

**As Reported by the House Health and Aging Committee**

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**Sub. S. B. No. 258**

**Senator Balderson**

**Cosponsors: Senators Beagle, Brown, Coley, Gentile, Hite, LaRose, Lehner,  
Oelslager, Patton, Peterson, Schaffer, Uecker  
Representatives Brown, Bishoff, Wachtmann**

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**A B I L L**

To amend sections 4725.01 and 4725.091 and to enact 1  
sections 3901.81, 3901.811, 3901.812, 3901.813, 2  
3901.814, and 3901.815 of the Revised Code to 3  
establish standards for the performance of 4  
pharmacy audits in Ohio and to authorize the 5  
continued use of certain analgesic controlled 6  
substances in the practice of optometry. 7

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

**Section 1.** That sections 4725.01 and 4725.091 be amended and 8  
sections 3901.81, 3901.811, 3901.812, 3901.813, 3901.814, and 9  
3901.815 of the Revised Code be enacted to read as follows: 10

Sec. 3901.81. As used in this section and sections 3901.811 11  
to 3901.815 of the Revised Code: 12

(A) "Auditing entity" means any person or government entity 13  
that performs a pharmacy audit, including a payer, a pharmacy 14  
benefit manager, or a third-party administrator licensed under 15  
Chapter 3959. of the Revised Code. 16

(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. 17  
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(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. 20  
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(D) "Dangerous drug," "pharmacy," "practice of pharmacy," and "prescription" have the same meanings as in section 4729.01 of the Revised Code. 25  
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(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: 28  
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(1) A health insuring corporation, as defined in section 1751.01 of the Revised Code; 31  
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(2) A person authorized to engage in the business of sickness and accident insurance under Title XXXIX of the Revised Code; 33  
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(3) A person or government entity providing coverage of dangerous drugs or pharmacy services to individuals on a self-insurance basis; 35  
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(4) A group health plan, as defined in 29 U.S.C. 1167; 38

(5) A service benefit plan, as referenced in 42 U.S.C. 1396a(a)(25); 39  
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(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; 41  
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(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 44  
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services. 47

(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. 48  
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(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. 53  
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(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. 61  
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**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 on or after January 1, 2015: 65  
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(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 69  
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will select pharmacy records to audit shall be received by the 78  
pharmacy not less than seven business days before the date of the 79  
audit is to commence. 80

(2) The auditing entity shall not include in the pharmacy 81  
audit a review of a claim for payment for the provision of 82  
dangerous drugs or pharmacy services if the date of the pharmacy's 83  
initial submission of the claim for payment occurred more than 84  
twenty-four months before the date the audit commences. 85

(3) Absent an indication that there was an error in the 86  
dispensing of a drug, the auditing entity or payer shall not seek 87  
to recoup from the pharmacy that is the subject of the audit any 88  
amount that the pharmacy audit identifies as being the result of 89  
clerical or recordkeeping errors in the absence of financial harm. 90  
For purposes of this provision, an error in the dispensing of a 91  
drug is any of the following: selecting an incorrect drug, issuing 92  
incorrect directions, or dispensing a drug to the incorrect 93  
patient. 94

(4) The auditing entity shall not use the accounting practice 95  
of extrapolation when calculating a monetary penalty to be imposed 96  
or amount to be recouped as the result of the pharmacy audit. 97

(B)(1) The condition in division (A)(1) of this section does 98  
not apply if, prior to the audit, the auditing entity has 99  
evidence, from its review of claims data, statements, or physical 100  
evidence or its use of other investigative methods, indicating 101  
that fraud or other intentional or willful misrepresentation 102  
exists. 103

(2) The condition in division (A)(3) of this section does not 104  
apply if the auditing entity has evidence, from its review of 105  
claims data, statements, or physical evidence or its use of other 106  
investigative methods, indicating that fraud or other intentional 107  
or willful misrepresentation exists. 108

(3) Division (A)(4) of this section does not apply when the 109  
accounting practice of extrapolation is required by state or 110  
federal law. 111

Sec. 3901.812. A pharmacy may do any of the following when a 112  
pharmacy audit is performed: 113

(A) Validate a pharmacy record by using original or 114  
photocopied records from hospitals, physicians, or other health 115  
care providers; 116

(B) Validate one or more claims for payment for the provision 117  
of dangerous drugs or pharmacy services by using either of the 118  
following: 119

(1) An original pharmacy record or photocopy of the record; 120

(2) An original prescription or photocopy of the prescription 121  
in any form that constitutes a valid prescription in this state, 122  
including a written prescription, a prescription made through an 123  
electronic prescribing system, a prescription delivered by 124  
facsimile, a prescription made by issuing an order for medication 125  
administration, and the record a pharmacist maintains under 126  
section 4729.37 of the Revised Code documenting a prescription 127  
received by telephone. 128

(C) Resubmit a disputed or denied claim for payment using any 129  
commercially reasonable method of resubmission, including 130  
resubmission by facsimile, mail, or electronic means, as long as 131  
the time period for resubmissions established by the relevant 132  
payer has not expired. 133

Sec. 3901.813. (A) Except as provided in division (B) of this 134  
section, all of the following apply after a pharmacy audit is 135  
completed: 136

(1) A pharmacy shall be given not less than thirty days from 137

the date of the on-site audit to provide the auditing entity any 138  
additional information necessary to complete the preliminary audit 139  
report. 140

(2) Not later than sixty business days after the audit is 141  
completed, the auditing entity shall deliver a preliminary audit 142  
report to the pharmacy that was the subject of the audit. 143

(3) A pharmacy that disputes any finding in the preliminary 144  
audit report may submit documentation to the auditing entity to 145  
appeal the finding. A pharmacy shall be given not less than thirty 146  
business days to make the submission and may request an extension 147  
of the time period given. The auditing entity shall grant a 148  
request for an extension if it is reasonable. 149

A pharmacy's submission of documentation to appeal the 150  
finding shall be made in accordance with the procedure the 151  
auditing entity has established under section 3901.814 of the 152  
Revised Code. 153

(4)(a) An auditing entity shall deliver a final audit report 154  
to the pharmacy that was the subject of the audit. Except as 155  
provided in division (A)(4)(b) of this section, the report shall 156  
be delivered not later than one hundred twenty business days after 157  
the pharmacy's receipt of a preliminary audit report. 158

(b) If an auditing entity has granted a pharmacy's request 159  
for an extension of the time to submit documentation to appeal a 160  
finding in the preliminary audit report under division (A)(3) of 161  
this section, the time limit described in division (A)(4)(a) of 162  
this section for the delivery of the final audit report is waived. 163  
Instead, the auditing entity shall deliver the final audit report 164  
not later than one hundred twenty days after the pharmacy's 165  
submission of the documentation. 166

(B) The provisions of division (A) of this section do not 167  
apply if the auditing entity has evidence, from its review of 168

claims data, statements, or physical evidence or its use of other 169  
investigative methods, indicating that fraud or other intentional 170  
or willful misrepresentation exists. 171

Sec. 3901.814. Each auditing entity in this state shall 172  
establish in writing separate procedures for a pharmacy to appeal 173  
one or more findings in a preliminary audit report issued under 174  
section 3901.813 of the Revised Code. 175

Sec. 3901.815. Sections 3901.811 to 3901.814 of the Revised 176  
Code shall not apply to an auditing entity that is a medicaid 177  
managed care organization if application of those sections to the 178  
entity would be in violation of federal law. 179

**Sec. 4725.01.** As used in this chapter: 180

(A)(1) The "practice of optometry" means the application of 181  
optical principles, through technical methods and devices, in the 182  
examination of human eyes for the purpose of ascertaining 183  
departures from the normal, measuring their functional powers, 184  
adapting optical accessories for the aid thereof, and detecting 185  
ocular abnormalities that may be evidence of disease, pathology, 186  
or injury. 187

(2) In the case of a licensed optometrist who holds a topical 188  
ocular pharmaceutical agents certificate, the "practice of 189  
optometry" has the same meaning as in division (A)(1) of this 190  
section, except that it also includes administering topical ocular 191  
pharmaceutical agents. 192

(3) In the case of a licensed optometrist who holds a 193  
therapeutic pharmaceutical agents certificate, the "practice of 194  
optometry" has the same meaning as in division (A)(1) of this 195  
section, except that it also includes all of the following: 196

(a) Employing, applying, administering, and prescribing 197

instruments, devices, and procedures, other than invasive 198  
procedures, for purpose of examination, investigation, diagnosis, 199  
treatment, or prevention of any disease, injury, or other abnormal 200  
condition of the visual system; 201

(b) Employing, applying, administering, and prescribing 202  
topical ocular pharmaceutical agents; 203

(c) Employing, applying, administering, and prescribing 204  
therapeutic pharmaceutical agents; 205

(d) Assisting an individual in determining the individual's 206  
blood glucose level by using a commercially available 207  
glucose-monitoring device. Nothing in this section precludes a 208  
licensed optometrist who holds a therapeutic pharmaceutical agents 209  
certificate from using any particular type of commercially 210  
available glucose-monitoring device. 211

(B) "Topical ocular pharmaceutical agent" means a drug or 212  
dangerous drug that is a topical drug and used in the practice of 213  
optometry as follows: 214

(1) In the case of a licensed optometrist who holds a topical 215  
ocular pharmaceutical agents certificate, for evaluative purposes 216  
in the practice of optometry as set forth in division (A)(1) of 217  
this section; 218

(2) In the case of a licensed optometrist who holds a 219  
therapeutic pharmaceutical agents certificate, for purposes of 220  
examination, investigation, diagnosis, treatment, or prevention of 221  
any disease, injury, or other abnormal condition of the visual 222  
system. 223

(C) "Therapeutic pharmaceutical agent" means a drug or 224  
dangerous drug that is used for examination, investigation, 225  
diagnosis, treatment, or prevention of any disease, injury, or 226  
other abnormal condition of the visual system in the practice of 227  
optometry by a licensed optometrist who holds a therapeutic 228

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| pharmaceutical agents certificate, and is any of the following:  | 229 |
| (1) An oral drug or dangerous drug in one of the following classifications:  | 230 |
| (a) Anti-infectives, including antibiotics, antivirals, antimicrobials, and antifungals;   | 231 |
| (b) Anti-allergy agents;   | 232 |
| (c) Antiglaucoma agents;   | 233 |
| (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 <del>schedule III</del> <u>analgesic drugs that are</u> controlled substances <u>and</u> authorized by the state board of optometry in rules adopted under section 4725.091 of the Revised Code; | 234 |
| (e) Anti-inflammatories, excluding all drugs or dangerous drugs classified as oral steroids other than methylpredisolone, <del>7</del> except that methylpredisolone may be used under a therapeutic pharmaceutical agents certificate only if it is prescribed under all of the following conditions:   | 235 |
| (i) For use in allergy cases;  | 236 |
| (ii) For use by an individual who is eighteen years of age or older;   | 237 |
| (iii) On the basis of an individual's particular episode of illness;   | 238 |
| (iv) In an amount that does not exceed the amount packaged for a single course of therapy.   | 239 |
| (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.  | 240 |
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(3) An oral drug or dangerous drug that is not included under 259  
division (C)(1) of this section, if the drug or dangerous drug is 260  
approved, exempt from approval, certified, or exempt from 261  
certification by the federal food and drug administration for 262  
ophthalmic purposes and the drug or dangerous drug is specified in 263  
rules adopted by the state board of optometry under section 264  
4725.09 of the Revised Code. 265

(D) "Controlled substance" has the same meaning as in section 266  
3719.01 of the Revised Code. 267

(E) "Drug" and "dangerous drug" have the same meanings as in 268  
section 4729.01 of the Revised Code. 269

(F) "Invasive procedure" means any procedure that involves 270  
cutting or otherwise infiltrating human tissue by mechanical means 271  
including surgery, laser surgery, ionizing radiation, therapeutic 272  
ultrasound, administering medication by injection, or the removal 273  
of intraocular foreign bodies. 274

(G) "Visual system" means the human eye and its accessory or 275  
subordinate anatomical parts. 276

(H) "Certificate of licensure" means a certificate issued by 277  
the state board of optometry under section 4725.13 of the Revised 278  
Code authorizing the holder to practice optometry as provided in 279  
division (A)(1) of this section. 280

(I) "Topical ocular pharmaceutical agents certificate" means 281  
a certificate issued by the state board of optometry under section 282  
4725.13 of the Revised Code authorizing the holder to practice 283  
optometry as provided in division (A)(2) of this section. 284

(J) "Therapeutic pharmaceutical agents certificate" means a 285  
certificate issued by the state board of optometry under division 286  
(A)(3) or (4) of section 4725.13 of the Revised Code authorizing 287  
the holder to practice optometry as provided in division (A)(3) of 288  
this section. 289

Sec. 4725.091. (A) The state board of optometry shall adopt 290  
rules governing the authority of licensed optometrists practicing 291  
under therapeutic pharmaceutical agents certificates to employ, 292  
apply, administer, and prescribe ~~schedule III analgesic drugs that~~ 293  
are controlled substances ~~under a therapeutic pharmaceutical~~ 294  
~~agents certificate~~. The rules shall be adopted in accordance with 295  
Chapter 119. of the Revised Code and in consultation with the 296  
state board of pharmacy. 297

(B) All of the following apply to the state board of 298  
optometry in the adoption of rules under this section: 299

(1) The board shall not permit an optometrist to employ, 300  
apply, administer, or prescribe ~~a schedule III~~ an analgesic drug 301  
that is a controlled substance other than a drug that is either of 302  
the following: 303

(a) A drug that is included in section 3719.41 of the Revised 304  
Code within the schedule III narcotics-narcotic preparations 305  
category; 306

(b) A drug that immediately prior to the effective date of 307  
this amendment was included in section 3719.41 of the Revised Code 308  
within the schedule III narcotics-narcotic preparations category, 309  
even if that drug subsequently is transferred to a different 310  
schedule or category by the general assembly, the state board of 311  
pharmacy pursuant to section 3719.44 of the Revised Code, or the 312  
United States attorney general pursuant to the federal drug abuse 313  
control laws, as defined in section 3719.01 of the Revised Code. 314

(2) The board shall limit the ~~schedule III analgesic drugs~~ 315  
that are controlled substances that optometrists may employ, 316  
apply, administer, or prescribe to the drugs that the board 317  
determines are appropriate for use in the practice of optometry 318  
under a therapeutic pharmaceutical agents certificate. 319

(3) With regard to the prescribing of ~~schedule III~~ analgesic drugs that are 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 drugs that are 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.