APA-1
Revised 4/2018

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**
____ New **X** Amendment ____ Repeal ____ Adopt by Reference

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 and, if so, to what degree?	No
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	No
Are all facets of the rulemaking 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

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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.

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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.

Signature of certifying officer Donna C Graham

Date 5/14/2020

RECD & FILED
MAY 14 2020
LEGISLATIVE SVC AGENCY

APA-2

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.23 **Drug Manufacturers; Wholesale Distributors**

INTENDED ACTION:

Amend Rule

SUBSTANCE OF PROPOSED ACTION:

Add language consistent with federal requirements and provide clarity for new categories and facilities

TIME, PLACE, MANNER OF PRESENTING VIEWS:

Oppositions can be submitted to the Alabama State Board of Pharmacy office. Business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be held July 22, 2020 at 9:00am

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Comments concerning this change must be received by the Alabama State Board of Pharmacy no later than July 15, 2020

CONTACT PERSON AT AGENCY:

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Donna C. Yeatman

Donna C. Yeatman, R.Ph. Executive Secretary

680-X-2-.23 Drug Manufacturers; Wholesale Distributors; Private Label Distributors, Repackagers, Third Party Logistics, 503B Outsource

(1) Section 1. Definitions.

(a) Drug Outlet -All pharmacies, hospitals, drug abuse treatment centers, retail stores, penal institutions, and state jurisdictions that are engaged in delivery or distribution of drugs.

(b) Legend Drugs -Any drug, medicine, device, chemical or poison bearing on the label the words "CAUTION: Federal Law prohibits dispensing without prescription" or similar wording indicating that such drug, medicine, device, chemical or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(c) Manufacturer -Every person, except a pharmacy, in this state who prepares, derives, produces, compounds, packages or repackages any drug, medicine, chemical or poison.

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

(e) 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.

(f) Medicine -Any drug or combination of drugs that has the property of curing, diagnosing, preventing, treating, or mitigating diseases or that which may be used for such purposes.

(g) Wholesale Drug Distributor -Every person in this state engaged in the business of distributing drugs and medicines for resale to pharmacies, hospitals, practitioners, government agencies or other lawful outlets permitted to sell drugs or medicines. 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.

(h) Private Label Distributor - A firm that does not participate in the manufacture 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.

(i) Repackager - A person who purchases or acquires from a manufacturer or distributor, a drug, medicine, 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 any drug to a patient.

(j) 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, wholesale distributor, or dispenser of a product, that does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(k) Outsourcing Facility -A facility at one geographic location or address that is engaged in the compounding of sterile drugs, which has elected to register with the federal 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.

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

(m) Blood -Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(n) Blood Component -That part of blood separated by physical or mechanical means.

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

(p) 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) Section 2. Standards.

(a) Storage Conditions:

1. All facilities at which drugs or medicine 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 or medicine 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 same 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 or medicines 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.

(b) Facilities:

1. All buildings in which drugs or medicines 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.

(c) Security:

1. All ~~facilities used for wholesale drug distribution~~ permitted entities shall be secure from unauthorized entry.

2. All ~~wholesale drug distribution centers~~ permitted entities must be equipped with an alarm system to detect entry after hours.

3. All permitted entities ~~Wholesale drug distributors~~ must 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.

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

5. Entry into areas where drugs are held shall be limited to authorized personnel.

~~(d) Examination of Drugs and Medicines:~~

~~1. 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.~~

~~2. Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.~~

~~3. The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments.~~

~~(c)~~(d) Recordkeeping:

1. All permitted entities ~~Wholesale drug distributors~~ 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:

(i) 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;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

2. 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.

3. 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.

4. All charge back transactions shall be maintained separately from all other records.

5. 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.

6. The recordkeeping requirements of this Rule shall be followed for all incoming and outgoing shipments in compliance with the Drug Supply Chain Security Act (DSCSA) standards.

~~(f)~~ (e) Inspections:

1. All permitted entities ~~Wholesale drug distributors~~ shall ~~permit~~ allow the Board of Pharmacy and authorized Federal and 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~~, to the extent authorized by law~~. Such officials shall be required to show appropriate identification prior to being ~~permitted~~ granted access to ~~wholesale drug distributors'~~ permitted premises and delivery vehicles.

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

3. Costs for out of state inspections will be the responsibility of the permit holder.

~~(g)~~ (f) Written Policies and Procedures:

1. Wholesale drug distributors and private label 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. Wholesale drug distributors and private label distributors shall include in their written policies and procedures the following:

(i) A procedure to ensure that wholesale drug distributors ~~prepares~~ and private label distributors 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.

(ii) 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.

(iii) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(iv) A procedure for examination of drugs and medicines:

(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 have been damaged in storage or held under improper conditions.

~~(iv)~~ (v) 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.

2. Repackagers 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. Repackagers shall include in their written policies and procedures the following:

(i) A procedure to ensure that repackagers 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.

(ii) 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

(iii) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(iv) A procedure for examination of drugs and medicines:

(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 have been damaged in storage or held under improper conditions.

(v) 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.

3. Third party logistics providers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the documentation of 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.

(i) A procedure to ensure that third party logistics providers prepare for, protect against, and handle any crisis that affects security or operation in the event of strike, fire, flood, or other natural disaster or any other situation of local, state, or national emergency.

4. Outsourcing facilities shall establish, maintain, and adhere to written policies and procedures, which shall be

followed for the 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. Outsourcing facilities shall include in their written policies and procedures the following:

(i) A procedure to ensure that outsourcing facilities 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.

(ii) 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

(iii) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(iv) 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; or

(II) Any voluntary action by the facility to remove defective or potentially defective drugs from the market.

~~(h) Returned, Damaged and Outdated Drugs~~

~~1. 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.~~

~~2. 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.~~

~~3. 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 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.~~

~~(i)~~ (g) Responsibility for Operation:

1. ~~A wholesale drug distribution operation~~ All permitted entities should maintain a list of principals and persons in charge (including officers, directors, or primary stockholders) including a list of their duties and their qualifications.

2. All applicants for a permit as a controlled substance must be registered with the Board of Pharmacy and with the U.S. Drug Enforcement Administration and comply with all DEA regulations.

3. The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of ~~those persons who engage in the wholesale distribution of drugs~~ those entities permitted for operation within Alabama:

(i) 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;

(ii) Any felony convictions of the applicant under Federal, State, or Municipal laws;

(iii) The applicant's past experience ~~in the manufacturing or distribution of drugs, including controlled substances~~ with pharmaceutical activities including, but not limited to, those described in this rule;

(iv) The furnishing by the applicant of false or fraudulent material in any application made in connection ~~with drug manufacturing or distribution~~ with pharmaceutical activities including, but not limited to, those described in this rule;

(v) ~~Suspension or revocation~~ Any discipline by any Federal, State ~~or~~ ,Municipal government or entity thereof, of any license, permit, registration, etc. currently or previously held by the applicant ~~for the manufacturing or distribution of any drugs, including controlled substances~~;

(vi) Compliance with licensing requirements under previously granted licenses, if any;

(vii) 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 ~~by wholesale drug distributors~~; and

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

4. 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.

5. A transfer of ownership requires filing of an application for a permit.

6. Any change in the control of ownership of an entity shall be reported to the board in writing within 10 days of such occurrence.

~~(j)~~ (h) Personnel:

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

(i) The designated representative must:

(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 entity full-time in a position of authority

(IV) Be actively involved in and aware of the actual daily operation of the entity.

(V) Be physically present at the entity during regular business hours.

(VI) Serve as a designated representative for only one entity at any one time.

(VII) 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.

(ii) 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 of the change in designated representative.

2. 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.

~~(k)~~ (i) Violations:

1. It shall be a violation of these rules ~~for a wholesale drug distributor to distribute legend drugs directly to an employee, consumer, or a patient, or~~ any permitted entity to operate in such a manner as to endanger the public health.

2. 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 ~~wholesale drug distributors~~ entities 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.

3. ~~Wholesale drug distributors~~ Permitted entities shall operate in compliance with applicable Federal, State and Municipal laws and regulations.

Authors: ~~Vance L. Alexander~~, Donna C. Yeatman R.Ph, ~~President~~ Executive Secretary

Statutory Authority: Code of Ala. 1975, §34-23-92.

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:** Filed May 15, 2020; effective: September 14, 2020