

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF  
PHARMACY RULES,  
RULE 480-7-.05 REVERSE DISTRIBUTORS, AND NOTICE OF PUBLIC HEARING**

TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-7-.05 REVERSE DISTRIBUTORS (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street, NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at [www.gbp.georgia.gov](http://www.gbp.georgia.gov).

A public hearing is scheduled to begin at 9:00 AM on November 8, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36<sup>th</sup> Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to November 1, 2017. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. You may email your comments to [tbattle@dch.ga.gov](mailto:tbattle@dch.ga.gov).

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on 11/8/2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36<sup>th</sup> Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-113, and 26-4-115.

At its meeting on July 12, 2017, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

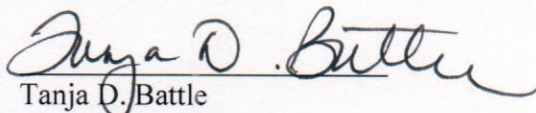
At its meeting on 7/12/2017, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.



For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 3<sup>rd</sup> day of Oct., 2017.



Tanja D. Battle  
Executive Director  
Georgia Board of Pharmacy

Posted: Oct. 3, 2017



**SYNOPSIS OF PROPOSED AMENDMENTS TO THE  
GEORGIA STATE BOARD OF PHARMACY RULE  
480-7-.05 REVERSE DISTRIBUTORS**

Purpose of Rule: The purpose of this rule is to set forth licensure requirements for reverse distributors.

Main Features: The main feature of this rule is to change the record-keeping requirements for reverse distributors.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE  
GEORGIA STATE BOARD OF PHARMACY RULE  
480-7-.05 REVERSE DISTRIBUTORS**

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

**RULE 480-7-.05 REVERSE DISTRIBUTORS**

(1) Every firm, whether located inside or outside the State of Georgia, which receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant located in the State of Georgia which holds a permit or license to dispense or possess drugs, shall be known as a Reverse Distributor or a Reverse Drug Distributor.

(2) In order or any Reverse Distributor, wherever located, to engage in the business of receiving drugs for destruction, return credit, or other disposal from a registrant located in Georgia, it must be licensed as a Reverse Distributor by the Georgia State Board of Pharmacy ("Board").

(3) The minimum information required by the Board in order to register a Reverse Distributor will be the same as required under Rule 480-7-.03(2).

(4) The minimum requirements for applications for registration as a Reverse Distributor with the Board will be the same as required under Rule 480-7-.03(3).

(5) Personnel: The licensed Reverse Distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the process of receiving drugs for destruction, credit return, or other means of disposal. Each such person shall have a working knowledge of the requirements for the law and rules for handling such drugs.

(6) Violations:

(a) A license issued to a Reverse Distributor pursuant to this part ~~shall~~ may be subject to revocation or suspension upon conviction of the license holder or of an employee of a reverse distributor for violations related to federal, state or local laws and/or rules.

(b) Violation of any provisions of any applicable Board Rules shall be grounds for the suspension, revocation, or other sanctions of the permit issued hereunder.

(c) Any action taken on a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50, Chapter 13.

(7) Minimum requirements for the storage and handling of prescription drugs and or the establishment and maintenance of prescription drug distribution records by Reverse Distributors. A Reverse Distributor shall follow the same requirements as listed under Board Rule 480-7-.03(7), except as follows:

(a) A Reverse Distributor does not have to maintain a separate quarantine area for storing drugs which are outdated, damaged, etc., as noted under Rule 480-7-.03;



(b) A Reverse Distributor does not have to maintain drugs under controlled temperature and humidity as required under Rule 480-7-.03;

(c) A Reverse Distributor does not have to ensure the condition of drugs that are received or shipped as required under Rule 480-7-.03(7)(d) or (e);

(d) ~~In addition to a Reverse Distributor having to follow all of the requirements of Rule 480-7-.03(7),~~ Prior to a Reverse Distributor removing or receiving drugs from a registrant, the Reverse Distributor must generate paperwork, a copy of which must be provided to and maintained by the registrant and a copy to be maintained by the Reverse Distributor, both for two (2) years, which at minimum records the following:

1. The date and time that the drugs left or were taken from the registrant;
2. A complete inventory of the drugs being transferred to the Reverse Distributor;
3. The name, Board permit number, address, and telephone number of the Reverse Distributor removing the drugs;
4. The name and signature of the responsible person representing the Reverse Distributor physically removing the drugs ~~or receiving the drugs~~; and
5. The name and signature of the pharmacist representing a pharmacy; or responsible person representing another type of registrant transferring the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are removed; and
6. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

(e) Upon a Reverse Distributor's receipt of drugs from a registrant by contract or common carrier, the Reverse Distributor must generate paperwork, a copy of which must be maintained by the Reverse Distributor for two (2) years, which at minimum records the following:

1. The date and time that the drugs were received by the Reverse Distributor;
2. A complete inventory of the drugs received by the Reverse Distributor;
3. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant sending the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are sent; and
4. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

Authority: O.C.G.A §§ 26-4-5, 26-4-27, 26-4-28, 26-4-113, and 26-4-115