



Ohio Legislative Service Commission

Bill Analysis

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S.B. 258

130th General Assembly
(As Introduced)

Sen. Balderson

BILL SUMMARY

- Requires notice to be given if a pharmacy audit is to be conducted on the premises of a pharmacy.
- Prohibits a pharmacy audit from being performed during the first five business of the month, unless otherwise agreed to by the pharmacy.
- Specifies transactions over two years old cannot be subject to audit.
- Prohibits an auditing entity or payer from seeking to recoup from a pharmacy any amount that the audit identifies as being the result of clerical or record keeping errors, absent an indication that there was an error in the dispensing of a drug.
- Prohibits auditing entities from using the accounting practice of extrapolation when calculating monetary penalties or amounts to be recouped.
- Specifies how a pharmacy may validate a pharmacy record or claims for payment.
- Enables a pharmacy to resubmit a disputed or denied claim for payment, so long as the time period for resubmission has not expired.
- Requires auditing entities to submit a preliminary report to pharmacies prior to completing the final report.
- Enables a pharmacy to dispute the preliminary report.
- Requires pharmacies to submit a final report.

CONTENT AND OPERATION

Overview

The bill establishes requirements in relation to entities that audit pharmacies. These entities are often hired by third-party payers, such as health insurers, to ensure that claims and payments have been made correctly.

Conducting an audit

The bill requires that if it is necessary for a pharmacy audit to be performed on the premises of a pharmacy, the auditing entity is required to give the pharmacy written notice of the date or dates on which the audit will be performed and the range of prescription numbers from which the auditing entity will select pharmacy records to audit. This notice is to be given not less than ten business days before the date the audit is to commence. The bill stipulates that a pharmacy audit is not to be performed during the first five business days of a calendar month unless the pharmacy that is the subject of the audit consents to the audit being performed during those days. These two conditions do not apply if, prior to the audit, the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.¹

The bill specifies that an auditing entity is not to include in the pharmacy audit a review of a claim for payment for the provision of dangerous drugs or pharmacy services that occurred two years before the date the audit commences.²

Absent an indication that there was an error in the dispensing of a drug, the auditing entity or payer (insurer) is not to seek to recoup from a pharmacy that is being audited any amount that the pharmacy audit identifies as being the result of clerical or recordkeeping errors. For purposes of this provision, an error in the dispensing of a drug is any of the following:

- Selecting an incorrect drug;
- Issuing incorrect directions;
- Dispensing a drug to the incorrect patient.³

¹ R.C. 3901.411(A)(1) and (2) and (B)(1).

² R.C. 3901.411(A)(3).

³ R.C. 3901.411(A)(4).



This provision does not apply if the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.⁴

The bill prohibits an auditing entity from using the accounting practice of extrapolation when calculating a monetary penalty to be imposed or amount to be recouped as the result of the pharmacy audit. This provision does not apply unless it is required by state or federal law.⁵

The bill subjects an auditing entity to the preceding requirements when the auditing entity is performing a pharmacy audit in Ohio on or after April 1, 2014.⁶

Rights of the audited pharmacy

The bill authorizes a pharmacy to do any of the following when a pharmacy audit is performed:

- Validate a pharmacy record by using original or photocopied records from hospitals, physicians, or other health care providers;⁷
- Validate one or more claims for payment for the provision of dangerous drugs or pharmacy services by using either of the following:
 - An original pharmacy record or photocopy of the record;
 - An original prescription or photocopy of the prescription in any form that constitutes a valid prescription in this state, including a written prescription, a prescription made through an electronic prescribing system, a prescription delivered by facsimile, a prescription made by issuing an order for medication administration, and the record a pharmacist maintains as required by law, documenting a prescription received by telephone.⁸

⁴ R.C. 3901.411(B)(2).

⁵ R.C. 3901.411(A)(5) and (B)(3).

⁶ R.C. 3901.411(A).

⁷ R.C. 3901.412(A).

⁸ R.C. 3901.412(B).

- Resubmit a disputed or denied claim for payment using any commercially reasonable method of resubmission, including resubmission by facsimile, mail, or electronic means, as long as the time period for resubmissions established by the relevant payer has not expired.⁹

After the audit

The bill establishes requirements that apply only after an audit has been completed. However, these provisions do not apply if the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.¹⁰

Not later than 60 business days after the audit is completed, an auditing entity must deliver a preliminary audit report to the pharmacy that was the subject of the audit. A pharmacy that disputes any finding in the preliminary audit report may submit documentation to the auditing entity to appeal the finding. A pharmacy is to be given not less than 30 business days to make the submission and may request an extension of the time period given. The auditing entity is to grant a request for an extension if it is reasonable.¹¹

Each auditing entity in Ohio is to establish in writing separate procedures for a pharmacy to appeal one or more findings in a preliminary audit report. A pharmacy's submission of documentation to appeal the finding is to be made in accordance with the procedure of the entity conducting the audit.¹²

An auditing entity is to deliver a final audit report to the pharmacy that was the subject of the audit. The report is to be delivered not later than 120 business days after a pharmacy's receipt of a preliminary audit report.¹³ However, if an auditing entity has granted a pharmacy's request for an extension of the time to submit documentation to appeal a finding in the preliminary audit report, the time limit for the delivery of the

⁹ R.C. 3901.412(C).

¹⁰ R.C. 3901.413(B).

¹¹ R.C. 3901.413(A)(1) and (2).

¹² R.C. 3901.413(A)(2) and 3901.414.

¹³ See **COMMENT**.



final audit report is waived and the auditing entity is to deliver the final audit report not later than 120 days after the pharmacy's submission of the documentation.¹⁴

Definitions

The bill makes the following definitions in relation to the regulation of pharmacy auditing entities.¹⁵

"Auditing entity" means any person or government entity that performs a pharmacy audit, including a payer, a pharmacy benefit manager, or a licensed third-party administrator.

"Business day" means any day of the week excluding Saturday, Sunday, and a legal holiday.

"Concurrent review" means a temporary electronic review of claims for payment for the provision of dangerous drugs or pharmacy services conducted at the point of sale.

"Dangerous drug" means any of the following:

- Any drug to which either of the following applies: (1) under the "Federal Food, Drug, and Cosmetic Act," the drug may be dispensed only upon a prescription or the drug is required to bear a label stating that federal law prohibits dispensing without prescription or the order of a licensed veterinarian or a similar restrictive statement, or (2) under the Ohio Pure Food and Drug Law or the Ohio Controlled Substances Law, the drug may be dispensed only upon a prescription;
- Any drug that contains a Schedule V controlled substance and that is exempt from the Ohio Controlled Substances Law or to which that Law does not apply;
- Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

"Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of those places where the practice of pharmacy is conducted.

¹⁴ R.C. 3901.413(B)(3).

¹⁵ R.C. 3901.41.



"Practice of pharmacy" means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences.

"Prescription" means a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs.

"Payer" means any of the following that pays for or processes a claim for payment for the provision of dangerous drugs or pharmacy services:

- A health insuring corporation;
- A person authorized to engage in the business of sickness and accident insurance in Ohio;
- A person or government entity providing coverage of dangerous drugs or pharmacy services to individuals on a self-insurance basis;
- A group health plan;
- A service benefit plan;
- The Medicaid program, including a Medicaid managed care organization that has entered into a contract with the Department of Medicaid;
- Any other person or government entity that is, by law, contract, or agreement, responsible for paying for or processing a claim for payment for the provision of dangerous drugs or pharmacy services.

"Pharmacy audit" means a review of one or more pharmacy records conducted by an auditing entity, one purpose of which is to identify discrepancies in claims for payment for the provision of dangerous drugs or pharmacy services. "Pharmacy audit" does not include a concurrent review for which the auditing entity does not demand to recoup from the pharmacy any amount.

"Pharmacy benefit manager" means a person that provides administrative services related to the processing of claims for payment for the provision of dangerous drugs or pharmacy services, including performing pharmacy audit compliance, negotiating pharmaceutical rebate agreements, developing and managing drug formularies and preferred drug lists, and administering programs for payers' prior

authorization of claims for payment for the provision of dangerous drugs or pharmacy services.

"**Pharmacy record**" means any record stored electronically or as a hard copy by a pharmacy that relates to the provision of dangerous drugs or pharmacy services or any other component of pharmacist care that is included in the practice of pharmacy.

COMMENT

The text of this provision states "the report shall be delivered not later than one hundred and twenty days after *the later of* a pharmacy's receipt of a preliminary audit report" (emphasis added). This appears to be a drafting error.

HISTORY

ACTION	DATE
Introduced	01-08-14

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