As Introduced

135th General Assembly Regular Session 2023-2024

H. B. No. 136

Representatives Holmes, Stewart

A BILL

To amend section 4729.285 and to enact section	1
4729.554 of the Revised Code to authorize the	2
operation of remote dispensing pharmacies.	3

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

Section 1. That section 4729.285 be amended and section	4
4729.554 of the Revised Code be enacted to read as follows:	5
Sec. 4729.285. A pharmacist may provide telehealth	6
services in accordance with section 4743.09 of the Revised Code,	7
except that in the case of dispensing a dangerous drug, a	8
pharmacist shall not use telehealth mechanisms or other virtual	9
means to perform any of the actions involved in dispensing the	10
dangerous drug unless the action is authorized by section	11
4729.554 of the Revised Code or by the state board of pharmacy	12
through rules it adopts under this chapter or s ection 4743.09 of	13
the Revised Code.	14
Sec. 4729.554. (A) As used in this section:	15
(1) "Remote dispensing pharmacy" means a pharmacy where	16
the dispensing of drugs, patient counseling, and other	17
pharmacist care is provided through a telepharmacy system. The	18
dispensing of drugs at a remote dispensing pharmacy may include	19

the dispensing of drug therapy related devices.	20
(2) "Telepharmacy system" means a system that monitors the	21
dispensing of drugs and provides for related drug utilization	22
review and patient counseling services by an electronic method.	23
(B) The state board of pharmacy shall regulate remote	24
dispensing pharmacies in accordance with this section. A remote	25
dispensing pharmacy may operate only by using a telepharmacy	26
system that meets standards established in rules adopted under	27
this section and by complying with all other requirements of	28
this section and the rules adopted under it for operating a	29
remote dispensing pharmacy.	30
(C)(1) To be eligible to operate as a remote dispensing	31
pharmacy, a pharmacy shall meet all of the following conditions:	32
(a) Be licensed under this chapter as a terminal_	33
distributor of dangerous drugs;	34
(b) Be physically located in this state, in a building	35
that is zoned for commercial use, and in an area that meets the	36
conditions of division (C)(2) of this section;	37
(c) Have a supervising pharmacy that meets the	38
requirements of division (D) of this section and a supervising	39
pharmacist that meets the requirements of division (E) of this	40
section;	41
(d) 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
(2)(a) Except as provided in division (C)(2)(b) of this	46
section, a remote dispensing pharmacy shall not be located_	47

within ten miles of a pharmacy that serves the public as an 48 outpatient pharmacy. 49 (b) A remote dispensing pharmacy may be located within the 50 ten-mile limitation described in division (C)(2)(a) of this 51 section if either of the following is the case: 52 (i) The remote dispensing pharmacy is part of a federally 53 54 qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code. 55 (ii) The board, based on a demonstration of need that 56 meets the standards established in rules adopted under this 57 section, approves the remote dispensing pharmacy's physical 58 location. 59 (D) (1) To be eligible to serve as the supervising pharmacy 60 of a remote dispensing pharmacy, a pharmacy shall meet all of 61 the following conditions: 62 (a) Be licensed under this chapter as a terminal 63 distributor of dangerous drugs; 64 (b) Be physically located in this state; 65 (c) Be under common ownership and control with the remote 66 dispensing pharmacy or, pursuant to a contract that meets 67 requirements specified in rules adopted under this section, 68 operate under contract with the remote dispensing pharmacy. 69 (2) In serving as a supervising pharmacy, the supervising 70 pharmacy shall control the telepharmacy system used by the 71 remote dispensing pharmacy and shall employ or contract with the 72 supervising pharmacist of the remote dispensing pharmacy. 73 (E) (1) To be eligible to serve as the supervising 74

pharmacist of a remote dispensing pharmacy, a pharmacist shall

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meet all of the following conditions:	76
(a) Be licensed under this chapter as a pharmacist;	77
(b) Be physically located in this state when acting as the	78
supervising pharmacist;	79
(c) Be employed by or under contract with the supervising	80
pharmacy.	81
(2) In serving as a supervising pharmacist, the	82
supervising pharmacist shall do all of the following:	83
(a) Be in full and actual charge of the remote dispensing	84
pharmacy by using the the pharmacy's telepharmacy system and by	85
using a surveillance system that meets standards established in	86
rules adopted under this section;	87
(b) Through the telepharmacy system and surveillance	88
system, oversee the pharmacy interns and certified pharmacy	89
technicians who are staffing the remote dispensing pharmacy;	90
(c) Verify each prescription and drug dispensed pursuant	91
to the prescription before the drug leaves the remote dispensing	92
pharmacy and provide the verification through visual review and	93
the use of barcoding and any other technology required in rules	94
adopted under this section;	95
(d) Offer to provide the service of counseling for each	96
drug dispensed pursuant to a new prescription for a patient at	97
the remote dispensing pharmacy.	98
(3) Unless otherwise approved by the board in accordance	99
with standards established in rules adopted under this section,	100
a supervising pharmacist shall not simultaneously oversee the	101
activities of more than one remote dispensing pharmacy.	102

(F) All of the following apply to the operation of a 103 remote dispensing pharmacy: 104 (1) Unless otherwise approved by the board, a remote 105 dispensing pharmacy shall not dispense drugs pursuant to more 106 than an average of one hundred fifty prescriptions per day 107 during a ninety-day period. 108 (2) A remote dispensing pharmacy shall implement a quality 109 assurance plan to ensure that there is a planned and systematic 110 process for monitoring and evaluating the guality and 111 appropriateness of the pharmacy services being provided and for 112 identifying and resolving problems. 113 (3) A remote dispensing pharmacy that holds a category III 114 terminal distributor of dangerous drugs license shall maintain a 115 perpetual controlled substance inventory, as specified in rules 116 adopted under this section. 117 (G) Notwithstanding section 4729.91 of the Revised Code or 118 any other section of this chapter to the contrary, both of the 119 following apply to a pharmacy intern or certified pharmacy 120 technician staffing a remote dispensing pharmacy: 121 (1) The intern or technician may assist in the process of 122 dispensing drugs at the pharmacy. 123 124 (2) The intern or technician shall not do any of the following: 125 (a) Counsel an individual regarding drugs that are 126 dispensed, recommend drugs and drug therapy related devices or 127 otherwise provide advice regarding drug therapy, or assist with 128 selecting drugs and drug therapy related devices for treatment 129 of common diseases and injuries or assist with providing 130 131 instruction on their use;

(b) Perform compounding of sterile or nonsterile drugs,	132
except for the reconstitution of prepackaged dangerous drugs;	133
(c) Engage in the repackaging of dangerous drugs;	134
(d) Administer immunizations or perform diagnostic	135
testing, unless a pharmacist is onsite to provide direct	136
supervision;	137
(e) Perform any other activity prohibited by rules adopted_	138
under this section.	139
(H) The board shall adopt rules for purposes of its	140
regulation of remote dispensing pharmacies. The rules shall be	141
adopted in accordance with Chapter 119. of the Revised Code and	142
include all of the following:	143
<u>(1) Standards for a system of continuous video</u>	144
surveillance and recording of remote dispensing pharmacies,	145
including standards for both of the following:	146
(a) An adequate number of views of the entire remote	147
dispensing pharmacy to ensure that the supervising pharmacist	148
<u>can maintain oversight;</u>	149
(b) Retention of each recording made by the system for at	150
least sixty days after the date of the recording.	151
(2) Standards for telepharmacy systems and surveillance	152
systems used by remote dispensing pharmacies, supervising	153
pharmacies, and supervising pharmacists, including standards to	154
ensure that the systems are capable of all of the following:	155
(a) Facilitating a safe and secured method for appropriate	156
pharmacist supervision;	157
(b) Allowing an appropriate exchange of visual, verbal,	158

and written communications for patient counseling and other	159
pharmacy services;	160
(c) Being secure and compliant with the "Health Insurance	161
Portability and Accountability Act of 1996," 42 U.S.C. 1320d et	162
seq.	163
(3) Requirements for any contract between a supervising	164
pharmacy and a remote dispensing pharmacy;	165
(4) Standards that must be met to make a demonstration of	166
need for purposes of division (C)(2)(b)(ii) of this section;	167
(5) Requirements for the implementation of a quality	168
assurance plan by a remote dispensing pharmacy;	169
(6) The qualifications and training necessary for pharmacy	170
interns and certified pharmacy technicians who staff remote	171
dispensing pharmacies, including the number of experiential	172
hours required;	173
(7) Any additional activities that pharmacy interns and	174
certified pharmacy technicians staffing remote dispensing	175
pharmacies are prohibited from performing;	176
(8) The number of pharmacy interns and certified pharmacy	177
technicians that a supervising pharmacist may supervise at any	178
given time;	179
(9) The maximum distance a supervising pharmacist may be	180
physically located from the remote dispensing pharmacy;	181
(10) Standards for remote patient counseling by a	182
supervising pharmacist, including the counseling that is	183
required to be offered for each drug dispensed pursuant to a new	184
prescription for a patient by the remote dispensing pharmacy;	185

<u>(11) Standards for and frequency of inspection of a remote</u>	186
dispensing pharmacy by the supervising pharmacist;	187
(12) Requirements for the closure of a remote dispensing	188
pharmacy if the required telepharmacy system or surveillance	189
system, or any related security system used by or for the	190
pharmacy, is malfunctioning;	191
(13) Requirements related to perpetual controlled	192
substance inventories;	193
(14) Security requirements for remote dispensing	194
pharmacies that include methods for supervising pharmacists to	195
determine who has accessed the pharmacy;	196
(15) Standards by which a supervising pharmacist may be	197
approved by the board to oversee simultaneously more than one	198
remote dispensing pharmacy;	199
(16) Requirements for a remote dispensing pharmacy's	200
responsible person, as that term is defined in rules adopted by	201
responsible person, as that term is defined in rules adopted by <u>the board;</u>	201 202
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the board;	202
the board; (17) Any other standards or procedures the board considers	202 203
the board; (17) Any other standards or procedures the board considers necessary to implement this section.	202 203 204
<pre>the board; (17) Any other standards or procedures the board considers necessary to implement this section. Section 2. That existing section 4729.285 of the Revised</pre>	202 203 204 205
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<pre>the board; (17) Any other standards or procedures the board considers necessary to implement this section. Section 2. That existing section 4729.285 of the Revised Code is hereby repealed. Section 3. The State Board of Pharmacy shall adopt the rules required by section 4729.554 of the Revised Code not later</pre>	202 203 204 205 206 207 208
<pre>the board; (17) Any other standards or procedures the board considers necessary to implement this section. Section 2. That existing section 4729.285 of the Revised Code is hereby repealed. Section 3. The State Board of Pharmacy shall adopt the rules required by section 4729.554 of the Revised Code not later than eighteen months after the effective date of this section.</pre>	202 203 204 205 206 207 208 209
<pre>the board;</pre>	202 203 204 205 206 207 208 209 210