(130th General Assembly)
(Amended Substitute Senate Bill Number 258)

AN ACT

To amend sections 4725.01 and 4725.091 and to enact sections 3901.81, 3901.811, 3901.812, 3901.813, 3901.814, and 3901.815 of the Revised Code to establish standards for the performance of pharmacy audits in Ohio and to authorize the continued use of certain analgesic controlled substances in the practice of optometry.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That sections 4725.01 and 4725.091 be amended and sections 3901.81, 3901.811, 3901.812, 3901.813, 3901.814, and 3901.815 of the Revised Code be enacted to read as follows:

Sec. 3901.81. As used in this section and sections 3901.811 to 3901.815 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. 3901.811. (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:

(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. 3901.812. 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. 3901.813. (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-site 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 3901.814 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 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. 3901.814. 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 3901.813 of the Revised Code.

Sec. 3901.815. Sections 3901.811 to 3901.814 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.

Sec. 4725.01. As used in this chapter:

(A)(1) The "practice of optometry" means the application of optical principles, through technical methods and devices, in the examination of human eyes for the purpose of ascertaining departures from the normal, measuring their functional powers, adapting optical accessories for the aid thereof, and detecting ocular abnormalities that may be evidence of disease, pathology, or injury.

(2) In the case of a licensed optometrist who holds a topical ocular pharmaceutical agents certificate, the "practice of optometry" has the same meaning as in division (A)(1) of this section, except that it also includes administering topical ocular pharmaceutical agents.

(3) In the case of a licensed optometrist who holds a therapeutic pharmaceutical agents certificate, the "practice of optometry" has the same meaning as in division (A)(1) of this section, except that it also includes all of the following:

(a) Employing, applying, administering, and prescribing instruments, devices, and procedures, other than invasive procedures, for purpose of examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system;

(b) Employing, applying, administering, and prescribing topical ocular pharmaceutical agents;

(c) Employing, applying, administering, and prescribing therapeutic pharmaceutical agents;

(d) Assisting an individual in determining the individual's blood glucose level by using a commercially available glucose-monitoring device. Nothing in this section precludes a licensed optometrist who holds a therapeutic pharmaceutical agents certificate from using any particular type of commercially available glucose-monitoring device.

(B) "Topical ocular pharmaceutical agent" means a drug or dangerous drug that is a topical drug and used in the practice of optometry as follows:

(1) In the case of a licensed optometrist who holds a topical ocular pharmaceutical agents certificate, for evaluative purposes in the practice of optometry as set forth in division (A)(1) of this section;

(2) In the case of a licensed optometrist who holds a therapeutic pharmaceutical agents certificate, for purposes of examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system.

(C) "Therapeutic pharmaceutical agent" means a drug or dangerous drug

that is used for examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system in the practice of optometry by a licensed optometrist who holds a therapeutic pharmaceutical agents certificate, and is any of the following:

(1) An oral drug or dangerous drug in one of the following classifications:

(a) Anti-infectives, including antibiotics, antivirals, antimicrobials, and antifungals;

(b) Anti-allergy agents;

(c) Antiglaucoma agents;

(d) Analgesics, including only analgesic drugs that are available without a prescription, analgesic drugs or dangerous drugs that require a prescription but are not controlled substances, and ~~schedule III controlled substances~~, to the extent authorized by the state board of optometry in rules adopted under section 4725.091 of the Revised Code, analgesic controlled substances;

(e) Anti-inflammatories, excluding all drugs or dangerous drugs classified as oral steroids other than methylpredisolone, ~~,~~ except that methylpredisolone may be used under a therapeutic pharmaceutical agents certificate only if it is prescribed under all of the following conditions:

(i) For use in allergy cases;

(ii) For use by an individual who is eighteen years of age or older;

(iii) On the basis of an individual's particular episode of illness;

(iv) In an amount that does not exceed the amount packaged for a single course of therapy.

(2) Epinephrine administered by injection to individuals in emergency situations to counteract anaphylaxis or anaphylactic shock. Notwithstanding any provision of this section to the contrary, administration of epinephrine in this manner does not constitute performance of an invasive procedure.

(3) An oral drug or dangerous drug that is not included under division (C)(1) of this section, if the drug or dangerous drug is approved, exempt from approval, certified, or exempt from certification by the federal food and drug administration for ophthalmic purposes and the drug or dangerous drug is specified in rules adopted by the state board of optometry under section 4725.09 of the Revised Code.

(D) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(E) "Drug" and "dangerous drug" have the same meanings as in section 4729.01 of the Revised Code.

(F) "Invasive procedure" means any procedure that involves cutting or otherwise infiltrating human tissue by mechanical means including surgery,

laser surgery, ionizing radiation, therapeutic ultrasound, administering medication by injection, or the removal of intraocular foreign bodies.

(G) "Visual system" means the human eye and its accessory or subordinate anatomical parts.

(H) "Certificate of licensure" means a certificate issued by the state board of optometry under section 4725.13 of the Revised Code authorizing the holder to practice optometry as provided in division (A)(1) of this section.

(I) "Topical ocular pharmaceutical agents certificate" means a certificate issued by the state board of optometry under section 4725.13 of the Revised Code authorizing the holder to practice optometry as provided in division (A)(2) of this section.

(J) "Therapeutic pharmaceutical agents certificate" means a certificate issued by the state board of optometry under division (A)(3) or (4) of section 4725.13 of the Revised Code authorizing the holder to practice optometry as provided in division (A)(3) of this section.

Sec. 4725.091. (A) The state board of optometry shall adopt rules governing the authority of licensed optometrists practicing under therapeutic pharmaceutical agents certificates to employ, apply, administer, and prescribe ~~schedule III~~ analgesic controlled substances ~~under a therapeutic pharmaceutical agents certificate~~. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and in consultation with the state board of pharmacy.

(B) All of the following apply to the state board of optometry in the adoption of rules under this section:

(1) The board shall not permit an optometrist to employ, apply, administer, or prescribe ~~a schedule III~~ an analgesic controlled substance other than a drug ~~included in section 3719.41 of the Revised Code within the schedule III narcotics-narcotic preparations category~~ product that is used for the treatment of pain and meets one of the following conditions:

(a) 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.

(b) 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.

(c) 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 effective date of this amendment, was not a controlled substance at that time, and subsequently becomes a schedule II, III, IV, or V controlled substance.

(2) The board shall limit the ~~schedule III~~ analgesic controlled substances that optometrists may employ, apply, administer, or prescribe to the drugs that the board determines are appropriate for use in the practice of optometry under a therapeutic pharmaceutical agents certificate.

(3) With regard to the prescribing of ~~schedule III~~ analgesic controlled substances, the board shall establish prescribing standards to be followed by optometrists who hold therapeutic pharmaceutical agents certificates. The board shall take into account the prescribing standards that exist within the health care marketplace.

(4) The board shall establish standards and procedures for employing, applying, administering, and prescribing ~~schedule III~~ analgesic controlled substances under a therapeutic pharmaceutical agents certificate by taking into consideration and examining issues that include the appropriate length of drug therapy, appropriate standards for drug treatment, necessary monitoring systems, and any other factors the board considers relevant.

SECTION 2. That existing sections 4725.01 and 4725.091 of the Revised Code are hereby repealed.

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Speaker _____ of the House of Representatives.

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President _____ of the Senate.

Passed _____, 20____

Approved _____, 20____

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Governor.

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

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Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the ____ day of _____, A. D. 20____.

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Secretary of State.

File No. _____ Effective Date _____