NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-13-.11 REQUIRED NOTIFICATIONS TO THE BOARD.

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 480-13-.11 REQUIRED NOTIFICATIONS TO THE BOARD. (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.

A public hearing is scheduled to begin at 11:30 AM on November 9, 2016 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 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 2, 2016. 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 rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:35 AM on November 9, 2016 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 rule pursuant to authority contained in O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-110, and 26-4-112.

At its meeting on August 3, 2016, 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 August 3, 2016, 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 4th day of October, 2016.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 4, 2016

SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-13-.11 REQUIRED NOTIFICATIONS TO THE BOARD.

Purpose of Rule: The purpose of this rule is to clarify in the rules the notification requirements for hospital pharmacies that are required by law.

Main Features: The main feature of this rule is to set time limits for written notifications.

PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-13-.11 REQUIRED NOTIFICATIONS TO THE BOARD.

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

480-13-.11 Required Notifications to the Board.

(1) For purposes of this rule, the following terms shall means as follow:
(a) "Board" shall mean the Georgia Board of Pharmacy;
(b) "Immediate notification" shall mean written notification sent within twenty-four (24) hours of the event;
(c) "Sentinel event" shall mean any unanticipated patient death from medication not related to the natural course of the patient's illness or underlying condition;
(d) "Written notification" shall mean in writing and sent by statutory overnight delivery or by email.
(2) The following occurrences require immediate notification to the Board at its address of record, unless otherwise provided:
(a) Permanent closing of a licensed pharmacy. Notification shall include the name and contact information for the person responsible for maintaining the pharmacy records after the pharmacy has closed and location of the records.
(b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of the appropriate applications, the existing pharmacy license is void, and there is no continuing authority to operate as a pharmacy.
(c) Change in management of a licensed pharmacy.
(d) Change of the Director of Pharmacy of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a Director of Pharmacy and no replacement Director of Pharmacy is named, the pharmacy's license is suspended pending further action by the Board.
(e) Any theft or loss of drugs of a licensed pharmacy. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the pharmacy must comply with Rule 480-13-.06.
(f) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws, not previously reported.
(g) Disasters or accidents involving the licensed pharmacy.
(h) Thefts or break-ins at the licensed pharmacy.
(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law.

(j) Occurrence of a sentinel event, where the Director of Pharmacy has reasonable cause to believe that a sentinel event occurred.
1. The immediate notification from the Director of Pharmacy to the Board shall include but not be limited to the name of the licensed pharmacy and its pharmacy number; the date of the sentinel event and the date on which the Director of Pharmacy became aware that a sentinel event may have occurred; a brief description of the sentinel event; and any immediate corrective or preventative action taken by the licensed pharmacy to ensure against any future occurrences prior to the completion of the hospital's investigation.
2. Within forty-five (45) business days of the completion of any internal investigation or review of the sentinel event, the Director of Pharmacy shall provide a supplemental report to the Board that includes but is not limited to the following:
(i) An explanation of the circumstances surrounding the sentinel event, including the results of a root cause analysis or other systematic analysis;
(ii) Any finding or conclusions associated with the investigation or review;
(iii) A summary of any actions taken to correct identified problems associated with the sentinel event and to prevent recurrence of a similar incident;
(iv) Any changes in procedure or practices resulting from the internal evaluation using the hospital's peer review and quality management processes or the pharmacy's internal investigation or review.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-110, and 26-4-112.