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 managed care company, insurance company, Medicare Part B audit contractors, third-party payor, pharmacy benefits manager, health program administered by a state agency, or any entity that represents such companies.

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

Subdivision 1. **Scope.** For the purposes of sections 151.60 to 151.66, the following terms have the meanings given.

Subd. 2. **Audit contractor.** "Audit contractor" means a contractor that detects and corrects improper payments for an entity.

Subd. 3. **Entity.** "Entity" means a managed care company, an insurance company, a third-party payor, a pharmacy benefits manager, or any other organization that represents these companies, groups, or organizations.

Subd. 4. **Insurance company.** "Insurance company" means any corporation, association, benefit society, exchange, partnership, or individual engaged as principal in the business of insurance.

Subd. 5. **Managed care company.** "Managed care company" means the entity or organization that handles health care and financing.

Subd. 6. **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 for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor of health program administered by a state agency.

Subd. 7. **State agency health program.** "State agency health program" means any program sponsored or administered by an agency of the state, except for Medicaid.

Subd. 8. **Third-party payor.** "Third-party payor" means an organization other than the patient or health care provider involved in the financing of personal health services.

Sec. 3. **[151.62] PHARMACY BENEFIT MANAGER CONTRACT.**

(a) A pharmacy benefit manager (PBM) contract that is altered or amended by that entity may be substituted for a current contract but is not effective without the written consent of a pharmacy. The pharmacy must receive a copy of the proposed contract changes or renewal along with a disclosure by the PBM of all material changes in terms of the contract or methods of reimbursement from the previous contract.

(b) An amendment or change in terms of an existing contract between a PBM and a pharmacy must be disclosed to the pharmacy at least 120 days prior to the effective date of the proposed change. A PBM may not alter or amend a PBM contract, or impose any additional contractual obligation on a pharmacy, unless the PBM complies with the requirements in this section.

Sec. 4. **[151.63] PROCEDURES FOR CONDUCTING AND REPORTING AN AUDIT.**

(a) Any entity conducting a pharmacy audit must follow the following procedures:

(1) a pharmacy must be given a written notice at least 14 business days 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) the period covered by the audit may not exceed 18 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is permitted under federal law;

(4) the PBM may not audit more than 40 prescriptions per audit;

(5) the audit may not take place during the first seven business days of the month due to the high volume of prescriptions filled during that time unless consented to by the pharmacy;

(6) the pharmacy may use the records of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery and includes a medication administration record;

(7) any legal prescription which 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 their agents;

(8) audit parameters must use consumer-oriented parameters based on manufacturer listings or recommendations as follows:

(i) day supply for eye drops, so that the consumer pays only one 30-day co-payment when the bottle of eye drops is intended by the manufacturer to be a 30-day supply;

(ii) when calculating the day supply for insulin, the highest dose prescribed must be used to determine the day supply and patient co-payments; and

(iii) when calculating the day supply for topical products, the pharmacist's judgment shall take precedence;

(9) 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;

(10) each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies;

(11) the commissioner of commerce shall address issues with questionable auditing practices;

(12) the entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports;

(13) if either party is not satisfied with the appeal, that party may seek mediation; and

(14) if copies of records are requested by the auditing entity, they will pay 25 cents per page to cover costs incurred to the pharmacy.

(b) The entity conducting the audit shall also comply with the following requirements:

(1) 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;

(2) the pharmacy must provide an area for auditors to conduct their business;

(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) in the case of errors which have no financial harm to the patient or plan, the PBM must not assess any chargebacks;

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

(6) the entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits;

(7) any recoupment will not be deducted against future remittances and shall be invoiced to the pharmacy for payment;

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

(9) the auditing company or agent may not receive payment based on a percentage of the amount recovered;

(10) interest may not accrue during the audit period, which begins with the notice of audit and ends with the final audit report;

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

(12) a person shall not be subject to criminal penalties for errors provided for in clause (11) without proof of intent to commit fraud;

(13) the commissioner of commerce may determine and assess a civil penalty for each violation of sections 151.60 to 151.64; and

(14) the commissioner of commerce may require the entity to make restitution to any person who has suffered financial injury because of the violation.

Sec. 5. **[151.64] 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 only have access to previous audit reports on a particular pharmacy conducted by that same auditing entity.

Sec. 6. **[151.65] 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 the money shall be returned to the plan sponsor and the co-payment shall be returned directly to the patient.

Sec. 7. **[151.66] APPLICABILITY OF OTHER LAWS AND REGULATIONS.**

(a) Sections 151.60 to 151.65 do not apply to any investigative audit that involves fraud, willful misrepresentation, or abuse, including without limitation:

(1) insurance fraud;

(2) billing for services not furnished or supplies not provided;

(3) billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both the beneficiary and the PBM or payor for the same service;

(4) altering claim forms, electronic claim records, and medical documentation to obtain a higher payment amount;

(5) soliciting, offering, or receiving a kickback or bribe;

(6) participating in schemes that involve collusion between a provider and a beneficiary, or between a supplier and a provider, and result in higher costs or charges to the entity;

(7) misrepresentations of dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services;

(8) billing for prescriptions without a prescription on file, when over-the-counter items are dispensed;

(9) dispensing prescriptions using outdated drugs;

(10) billing with the wrong National Drug Code (NDC) or billing for a brand name when a generic drug is dispensed;

(11) not crediting the payor for medications or parts of prescriptions that were not picked up within 14 days;

(12) billing the payor a higher price than the pharmacy's usual and customary charge to the general public; and

(13) billing for a product when there is no proof that the product was purchased.

(b) All cases of suspected fraud or violations of law must be reported by the auditor to the Board of Pharmacy.

Sec. 8. **EFFECTIVE DATE.**

Sections 1 to 7 apply to claims adjudicated on or after January 1, 2011.