An Act To Further Expand Drug Price Transparency

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

Sec. 1. 22 MRSA c. 603, sub-c. 5 is enacted to read:

SUBCHAPTER 5

PRESCRIPTION DRUG PRICING FOR PURCHASERS

§ 2699-A. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Course of therapy. "Course of therapy" means:

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 30 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 30 days.

2. Office. "Office" means the Maine Health Data Organization established under 1683.

3. Purchaser. "Purchaser" means a State purchaser, an insurance company licensed in accordance with Title 24-A to provide health insurance, a health maintenance organization licensed pursuant to Title 24-A or a pharmacy benefit manager as defined in Title 24-A, section 1913 subsection 1, paragraph A.

4. State purchaser. "State purchaser" means a State entity that purchases or reimburses the purchase of prescription drugs. "State purchaser" includes, but is not limited to, the Department of Health and Human Services, the Department of Corrections, the Department of Administrative and Financial Services, the Maine Public Employees Retirement System, and any entity that acts on behalf of a State entity that purchases or reimburses the purchase of prescription drugs.

5. Wholesale acquisition cost. "Wholesale acquisition cost" means the list price of a manufacturer to a wholesaler or direct purchaser in the United States, not including prompt pay or other discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of pharmaceutical pricing data or as estimated by the organization using the all-payer claims data and the ingredient cost and list price and dispensing fee information that is submitted to the organization.

§ 2699-B. Registration of purchasers

A purchaser may receive notification of increases in wholesale acquisition costs in accordance with section 2699-C if that purchaser registers with the office for the purpose of receiving such notification. The office shall make available to manufacturers of prescription drugs a list of purchasers that are registered to receive notification pursuant to this section.

§ 2699-C. Notification of increase in wholesale acquisition cost

1. Notice by manufacturer. If a prescription drug has a wholesale acquisition cost of more than $40 for a course of therapy and there is an increase in the wholesale acquisition cost of that prescription drug of more than 16%, including the proposed increase and the cumulative increases that occurred within the previous 2 calendar years prior to the current year, the manufacturer of the prescription drug shall provide notice in accordance with this subsection to every purchaser from whom it receives payment or reimbursement for that prescription drug.

A. The manufacturer shall provide notice in writing at least 60 days prior to the planned effective date of the increase in the wholesale acquisition cost.

B. The notice must include the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug.

C. The notice must include a statement regarding whether a change or improvement in the drug necessitates the price increase, and if applicable, the notice must describe the change or improvement.

2. Notification by pharmacy benefit managers. Upon receipt of notice of an increase in wholesale acquisition cost from a manufacturer of prescription drugs in accordance with subsection 1, a pharmacy benefits manager shall forward notice of that increase to any client that provides coverage to more than 500 individuals.

Sec. 2. 22 MRSA §8702, sub-§5-C is enacted to read:

5-C. Manufacturer. "Manufacturer" means a manufacturer of prescription drugs.

Sec. 3. 22 MRSA §8702, sub-§12 is enacted to read:

12. Wholesale acquisition cost. "Wholesale acquisition cost" means the list price of a manufacturer to a wholesaler or direct purchaser in the United States, not including prompt pay or other discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of pharmaceutical pricing data or as estimated by the organization using the all-payer claims data and the ingredient cost and list price and dispensing fee information that is submitted to the organization.

Sec. 4. 22 MRSA §8703, sub-§1, as amended by PL 2003, c. 469, Pt. C, §22, is further amended to read:

1. Objective. The purposes of the organization are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. The organization shall collect, process, analyze and report clinical, financial, quality ~~and,~~ restructuring and prescription drug price data as defined in this chapter.

Sec. 5. 22 MRSA §8704, sub-§1, ¶A, as amended by PL 2003, c. 469, Pt. C, §23, is further amended to read:

A. The board shall develop and implement policies and procedures for the collection, processing, storage and analysis of clinical, financial, quality ~~and,~~ restructuring and prescription drug price data in accordance with this subsection for the following purposes:

(1) To use, build and improve upon and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts;

(2) To coordinate the development of a linked public and private sector information system;

(3) To emphasize data that is useful, relevant and not duplicative of existing data;

(4) To minimize the burden on those providing data; and

(5) To preserve the reliability, accuracy and integrity of collected data while ensuring that the data is available in the public domain.

Sec. 6. 22 MRSA §8710-A is enacted to read:

§ 8710-A. Prescription drug price transparency

1. Annual identification; list. The organization shall annually identify and compile a list of the following prescription drugs, including brand name and generic drugs:

A. The 25 most frequently prescribed drugs in the State;

B. The 25 costliest drugs as determined by the total amount spent on those drugs in the State; and

C. The 25 drugs with the highest year-over-year cost increases as determined by the total amount spent on those drugs in the State.

The list must also include along with each identified prescription drug the corresponding wholesale acquisition cost and the percentage of wholesale acquisition cost increase, if applicable. The organization shall make the list and cost information compiled pursuant to this section available to the public and post it on the publicly accessible website of the organization.

2. Required information. Beginning July 1, 2021 and annually thereafter, the organization shall require the manufacturer of each of the drugs listed in subsection 1 to provide to the organization, in such form and format and on a schedule determined by the organization, information to explain prescription drug prices, including but not limited to the following:

A. Total cost of production and total cost per dose of the drug;

B. Research and development costs of the drug, including those costs paid with public funds, those costs reported as after-tax costs and those costs paid by 3rd parties;

C. Marketing and advertising costs of the drug, including those costs directed to consumers, those costs directed to prescribers and the total of those costs directed to consumers and prescribers in the State;

D. The retail prices of the drug charged to purchasers outside the United States in countries that are members of the Organisation of Economic Co-operation and Development or successor organization; and

E. The retail prices of the drug typically charged to purchasers in the State, including but not limited to pharmacies, pharmacy wholesalers and other direct purchasers.

A manufacturer of a brand-name drug or a generic drug directed to provide information under this section shall provide the information within 60 days after the information is requested by the organization and shall certify as accurate the information provided. The organization may request that a manufacturer provide additional information related to the information required in this subsection.

3. Additional information. A manufacturer of each of the drugs listed in subsection 1 may voluntarily provide any other information the manufacturer determines relevant to the increase in wholesale acquisition cost, including but not limited to a description of all manufacturer-sponsored assistance programs for a drug identified in subsection 1 in the previous year, including the terms of the programs, the total amount of financial assistance provided to residents of the State and the average amount of assistance per resident of the State for whom assistance was provided. Information provided by manufacturers pursuant to this subsection is not confidential and may be released in a manner that identifies both the individual drug to which the information pertains as well as the manufacturer.

4. Reports to Legislature. Beginning December 1, 2020 and annually thereafter, the organization shall submit a written report to the Legislature that includes the list of prescription drugs compiled pursuant to subsection 1 and their wholesale acquisition cost and cost increases, if any. The organization may include in the report recommendations for improving the transparency of prescription

drug pricing. Beginning December 1, 2021, the report must include a summary of the information provided by manufacturers pursuant to this section. The organization shall post the report on the publicly accessible website of the organization.

5. Confidentiality; exceptions. Information provided by manufacturers pursuant to subsection 2, unless already publicly accessible or available or previously released in the public domain, must, at the request of the manufacturer, be held as confidential and not subject to public inspection and copying under the Freedom of Access Act. The organization may release information that was previously accessible or available or released in the public domain. The organization may release other information provided pursuant to subsection 2 except for information that is a trade secret as defined in Title 10, section 1542, subsection 4. The organization shall treat information submitted by manufacturers as Level II data in accordance with 90-590 CMR, Chapter 120, Release of Data to the Public.

6. Penalties for noncompliance. When a manufacturer violates the requirements of this section, the board may impose a fine of not more than $10,000 per day after the deadline for reporting required information. If the manufacturer fails to pay a fine, or if an injunction is necessary, the board may refer the matter to the Attorney General. The Attorney General may bring an action in Superior Court for injunctive relief, enforcement of fines, costs, attorney's fees and any other appropriate remedy.

7. Legal ability to change prices. Nothing in this section may be construed to restrict the legal ability of a manufacturer to change prices to the extent permitted under federal law.

Sec. 7. 22 MRSA §8712, sub-§5, as enacted by PL 2017, c. 406, §1, is repealed.

SUMMARY

This bill requires that, if a prescription drug has a wholesale acquisition cost of more than $40 for a course of therapy and there is an increase in the wholesale acquisition cost of that prescription drug of more than 16%, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year, the manufacturer of the prescription drug must provide notice to certain registered purchasers.

Under current law the Maine Health Data Organization, referred to as the "organization," is required to collect and report information with regard to the 25 prescription drugs that are the most frequently prescribed in the State, the 25 costliest as determined by the total amount spent on those drugs in the State and the 25 drugs that have the highest year-over-year cost increases in total spending in the State. This bill requires the organization to post online a list of the identified prescription drugs, along with the corresponding wholesale acquisition cost and the percentage of wholesale acquisition cost increase, if applicable, for each identified prescription drug.

The bill directs the organization to develop a plan to collect data from manufacturers that will help explain how prescription drug prices are established. The organization is required to work with other state and national agencies and organizations to determine how to conduct the data collection. The organization is required to submit the plan as well as any recommendations for legislation to the joint standing committee of the Legislature having jurisdiction over judiciary matters by April 1, 2020. That committee may report out legislation to the First or Second Regular Session of the 130th Legislature.

Using the plan developed and reported to the Legislature, starting in 2021 the organization must require the manufacturer of each drug on the list to disclose drug production, research and development costs, marketing and advertising costs and actual costs paid by purchasers. The manufacturer must certify the accuracy of the information and provide it within 60 days after the information is requested by the organization. The organization is authorized to request additional information related to the required information.

The information that the manufacturers are directed to provide to the organization, unless the information is already publicly accessible or available or previously released in the public domain, must be held confidential at the request of the manufacturer. The organization may release information that was previously accessible or available or released in the public domain. The organization may release additional information as long as the information released is not a trade secret. The organization must treat the information as "Level II" information as required by rules that have already been adopted by the organization.

This amendment provides that the manufacturer may voluntarily provide any other information the manufacturer determines relevant to the increase in wholesale acquisition cost, including but not limited to information about all manufacturer-sponsored assistance programs for that drug in the previous year, including the terms of the programs, the total amount of financial assistance provided to residents of the State and the average amount of assistance per resident of the State for whom assistance was provided. This information is not considered confidential and the organization may release it, identifying both the manufacturer and the individual drug.

The organization is required to submit an annual report to the Legislature based on the list of up to 75 drugs and the wholesale acquisition cost information. The organization may include in the report recommendations for increasing prescription drug pricing transparency. Once the organization starts collecting information from manufacturers in 2021, the report must also include at least a summary of the manufacturer information. The organization is required to post the report online.

The bill provides that when a manufacturer violates the reporting requirements, the Board of Directors of the Maine Health Data Organization may impose a fine of not more than $10,000 per day after the deadline for reporting required information. If the manufacturer fails to pay a fine, or if an injunction is necessary, the board may refer the matter to the Attorney General. The Attorney General may bring an action in Superior Court for injunctive relief, enforcement of fines, costs, attorney's fees and any other appropriate remedy.

The legislation does not restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.