As Introduced

134th General Assembly Regular Session 2021-2022

pharmacies.

H. B. No. 645

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Representatives Fraizer, Holmes

A BILL

To enact section 4729.554 of the Revised Code to

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

authorize the operation of remote dispensing

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	18
distributor of dangerous drugs;	19
(2)(a) Be physically located in this state, in a building	20
that is zoned for commercial use, and, except as provided in	21
division (C)(2)(b) of this section, not within ten miles of a	22
pharmacy that serves the public as an outpatient pharmacy;	23
(b) A remote dispensing pharmacy may be located within the	24
ten-mile limitation described in division (C)(2)(a) of this	25
section if either of the following applies to the pharmacy:	26
(i) The pharmacy is part of a federally qualified health	27
center or federally qualified health center look-alike, as	28
defined in section 3701.047 of the Revised Code.	29
(ii) The beard based on a demonstration of need in	30
(ii) The board, based on a demonstration of need in	
accordance with standards established in rules adopted under	31
this section, approves the pharmacy's physical location.	32
(3) Be overseen and operated by a supervising pharmacy in	33
accordance with division (D) of this section and have a	34
supervising pharmacist who is in full and actual charge of the	35
remote dispensing pharmacy through the use of a telepharmacy	36
system and surveillance system, both of which meet the standards	37
established in rules adopted under this section;	38
(4) Operate only by using a telepharmacy system that meets	39
standards established in rules adopted under this section and	40
that is under the control of its supervising pharmacy;	41
(5) Be staffed by two or more pharmacy interns or	42
certified pharmacy technicians who meet qualifications and	43
training requirements established in rules adopted under this	44
section.	45

(D) All of the following apply to a pharmacy acting as a	46
supervising pharmacy under this section:	47
(1) The supervising pharmacy shall be licensed under this	48
chapter as a terminal distributor of dangerous drugs and be	49
physically located in this state.	50
(2) The supervising pharmacy and remote dispensing	51
pharmacy shall be under common ownership and control or shall	52
operate under a contract that meets requirements specified in	53
rules adopted under this section.	54
(3) Unless otherwise approved by the board, the	55
supervising pharmacy shall not oversee or operate more than one	56
remote dispensing pharmacy.	57
(E) All of the following apply to the supervising	58
pharmacist that is in full and actual charge of the remote	59
dispensing pharmacy:	60
(1) The supervising pharmacist shall be licensed under	61
this chapter and physically located in this state.	62
(2) The supervising pharmacist shall be employed by or	63
under contract with the supervising pharmacy.	64
(3) Unless otherwise approved by the board, the	65
supervising pharmacist shall not simultaneously oversee the	66
activities of a remote dispensing pharmacy and a nonremote	
dispensing pharmacy or any other location licensed by the board.	68
(4) The supervising pharmacist shall oversee the pharmacy	69
interns and certified pharmacy technicians who are assisting in	70
the dispensing process at the remote dispensing pharmacy and	71
shall provide the oversight by using a telepharmacy system and	72
surveillance system.	73

(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	
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

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

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

required to be offered for each drug dispensed pursuant to a new	157
prescription for a patient by the remote dispensing pharmacy;	158
(11) Standards for and frequency of inspection of a remote	159
dispensing pharmacy by the supervising pharmacist;	160
(12) Requirements for the closure of a remote dispensing	161
pharmacy if the pharmacy's telepharmacy system or surveillance	162
system, or any related security system used by the pharmacy, is	163
malfunctioning;	164
(13) Requirements related to perpetual controlled	165
<pre>substance inventories;</pre>	166
(14) Security requirements for remote dispensing	167
pharmacies that include methods for supervising pharmacists to	168
determine who has accessed the pharmacy;	169
(15) Limits on the number of remote dispensing pharmacies	170
that a supervising pharmacist may oversee at one time to ensure	171
patient safety and sufficient staffing to meet the prescription	172
workload;	173
(16) Requirements for a remote dispensing pharmacy's	174
responsible person, as that term is defined in rules adopted by	175
the board;	176
(17) Any other standards or procedures the board considers	177
necessary to implement this section.	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

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adoption of the rules.

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