

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 680 Department or Agency: Alabama State Board of Pharmacy
Rule No. 680-X-2-.19
Rule Title: Parenteral Sterile Therapy
 New X Amendment Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer: Donna C. Gresham

Date: 10/16/2020

REC'D & FILED

OCT 19 2020

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.19 Parenteral Sterile Therapy.

INTENDED ACTION:

Amend Rule

SUBSTANCE OF PROPOSED ACTION:

The Alabama State Board of Pharmacy proposes to amend Rule No.680-X-2.19 - Parenteral Sterile Therapy. To ensure the public's safety by requiring ongoing proficiency of parenteral standards.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

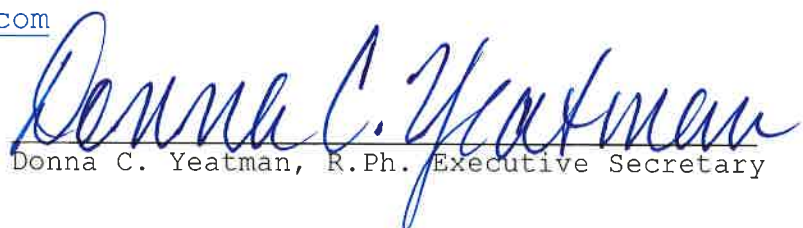
Oppositions can be submitted to the Alabama State Board of Pharmacy office. Business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be held December 16, 2020 at 9:00am

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Comments concerning this change must be received by the Alabama State Board of Pharmacy no later than December 9, 2020

CONTACT PERSON AT AGENCY:

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Donna C. Yeatman, R.Ph. Executive Secretary

680-X-2-.19 Parenteral Sterile Therapy.

(1) Purpose: Whereas the Alabama State Board of Pharmacy is charged with the duty and responsibility to control the compounding and distribution of prescription drug products in the State of Alabama and is further charged to protect the citizens from inferior drug products and inappropriate compounding procedures. This rule shall provide guidelines and regulations for the compounding and distributing of parenteral products in Alabama, and to assure the Alabama consumer of sterile parenteral products that are dispensed or prepared by qualified pharmacists using acceptable pharmaceutical techniques and equipment.

(2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of products which should be sterile shall be registered with the Alabama State Board of Pharmacy biennially which shall expire on December 31 of even-numbered years and Alabama pharmacies shall receive a permit in accordance with Code of Ala. 1975, §34-23-30. Such pharmacies shall be certified, further, by the Alabama State Board of Pharmacy as a parenteral sterile compounding pharmacy.

(3) Registration and Certification, Pharmacists: All pharmacists, permitted and practicing in Alabama, engaged in compounding and dispensing of product which should be sterile, including cytotoxic agents, shall register ~~biennially which shall expire on December 31 of even-numbered years~~ each renewal cycle with the Board of Pharmacy in accordance with Code of Ala. 1975, §§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for sterile compounding ~~pharmacists who have been~~ approved by the Board, will not be registered as sterile compounding pharmacists ~~with the Board~~ until they have completed said certifying course. Programs submitted for certification shall be a minimum of ~~five~~ (5) eight (8) contact hours, including didactic and hands on experience. All programs certified by the Board shall require a written exam as a part of the training. Pharmacists performing high risk sterile compounding shall complete an additional four (4) hour board approved high risk program. All pharmacists approved by the Alabama State Board of Pharmacy as sterile compounding pharmacists must successfully complete two (2) continuing education hours approved by the Board including didactic and hands on training each renewal cycle.

(4) It shall be the responsibility of the supervising pharmacist to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

Author: ~~Susan Alverson~~ Donna C. Yeatman, R.Ph., Executive Secretary

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed July 18, 1989. **Amended:** March 19, 1993. **Amended:** Filed July 24, 2012; effective August 28, 2012. **Amended:** Filed July 25, 2018; effective September 8, 2018.