

INDIANA REGULATORY ADDENDUM – Pharmacy Audit Practices

Limitations on Frequency of Onsite Audits (IN ST 25-26-22-4.2):

- a) A third party payer may cause an onsite audit to occur at a particular pharmacy location not more than one (1) time per calendar year.
- b) A company that conducts an audit for a third party payer may conduct an onsite audit at a particular pharmacy location not more than one (1) time per calendar year for each third party payer. However, if the audit results in a finding of a particular problem at the pharmacy, the auditor may return within the calendar year to determine ongoing compliance.

General Requirements (IN ST 25-26-22-5):

An auditor conducting an audit shall comply with all of the following:

- 1) The contract under which the audit is performed must provide a description of audit procedures that will be followed.
- 2) For an onsite audit conducted at a pharmacy's location, the auditor that conducts the audit shall provide written notice to the pharmacy at least two (2) weeks before the initial onsite audit is performed for each audit cycle.
- 3) The auditor shall not interfere with the delivery of pharmacist services to a patient and shall use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the pharmacy.
- 4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with a licensed pharmacist.
- 5) The auditor shall allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record with respect to a prescription for a legend drug.
- 6) The auditor shall perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies on behalf of the third party payer.
- 7) The period covered by the audit must not exceed twenty-four (24) months after the date on which the claim that is the subject of the audit was submitted to or adjudicated by the third party payer, and the pharmacy must be permitted to resubmit electronically any claims disputed by the audit. This subdivision does not limit the period for audits under the Medicaid program that are conducted due to a federal requirement.
- 8) The audit must not be initiated or scheduled during the first seven (7) calendar days of any month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or any other means.
- 9) Payment to the onsite auditor for conducting the audit must not be based on a percentage of any amount recovered as a result of the audit.
- 10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) day period, the auditor shall select and reschedule the audit for a date after the fourteen (14) day period.
- 11) This subdivision does not apply to an audit conducted by the Medicaid program. If a clerical error is identified by the auditor during the course of an audit, the auditor shall allow the pharmacy to obtain a prescription that corrects the clerical error from the prescribing physician. However, if the clerical error

results in an overpayment to the pharmacy, the overpayment may be recouped by the third party payer.

Audit Reports (IN ST 25-26-22-6):

- a) This section does not apply to an audit conducted by the Medicaid, Medicare, or any other federal program.
- b) Following an audit, the auditor shall provide to the pharmacy written audit reports as follows:
 - 1) The auditor shall deliver a preliminary audit report to the pharmacy not later than ninety (90) days after the audit is concluded.
 - 2) The auditor shall provide with the preliminary audit report a written appeal procedure for the pharmacy to follow if the pharmacy desires to appeal a finding contained in the preliminary audit report. The written appeal procedure must provide for a period of at least thirty (30) days after the pharmacy receives the preliminary audit report during which the pharmacy may file an appeal of findings contained in the preliminary audit report.
 - 3) The auditor shall deliver a final audit report to the pharmacy not later than one hundred twenty (120) days after:
 - A. the preliminary audit report is received by the pharmacy; or
 - B. if an appeal is filed, a final appeal determination is made;whichever is later.
 - 4) Each audit report must be signed by the auditor and a pharmacist participating in the audit.
 - 5) The auditor shall provide a copy of the final audit report to the third party payer.
- c) If requested by the pharmacy, the auditor shall provide the audit report under this section to the pharmacy by a means that allows signature confirmation, including an electronic signature (as defined by IC 25-26-13-2). If the audit report is sent by electronic mail, any other verification system may be used, provided that the receipt is acknowledged by the pharmacy.

Clerical Errors (IN ST 25-26-22-7):

- a) A clerical error related to or contained in a document that is necessary to the conduct of an audit does not constitute fraud without proof of intent to commit fraud.
- b) A clerical error that results in inappropriate payment of a claim by the third party payer may result in recoupment of any inappropriately made payment.

Overpayment or Underpayment of Claim (IN ST 25-26-22-8)

An audit finding of an overpayment or underpayment of a claim:

- 1) must be based on an actual overpayment or underpayment; and
- 2) may not be based on a projection that is based on the number of:
 - A. patients who:
 - i. have similar diagnoses; and
 - ii. are served by the pharmacy; or
 - B. prescriptions for or refills of similar legend drugs that are dispensed by the pharmacy.

Final Audit Report (IN ST 25-26-22-9)

- a) This section does not apply to an audit conducted by the Medicaid, Medicare, or any other federal program.
- b) Before recoupment of funds may be made based on an audit finding of overpayment or underpayment:
 - 1) a final audit report must be distributed; and
 - 2) except when an audit finds that fraud, willful misrepresentation, or alleged serious abuse has occurred,

at least thirty (30) days must elapse after the date on which the final audit report is distributed before the recoupment of funds exceeding ten thousand dollars (\$10,000).

- c) Interest on funds described in subsection (b) does not accrue during the audit period.

Results of Extrapolation Audit (IN ST 25-26-22-10)

The results of an extrapolation audit may not be used by an auditor as a basis for calculating overpayment or underpayment recoupments or penalties.

Investigative Audits (IN ST 25-26-22-11)

[The auditing provisions do] not apply to an investigative audit conducted for purposes of determining whether fraud, willful misrepresentation, or alleged serious abuse has occurred.

Pharmacy Benefit Manager; Duties; Appeal (IN ST 27-1-24.5-22(b)(5)):

- ...
- (5) The establishment of procedures for auditing submitted claims by a contracted pharmacy in a manner established by administrative rules under IC 4-22-2 by the department. The auditing procedures:
 - A. may not use extrapolation or any similar methodology;
 - B. may not allow for recovery by a pharmacy benefit manager of a submitted claim due to clerical or other error where the patient has received the drug for which the claim was submitted;
 - C. must allow for recovery by a contracted pharmacy for underpayments by the pharmacy benefit manager; and
 - D. may only allow for the pharmacy benefit manager to recover overpayments on claims that are actually audited and discovered to include a recoverable error.

Limitations (760 IAC 5-3-2):

- a) A pharmacy benefit manager may cause an audit to occur at a particular pharmacy location not more than one (1) time per calendar year. However, if the audit results in a finding of material noncompliance at the pharmacy, the pharmacy benefit manager or auditor may return within the calendar year to determine ongoing compliance.
- b) An independent auditor that conducts an audit on behalf of a pharmacy benefit manager may conduct an audit at a particular pharmacy location not more than one (1) time per calendar year for each pharmacy benefit manager. However, if the audit results in a finding of material noncompliance at the pharmacy, the auditor may return within the calendar year to determine ongoing compliance.
- c) A pharmacy benefit manager may not conduct an audit at a particular pharmacy location and engage an independent auditor to conduct an audit on behalf of the pharmacy benefit manager at the same pharmacy location within the same calendar year. However, if an audit results in a finding of material noncompliance at the pharmacy, the pharmacy benefit manager or auditor may return within the calendar year to determine ongoing compliance.

Conduct of Audit (760 IAC 5-3-3):

An auditor conducting an audit must comply with all of the following:

- 1) The contract under which the audit is performed must provide a description of audit procedures that will be followed.
- 2) For an onsite audit conducted at a pharmacy's location, the auditor that conducts the audit must provide written notice to the pharmacy or pharmacist at least fourteen (14) calendar days before conducting the initial onsite audit for each audit cycle.
- 3) The auditor must not interfere with the delivery of pharmacist services to a patient, and must use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This

subdivision does not prohibit audits during normal business hours of the pharmacy.

- 4) If the audit requires use of clinical or professional judgment, the audit must be conducted by or in consultation with an individual licensed as a pharmacist under IC 25-26.
- 5) The auditor must allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record.
- 6) The auditor must perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies.
- 7) The period covered by the audit must not exceed twenty-four (24) months after the date on which a claim that is the subject of the audit was submitted to or adjudicated by the pharmacy benefit manager, unless a longer period is required under federal or state law. The pharmacy must be permitted to resubmit electronically any claims disputed by the audit. Audit procedures must provide for a period of at least thirty (30) calendar days during which the pharmacy may resubmit a disputed claim.
- 8) The auditor must not schedule an audit to begin during the first seven (7) calendar days of a month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or other means.
- 9) Payment to the auditor for conducting the audit must not be based on a percentage of the amount recovered as a result of the audit.
- 10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) calendar days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) calendar day period, the auditor must select and reschedule the audit for a date after the fourteen (14) calendar day period.
- 11) The auditor must allow a pharmacy or pharmacist to produce documentation to address a discrepancy found during the audit.

Written Audit Reports (760 IAC 5-3-4):

Following an audit, an auditor must provide to the pharmacy written audit reports as follows:

- 1) Deliver the preliminary audit report to the pharmacy or pharmacist not later than ninety (90) calendar days after the audit is concluded, with reasonable extensions allowed.
- 2) Provide with the preliminary audit report a written appeal procedure for the pharmacy to follow if the pharmacy desires to appeal a finding contained in the preliminary audit report. The written appeal procedure must provide for a period of at least thirty (30) calendar days after the pharmacy receives the preliminary audit report, during which the pharmacy may file an appeal of findings contained in the preliminary audit report.
- 3) Deliver a final audit report to the pharmacy or pharmacist not later than one hundred twenty (120) calendar days after:
 - A. the preliminary audit report is received by the pharmacy; or
 - B. if an appeal is filed, a final appeal determination is made;

whichever is later.

Clerical Errors; Fraud; Recoupment of Payment (760 IAC 5-3-5)

- a) A clerical or record keeping error, such as a typographical error, scrivener's error, or computer error related to or contained in a document that is necessary to the conduct of an audit, does not constitute fraud without proof of intent to commit fraud.
- b) If a clerical error is identified during the course of an audit, the pharmacy must be allowed to obtain a prescription that corrects the clerical error from the prescriber.
- c) A clerical or record keeping error may not result in the recoupment of payment if the patient has received the drug for which the claim was submitted.

Overpayment and Underpayment Audit Findings (760 IAC 5-3-6):

An audit finding of an overpayment or underpayment of a claim:

- 1) must be based on an actual overpayment or underpayment of an audited claim discovered to include a recoverable error;
- 2) must not be based on a projection that is based on the number of:
 - A. patients who:
 - i. have similar diagnoses; and
 - ii. are served by the pharmacy; or
 - B. prescriptions for or refills of similar prescription drugs that are dispensed by the pharmacy; and
- 3) must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee.

Audit Report; Distribution; Interest Accrual (760 IAC 5-3-7):

- a) Before recoupment of funds may be made based on an audit finding of overpayment or underpayment:
 - 1) a final audit report must be distributed; and
 - 2) except when an audit finds that fraud, willful misrepresentation, or alleged serious abuse has occurred, at least thirty (30) calendar days must elapse after the date on which the final audit report is distributed before the recoupment of funds exceeding ten thousand dollars (\$10,000).
- b) A pharmacy benefit manager must remit all monies due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty (30) calendar days after the final audit report has been delivered to the pharmacy or pharmacist.
- c) Interest on funds described in this section does not accrue during the audit and appeal period.

Prohibition on Use of Extrapolation for Calculating Recoupments or Penalties (760 IAC 5-3-8):

The results of an extrapolation audit or any similar methodology may not be used by an auditor as a basis for calculating overpayment or underpayment recoupments or penalties, unless required by state or federal law.

Internal Appeal Process (760 IAC 5-3-9):

- a) An auditor must establish an internal appeal process under which a pharmacy or pharmacist may appeal a disputed claim in a preliminary audit report.
- b) Under the internal appeals process, an auditor must allow a pharmacy or pharmacist to request an internal appeal within thirty (30) calendar days after receipt of a preliminary audit report, with reasonable extensions allowed.
- c) An auditor must include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person or entity to whom an internal appeal should be addressed.
- d) The decision of the auditor on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist must be reflected in the final audit report.
- e) An auditor must deliver a final audit report to a pharmacy or pharmacist not later than one hundred twenty (120) calendar days after a final appeal determination is made. The final report must include a final accounting of all monies to be recovered or returned by the pharmacy benefit manager.

Use of Third Party Auditors (760 IAC 5-3-10):

The acts of an independent auditor are considered to be the acts of the pharmacy benefit manager on whose behalf the independent auditor is acting.