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STATE OF MAINE

SENATE

128TH LEGISLATURE

SECOND REGULAR SESSION

COMMITTEE AMENDMENT “ ” to S.P. 484, L.D. 1406, Bill, “An Act To Promote Prescription Drug Price Transparency”

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

Sec. 1. 22 MRSA §8702, sub-§5-C is enacted to read:

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

Sec. 2. 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. 3. 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. 4. 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

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1 prescription drug price data in accordance with this subsection for the following
2 purposes:

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

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

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

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

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

13 **Sec. 5. 22 MRSA §8710-A** is enacted to read:

14 **§8710-A. Prescription drug price transparency**

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

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

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

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

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

27 **2. Required information.** Beginning July 1, 2019 and annually thereafter, the
28 organization shall require the manufacturer of each of the drugs listed in subsection 1 to
29 provide to the organization, in such form and format and on a schedule determined by the
30 organization, information to explain prescription drug prices, including but not limited to
31 the following:

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

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

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

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

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

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

11 **3. Additional information.** A manufacturer of each of the drugs listed in subsection
12 1 may voluntarily provide any other information the manufacturer determines relevant to
13 the increase in wholesale acquisition cost, including but not limited to a description of all
14 manufacturer-sponsored assistance programs for a drug identified in subsection 1 in the
15 previous year, including the terms of the programs, the total amount of financial
16 assistance provided to residents of the State and the average amount of assistance per
17 resident of the State for whom assistance was provided. Information provided by
18 manufacturers pursuant to this subsection is not confidential and may be released in a
19 manner that identifies both the individual drug to which the information pertains as well
20 as the manufacturer.

21 **4. Reports to Legislature.** Beginning December 1, 2018 and annually thereafter,
22 the organization shall submit a written report to the Legislature that includes the list of
23 prescription drugs compiled pursuant to subsection 1 and their wholesale acquisition cost
24 and cost increases, if any. The organization may include in the report recommendations
25 for improving the transparency of prescription drug pricing. Beginning December 1,
26 2019, the report must include a summary of the information provided by manufacturers
27 pursuant to this section. The organization shall post the report on the publicly accessible
28 website of the organization.

29 **5. Confidentiality; exceptions.** Information provided by manufacturers pursuant to
30 subsection 2, unless already publicly accessible or available or previously released in the
31 public domain, must, at the request of the manufacturer, be held as confidential and not
32 subject to public inspection and copying under the Freedom of Access Act. The
33 organization may release information that was previously accessible or available or
34 released in the public domain. The organization may release other information provided
35 pursuant to subsection 2 except for information that is a trade secret as defined in Title
36 10, section 1542, subsection 4. The organization shall treat information submitted by
37 manufacturers as Level II data in accordance with 90-590 CMR, Chapter 120, Release of
38 Data to the Public.

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

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

4 **Sec. 6. Further data collection by Maine Health Data Organization.** The
 5 Maine Health Data Organization shall develop a plan to collect data from manufacturers
 6 related to the cost and pricing of prescription drugs in order to provide transparency in
 7 and accountability for prescription drug pricing as required in the Maine Revised
 8 Statutes, Title 22, section 8710-A, subsection 2. The organization shall consult with
 9 other state and national agencies and organizations to determine how to institute the data
 10 collection. The organization shall submit the plan, its findings and any recommendations
 11 for suggested legislation to the First Regular Session of the 129th Legislature no later
 12 than April 1, 2019. The joint standing committee of the Legislature having jurisdiction
 13 over judiciary matters may report out legislation related to prescription drug price
 14 transparency and the organization's findings and recommendations to the First or Second
 15 Regular Session of the 129th Legislature.

16 **Sec. 7. Appropriations and allocations.** The following appropriations and
 17 allocations are made.

18 **HEALTH DATA ORGANIZATION, MAINE**

19 **Maine Health Data Organization 0848**

20 Initiative: Provides a one-time allocation to the Maine Health Data Organization to
 21 collect and present certain data to the Legislature and to develop a plan for further data
 22 collection.

23	OTHER SPECIAL REVENUE FUNDS	2017-18	2018-19
24	All Other	\$0	\$100,000
25			
26	OTHER SPECIAL REVENUE FUNDS TOTAL	\$0	\$100,000
27			

28 **SUMMARY**

29 This amendment is the majority report of the Joint Standing Committee on Judiciary.
 30 The amendment replaces the bill and amends the statutes governing the Maine Health
 31 Data Organization to address the collection and reporting of information about
 32 prescription drug prices.

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

1 This amendment directs the organization to develop a plan to collect data from
2 manufacturers that will help explain how prescription drug prices are established. The
3 organization is required to work with other state and national agencies and organizations
4 to determine how to conduct the data collection. The organization is required to submit
5 the plan as well as any recommendations for legislation to the joint standing committee of
6 the Legislature having jurisdiction over judiciary matters by April 1, 2019. That
7 committee may report out legislation to the First or Second Regular Session of the 129th
8 Legislature.

9 Using the plan developed and reported to the Legislature, starting in 2019, the
10 organization must require the manufacturer of each drug on the list to disclose drug
11 production, research and development costs, marketing and advertising costs and actual
12 costs paid by purchasers. The manufacturer must certify the accuracy of the information
13 and provide it within 60 days after the information is requested by the organization. The
14 organization is authorized to request additional information related to the required
15 information.

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

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

32 The organization is required to submit an annual report to the Legislature based on
33 the list of up to 75 drugs and the wholesale acquisition cost information. The
34 organization may include in the report recommendations for increasing prescription drug
35 pricing transparency. Once the organization starts collecting information from
36 manufacturers in 2019, the report must also include at least a summary of the
37 manufacturer information. The organization is required to post the report online.

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

