HOUSE RESEARCH

Bill Summary

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Subject: Pharmacy Audit Integrity Program

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Overview

This bill specifies procedures that must be followed during pharmacy audits. The bill also establishes procedures for modifying contracts between pharmacy benefit managers and pharmacies.

1 **Pharmacy audit integrity program.** Adds § 151.60. Establishes the pharmacy audit integrity program to provide standards for audits of pharmacy records.

2 **Definitions.** Adds § 151.61. Defines the following terms: entity, pharmacy benefits manager (PBM), and plan sponsor. "Entity" is defined as a pharmacy benefits manager or any person or organization that represents a PBM. "Plan sponsor" is defined as the employer or employee organization that establishes or maintains the employee benefit plan or a group purchaser.

3 **Pharmacy benefit manager contract.** Adds § 151.62. (a) Provides that a PBM contract that is modified by that entity is not effective without the written consent of the pharmacy. Requires the pharmacy to receive a copy of the proposed changes or renewal and requires the PBM to disclose all material changes.

(b) Requires amendments or changes to existing contracts to be disclosed to the pharmacy at least 120 days prior to the effective date of the proposed change.

4 **Procedure and process for conducting and reporting an audit.** Adds § 151.63. Requires entities conducting a pharmacy audit, unless prohibited by federal requirements or regulations, to:

(1) provide written notice to the pharmacy before conducting an on-site audit;

(2) use or consult with a pharmacist when an audit involves clinical or professional judgment;

(3) use the same standards and parameters when auditing similarly situated pharmacies; and

(4) pay for the cost of copying health records, if these are requested.

Subd. 2. Audit process. Requires entities conducting a pharmacy audit to comply with the following audit items, unless prohibited by federal requirements or regulations:

(1) the audit period may not exceed 24 months, unless federal law permits a longer period;

(2) the sample size may not exceed 60 prescriptions;

(3) the audit may not take place during the first seven business days of the month, unless the pharmacy consents;

(4) auditors may not access any area where patient-specific information is available and must be of out of sight and hearing range of customers;

(5) any recoupment must be invoiced and not deducted against future remittances;

(6) recoupment may not be assessed for items on the face of a prescription not required by the Board of Pharmacy; and

(7) the auditing company or agent must not receive payment based on a percentage of the amount recovered.

5 **Requirements for recoupment or chargeback.** Adds § 151.64. Specifies the following criteria for recoupment or chargebacks:

(1) audit parameters must consider consumer-oriented parameters based on manufacturer listings;

(2) the usual and customary price must be considered the reimbursable cost unless an alternative price is agreed to in the contract;

(3) overpayment or underpayment amounts must be based on actual findings and not projections;

(4) extrapolation shall not be used in calculating the recoupment or penalties;

(5) overpayment calculations must not include dispensing fees unless a prescription was not dispensed or not authorized;

(6) clerical or record keeping errors must not be considered fraud, but may be subject to recoupment;

(7) the PBM must not assess chargebacks for errors that have no financial harm to the patient or plan; and

(8) interest may not accrue during the audit period.

6 **Documentation.** Adds § 151.65. (a) Allows the pharmacy to use medication administration records of an authorized practitioner, or other records, to validate the pharmacy record and delivery.

(b) Provides that any legal prescription may be used to validate claims, including medication administration records, faxes, e-prescriptions, or documented phone calls.

7 **Appeals process.** Adds § 151.66. Requires the entity conducting the audit to establish a written appeals process that includes appeals of preliminary and final reports. Allows either party to seek mediation.

8 **Audit information and reports.** Adds § 151.67. (a) Requires preliminary audit reports to be delivered to the pharmacy within 30 days of conclusion of the audit.

(b) Requires the pharmacy to have at least 30 days to provide documentation to address any discrepancies.

(c) Requires the final audit report to be delivered to the pharmacy within 90 days of receipt of the

preliminary audit report or final appeal.

(d) Prohibits chargebacks, recoupment, or other penalties from being assessed until the appeals process has been exhausted and the final report issued.

(e) Requires an entity to remit money related to underpayments within 30 days after the appeals process has been exhausted and the final report issued.

(f) Unless superseded by state or federal law, prohibits audit information from being shared. Allows auditors to have access to previous audit reports of a pharmacy only if conducted by the same auditing entity.

9 **Disclosures to plan sponsor.** Adds § 151.68. Requires an auditing entity to provide a copy of the final report to the plan sponsor whose claims were included in the audit, and to return any recouped money to the plan sponsor.

10 **Applicability of other laws and regulations.** Adds § 151.69. Provides that sections 151.60 to 151.68 do not apply to any investigative audit that involves fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.