As Reported by the Senate Insurance and Financial Institutions Committee

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Am. S. B. No. 258

Senator Balderson

A B I L L

To enact sections 3901.41, 3901.411, 3901.412, 3901.413, 3901.414, and 3901.415 of the Revised Code to establish standards for the performance of pharmacy audits in Ohio.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3901.41, 3901.411, 3901.412, 3901.413, 3901.414, and 3901.415 of the Revised Code be enacted to read as follows:

Sec. 3901.41. As used in this section and sections 3901.411 to 3901.415 of the Revised Code:

(A) "Auditing entity" means any person or government entity that performs a pharmacy audit, including a payer, a pharmacy benefit manager, or a third-party administrator licensed under Chapter 3959. of the Revised Code.

(B) "Business day" means any day of the week excluding Saturday, Sunday, and a legal holiday, as defined in section 1.14 of the Revised Code.

(C) "Concurrent review" means 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 auditing

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

(D) "Dangerous drug," "pharmacy," "practice of pharmacy," and "prescription" have the same meanings as in section 4729.01 of the Revised Code.

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

(1) A health insuring corporation, as defined in section 1751.01 of the Revised Code;

(2) A person authorized to engage in the business of sickness and accident insurance under Title XXXIX of the Revised Code;

(3) A person or government entity providing coverage of dangerous drugs or pharmacy services to individuals on a self-insurance basis;

(4) A group health plan, as defined in 29 U.S.C. 1167;

(5) A service benefit plan, as referenced in 42 U.S.C. 1396a(a)(25);

(6) A medicaid managed care organization that has entered into a contract with the department of medicaid pursuant to section 5167.10 of the Revised Code;

(7) 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.

(F) "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 concurrent review.

(G) "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.

(H) "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.

Sec. 3901.411. (A) Except as provided in division (B) of this section, an auditing entity is subject to all of the following conditions when performing a pharmacy audit in this state on or after April 1, 2014:

(1) If it is necessary that the pharmacy audit be performed on the premises of a pharmacy, the auditing entity shall give the pharmacy that is the subject of the audit 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 will be performed shall be given not less than ten business days before the date the audit is to commence. Notice of the range of prescription numbers from which the auditing entity will select pharmacy records to audit shall be received by the pharmacy not less than seven business days before the date of the audit is to commence.

(2) The auditing entity shall not include in the pharmacy audit a review of a claim for payment for the provision of dangerous drugs or pharmacy services if the date of the pharmacy's

initial submission of the claim for payment occurred more than twenty-four months before the date the audit commences.

(3) Absent an indication that there was an error in the dispensing of a drug, the auditing entity or payer shall not seek to recoup from the pharmacy that is the subject of the audit any amount that the pharmacy audit identifies as being the result of clerical or recordkeeping errors in the absence of financial harm. 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, or dispensing a drug to the incorrect patient.

(4) The auditing entity shall not use 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.

(B)(1) The condition in division (A)(1) of this section does 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.

(2) The condition in division (A)(3) of this section 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.

(3) Division (A)(4) of this section does not apply when the accounting practice of extrapolation is required by state or federal law.

Sec. 3901.412. A pharmacy may do any of the following when a pharmacy audit is performed:

(A) Validate a pharmacy record by using original or photocopied records from hospitals, physicians, or other health care providers;

(B) Validate one or more claims for payment for the provision of dangerous drugs or pharmacy services by using either of the following:

(1) An original pharmacy record or photocopy of the record;

(2) 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 under section 4729.37 of the Revised Code documenting a prescription received by telephone.

(C) 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.

Sec. 3901.413. (A) Except as provided in division (B) of this section, all of the following apply after a pharmacy audit is completed:

(1) A pharmacy shall be given not less than thirty days from the date of the on-sight audit to provide the auditing entity any additional information necessary to complete the preliminary audit report.

(2) Not later than sixty business days after the audit is completed, the auditing entity shall deliver a preliminary audit report to the pharmacy that was the subject of the audit.

(3) A pharmacy that disputes any finding in the preliminary audit report may submit documentation to the auditing entity to appeal the finding. A pharmacy shall be given not less than thirty business days to make the submission and may request an extension of the time period given. The auditing entity shall grant a request for an extension if it is reasonable.

A pharmacy's submission of documentation to appeal the finding shall be made in accordance with the procedure the auditing entity has established under section 3901.414 of the Revised Code.

(4)(a) An auditing entity shall deliver a final audit report to the pharmacy that was the subject of the audit. Except as provided in division (A)(4)(b) of this section, the report shall be delivered not later than one hundred twenty business days after the later of a pharmacy's receipt of a preliminary audit report.

(b) 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 under division (A)(3) of this section, the time limit described in division (A)(4)(a) of this section for the delivery of the final audit report is waived. Instead, the auditing entity shall deliver the final audit report not later than one hundred twenty days after the pharmacy's submission of the documentation.

(B) The provisions of division (A) of this section 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.

Sec. 3901.414. Each auditing entity in this state shall establish in writing separate procedures for a pharmacy to appeal one or more findings in a preliminary audit report issued under

section 3901.413 of the Revised Code.

Sec. 3901.415. Sections 3901.411 to 3901.414 of the Revised Code shall not apply to an auditing entity that is a medicaid managed care organization if application of those sections to the entity would be in violation of federal law.