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An Act To Increase Prescription Drug Pricing Transparency

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DAREK M. GRANT Secretary of the Senate

Presented by Senator VITELLI of Sagadahoc.

Cosponsored by Senators: BRENNER of Cumberland, CLAXTON of Androscoggin, CURRY of Waldo, President JACKSON of Aroostook, LUCHINI of Hancock, MAXMIN of Lincoln, RAFFERTY of York.

1	Be it enacted by the People of the State of Maine as follows:
2	Sec. 1. 22 MRSA §8731, sub-§1-A is enacted to read:
3 4	<u>1-A.</u> 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.
5 6	Sec. 2. 22 MRSA §8731, sub-§3, as enacted by PL 2019, c. 470, §8, is amended to read:
7 8 9	3. Manufacturer. "Manufacturer" means <u>a manufacturer of an entity that</u> <u>manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs</u> that are distributed in the State.
10	Sec. 3. 22 MRSA §8731, sub-§3-A is enacted to read:
11 12 13	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:
14	A. Is intended for human use;
15	B. Is not a device within the meaning of 21 United States Code, Section 321(h); and
16 17	C. By federal or state law, can be lawfully dispensed only on prescription by a licensed health care professional.
18 19	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:
20	This subsection is repealed January 30, 2022.
21	Sec. 5. 22 MRSA §8732, sub-§1-A is enacted to read:
22 23 24 25	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:
26 27	A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;
28 29	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
30 31 32 33	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.
34 35	Sec. 6. 22 MRSA §8732, sub-§2, as enacted by PL 2019, c. 470, §8, is repealed and the following enacted in its place:
36 37 38	2. Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers. The following disclosures apply to manufacturers, wholesale drug distributors and pharmacy benefits managers.

1 2 3 4 5 6 7 8	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:
9 10	(1) Included in the public notice of substantial drug price change or introduction under subsection 1-A; and
11 12 13 14	(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.
15 16 17	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.
18 19 20 21	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.
22	Sec. 7. 22 MRSA §8733, as enacted by PL 2019, c. 470, §8, is amended to read:
23	§8733. Confidentiality
24 25 26 27	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:
28 29 30	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
31 32 33 34	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
35	3. Publicly available. That is available, for purchase or otherwise, to the public.
36	Sec. 8. 22 MRSA §8734, as enacted by PL 2019, c. 470, §8, is amended to read:
37	§8734. Registration requirements
38 39 40	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.
41	Sec. 9. 22 MRSA §8736, as enacted by PL 2019, c. 470, §8, is amended to read:

1 §8736. Public report

2 Beginning November 1, 2020 and annually thereafter, the organization shall produce 3 and post on its publicly accessible website an annual report, including information developed from the notifications and disclosures received pursuant to this subchapter on 4 5 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 6 7 on insurance premiums and cost sharing and any other information the organization 8 determines is relevant to providing greater consumer awareness of the factors contributing 9 to the cost of prescription drugs in the State. The report may not disclose information 10 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 11 confidential pursuant to section 8733. The organization shall submit the report required by 12 13 this section to the joint standing committee of the Legislature having jurisdiction over 14 health data reporting and prescription drug matters and the committee may report out 15 legislation to the first regular or second regular session of the Legislature, depending on 16 the year in which the report is submitted.

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SUMMARY

18 This bill amends the law governing prescription drug pricing for purchasers. It changes 19 a requirement that a manufacturer notify the Maine Health Data Organization when the 20 manufacturer has taken certain actions regarding high prescription drug pricing to a 21 requirement that the organization produce and post on its publicly accessible website a list 22 of prescription drugs for which manufacturers have taken those actions. It requires the 23 organization to produce and post on its publicly accessible website a list of drug product 24 families for which it intends to request pricing component data from manufacturers, 25 wholesale drug distributors and pharmacy benefits managers and to notify the 26 manufacturers, wholesale drug distributors and pharmacy benefits managers before 27 requesting pricing component data. It also amends related public reporting and 28 confidentiality requirements.