

# MAINE STATE LEGISLATURE

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Date: 4/10/2018 Majority

(Filing No. S-451)

JUDICIARY

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STATE OF MAINE

SENATE

128TH LEGISLATURE

SECOND REGULAR SESSION

COMMITTEE AMENDMENT "A" 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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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. 5. 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, 2019 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;

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.

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

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

**HEALTH DATA ORGANIZATION, MAINE**

**Maine Health Data Organization 0848**

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

<b>OTHER SPECIAL REVENUE FUNDS</b>	<b>2017-18</b>	<b>2018-19</b>
All Other	\$0	\$100,000
<b>OTHER SPECIAL REVENUE FUNDS TOTAL</b>	<b>\$0</b>	<b>\$100,000</b>

**SUMMARY**

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

This amendment directs the Maine Health Data Organization, referred to as the "organization," 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. The organization is required 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.

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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.

# COMMITTEE AMENDMENT

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COMMITTEE AMENDMENT "A" to S.P. 484, L.D. 1406

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

3 The amendment includes an appropriations and allocations section.

4 **FISCAL NOTE REQUIRED**

5 **(See attached)**



# 128th MAINE LEGISLATURE

LD 1406

LR 994(02)

## An Act To Promote Prescription Drug Price Transparency

Fiscal Note for Bill as Amended by Committee Amendment "A" (S-451)

Committee: Judiciary

Fiscal Note Required: Yes

### Fiscal Note

Minor cost increase - General Fund  
 Minor revenue increase - General Fund

	FY 2017-18	FY 2018-19	Projections FY 2019-20	Projections FY 2020-21
<b>Appropriations/Allocations</b>				
Other Special Revenue Funds	\$0	\$100,000	\$0	\$0
<b>Revenue</b>				
Other Special Revenue Funds	\$0	\$100,000	\$0	\$0

### Correctional and Judicial Impact Statements

Increases the number of civil suits  
 The additional workload associated with the minimal number of new cases filed in the court system does not require additional funding at this time.  
 The collection of additional filing fees may increase General Fund revenue by minor amounts.

### Fiscal Detail and Notes

The bill includes a one-time allocation to the Maine Health Data Organization of \$100,000 to collect and present certain data to the legislature and to develop a plan for further data collection. The Maine Health Data Organization has sufficient resources available to fund the allocation.

Additional costs to the Department of the Attorney General are expected to be minor and can be absorbed within existing budgeted resources.