

**Sixty-second Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 4, 2011**

HOUSE BILL NO. 1418
(Representatives Kasper, N. Johnson, Keiser, Vigesaa)
(Senators Wardner, Klein)

AN ACT to provide standards for audits of pharmacy records; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1.

Definitions.

For the purposes of this Act:

1. "Entity" means a managed care company, an insurance company, a third-party payer, a pharmacy benefits manager, or any other organization that represents an insurance company, a third-party payer, or a pharmacy benefits manager.
2. "Insurance company" includes any corporation, association, benefit society, exchange, partnership, or individual engaged as principal in the business of insurance.
3. "Managed care company" is an entity that handles both health care and health care financing.
4. "Pharmacy benefits manager" means a person that performs pharmacy benefits management and includes any other person acting for such person under 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 payer, or health program administered by a state agency.
5. "Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, 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.
6. "Third-party payer" means an organization other than the patient or health care provider involved in the financing of personal health services.

SECTION 2.

Pharmacy benefits manager audit - Rules.

1. An entity conducting an audit of a pharmacy shall:
 - a. If conducting an onsite audit, give the pharmacy a written notice at least fourteen business days before conducting an initial audit.
 - b. If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in any state and employed by or contracted with the pharmacy benefits manager.
 - c. Limit the audit to no more than twenty-four months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than twenty-four months from the date of the audit, unless a longer period is permitted under federal law.

- d. Refrain from conducting the audit during the first five business days of the month unless otherwise consented to by the pharmacy.
 - e. Refrain from entering the pharmacy area where patient-specific information is available and remain out of sight and hearing range of the pharmacy customers. The pharmacy shall designate an area for auditors to conduct their business.
 - f. Allow the pharmacy to use the records, including a medication administration record, of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery.
 - g. Allow the pharmacy to use any legal prescription, including medication administration records, electronic documents, or documented telephone calls from the prescriber or the prescriber's agents, to validate claims in connection with prescriptions and refills or changes in prescriptions.
2. An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the state board of pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs.
 3. A finding of overpayment or underpayment may be based only on the actual overpayment or underpayment and not on 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. A calculation of an overpayment may not include dispensing fees, unless a prescription was not dispensed or the prescriber denied authorization. In the case of an error that has no financial harm to the patient or plan, the pharmacy benefits manager may not assess any chargeback. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits. Any recoupment may not be deducted against future remittances and must be invoiced to the pharmacy for payment. An entity performing an audit may not receive payment based on a percentage of the amount recovered. Interest may not accrue during the audit period, which begins with the notice of audit and ends with the final audit report.
 4. A clerical or recordkeeping error may not be considered fraud, but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud.
 5. The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:
 - a. The day supply for eye drops must be calculated so that the consumer pays only one 30-day copayment if the bottle of eye drops is intended by the manufacturer to be a thirty-day supply.
 - b. The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment.
 - c. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area.
 6. Unless an alternate price is published in a provider contract and signed by both parties, the usual and customary price charged by a pharmacy for compounded medications is considered to be the reimbursable cost.
 7. An entity conducting an audit shall utilize the same standards and parameters in auditing a pharmacy the entity uses with other similarly situated pharmacies.
 8. An entity conducting an audit shall establish a written appeals process.

SECTION 3.

Audit reports - Disclosure - Distribution of recouped funds - Review of auditor.

1. A preliminary audit report must be delivered to the pharmacy within one hundred twenty days after the conclusion of the audit.
2. A pharmacy must be allowed at least sixty days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.
3. A final audit report must be delivered to the pharmacy within ninety days after receipt of the preliminary audit report or final appeal, whichever is later.
4. No chargeback, recoupment, or other penalty may be assessed until the appeal process has been exhausted and the final report issued.
5. An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty days after the appeals process has been exhausted and the final audit report has been issued.
6. An auditing entity shall provide a copy of the final report to the plan sponsor for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor.

SECTION 4.

Applicability.

1. This Act applies to claims adjudicated after July 31, 2011.
2. This Act does not apply to any audit, review, or investigation that is initiated based upon alleged fraud, willful misrepresentation, or abuse, including:
 - a. Insurance fraud as defined in chapter 26.1-02.1.
 - b. Billing for services not furnished or supplies not provided.
 - c. Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both the beneficiary and the pharmacy benefits manager or payer for the same service.
 - d. Altering claim forms, electronic claim records, or medical documentation to obtain a higher payment amount.
 - e. Soliciting, offering, or receiving a kickback or bribe.
 - f. Participating in any scheme that involves collusion between a provider and a beneficiary or between a supplier and a provider which results in higher costs or charges to the entity.
 - g. Misrepresenting a date or description of services furnished or the identity of the beneficiary or the individual who furnished the services.
 - h. Billing for a prescription without a prescription on file in a situation in which an over-the-counter item is dispensed.
 - i. Dispensing a prescription using an out-of-date drug.
 - j. Billing with an incorrect national drug code or billing for a brand name when a generic drug is dispensed.

- k. Failing to credit the payer for a medication or a portion of a prescription that was not obtained by the payer within fourteen days unless extenuating circumstances exist.
 - l. Billing the payer a higher price than the usual and customary charge of the pharmacy to the general public.
 - m. Billing for a product without proof that the purchaser purchased the product.
3. Any case of suspected fraud or violation of law must be reported by an auditor to the licensing board.
 4. This Act does not apply to state medicaid programs.

SECTION 5.

Penalty.

Any person violating this Act is guilty of a class B misdemeanor.

Speaker of the House

President of the Senate

Chief Clerk of the House

Secretary of the Senate

This certifies that the within bill originated in the House of Representatives of the Sixty-second Legislative Assembly of North Dakota and is known on the records of that body as House Bill No. 1418.

House Vote: Yeas 92 Nays 2 Absent 0

Senate Vote: Yeas 47 Nays 0 Absent 0

Chief Clerk of the House

Received by the Governor at _____ M. on _____, 2011.

Approved at _____ M. on _____, 2011.

Governor

Filed in this office this _____ day of _____, 2011,

at _____ o'clock _____ M.

Secretary of State