APPROVEDCHAPTERJUNE 21, 2021305BY GOVERNORPUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD

TWO THOUSAND TWENTY-ONE

S.P. 274 - L.D. 686

An Act To Increase Prescription Drug Pricing Transparency

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §8731, sub-§1-A is enacted to read:

1-A. Drug product family. "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description and drug form.

Sec. 2. 22 MRSA §8731, sub-§3, as enacted by PL 2019, c. 470, §8, is amended to read:

3. Manufacturer. "Manufacturer" means a manufacturer of <u>an entity that</u> <u>manufactures or repackages, and sets the wholesale acquisition cost for</u>, prescription drugs that are distributed in the State.

Sec. 3. 22 MRSA §8731, sub-§3-A is enacted to read:

3-A. Prescription drug. "Prescription drug" means a drug, as defined in 21 United States Code, Section 321(g) or a biological product as defined in 42 United States Code, Section 262(i)(1) that:

A. Is intended for human use;

B. Is not a device within the meaning of 21 United States Code, Section 321(h); and

C. By federal or state law, can be lawfully dispensed or administered only on prescription by a licensed health care professional.

Sec. 4. 22 MRSA §8732, sub-§1, as enacted by PL 2019, c. 470, §8, is amended by enacting at the end a new blocked paragraph to read:

This subsection is repealed January 30, 2022.

Sec. 5. 22 MRSA §8732, sub-§1-A is enacted to read:

1-A. Public notice of substantial drug price change or introduction. No later than January 30, 2022 and annually thereafter, the organization shall produce and post on its publicly accessible website a list of prescription drugs for which the manufacturer has during the prior calendar year:

A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;

B. Increased the wholesale acquisition cost of a generic drug that costs at least \$10 per pricing unit by more than 20% per pricing unit; or

C. Introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. For the purposes of this paragraph, "Medicare Part D" has the same meaning as in section 254-D, subsection 1, paragraph F.

Sec. 6. 22 MRSA §8732, sub-§2, as enacted by PL 2019, c. 470, §8, is repealed and the following enacted in its place:

2. Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers. The following disclosures apply to manufacturers, wholesale drug distributors and pharmacy benefits managers.

A. On or before February 15th of each year, the organization shall produce and post on its publicly accessible website a list of drug product families for which it intends to request pricing component data from manufacturers, wholesale drug distributors and pharmacy benefits managers. The organization shall base its inclusion of drug product families on any information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State, and the organization shall consider drug product families that include prescription drugs:

(1) Included in the public notice of substantial drug price change or introduction under subsection 1-A; and

(2) For which the organization is required to produce an annual report pursuant to section 8712, subsection 5, including, but not limited to, the 25 costliest drugs, the 25 most frequently prescribed drugs in the State and the 25 drugs with the highest year-over-year cost increases.

B. Not sooner than 30 days after publicly posting the list of drug product families pursuant to paragraph A, the organization shall notify, via e-mail, manufacturers, wholesale drug distributors and pharmacy benefits managers pursuant to paragraph C.

C. Within 60 days from the date of a request from the organization relating to a specific prescription drug, a manufacturer, wholesale drug distributor or pharmacy benefits manager shall notify the organization of pricing component data per pricing unit of the prescription drug.

Sec. 7. 22 MRSA §8733, as enacted by PL 2019, c. 470, §8, is amended to read:

§8733. Confidentiality

Information provided to the organization as required by this subchapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the organization may share information:

1. Bureau of Insurance. With the Department of Professional and Financial Regulation, Bureau of Insurance, to the extent necessary for the bureau to enforce the provisions of Title 24-A, as long as any information shared is kept confidential; and

2. Aggregate. In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager.; and

3. Publicly available. That is available, for purchase or otherwise, to the public.

Sec. 8. 22 MRSA §8734, as enacted by PL 2019, c. 470, §8, is amended to read:

§8734. Registration requirements

Beginning January 1, 2020, a manufacturer and manufacturers, wholesale drug distributor distributors and pharmacy benefits managers subject to this subchapter shall register annually with the organization in a manner prescribed by the organization.

Sec. 9. 22 MRSA §8736, as enacted by PL 2019, c. 470, §8, is amended to read:

§8736. Public report

Beginning November 1, 2020 and annually thereafter, the organization shall produce and post on its publicly accessible website an annual report, including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not disclose information attributable to any particular manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter and may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.