Your Generics & Biosimilars Industry

STATEMENT OF OPPOSITION AND REQUEST FOR AMENDMENTS TO LD 1162

The Association for Accessible Medicines' (AAM) core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. AAM is the nation’s leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Our members provide more than 36,000 jobs at nearly 150 facilities, and manufacture more than 61 billion doses of prescription medicines in the United States every year. Last year generics saved Maine $1.1 billion.

Generic drug spending is not what is driving the increase in health care costs.

- In April, 2019 AARP issued their Year End Report on Trends in Drug Pricing.
- In that report, AARP found that prices for generic medicines dropped by 9.3%. This decrease in price is a trend that has continued from previous years.
- In the same report, AARP found that brand prices increased by 8.4%.
- AARP found in 2017, the average retail price for brand drugs was 18 times higher than the average annual price of generic therapies.
- In a year, patients on branded medicines paid almost $7,000 where patients on generic equivalents paid $365.

- In its 2017 National Health Expenditures report released in December 2018, CMS reported that U.S. net spending on outpatient prescription drugs in 2017 was $333.4 billion, up only 0.4% from 2016. CMS indicated that factors contributing to the 2017 slowdown in drug spending included:
  - Continued growth in the generic dispensing rate.
  - Deflation in generic drug prices and lower price increases for brand-name drugs.
  - Slower growth in prescriptions dispensed, due partly to a decline in opioid dispensing.

- Generic medicines typically come to market with a price 50% lower than the brand reference product.
- Once a generic drug is introduced to the market, it typically controls the market share quickly.
  - Generic medicines represent 90% of all US prescriptions dispensed but only 23% of the US spend on medicines.
  - The California Department of Managed HealthCare, based on 2017 reporting, found that generics accounted for 90% of all prescribed drugs but only represented 23.6% of the total pharmaceutical spend. The California report also found that the 25 generics drugs with the highest year-over-year increase accounted for only 4.7% of the total annual spend on prescription drugs.
Because of low generic medicine prices, they are more available to patients. Generic copays average $6.06, compared to more than $40 for brand drugs.

In 2017, patients were 2-3 times more likely to abandon their prescriptions for more expensive brand name drugs. The overall abandonment rate for generics is 8.1% compared with 21.3% for brands.

The hypercompetitive and rapidly changing nature of generic drug markets leaves generic drugs particularly vulnerable to drug shortages. The highly competitive generic market has more than 200 manufacturers and only three primary purchasers who leverage their power to keep prices very low.

The nature of competitive generic markets can prevent generic manufacturers from raising prices to reflect changing demand or increases in manufacturing costs for products. This results in a dynamic landscape in which manufacturers regularly enter and exit markets as conditions change.

Generic manufacturers have a portfolio of products they sell to payors. If some product prices are decreased significantly, the prices for other products in the portfolio may be increased to balance out the overall value of the portfolio and allow the manufacturer to maintain a positive revenue flow.

Many drug supply chain entities impact the costs patients pay at the pharmacy counter. Once a generic drug manufacturer sells its products to a wholesaler, the company no longer plays a role in the price of those products.

Unlike brand manufacturers who sell to pharmacy benefit managers (PBMs) and negotiate formulary placement based on rebates, generic manufacturers sell to wholesalers.

Three large wholesale/pharmacy buying consortium control more than 90% of the market for generic drug purchasing. They then sell those drugs to pharmacies — with pricing and distribution outside the control of manufacturers.

Wholesalers also generate revenue from sales to pharmacies and fees related to other services provided to customers. Like any other supply chain market, wholesalers can capitalize on price fluctuations — especially those in the generic market.

Retail pharmacies generate revenue from prescriptions in two ways: any margin between the payment from a patient’s health insurance company (or the patient himself) and the acquisition cost of the drug, and a flat, per-prescription dispensing fee negotiated between a payor and a pharmacy (dispensing fee).
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• The price a patient pays for a generic drug is affected not only by pricing markups by the wholesaler and pharmacy, but also by insurance copay and formulary design choices made by insurance plans and pharmacy benefit managers.
  
  • Health plans in Medicare Part D rapidly moved generic prescription drugs to higher tiers between 2011 and 2015. In 2011, 71% of generics were on tier 1, the lowest tier in the formulary. By 2015, only 19% of generics were on tier 1.
  
  • This change caused patient out of pocket spending on these products to increase by $6.2 billion (93%) even though the price of these products increased by only 1% and the volume of sales for the products increased by only 22%.

LD 1162 as drafted will not get at the true driver of cost in the healthcare system. As drafted, LD 1162 will place a substantial burden on the generic industry and will do nothing to rein in prices of costly brands.

Setting a percentage increase trigger without a base WAC price could result in the collection of data on drug price increases that have little to no impact on state costs, insurance premiums, or patient out-of-pocket costs.

  • Often, generic medicines cost pennies a day. A 200% increase on a $.0.25 drug would trigger manufacturer reporting, but would still cost a patient less than a dollar a day.

Requiring generic manufacturers to give prior notice of price changes could negatively impact the ability to provide low cost alternatives to costly brands.

  • Unlike brand drugs, generic manufacturers have a less regular pricing scheme. The generics market is based on price and ability to meet demand (volume). Manufacturers have large portfolios of low costs medicines, and the ability to rebalance a portfolio is essential. The generics market operates more like a commodities market.

LD 1162 could negatively impact manufacturers’ ability to bring biosimilars to market. When a generic or biosimilar comes to market, the majority of market share typically shifts to that product over a relatively short timeframe. This decreases overall health care costs without the need for patients or states to do anything. It also reduces patient costs making access to needed medicines more affordable. Generally, generic products come to market at a price that is at least 50% lower than the brand product and all but one biosimilar has entered the U.S. market at a price that is at least 30% lower than the reference biologic product.
For the reasons stated herein, AAM respectfully asks for the following amendments. By including these amendments, you will ensure that generic medicines will still be available at a fraction of the cost of their brand counterparts.

Recommended Amendments to LD 1162 as Amended
April 16, 2019

Sen. Vitelli For presentation at public hearing Tuesday, April 16 @1:00

An Act To Further Expand Drug Transparency

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

Sec. 1. 22 MRSA §8703, sub-§1 is 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 and section 2699-Q. 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 data as defined in this chapter.

Sec. 2. 22 MRSA §8704, sub-§1, ¶A is 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. 3. 22 MRSA §8705-A, first ¶ is amended to read:

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 8714, subsections 2, 3 and 4; and that payors and providers pay all assessments as required by section 8706, subsection 2.
Sec. 4. 22 MRSA §8705-A, sub-§3 is amended to read:
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 or pharmacy benefit 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.
A. When a person or entity that is a health care facility or payor, manufacturer or pharmacy benefit manager violates the requirements of this chapter, except for section 8714, 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.
B. A person or entity that receives data or information under the terms and conditions of section 8714 and intentionally or knowingly uses, sells or transfers the data in violation of the board's rules for commercial advantage, pecuniary gain, personal gain or malicious harm commits a civil violation for which a fine not to exceed $500,000 may be adjudged.
C. A person or entity not covered by paragraph A or B that violates the requirements of this chapter, except for section 8714, commits a civil violation for which a fine of not more than $100 per day may be adjudged. A fine imposed under this paragraph may not exceed $2,500 for any one occurrence.
Sec. 5. 22 MRSA §8706, sub-§2 is amended to read:
2. Permanent funding. Permanent funding for the organization is provided from reasonable costs, user fees and assessments according to this subsection and as provided by rules adopted by the board.
A. Fees may be charged for the reasonable costs of duplicating, mailing, publishing and supplies.
B. Reasonable user fees must be charged on a sliding scale for the right to access and use the health data and information available from the organization. Fees may be charged for services provided to the department on a contractual basis. Fees may be reduced or waived for users that demonstrate a plan to use the data or information in research of general value to the public health or inability to pay the scheduled fees, as provided by rules adopted by the board.
C. The operations of the organization must be supported from 3 sources as provided in this paragraph:
   (1) Fees collected pursuant to paragraphs A and B;
   (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. Annual assessments of $500 against entities registered under Title 22, section 2699-E. The assessments are to be determined on an annual basis by the board. 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

(3) Annual assessments of not less than $100 assessed by the organization against providers. The assessments are to be determined on an annual basis by the board. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (2). The aggregate level of annual assessments under subparagraphs (2) and (3) must be an amount sufficient to meet the organization's expenditures authorized in the state budget established under Title 5, chapter 149. The annual assessment may not exceed $1,346,904 in fiscal year 2002-03. In subsequent fiscal years, the annual assessment may increase above $1,346,904 by an amount not to exceed 5% per fiscal year. The board may waive assessments otherwise due under subparagraphs (2) and (3) when a waiver is determined to be in the interests of the organization and the parties to be assessed.

Sec. 6. 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. BIOSIMILAR. “BIOSIMILAR” MEANS: A DRUG THAT IS PRODUCED OR DISTRIBUTED PURSUANT TO A BIOLOGICS LICENSE APPLICATION, APPROVED UNDER 42 U.S.C. § 262(k)(3)

2. BRAND NAME DRUG. “BRAND NAME DRUG” MEANS: A DRUG THAT IS PRODUCED OR DISTRIBUTED PURSUANT TO —

(a) AN ORIGINAL NEW DRUG APPLICATION, APPROVED UNDER 21 U.S.C. §355(e) EXCEPT FOR AN AUTHORIZED GENERIC AS DEFINED BY 42 C.F.R. § 447.502; OR

(b) A BIOLOGICS LICENSE APPLICATION, APPROVED UNDER 42 U.S.C. § 262(a)(C).

3. COURSE OF THERAPY. “COURSE OF THERAPY” MEANS: THE AMOUNT OF A DRUG THAT IS
(a) A DRUG SUPPLY LASTING A PATIENT FOR A PERIOD CONSISTING OF 30 CONSECUTIVE DAYS BASED ON THE RECOMMENDED DOSAGE IN THE FDA-APPROVED LABELING; OR
(b) A DRUG SUPPLY LASTING FEWER THAN 30 DAYS IF SUCH DOSAGE IS RECOMMENDED IN THE FDA-APPROVED LABELING FOR SUCH DRUG; OR
(c) ONE UNIT OF THE DRUG IF THERE IS NO FINITE DOSAGE IN THE FDA-APPROVED LABELING.

4. GENERIC DRUG. “GENERIC DRUG” MEANS: A RETAIL DRUG THAT IS MARKETED OR DISTRIBUTED PURSUANT TO:
   (a) AN ABBREVIATED NEW DRUG APPLICATION, APPROVED UNDER 21 U.S.C. §355(i); OR
   (b) AN AUTHORIZED GENERIC AS DEFINED BY 42 C.F.R. § 447.502; OR
   (c) A DRUG THAT ENTERED THE MARKET BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW DRUG APPLICATION.

5 1. Manufacturer. “Manufacturer” means a manufacturer of prescription drugs that are distributed in the State.


7. 3. Pricing component data. “Pricing component data” means data unique to each manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier subject to this subchapter that evidences the cost to each manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier to make a prescription drug available to consumers, taking into account any price concessions, and that is measured uniformly among and between the entities, as determined by rules adopted by the organization pursuant to section 2699-G.

4. Pricing unit. “Pricing unit” means a unit of measurement that allows for consistent measurement of a specific quantity of a prescription drug from production to consumption, as determined by rules adopted by the organization pursuant to section 2699-G.

8-5. Wholesale acquisition cost. “Wholesale acquisition cost” means a prescription drug manufacturer’s listed price for sale to a prescription drug wholesaler or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

§2699-B. Drug price notifications and disclosures.
   1. Notifications by prescription drug manufacturers.
a. A BRAND NAME DRUG manufacturer shall notify the organization at least 60 days prior to the date when the manufacturer is:
   i. Increasing the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit during any 12-month period:

b. A GENERIC DRUG manufacturer shall notify the organization at least 60 days prior to the date ON THE EFFECTIVE DATE when the manufacturer is:
   i. Increasing the wholesale acquisition cost of a generic drug WITH A WAC OF $100 OR MORE, by more than:
      (a) 200% 100% during any 12-month period; or
      (2) $50 during any 12-month period;

c. A manufacturer Introducing a new drug that will be distributed in this State when the wholesale acquisition cost is $670 or greater per pricing unit.
   i. THIS SECTION SHALL NOT APPLY TO GENERIC DRUGS AND BIOSIMILARS THAT COME TO MARKET WITH A LAUNCH PRICE THAT IS AT LEAST 15% LOWER THAN THE REFERENCED BRAND DRUG OR BIOLOGIC DRUG AT THE TIME THE GENERIC OR BIOSIMILAR IS LAUNCHED.

2. Disclosures by prescription drug manufacturers. A manufacturer shall notify the organization, within 60 days of a request from the organization, of pricing component data per pricing unit of a drug.

3. Disclosures by wholesale drug distributors. A wholesale drug distributor operating in this State shall notify the organization, within 60 days of a request from the organization, of pricing component data per pricing unit for a drug.

4. Disclosures by pharmacy benefit managers. A pharmacy benefit manager operating in this State shall notify the organization, within 60 days of a request from the organization, of pricing component data per pricing unit for a drug.

§2699-C. Insurance carrier annual reporting.
An insurance carrier operating in the State shall report to the organization on March 1 annually the 25 prescription drugs, BY DRUG CATEGORY, for which the carrier in the previous calendar year:

1. Greatest total spending by drug. Had the greatest total expenditures for plan enrollees, before any cost-sharing amount paid by the enrollee;

2. Greatest total spending by drug per user. Had the greatest total expenditures for plan enrollees, per user of the prescription drug, before any cost-sharing amount paid by the user-enrollee;

3. Most frequently prescribed. Received the most claims as a result of enrollees filling prescriptions for the drug;

4. Greatest increase in spending. Made the greatest total expenditures for plan enrollees over the total expenditures for plan enrollees for the same drug in the previous year, before any cost-sharing amount paid by the user-enrollee; and
5. Greatest increase in spending per user. Made the greatest total expenditures for plan enrollees, per user of the prescription drug, before any cost-sharing amount paid by the user enrollee.

6. THE PERCENTAGE OF THE PREMIUM ATTRIBUTABLE TO PRESCRIPTION DRUG COSTS, BROKEN DOWN BY DRUG CATEGORY.

7. THE YEAR-OVER-YEAR INCREASE IN PER-MEMBER, PER MONTH COSTS FOR DRUG PRICES COMPARED TO THE OTHER COMPONENTS OF THE HEALTH CARE PREMIUM.

8. ALL CHANGES IN GENERIC FORMULARY PLACEMENT BETWEEN THE PRIOR PLAN YEAR TO THE CURRENT PLAN YEAR.

§2699-D. Confidentiality.
The information provided to the organization under subsection 1 is confidential and not a public record under Title 1, chapter 13, except that the organization may share information 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-B. Any information shared must be kept confidential.

§2699-E. Registration requirements.
Beginning January 1, 2020, manufacturers and wholesale drug distributors subject to this subchapter shall register annually with the organization in a manner prescribed by the organization.

§2699-F. Compliance
1. Certification of accuracy. A manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier that submits a notification or report to the organization pursuant to this subchapter shall accompany the notification or report with a signed written certification of the notification or report’s accuracy.

2. Civil penalty. A manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier that violates this subchapter commits a civil violation for which a fine of $30,000$10,000 shall be adjudged for each day of the violation.

3. Audit. The organization may audit the data submitted by a manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier pursuant to this subchapter. The manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier shall pay for the costs of the audit.

4. Corrective action plan. The organization may require a manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier subject to this subchapter to develop a corrective action plan to correct any deficiencies the organization finds with the manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier’s compliance with this subchapter.

§2699-G. Public report.
Beginning November 1 2020 and by November 1 of each year, the organization shall produce and post on its publicly-accessible website an annual report, including information developed from the notifications and disclosures received pursuant to this subchapter on: 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 on insurance premiums and cost-sharing; and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not disclose information attributable to any particular manufacturer, wholesale drug distributor, pharmacy benefit manager or insurance carrier subject to this subchapter and may not make public any information that is confidential pursuant to section 2699-D.

§2699-G. Rulemaking.
The organization may adopt rules to implement this subchapter. Rules adopted are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 7. Initial rulemaking. Notwithstanding Title 22, section 2699-G of the Maine Revised Statutes, the Maine Health Data Authority may adopt emergency rules that are otherwise in accordance with section 2699-G to implement the provisions of Title 22, subchapter 5 and may adopt routine technical rules to implement that subchapter until April 1, 2020.

SUMMARY
This bill establishes notification and disclosure requirements for prescription drug manufacturers, wholesalers, pharmacy benefit managers and insurance carriers. The bill requires the Maine Health Data Organization to adopt rules that allow for measurement of prescription drug price components as prescription drugs are transferred from the manufacturer to the consumer.

The bill requires manufacturers, wholesalers and pharmacy benefit managers to disclose, within 60 days of a request by the Maine Health Data Organization, information that evidences the costs to that entity to make a prescription drug available to consumers and the payments received by that entity to make a prescription drug available to consumers. The bill requires manufacturers to notify the Maine Health Data Organization of prescription drug price increases above a certain level and when drugs are being introduced to market above a certain price.

The bill requires insurance carriers to report annually to the Maine Health Data Organization of those drugs for which the carriers experienced: the greatest total spending by drug; the greatest total spending by drug per user; the greatest total expenditures for plan enrollees, per user of the prescription drug, before any cost-sharing amount paid by the userenrollee; the most frequently prescribed. Received the most claims as a result of enrollees filling prescriptions for the drug; the greatest increase in spending; and the greatest increase in spending per user.

The bill directs the Maine Health Data Organization to produce an annual report on trends in the cost of prescription drugs, the major components of the price of prescription drugs and the effect of prescription drug prices on insurance rates and cost-sharing amounts. Information provided to the Maine Health Data
Organization is confidential and may not be disclosed in a manner that is attributable to any particular reporting entity.