APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control:	680
Department or Agency:	Alabama State Board of Pharmacy
Rule No.:	680-X-2-.23
Rule Title:	Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers
Intended Action	Amend

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety?	Yes
Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved?	No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?	Yes
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?	No

Does the proposed rule have an economic impact?	No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

REC'D & FILED
DEC 19, 2025
LEGISLATIVE SVC AGENCY

Signature of certifying officer	Anne Marie Nolen Anne Nolen
Date	Friday, December 19, 2025

APA-2

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Pharmacy

RULE NO. & TITLE: 680-X-2-.23 Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
This amendment is being proposed to amend licensing fees for designated representatives and facilities.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
The public hearing will be February 11, 2026 during the business meeting beginning at 9:00 am CST at the Board of Pharmacy office, located at 111 Village Street, Birmingham, AL 35242. Comments may be submitted to Anne Marie Nolen via email to anolen@albop.com by EOB February 6, 2026.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Friday, February 6, 2026

CONTACT PERSON AT AGENCY:
Anne Marie Nolen
anolen@albop.com

Anne Marie Nolen

Anne Nolen

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

680-X-2-.23 **Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third-Party Logistics Providers, Outsourcing Facilities; Reverse Distributors; Retail Medical Oxygen Suppliers.**

(1) Definitions.

(a) Drug Manufacturer -Every facility, except a pharmacy, that prepares, derives, produces, compounds, or packages any drug, chemical or poison.

(b) Principals -Officers, directors and primary stockholders of a business entity or corporation.

(c) Drugs -All medicinal substances, preparations and devices recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal uses in the cure, diagnosis, mitigation, treatment or prevention of disease in man or animal and all substances and preparations other than food intended to affect the structure or any function of the body of man or animal.

(d) Medical Oxygen – Oxygen USP is liquid or gaseous form intended for human consumption.

(e) Wholesale distributor -Every facility engaged in the business of distributing drugs, to include medical oxygen, for resale to pharmacies, hospitals, practitioners, government agencies, or other lawful outlets permitted to sell drugs. The sale, purchase, or trade of a drug by a retail pharmacy to another retail pharmacy or practitioner, for relief of temporary shortages, is exempt from this definition. Also exempt from this definition shall be (a) intracompany sales, (b) manufacturer and distributor sales representatives who distribute drug samples, (c) charitable organizations distributing to nonprofit affiliates of that organization, (d) certain purchases by hospitals or other health care entities that are members of a group purchasing organization, (e) the distributors of blood and blood components, and (f) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(f) Private Label Distributor – A firm that does not participate in the manufacturing or processing of a drug but instead markets and distributes under its own trade name, and labels a drug product made by someone else. A private label

distributor is responsible for the products it introduces into interstate commerce and for compliance with federal Food, Drug and Cosmetic Act requirements and Current Good Manufacturing Practices regulations.

(g) Repackager – A facility that purchases or acquires from a manufacturer or distributor, a drug, chemical, or poison for the purpose of bottling, labeling, or otherwise repackaging for sale or distribution. This definition shall not apply to a physician licensed to practice medicine who, as a part of his or her professional practice dispenses, administers, sells, or otherwise distributes and drug to a patient.

(h) Third Party Logistics Provider – Abbreviated as 3PL or TPL, an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer or wholesale distributor of a product that neither takes ownership of the product nor has responsibility to direct the sale or disposition of the product.

(i) Outsourcing Facility – A facility at one geographic location or address that is engaged in the compounding of sterile drugs, which as elected to register with the Food and Drug Administration as an outsourcing facility and complies with the requirements of Section 503B(d)(4)(A) of the federal Food, Drug, and Cosmetic Act.

(j) Reverse Distributor – A facility that acts as an agent for pharmacies, wholesalers, third party logistics providers, drug manufacturers and others by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable drugs or devices.

(k) Retail Medical Oxygen Supplier – Any person, agency, business, or entity of any kind which sells or provides medical oxygen to patients or consumers and which bill the patient or consumer or their insurance, Medicare, Medicaid, or other third-party payor.

(l) Charge Back - A process whereby a wholesale drug distributor is reimbursed for preferential pricing.

(m) Drug Sample - A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug.

(n) Intracompany Sales - Any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity.

(2) Storage Conditions.

(a) Storage Conditions:

1. All facilities at which drugs are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale or kept for sale must provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. These storage area facilities must be kept free from infestation by insects, rodents, birds, or vermin of any kind and be maintained in a clean and orderly condition. All drugs or medicines must be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or medicines or with requirements in the current edition of an official compendium. If no storage requirements are established for a drug, they may be held at "controlled" room temperature as defined in an official compendium to help ensure that the identity, strength, quality, and purity of the drug are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs. A separate quarantine storage section must be provided for drugs that are deteriorated, outdated, misbranded, or otherwise adulterated, or that are in immediate or sealed secondary containers that have been opened. All incoming and outgoing drug shipments must be visually examined for identity and to prevent the acceptance or distribution of contaminated or damaged product.

(3) Facilities.

(a) All buildings in which drugs, and/or medical oxygen are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale must be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations. Buildings must meet all applicable federal, state and local standards. A facility may not be located in a residence.

(4) Security.

(a) All permitted facilities shall be secure from unauthorized entry.

(b) All permitted facilities shall be equipped with an alarm system to detect entry after hours.

(c) All permitted facilities shall ensure that access from outside their premises is reduced to a minimum and well controlled. This includes, but is not limited to, the installation of adequate lighting at the outside perimeter.

(d) Internal security policies must be developed to provide reasonable protection against theft by personnel. These policies shall provide protection against computer theft and crimes.

(e) Entry into areas where drugs are held shall be limited to authorized personnel.

(5) Recordkeeping.

(a) All permitted facilities shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs.

(b) Inventories and records shall be made available for inspection and photocopying by authorized personnel for a period of two years following disposition of the drugs.

(c) Records described in this Rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by authorized personnel.

(d) All charge back transactions shall be maintained separately from all other records.

(e) Copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases

or high or unusual volumes purchased by pharmacies shall be forwarded to the Board of Pharmacy.

(f) The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments in compliance with all state and federal laws and regulations.

(6) Inspections.

(a) All permitted facilities shall allow the Board of Pharmacy and authorized federal, state, and municipal law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner. Such officials shall be required to show appropriate identification prior to being granted access to permitted premises and delivery vehicles.

(b) The Board may contract inspections for out of state facilities to other state boards, NABP, or other inspection entities.

(c) Costs for out of state inspections will be the responsibility of the permit holder.

(7) Written Policies and Procedures.

(a) Drug manufacturers, wholesale distributors, private label distributors, repackagers, third party logistics providers, outsourcing facilities, and reverse distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. All facilities shall include a procedure to prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or any other situation of local, state, or national emergency.

(b) In addition to (a), drug manufacturers, wholesale distributors, private label distributors, repackagers, third party logistics providers, and outsourcing facilities shall also include in their written policies and procedures the following:

1. A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the

manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the outdated drugs and shall be maintained for two (2) years after the disposition of the same. The procedure shall include the following:

(i) Any drug that is outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other drugs until destroyed or returned to the supplier.

(ii) Any drug whose immediate or sealed outer or secondary container has been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until destroyed or returned to the supplier.

(iii) If the conditions under which a drug has been returned casts doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned casts doubt on the drug's safety, identity, strength, quality, or purity, then the wholesale distributor and private label distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling as a result of storage or shipping.

2. A procedure for examination of drugs:

(i) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(ii) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that has been damaged in storage or held under improper conditions.

3. A procedure to be followed for handling recalls and withdrawals of drugs which shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other federal, state, or municipal law enforcement or other governmental agency, including the Alabama State Board of Pharmacy.

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing existing merchandise with an approved product or new package design.

(c) Retail medical oxygen suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the security, storage, inventory and distribution of medical oxygen, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

1. Retail Medical Oxygen Suppliers shall include in their written policies and procedures the following:

(i) A procedure to ensure employment of adequate, trained personnel for the delivery and supplying of medical oxygen so that they can safely and properly deliver and supply the same; and

(ii) A designated person to ensure compliance with all USP, FDA, DOT and OSHA requirements, any other applicable requirements of state or federal law and any rules or regulations promulgated thereunder regarding the storage, packaging, labeling, shipping, dispensing, transfilling, and repackaging of medical oxygen; and

(iii) A procedure to supply patients information for obtaining medical oxygen on a twenty-four (24) hour, seven (7) day a week basis when essential to the maintenance of life or when lack of services might reasonably cause harm; and

(iv) A written procedure at each location for handling complaints and problems and resolution of the complaint and problems; and

(v) A procedure to ensure that all medical oxygen stored and available for sale is properly identified by a tag or label to its current status of use; and

(vi) A procedure to ensure that lot numbers area fixed to each cylinder delivered; and

(vii) A procedure to maintain a tracking system for all medical oxygen delivered.

2. Nothing in this section shall prohibit the non-hospital emergency administration of medical oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

3. Prescription Requirements.

(i) Retail medical oxygen suppliers shall not provide any medical oxygen to a patient without a valid prescription issued by a person authorized to prescribe medical oxygen in the course of that person's professional practice.

(ii) Retail medical oxygen suppliers shall make a record at the time of dispensing. The record of dispensing shall be maintained for two (2) years from the date of dispensing and shall include:

(I) Name and address of patient;

(II) Name and address of prescriber;

(III) Item dispensed and quantity;

(IV) Date of dispensing.

(iii) Retail medical oxygen suppliers will instruct the patient about emergency and routine contact procedures.

(iv) Retail medical oxygen suppliers will develop, implement, and document a written plan of service in the patient record for the purpose of ensuring that patients and/or caregivers are properly instructed

in the safe and effective use of medical oxygen, and in compliance with physician prescriptions and orders.

(v) The requirements of this section do not apply to licensed pharmacies or pharmacists.

(8) Responsibility for Operation:

(a) All permitted facilities should maintain a list of principals and persons in charge (including officers, directors, or primary stockholders) including a list of their duties and qualifications.

(b) All applicants for a controlled substance permit shall be permitted with the Board of Pharmacy and with the U.S. Drug Enforcement Administration and comply with all DEA regulations.

(c) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of the applicant, including the applicant's owners, partners, officers, stockholders, members, and designated representatives:

1. Any convictions of the applicant under any federal, state, or municipal laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2. Any felony convictions under federal, state, or municipal laws;

3. Past experience with pharmaceutical activities including, but not limited to, those described in this rule;

4. The furnishing of false or fraudulent material in any application made in connection with pharmaceutical activities including, but not limited to, those described in this rule;

5. Any discipline by any federal, state, municipal government or entity thereof, of any license, permit, registration, etc. currently or previously held by the applicant;

6. Compliance with licensing requirements under previously granted licenses, if any;

7. Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state, or municipal law enforcement officials those records required to be maintained; and

8. Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

(d) The Board of Pharmacy reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

(e) A transfer of ownership requires filing of an application for a permit.

(f) Any change in the control of ownership of an entity shall be reported to the board by completing the "Change in Ownership" form provided by the Board within 10 days of such occurrence.

(9) Personnel.

(a) The Alabama State Board of Pharmacy shall require that drug manufacturers, wholesale distributors, private label distributors, repackagers, and third-party logistics providers have a designated representative who has appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

1. All designated representatives shall register with the Alabama State Board of Pharmacy. The initial registration fee and renewal fee shall be one hundred dollars (~~$100~~$250). All designated representatives shall pay the renewal fee annually with this fee being due on October 31 and delinquent after December 31 annually. All designated representative registrations shall expire on December 31 annually. If the renewal is not timely received by the board, the applicant shall pay a penalty of fifty dollars ($50) for each month the renewal is late, not to exceed one thousand dollars ($1,000).

2. The designated representative shall:

(i) Be at least 21 years of age.

(ii) Be a citizen of the United States or, if not a citizen of the United States, a person who is legally present in the United States with appropriate documentation for the federal government.

(iii) Be employed by the facility full-time in a position of authority and be physically present at the facility for a minimum of 50% of the hours the facility is in operation or at least thirty (30) hours per week, whichever is less.

(iv) Be actively involved in and aware of the actual daily operation of the facility.

(v) Serve as a designated representative for only one physical location for a permitted facility at any one time.

(vi) Not have been convicted of a violation of any federal, state, or local law relating to any drug offense.

vii. Not have been convicted, received adjudication, community supervision, or deferred prosecution of any felony offense or any crime related to fraud, violence, sexual violations or related to the practice of pharmacy.

3. If the permit holder's designated representative will be or is no longer employed or no longer desires to act as a designated representative, the permit holder shall notify the Board within ten (10) days by completing the "Notice of Change of Designated Representative" form provided by the Board.

4. If the permit holder is unable to maintain a designated representative, the permit holder shall notify the Board within ten (10) days with an action plan to designate another designated representative. This plan shall not exceed ninety (90) days before the permit holder is in violation of operating a facility without a designated representative, at which time the Board may require closure of the facility until a designated representative assumes his/her duties.

5. In addition to all other applicable requirements for registration as a designated representative and

a prerequisite for consideration of registration as a designated representative, each individual seeking registration shall consent and be subject to a Board approved criminal background check, the cost of which to be paid by the applicant. The information received as a result of the background check shall be relied upon in determining whether the applicant meets the applicable qualifications to obtain the referenced registration.

(b) The Alabama State Board of Pharmacy shall require that outsourcing facilities have an Alabama licensed supervising pharmacist for the individual location and comply with 680-X-2-.12.

(10) Violations:

(a) It shall be a violation of these rules any permitted facility to operate in such a manner as to endanger the public health.

(b) Conviction of any federal, state or municipal drug laws or regulations or violation of any provisions of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit granted to facilities described herein by the Board of Pharmacy and/or the imposition of a fine not to exceed the sum of $1,000.00 for each such conviction or violation.

(c) Permitted facilities shall operate in compliance with applicable federal, state and municipal laws and regulations.

(11) Permit Fees

(a) An annual permit must be obtained from the Alabama State Board of Pharmacy by any drug manufacturer, wholesale distributor, private label distributor, repackager, third party logistics provider, outsourcing facility, or reverse distributor of drugs, chemicals, or poisons for medicinal purposes. A biannual permit must be obtained by any retail medical oxygen supplier. All permits shall be issued only after the filing of an application on a form furnished by the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall be accompanied by the fee set forth in paragraph (b). The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) The initial fee for the annual permit, with the exception of retail medical oxygen, shall be in the amount of ~~$750.00~~$1,500.00. The initial retail medical oxygen permit fee shall be $400.00.

(c) The fee for any renewal permit, with the exception of retail medical oxygen, shall be in the amount of ~~$500.00~~$1,000.00. The fee for any renewal permit for retail medical oxygen shall be $250.00

(d) The fee to transfer ownership of the permit shall be in the amount of $750.00.

(e) All permits issued by the Alabama State Board of Pharmacy shall become due on October 31 and shall become null and void on December 31 of the applicable year. Each application for the renewal of the permit shall be made on or before December 31 of the applicable year, at which time the previous permit shall become null and void. A penalty of one hundred dollars ($100.00) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits.

Author: Alabama Board of Pharmacy
Statutory Authority: Code of Ala. 1975, §34-23-32.
History: Filed May 30, 1990. **Amended:** Filed October 18, 1991; August 10, 1992. **Amended:** May 20, 1996; effective June 24, 1996; operative August 15, 1996. **Amended:** Published August 31, 2020; effective October 15, 2020. **Amended:** Published March 31, 2022; effective May 15, 2022. **Amended:** Published July 29, 2022; effective September 12, 2022. **Amended:** Published November 30, 2022; effective January 14, 2023. **Amended:** Published November 30, 2023; effective January 14, 2024. **Amended:** Published October 31, 2025; effective December 15, 2025. **Amended:** Published _____; effective _____.