

**NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-11-.10 EXCEPTIONS, 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 480-11-.10 EXCEPTIONS (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 April 9, 2025 at South University, School of Pharmacy, 709 Mall Blvd., Savannah, GA 31406 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 April 8, 2025. 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 james.joiner@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 April 9, 2025 at South University, School of Pharmacy, 709 Mall Blvd., Savannah, GA 31406. 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, and 43-1-25.

At its meeting on December 18, 2024, 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 December 18, 2024, 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 5th day of March, 2025.



J. Clinton Joiner, II
Executive Director
Georgia State Board of Pharmacy

Posted: March 5, 2025.

**SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-11-.10 EXCEPTIONS**

Purpose: To provide that the definition of an act of pharmaceutical compounding shall not include the act of adding flavoring agents to manufactured drug products.

Main Features: This rule provides that the act of adding flavoring agents to a drug is not an act of compounding.

**TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-11-.10 EXCEPTIONS**

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 480-11-.10. Exceptions

- (1) The requirements of this chapter do not apply to the compounding or mixing of FDA-approved drugs preparations pursuant to the manufacturer's directions for dispensing including but not limited to the reconstitution of oral suspensions, combination of the components of topical preparations, etc.
- (2) The act of adding flavoring agents to conventionally manufactured drug products, on its own, shall not be considered an act of pharmaceutical compounding.

~~(1)~~

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