

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-7-.07 CREDIT FOR RETURNED EXPIRED DRUGS, 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-.07 CREDIT FOR RETURNED EXPIRED DRUGS, AND NOTICE OF PUBLIC HEARING (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.

A public hearing is scheduled to begin at 9:00 AM on December 13, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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 December 6, 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.

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 12/13/2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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. §§ 26-4-27, 26-4-28, and 26-4-115.

At its meeting on November 8, 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.

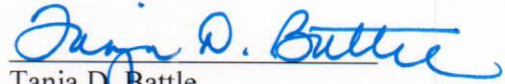
At its meeting on 11/8/2017, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these

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 13th day of Nov., 2017.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 13th, 2017

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-7-.07 CREDIT FOR RETURNED EXPIRED DRUGS**

Purpose of Rule: The purpose of this rule is to establish requirements and procedures for returning expired drugs for credit.

Main Features: The main features of this rule are to establish a required return policy, provide for exemptions, set appropriate timeframes, define key terms, and outline fraudulent and unprofessional conduct.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-7-.07 CREDIT FOR RETURNED EXPIRED DRUGS**

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

RULE 480-7-.07 CREDIT FOR RETURNED EXPIRED DRUGS

(1) Effective with all drug orders placed on or after July 1, 2002, all wholesale drug distributors shall make adequate provisions for the return of outdated prescription drugs, both full and partial containers, for up to six months after the labeled expiration date for prompt full credit or replacement.

(2) Wholesale drug distributors shall establish a written policy consistent with O.C.G.A. Section 26-4-115(c) providing for the return of outdated prescription drugs sold to a client by such wholesale drug distributor. Such policy may include a procedure for the drugs to be returned to the drug manufacturer, may include a requirement that the drugs be returned in the original containers in which it was purchased, and may include the use of a reverse drug distributor. Said policy shall be available to the Board or its agents upon request.

(3) The Board has determined the following listed drugs will be exempt from the requirements of this provision as they are essential to health care treatment and have an expiration date of less than one year from the date such drug is manufactured:

(a) Influenza Vaccines

~~(3)~~ (4) In order to be eligible for full credit or replacement, the drug must be received by the wholesale drug distributor, or if not the wholesale drug distributor, its agent designated in its return policy, no later than the sixth month from the labeled expiration date. A signed delivery receipt shall constitute evidence of the drugs having been returned.

(4) ~~(5)~~ Prompt full credit to the purchaser shall occur within sixty days from the date the return drugs were received by the wholesale drug distributor or its designated agent. If the wholesale drug distributor determines that the drugs were not returned within six months of the labeled expiration date, or were not returned consistent with the written return policy, then the wholesale drug distributor shall notify said purchaser in writing within thirty (30) days of the receipt of the drugs of its intent not to give full credit or replacement. Wholesale drug distributors shall maintain documentation supporting its refusal to give full credit or replacement for a period of two (2) years. Such documentation shall be available to the Board or its agent upon request.

(a) "Full credit" shall be defined to include a cash refund or credit with the drug wholesale distributor for the purchase price of the drug as established by drug invoice less a reasonable fee

for handling of the returned drugs. A reasonable fee shall not be more than 7% of the total invoice price of the returned drugs.

~~(5)~~ (6) In lieu of full credit, a wholesale drug distributor may elect to replace the drug. Said replacement drug must be a drug of like value mutually agreed upon by the wholesale drug distributor and the original drug purchaser. Said replacement drug must be sent to the original drug purchaser within sixty (60) days from the date of return.

~~(6)~~ (7) Wholesale drug distributors shall maintain records of all credits and replacements made under this rule for a period of two (2) years and such record shall be made available to the Board or its agent upon request.

~~(7)~~ (8) The submission of drugs by a purchaser licensed by the Board in State of Georgia for refund or credit to a wholesale drug distributor pursuant to O.C.G.A. Section 26-4-115 and this rule when said drugs are in a container other than the one in which it was purchased, when said drugs were not purchased from that wholesale drug distributor, or when the drugs were purchased for a pharmacy or facility outside the State Of Georgia shall constitute fraudulent and unprofessional conduct and may subject the purchaser to disciplinary action by the Board.

~~(8)~~ (9) The return of drugs under this rule shall also be consistent with all other applicable Federal, State, and local laws and regulations.

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