

1 State of Arkansas
2 94th General Assembly
3 Regular Session, 2023
4

A Bill

SENATE BILL 502

5 By: Senator J. Petty
6 By: Representative Gazaway
7

For An Act To Be Entitled

9 AN ACT TO REQUIRE WHOLESALE DISTRIBUTORS OF
10 CONTROLLED SUBSTANCES AND LEGEND DRUGS TO EDUCATE,
11 COMMUNICATE, AND PROVIDE A WELL-DEFINED PROCEDURAL
12 DUE PROCESS FOR LICENSED PROFESSIONALS BEFORE
13 LIMITING OR TERMINATING SALES OF CONTROLLED
14 SUBSTANCES TO CERTAIN LICENSED PROFESSIONALS; TO
15 DECLARE AN EMERGENCY; AND FOR OTHER PURPOSES.
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Subtitle

18 TO REQUIRE WHOLESALE DISTRIBUTORS OF
19 CONTROLLED SUBSTANCES TO EDUCATE,
20 COMMUNICATE, AND PROVIDE DUE PROCESS FOR
21 LICENSED PROFESSIONALS BEFORE LIMITING OR
22 TERMINATING SALES OF CONTROLLED
23 SUBSTANCES; AND TO DECLARE AN EMERGENCY.
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27 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
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29 SECTION 1. DO NOT CODIFY. Legislative intent.

30 It is the intent of the General Assembly to:

31 (1) Provide clarity to processes by which pharmaceutical
32 wholesale distributors that reduce or eliminate distribution of controlled
33 substances to providers or pharmacies in this state, particularly in the case
34 of pharmaceutical wholesaler distributors subject to federal injunctive
35 relief that became effective on July 1, 2022;

36 (2) Ensure that the Arkansas State Board of Pharmacy, as the



1 licensing, regulatory, and oversight entity for pharmaceutical wholesalers in
2 this state, is involved in and understands business practices and specific
3 data elements that cause the pharmaceutical wholesaler distributors to desire
4 to reduce or eliminate distribution of controlled substances to providers or
5 pharmacies in this state;

6 (3) Ensure that wholesale distributors of controlled substances
7 provide timely education, communication, and a well-defined due process for
8 licensed professionals to identify and resolve concerns related to
9 distribution, including ordering, administration, and dispensing of
10 controlled substances; and

11 (4) Provide for a complaint-driven process to ensure wholesale
12 distributor compliance with state law.

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14 SECTION 2. Arkansas Code § 20-64-506, concerning whole distributors of
15 controlled substances and legend drugs and shipments to certain licensed
16 professionals, is amended to add additional subsections to read as follows:

17 (c) A wholesale distributor shall not limit or terminate the sale of
18 controlled substances, or materially alter pricing of any items or services
19 intended to limit or terminate sale of controlled substances, to any entity
20 identified in subsection (a) of this section except if the wholesale
21 distributor has:

22 (1) Proactively provided local or virtual information and
23 education opportunities to the customer at least annually about controlled
24 substances program including a description of suspicious activities regarding
25 dispensing, prescribing, and dispensing habits or patterns, the process for
26 notifying customers of anticipated actions to purchase limits or terminating
27 eligibility for controlled substances, the reconsideration review due process
28 prior to limiting or terminating eligibility, and final actions;

29 (2)(A) Interviewed the pharmacist-in-charge and the permit
30 holder, either over the telephone, via videoconference, or in person.

31 (B) The interview shall include questions regarding the
32 manner in which the potential customer maintains effective controls against
33 the potential diversion of controlled substances;

34 (3) To the extent consistent with other laws, provided the
35 pharmacy with a minimum of five (5) business days' notice of a potential or
36 actual violation of policies and procedures that may result in the temporary

1 or permanent limitation or termination of its eligibility for any controlled
2 substance;

3 (4)(A) Conducted an onsite inspection or review at the physical
4 location of the pharmacy or customer within the previous fourteen (14) days
5 prior to issuing termination notice for controlled substance.

6 (B) This onsite review shall include an opportunity to
7 review relevant clinical information with the customers regarding any
8 unresolved concerns with dispensing of controlled substances.

9 (C) The Arkansas State Board of Pharmacy shall be notified
10 by the wholesale distributor with the date and time of the onsite visit in
11 advance of the visit.

12 (D) A representative of the board may attend the onsite
13 visit to assist with resolving concerns for both the wholesale distributor
14 and impacted customer;

15 (5)(A) Notified the customer regarding any procedure, or series
16 of orders, patterns, or practices that forms the basis for the proposed
17 action.

18 (B) The customer shall have a minimum of an additional
19 five (5) business days to respond before eligibility for controlled
20 substances is limited or terminated.

21 (C) The wholesale distributor shall promptly review the
22 response under subdivision (c)(5)(B) of this section and make reasonable
23 efforts to diligently identify, request, and gather relevant information from
24 the customer before making a decision to limit or terminate the sale of
25 controlled substances.

26 (D) If a wholesale distributor requires limitation or
27 termination of a customer's eligibility for controlled substance, the
28 wholesale distributor shall provide the customer and the board with a notice
29 in writing to include the appeal process for the decision giving the customer
30 a minimum of five (5) days to respond as required under subdivision (c)(5) of
31 this section; and

32 (6)(A) Conducted an onsite inspection or review at the physical
33 location of the customer before termination notice for controlled substances.

34 (B) The onsite review under subdivision (c)(6)(A) of this
35 section shall include an opportunity to review relevant clinical patient
36 chart reviews with the licensed professionals regarding any unresolved

1 concerns with dispensing controlled substances.

2 (d)(1) Notwithstanding action by a state or federal authority, a
3 wholesale distributor's final determination for the termination of sales of
4 controlled substances to a customer in good standing with the board shall
5 include a minimum of fifteen (15) days' notice before stopping the customer's
6 ability to procure controlled substances.

7 (2) The wholesale distributor may extend this period or reverse
8 the announced restriction against the pharmacy during this period.

9 (3) Upon final decision to permanently terminate distribution to
10 a customer, the wholesale distributor shall publish the decision in the local
11 news outlets to stop servicing the local customer and the community.

12 (e)(1) A third-party compliance consultant or any third-party entity
13 that is used by a wholesale distributor to collect, evaluate, and analyze
14 controlled substance ordering, administrating, and dispensing data from a
15 pharmacy either remotely or onsite shall be approved by the board.

16 (2)(A) A third-party compliance consultant or any third-party
17 entity that is used by a wholesale distributor to conduct interviews via
18 telephone, video conference, or onsite visits to customers or with licensed
19 professionals to review or address concerns with controlled substance
20 ordering, administrating, and dispensing policies and procedures shall be
21 approved by the board.

22 (B) This includes both visits that are both proactive to
23 strengthen policies and reactive reviews that may address concerns identified
24 by data analytics.

25 (f) During a site visit, a personnel member of the wholesale
26 distributor or a board-approved third-party compliance consultant shall
27 interview the pharmacist-in-charge, permit holders, and other relevant
28 employees, if appropriate, about any potential controlled substance
29 dispensing concerns and the customer's maintenance of effective controls
30 against the potential diversion of controlled substances.

31 (g) A wholesale distributor shall not take punitive action against a
32 pharmacy based on purchases that relied upon allocations set by the wholesale
33 distributor.

34 (h) A customer may file a complaint with the board regarding a
35 wholesale distributor's final action limiting access to controlled substances
36 that adversely affects patient care.

1 (i)(1) This section does not prevent a registrant of the United States
2 Drug Enforcement Administration from stopping a specific suspicious order as
3 defined in federal regulations.

4 (2) However, a wholesale distributor shall provide the customer:

5 (A) An explanation for why the order is suspicious,
6 including without limitation details that are order-specific regarding why an
7 order was flagged as a suspicious order, including specific criteria used by
8 a wholesale distributor; and

9 (B) The name and contact information for a knowledgeable
10 designee within the wholesale distributor to be a point of contact for the
11 suspicious order report that can outline the appeal process for resolution of
12 the order prior to reporting to the board and the Attorney General.

13 (j) A wholesale distributor that conducts business with pharmacies in
14 this state and distributes controlled substances to pharmacies shall provide:

15 (1) The pharmacy with:

16 (A) The name, telephone number, and email of the person
17 responsible for resolving any controlled substance action; and

18 (B) The process for submitting materials:

19 (i) For any decisions or actions on concerns for
20 temporary or permanent limitation or termination of the pharmacy's
21 eligibility for any controlled substances; and

22 (ii) To request changes to the pharmacy's eligibility
23 for purchasing any controlled substances;

24 (2) All customers, both new and existing, with clear
25 expectations of the processes for reviewing controlled substance dispensing
26 activity and what to expect if a concern arises and the procedural due
27 process to resolve any concerns that might arise.

28 (k)(1) A violation of subsection (c) of this section shall be a
29 violation of this subchapter.

30 (2) The board shall take disciplinary action against a wholesale
31 distributor that violates subsection (c) of this section with a minimum fine
32 of ten thousand dollars (\$10,000) per violation and may include probation or
33 revocation of a wholesale distributor license.

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35 SECTION 3. DO NOT CODIFY. Rules.

36 (a) When adopting the initial rules required under this act, the

1 Arkansas State Board of Pharmacy shall file the final rules with the
2 Secretary of State for adoption under § 25-15-204(f):

3 (1) On or before January 1, 2024; or

4 (2) If approval under § 10-3-309 has not occurred by January 1,
5 2024, as soon as practicable after approval under § 10-3-309.

6 (b) The board shall file the proposed rules with the Legislative
7 Council under § 10-3-309(c) sufficiently in advance of January 1, 2024, so
8 that the Legislative Council may consider the rules for approval before
9 January 1, 2024.

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11 SECTION 4. EMERGENCY CLAUSE. It is found and determined by the
12 General Assembly of the State of Arkansas that the whole distribution of
13 controlled substances in this state is of critical importance to the citizens
14 of this state to maintain their health and safety; that wholesale
15 distributors must follow certain practices before making any changes in the
16 distribution of controlled substances in this state; that the changes in the
17 distribution of controlled substances should be done only with the
18 involvement of state licensing boards when a wholesale distributor suspects
19 purchasing or dispensing behavior is an aberration compared to similar
20 providers or pharmacies in the same geographic region within this state; and
21 that this act is immediately necessary to ensure the safe distribution of
22 controlled substances and legend drugs in this state and to protect the
23 health and safety of the citizens of this state. Therefore, an emergency is
24 declared to exist, and this act being immediately necessary for the
25 preservation of the public peace, health, and safety shall become effective
26 on:

27 (1) The date of its approval by the Governor;

28 (2) If the bill is neither approved nor vetoed by the Governor,
29 the expiration of the period of time during which the Governor may veto the
30 bill; or

31 (3) If the bill is vetoed by the Governor and the veto is
32 overridden, the date the last house overrides the veto.