
15 sixty (60) days after receiving notification by the Insurance
16 Department indicating the specific drugs for which reporting is
17 required.

18 B. Disclosure of all information reported under this section is
19 subject to protections defined in Section 8 of this act.

20 SECTION 5. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 6734 of Title 36, unless there
22 is created a duplication in numbering, reads as follows:

23 Each insurer designated by the Insurance Department as a
24 reporting entity shall report annually to the Department, to the

1 extent allowed by federal and state law, spending on prescription
2 drugs before enrollee cost sharing, in total and per prescription
3 drug user, and spending on the top twenty-five (25) prescription
4 drugs prescribed in this state, in total and individually, as
5 determined by the Insurance Department. The report shall include:

6 1. The greatest total spending before enrollee cost sharing in
7 the last calendar year;

8 2. The greatest total spending per user of any drug before
9 enrollee cost sharing in the last calendar year;

10 3. Highest year-over-year increase in total spending before
11 enrollee cost sharing; and

12 4. The highest year-over-year increase in total spending per
13 user of any drug before enrollee cost sharing.

14 For each drug and drug group, the insurer shall report to the
15 Department all data elements specified in the National Academy for
16 State Health Policy Model Act report template within sixty (60) days
17 of the close of each calendar year.

18 SECTION 6. NEW LAW A new section of law to be codified
19 in the Oklahoma Statutes as Section 6735 of Title 36, unless there
20 is created a duplication in numbering, reads as follows:

21 A. Beginning on January 1, 2022, each reporting entity shall
22 register with the Insurance Department no later than January 31 of
23 each calendar year, in a form and manner specified by the Insurance
24 Department.

1 B. 1. Each reporting entity shall pay an annual assessment, in
2 an amount to be determined by the Insurance Commissioner but not to
3 be less than One Hundred Dollars (\$100.00) for each individual
4 entity required to pay an assessment under this act, to support the
5 operational costs of the Department in implementing the provisions
6 of this this act. The costs shall include staff salaries,
7 administrative expenses, data system expenses and consulting fees of
8 the Department. Total annual assessments shall be based on the
9 total annual allocation authorized by the Legislature for the
10 operational costs of the activities of the Department under this
11 act, as indicated in the fiscal year budget of the Department. The
12 amount to be assessed shall be reduced by the difference between the
13 total annual authorized allocation for the next fiscal year and the
14 beginning fund balance in the Department's account for the prior
15 fiscal year. Any assessment reduction shall be applied
16 proportionately to the categorical groups assessed.

17 2. The assessments shall be placed in the State Insurance
18 Commissioner Revolving Fund pursuant to Section 307.3 of Title 36 of
19 the Oklahoma Statutes.

20 C. The Department shall send request for payment of the
21 assessment to all reporting entities under this act by certified
22 mail beginning July 1, 2022, and annually thereafter. All
23 assessments shall be due to the Department within thirty (30) days
24 of receipt of the request for payment. Any reporting entity that

1 fails to pay the assessment pursuant to this act shall be subject to
2 the penalty pursuant to Section 7 of this act.

3 SECTION 7. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 6736 of Title 36, unless there
5 is created a duplication in numbering, reads as follows:

6 A. The reporting entity shall certify required reporting under
7 this act as accurate under the penalty of perjury.

8 B. Failure of a reporting entity to comply with the provisions
9 of this act may result in a civil penalty, at the discretion of the
10 Insurance Commissioner. Civil penalties under this act shall not
11 exceed Thirty Thousand Dollars (\$30,000.00) per day that the
12 reporting entity is found to be in violation of the provisions of
13 this act.

14 C. The Insurance Department may audit the data submitted to the
15 Department by a reporting entity pursuant to the provisions of this
16 act, in a form and manner to be specified by the Department. The
17 reporting entity shall pay all costs associated with the audit.

18 D. The Insurance Department may require a reporting entity to
19 submit a corrective action plan, in a form and manner to be
20 specified by the Department, to correct deficiencies in reporting
21 pursuant to the provisions of this act.

22 E. The Insurance Department is authorized to call one or more
23 public hearings on the price of prescription drugs in this state and
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1 may subpoena any reporting entity pursuant to the provisions of this
2 act.

3 SECTION 8. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 6737 of Title 36, unless there
5 is created a duplication in numbering, reads as follows:

6 A. Not later than July 1, 2022, the Insurance Department shall
7 develop and publish on its website a report on emerging trends in
8 prescription drug prices in this state and conduct an annual public
9 hearing based on the report findings. The report shall include, but
10 not be limited to, analysis of manufacturer prices and price
11 increases as reported under this act, analysis of information
12 reported under this act by issuers, pharmacy benefit managers and
13 wholesale drug distributors, in order to make clear the main
14 components of prescription drug pricing along the supply chain, and
15 the impacts on insurance premiums and consumer cost sharing. The
16 data in the report shall not reveal information specific to any
17 individual reporting entity.

18 B. Except as provided in this section, the Insurance Department
19 shall keep confidential all information submitted by an individual
20 reporting entity and protect it from public disclosure. The
21 Insurance Department may share such information with the Attorney
22 General; provided, however, that the Attorney General shall keep
23 confidential any information shared by the Insurance Department.
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1 The information shall not be subject to the Oklahoma Open Records
2 Act.

3 C. The Insurance Department shall promulgate rules and
4 regulations to implement the provisions of this section.

5 SECTION 9. This act shall become effective November 1, 2021.

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