

As Reported by the House Health Committee

134th General Assembly

Regular Session

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H. B. No. 645

Representatives Fraizer, Holmes

A BILL

To enact section 4729.554 of the Revised Code to 1
authorize the operation of remote dispensing 2
pharmacies. 3

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

Section 1. That section 4729.554 of the Revised Code be 4
enacted to read as follows: 5

Sec. 4729.554. (A) As used in this section: 6

(1) "Remote dispensing pharmacy" means a pharmacy where 7
the dispensing of drugs and drug therapy related devices, 8
patient counseling, and other pharmacist care is provided by a 9
supervising pharmacist using a telepharmacy system. 10

(2) "Telepharmacy system" means a system that monitors the 11
dispensing of drugs and provides for related drug utilization 12
review and patient counseling services by an electronic method. 13

(B) The state board of pharmacy shall regulate remote 14
dispensing pharmacies in accordance with this section. 15

(C) To operate as a remote dispensing pharmacy, a pharmacy 16
shall comply with all of the following: 17

- (1) Be licensed under this chapter as a terminal distributor of dangerous drugs; 18
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- (2) (a) Be physically located in this state, in a building that is zoned for commercial use, and, except as provided in division (C) (2) (b) of this section, not within ten miles of a pharmacy that serves the public as an outpatient pharmacy; 20
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- (b) A remote dispensing pharmacy may be located within the ten-mile limitation described in division (C) (2) (a) of this section if either of the following applies to the pharmacy: 24
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- (i) The pharmacy is part of a federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code. 27
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- (ii) The board, based on a demonstration of need in accordance with standards established in rules adopted under this section, approves the pharmacy's physical location. 30
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- (3) Be overseen and operated by a supervising pharmacy in accordance with division (D) of this section and have a supervising pharmacist who is in full and actual charge of the remote dispensing pharmacy through the use of a telepharmacy system and surveillance system, both of which meet the standards established in rules adopted under this section; 33
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- (4) Operate only by using a telepharmacy system that meets standards established in rules adopted under this section and that is under the control of its supervising pharmacy; 39
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- (5) Be staffed by two or more pharmacy interns or certified pharmacy technicians who meet qualifications and training requirements established in rules adopted under this section. 42
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(D) All of the following apply to a pharmacy acting as a supervising pharmacy under this section: 46
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(1) The supervising pharmacy shall be licensed under this chapter as a terminal distributor of dangerous drugs and be physically located in this state. 48
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(2) The supervising pharmacy and remote dispensing pharmacy shall be under common ownership and control or shall operate under a contract that meets requirements specified in rules adopted under this section. 51
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(3) Unless otherwise approved by the board, the supervising pharmacy shall not oversee or operate more than one remote dispensing pharmacy. 55
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(E) All of the following apply to the supervising pharmacist that is in full and actual charge of the remote dispensing pharmacy: 58
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(1) The supervising pharmacist shall be licensed under this chapter and physically located in this state. 61
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(2) The supervising pharmacist shall be employed by or under contract with the supervising pharmacy. 63
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(3) Unless otherwise approved by the board, the supervising pharmacist shall not simultaneously oversee the activities of a remote dispensing pharmacy and a nonremote dispensing pharmacy or any other location licensed by the board. 65
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(4) The supervising pharmacist shall oversee the pharmacy interns and certified pharmacy technicians who are assisting in the dispensing process at the remote dispensing pharmacy and shall provide the oversight by using a telepharmacy system and surveillance system. 69
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(5) The supervising pharmacist shall verify each 74
prescription and drug dispensed pursuant to the prescription 75
before the drug leaves the remote dispensing pharmacy and shall 76
provide the verification through visual review and the use of 77
barcoding and any other technology required in rules adopted 78
under this section. 79

(6) The supervising pharmacist shall offer to provide the 80
service of counseling for each drug dispensed pursuant to a new 81
prescription for a patient at the remote dispensing pharmacy. 82

(F) Unless otherwise approved by the board, a remote 83
dispensing pharmacy shall not dispense drugs pursuant to more 84
than an average of one hundred fifty prescriptions per day 85
during a ninety-day period. 86

(G) A remote dispensing pharmacy shall implement a quality 87
assurance plan to ensure that there is a planned and systematic 88
process for monitoring and evaluating the quality and 89
appropriateness of the pharmacy services being provided and for 90
identifying and resolving problems. 91

(H) A remote dispensing pharmacy that holds a category III 92
terminal distributor of dangerous drugs license shall maintain a 93
perpetual controlled substance inventory, as specified in rules 94
adopted under this section. 95

(I) Notwithstanding section 4729.91 of the Revised Code or 96
any other section of this chapter to the contrary, a pharmacy 97
intern or certified pharmacy technician staffing a remote 98
dispensing pharmacy shall not do any of the following: 99

(1) Counsel an individual regarding the individual's drug 100
therapy, recommend drugs and drug therapy related devices, or 101
assist with selecting drugs and drug therapy related devices for 102

<u>treatment of common diseases and injuries or assist with</u>	103
<u>providing instruction on their use;</u>	104
<u>(2) Perform compounding of sterile or nonsterile drugs,</u>	105
<u>except for the reconstitution of prepackaged dangerous drugs;</u>	106
<u>(3) Engage in the repackaging of dangerous drugs;</u>	107
<u>(4) Administer immunizations or perform diagnostic</u>	108
<u>testing, unless a pharmacist is onsite to provide direct</u>	109
<u>supervision;</u>	110
<u>(5) Any other activities prohibited in rules adopted under</u>	111
<u>this section.</u>	112
<u>(J) The board shall adopt rules for purposes of its</u>	113
<u>regulation of remote dispensing pharmacies. The rules shall be</u>	114
<u>adopted in accordance with Chapter 119. of the Revised Code and</u>	115
<u>include all of the following:</u>	116
<u>(1) Standards for a system of continuous video</u>	117
<u>surveillance and recording of remote dispensing pharmacies,</u>	118
<u>including standards for both of the following:</u>	119
<u>(a) An adequate number of views of the entire remote</u>	120
<u>dispensing pharmacy to ensure that the supervising pharmacist</u>	121
<u>can maintain oversight;</u>	122
<u>(b) Retention of each recording made by the system for at</u>	123
<u>least sixty days after the date of the recording.</u>	124
<u>(2) Standards for telepharmacy systems and surveillance</u>	125
<u>systems used by remote dispensing pharmacies, including</u>	126
<u>standards to ensure that the systems are capable of all of the</u>	127
<u>following:</u>	128
<u>(a) Facilitating a safe and secured method for appropriate</u>	129

<u>pharmacist supervision;</u>	130
<u>(b) Allowing an appropriate exchange of visual, verbal,</u>	131
<u>and written communications for patient counseling and other</u>	132
<u>pharmacy services;</u>	133
<u>(c) Being secure and compliant with the "Health Insurance</u>	134
<u>Portability and Accountability Act of 1996," 42 U.S.C. 1320d et</u>	135
<u>seq.</u>	136
<u>(3) Requirements for the contract between a supervising</u>	137
<u>pharmacy and a remote dispensing pharmacy;</u>	138
<u>(4) Standards for making a determination of need, as set</u>	139
<u>forth in division (C) (2) (b) (ii) of this section;</u>	140
<u>(5) Requirements for the implementation of a quality</u>	141
<u>assurance plan by a remote dispensing pharmacy;</u>	142
<u>(6) The qualifications and training necessary for pharmacy</u>	143
<u>interns and certified pharmacy technicians who staff remote</u>	144
<u>dispensing pharmacies, including the number of experiential</u>	145
<u>hours required;</u>	146
<u>(7) Any additional activities that pharmacy interns and</u>	147
<u>certified pharmacy technicians staffing remote dispensing</u>	148
<u>pharmacies are prohibited from performing;</u>	149
<u>(8) The number of pharmacy interns and certified pharmacy</u>	150
<u>technicians that a supervising pharmacist may supervise at any</u>	151
<u>given time;</u>	152
<u>(9) The maximum distance a supervising pharmacist may be</u>	153
<u>physically located from the remote dispensing pharmacy;</u>	154
<u>(10) Standards for remote patient counseling by a</u>	155
<u>supervising pharmacist, including the counseling that is</u>	156

<u>required to be offered for each drug dispensed pursuant to a new</u>	157
<u>prescription for a patient by the remote dispensing pharmacy;</u>	158
<u>(11) Standards for and frequency of inspection of a remote</u>	159
<u>dispensing pharmacy by the supervising pharmacist;</u>	160
<u>(12) Requirements for the closure of a remote dispensing</u>	161
<u>pharmacy if the pharmacy's telepharmacy system or surveillance</u>	162
<u>system, or any related security system used by the pharmacy, is</u>	163
<u>malfunctioning;</u>	164
<u>(13) Requirements related to perpetual controlled</u>	165
<u>substance inventories;</u>	166
<u>(14) Security requirements for remote dispensing</u>	167
<u>pharmacies that include methods for supervising pharmacists to</u>	168
<u>determine who has accessed the pharmacy;</u>	169
<u>(15) Limits on the number of remote dispensing pharmacies</u>	170
<u>that a supervising pharmacist may oversee at one time to ensure</u>	171
<u>patient safety and sufficient staffing to meet the prescription</u>	172
<u>workload;</u>	173
<u>(16) Requirements for a remote dispensing pharmacy's</u>	174
<u>responsible person, as that term is defined in rules adopted by</u>	175
<u>the board;</u>	176
<u>(17) Any other standards or procedures the board considers</u>	177
<u>necessary to implement this section.</u>	178
Section 2. The State Board of Pharmacy shall adopt the	179
rules required by section 4729.554 of the Revised Code not later	180
than eighteen months after the effective date of this section.	181
If the Board fails to adopt the rules within that time period,	182
the Attorney General or a county prosecuting attorney may apply	183
to a court of common pleas for a court order requiring the	184

adoption of the rules.

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