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.~~