APA-1
07/04

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control No. 680 Department or Agency Alabama State Board of Parmacy
Rule No. 680-X-2-.19
Rule Title:
_____ New __x__ Amend _____ 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

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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.

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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 Reference Service.

Signature of certifying officer Lemuel Stevenson

Date May 31, 2017

(DATE FILED)
(STAMP)

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

RULE NUMBER: **680-X-2-.19**

TITLE OF RULE: **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 citizens of Alabama of sterile parenteral products that are dispensed or prepared by qualified pharmacist using acceptable pharmaceutical techniques and equipment.

(2)Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of ~~parenterals~~ 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 Alabama 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 ~~Parenteral Solutions~~ products which should be sterile including cytoxic agents shall register biennially which shall expire on December 31 of even-numbered years with the Board of Pharmacy in accordance with the Code of Alabama 1975, §§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for ~~parenteral~~ sterile compounding pharmacists ~~which~~ who ~~has~~ have been approved by the Board, will not be registered as ~~parenteral~~ sterile compounding pharmacists with the Board until they have completed said certifying course. Programs submitted for certification shall be a minimum of five (5) 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.

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

~~(b) Effective January 1, 1994, the annual one (1) hour of mandatory parenteral continuing education will no longer be required.(4) Compounding Area for Parenteral Solutions: The parenteral pharmacy shall have a designated area complying with the clean room concept and contain a certified laminar airflow hood with the intact HEPA filters and shall:(a) Have cleanable surfaces, walls and floors. (b) Be ventilated with a filtered air source to inhibit the induction of particulate matter from areas outside the clean room.(c) The laminar air flow hood shall be certified annually, in accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Services, United States General Services Administration, as amended, (available from the U.S. General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, D.C. 20407). Certification records must be retained for at least 2 years.(d) The pharmacy shall be arranged in such a manner that the laminar flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related tothe compounding of parenteral solutions. There shall be no obstruction of the intake of the laminar flow hood. 1. There shall be sufficient space, well separated from the laminar flow hood area, for the storage of bulk materials, equipment and waste materials. (e) A sink with hot and cold running water must be within or adjacent to the parenteral solution compounding area.(f) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirement for all material requiring refrigeration.(5) Laminar Flow Biological Safety Cabinet: In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood. The pharmacy must ensure that contaminated air plenums thatare under positive air pressure are leak tight. The hood must be certified annually in accordance with the National Sanitation Foundation International Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised (available from the National Sanitation Foundation International, 789 North DixboroRoad, P.O. Box 130140, Ann Arbor, Michigan 48113-0140) or manufacturer's specifications. Certification records must be retained for at least two (2) years.~~

~~50(6) Labeling Requirements: In addition to existing labeling requirements, parenteral products labels shall include:(a) Telephone number of the pharmacy when the parenteral product will be administered outside of the facility in which it was prepared.(b) Names and amounts of all ingredients contained in the parenteral products, including primary solution.(c) Instructions for storage and handling including expiration date and date prepared.(d) All cytotoxic agents shall bear a special label regarding proper disposal.(7) Recordkeeping Requirements: Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises or readily accessible, a patient record for each patient being treated with parenteral therapy. In addition to existing recording requirements, the following records shall be maintained.(a) Records of the furnishing of all medications.(b) Information relevant to the patient's parenteral therapy shall include but not be limited to:1. Patient's name, age, sex and address; telephone number of location where patient is receiving parenteral therapy.2. Primary diagnosis related to need for prescribed therapy; secondary diagnosis.3. Summary of most recent hospitalization and/or previous history.4. Medication history, including current diet/medication regimen and drug/food allergies.(c) Progress notes documenting contact with the patient or physician relative to parenteral therapy.(d)Laboratory data relevant to parenteral therapy.(8) Protective Clothing: When preparing cytotoxic agents, gowns and gloves shall be worn. In addition, spill kits shall be available.(9) Training of Staff, Patient and Caregiver: Consultation shall be available on a 24 hour basis to the patient and/or primary caregiver concerning proper use of parenterals and related supplies furnished by the pharmacy.(a) The Supervising Pharmacist shall insure that all pharmacists engaged in dispensing or preparing compounded parenteral solutions are registered with the Board of Pharmacy and currently certified as parenteral pharmacists by the Board.(10) Disposal of Waste Material: Pharmacies providing parenteral services shall have written policies and procedure for the disposal of medical waste, infectious materials and/or materials containing cytotoxic residues including spills. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction. The pharmacy shall ensure the return of such materials or shall communicate the proper destruction of such materials to the caregiver. (11) Quality Assurance: The Supervising Pharmacist is responsible for developing and maintaining a quality assurance program that insures a clean and sanitary environment for the preparation of sterile products. Documentation of such activities shall be available. The Quality Assurance Program shall include at least the following:(a) Cleaning and~~

~~sanitization of the parenteral medication preparation area.(b) Surveillance of parenteral solutions for microbiological contamination and actions taken in the event that testing for contamination proves positive.(c) Periodic documentation of the room and refrigerator temperatures in which compounded parenteral products are stored.(d) Steps to be taken in the event of a drug recall.(e) Justification of expiration dates for compounded parenteral products.(12) Policies and Procedures: Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedures which describe the methods employed by the pharmacy in all areas of the pharmacy's parenteral therapy services. 51(13) Reference Materials: Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have current reference materials locatedin or immediately available to the pharmacy. The pharmacy shall have adequate reference materials related to the compounding and dispensing of parenteral products. Some suggested sources include:Handbook on Injectable Drugs (ASHP)King'sGuide to Parenteral AdmixturesAHFS Drug InformationFacts and ComparisonsHansten's Drug InteractionsRemington Practice of Pharmacy~~

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Statutory Authority: *Code of Alabama 1975, §34-23-92*
History: *Filed: July 18, 1989; Effective: September 15, 1989. Amended: Filed January 25, 1993; Amended: Filed March 19, 1993; Effective January 1, 1994; Amended July 24, 2012; Effective August 28, 2012; Amended: Filed July 24, 2012; effective August 28, 2012. Amended: Filed ? ; effected ?*