SECOND REGULAR SESSION

HOUSE BILL NO. 1850

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HEWKIN.

5331H.01I JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal sections 338.600, 376.387, and 376.388, RSMo, and to enact in lieu thereof four new sections relating to pharmacies.

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

Section A. Sections 338.600, 376.387, and 376.388, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 338.600, 338.840, 376.387, and 376.388, to read as follows:

338.600. 1. **As used in this section, the following terms mean:**

(1) "Audit", any review, inspection, or analysis conducted by an entity of a pharmacy's records, practices, or compliance with contractual obligations;

(2) "Entity":

(a) Any managed care company, insurance company, or third-party payer or a representative of a managed care company, insurance company, or third-party payer; or

(b) Any pharmacy benefits manager or subcontractor of a pharmacy benefits manager or a representative of a pharmacy benefits manager or subcontractor of a pharmacy benefits manager;

(3) "Pharmacy benefits manager", the same meaning given to the term in section 376.387.

2. Notwithstanding any other provision of law to the contrary, when an audit of the records of a pharmacy licensed in this state is conducted by **[**~~a managed care company, insurance company, third-party payor, or~~**]** any entity **[**~~that represents such companies or groups~~**]**, such audit shall be conducted in accordance with the following:

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.

(1) The entity conducting the initial on-site audit shall provide the pharmacy with notice at least **[**~~one week~~**] fourteen days** prior to conducting the initial on-site audit for each audit cycle **and identify specific prescriptions to be audited. If the entity identifies the prescriptions to be audited by providing prescription numbers, the entity may omit the final two digits of the prescription numbers**;

(2) Any audit which involves clinical judgment shall be conducted by or in consultation with a **[**~~licensed~~**]** pharmacist **licensed by the board of pharmacy who shall be made available to the audited pharmacy to discuss clinical rationale**;

(3) Any clerical error, record-keeping error, typographical error, or scrivener's error regarding a required document or record shall not constitute fraud or grounds for recoupment, so long as the prescription was otherwise legally dispensed and the claim was otherwise materially correct; except that, such claims may be otherwise subject to recoupment of overpayments or payment of any discovered underpayment. No claim arising under this subdivision shall be subject to criminal penalties without proof of intent to commit fraud**. The pharmacy shall have the right to submit amended claims within thirty days of the discovery of an error to correct clerical or record-keeping errors in lieu of recoupment if the prescription was dispensed according to requirements set forth in state or federal law**;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts involving drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug. Electronically stored images of prescriptions, electronically created annotations and other related supporting documentation shall be considered valid prescription records. Hard copy and electronic signature logs that indicate the delivery of pharmacy services shall be considered valid proof of receipt of such services by a program enrollee;

(5) A finding of an overpayment or underpayment may be a projection based on the number of patients served and having a similar diagnosis or on the number of similar orders or refills for similar drugs; except that, recoupment of claims shall be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy;

(6) Each pharmacy shall be audited under the same standards and parameters as other pharmacies audited by the entity;

(7) A pharmacy shall be allowed at least thirty days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) **An audit shall be limited to twenty-five prescriptions that have been randomly selected from a pool of prescriptions of a similar type as the prescriptions that are collectively adjudicated. If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site;**

(9) An entity shall not initiate an audit of a pharmacy more than two times in a calendar year. Any prescription information request by an entity that could result in recoupment shall count as an audit under this subdivision;

(10) A recoupment shall not be based on:

(a) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the board of pharmacy; or

(b) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the board of pharmacy;

(11) Recoupment shall occur only following the correction of a claim and shall be limited to amounts adjudicated by the pharmacy benefits manager;

(12) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;

(13) Any entity conducting an audit shall not be compensated, nor shall any of its employees be compensated, directly or indirectly, based on any amounts recouped;

(14) An entity shall not charge a fee for conducting an on-site audit or a desk audit unless there is a finding of actual fraud;

(15) The period covered by the audit shall not exceed a two-year period beginning **[**~~two years prior to the initial date of the on-site portion of the audit unless otherwise provided by contractual agreement or if~~**] on the date a claim being audited was submitted for payment unless** there has been a previous finding of fraud or as otherwise provided by state or federal law;

[~~(9)~~**] (16)** An audit shall not be initiated or scheduled during the first **[**~~three~~**] five** business days of any month due to the high volume of prescriptions filled during such time unless otherwise consented to by the pharmacy;

[~~(10)~~**] (17)** The preliminary audit report shall be delivered to the pharmacy within one hundred twenty days after conclusion of the audit, with reasonable extensions permitted. A final audit report shall be delivered to the pharmacy within six months of receipt by the pharmacy of the preliminary audit report or final appeal, as provided for in subsection **[**~~3~~**] 4** of this section, whichever is later**. If an audit report is not delivered to the pharmacy within the time frame required under this subdivision, the audit shall be deemed free of discrepancies, and no recoupment shall be permitted**;

[~~(11)~~**] (18) The days' supply for unit-of-use items, such as topicals, drops, vials, and inhalants, shall not be limited beyond manufacturer recommendations;**

(19) If the only commercially available package size exceeds an entity's maximum days' supply, the dispensing of such package size shall be accepted by the entity and shall not be the basis for recoupment;

(20) If the only commercially available package size exceeds an entity's maximum days' supply and the entity accepts the refill of such prescription, the entity shall not recoup such claim as an early refill;

(21) The failure of a pharmacy to collect a co-payment shall not be the basis for recoupment if the pharmacy provides documentation of billing of the claim and a reasonable attempt to collect the co-payment;

(22) An entity conducting a wholesale invoice audit shall comply with the following provisions:

(a) The entity shall not audit the claims of another entity;

(b) The following shall not form the basis for recoupment:

a. The National Drug Code for the dispensed drug is in a quantity that is a subunit or multiple of the purchased drug as reflected on a supporting wholesale invoice;

b. The correct quantity dispensed is reflected on the audited pharmacy claim; or

c. The drug dispensed by the pharmacy on an audited pharmacy claim is identical to the strength and dosage form of the drug purchased;

(c) The entity shall accept as evidence:

a. Supplier invoices issued prior to the date of dispensing the drug underlying the audited claim;

b. Invoices from any supplier authorized by law to transfer ownership of the drug acquired by the audited pharmacy;

c. Copies of supplier invoices in the possession of the audited pharmacy; and

d. Reports required by any state board or agency; and

(d) Within five business days of any request by the audited pharmacy, the entity shall provide supporting documentation provided to the entity by the audited pharmacy's suppliers; and

(23) Notwithstanding any other provision in this subsection, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits, except as otherwise authorized under subdivision (5) of this subsection.

[~~2.~~**] 3.** Recoupments of any disputed moneys shall only occur after final internal disposition of the audit, including the appeals process set forth in subsection **[**~~3~~**] 4** of this section. Should the identified discrepancy for an individual audit exceed twenty-five

thousand dollars, future payments to the pharmacy in excess of twenty-five thousand dollars may be withheld pending finalization of the audit.

[~~3.~~**] 4.** Each entity conducting an audit shall establish an appeals process, lasting no longer than six months, under which a licensed pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following such appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

[~~4.~~**] 5.** Each entity conducting an audit shall provide a copy of the final audit report, after completion of any appeal process, to the plan sponsor. **If any recoupment occurred, the report shall include the total amount of recoupment returned to the plan sponsor.**

[~~5.~~**] 6.** This section shall not apply to any investigative audit that involves probable fraud, willful misrepresentation, or abuse.

[~~6.~~**] 7.** This section shall not apply to any audit conducted as part of any inspection or investigation conducted by any governmental entity or law enforcement agency.

338.840. The department of health and senior services shall establish a critical access care pharmacy program to ensure the sustainability of critical access care pharmacies throughout this state. The program shall assist pharmacies identified as critical access care pharmacies based on their location in an area where pharmacy services are needed.

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 whose prescription drug coverage is administered through a pharmacy benefits manager or a health benefit plan**;

(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. The department of commerce and insurance shall enforce this section **and may audit any information provided by a pharmacy benefits manager under 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~~**] "Health benefit plan", the same meaning given to the term in section 376.1350**;

(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~~**] or health benefit plans to provide prescription drug and pharmacist services;**

(7) "Pharmacy benefits manager affiliate" or "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;

(8) "Pharmacy benefits manager rebate aggregator", any entity that negotiates with a pharmaceutical manufacturer on behalf of a pharmacy benefits manager for a rebate;

(9) "Pharmacy claims data", information regarding a prescription transaction that is adjudicated by a pharmacy benefits manager for a covered person, as defined in section 376.387, between the pharmacy and the pharmacy benefits manager and between the pharmacy benefits manager and the plan sponsor, which shall include, at a minimum:

(a) The prescription drug's National Drug Code;

(b) The contracted compensation rate to the plan sponsor for each drug;

(c) The amount paid to the pharmacy for each unit;

(d) The channel of dispensing, whether by retail, mail-order, or specialty pharmacy;

(e) For brand-name drugs, the wholesale acquisition cost per unit;

(f) For generic drugs, the average wholesale price per unit;

(g) The number of claims, participants, dosage units dispensed, and days' supply;

(h) The net price of the drug after accounting for all rebates, including from pharmacy benefits manager rebate aggregators, discounts, and fees;

(i) The total out-of-pocket cost paid by the participant per claim; and

(j) All amounts received by the plan sponsor, the pharmacy benefits manager, or any affiliate including, but not limited to, co-payment assistance, co-payment cards, or remuneration provided by pharmaceutical manufacturers;

(10) "Plan sponsor", any sponsor of a health benefit plan;

(11) "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 for the dispensation or administration of a prescription drug on behalf of itself or another entity.

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. 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) The right to appeal shall be limited to fourteen calendar days following the reimbursement of the initial claim; and

(2) 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.

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.

9. A pharmacy benefits manager shall provide each plan sponsor with the plan sponsor's pharmacy claims data as reasonably requested by the plan sponsor.

10. An entity shall define and apply the term "rebate" as having the same meaning given to the term in this section if the entity enters into a contract to sell, provide, pay, negotiate rebates for, or reimburse a pharmacy, pharmacy benefits manager, pharmacy benefits manager affiliate, or pharmacy benefits manager rebate aggregator for prescription drugs on behalf of itself or another entity.

11. A pharmacy benefits manager shall provide each plan sponsor and the department of commerce and insurance with documentation of any benefit design that encourages or requires enrollees to fill prescriptions at its affiliates.

12. A pharmacy benefits manager shall owe a fiduciary duty to each plan sponsor.

13. All disclosures required under this section shall be provided to the plan sponsor or its authorized agent in a universally accessible format.

14. If a pharmacy benefits manager has an affiliate, the pharmacy benefits manager shall disclose to the plan sponsor and the department of commerce and insurance:

(1) The amount charged per dosage unit to the affiliate; and

(2) The median amount charged per dosage unit at in-network pharmacies that are not affiliates.

15. The department of commerce and insurance may audit a pharmacy benefits manager to ensure compliance with this section.

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