

**CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR**

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on Wednesday, February 19, 2025, and filed with the agency secretary on Wednesday, February 26, 2025.

AGENCY NAME: Alabama State Board of Pharmacy

INTENDED ACTION: Amend

RULE NO.: 680-X-2-.19

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **(3)**

RULE TITLE: Parenteral Sterile Therapy

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes. n/a

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLIII, ISSUE NO. 3, AAM, DATED TUESDAY, DECEMBER 31, 2024.

STATUTORY RULEMAKING AUTHORITY: 34-23-162

(Date Filed)
(For LRS Use Only)

REC'D & FILED
FEB 26, 2025
LEGISLATIVE SVC AGENCY

Anne Marie Nolen

Anne Nolen

Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

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 who prepare compounded sterile products from one or more non-sterile starting components shall complete an additional four (4) hour board approved 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: Alabama State Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §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 March 31, 2025; effective May 15, 2025.