FIRST REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 197

102ND GENERAL ASSEMBLY

0404H.03C DANA RADEMAN MILLER, Chief Clerk

AN ACT

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

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Section A. Sections 338.015, 376.387, and 376.388, RSMo, are repealed and seven new sections enacted in lieu thereof, to be known as sections 103.200, 338.015, 376.387, 376.388, 376.414, 376.687, and 376.689, to read as follows:

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

(1) "Pharmacy", the same meaning given to the term in section 338.210;

(2) "Plan", the Missouri consolidated health care plan as described in section 103.005;

(3) "Rebate", 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 dispensation or administration of a prescription drug on behalf of itself or another entity.

2. Before March 1, 2025, and annually thereafter, the pharmacy benefits manager utilized by the Missouri consolidated health care plan shall file a report with the plan for the immediately preceding calendar year. The report shall contain the following information regarding the plan:

(1) The aggregate dollar amount of all rebates that the pharmacy benefits manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

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

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.

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

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

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

(b) Were attributable to patient utilization of such drugs by covered persons under the plan during such calendar year.

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. No documents, materials, or other information submitted to the plan under subsection 2 of this section shall be subject to disclosure under chapter 610, except to the extent they are included on an aggregated basis in the reports required under subsection 5 of this section. The plan shall not disclose information submitted under subsection 2 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) Before July 1, 2025, 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 under 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) Before July 1, 2025, 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 benefits manager. The plan shall provide the report to the standing committees of the general assembly having jurisdiction over health insurance matters and the director of the department of commerce and insurance. The report 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) A statement describing 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 no 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 covered person, as defined in section 376.387, from obtaining prescription services, consultation, or advice from a contracted pharmacy, as defined in section 376.388.

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~~**]** **a policyholder, subscriber, enrollee, or other individual who receives prescription drug coverage through a pharmacy benefits manager**;

(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 with which it contracts if the pharmacy benefits manager has a conflict of interest, any commonality of ownership, or any other relationship, financial or otherwise, between the pharmacy benefits manager and any other health carrier with which the pharmacy benefits manager contracts.

[~~7.~~**] 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" as having the same meaning given to the term in section 103.200.

8. A pharmacy benefits manager that has contracted with an entity 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)~~**] (3)** "Maximum allowable cost list" or "MAC list", a listing of drug products that meet the standard described in this section;

[~~(5)~~**] (4)** "Pharmacy", as such term is defined in chapter 338;

[~~(6)~~**] (5)** "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~~**] administers or manages a pharmacy benefits plan or program;**

(6) "Pharmacy benefits manager affiliate", a pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager;

(7) "Pharmacy benefits plan or program", a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for prescription drugs and pharmacist services to individuals who reside in or are employed in this 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.

(3) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

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.

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

(1) "340B drug", a drug that is:

(a) A covered outpatient drug as defined in Section 340B of the Public Health Service Act, 42 U.S.C. Section 256b, enacted by Section 602 of the Veterans Health Care Act of 1992, Pub. L. 102-585; and

(b) Purchased under an agreement entered into under 42 U.S.C. Section 256b;

(2) "Covered entity", the same meaning given to the term in Section 340B(a)(4) of the Public Health Service Act, 42 U.S.C. Section 256b(a)(4);

(3) "Health carrier", the same meaning given to the term in section 376.1350;

(4) "Pharmacy", an entity licensed under chapter 338;

(5) "Pharmacy benefits manager", the same meaning given to the term in section 376.388.

2. A health carrier, pharmacy benefits manager, or an agent or affiliate of such health carrier or pharmacy benefits manager shall not discriminate against a covered entity or a pharmacy including, but not limited to, any of the following:

(1) Reimbursing a covered entity or pharmacy for a quantity of a 340B drug in an amount less than it would pay to any other similarly situated pharmacy that is not a covered entity or a pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or pharmacy or that the entity or pharmacy dispenses 340B drugs;

(2) Imposing any terms or conditions on covered entities or pharmacies that differ from such terms or conditions applied to other similarly situated pharmacies that are not covered entities or pharmacies on the basis that the entity or pharmacy is a covered entity or pharmacy or that the entity or pharmacy dispenses 340B drugs including, but not limited to, terms or conditions with respect to any of the following:

(a) Fees, chargebacks, clawbacks, adjustments, or other assessments;

(b) Professional dispensing fees;

(c) Restrictions or requirements regarding participation in standard or preferred pharmacy networks;

(d) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles; and

(e) Any other restrictions, conditions, practices, or policies that, as specified by the director of the department of commerce and insurance, interfere with the ability of a covered entity to maximize the value of discounts provided under 42 U.S.C. Section 256b;

(3) Interfering with an individual's choice to receive a 340B drug from a covered entity or pharmacy, whether in person or via direct delivery, mail, or other form of shipment by any means including, but not limited to, modifying a patient's payment limitations or cost-sharing obligations on the basis of participation, in whole or in part, in the 340B drug pricing program;

(4) Requiring a covered entity or pharmacy to identify, either directly or through a third party, 340B drugs;

(5) Refusing to contract with a covered entity or pharmacy for reasons other than those that apply equally to entities or pharmacies that are not covered entities or pharmacies, or on the basis that:

(a) The entity or pharmacy is a covered entity or a pharmacy; or

(b) The entity or pharmacy is described in any of subparagraphs (A) to (O) of 42 U.S.C. Section 256b(a)(4);

(6) Denying the covered entity the ability to purchase drugs at 340B program pricing by substituting a rebate discount;

(7) Refusing to cover drugs purchased under the 340B drug pricing program; or

(8) Requiring a covered entity or contract pharmacy to reverse, resubmit, or clarify a 340B-drug pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

3. The director of the department of commerce and insurance shall impose a civil penalty on any health carrier, pharmacy benefits manager, or an agent or affiliate of such health carrier or pharmacy benefits manager that violates the requirements of this section. Such penalty shall not exceed five thousand dollars per violation per day.

4. The director of the department of commerce and insurance shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul

a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2023, shall be invalid and void.

376.687. 1. As used in this section, "prescription insulin drug" means a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes, but does not include an insulin drug that is administered to a patient intravenously.

2. This section applies to any group or individual policy of accident and health insurance amended, delivered, issued, or renewed on or after August 28, 2023.

3. An insurer that provides coverage for prescription insulin drugs under the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for a thirty-day supply of covered prescription insulin drugs at an amount not to exceed seventy-five dollars, regardless of the quantity or type of covered prescription insulin drug used to fill the insured's prescription.

4. On January first of each year, the limit on the amount that an insured is required to pay for a thirty-day supply of a covered prescription insulin drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the Consumer Price Index of the Bureau of Labor Statistics of the United States Department of Labor.

5. The director of the department of commerce and insurance may promulgate all necessary rules and regulations for the administration of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2023, shall be invalid and void.

376.689. 1. Before November 2, 2023, the department of commerce and insurance, in conjunction with the department of health and senior services and the department of social services, shall make available to the public a report that details each department's findings for the following:

(1) A summary of insulin pricing practices and variables that contribute to the pricing of health coverage plans;

(2) Public policy recommendations to control and prevent overpricing of prescription insulin drugs made available to Missouri consumers; and

(3) Any other information that the department of commerce and insurance finds necessary.

2. The provisions of this section terminate on January 1, 2024.

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