

**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 notice 14 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 licensed pharmacist.
- (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 required under state or federal law.
- (2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit.
- (3) An on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy.
- (4) Auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy 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 the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:
  - (i) additional information is required in the provider manual; or
  - (ii) the information is required by the Food and Drug Administration (FDA); or
  - (iii) the information is required by the drug manufacturer's product safety program; and
  - (iv) the information in clause (i), (ii), or (iii) is not readily available for the auditor at the time of the audit.
- (7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:
  - (i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

**History:** *2012 c 215 s 4*