

**NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD  
OF PHARMACY RULES,  
RULE 480-24-.08 CRISIS STABILIZATION UNIT (CSU) EMERGENCY DRUG KITS, 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 a new Rule to the Georgia Board of Pharmacy Rules: Rule 480-24-.08 CRISIS STABILIZATION UNIT (CSU) EMERGENCY DRUG KITS (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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 proposed rule, and a synopsis of the proposed rule 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](http://www.gbp.georgia.gov).

A public hearing is scheduled to begin at 9:00 AM on November 8, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36<sup>th</sup> Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 1, 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](mailto:tbattle@dch.ga.gov).

The proposed rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on November 8, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36<sup>th</sup> 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 rule pursuant to authority contained in O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-36, 16-13-39, 16-13-41, 16-13-72, 26-4-27, 26-4-28, 26-4-29, 26-4-110, and 26-4-111.

At its meeting on July 12, 2017, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule 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.

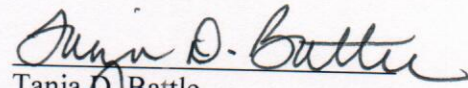
Also, at its meeting on July 12, 2017, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of

this rule 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 3<sup>rd</sup> day of Oct, 2017.



Tanja D. Battle  
Executive Director  
Georgia Board of Pharmacy

Posted: Oct. 3, 2017

**SYNOPSIS OF PROPOSED RULE OF THE  
GEORGIA STATE BOARD OF PHARMACY RULES  
RULE 480-24-.08 CRISIS STABILIZATION UNIT (CSU) EMERGENCY DRUG KITS**

Purpose of Rule: The purpose of this rule is to establish a formal protocol for placing emergency drug kits in licensed Crisis Stabilization Units (CSU).

Main Features: The main features of this rule are requirements for record keeping; limited access; storage; inventory maintenance; GDNA inspection; applications; proper labeling of individual drugs and kit; drug or dosage change notifications; and grant the Board authority to approve applications, revoke approval, and control the individual drugs and dosages in each kit.

**PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES  
RULE 480-24-.08 CRISIS STABILIZATION UNIT (CSU) EMERGENCY DRUG KITS**

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

**480-24-.08 Crisis Stabilization Unit (CSU) Emergency Drug Kits.**

Emergency drug kits may be placed in licensed Crisis Stabilization Units (CSU) by the pharmacy of the consultant or vendor pharmacist provided the following conditions are met:

- (1) A record of the drugs to be kept in an emergency drug kit must be kept in the CSU and the provider pharmacy;
- (2) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a prescription drug order from a licensed practitioner. A valid, signed prescription drug order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit:
  - (a) Whenever an emergency drug kit is accessed and a drug is removed, personnel shall immediately reseal the kit with a tamper-proof, serial-numbered seal, with the seal serial number to be recorded in a log along with the name of the person removing the drug and resealing the kit and date the kit was opened;
- (3) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;
- (4) An emergency drug kit must be inventoried once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections;
- (5) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate and the emergency drug kit is being properly used;
- (6) The provider pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual CSU and a copy of this approval will be kept on file in both the CSU and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any CSU where abuse or misuse of drugs from the emergency drug kit is noted;

(7) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the CSU. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit;

(8) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(9) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY", and the label shall be physically signed and dated by the pharmacist who sealed the kit. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-36, 16-13-39, 16-13-41, 16-13-72, 26-4-27, 26-4-28, 26-4-29, 26-4-110, and 26-4-111.