

**NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-19-.04 RECORD KEEPING FOR OVER-THE-COUNTER (OTC) SALES OF
EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS
CONTAINING PSEUDOEPHEDRINE, 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 adoption of new Georgia Board of Pharmacy Rules, Rule 480-19-.04 RECORD KEEPING FOR OVER-THE-COUNTER (OTC) SALES OF EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE (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 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334 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, 2023. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. You may email your comments to elacefield@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 9:00 AM on December 13, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. 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.

At its meeting on July 19, 2023, 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.

Also, at its meeting on July 19, 2023, the Board 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 this chapter 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 13 day of November, 2023.



Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: November 13, 2023.

**SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-19-.04 RECORD KEEPING FOR OVER-THE-COUNTER (OTC) SALES OF
EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS
CONTAINING PSEUDOEPHEDRINE**

Purpose: To amend the rule to update the address of the Georgia Drugs and
Narcotics Agency's offices to reflect relocation of same.

Main Features: Updated the address of the Georgia Drugs and Narcotics Agency's offices.

**TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-19-.04 RECORD KEEPING FOR OVER-THE-COUNTER (OTC) SALES OF
EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS
CONTAINING PSEUDOEPHEDRINE**

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

Text of the proposed rule is attached hereto.

Rule 480-19-.04. Record Keeping for Over-the-Counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine

- (1) A record created this rule must be maintained in the pharmacy at which the transaction occurred, except that records may be kept either at a single, central location for the pharmacy or by a third party information technology company on behalf of the pharmacy only if the pharmacy has notified the GDNA of its intention to do so and received GDNA approval.
 - (a) Written notification must be submitted by registered or certified mail, return receipt requested, to the Director, Georgia Drugs and Narcotics Agency, ~~40 Pryor Street, SW, Suite 2000, Atlanta, Georgia 30303~~ 254 Washington Street SW, Suite G2000, Atlanta, GA 30334.
 - (b) This notification must include telephone and address contact information as well as a telephone number and email address for a point of contact person who is responsible for providing requested record for either the pharmacy's central record keeping location or any third party information technology company.
 - (c) The Director of the Georgia Drugs and Narcotics Agency shall issue written approval of any central record keeping location or third party information technology company prior to records being maintained in such a manner.
- (2) The records required to be kept under this rule must be readily retrievable and available for inspection and copying by GDNA or other law enforcement officers as requested as provided for under the provisions of 21 U.S.C. 880, and the U.S. Combat Methamphetamine Epidemic Act of 2005.
 - (a) A record developed and maintained to comply with federal law may be used to meet the requirements of this rule if the record includes the information specified by this rule.
 - (b) Readily retrievable shall mean records must be produced by the pharmacy or the pharmacy's third party information technology company in less than 6 hours for all electronically maintained records or 24 hours for any handwritten records.
- (3) If a pharmacy fails to produce records or to produce records in the required time, ~~is such~~ failure shall be considered a violation of O.C.G.A. ~~Sections §§~~ 16-13-37, 16-13-39, and 16-13-42.

Authority: O.C.G.A. §§. 16-13-22, 16-13-29, 16-13-29.2, 16-13-34, 16-13-35, 26-4-27, 26-4-28, 26-4-60.