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GOVERNOR

MHDO Maine Health Data Organization
Information | Insight | Improvement

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DATE: March 15, 2019

TO: Honorable Troy D. Jackson, President of the Senate
Honorable Sara Gideon, Speaker of the House
Honorable Nathan L. Libby, Senate Democratic Leader
Honorable Eloise A. Vitelli, Assistant Senate Democratic Leader
Honorable Dana L. Dow, Senate Republican Leader
Honorable Jeffrey L. Timberlake, Assistant Senate Republican Leader
Honorable Matt W. Moonen, Majority Leader
Honorable Ryan M. Fecteau, Assistant Majority Leader
Honorable Kathleen R. J. Dillingham, House Republican Leader
Honorable Harold Trey L. Stewart, Assistant Republican Leader
Senator Sanborn, Representative Tepler and Members of the Joint Standing Committee on Health Coverage, Insurance and Financial Services
Senator Carpenter, Representative Bailey and Members of the Joint Standing Committee on Judiciary

FROM: Karynlee Harrington, Executive Director, Maine Health Data Organization

CC: BJ McCollister, Chief of Staff, Senate President
Jonathan Asen, Chief of Staff, Speaker of the House
Isabel Mullin, Chief of Staff, Senate Democratic Office
Heather Priest, Chief of Staff, Senate Republican Office
Megan Rochelo, Chief of Staff, House Majority Office
William Thompson, Chief of Staff, House Minority Office
Colleen McCarthy Reid, OPLA Analyst
Peggy Reinsch, OPLA Analyst
Bethany Beausang, Senior Policy Advisor, Office of Governor Janet T. Mills
Neil Korsen, MD, Chair MHDO Board of Directors
Commissioner Head, Vice-Chair, MHDO Board of Directors

RE: Prescription Drug Pricing Report-Findings and Recommendations

Public Law, Chapter 406, Section 2, requires the Maine Health Data Organization to develop a plan to collect data from manufacturers related to the cost and pricing of prescription drugs to provide transparency in and accountability for prescription drug pricing. Attached are the findings and recommendations of the Maine Health Data Organization.

Please don't hesitate to contact me directly with any questions.

Requirement

Public Law, Chapter 406, Section 2, requires the Maine Health Data Organization to *develop a plan to collect data from manufacturers related to the cost and pricing of prescription drugs to provide transparency in and accountability for prescription drug pricing.*

The organization shall consult with other state and national agencies and organizations to determine how to institute such 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.

Environmental Scan

As of June 4, 2018, there are six states (Vermont, Connecticut, Nevada, Oregon, California and Maryland) that have passed prescription drug transparency laws that require the pharmaceutical manufactures and or pharmacy benefit managers to report data and information to the state including the reasons for their more significant price increases (defined differently by each state).

Shortly following the enactment of these laws, PhRMA (the trade group representing companies in the pharmaceutical industry in the United States) filed law suits challenging the constitutionality of California and Nevada's new laws. In Nevada the lawsuit was dropped after the State adopted regulations that allow manufacturers and pharmacy benefit managers (PBMs) to request that specific price report information be kept confidential. In California, there has not been any action in the lawsuit since PhRMA filed an amended complaint which focuses on how California's law, SB 17 directly harms individual PhRMA member companies.

As reported by the National Academy for State Health Policy (NASHP), a nonpartisan forum of health care policymakers, 17 states have introduced 27 transparency bills in the 2019 state legislative session, all aimed at addressing the rising costs of prescription drugs. These bills focus on different aspects of the supply chain, including pharmaceutical pricing transparency, regulation of pharmacy benefit managers, wholesale drug importation programs, and other drug cost containment initiatives.

It is apparent that based on the activity to date, there is interest across the country to address the issue of rising drug costs at a state level. What is not yet known because these laws are new and are still in the early stages of implementation, is, how will the legal challenges impact these laws; what are the specific data elements that should be defined and collected that will allow for meaningful analysis; and how will states approach the implementation of these new data collection laws where a national standard does not yet exist. It is because of these unknowns that the Maine Health Data Organization is cautious about taking on a new mandate to collect data from pharmaceutical manufacturers. The MHDO Board strongly recommends an incremental approach to any data collection requirement while we continue to monitor the progress of the other states that are further along in the process.

Consultation with States and National Organization

The National Academy for State Health Policy (NASHP), a nonpartisan forum of health care policymakers, established a workgroup in the summer of 2018, comprised of state officials charged with implementing prescription drug price transparency laws. These states include: California, Nevada, Oregon, Connecticut and Vermont. In addition, NASHP included representatives from Maine and New Hampshire who have been charged with studying potential approaches to prescription drug transparency and are required to report back to their legislatures.

The members of the workgroup representing the states identified the need for uniformity in defining the data elements to support state transparency laws. The reasons cited include the reduction in administrative burden for those entities reporting, and with alignment, there is the ability to perform cross-state analysis of the data. The workgroup also discussed the need for a comprehensive common data set that included data elements for the different entities in the supply chain, including manufacturers, wholesalers, pharmacy benefit managers and health insurers.

In the absence of a national data standard for the collection of this type of data, NASHP released a request for proposal (RFP) in September 2018, seeking a partner to assist states in developing a national common data set of drug pricing data elements and definitions that states could adopt to support their drug transparency programs. NASHP selected Mathematica Policy Research to partner with and lead the effort to establish a Drug Pricing Transparency Minimum Dataset (DPTMD). The development of the DPTMD considered feedback from the industry, including PhaRMA, which was provided directly from states that are in the process of defining data elements as part of their rulemaking process.

As part of the process of developing the DPTMD, the members of the workgroup discussed with NASHP and Mathematica the various questions that each state's prescription drug price transparency program is trying to answer. A common theme in these discussions was that the information generated from the common data set needs to identify the extent of price increases across time, and provide an understanding of the contributors to those price increases both as reported by manufacturers and across the supply chain. Outlined below are the specific questions the common data set has been designed to respond to:

Pharmaceutical Manufacturers and drug price changes:

- What is the recent history of the manufacturer's price (wholesale acquisition cost (WAC)) for this drug before rebates or price concessions?
- What has been the recent history of the manufacturer's revenues and costs for this drug group?
- How much has the price of this drug before rebates (WAC) changed since launch or acquisition?
- How much do major components of cost (manufacturing, marketing, etc.) contribute to the current cost of this drug group?

Pharmaceutical Manufacturers reporting for new drug/s:

- What is the price of this drug (WAC) before rebates, and how much does the manufacturer project that this drug will cost per patient in the next year?

Insurer/PBM reporting (Insurers report separately for commercially-insured and Medicaid):

- What were the costliest drugs (individual National Drug Code (NDC) or NDC group of alternative formulations by the same manufacturer) that insurers purchased *before* rebates and price concessions last year?
- For each drug, how much did consumers spend (including cost-sharing) on all formulations from the same manufacturer?
- What was the total value of rebates and negotiated price concessions from the manufacturer for the identified drugs?
- How much of the total value of negotiated rebates and price concessions from the manufacturer was retained by PBMs? Retained by insurers? Passed on to consumers?

Overview of the Minimum Dataset

The data elements defined in the *Drug Pricing Transparency Minimum Dataset*, for the pharmaceutical manufacturers are intended to provide information for price increases including the pricing of new drugs.

The minimum data elements for manufacturers include:

- Data elements to respond to price increases: the drug's wholesale acquisition cost history, manufacturer costs, sales volume, revenue and profit, and rebate data.
- Data elements to respond to a new acquisition or launch: wholesale acquisition cost at launch, U.S. Food and Drug Administration (FDA) approval designation, expected sales volume, projected U.S. revenue, use of public funding for research and development, and qualitative information such as the manufacturer's marketing plan and pricing methodology.

The minimum data elements that pharmacy benefit managers (PBMs) and health insurers would report include:

- The total volume of spending, the amount of rebates negotiated and retained by the PBM, and the insurer's retention and expenditure from premiums.

Standard Reports

Mathematica developed a set of standard reports that can be generated from the minimum data elements described above.

The reports generated from the manufacturer-reported minimum data elements address the following questions related to:

1. **Price increases:**
    - What is the recent history of the manufacturer's pricing for this drug before rebates?
    - What is the recent history of the manufacturer's revenues and costs for this drug?
    - How much has this drug's price before rebates changed since launch or acquisition?
    - What are the largest components of cost for this drug?

2. **Newly acquired drug or drug launch:**
    - What is the price of this drug (WAC) before rebates
    - How much does the manufacturer project that this drug will cost per patient in the next year?

The reports generated from the PBM- and insurer-reported minimum data elements address the following questions related to:

1. **The level and increase in total spending**:
    - What were the costliest drugs that insurers/PBMs purchased before rebates and price concessions last year?
    - For each drug, how much did consumers spend (including cost-sharing) on all formulations from the same manufacturer?
    - What was the total value of negotiated rebates and price concessions from the manufacturer?
    - How much of the total value of negotiated rebates and price concessions from the manufacturer was retained by PBMs, retained by insurers, or passed on to consumers?

Conclusion

If Maine moves forward with legislation that requires the Maine Health Data Organization to define and collect data from specific entities in the pharmaceutical supply chain, MHDO would suggest an incremental approach to this data collection for the reasons stated above and would use the DPTMD as the common data set for a proposed rule the agency would develop for the submission of data by the pharmaceutical manufacturers and pharmacy benefits managers.

Attachment A is the MHDO's suggested language changes to its governing statute to allow the MHDO to collect and report data from pharmaceutical manufacturers and pharmacy benefits managers. We offer this language for consideration as a replacement to the language in LD 1162.

Attachment A
Proposed replacement language to LD 1162

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

5-C. Manufacturer. "Manufacturer" means a manufacturer of prescription drugs whose products are distributed in the State.

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 sections 8712 and 8710-A. 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 18 ensuring that the data is available in the public domain.

§8705-A. ENFORCEMENT

The board shall adopt rules to ensure that payors, ~~and~~ providers, manufacturers and pharmacy benefit managers file data as required by section 8704, subsection 1; that users that obtain health data and information from the organization safeguard the identification of patients and health care practitioners as required by section 8707, subsections 1 and 3; and that payors, ~~and~~

providers, manufacturers and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2.

3. Fines. The following provisions apply to enforcement actions under this section except for circumstances beyond a person's or entity's control.

A. When a person or entity that is a health care facility, ~~or~~ payor, manufacturer and pharmacy benefits manager violates the requirements of this chapter, except for section 8707, that person or entity commits a civil violation for which a fine of not more than $1,000 per day may be adjudged. A fine imposed under this paragraph may not exceed $25,000 for any one occurrence.

§8706. REVENUES AND EXPENDITURES

(2) Annual assessments of not less than $100 assessed against the following entities licensed under Titles 24 and 24-A: nonprofit hospital and medical service organizations, health insurance carriers and health maintenance organizations on the basis of the total annual health care premium; and 3rd-party administrators, carriers that provide only administrative services for a plan sponsor ~~and pharmacy benefits managers~~ that process and pay claims on the basis of claims processed or paid for each plan sponsor. The assessments are to be determined on an annual basis by the board. An annual assessment of $500 against each licensed manufacturer and pharmacy benefits manager. Health care policies issued for specified disease, accident, injury, hospital indemnity, disability, long term care or other limited benefit health insurance policies are not subject to assessment under this subparagraph. For purposes of this subparagraph, policies issued for dental services are not considered to be limited benefit health insurance policies. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (3); and

§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.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 and pharmacy benefits manager pursuant to this section. The organization shall post the report on the publicly accessible website of the organization.

3.Confidentiality; exceptions. Information provided by manufacturers and pharmacy benefits managers pursuant to subsection 2, will be treated as confidential MHDO data and may be released in accordance with 95-590 CMR, Chapter 120, Release of Data to the Public when that rule is amended to include such data.

4.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.