SECOND REGULAR SESSION

HOUSE BILL NO. 1910

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE CLEMENS.

4352H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

To amend chapter 376, RSMo, by adding thereto nine new sections relating to prescription drug costs.

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

Section A. Chapter 376, RSMo, is amended by adding thereto nine new sections, to be known as sections 376.2060, 376.2061, 376.2062, 376.2064, 376.2066, 376.2068, 376.2070, 376.2072, and 376.2073, to read as follows:

376.2060. As used in sections 376.2060 to 376.2070, unless otherwise clearly indicated by context, the following terms mean:

(1) "Closed meeting", as defined under section 610.010;

(2) "Commission", the drug cost review commission established under section 376.2061;

(3) "Department", the department of commerce and insurance;

(4) "Director", the director of the department;

(5) "Drug", as defined under section 376.1350;

(6) "Enrollee", as defined under section 376.1350;

(7) "Health benefit plan", as defined under section 376.1350; however, for purposes of sections 376.2060 to 376.2070, the term "health benefit plan" shall be limited to plans providing coverage for outpatient prescription drugs;

(8) "Health carrier", as defined under section 376.1350;

(9) "Person", an individual, corporation, partnership, limited liability company, association, joint stock company, business trust, unincorporated organization, or other legal entity;

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.

(10) "Pharmacist", an individual licensed to practice pharmacy under chapter 338;

(11) "Pharmacy", as defined under section 338.210;

(12) "Pharmacy benefits manager", as defined under section 376.388;

(13) "Practice of pharmacy", as defined under section 338.010;

(14) "Public meeting", as defined under section 610.010;

(15) "Public vote", as defined under section 610.010;

(16) "Rebate", a discount or concession that affects the price of an outpatient prescription drug and that a pharmaceutical manufacturer directly provides to a:

(a) Health carrier for an outpatient prescription drug manufactured by the pharmaceutical manufacturer; or

(b) Pharmacy benefits manager after the manager processes a claim from a pharmacy or pharmacist for an outpatient prescription drug manufactured by the pharmaceutical manufacturer.

Such term shall not include a "bona fide service fee", as defined in 42 CFR 447.502, as amended;

(17) "Specialty drug", a prescription outpatient specialty drug covered under the Medicare Part D program established under Pub. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended, that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

376.2061. 1. There is hereby established within the department of commerce and insurance the "Drug Cost Review Commission" for the purpose of protecting state residents, state and local governments, commercial health benefit plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from excessive costs of prescription drugs.

2. (1) The commission shall consist of the following members:

(a) The governor or his or her designee;

(b) The director of the department of commerce and insurance;

(c) The president pro tempore of the senate or his or her designee;

(d) The speaker of the house of representatives or his or her designee; and

(e) The attorney general or his or her designee.

(2) The director of the department of commerce and insurance shall appoint two additional members to serve during his or her tenure as director as alternative members who shall participate in deliberations of the commission if a member is recused.

(3) Any potential conflict of interest, including financial or personal association, that has the potential to bias or the appearance of biasing an individual's decisions in matters related to the commission or the conduct of the commission's activities shall be considered and disclosed when appointing members to the commission.

3. (1) No person shall receive compensation as a member of the commission, but members shall receive reimbursement for the actual and necessary expenses incurred in attending meetings of the commission or any subcommittee thereof.

(2) The chair of the commission shall be elected by the members of the commission.

(3) The chair shall hire an executive director, general counsel, and staff for the commission, who shall receive compensation as provided in the budget of the commission.

4. (1) (a) Except as provided in this subdivision, the commission shall hold a public meeting at least every six weeks to review prescription drug product information submissions.

(b) The chair may cancel or postpone a meeting if there are no prescription drug product submissions to review.

(c) The commission may additionally hold closed meetings as specified under chapter 610, but decisions of the commission shall be made by public vote.

(2) The commission shall give notice of meetings as specified under section 610.020 no less than two weeks prior to each meeting.

(3) Materials for each commission meeting shall be made available to the public on the department's website no less than one week prior to the meeting.

(4) The commission shall provide opportunity for public comment at each public meeting of the commission.

(5) The commission shall provide the public with the opportunity to provide written comments on pending decisions of the commission.

(6) The commission may allow expert testimony at commission meetings, including during closed meetings.

(7) The following actions shall only be taken in a public meeting:

(a) Deliberation on whether to subject a prescription drug to a full cost review;

(b) Review of a prescription drug cost analysis; and

(c) Voting on whether to impose a cost or payment limit on health carriers for a prescription drug product.

(8) A majority of the members of the commission shall constitute a quorum.

(9) A member of the commission shall recuse himself or herself from discussions and decisions related to a prescription drug under review if the member or a person within

the second degree of consanguinity or affinity has received or could receive any of the following:

(a) A direct financial benefit of any amount deriving from the findings of a study or determination by or for the commission; or

(b) A financial benefit from individuals or companies that own, manufacture, or provide prescription drugs, services, or items to be studied by the commission that in the aggregate exceeds five thousand dollars per year.

376.2062. 1. Before March 1, 2023, and annually thereafter, each pharmacy benefits manager shall file a report with the commission for the immediately preceding calendar year. The report shall contain the following information for health carriers that delivered, issued for delivery, renewed, amended, or continued health benefit plans that included a pharmacy benefit managed by the pharmacy benefits manager during such calendar year:

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

(a) Were covered by such health carriers during such calendar year; and

(b) Are 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 such health carriers, concerning drug formularies, which such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that:

(a) Were covered by such health carriers during such calendar year; and

(b) Are attributable to patient utilization of such drugs by covered persons under such health care plans during such calendar year.

2. In consultation with pharmacy benefit managers, the commission shall establish a standardized form for reporting the information required under subsection 1 of this section. The form shall be designed to minimize the administrative burden and cost of reporting for the commission and pharmacy benefit managers.

3. All documents, materials, or other information submitted to the commission under subsection 1 of this section shall not be subject to disclosure under chapter 610, except to the extent it is included on an aggregate basis in the report required under subsection 4 of this section. The commission shall not disclose information submitted under 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 a health benefit plan, health carrier, pharmacy benefits manager, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

4. Before July 1, 2023, and annually thereafter, the commission shall submit a report to the standing committees of the general assembly having jurisdiction over health insurance matters. The report shall contain an aggregate of the information submitted to the commission under subdivision (1) of subsection 1 of this section for the immediately preceding calendar year, and such other information as the commission in its discretion deems relevant for the purposes of this section. The commission shall provide each 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.

5. The commission may impose a penalty of no more than seven thousand five hundred dollars on a pharmacy benefits manager for each violation of this section.

6. The commission may promulgate rules as necessary 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, 2020, shall be invalid and void.

376.2064. 1. Any health carrier that delivers, issues for delivery, renews, amends, or continues a health benefit plan after December 31, 2022, shall submit the following information and data to the commission for such health benefit plan for the immediately preceding calendar year at the time that the health carrier submits a rate filing for such health benefit plan under section 376.465 or 379.321:

(1) For covered outpatient prescription drugs that were prescribed to enrollees under such health benefit plan during such calendar year, the names of:

(a) The twenty-five most frequently prescribed outpatient prescription drugs;

(b) The twenty-five outpatient prescription drugs that the health benefit plan covered at the greatest cost, calculated by using the total annual plan spending by such health benefit plan for each outpatient prescription drug; and

(c) The twenty-five outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated by using the total annual plan spending by such health benefit plan for each outpatient prescription drug;

(2) The portion of the premium for such health benefit plan that is attributable to each of the following categories of covered outpatient prescription drugs that were prescribed to enrollees under such health benefit plan during such calendar year:

(a) Brand name drugs;

(b) Generic drugs; and

(c) Specialty drugs;

(3) The year-over-year increase, calculated on a per member, per month basis and expressed as a percentage, in the total annual cost of each category of covered outpatient prescription drugs set forth in subdivision (2) of this subsection;

(4) A comparison, calculated on a per member, per month basis, of the year-over-year increase in the cost of covered outpatient prescription drugs to the year-over-year increase in the costs of other contributors to the premium cost of such health benefit plan;

(5) The name of each specialty drug covered under such calendar year; and

(6) The names of the twenty-five most frequently prescribed outpatient drugs for which the health carrier received rebates from pharmaceutical manufacturers during such calendar year.

2. The commission may promulgate rules as necessary 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, 2020, shall be invalid and void.

376.2066. Before March 1, 2023, and annually thereafter, each health carrier shall submit to the director, in a form and manner prescribed by the director, a written certification for the immediately preceding calendar year certifying that the health carrier accounted for all rebates in calculating the premium for health benefit plans that such health carrier delivered, issued for delivery, renewed, amended, or continued during such calendar year.

376.2068. Before March 1, 2023, and annually thereafter, the commission shall submit a report to the standing committees of the general assembly having jurisdiction over health insurance matters. The report shall contain:

(1) An aggregate of the information and data submitted to the commission under section 376.2064 for the immediately preceding calendar year;

(2) A description of the impact of the cost of outpatient prescription drugs on health insurance premiums in this state; and

(3) Such other information as the commission, in its discretion, deems relevant to the cost of outpatient prescription drugs in this state.

376.2070. Before March 1, 2023, and annually thereafter, the commission shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of health carriers. The report shall be published on the department's public website and shall contain:

(1) An explanation of the manner in which health carriers accounted for rebates in calculating premiums for health benefit plans delivered, issued for delivery, renewed, amended, or continued during such year;

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

(3) Any other manner in which health carriers applied rebates during such year; and

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

376.2072. 1. As used in this section and section 376.2073, the following terms mean:

(1) "Accelerated approval", as defined under 21 U.S.C. Section 356, as amended;

(2) "Biologics license application", an application filed under 21 CFR 601.2, as amended;

(3) "Breakthrough therapy", as defined under 21 U.S.C. Section 356, as amended;

(4) "Commission", the drug cost review commission established under section 376.2061;

(5) "Drug", as defined under section 376.1350;

(6) "Excess costs", costs of appropriate use of a prescription drug product that are not sustainable for public or private health care systems over a ten-year time frame;

(7) "Fast-track product", as defined under 21 U.S.C. Section 356, as amended;

(8) "New drug application", as defined under 21 CFR 314.3, as amended;

(9) "New molecular entity", as defined under 21 U.S.C. Section 355-1, as amended;

(10) "Orphan drug", as defined under 21 CFR 316.3, as amended;

(11) "Pipeline drug", a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with and received an action date from the Food and Drug Administration;

(12) "Prescription drug", a drug prescribed by a health care provider to an individual in this state;

(13) "Priority review", as defined under 21 U.S.C. Section 356, as amended;

(14) "Rebate", as defined under section 376.2060;

(15) "Research and development cost", a cost that a pharmaceutical manufacturer incurs in researching and developing a new product, process, or service including, but not limited to, a cost that a pharmaceutical manufacturer incurs in researching and developing a product, process, or service that the pharmaceutical manufacturer has acquired from another person by license;

(16) "Sponsor", as defined under 21 CFR 316.3, as amended;

(17) "Wholesale acquisition cost", as defined under 42 U.S.C. Section 1395w-3a, as amended.

2. Beginning January 1, 2022, each sponsor shall submit to the commission, in a form and manner prescribed by the commission, written notice that such sponsor has filed with the Food and Drug Administration:

(1) A new drug application or biologics license application for a pipeline drug, within sixty days after such sponsor receives an action date from the Food and Drug Administration regarding such application; or

(2) A biologics license application for a biosimilar drug, within sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.

3. (1) Beginning January 1, 2022, and not more frequently than annually thereafter, the commission may, in consultation with the commissioner of administration, conduct a study of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the commission in consultation with the commissioner of administration and the director of the department of social services, may have significant impact on state expenditures for outpatient prescription drugs. The commission may work with the commissioner of administration to use existing state resources and contracts or contract with a third party including, but not limited to, an accounting firm to conduct such study.

(2) Each pharmaceutical manufacturer that is the subject of a study conducted as specified under subdivision (1) of this subsection shall submit to the commission, or to any contractor engaged by the commission or the commissioner of administration to perform

such study, the following information for the pipeline drug that is the subject of such study:

(a) The primary disease, condition, or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition, or therapeutic area;

(b) Each route of administration studied for such drug;

(c) Clinical trial comparisons, if applicable, for such drug;

(d) The estimated year of market entry for such drug;

(e) Whether the Food and Drug Administration has designated the drug as an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the federal Food and Drug Administration has designated the drug for accelerated approval and, if the drug contains a new molecular entity, for priority review.

4. (1) Before March 1, 2022, and annually thereafter, the commission, in consultation with the commissioner of administration, the director of the department of social services, and the director of the department of health and senior services, shall prepare a list of no more than ten outpatient prescription drugs that the commission, in its discretion, determines are provided at substantial cost to the state, considering the net cost of such drugs, or are critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

(2) The commission shall not list any outpatient prescription drug under subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year:

(a) Increased by at least twenty percent during the immediately preceding calendar year, or by at least fifty percent during the immediately preceding three calendar years; and

(b) Was no less than sixty dollars for a thirty-day supply of the drug or for a course of treatment of the drug lasting less than thirty days.

(3) (a) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the commission under subdivision (1) of this subsection shall provide to the commission, in a form specified by the commission:

a. A written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug; and

b. Aggregate, company-level research and development costs and such other capital expenditures that the commission, in its discretion, deems relevant for the most recent year for which the final audited data is available.

(b) The quality and types of data that a pharmaceutical manufacturer submits to the commission under this subdivision shall be consistent with the quality and types of data that the pharmaceutical manufacturer includes in its annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(4) The commission shall establish a standardized form for reporting information and data under this subsection after consulting with pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the commission and pharmaceutical manufacturers.

5. The commission may impose a penalty not to exceed seven thousand five hundred dollars on a pharmaceutical manufacturer or sponsor for each violation of this section by the pharmaceutical manufacturer or sponsor.

6. The commission may promulgate rules as necessary 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, 2020, shall be invalid and void.

376.2073. 1. (1) A manufacturer of a patent-protected brand-name drug or biologic shall notify the commission:

(a) If the wholesale acquisition cost of the drug is increasing by more than ten percent or by more than ten thousand dollars during any twelve-month period; or

(b) If the manufacturer intends to introduce to market a brand-name drug that has a wholesale acquisition cost of thirty thousand dollars per calendar year or per course of treatment.

(2) The notice provided by manufacturers under subdivision (1) of this subsection shall:

(a) Be provided in writing at least thirty days before the planned effective date of the increase or the introduction of the drug to market; and

(b) Include a justification for the proposed pricing that includes any documents and research related to the manufacturer's selection of the introductory price or price increase,

including but not limited to life cycle management, net average price to the state, market competition and context, projected revenue, and the estimated value or cost effectiveness of the product, if available.

2. The commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of brand prescription drugs, including biologics and biosimilars. The reporting threshold shall apply to brand-name prescription drugs that are not reported under subsection 1 of this section but that impose costs on the state health care system that create significant challenges to affordability.

3. (1) A manufacturer of a generic or off-patent sole-source branded product drug shall notify the commission if the manufacturer is increasing the wholesale acquisition cost of the drug by more than twenty-five percent or by more than three hundred dollars during any twelve-month period.

(2) The notice provided under subdivision (1) of this subsection shall:

(a) Be provided in writing at least thirty days before the planned effective date of the increase or the introduction of the drug to market; and

(b) Include a justification for the proposed pricing that includes any documents and research related to the manufacturer's selection of the price increase, including but not limited to life cycle management, net average price to the state, market competition and context, projected revenue, and the estimated value or cost effectiveness of the product, if available.

4. The commission, in consultation with stakeholders and experts, shall establish a threshold for manufacturer reporting of generic and off-patent sole-source branded prescription drugs. The reporting threshold established by the commission under this subsection shall apply to generic and off-patent sole-source branded prescription drugs that are not reported under subsection 1 of this section but that impose costs on the state health care system that create significant challenges to affordability.

5. If possible, the commission shall access manufacturer justification information made public by other states. If manufacturer justification information is not available from other state sources, the commission shall require manufacturers to submit to the commission any documents and research related to the manufacturer's selection of the introductory price or price increase, including but not limited to life cycle management, net average price in the state, market competition and context, projected revenue, and the estimated value or cost effectiveness of the product, if available.

6. (1) The commission shall inform the public of the reports provided under this section and section 376.2072.

(2) The public may request commission review of the cost of any prescription drug reported under this section or section 376.2072 through a method to be developed by the commmission.

(3) (a) The chair of the commission shall review any request made under subdivision (2) of this subsection to determine whether to review the cost of the prescription drug.

(b) The chair of the commission may initiate a review of the cost of a prescription drug reported under this section in the absence of a request made under subdivision (2) of this subsection.

(c) Notwithstanding the other provisions of this subdivision, any member of the commission may request a vote on whether to review a prescription drug.

7. (1) If the commission conducts a review of the cost of a prescription drug, the review shall determine whether a use of the drug that is fully consistent with the Food and Drug Administration label has led or will lead to excess costs for health care systems in the state.

(2) In determining costs and excess costs, the commission shall consider:

(a) The price at which the prescription drug has been or will be sold in the state;

(b) The average monetary price concession, discount, or rebate the manufacturer provides to health carriers in the state or is expected to provide to health carriers in the state as reported by manufacturers and health carriers, expressed as a percent of the wholesale acquisition cost;

(c) The total amount of the concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager operating in the state for the prescription drug under review, expressed as a percent of the wholesale acquisition cost;

(d) The price at which therapeutic alternatives have been or will be sold in the state;

(e) The average monetary price concession, discount, or rebate the manufacturer provides to health carriers in the state or is expected to provide to health carriers in the state for therapeutic alternatives;

(f) The cost to health carriers based on patient access consistent with Food and Drug Administration labeled indications;

(g) The impact on patient access resulting from the cost of the product relative to insurance benefit design;

(h) The current or expected dollar value of drug-specific patient access programs that are supported by manufacturers;

(i) The relative financial impacts to health, medical, or other social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives; and

(j) Any other factor deemed relevant by the commission and established by rule.

(3) If the commission is unable to determine whether a prescription drug product will produce or has produced excess costs using the factors listed in subdivision (2) of this subsection, the commission shall consider the following factors:

(a) Manufacturer research and development costs, as indicated on the manufacturer's federal tax filing for the most recent tax year, in proportion to the manufacturer's sales in the state;

(b) The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that is specific to the prescription drug product under review, multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the product under review;

(c) Gross and net manufacturer revenues for the most recent tax year;

(d) Any additional factors proposed by the manufacturer that the commission deems relevant; and

(e) Any additional factors deemed relevant by the commission and established by rule.

8. (1) If the commission finds that the spending on a prescription drug product reviewed under this section creates excess costs for health carriers or consumers, the commission shall establish the level of reimbursement that shall be billed and paid among:

(a) Health carriers and pharmacies or administering providers;

(b) Wholesalers, distributers, and pharmacies or administering providers; and

(c) Pharmacies or administering providers and uninsured consumers or enrollees in a deductible period.

(2) The commission shall determine how each participant in the supply chain of the prescription drug shall be remunerated.

9. (1) Subject to subdivision (2) of this subsection, any submission made to the commission related to a drug cost review shall be made available to the public, with the exception of information determined by the commission to be proprietary.

(2) The commission, after public notice and comment, shall establish standards for the information to be considered proprietary under subdivision (1) of this subsection, including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the Food and Drug Administration.

10. (1) Subject to subdivision (3) of this subsection, the commission shall be funded by an assessment on each manufacturer required to provide notice to the commission under subsection 1 or 3 of this section.

(2) The commission shall determine by rule the amount of the assessment required under subdivision (1) of this subsection.

(3) The commission shall be established using funds appropriated from general revenue, which shall be repaid to the state with the assessments required under subdivision (2) of this subsection.

11. Before August 28, 2021, and annually thereafter, the commission shall publish on the department's public website a report on:

(1) Prescription drug price trends;

(2) The number of manufacturers required to notify the commission about drug pricing under subsection 1 or 3 of this section; and

(3) The number of products that were subject to commission review, including the results of the review and the number and disposition of appeals and administrative or judicial reviews of commission decisions.

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