House Research
Act Summary

CHAPTER: 215 **SESSION:** 2012 Regular Session

TOPIC: Pharmacy Audit Integrity Program

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Overview

This act specifies procedures that must be followed during pharmacy audits. The act 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. Requires amendments to pharmacy audit terms in contracts to be disclosed to the pharmacy at least 60 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 14 days notice to the pharmacy before conducting an initial on-site audit;

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

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

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 state or federal law requires a longer period;

(2) if random sampling is used, the sample size must be statistically appropriate;

(3) an on-site audit may not take place during the first five business days of the month, unless the pharmacy consents;

(4) auditors may not access any area where patient-specific information is available unless escorted, and to the extent possible, must be of out of sight and hearing range of customers;

(5) any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit;

(6) a PBM may not require information to be written on a prescription unless this information is required by law, and recoupment may be assessed for items not written on the prescription if specified conditions are met; 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 the pricing methodology is outlined 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 unless required by law or regulations;

(5) overpayment calculations must not include dispensing fees unless certain conditions are met;

(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.

8 **Audit information and reports.** Adds § 151.67. (a) Requires preliminary audit reports to be delivered to the pharmacy within 60 days of conclusion of the audit.

(b) Requires the pharmacy to have at least 45 days to provide documentation to address any discrepancies.

(c) Requires the final audit report to be delivered to the pharmacy within 120 days of receipt of the preliminary audit report or final appeal, whichever is later.

(d) Requires an entity to remit money related to underpayments within 45 days after the appeals process has been exhausted and the final report issued.

9 **Disclosures to plan sponsor.** Adds § 151.68. When contractually required, an auditing entity must 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. States that sections 151.62 to 151.67 do not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

11 **Violations.** Adds § 151.70. Provides that sections 151.62 to 151.68 may be grounds for action, but are not misdemeanors as described in section 151.29.