

**NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-34-.16 NALOXONE HYDROCHLORIDE NASAL SPRAY, 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 480-34-.16 NALOXONE HYDROCHLORIDE NASAL SPRAY (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. §§ 16-13-71, 26-4-5, 26-4-27, and 26-4-28.

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 480-34-.16 NALOXONE HYDROCHLORIDE NASAL SPRAY**

- Purpose:** To remove 4mg naloxone hydrochloride nasal spray from the dangerous drugs list.
- Main Features:** Removal of 4mg naloxone hydrochloride nasal spray from the dangerous drugs list.

**TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-34-.16 NALOXONE HYDROCHLORIDE NASAL SPRAY**

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 480-34-.16. Naloxone Hydrochloride Nasal Spray

- (1) This rule was adopted to protect the health, safety, and welfare of the public. Four mg naloxone hydrochloride nasal spray, is hereby deleted from the dangerous drug list as referenced in the Official Code of Georgia Annotated (O.C.G.A.) §§ 16-13-71(b)(635) and 16-13-71(c)(14.25).
- (2) This rule is based on the following findings of the Board:
 - (a) that Narcan, 4mg naloxone hydrochloride nasal spray, does not have a high potential for abuse;
 - (b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and
 - (c) that the drug, when in nasal spray form of 4 mg per spray has been approved for non-prescription status by the Federal Food and Drug Administration.

Authority: O.C.G.A. §§ 16-13-71, 26-4-5, 26-4-27, 26-4-28.