SECOND REGULAR SESSION

HOUSE BILL NO. 2412

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HELMS.

5343H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal sections 338.015, 376.387, and 376.388, RSMo, and to enact in lieu thereof six new sections relating to payments for prescription drugs.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 338.015, 376.387, and 376.388, RSMo, are repealed and six new sections enacted in lieu thereof, to be known as sections 103.200, 338.015, 376.387, 376.388, 376.393, and 376.2066, to read as follows:

103.200. 1. As used in this chapter, the term "rebate" shall mean any discount, negotiated concession, or other payment provided by a pharmaceutical manufacturer, pharmacy, or health benefit plan to an entity to sell, provide, pay, or reimburse a pharmacy or other entity in the state for the dispensing or administration of prescription drugs on behalf of itself or another entity. As used in this section, the term "pharmacy" shall have the same meaning as ascribed to it in section 338.210, and the term "health benefit plan" shall have the same meaning as ascribed to it in section 376.1350.

2. No later than March 1, 2022, and annually thereafter, the pharmacy benefits manager utilized by the Missouri consolidated health care plan shall file a report with the department for the immediately preceding calendar year. The report shall contain the following information regarding the plan:

(1) The aggregate dollar amount of all rebates concerning drug formularies used by the plan which such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

(a) Were covered by the plan during such calendar year; and

(b) Are attributable to patient utilization of such drugs during such calendar year;

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(2) The aggregate dollar amount of all rebates, excluding any portion of the rebates received by the plan, concerning drug formularies that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

(a) Were covered by the plan during such calendar year; and

(b) Are attributable to patient utilization of such drugs by covered persons under the plan during such calendar year; and

(3) The aggregate dollar amount of all administrative fees the pharmacy benefits manager received from pharmaceutical manufacturers.

3. In consultation with its pharmacy benefits manager, the plan shall establish a form for reporting the information required under subsection 2 of this section. The form shall be designed to minimize the administrative burden and cost of reporting on the plan and its pharmacy benefits manager.

4. All documents, materials, or other information submitted to the plan pursuant to subsection 2 of this section shall not be subject to disclosure under chapter 610, except to the extent they are included on an aggregated basis in the report required under subsection 5 of this section. The plan shall not disclose information submitted pursuant to subsection 1 of this section in a manner that:

(1) Is likely to compromise the financial, competitive, or proprietary nature of such information; or

(2) Would enable a third party to identify the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

5. (1) No later than July 1, 2022, and annually thereafter, the plan shall submit a report to the standing committees of the general assembly having jurisdiction over health insurance matters. The report shall contain an aggregation of the information submitted to the plan pursuant to subdivision (1) of subsection 2 of this section for the immediately preceding calendar year, and such other information as the plan in its discretion deems relevant for the purposes of this section. The plan shall provide its pharmacy benefits manager and any third party affected by submission of a report required by this subsection with a written notice describing the content of the report.

(2) No later than July 1, 2022, and annually thereafter, the plan shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of the plan and its pharmacy benefit manager. The report shall be provided to the standing committees of the general assembly having jurisdiction over health insurance matters and shall contain:

(a) An explanation of the manner in which the plan accounted for rebates in calculating premiums for such year;

(b) A statement disclosing whether, and describing the manner in which, the plan made rebates available to enrollees at the point of purchase during such year;

(c) Any other manner in which the plan applied rebates during such year; and

(d) Such other information as the plan, in its discretion, deems relevant for the purposes of this section.

6. The plan may impose a penalty of not more than seven thousand five hundred dollars on its pharmacy benefits manager for each violation of this section.

338.015. 1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain prescription services from any licensed pharmacist **or pharmacy**. **[**~~However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.~~**]**

2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.

3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice or to have an electronic prescription transmitted to the facility of their choice.

4. No pharmacy benefits manager as defined in section 376.388 shall prohibit or redirect by contract, or otherwise penalize or restrict, a health carrier or the carrier's enrollees from obtaining prescription services, consultation, or advice from a contracted pharmacy, as defined in section 376.388, in the state.

376.387. 1. For purposes of this section, the following terms shall mean:

(1) "Covered person", the same meaning as such term is defined in section 376.1257;

(2) "Health benefit plan", the same meaning as such term is defined in section 376.1350;

(3) **"Health carrier" or "carrier", the same meaning as such term is defined in section 376.1350;**

(4) "Pharmacy", the same meaning as such term is defined in chapter 338;

(5) "Pharmacy benefits manager", the same meaning as such term is defined in section 376.388.

2. No pharmacy benefits manager shall include a provision in a contract entered into or modified on or after August 28, 2018, with a pharmacy or pharmacist that requires a covered person to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

(1) The copayment amount as required under the health benefit plan; or

(2) The amount an individual would pay for a prescription if that individual paid with cash.

3. A pharmacy or pharmacist shall have the right to provide to a covered person information regarding the amount of the covered person's cost share for a prescription drug, the covered person's cost of an alternative drug, and the covered person's cost of the drug without adjudicating the claim through the pharmacy benefits manager. Neither a pharmacy nor a pharmacist shall be proscribed by a pharmacy benefits manager from discussing any such information or from selling a more affordable alternative to the covered person.

4. No pharmacy benefits manager shall, directly or indirectly, charge or hold a pharmacist or pharmacy responsible for any fee amount related to a claim that is not known at the time of the claim's adjudication, unless the amount is a result of improperly paid claims or charges for administering a health benefit plan.

5. **[**~~This section shall not apply with respect to claims under Medicare Part D, or any other plan administered or regulated solely under federal law, and to the extent this section may be preempted under the Employee Retirement Income Security Act of 1974 for self-funded employer-sponsored health benefit plans.~~

~~6.~~**] A pharmacy benefits manager shall notify in writing any health carrier or pharmacy with which it contracts if the pharmacy benefits manager has a potential conflict of interest including, but not limited to, any commonality of ownership or any other relationship, financial or otherwise, between the pharmacy benefits manager and any other health carrier or pharmacy with which the pharmacy benefits manager contracts.**

6. Any entity that enters into a contract to sell, provide, pay, or reimburse a pharmacy in the state for prescription drugs on behalf of itself or another entity shall define and apply the term "generic", with respect to prescription drugs, to mean any "authorized generic drug", as defined in 21 CFR 314.3, approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, as amended.

7. Any entity that enters into a contract to sell, provide, pay, or reimburse a pharmacy in the state for prescription drugs on behalf of itself or another entity shall define and apply the term "rebate" to mean a discount, payment, or other concession provided by a pharmaceutical manufacturer directly to that contracting entity.

8. A pharmacy benefits manager that has contracted with a health carrier, health benefit plan, the state, or a political subdivision of the state to provide pharmacy benefit management services for such an entity shall owe a fiduciary duty to that entity, and shall discharge that duty in accordance with federal and state law.

9. The department of commerce and insurance shall enforce this section.

376.388. 1. As used in this section, unless the context requires otherwise, the following terms shall mean:

(1) "Contracted pharmacy" **[**~~or "pharmacy"~~**]**, a pharmacy located in Missouri participating in the network of a pharmacy benefits manager through a direct or indirect contract;

(2) "Health carrier", an entity subject to the insurance laws and regulations of this state that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health services, except that such plan shall not include any coverage pursuant to a liability insurance policy, workers' compensation insurance policy, or medical payments insurance issued as a supplement to a liability policy;

(3) "Maximum allowable cost", the per-unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding a dispensing or professional fee;

(4) "Maximum allowable cost list" or "MAC list", a listing of drug products that meet the standard described in this section;

(5) "Pharmacy", as such term is defined in chapter 338;

(6) "Pharmacy benefits manager", an entity that contracts with pharmacies on behalf of health carriers or any health plan sponsored by the state or a political subdivision of the state.

2. Upon each contract execution or renewal between a pharmacy benefits manager and a pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, a pharmacy benefits manager shall, with respect to such contract or renewal:

(1) Include in such contract or renewal the sources utilized to determine maximum allowable cost and update such pricing information at least every seven days; and

(2) Maintain a procedure to eliminate products from the maximum allowable cost list of drugs subject to such pricing or modify maximum allowable cost pricing at least every seven days, if such drugs do not meet the standards and requirements of this section, in order to remain consistent with pricing changes in the marketplace.

3. A pharmacy benefits manager shall reimburse pharmacies for drugs subject to maximum allowable cost pricing that has been updated to reflect market pricing at least every seven days as set forth under subdivision (1) of subsection 2 of this section.

4. A pharmacy benefits manager shall not place a drug on a maximum allowable cost list unless there are at least two therapeutically equivalent multisource generic drugs, or at least one generic drug available from at least one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

5. **(1)** All contracts between a pharmacy benefits manager and a contracted pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, shall include a process to internally appeal, investigate, and resolve disputes regarding maximum allowable cost pricing. The process shall include the following:

[~~(1)~~**]** **(a)** The right to appeal shall be limited to fourteen calendar days following the reimbursement of the initial claim; and

[~~(2)~~**]** **(b)** A requirement that the pharmacy benefits manager shall respond to an appeal described in this subsection no later than fourteen calendar days after the date the appeal was received by such pharmacy benefits manager.

(2) If a reimbursement to a contracted pharmacy is below the pharmacy's cost to purchase the drug, the pharmacy benefits manager shall sustain an appeal and increase reimbursement to the pharmacy and other contracted pharmacies to cover the cost of purchasing the drug.

6. For appeals that are denied, the pharmacy benefits manager shall provide the reason for the denial and identify the national drug code of a drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost and, when applicable, may be substituted lawfully.

7. If the appeal is successful, the pharmacy benefits manager shall:

(1) Adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;

(2) Apply the adjusted maximum allowable cost price to all similarly situated pharmacies as determined by the pharmacy benefits manager; and

(3) Allow the pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefits claim giving rise to the appeal.

8. Appeals shall be upheld if:

(1) The pharmacy being reimbursed for the drug subject to the maximum allowable cost pricing in question was not reimbursed as required under subsection 3 of this section; or

(2) The drug subject to the maximum allowable cost pricing in question does not meet the requirements set forth under subsection 4 of this section.

376.393. 1. As used in this section, the following terms shall mean:

(1) "Health carrier" or "carrier", the same meaning as is ascribed to such term in section 376.1350;

(2) "Pharmacy benefits manager", the same meaning as is ascribed to such term in section 376.388.

2. No entity subject to the jurisdiction of this state shall act as a pharmacy benefits manager without a license issued by the department. The department shall establish by rule the application process and license fee for pharmacy benefits managers.

3. The department may cause a complaint to be filed with the administrative hearing commission as provided in chapter 621 against any holder of a license issued under this section for:

(1) Violation of the laws or regulations of any state or of the United States, where the offense is reasonably related to the qualifications, functions, or duties of a pharmacy benefit manager, including but not limited to where an essential element of the offense is fraud, dishonesty, or an act of violence, or where the offense involves moral turpitude, or where the offense involves failure to comply with a requirement of this chapter, whether or not sentence or penalty is imposed;

(2) Use of fraud, deception, misrepresentation, or bribery for any reason;

(3) Obtaining or attempting to obtain any fee, charge, tuition, or other compensation by fraud, deception, or misrepresentation;

(4) Incompetence, misconduct, gross negligence, or dishonesty in the performance of the functions or duties of a pharmacy benefits manager or other regulated profession or activity; or

(5) Disciplinary action taken against the holder of a license or other right to practice as a pharmacy benefits manager or other regulated profession.

After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that grounds provided in this subsection for disciplinary action are met, the department may, singly or in combination, censure or place the person named in the complaint on probation with such terms and conditions as the department deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. An individual whose license has been revoked shall wait at least one year from the date of revocation to apply for relicensure. Relicensure shall be at the discretion of the department.

376.2066. No later than March 1, 2022, and annually thereafter, each health carrier shall submit to the department, in a form and manner prescribed by the department, a written certification for the immediately preceding calendar year, certifying that the health carrier accounted for all rebates, as such term is defined in section 376.2062, in calculating the premium for health benefit plans that such health carrier delivered, issued for delivery, renewed, amended, or continued during such calendar year.

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