

APA-1

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
Intended Action: Amend

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? No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule? NA

Are all facets of the rule-making 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 Yeatman
Donna Yeatman

Date

Thursday, December 12, 2024

REC'D & FILED
DEC 17, 2024
LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Pharmacy

RULE NO. & TITLE: 680-X-2-.19 Parenteral Sterile Therapy

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
Update terminology to align with current USP <797> standards.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
The public hearing will take place February 19th, 2025, during the Business meeting beginning at 9:00 am CST. Comments may be submitted to anolen@albop.com by no later than Friday, February 14th at 4:00 pm CST.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Friday, February 14, 2025

CONTACT PERSON AT AGENCY:
Anne Marie Nolen
anolen@albop.com

Anne Marie Nolen

Anne Nolen

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

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 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 approved by the Board, will not be registered as sterile compounding pharmacists until they have completed said certifying course. Programs submitted for certification shall be a minimum of 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~~ who prepare compounded sterile products from one or more non-sterile starting components 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: ~~Donna C. Yeatman, R.Ph., Executive Secretary~~ Alabama State Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §~~34-23-92~~.34-23-162

History: Filed July 18, 1989. **Amended:** March 19, 1993.

Amended: Filed July 24, 2012; effective August 28, 2012.

Amended: Filed July 24, 2012; effective August 28, 2012.
Amended: Filed July 25, 2018; effective September 8, 2018.
Amended: Published December 31, 2020; effective February 14,
2021. **Amended:** Published ; effective .