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NOTICE OF DRUG PRICE INCREASE

2020 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Mike Winder

Senate Sponsor: _____

LONG TITLE

General Description:

This bill requires a prescription drug manufacturer to provide notice of certain drug cost increases and requires the Insurance Department to publish related information.

Highlighted Provisions:

This bill:

- defines terms;
- requires a drug manufacturer to notify and provide information to a purchaser if an increase in the wholesale acquisition cost of a drug meets certain criteria;
- requires a drug manufacturer that is required to provide notice to submit certain information to the Insurance Department;
- requires a drug manufacturer that introduces a new drug to market to report certain information to the Insurance Department;
- requires the Insurance Department to publish information it receives from drug manufacturers;
- requires rulemaking; and
- creates a penalty.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

H.B. 263

Utah Code Sections Affected:

ENACTS:

31A-47-101, Utah Code Annotated 1953

31A-47-102, Utah Code Annotated 1953

31A-47-103, Utah Code Annotated 1953

31A-47-104, Utah Code Annotated 1953

31A-47-105, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **31A-47-101** is enacted to read:

CHAPTER 47. PRESCRIPTION DRUG PRICE TRANSPARENCY

31A-47-101. Title.

This chapter is known as "Prescription Drug Price Transparency."

Section 2. Section **31A-47-102** is enacted to read:

31A-47-102. Definitions.

As used in this chapter:

(1) "Drug" means a prescription drug, as defined in Section 58-17b-102.

(2) "Health insurer" means:

(a) an insurer that offers health care insurance;

(b) the Public Employees' Benefit and Insurance Program created in Section 49-20-103; or

(c) a workers' compensation insurer that is:

(i) authorized to provide workers' compensation insurance in the state; or

(ii) a self-insured employer as defined in Section 34A-2-201.5.

(3) "Manufacturer" means a person that is engaged in the manufacturing of a drug that is available for purchase by residents of the state.

(4) "Purchaser" means a:

(a) health insurer;

(b) pharmacy service entity as defined in Section 31A-46-302; or

(c) department, division, or other agency or instrumentality of the state, including an independent state agency as defined in Section 63E-1-102.

(5) "Wholesale acquisition cost" means the same as that term is defined in 42 U.S.C. Sec. 1395w-3a.

Section 3. Section **31A-47-103** is enacted to read:

31A-47-103. Manufacturer notice of drug cost increase.

(1) As used in this section:

(a) (i) "Qualified drug" means a drug whose wholesale acquisition cost increases 10% or more over a 12-month period.

(ii) "Qualified drug" does not include a new drug introduced into the market by a manufacturer.

(b) "Registered purchaser" means a purchaser that submits a request for notice to the department under Subsection 31A-47-105(2)(b).

(2) A manufacturer shall send a notice in accordance with this section for each qualified drug no later than 60 days before the day on which the increase to the wholesale acquisition cost of the qualified drug results in a one-year percentage increase greater than or equal to 10%.

(3) A manufacturer shall send a notice to each registered purchaser that includes:

(a) the date on which the wholesale acquisition cost of the qualified drug will increase;

(b) a description of any improvements or other changes to the qualified drug that makes the increase in the wholesale acquisition cost of the qualified drug necessary;

(c) the wholesale acquisition cost of the qualified drug after the increase to the wholesale acquisition cost;

(d) the amount of the increase to the wholesale acquisition cost of the qualified drug;

(e) the percentage increase to the wholesale acquisition cost of the qualified drug;

(f) the wholesale acquisition cost of the qualified drug 12 months before the date of the increase to the wholesale acquisition cost of the qualified drug;

(g) the amount of the increase in the wholesale acquisition cost over the 12-month period immediately before the increase in the wholesale acquisition cost of the qualified drug; and

(h) the percentage increase in the wholesale acquisition cost of the qualified drug over the 12-month period immediately before the increase in the wholesale acquisition cost of the qualified drug.

(4) Except as provided in Subsection (5), a manufacturer shall send a notice to the department that includes:

(a) the information described in Subsection (3);

(b) an explanation of how financial and nonfinancial factors justify the increase in the wholesale acquisition cost of the qualified drug, including any improvement or other modification of the qualified drug;

(c) (i) for a qualified drug that has been manufactured by the manufacturer for longer than the previous five years, the wholesale acquisition cost of the qualified drug over the previous five-year period; or

(ii) for a qualified drug that has been manufactured by the manufacturer for less than five years:

(A) the date on which the manufacturer began manufacturing the qualified drug;

(B) the date on which the manufacturer began selling the qualified drug; and

(C) the wholesale acquisition cost of the qualified drug over the period beginning on the day on which the manufacturer began selling the qualified drug; and

(d) for a qualified drug that the manufacturer acquired the right to manufacture within the previous five years, to the extent the information is publicly available:

(i) the name of the person from which the manufacturer acquired the right to manufacture the qualified drug;

(ii) the wholesale acquisition cost of the qualified drug immediately before the manufacturer acquired the right to manufacture the qualified drug; and

(iii) the wholesale acquisition cost of the qualified drug one year before the day on which the manufacturer acquired the right to manufacture the qualified drug.

(5) A manufacturer is not required to report a trade secret as defined in Section 13-24-2, in the notice to the department under Subsection (4).

Section 4. Section **31A-47-104** is enacted to read:

31A-47-104. Manufacturer submission of new drug information to the department -- Report of new drug.

If a new drug available for purchase by residents of the state has a wholesale acquisition cost that exceeds the upper limit of payment for the new drug under 42 C.F.R. Sec. 447.512, the manufacturer of the new drug shall submit to the department:

(1) no later than three days after the day on which the new drug is sold in the state, a written notice of the introduction of the new drug; and

(2) no later than 30 days after the day on which the new drug is sold in the state, a report that includes publicly available information regarding:

(a) the wholesale acquisition cost of the new drug;

(b) a description of the marketing and pricing plans used in the launch of the new drug:

(i) in the United States; and

(ii) outside of the United States;

(c) the estimated number of patients that are expected to be prescribed the new drug;

(d) whether the new drug was granted breakthrough therapy designation or priority review by the United States Food and Drug Administration; and

(e) if the manufacturer did not develop the drug, the acquisition date and price for the new drug.

Section 5. Section **31A-47-105** is enacted to read:

31A-47-105. Publication of information submitted to the department -- Rulemaking -- Penalties.

(1) The department shall publish on the department's website the information submitted by a manufacturer under Sections 31A-47-103 and 31A-47-104 no later than 60 days after the day on which the department receives the information from the manufacturer.

(2) The department shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, regarding:

(a) the format for a manufacturer to submit a notice under Sections 31A-47-103 and 31A-47-104;

(b) procedures for a purchaser to register to receive notice of a drug price increase as a registered purchaser under Section 31A-47-103; and

(c) procedures for a manufacturer to obtain the contact information for each registered purchaser.

(3) The department may impose a penalty of up to $1,000 per day for each day a manufacturer is in violation of this chapter.