

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-11-.08 RECORDS AND REPORTS,
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 480-11-.08 RECORDS AND REPORTS (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 12:00 PM on November 19, 2014 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th 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 12, 2014. 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 12:05 PM on November 19, 2014 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th 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, 26-4-86.

At its meeting on September 17, 2014, 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.

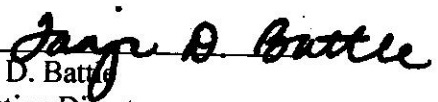
At its meeting on September 17, 2014, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of

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 16th day of October, 2014.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 16, 2014

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-11-.08 RECORDS AND REPORTS**

Purpose of Rule: The purpose of this rule is to establish record-keeping requirements under Chapter 480-11.

Main Features: The main feature of this rule is to establish additional record-keeping requirements for sterile pharmaceuticals.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-11-.08 RECORDS AND REPORTS**

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

480-11-.08 Records and Reports.

(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in chapter 480-10 of the Board Rules for the retention of prescription files.

(2) All records required to be retained under this chapter or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, electronic files or other accurate reproductions of the original records. All records or reports must be producible immediately if requested by the Board or an agent of the GDNA or within forty-eight (48) hours if maintained in a central database.

(4) In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:

(a) A policy and procedure manual, including policies and procedures for cytotoxic and/or infectious waste, if applicable; and

(b) Lot numbers and expiration dates of all the components used in compounding sterile prescription drug orders.

(c) This record-keeping requirement does not apply when FDA approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86.