SENATE SUBSTITUTE

FOR

SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILLS NOS. 984 & 968

AN ACT

To repeal sections 338.600 and 376.387, RSMo, and to enact in lieu thereof four new sections relating to pharmacy benefits managers.

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

Section A. Sections 338.600 and 376.387, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 338.600, 376.387, 376.394, and 376.399, to read as follows:

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

(1) "Audit", any review, inspection, investigation, examination, or analysis conducted by a pharmacy benefits manager (PBM) or its representative of a pharmacy's records, claims, practices, or compliance with contractual obligations or legal requirements, which may result in recoupment, repayment demand, chargeback, penalty, or other financial adjustment. Routine verification or inquiry regarding claim elements or documentation shall not constitute an audit; however, no recoupment, repayment demand, chargeback, penalty, or financial adjustment shall be based upon or initiated through such inquiry unless the inquiry is converted to an audit and conducted in compliance with the requirements of this section;

(2) "Entity", a managed care company, insurance company or third-party payor, or representative of a managed care company, insurance company or third-party payor, or a

pharmacy benefits manager or a subcontractor of a pharmacy benefits manager.

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:

(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 shall specify specific prescriptions to be audited which may or may not include the final two digits of the prescription numbers. The notice required under this subsection shall be in writing and shall be sent by means that allows tracking of delivery to the pharmacist or pharmacy not later than the fourteenth day before the date on which the on-site audit is scheduled to occur. A pharmacy benefit manager is not required to provide notice before conducting an audit if, after reviewing claims data, written or oral statements of pharmacy staff, wholesalers, or other investigative information, including patient referrals, the plan issuer or pharmacy benefit manager suspects the pharmacist or pharmacy subject to the audit committed fraud or made an intentional misrepresentation related to the pharmacy business, which cause and suspicion shall be disclosed to pharmacy upon initiation of the audit;

(2) Any audit which involves clinical judgment shall be conducted by or in consultation with a **[**licensed**]** pharmacist licensed by the Missouri board of pharmacy, and said pharmacist shall be made available to the audited

pharmacy to discuss clinical rationale and Missouri legal requirements;

(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 forty unique prescriptions, with a maximum of two hundred separately adjudicated claims, that have been randomly selected, and such randomness shall be reflected by auditing a similar type of prescriptions as are collectively adjudicated.

(a) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site.

(b) An entity shall not initiate an audit of a pharmacy more than two times in a calendar year, unless fraud is suspected as described in subdivision (1) of this subsection; such audit of pharmacy records includes any prescription information request by an auditing entity that could result in recoupment.

(c) The list of the claims subject to an on-site audit shall be provided in the notice under paragraph (a) of this subdivision to the pharmacist or pharmacy and shall identify the claims only by the prescription numbers or a date range for prescriptions subject to the audit. The last two digits of the prescription numbers provided may be omitted;

(9) A recoupment shall not be based on a requirement that a pharmacy or pharmacist perform a professional duty in

addition to or exceeding professional duties prescribed by the Missouri board of pharmacy;

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

(11) Except for MO HealthNet 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, abuse, waste, a misrepresentation of claim elements, or claims that were not properly rendered or billed by a pharmacy or pharmacist, or otherwise in accordance with state pharmacy audit laws.

(a) This subdivision does not preclude a pharmacy benefits manager from engaging in claims reconciliation activities if the activities do not result in a retroactive reduction or recoupment of payment to the pharmacist or pharmacy for a previously adjudicated covered claim:

(b) A pharmacy benefits manager may not charge a pharmacy or pharmacist a fee relating to the adjudication of a claim;

(12) 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;

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

(14) 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**]** the date the claim was submitted for payment **[**if**]** unless there has been a previous finding of fraud or as otherwise provided by state or federal law;

[(9)**]** (15) 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)**]** (16) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty days **[**after conclusion of the audit**]** from the date the pharmacy submits the audit information to the pharmacy benefits manager, 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 of this section, whichever is later. Audit reports not delivered to the pharmacy in this timeline shall be deemed to have no discrepancies and no recoupment shall be made;

[(11)**]** (17) 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;

(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 copayment shall not be the basis for recoupment if the pharmacy

provides documentation of billing of the claim and a reasonable attempt to collect the copayment; and

(22) In a wholesale invoice audit conducted by an entity:

(a) An 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 sub-unit 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 a request by the audited pharmacy, the entity shall provide supporting documentation provided to the entity by the audited pharmacy's suppliers.

[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 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. Such report shall include the total amount of recoupment returned to the plan sponsor, if any.

[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.

376.387. 1. For purposes of **[**this section**]** sections 376.387 to 376.399, the following terms shall mean:

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

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

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

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

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

[(5)**]** (6) "Pharmacy benefits manager", **[**the same meaning as such term is defined in section 376.388**]** an entity that contracts with pharmacies on behalf of health carriers or health benefit plans to provide prescription drug and pharmacist services;

(7) "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;

(8) "Plan sponsor", the sponsor of the health benefit plans.

2. No pharmacy benefits manager, or prescription claims processor of any kind, 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; or

(3) The contracted rate the pharmacy would be reimbursed for the drug.

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**]** The pharmacy benefits manager or plan sponsor shall provide the plan sponsor documentation of any benefit design that encourages or requires enrollees to fill prescriptions at affiliated pharmacies.

8. A pharmacy benefits manager shall exercise good faith and fair dealing in the administration of pharmacy benefits and shall ensure that any conflicts of interest that may clinically or financially impact covered persons or the health benefit plan sponsor in a negative manner are disclosed.

9. All disclosures required under this section shall be provided to the plan sponsor or its authorized agent in a universal manner.

10. If a pharmacy benefits manager or health carrier has an affiliated pharmacy or a pharmacy under common ownership, the pharmacy benefits manager shall disclose to the plan sponsor:

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

(2) The median amount charged per dosage unit at nonaffiliated, in-network pharmacies.

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

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

(1) "Acquisition cost", the set of National Average Drug Acquisition Costs, "NADAC", as calculated by the

Centers for Medicare and Medicaid Services and reflected in the most recently released public file, except in cases where the NADAC price is not available, the wholesale acquisition cost;

(2) "Critical access care pharmacy", a Missouri-domiciled pharmacy with a physical location in the state of Missouri that is a pharmacy that is either stand alone or part of a group of twenty-five or fewer pharmacies under common ownership as identified by the state.

The Missouri board of pharmacy shall release quarterly a list of critical access pharmacies eligible under this section;

(3) "Similarly situated", a critical access care pharmacy:

(a) That is in any of the pharmacy benefits manager's networks; and

(b) To which the pharmacy benefits manager also applies the challenged rate of reimbursement or acquisition cost.

2. Notwithstanding any provision of law to the contrary, a pharmacy benefits manager shall not reimburse a critical access care pharmacy for a prescription drug or device an amount that is less than the acquisition cost to that pharmacy for the prescription drug or device.

(1) A pharmacy benefits manager shall establish a process for a pharmacy to appeal a reimbursement for failing to pay at least the acquisition cost to the critical access care pharmacy for the prescription drug or device and shall permit a critical access care pharmacy or its designated agent to file an appeal using the standard appeal form described in this section.

(2) If a critical access care pharmacy chooses to contest a reimbursement for failing to pay at least the acquisition cost the critical access care pharmacy incurred for a particular drug or medical product or device, then the critical access care pharmacy has the right to designate a pharmacy services administrative organization or other agent to file and handle its appeal.

(3) The department of commerce and insurance shall create and make available to pharmacy benefits managers and covered entities a standard form to be used by a critical access care pharmacy or its designated agent to file an appeal pursuant to this subsection with a pharmacy benefits manager or covered entity.

3. If a critical access care pharmacy or agent acting on behalf of a critical access care pharmacy prevails in an appeal provided for in this section, then within seven business days after notice of the decision is received by the pharmacy benefits manager or covered entity, the pharmacy benefits manager or covered entity shall:

(1) Make the necessary change to the challenged rate of reimbursement or acquisition cost;

(2) If the product involved in the appeal is a drug, provide to the critical access care pharmacy or agent the national drug code number for the drug on which the change is based;

(3) Permit the challenging critical access care pharmacy to reverse and rebill the claim upon which the appeal is based;

(4) Pay or waive the cost of any transaction fee required to reverse and rebill the claim;

(5) Reimburse the critical access care pharmacy at least in an amount equal to the critical access care

pharmacy's acquisition cost for the prescription drug or device; and

(6) Apply the findings from the appeal as to the rate of reimbursement and acquisition cost for the particular drug or medical product or device to other similarly situated critical access care pharmacies.

4. It is a violation of this section if, after an appeal in which a pharmacy or agent acting on behalf of a critical access care pharmacy prevails, a pharmacy benefits manager or covered entity fails to reimburse the critical access care pharmacy at least acquisition cost.

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

376.399. 1. Health carriers shall comply with H.R. 7148, the Consolidated Appropriations Act, by September 1, 2028.

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