SENATE
STATE OF MINNESOTA
EIGHTY-SEVENTH LEGISLATURE

S.F. No. 973

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DATE	D-PG	OFFICIAL STATUS
03/21/2011	607	Introduction and first reading Referred to Health and Human Services
04/11/2011	1267	Author stricken Hall
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04/17/2012	5879	HF substituted on General Orders HF1236

A bill for an act

relating to health; establishing a pharmacy audit integrity program; proposing coding for new law in Minnesota Statutes, chapter 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[151.60] PHARMACY AUDIT INTEGRITY PROGRAM.**

The pharmacy audit integrity program is established to provide standards for an audit of pharmacy records carried out by a pharmacy benefits manager or any entity that represents pharmacy benefits managers.

Sec. 2. **[151.61] DEFINITIONS.**

Subdivision 1. **Scope.** For the purposes of sections 151.60 to 151.68, the following terms have the meanings given.

Subd. 2. **Entity.** "Entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

Subd. 3. **Pharmacy benefits manager or PBM.** "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management.

Subd. 4. **Plan sponsor.** "Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, a group purchaser as defined in section 62J.03, subdivision 6, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board of trustees, committee, or other similar group that establishes or maintains the plan.

Sec. 3. **[151.63] PROCEDURE AND PROCESS FOR CONDUCTING AND REPORTING AN AUDIT.**

Subdivision 1. **Audit procedures.** Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures.

(1) A pharmacy must be given a written notice before an initial on-site audit is conducted.

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist licensed in this state or the Board of Pharmacy.

(3) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

Subd. 2. **Audit process.** Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following audit items apply.

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is permitted under federal law.

(2) If an entity uses sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample but may not exceed 60 prescriptions.

(3) The audit may not take place during the first seven business days of the month unless consented to by the pharmacy.

(4) Auditors may not enter the pharmacy area where patient-specific information is available and must be out of sight and hearing range of the pharmacy customers.

(5) Any recoupment will not be deducted against future remittances and shall be invoiced to the pharmacy for payment.

(6) Recoupment may not be assessed for items on the face of a prescription not required by the Board of Pharmacy.

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

Sec. 4. **[151.64] REQUIREMENTS FOR RECOUPMENT OR CHARGEBACK.**

For recoupment or chargeback, the following criteria apply.

(1) Audit parameters must consider consumer-oriented parameters based on manufacturer listings.

(2) A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless an alternate price is published in the provider contract and signed by both parties.

(3) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(4) The entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits.

(5) Calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed or the prescriber denied authorization.

(6) An entity may not consider as fraud any clerical or record keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record; however, such errors may be subject to recoupment.

(7) In the case of errors that have no financial harm to the patient or plan, the PBM must not assess any chargebacks.

(8) Interest may not accrue during the audit period, beginning with the notice of the audit and ending with the final audit report.

Sec. 5. **[151.65] DOCUMENTATION.**

Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

Sec. 6. **[151.66] APPEALS PROCESS.**

The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports. If either party is not satisfied with the appeal, that party may seek mediation.

Sec. 7. **[151.67] AUDIT INFORMATION AND REPORTS.**

(a) A preliminary audit report must be delivered to the pharmacy within 30 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 30 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 90 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) No chargeback, recoupment, or other penalties may be assessed until the appeals process has been exhausted and the final report issued.

(e) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 30 days after the appeals process has been exhausted and the final audit report has been issued.

(f) Where not superseded by state or federal law, audit information may not be shared. Auditors shall have access to previous audit reports on a particular pharmacy conducted only by that same auditing entity.

Sec. 8. **[151.68] DISCLOSURES TO PLAN SPONSOR.**

An auditing entity must provide a copy of the final report to the plan sponsor whose claims were included in the audit, and any recouped money shall be returned to the plan sponsor.

Sec. 9. **[151.69] APPLICABILITY OF OTHER LAWS AND REGULATIONS.**

Sections 151.60 to 151.68 do not apply to any investigative audit that involves fraud, willful misrepresentation, or abuse, or any audit completed by Minnesota health care programs.