LB567
2019

LEGISLATURE OF NEBRASKA

ONE HUNDRED SIXTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 567

Introduced by Morfeld, 46.

Read first time January 22, 2019

Committee: Health and Human Services

A BILL FOR AN ACT relating to prescription drugs; to adopt the Prescription Drug Cost Transparency Act.

Be it enacted by the people of the State of Nebraska,

LB567
2019

Section 1. Sections 1 to 10 of this act shall be known and may be cited as the Prescription Drug Cost Transparency Act.

Sec. 2. (1) The Legislature finds that the State of Nebraska has a substantial public interest in the price and cost of prescription drugs.

(2) It is the intent of the Legislature to:

(a) Require notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing;

(b) Permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding the prescription drug, including any price increases; and

(c) Permit both public and private purchasers of prescription drugs to negotiate discounts and rebates for prescription drugs consistent with state and federal law.

Sec. 3. For purposes of the Prescription Drug Cost Transparency Act:

(1) Course of therapy means either:

(a) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for thirty days; or

(b) The recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the federal Food and Drug Administration for a normal course of treatment that is less than thirty days;

(2) Department means the Department of Administrative Services; and

(3) Pharmacy benefit manager has the same meaning as in section 68-952.

Sec. 4. The Prescription Drug Cost Transparency Act applies to the manufacturer of a prescription drug that is purchased or the price of which is reimbursed by any of the following:

(1) A state purchaser in Nebraska, including, but not limited to,

LB567
2019

the Department of Administrative Services, the Department of Correctional Services, and the Department of Health and Human Services, and an entity acting on behalf of a state purchaser;

(2) A health maintenance organization producer as defined in section 44-32,106;

(3) A health insurer authorized to transact sickness and accident insurance business specified in section 44-201 holding a valid certificate of authority from the Department of Insurance;

(4) A fraternal benefit society authorized to transact business specified in sections 44-1072 to 44-10,109; or

(5) A pharmacy benefit manager.

Sec. 5. (1) A manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars for a course of therapy shall provide notice to persons identified in subsection (2) of this section if the increase in the wholesale acquisition cost of a prescription drug is more than sixteen percent, including the proposed increase and any cumulative increase that occurred within the previous two calendar years prior to the year in which the sale is made.

(2) The notice required by this section shall be provided to (a) each state purchaser identified in section 4 of this act and (b) any other entity identified in section 4 of this act if such entity registers with the Department of Administrative Services to receive such notification. The department shall make a list of registered entities available to manufacturers.

(3) The notice required by this section (a) shall be provided in writing at least sixty days prior to the planned effective date of the increase, (b) shall include the date of the increase, the wholesale acquisition cost at the time of the notice, and the dollar amount of the increase in the wholesale acquisition cost, and (c) shall include a statement regarding whether a change or improvement in the prescription drug necessitated the price increase and, if so, a description of the

LB567
2019

change or improvement.

Sec. 6. If a pharmacy benefit manager receives a notice under section 5 of this act, the pharmacy benefit manager shall provide notice of the increase to contracting public and private purchasers which provide coverage for more than five hundred lives.

Sec. 7. (1) A manufacturer shall report each calendar quarter to the department the following information as provided in subsection (2) of this section for each prescription drug for which a notice is required under subsection (1) of section 5 of this act:

(a) If the manufacturer manufactured the prescription drug during the past five years, a schedule of wholesale acquisition cost increases for the prescription drug for the previous five years;

(b) If the manufacturer acquired the prescription drug within the previous five years, the wholesale acquisition cost of the prescription drug at the time of acquisition and in the calendar year prior to acquisition, the name of the company from which the prescription drug was acquired, the date of the acquisition, and the purchase price;

(c) The year the prescription drug was introduced to market and the wholesale acquisition cost of the prescription drug at that time;

(d) The patent expiration date for the prescription drug if it is under patent protection;

(e) An indication of whether the prescription drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug as defined in 42 U.S.C. 1396r-8(k)(7)(A);

(f) A description of the change or improvement in the prescription drug, if any, that necessitated the increase in the wholesale acquisition cost; and

(g) The volume of sales by the manufacturer of the prescription drug in the United States for the calendar year prior to the increase in the wholesale acquisition cost.

LB567
2019

(2) The department shall prescribe a format and a quarterly schedule for the report. The manufacturer may limit the information on the report to that information which is otherwise in the public domain or publicly available.

(3) The department shall publish the information received in the reports on the web site of the department within sixty days after receipt from the manufacturer and shall update the information quarterly. The information shall be published in a manner that identifies the disclosures for each prescription drug and shall not be aggregated in a manner that would prevent associating the disclosures with the applicable prescription drug.

Sec. 8. (1) A manufacturer of a prescription drug shall notify the department in writing if it introduces a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173. The notification shall be provided in writing within three days after the release of the prescription drug in the commercial market. A manufacturer may make this notification pending approval by the federal Food and Drug Administration if commercial availability is expected within three days after approval.

(2) Within thirty days after notification pursuant to subsection (1) of this section, a manufacturer shall report to the department the following information as provided in subsection (3) of this section for each prescription drug for which a notice is required under subsection (1) of this section:

(a) A description of the pricing plans used in the launch of the new prescription drug in the United States and internationally;

(b) The estimated volume of patients that may be prescribed the prescription drug;

(c) An indication of whether the prescription drug was granted breakthrough therapy designation or priority review by the federal Food

LB567
2019

and Drug Administration prior to final approval by the federal Food and Drug Administration; and

(d) The date and price of acquisition if the prescription drug was not developed by the manufacturer.

(3) The department shall prescribe a format for the report. The manufacturer may limit the information on the report to that information which is otherwise in the public domain or publicly available.

(4) The department shall publish the information received in the reports on the web site of the department within sixty days after receipt from the manufacturer and shall update the information quarterly. The information shall be published in a manner that identifies the disclosures for each prescription drug and shall not be aggregated in a manner that would prevent associating the disclosures with the applicable prescription drug.

Sec. 9. The department shall adopt and promulgate rules and regulations necessary for implementation of the Prescription Drug Cost Transparency Act. For purposes of this section, the department may consult with the Department of Health and Human Services, the Department of Insurance, the Board of Pharmacy, any other state purchaser of prescription drugs, and any entity acting on behalf of a state purchaser.

Sec. 10. The notifications and reports pursuant to the Prescription Drug Cost Transparency Act shall be required beginning January 1, 2021, for any activity subject to the act after such date.