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§4350-D. Treatment of pharmacy benefits manager compensation

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Anticipated loss ratio" means the ratio of the present value of the future benefits payments to the present value of the future premiums of a policy form over the entire period for which rates are computed to provide health insurance coverage.

B. "Pharmacy benefits manager compensation" means the difference between:

(1) The value of payments made by a carrier of a health plan to its pharmacy benefits manager; and

(2) The value of payments made by the pharmacy benefits manager to dispensing pharmacists for the provision of prescription drugs or pharmacy services with regard to pharmacy benefits covered by the health plan.

2. Pharmacy benefits manager compensation included as administrative cost. If a carrier uses a pharmacy benefits manager to administer or manage prescription drug benefits provided for the benefit of covered persons, for purposes of calculating a carrier's anticipated loss ratio, any pharmacy benefits manager compensation:

A. Constitutes an administrative cost incurred by the carrier in connection with a health plan; and

B. May not constitute a benefit provided under a health plan.

A carrier may claim only the amounts paid by the pharmacy benefits manager to a pharmacy or pharmacist as an incurred claim.

3. Calculation of pharmacy benefits manager compensation. Each rate filing submitted by a carrier with respect to a health plan that provides coverage for prescription drugs or pharmacy services that is administered or managed by a pharmacy benefits manager must include:

A. A memorandum prepared by a qualified actuary describing the calculation of the pharmacy benefits manager compensation; and

B. Such records and supporting information as the superintendent reasonably determines is necessary to confirm the calculation of the pharmacy benefits manager compensation.

4. Records. Upon request, a carrier shall provide any records to the superintendent that relate to the calculation of the pharmacy benefits manager compensation.

5. Documentation from pharmacy benefits manager. A pharmacy benefits manager shall provide any necessary documentation requested by a carrier that relates to pharmacy benefits manager compensation in order to comply with the requirements of this section.

§4350-E. Effective date

This chapter takes effect January 1, 2020.

Sec. 9. Effective date. This Act takes effect January 1, 2020.

Effective January 1, 2020.

CHAPTER 470

S.P. 350 - L.D. 1162

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 §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~~ sections 8712 and 8736. 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, 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. 3. 22 MRSA §8705-A, first ¶, as enacted by PL 2003, c. 659, §2 is further amended to read:

The board shall adopt rules to ensure that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits 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, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2.

Sec. 4. 22 MRSA §8705-A, first ¶, as amended by PL 2013, c. 528, §6 and affected by §12, is further amended to read:

The board shall adopt rules to ensure that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits 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, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2.

Sec. 5. 22 MRSA §8705-A, sub-§3, ¶A, as amended by PL 2007, c. 136, §4, is further amended to read:

A. When a person or entity that is a health care facility ~~or~~, payor, prescription drug manufacturer, wholesale drug distributor or 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.

Sec. 6. 22 MRSA §8705-A, sub-§3, ¶A, as amended by PL 2013, c. 528, §7 and affected by §12, is further amended to read:

A. When a person or entity that is a health care facility ~~or~~, payor, prescription drug manufacturer, wholesale drug distributor or pharmacy benefits 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.

Sec. 7. 22 MRSA §8706, sub-§2, as amended by PL 2007, c. 136, §5, is further 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~~ 4 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. 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 subpara-

graph must equal the assessments under subparagraph (2).; and

(4) Annual assessments of $500 assessed by the organization against prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers.

The aggregate level of annual assessments under subparagraphs (2) and, (3) and (4) 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) and (4) when a waiver is determined to be in the interests of the organization and the parties to be assessed.

Sec. 8. 22 MRSA c. 1683, sub-c. 3 is enacted to read:

SUBCHAPTER 3

PRESCRIPTION DRUG PRICING FOR PURCHASERS

§8731. Definitions

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

1. Brand-name drug. "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

2. Generic drug. "Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. "Generic drug" includes a biosimilar product.

3. Manufacturer. "Manufacturer" means a manufacturer of prescription drugs that are distributed in the State.

4. Pricing component data. "Pricing component data" means data unique to each manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter that evidences the cost to each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers, taking into account any price concessions, and that is measured uniformly among the entities, as determined by rules adopted by the organization pursuant to section 8737.

5. Pricing unit. "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed.

6. Wholesale acquisition cost. "Wholesale acquisition cost" means a manufacturer's listed price for sale to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

§8732. Drug price notifications and disclosures

1. Notifications by manufacturers. No later than January 30, 2020 and annually thereafter, a manufacturer shall notify the organization when the manufacturer has during the prior calendar year:

A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;

B. Increased the wholesale acquisition cost of a generic drug that costs at least $10 per pricing unit by more than 20% per pricing unit; or

C. Introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. For the purposes of this subsection, "Medicare Part D" has the same meaning as in section 254-D, subsection 1, paragraph F.

2. Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers. Within 60 days of a request from the organization relating to a specific prescription drug, a manufacturer, wholesale drug distributor or pharmacy benefits manager shall notify the organization of pricing component data per pricing unit of a drug.

§8733. Confidentiality

Information provided to the organization as required by this subchapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the organization may share information:

1. Bureau of Insurance. 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-A, as long as any information shared is kept confidential; and

2. Aggregate. In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or manufacturer, wholesale drug distributor or pharmacy benefits manager.

§8734. Registration requirements

Beginning January 1, 2020, a manufacturer and wholesale drug distributor subject to this subchapter shall register annually with the organization in a manner prescribed by the organization.

§8735. Compliance

1. Certification of accuracy. A manufacturer, wholesale drug distributor or pharmacy benefits manager that submits a notification or report to the organization pursuant to this subchapter shall submit with the notification or report a signed written certification of the notification's or report's accuracy.

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

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

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

§8736. Public report

Beginning November 1, 2020 and annually thereafter, 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 or pharmacy benefits manager subject to this subchapter and may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

§8737. Rulemaking

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

Sec. 9. Maine Revised Statutes headnote amended; revision clause. In the Maine Revised Statutes, Title 22, chapter 1683, before section 8701, the headnote "subchapter 1, general provisions" is enacted and the Revisor of Statutes shall implement this revision when updating, publishing or republishing the statutes.

Sec. 10. Initial rulemaking. Notwithstanding the Maine Revised Statutes, Title 22, section 8737, the Maine Health Data Organization may adopt emergency rules that are otherwise in accordance with section 8737 to implement the provisions of Title 22, chapter 1683, subchapter 3 and may adopt routine technical rules to implement that subchapter before April 1, 2020.

See title page for effective date.

CHAPTER 471

S.P. 461 - L.D. 1499

An Act To Establish the Maine Prescription Drug Affordability Board

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

Sec. 1. 5 MRSA c. 167 is enacted to read:

CHAPTER 167

MAINE PRESCRIPTION DRUG AFFORDABILITY BOARD

§2041. Maine Prescription Drug Affordability Board established

1. Board established. The Maine Prescription Drug Affordability Board, as established in section 12004-G, subsection 14-I and referred to in this chapter as "the board," shall carry out the purposes of this chapter.

2. Membership. The board has 5 members with expertise in health care economics or clinical medicine, who may not be affiliated with or represent the interests of a public payor, as that term is defined in section 2042, and who are appointed as follows:

A. Two members by the President of the Senate. The President of the Senate shall also appoint one alternate board member who will participate in deliberations of the board in the event a member appointed by the President of the Senate elects to