STATE OF WEST VIRGINIA

OFFICE OF THE SECRETARY OF STATE

CHARLESTON 25305

A. JAMES MANCHIN
SECRETARY OF STATE

STATE REGISTER FILING

I, C. Herbert Traubert, Secretary
Title or Position,

WEST VIRGINIA BOARD OF PHARMACY, hereby submit to record in
Department or Division

the State Register on 8 1/2 x 11" paper two (2) copies of

(X) proposed rules and regulations concerning topics of material not covered by existing rules and regulations;

( ) proposed rules and regulations superseding rules and regulations already on file;

(X) notice of hearing;

(X) findings and determinations;

(X) rules and regulations; or

( ) other - specify (

This filing pertains to

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 7-24-84
Administrative Law Division

Chapter 30
Article 5
Series 1
Section 19
Page No. 22

( ) proposed rules and regulations are required to go to Legislative Rule Making Committee;

( ) proposed rules and regulations are excluded from Legislative Rule Making Committee;

July 12, 1984
Date Submitted

C. Herbert Traubert
Signature of Person Authorizing this Filing

WEST VIRGINIA

OFFICE
150 ROCKDALE ROAD
FOLLANSBEE, WEST VA. 26037
304-527-1270

Board of Pharmacy

SECRETARY
C. HERBERT TRAUBERT

NOTICE OF PUBLIC HEARING

Pursuant to Section five, Article three, Chapter twenty-nine-A of the Code of West Virginia, one thousand nine hundred thirty-one, as amended, the West Virginia State Board of Pharmacy shall convene a public hearing at 10:00 a.m. on September 24, 1984, Auditorium of Basic Science Addition, Medical Center, Morgantown, West Virginia for the purpose of taking evidence pertaining to the filing of proposed Parenteral/Enteral Compounding Regulations, Article 11 of the ammended regulations, Series 1. The proposed regulation is exactly the same as the document which was promulgated as Emergency Rules and Regulations on April 30, 1984.

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence to the West Virginia State Board of Pharmacy by mail to 150 Rockdale Road, Follansbee, West Virginia 26037 or in person not later than September 10, 1984 at 4:30 p. m. All written comments will be made part of the public record of comments received and will be considered as a part of the public hearing. The Board of Pharmacy requests that parties wishing to comment make an effort to submit written copies of their comments in order to facilitate review of said comments.

The issues to be heard shall be limited to the actual information contained in the proposed and abovementioned regulations. Copies of the regulations may be obtained from the address heretofore appearing or by telephoning 304-527-1270.

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A. JAMES MANCHIN
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THIS DATE 7-24-84
Administrative Law Division

C. Herbert Traubert

C. Herbert Traubert, Secretary
WEST VIRGINIA BOARD OF PHARMACY
July 12, 1984

PROPOSED RULES AND REGULATIONS

FOR

"PARENTERAL/ENTERAL COMPOUNDING"

FOR THE

WEST VIRGINIA BOARD OF PHARMACY

Pursuant to Chapter 29-A-3-5; procedures for promulgation; definitions.

Therefore, pursuant to Chapter 30, Article 5, Section 19, the Board of Pharmacy proposes the adoption of the following regulations and hereby amends Article 11 of the regulations - Regulation Governing Pharmacy Permits, Section 2 - Application for Permits.

ARTICLE 11. Regulation Governing Pharmacy Permits.

(1) Pharmacy Permits and Annual Registration.

Pharmacies or drug stores opening for business must first secure a permit and be registered with the Board of Pharmacy before they may lawfully conduct a pharmacy or drug store. The annual registration for renewal of permits shall be effective on the 1st day of July of each year.

(2) Applications for Permits.

The Board of Pharmacy shall require and provide for the annual registration of every pharmacy or drug store, as defined, doing business in this state. Any person, firm, corporation or copartnership desiring to operate, maintain, open or establish a pharmacy or drug store, as defined, in this state, shall apply to the Board of Pharmacy for a permit to do so. Every such place of business so registered shall be under the direct charge of a registered pharmacist and operate in compliance with the general provisions governing the practice of pharmacy and the operation of a drug store and pharmacy.

(1) A pharmacy engaged in the practice of parenteral/enteral compounding shall comply with the following regulations:

(a) A parenteral/enteral compounding pharmacy is a type of special pharmacy which is limited in scope of pharmacy practice to render parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures

by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services and parenteral/enteral products provided by a parenteral/enteral compounding pharmacy pursuant to prescription, as defined in Ch. 30-5-1 (6), shall be limited to the compounding and/or dispensing of:

All sterile preparations for parenteral therapy, and parenteral nutrition, including but not limited to

(a) Sterile preparations for jejunostomy feeding and sterile irrigation solutions, and/or

(b) Sterile preparations of parenteral cytotoxic, antineoplastic, anti-infective and analgesic agents.

Any pharmacy, prior to engaging in parenteral/enteral compounding, shall obtain a parenteral/enteral compounding permit as provided herein.

(2) Pharmacy Environment

(a) The compounding and dispensing of sterile parenteral/enteral prescription preparations shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General Requirements

(a) Parenteral/enteral compounding shall be under the control and supervision of a licensed pharmacist, who shall be designated pharmacist manager on the application for a parenteral/enteral compounding permit. The pharmacist manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of product preparation. Changes in pharmacist manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and pharmacist manager of record. A pharmacist manager of a parenteral/enteral compounding pharmacy shall not be designated pharmacist manager of record of more than one parenteral/enteral compounding pharmacy.

(b) A pharmacy engaged in parenteral/enteral compounding shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include time and/or date of expiration on the label and control number subcompounds. A parenteral/enteral compounding pharmacy shall provide telephone accessibility to its pharmacist for its patients at all hours.

(c) A patient profile shall be maintained for each patient. Said profile must contain available medical information consistent with prevailing pharmacy standards.

(d) A Policy and Procedure Manual shall be prepared and maintained at each parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. It shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random product sampling consistent with recommended standards for compounding and dispensing intravenous admixtures and a comprehensive patient drug profile and other parenteral medication as set forth by the Joint Commission on Accreditation of Hospitals, the National Coordinating Committee and Large Volume Parenterals, and as provided by the West Virginia Board of Pharmacy. The manual shall be maintained in current status. A copy of the Policy and Procedure Manual shall be provided to the Board of Pharmacy when applying for a permit.

(e) Additional requirements are necessary for the storage, compounding, dispensing, and discarding of cytotoxic agents. The pharmacy shall provide protection for its personnel involved in the handling of cytotoxic agents by utilizing the proper equipment and having a separate Policy and Procedure Manual for said agents. The manual shall identify, but not be limited to the following special procedures:

1. All compounding should be conducted within a certified vertical laminar air flow hood. Type A or B VLAP hood used should be dependent upon the volume of work anticipated.

2. Protective garb (gloves, face and eye, and gowns) shall be provided and used.

3. Proper asentic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

4. All unused drug and material used in the preparation of cytotoxic agents must be disposed of properly in accordance with accepted professional standards and applicable law.

(f) An applicant for a parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

1. Completed Board of Pharmacy permit application form.

2. Copy of Policy and Procedure Manual.

(4) Minimum Requirements for Space, Equipment, Supplies and Publications

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special

permit of a parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for in this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

3. Compounding and dispensing of cytotoxic agents should be performed in an area separate from the area used to prepare other sterile solutions. The use of a vertical laminar flow hood is required in the preparation of cytotoxic agents. A sink and running water shall be provided for in the sterile admixture space room.

(c) Equipment:

1. Laminar Air Flow Hood(s).

a. Vertical

2. Refrigerator/freezer.

3. Sink and wash area (as provided in (1) (c) above).

4. Appropriate waste containers for:

a. Used needles and syringes

b. All cytotoxic waste including disposal apparel used in the preparation act.

(d) Supplies:

1. Gloves, masks and gowns.

2. Disposable needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Liquid handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. "Spill kits" for cytotoxic agent spills.

(e) Current References:

1. United States Pharmacopia and National Formulary.

2. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

3. Procedures for Handling Cytotoxic Drugs by American Society of Hospital Pharmacists, Inc.

Date Submitted July 12, 1984

Signature of Person Authorizing this Filing C. Robert Imbert