



# Ohio Legislative Service Commission

## Bill Analysis

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### **Am. Sub. S.B. 258\***

130th General Assembly

(As Rereported by H. Rules and Reference)

**Sens.** Balderson, Beagle, Brown, Coley, Gentile, Hite, LaRose, Lehner, Oelslager, Patton, Peterson, Schaffer, Uecker

**Reps.** Brown, Bishoff, Wachtmann

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## **BILL SUMMARY**

### **Pharmacy audits**

- Requires notice to be given if a pharmacy audit is to be conducted on the premises of a pharmacy.
- Specifies that claims for payment over two years old cannot be included in a pharmacy audit.
- Prohibits an auditing entity or payer from seeking to recoup amounts from a pharmacy when the audit identifies a clerical or record-keeping error that caused no financial harm, absent an indication that there was an error in the dispensing of a drug.
- Prohibits, generally, 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 claim for payment.
- Permits 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.

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\* This analysis was prepared before the report of the House Rules and Reference Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- Authorizes a pharmacy to appeal findings in the preliminary report.
- Requires auditing entities to submit a final report to audited pharmacies.
- Excludes Medicaid managed care organizations from the provisions governing pharmacy auditing procedures if application of the provisions would violate federal law.

### **Analgesic controlled substances in the practice of optometry**

- Allows optometrists to continue to administer and prescribe certain analgesic controlled substances that are currently used in the practice of optometry.

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## **CONTENT AND OPERATION**

### **PHARMACY AUDITS**

#### **Overview**

The bill establishes requirements for entities that audit pharmacies. These entities are often used 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 must 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. Notice of the date or dates on which the audit is to be performed is to be given not less than ten business days before the date the audit is to commence. Notice of the range of prescription numbers is to be given not less than seven business days before the audit is to begin. These notice requirements 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.<sup>1</sup>

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

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<sup>1</sup> R.C. 3901.811(A)(1) and (B)(1).



services if the initial claim was submitted more than 24 months before the date the audit commences.<sup>2</sup>

Absent an indication that there was an error in the dispensing of a drug, the auditing entity or payer (insurer) cannot recoup from a pharmacy that is being audited any amount that the pharmacy audit identifies as being the result of clerical or recordkeeping errors in the absence of financial harm. Under 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.<sup>3</sup>

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.<sup>4</sup>

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 a pharmacy audit. However, the bill specifies that this provision does not apply when the accounting practice of extrapolation is required by state or federal law.<sup>5</sup>

### **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;<sup>6</sup>
- Validate one or more claims for payment for the provision of dangerous drugs or pharmacy services by using either of the following:

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<sup>2</sup> R.C. 3901.811(A)(2).

<sup>3</sup> R.C. 3901.811(A)(3).

<sup>4</sup> R.C. 3901.811(B)(2).

<sup>5</sup> R.C. 3901.811(A)(4) and (B)(3).

<sup>6</sup> R.C. 3901.812(A).



- 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 Ohio, 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 must maintain to document a prescription received by telephone.<sup>7</sup>
- 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.<sup>8</sup>

## **After the audit**

The bill establishes requirements regarding preliminary audit reports, appeals of findings, and final audit reports. 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.<sup>9</sup>

### **Preliminary report**

Under the bill, a pharmacy is to be given at least 30 days from the date of the on-site audit to provide the auditing entity any additional information necessary to complete the preliminary audit report. 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.<sup>10</sup>

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<sup>7</sup> R.C. 3901.812(B).

<sup>8</sup> R.C. 3901.812(C).

<sup>9</sup> R.C. 3901.813(B).

<sup>10</sup> R.C. 3901.813(A)(1), (2), and (3).

## Appeal procedures

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.<sup>11</sup>

## Final report

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. 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 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.<sup>12</sup>

## Medicaid exemption

The bill specifies that the bill's requirements do not apply to a Medicaid managed care organization if application of the requirements would be in violation of federal law.<sup>13</sup>

## Definitions

The bill defines the following terms in relation to the regulation of pharmacy auditing entities.<sup>14</sup>

**"Auditing entity"** – 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"** – any day of the week excluding Saturday, Sunday, and a legal holiday.

**"Concurrent review"** – a claims review within five business days of submission of claims for payment for the provision of dangerous drugs for which the payer or the

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<sup>11</sup> R.C. 3901.813(A)(3) and 3901.814.

<sup>12</sup> R.C. 3901.813(A)(4)(b).

<sup>13</sup> R.C. 3901.815.

<sup>14</sup> R.C. 3901.81.



auditing entity does not impose a penalty or demand to recoup money from the pharmacy in any amount.

**"Dangerous drug"** – a drug that is any of the following:

- A 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 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;
- A 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;
- A drug intended for administration by injection into the human body other than through a natural orifice of the human body.

**"Pharmacy"** – any area, room, rooms, place of business, department, or portion of any of those places where the practice of pharmacy is conducted.

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

**"Prescription"** – 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"** – 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;
- 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**" – 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 concurrent review.

"**Pharmacy benefit manager**" – 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**" – 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.

## **OPTOMETRISTS**

### **Analgesic controlled substances in the practice of optometry**

The bill allows optometrists to continue using in the practice of optometry certain analgesics (pain-relieving drugs) that are controlled substances and could be used by optometrists before the bill's effective date. This continued authority applies in the case of (1) drugs with limited amounts of codeine or hydrocodone and (2) drugs that currently are not controlled substances but become reclassified as such after the bill's effective date.<sup>15</sup>

#### **Categories of authorized analgesics**

Under current law, an optometrist who holds a therapeutic pharmaceutical agents certificate from the State Board of Optometry may employ, apply, administer, and prescribe analgesics in any of the following categories:

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<sup>15</sup> R.C. 4725.01 and 4725.091.

(1) Analgesics available without a prescription;

(2) Analgesics that require a prescription but are not controlled substances;

(3) To the extent authorized by Board rules, analgesics that are schedule III controlled substances in the narcotics-narcotic preparations category,<sup>16</sup> which includes drugs with limited amounts of codeine, dihydrocodeinone, ethylmorphine, opium, and morphine.<sup>17</sup>

Regarding schedule III controlled substances, the Board has adopted rules permitting optometrists to the use of the following drugs, with prescriptions for the drugs being limited to a four-day supply per episode of injury, illness, or treatment:

- **Codeine** – A preparation used for the treatment of pain that contains not more than 60 milligrams of codeine per dosage unit and also contains other active nonnarcotic ingredients, such as acetaminophen or aspirin, in a recognized therapeutic amount.
- **Hydrocodone** – A preparation used for the treatment of pain that contains not more than 7.5 milligrams of hydrocodone per dosage unit and also contains other active nonnarcotic ingredients, such as acetaminophen, aspirin, or ibuprofen, in a recognized therapeutic amount.<sup>18</sup>

On October 6, 2014, hydrocodone-combination products were rescheduled as schedule II controlled substances under both federal and state law.<sup>19</sup>

### **Continuation of authority to use controlled substances**

The bill specifies in statute the analgesic controlled substances that the Board has permitted, by rule, to be included in the practice of optometry under a therapeutic pharmaceutical agents certificate. In doing so, the bill removes references to schedule III controlled substances and, thereby, clarifies that optometrists retain authority to use hydrocodone-combination products that are now schedule II controlled substances. In addition to analgesics that contain codeine or hydrocodone, the bill permits the Board's

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<sup>16</sup> R.C. 4725.091(B)(1)(b).

<sup>17</sup> R.C. 3719.41(D), not in the bill.

<sup>18</sup> Ohio Administrative Code 4725-16-03.

<sup>19</sup> Ohio State Board of Pharmacy, *Rescheduling of Hydrocodone Combination Products Effective October 6, 2014* (available at <<http://www.pharmacy.ohio.gov/Documents/Pubs/Special/GuidanceDocs/Rescheduling%20of%20Hydrocodone%20Combination%20Products%20Effective%20October%206,%202014%20-%2008.28.2014.pdf>>).



rules to include an analgesic drug that currently is not a controlled substance, but becomes scheduled as a controlled substance after the bill's effective date.

Specifically, the provisions described above apply to the use an analgesic controlled substance for the treatment of pain if it meets one of the following conditions:

(1) The product is a preparation that contains an amount of codeine per dosage unit, as specified by the Board, and also contains other active, nonnarcotic ingredients, such as acetaminophen or aspirin, in a therapeutic amount;

(2) The product is a preparation that contains an amount of hydrocodone per dosage unit, as specified by the Board, and also contains other active, nonnarcotic ingredients, such as acetaminophen, aspirin, or ibuprofen, in a therapeutic amount;

(3) The product contains or consists of a drug or dangerous drug that was an analgesic included in the practice of optometry under a therapeutic pharmaceutical agents certificate immediately prior to the bill's effective date, was not a controlled substance at that time, and subsequently becomes a schedule II, III, IV, or V controlled substance.

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## HISTORY

ACTION	DATE
Introduced	01-08-14
Reported, S. Insurance and Financial Institutions	03-25-14
Passed Senate (30-0)	03-25-14
Reported, H. Health & Aging	06-04-14
Rereported, H. Rules & Reference	---

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