

Stricken language would be deleted from and underlined language would be added to present law.

State of Arkansas
94th General Assembly
Regular Session, 2023

A Bill

SENATE BILL 502

By: Senator J. Petty
By: Representative Gazaway

For An Act To Be Entitled

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

Subtitle

TO REQUIRE WHOLESALE DISTRIBUTORS OF CONTROLLED SUBSTANCES TO EDUCATE, COMMUNICATE, AND PROVIDE DUE PROCESS FOR LICENSED PROFESSIONALS BEFORE LIMITING OR TERMINATING SALES OF CONTROLLED SUBSTANCES; AND TO DECLARE AN EMERGENCY.

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

SECTION 1. DO NOT CODIFY. Legislative intent.

It is the intent of the General Assembly to:

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

concerns with dispensing controlled substances.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The pharmacy with:

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

(B) The process for submitting materials:

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

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

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

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

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

SECTION 3. DO NOT CODIFY. Rules.

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

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

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

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

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

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

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

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

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