# TITLE 15
# LEGISLATIVE RULE
# BOARD OF PHARMACY

## SERIES 2
## RULES AND REGULATIONS OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

### §15-2-1. General.

1.1. Scope. -- W. Va. Code §30-5-19 et seq mandates that the Board of Pharmacy shall make such Rules and Regulations, not inconsistent with law, as necessary, to carry out the purposes and enforce the provisions of this article.

1.2. Authority. -- W. Va. Code §60A.

1.3. Filing Date. -- December 28, 1982.

1.4. Effective Date. -- December 28, 1982.

1.5. Repeal of Former Rule. -- This repeals rules filed previously.

### §15-2-2. Definitions.

The following words and phrases as used in these Rules and Regulations shall have the following meanings, unless the context otherwise requires:

2.1. The term "Drug" means (a) substances recognized as drugs in the official "United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary," or any supplement to any of them; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure intended for use as a component of any article specified in clauses (a), (b) or (c) of this subdivision. It does not include devices or their components, parts or accessories.

2.2. The term "Poisonous Drug" means any drug likely to be destructive to adult human life in quantities of five (5) grains or less.

2.3. The term "Deleterious Drug" means any drug likely to be destructive to adult human life in quantities of sixty (60) grains or less.

2.4. The term "Habit-Forming Drug" means any drug which has been or may be designated as habit-forming under the regulations promulgated in accordance with Section 502 (d) of the Federal Food, Drug and Cosmetic Act of June 25, 1938, or any amendments, revisions, alterations, additions or modifications thereof.

2.5. "Patent or Proprietary Preparation" means a medicinal preparation which is intended for use in the cure, mitigation, treatment or prevention of disease in man or other animal pursuant to self-diagnosis; when the same is identified by and sold under a trademark, trade name or other trade symbol, privately owned or registered with the United States Patent Office; which preparation is sold in the original and unopened package of the manufacturer or primary distributor; which preparation in itself is not poisonous; which preparation is sold or offered for sale and is advertised for sale to the general public by the manufacturer or primary distributor; which preparation meets all of the requirements of the Federal Food, Drug and Cosmetic Act 1938 as amended and the laws of the State of West Virginia and regulations promulgated under either of these; and the labeling of which preparation does not contain the legend, "Caution: Federal Law Prohibits Dispensing Without Prescription" or any other legend or statement of like import.

Drugs and medicinal preparations considered not safe for self-medication under the

Food, Drug and Cosmetic Act 1938 as amended are defined as "Dangerous Drugs" and shall be used only under the supervision and on the prescription of a licensed medical practitioner.

2.6. "Controlled Substance" means a drug, substance, or immediate precursor in Schedules I through V of article two, chapter sixty-a of the West Virginia Code, (Uniform Controlled Substances Act).

2.7. "Immediate Precursor" means a substance which the "West Virginia Board of Pharmacy" has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture of such controlled substance.

2.8. "Marihuana" means all parts of the plant "Cannabis Sativa L.," whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

2.9. "Narcotic Drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) Opium and opiate and any salt, compound, derivative or preparation of opium or opiate.

(b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (a) of this subdivision, but not including the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Coca leaves and any salt, compound, derivative or preparation of coca leaves, any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

2.10. "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under section two hundred one, article two of the Uniform Controlled Substances Act, the dextrorotatory isomer of 3-methoxy-n-methylmorphianan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

2.11. "Opium Poppy" means the plant of the species "Papaver Somniferum L.", except its seeds.

2.12. "Poppy Straw" means all parts, except the seeds of the opium poppy, after mowing.

2.13. "Counterfeit Substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance.

2.14. The term "Cosmetic," which shall be held to include "Dentrifice" and "Toilet Articles," means (a) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or

otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and (b) articles intended for use as a component of any such articles, except that such term shall not include soap.

2.15. The term "Pharmacy" or "Drug Store" or "Apothecary" shall be held to mean any place where the practice of pharmacy is conducted and shall include every store or shop or other place (including, but not limited to, rest homes, nursing homes, hospitals, orphanages, clinics, homes for the aged and governmental agencies or institutions) (a) where drugs are administered, dispensed or compounded by or pursuant to the orders of a duly licensed medical practitioner in the course of professional practice, or where drugs are sold at retail or displayed for sale at retail; or (b) where appropriate licensed practitioners' prescriptions are compounded; or (c) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "Pharmacy," "Pharmacists," "Apothecary," "Drug Store," "Drugs," "Druggist," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or (d) any store or shop or other place, with respect to which any of the above words are used in any advertisement.

2.16. The "Practice of Pharmacy" is the practice concerned with the preparing, compounding and dispensing of drugs, medicines and medical supplies used in the diagnosis, treatment or prevention of disease, whether compounded or dispensed on the prescription of a medical practitioner or otherwise legally dispensed or sold and shall include the proper and safe storage, the maintenance of proper records and the dissemination of information concerning the therapeutic values and uses of such drugs and medicines.

2.17. "Dispensing" is that aspect of the practice of pharmacy which is concerned with the processing and handling of prescription orders of a licensed medical practitioner, including the delivery of the prescribed medication to the patient with consultation.

"Pharmaceutical Dispensing" shall not be construed to include the prescribing and administering of controlled substances as is included under the general definition of dispense found in the West Virginia Code, article one, chapter sixty-a of the Uniform Controlled Substances Act.

2.18. The term "Distribute" means to deliver other than by administering or dispensing a controlled substance.

2.19. A "Sale" is defined as the supplying of drugs and medicines for any consideration whether charged separately or incorporated with other charges for professional services. Further, the providing of patients with quantities of drugs and medicines beyond those amounts required for immediate administration shall be deemed a sale.

2.20. "Pharmacist" or "Druggist" means any person registered and/or licensed by the West Virginia Board of Pharmacy to practice the profession of Pharmacy in the State of West Virginia whose license is in good standing.

2.21. "Assistant Pharmacist" means any person licensed by the West Virginia Board of Pharmacy to practice the profession of pharmacy as an Assistant Pharmacist, whose license was issued prior to January 1, 1939, and which is in good standing.

2.22. The term "Practitioner" means:

(a) A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this State.

(b) A pharmacy, hospital, nursing home, home for the aged, orphanage, clinic, rest home, governmental agency or institution or other place or institution licensed, registered or otherwise permitted to distribute, dispense, conduct research

with respect to or to administer a controlled substance in the course of professional practice or research in this State.

2.23. The term "Board" means the West Virginia Board of Pharmacy.

2.24. The term "President" means the President of the West Virginia Board of Pharmacy.

2.25. The term "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

2.26. The term "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

2.27. "Original Drug Store Permit" means a permit issued for a pharmacy, drug store or apothecary under the following conditions:

(a) A new business.

(b) Transfer of an established business to a successor.

(c) Transfer of fifty percent (50%) or more of the ownership (as evidenced by interest listed on renewal application for previous years) of an established business to a successor.

(d) Transfer of ownership which results in controlling interest being acquired by one (1) or more persons.

Only pharmacy or drug store permits issued under section 12.2 chapter 30 of the West Virginia Code shall be considered a renewal.

2.28. The term "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association or any other legal entity.

2.29. "Recognized School of Pharmacy" means a school of pharmacy whose physical equipment, course of instruction and teaching personnel conforms to the standards and specifications or the equivalent thereof required by the American Council on Pharmaceutical Education for Accreditation.

2.30. "Intern" means an individual working in a pharmacy or drug store under the instruction and supervision of a registered pharmacist preceptor who has been duly registered and certified by the Board. The term "Intern" through common usage in the profession has become the usual term referring to apprentices, externs or interns who are gaining their practical experience during or after their formal college education. Hereinafter the Board will use "Intern" to refer to individuals registered with the Board to obtain the practical experience requirement.

2.31. The term "Internship" shall be used to describe the practical experience requirement, and "Nine (9) Months Practical Experience" shall mean an average work week of not less than forty (40) hours for a period of one (1) calendar year, except as herein provided for concurrent training programs.

2.32. "Gross Immorality" means conduct, acts and practices which are inconsistent with decency, good order and propriety of professional or personal conduct and/or which are hostile to the welfare of the general public. The word "Gross" means willful and flagrant, rather than great or excessive.

2.33. "Person Addicted" means one (1) who has acquired the habit of using spirituous liquors or narcotic or hypnotic drugs or other agents to such an extent as to deprive him of reasonable self-control.

2.34. "Act" or "Uniform Controlled Substance Act" when used in these regulations shall mean and refer to chapter sixty-a of the West Virginia Code as enacted by the West Virginia Legislature in 1971.

2.35. "Administer" means the direct application of a controlled substance, whether by

injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(a) A practitioner (or, in his presence, by his authorized agent); or

(b) The patient or research subject at the direction and in the presence of the practitioner.

2.36. "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging or labeling of a controlled substance:

(a) By a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(b) By a practitioner or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

**§15-2-3. Registration Of Manufacturers, Distributors, And Dispensers Of Controlled Substances.**

3.1. General information.

3.2. Scope of Part 301. -- Procedures governing the registration of manufacturers, distributors and dispensers of controlled substances pursuant to sections three hundred one through three hundred five of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code) are set forth generally by those sections and specifically by the sections of this Part.

(a) The provisions contained herein which regulate the dispensing or administering of controlled substances are applicable only insofar as they may affect pharmacists, pharmacies and practitioners as defined in Section 1-101 of these regulations. In every instance the said provisions shall apply to all pharmacists or druggists; to all pharmacies, drug stores or apothecaries; to every shop, store, rest home, nursing home, hospital, orphanage, clinic, home for the aged, governmental agency or institution or other places, wherein controlled substances, as defined by section one hundred one, article one, chapter sixty-a of the West Virginia Code are dispensed or administered. Nothing contained herein shall be taken to affect the dispensing or administering of controlled substances by persons or practitioners other than those set forth in this paragraph.

3.3. Definitions. -- As used in this Part, the following terms shall have the meanings specified:

(a) The term "Act" means the "Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code as adopted by the West Virginia Legislature 1971)."

(b) The term "Basic Class" means, as to controlled substances listed in Schedules I and II:

(1) Each of the opiates, including its isomers, esters, ethers, salts and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in Subsection 204 of this chapter.

(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, listed in Subsection 204 (c) of this chapter.

(3) Each of the hallucinogenic

substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in Subsection 204 (d) of this chapter.

(4) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

A) Opium, including raw opium, opium extracts, opium fluid extracts, powered opium, granulated opium, deodorized opium and tincture of opium;

B) Apomorphine;

C) Codeine;

D) Ethylmorphine;

E) Hydrocodone;

F) Hydromorphone;

G) Metopon;

H) Morphine;

I) Oxycodone;

J) Oxymorphone;

K) Thebaine;

L) Mixed alkaloids of opium listed in Subsection 206 (b) of this chapter;

M) Cocaine; and

N) Ecgonine.

(5) Each of the opiates, including its isomers, esters, ethers salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, listed in Subsection 206 (c) of this chapter.

(6) Methamphetamine, including its salts, isomers and salts of isomers, or combinations thereof.

(7) Amphetamines including its salts isomers and salts of isomers, or combinations thereof.

(c) The term "Board" means the West Virginia Board of Pharmacy.

(d) The term "Hearing" means any hearing held pursuant to this Part for the granting denial, revocation, or suspension of a registration pursuant to section three hundred five, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(e) The term "Person" includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association or other legal entity.

(f) The terms "Register" and "Registration" refer only to registration required and permitted by section three hundred three, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(g) The term "Registrant" means any person who is registered pursuant to section three hundred three, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(h) Any term not defined in this section shall have the definition set forth in Section 1-101 of these regulations or in section one hundred one, article one, chapter sixty-a of the Act.

3.4. Information; special instructions. -- Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Secretary of the West Virginia Board of Pharmacy.

3.5. Fees for registration and reregistration.

3.6. Fee amounts.

(a) For each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of fifty dollars ($50.00).

(b) For each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of fifty dollars ($50.00).

(c) For each registration or reregistration to dispense or to conduct research or instructional activities with, controlled substances listed in Schedules II through V, the registrant shall pay a fee of five dollars ($5.00).

(d) For each registration or reregistration to conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee of five dollars ($5.00).

(e) For each registration or reregistration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of five dollars ($5.00).

3.7. Time and method of payment; refund. -- Registration and reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing. Payment should be made in the form of a personal, certified or cashier's check or money order made payable to "West Virginia Board of Pharmacy." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

3.8. Persons exempt from fee.

(a) The West Virginia Board of Pharmacy shall exempt from payment of a fee for registration or reregistration the following persons:

(1) Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who is authorized to procure or purchase controlled substances for official use; and

(2) Any official, employee or other civil officer or agency of the United States, of any state or any political subdivision or agency thereof, who is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his official duties or employment.

(b) In order to claim exemption from payment of a registration or reregistration fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess or handle controlled substances.

(c) Exemption from payment of a registration or reregistration fee does not relieve the registrant of any other requirements or duties prescribed by law.

3.9. Requirements of registration.

3.10. Persons required to register.

(a) Every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or pursuant to Section 3.8 of these rules. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration).

3.11. Separate registration for independent activities.

(a) The following eight (8) groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing narcotic and nonnarcotic, and conducting research with nonnarcotic, and conducting instructional activities with narcotic and nonnarcotic, controlled substances listed in Schedules II through V;

(4) Conducting research with narcotic controlled substances listed in Schedules II through V;

(5) Conducting research and instructional activities with controlled substances listed in Schedule I;

(6) Conducting chemical analysis with controlled substances listed in any Schedule;

(7) Importing controlled substances; and

(8) Exporting controlled substances listed in Schedules I through IX.

(b) Every person who engages in more than one (1) group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities: **Provided,** That unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and control analysis with narcotic and nonnarcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the application for registration;

(4) A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes to distribute such substances to other persons registered to conduct chemical analysis or instructional activities and to persons exempted from registration pursuant to Sections 3.1 and 3.8 of these rules, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries and to conduct instructional activities with controlled substances; and

(5) A person registered to conduct research with narcotic controlled substances listed in Schedules II through V shall be authorized to conduct research with nonnarcotic controlled substances listed in Schedules II through V.

(c) A single registration to engage in any group of independent activities may include either one (1) or more controlled substances listed in Schedules II through V or one (1) basic class of

controlled substance listed in Schedule I, except that a registration to conduct chemical analysis may include more than one (1) basic class of controlled substance listed in Schedule I and also include one (1) or more controlled substances listed in Schedules II through V.

3.12. Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one (1) general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(b) The following locations shall be deemed not to be a place where controlled substances are manufactured, distributed or dispensed.

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registrants other than the registered person or to persons not required to register by virtue of subsection three hundred two (c) (2) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code);

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filing sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office and where no supplies of controlled substances are maintained.

(c) A separate registration shall be required by every place requiring the use of pharmacists, consultants, coordinators or pharmaceutical services including, but not limited to, rest homes, nursing homes, hospitals, clinics, orphanages, homes for the aged, governmental agencies or institutions whether or not such pharmacists, consultants or coordinators be registered in another capacity.

3.13. Exemption of law-enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Bureau, any officer of the United States Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal Law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties;

(2) Any officer or employee of any state, or any political subdivision or agency thereof, who is engaged in the enforcement of any state or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties; and

(3) Any official exempted by this section may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his official duties.

3.14. Exemption of civil defense officials.

(a) The requirement of registration is waived for any official of a civil defense or disaster relief organization who in the course of his official duties, is authorized to:

(1) Maintain and distribute for such maintenance, controlled substances held for emergency use; or

(2) Procure controlled substances for the purpose of maintaining supplies for emergency use: **Provided,** That all of such procurement is from the United States General Services Administration and in accordance with the rules of the United States Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within his jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his official duties, during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or

(2) Procure or distribute controlled substances: **Provided,** That all such procurement is on a special "Civil Defense Emergency Order Form," as described in this section.

(c) Civil Defense Emergency Order Forms shall be furnished by the United States Office of Emergency Preparedness and will contain the name of the civil defense or disaster relief organization. Such forms may be used and are valid only during a state of emergency or disaster proclaimed by the President or by a concurrent resolution of the Congress for the area in which the organization using such forms has civil defense or disaster relief jurisdiction, who shall state his position and the nature and legal designation of the emergency or disaster. Such forms may be filed by any person registered under the Uniform Controlled Substances Act. The organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Uniform Controlled Substances Act, for the purposes of recordkeeping pursuant to Section 7 of these rules.

3.15. Applications for registration.

3.16. Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and Certificate of Registration is issued by the West Virginia Board of Pharmacy to such person.

(b) Any person who is registered may apply to be reregistered not more than thirty (30) days before the expiration date of his registration.

3.17. Application forms; contents; signature.

(a) If any person is required to be registered and is not so registered and is applying for registration:

(1) To manufacture or distribute controlled substances, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(2) To dispense narcotic or nonnarcotic, or to conduct research with narcotic or nonnarcotic, or to conduct instructional activities with narcotic or nonnarcotic, controlled substances listed in Schedules II through V, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(3) To conduct research on humans or animals on the effects of narcotic controlled substances listed in Schedules II through V, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(4) To conduct research with a controlled substance listed in Schedule I, he shall apply on the West Virginia Board of Pharmacy Official Registration Form with three (3) copies of a research protocol describing the research project attached to the form;

(5) To conduct instructional activities with a controlled substance listed in Schedule I, he shall apply as a researcher on the West Virginia Board of Pharmacy Official Registration

Form, with two (2) copies of a statement describing the nature, extent and duration of such instructional activities attached to the form; and

(6) To conduct chemical analysis with controlled substances listed in any Schedule, he shall apply on the West Virginia Board of Pharmacy Official Registration Form.

(b) If any person is registered and is applying for reregistration:

(1) To manufacture or distribute controlled substances, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(2) To dispense narcotic or nonnarcotic, or to conduct research with narcotic or nonnarcotic, or to conduct instructional activities with narcotic or nonnarcotic, controlled substances listed in Schedules II through V, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(3) To conduct research on humans or animals on the effects of narcotic controlled substances listed in Schedules II through V, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(4) To continue to conduct research with a controlled substance listed in Schedule I under an approved research protocol, he shall apply on the West Virginia Board of Pharmacy Official Registration Form;

(5) To continue to conduct instructional activities with controlled substances listed in Schedule I under an approved instructional statement, he shall apply as a researcher on the West Virginia Board of Pharmacy Official Registration Form; and

(6) To conduct chemical analysis with controlled substances listed in any Schedule, he shall apply on the West Virginia Board of Pharmacy Official Registration Form.

(c) Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substances listed in Schedule II, or to conduct research with any narcotic controlled substance listed in Schedule II, shall include the West Virginia Board of Pharmacy Controlled Substances Code Number, as set forth in Part 3.8 of this chapter, for each basic class or substance to be covered by such registration.

(d) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(e) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant if a partnership; or by an officer of the applicant, if a corporation, corporate, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g., general power of attorney) accompanies the application.

(f) If the applicant is a pharmacy, as defined in Section 1.101 of these rules, it shall be necessary for the pharmacist in charge of the pharmacy to sign the application; and where the owner of such pharmacy is a person, as defined in Section 1.101 of these regulations, other than the practicing pharmacist, it shall be necessary for such other person, partnership or corporation, corporate division, association, trust or other entity, to sign the application form as provided in Paragraph (e) of this section in addition to any other persons required to sign said application.

(g) If the applicant is a rest home, nursing home, hospital, orphanage, clinic, home for the aged, governmental agency or institution or other place requiring the use of pharmacist consultants or coordinators of pharmaceutical services, it shall be necessary for such consultant or coordinator to sign the application in addition to any other

persons required to sign the application.

3.18. Filing of application; joint filings.

(a) All applications for registration shall be submitted for filing to the office of the Secretary of the Board of Pharmacy.

(b) Any person required to obtain more than one (1) registration may submit all applications in one (1) package. Each application must be complete and should not refer to accompanying application for required information.

3.19. Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Application failing to comply with the requirements of this Part will not generally be accepted for filing. In the case of minor defects as to completeness the West Virginia Board of Pharmacy may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within ten (10) days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the West Virginia Board of Pharmacy shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to Section 3.20 of these rules and has no bearing on whether the application will be granted.

3.20. Additional information.

The West Virginia Board of Pharmacy may require an applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the West Virginia Board of Pharmacy in granting or denying the application.

3.21. Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the West Virginia Board of Pharmacy at any time before the date on which the applicant receives an order to show cause pursuant to Section 3.29 of these rules, or before the date on which a notice of hearing on the application is published pursuant to section three hundred five, article three, chapter sixty-a of the West Virginia Code, whichever is sooner. An application may be amended or withdrawn with permission of the West Virginia Board of Pharmacy at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

3.22. Action on applications for registration; revocation or suspension of registration.

3.23. Administrative review generally.

The West Virginia Board of Pharmacy may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to article five of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code). The West Virginia Board of Pharmacy shall review the application for registration and other information gathered by the West Virginia Board of Pharmacy regarding an applicant in

order to determine whether the applicable standards of section three hundred three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code), have been met by the applicant.

3.24. Applications for research in Schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances in Schedule I, the West Virginia Board of Pharmacy shall determine the qualifications and competency of the applicant as well as the merits of the research protocol. The Board, in determining the merits of a research protocol, shall confer as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use. If the Board finds the applicant qualified and competent and the research protocol meritorious and adequately safeguarded, it shall register the applicant unless it finds registration should be denied for reasons set forth in section three hundred three, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(b) If the Board is unable to find the applicant qualified or the West Virginia Board of Pharmacy finds that grounds exist for the denial of the application, it shall issue an order to show cause pursuant to Section 3.29 of these rules and, if requested by the applicant, shall hold a hearing on the application.

3.25. Certificate of registration; denial of registration.

(a) The West Virginia Board of Pharmacy shall issue a Certificate of Registration Form to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section three hundred three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code). In the event that the issuance of registration or reregistration is not required, the West Virginia Board of Pharmacy shall deny the application. Before denying any application the West Virginia Board of Pharmacy shall issue an order to show cause pursuant to Section 3.29 of these rules and, if requested by the applicant, shall hold a hearing on the application.

(b) The Certificate of Registration shall contain the name, address and registration number of the registrant, the activity authorized by the registration, the schedules and/or Bureau Controlled Substances Code Number (as set forth in Part 308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption) and the expiration date of the registration. The registrant shall prominently display the Certificate of Registration at the registered location.

3.26. Suspension or revocation of registration.

(a) The West Virginia Board of Pharmacy may suspend any registration pursuant to section three hundred four (a) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(b) The West Virginia Board of Pharmacy may revoke any registration pursuant to section four hundred four (a) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(c) Before revoking or suspending any registration the West Virginia Board of Pharmacy shall issue order to show cause pursuant to Section 3.29 of these rules and, if requested by the registrant, shall hold a hearing. Notwithstanding the requirements of this section, however, the West Virginia Board of Pharmacy may suspend any registration pending a final order.

(d) Upon service of the order of the West Virginia Board of Pharmacy suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration and any order forms in his possession to the office of the West Virginia Board of Pharmacy. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing

or procurement quota fixed for the registrant pursuant to Part 303 of this chapter. Also, upon service of the order of the West Virginia Board of Pharmacy revoking registration, the registrant shall, as instructed by the West Virginia Board of Pharmacy:

(1) Deliver all controlled substances in his possession to the office of the West Virginia Board of Pharmacy or to authorized agents of the West Virginia Board of Pharmacy; or

(2) Place all controlled substances in his possession under seal as described in section three hundred four (c) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his possession to the office of the West Virginia Board of Pharmacy. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to Part three hundred three of this chapter. Also, the registrant shall, as instructed by the West Virginia Board of Pharmacy:

(1) Deliver to the office of the West Virginia Board of Pharmacy or to authorized agents of the West Virginia Board of Pharmacy all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Place all of such substances under seal as described in section three hundred four (c) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

3.27. Suspension of registration pending final order.

(a) The West Virginia Board of Pharmacy may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the West Virginia Board of Pharmacy so suspends, it shall serve with the order to show cause pursuant to Section 3.29 of these rules, an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration and any order forms in his possession to the office of the West Virginia Board of Pharmacy. The suspension of any registration under this section shall suspend any quota fixed for the registrant pursuant to Part 303 of this chapter. Also, upon service of the order of the West Virginia Board of Pharmacy immediately suspending registration, the registrant shall, as instructed by the West Virginia Board of Pharmacy:

(1) Deliver all affected controlled substances in his possession to the office of the West Virginia Board of Pharmacy or to authorized agents of the West Virginia Board of Pharmacy; or

(2) Place all of such substances under seal as described in section three hundred four (c) of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the West Virginia Board of Pharmacy or dissolved by a court of competent jurisdiction.

Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to Section 3.29 of these rules, which request shall be granted by the West Virginia Board of Pharmacy, who shall fix a date for such hearing as early as reasonably possible.

3.28. Extension of registration pending final order.

In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least thirty (30) days before the date on which the existing registration is due to expire, and the West Virginia Board of Pharmacy has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the West Virginia Board of Pharmacy so issues its order. The West Virginia Board of Pharmacy may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least thirty (30) days before expiration of the existing registration, with or without request by the registrant, if the West Virginia Board of Pharmacy finds that such extension is not inconsistent with the public health and safety.

3.29. Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the West Virginia Board of Pharmacy regarding the applicant, the West Virginia Board of Pharmacy is unable to make the determinations required by the applicable provisions of section three hundred three, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code), to register the applicant, the West Virginia Board of Pharmacy shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If upon information gathered by the West Virginia Board of Pharmacy regarding any registrant, the West Virginia Board of Pharmacy determines that the registration of such registrant is subject to suspension or revocation pursuant to section three hundred four, article three, Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code), the West Virginia Board of Pharmacy shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the West Virginia Board of Pharmacy at a time and place stated in the order, which shall not be less than thirty (30) days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing. If a hearing is requested, the West Virginia Board of Pharmacy shall hold a hearing at the time and place stated in the order, pursuant to section three hundred five, article three of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(e) When authorized by the West Virginia Board of Pharmacy any agent of the West Virginia Board of Pharmacy may serve the order to show cause.

3.30. Hearings.

3.31. Hearings generally.

(a) In any case where the West Virginia Board of Pharmacy shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the

Administrative Procedure Act (chapter twenty-nine-a, West Virginia Code), and by the procedures for hearings under the Act, set forth in West Virginia Code sections three hundred four and three hundred five, article three, chapter sixty-a.

(b) Any hearing under this Part shall be independent of, and not in lieu of, criminal prosecutions of other proceedings under the Act or any other law of the State of West Virginia or the United States.

3.32. Purpose of hearing.

If requested by a person entitled to a hearing, the West Virginia Board of Pharmacy, shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

3.33. Waiver or modification of rules.

The West Virginia Board of Pharmacy or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this Part by notice in advance of the hearing, if it determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

3.34. Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section three hundred three (a) of the Act (chapter sixty-a, (West Virginia Code) are satisfied. Any other person participating in the hearing shall have the burden of proving any propositions of fact of law asserted by him in the hearing.

(b) At any other hearing for the denial of a registration, the West Virginia Board of Pharmacy shall have the burden of proving that the requirements for such requirements for such registration pursuant to section three hundred three of the Act (chapter sixty-a, West Virginia Code) are not satisfied.

(c) At any hearing for the revocation or suspension of a registration, the registrant shall have the burden of proving that the requirements for such revocation or suspension to section three hundred four (a) of the Act (chapter sixty-a, West Virginia Code) are satisfied.

3.35. Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause unless expedited pursuant to Section 3.27 (c) of these rules, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

3.36. Final order.

As soon as practicable after the presiding officer has certified the record to the West Virginia Board of Pharmacy, the West Virginia Board of Pharmacy shall issue its order on the granting, denial, revocation or suspension of registration. In the event that an application for registration to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it is to take effect.

3.37. Modification, transfer and termination of registration.

3.38. Modification in registration.

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by filing an application in the same manner as an application for new registration. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

3.39. Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the West Virginia Board of Pharmacy promptly of such fact. In the event of a change in name or address the person may apply for a new Certificate of Registration in advance of the effective date of such change by filing an application and paying the appropriate fee in the same manner as an application for new registration. The application shall be handled in the same manner as an application for registration.

3.40. Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the West Virginia Board of Pharmacy may specifically designate and then only pursuant to its written consent.

**§15-2-4. Security Requirements.**

4.1. Security requirements.

4.2. Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the West Virginia Board of Pharmacy shall use the security requirement set forth in Sections 4.3 through 4.5 of these rules as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the West Virginia Board of Pharmacy after evaluation of the overall security system and needs of the applicant or registrant.

(b) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

(c) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

(d) Physical security controls of persons presently registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 shall be deemed to comply substantially with the standards set forth in Section 4.2 et seq. of these rules: **Provided,** That the West Virginia Board of Pharmacy has previously approved them. All such persons shall notify the Board before the first day of November, one thousand nine hundred seventy-one, indicating that prior Board approval was given and either describing the physical security controls or, if such a description has previously been filed with the Board, stating that such description has been so filed. Any new facilities or work or storage areas constructed or utilized by such persons for controlled substances, which facilities or work or storage areas have not been previously approved by the Board, shall not necessarily be deemed to comply substantially with the standards set forth in Section 4.2 et seq.

of these rules, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Board.

4.3. Other security controls for nonpractitioners.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Board or with the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Office of the West Virginia Board of Pharmacy of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Office of the West Virginia Board of Pharmacy of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The registrant shall also complete the form provided by the Secretary regarding such theft or loss.

(d) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition the requirements of Part 305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

4.4. Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substance.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

4.5. Other security controls for practitioners.

(a) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, at any time.

(b) The registrant shall notify the Office of the West Virginia Board of Pharmacy of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete the necessary form regarding such loss or theft which forms may be obtained from the office of the Secretary.

**§15-2-5. Labeling And Packaging Requirements For Controlled Substances.**

5.1. Labeling and packaging requirements for controlled substances.

5.2. Scope of article.

Requirements governing the labeling and packaging of controlled substances pursuant to section three hundred five of the Uniform

Controlled Substances Act (chapter sixty-a, West Virginia Code) are set forth generally by that section and specifically by the sections of this Part.

5.3. Definitions.

As used in this Part, the following terms shall have the meanings specified:

(a) The term "Commercial Container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "Commercial Container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(b) The term "Label" means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(c) The term "Labeling" means all labels and other written, printed or graphic matter (1) upon any controlled substance or any of its commercial containers or wrappers, or (2) accompanying such controlled substance.

(d) The term "Manufacture" means the producing, preparation, propagation, compounding or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term "Manufacture" means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(e) Any term not defined in this section shall have the definition set forth in section one hundred one of the Uniform Controlled Substances Act, West Virginia Code Chapter sixty-a.

5.4. Symbol required; exceptions.

(a) Each commercial container of a controlled substance except for a controlled substance accepted by the West Virginia Board of Pharmacy pursuant to section three hundred eight of this chapter, shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this Part.

(b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

(c) The following symbols shall designate the schedule corresponding thereto: Schedule

Schedule I .....CI or C-I.
Schedule II .....CII or C-II.
Schedule III .....CIII or C-III.
Schedule IV .....CIV or C-IV.
Schedule V .....CV or C-V.

The word "Schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.

(d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

(e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing

to an ultimate user.

(f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

(g) The symbol is not required on a commercial container containing, or on the labeling, of a controlled substance intended for export from the United States.

5.5. Location and size of symbol on label.

(a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedule I through V. The symbol must be at least two (2) times as large as the largest type otherwise printed on the label.

(b) In lieu of locating the symbol in the corner of the label, as prescribed in Paragraph (a) of this section, the symbol may be overprinted on the label, in which case the symbol must be printed at least one half (1/2) the height of the label and in a contrasting color providing clear visibility against the background color of the label.

(c) In all cases, the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

5.6. Location and size of symbol on labeling.

The symbol shall be prominently located on all labeling other than labels covered by Section 5.5 of these rules. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

5.7. Effective dates of labeling requirements.

(a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on June 15, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of Section 5.4 of these rules.

(b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on June 15, 1971, and thereafter transferred to another schedule or is added to any schedule after June 15, 1971, and which is packaged more than one hundred eighty (180) days following the date on which the transfer or addition becomes effective, shall comply with the requirements of Section 5.4 of these rules.

(c) The West Virginia Board of Pharmacy may, in the case of any controlled substance, require compliance with the requirements of Section 5.4 of these rules, within a period of time shorter than required by this section if it finds that public health or safety necessitate an earlier effective date.

(d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal Law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

5.8. Sealing of controlled substances.

(a) On each bottle, multiple dose, vial or other commercial container of any controlled substance listed in Schedules I and/or II, and of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid, covering or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

(b) Any seal accepted for use under Federal Law prior to May 1, 1971, shall be deemed acceptable for use under this section.

**§15-2-6. Quotas - Reserved.**

**§15-2-7. Records And Reports Of Registrants.**

7.1. General information.

7.2. Scope of Part 304.

Inventory and other records and reports required under section three hundred six, article three of the Act (chapter sixty-a, West Virginia Code) shall be in accordance with, and contain the information required by, those sections and by the sections of this Part.

7.3. Definitions.

As used in this Part, the following terms shall have the meaning specified:

(a) The term "Act" means the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code.)

(b) The term "Commercial Container" means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "Commercial Container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug or other package in which commercial containers are stored or are used for shipment of controlled substances.

(c) The term "Dispenser" means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(d) The term "Individual Practitioner" means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted by the state jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner.

(e) The term "Institutional Practitioner" means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the state jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(f) The term "Name" means the official name, common or usual name, chemical name or brand name of a substance.

(g) The term "Pharmacist" means any pharmacist licensed by a state to dispense controlled substances, and shall include assistant pharmacists and pharmacist intern authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

(h) The term "Readily Retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined or in some other manner visually identifiable apart from other items appearing on the records.

(i) Any term not defined in this section shall have the definition set forth in section one hundred one of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code.)

7.4. Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this Part, except as exempted by this section.

(b) A registered individual practitioner is not required to keep records with respect to

narcotic controlled substances listed in Schedules II through V, which he prescribes or administers in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he dispenses other than by prescribing or administering.

(c) A registered individual practitioner is not required to keep records with respect to nonnarcotic controlled substances listed in Schedules II through V which he dispenses in any manner unless he regularly charges his patients, either separately or together with charges for other professional services, for such substances so dispensed when his services are the same normally provided by a pharmacist for control of drug utilization.

7.5. Maintenance of records and inventories.

(a) Every inventory and other record required to be kept under the Act shall be kept by the registrant and be available, for at least two (2) years from the date of such inventory or record, for inspecting and copying by authorized employees of the West Virginia Board of Pharmacy.

(b) Each registered manufacturer, distributor, importer, and exporter shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(c) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in Paragraph (b) of this section.

(d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV and V only, or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed in the usual consecutively numbered prescription file for noncontrolled substances.

7.6. Inventory requirements.

7.7. General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "On Hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in Section 7.14 of these rules.

(d) A registrant may take an inventory on a date that is within four (4) days of his biennial inventory date pursuant to Section 7.9 of these rules, if he notifies in advance the West Virginia Board of Pharmacy in his region of the date on which he will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

7.8. Initial inventory date.

(a) Every person required to keep records who is provisionally registered on June 15, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with Sections 7.11 through 7.14 of these rules, as applicable.

(b) Every person required to keep records who is registered after June 15, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution or dispensing of controlled substances, in accordance with Sections 7.11 through 7.14 of these rules, as applicable.

7.9. Biennial inventory date.

Every two (2) years following the date on which the initial inventory is taken by a registrant pursuant to Section 7.8 of these rules, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken (a) on the day of the year on which the initial inventory was taken or (b) on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than six (6) months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the West Virginia Board of Pharmacy of this election and of the date on which the biennial inventory will be taken.

7.10. Inventory date for new controlled substances.

On the effective date of a rule by the West Virginia Board of Pharmacy pursuant to section two hundred one (a), article two of the Act (chapter sixty-a, West Virginia Code) adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substance shall be included in each inventory made by the registrant pursuant to Section 7.9 of these rules.

7.11. Inventories of manufacturers.

Each registered manufacturer shall include the following information in his inventory:

(a) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form:

(1) The name of the substance; and

(2) The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

(b) For each controlled substance in the process of manufacture on the inventory date:

(1) The name of the substance;

(2) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(3) The physical form which the substance is to take upon completion of the manufacturing process (e.g. granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g. ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce of milliliter) and the number or volume thereof.

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter);

(3) The number of units or volume of each finished form in each commercial container (e.g., one hundred (100) tablet bottles or six (6) three (3) milliliter vials); and

(4) The total quantity of the substance in all forms to the nearest metric unit weight.

(d) For each controlled substance not included in Paragraphs (a), (b) or (c) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings):

(1) The name of the substance;

(2) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(3) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

7.12. Inventories of distributors.

Each registered distributor shall include in his inventory the same information required of manufacturers pursuant to Section 7.11 (c) and (d) of these rules.

7.13. Inventories of dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to Section 7.4 of these rules, shall include in his inventory the same information required of manufacturers pursuant to Section 7.11 (c) and (d) of these rules. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(a) If the substance is listed in Schedule I or II, he shall make an exact count or measure of the content; and

(b) If the substance is listed in Schedule III, IV or V, he shall make an estimated count or measure of the contents, unless the container holds more than one thousand (1,000) tablets or capsules in which case he must make an exact count of the contents.

7.14. Inventories of importers and exporters.

Each registered importer or exporter shall include in his inventory the same information required of manufacturers pursuant to Section 7.11 (a), (c) and (d) of these rules. Each registered importer and exporter who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

7.15. Inventories for chemical analysts.

Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers pursuant to Section 7.11 (a), (c) and (d) of these rules, as to substances which have been manufactured, imported or received by the laboratory conducting the inventory, if less than one (1) kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than twenty (20) grams of a hallucinogenic substance listed in Schedule I, (other than lysergic acid diethylamide), or less than five tenths (0.5) gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the West Virginia Board of Pharmacy may possess up to one hundred fifty (150) grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

7.16. Continuing records.

7.17. General requirements for continuing records.

(a) On and after June 15, 1971, every registrant required to keep records pursuant to Section 7.4 of these rules, shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him, except that no registrant shall be required to maintain a perpetual inventory.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in Section 7.5 (a) of these rules. In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(c) Separate records shall be maintained by a registrant for each independent activity for which he is registered.

(d) In recording dates of receipt, importation, distribution, exportation or other transfer, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

7.18. Records of manufacturers.

Each registered manufacturer shall maintain records with the following information:

(a) For each controlled substance in bulk form to be used, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form:

(1) The name of the substance;

(2) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

(4) The quantity imported directly by

the registrant (under a registration as an importer) for use in manufacture by him, including the date, quantity and import permit or declaration number for each importation;

(5) The quantity used to manufacture the same substance in finished form, including:

A) The date and batch or other identifying number of each manufacture;

B) The quantity used in the manufacture;

C) The finished form (e.g., ten (10) milligram tablets or ten (10) milligram concentration per fluid ounce or milliliter);

D) The number of units of finished form manufactured;

E) The quantity used in quality control;

F) The quantity lost during manufacturing and the causes therefore, if known;

G) The total quantity of the substance

contained in the finished form;

H) The theoretical and actual yields; and

I) Such other information as is necessary

to account for all controlled substances used in the manufacturing process.

(6) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in Subparagraph (5) of this paragraph;

(7) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

(8) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity and export permit or declaration number of each exportation;

(9) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed.

(b) For each controlled substance in finished form.

(1) The name of the substance;

(2) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

(3) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to Subparagraph (5) of Paragraph (a) of this section;

(4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;

(5) The number of units of finished forms and/or commercial containers imported directly by the registrant (under a registration as an importer), including the date of and the number of units and for commercial containers in each importation;

(6) The number of units and/or commercial containers manufactured by the registrant from units in finished form received

from others or imported, including:

A) The date and batch or other identifying number of each manufacture;

B) The operation performed (e.g., repackaging or relabeling);

C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes therefore, if known; and

D) Such other information as is necessary to account for all controlled substances used in the manufacturing process.

(7) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address and registration number of the person to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

7.19. Records for distributors.

Each registered distributor shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) tablet bottle or three (3) milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(d) The number of commercial containers of each such finished form imported directly by the registrant (under a registration as an importer), including the date of and the number of containers in each importation;

(e) The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(f) The number of commercial containers of such finished form exported directly by the registrant (under a registration as an exporter), including the date of and the number of containers in each exportation; and

(g) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution as complimentary samples), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

7.20. Records for dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to Section 7.4 of these rules, shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., ten (10) milligram tablet or ten (10) milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one hundred (100) bottle or three (3) milliliter vial);

(c) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(d) The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and

(e) The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

7.21. Records for importers.

Each registered importer shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;

(c) The quantity (or number of units or volume in finished form) distributed to other persons, including the date and quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made;

(d) The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to Section 7.18 (a) (4) or (b) (5) of these rules, including the date and manner of disposal and the quantity disposed.

7.22. Records for chemical analysis.

(a) Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported or manufactured by the registrant (e.g., powder, granulation, tablet, capsule or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., ten (10) milligram tablet or ten (10) milligram concentration per milliliter);

(3) The total number of the forms received, imported or manufactured (e.g., one hundred (100) tablets, thirty (30) one (1) milliliter vial, or ten (10) grams of powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received;

(4) The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date, the manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Order forms, import and export

permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

(c) Records of controlled substances used in chemical analysis are not required.

(d) Records relating to known or suspected controlled substances received as samples for analysis are not required under Paragraph (a) of this section.

**§15-2-8. Order Forms.**

Part 1305 Code of Federal Regulations.

**§15-2-9. Prescriptions.**

9.1. General information.

9.2. Scope of Part 306.

Rules governing the issuance, filling and filing of prescriptions pursuant to article three hundred eight of the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code) are set forth generally in that section and specifically by the sections of this Part.

9.3. Definitions.

As used in this Part, the following terms shall have the meanings specified:

(a) The term "Act" means the Uniform Controlled Substances Act (chapter sixty-a, West Virginia Code).

(b) The term "Individual Practitioner" means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted, by the state jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner.

(c) The term "Institutional Practitioner" means a hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the state jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(d) The term "Pharmacist" means any pharmacist licensed by a state to dispense controlled substances and shall include an assistant pharmacist or a pharmacist intern authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

(e) The term "Prescription" means an order for medication which is dispensed to or for an ultimate user but does not include the immediate administration to the ultimate user.

(f) Any term not defined in this section shall have the definition set forth in section one hundred one, article one of the Act (chapter sixty-a, West Virginia Code).

9.4. Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe controlled substances in the State of West Virginia and licensed to practice herein.

(b) A prescription issued by an individual practitioner except for Schedule II controlled substance, may be communicated to a pharmacist by an employee or agent of the individual practitioner.

9.5. Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the

pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section three hundred eight, article three of the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

9.6. Manner of issuance of prescriptions.

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g. J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or a typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in these regulations.

9.7. Persons entitled to fill prescriptions.

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner (e.g., a hospital, nursing home, home for the aged, clinic, orphanage, governmental agency or institution or other place of similar character which dispenses controlled substances). It shall be necessary for all persons filling prescriptions to comply with all provisions of chapter thirty of the West Virginia Code (Michie 1960) and the Rules and Regulations promulgated and adopted pursuant thereto insofar as such provisions and Rules and Regulations regulate the filling of prescriptions.

9.8. Dispensing of narcotic drugs for maintenance purposes.

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research." Before such program is initiated, however, the person administering or dispensing said narcotic drugs must obtain written authorization from the Board of Pharmacy.

9.9. Controlled substances listed in Schedule II.

9.10. Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in Paragraph (d) of this section.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Section 9.8 of these rules.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner: **Provided,** That

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Section 9.6 of these rules, except for the signature of the prescribing individual practitioner;

(3) If the prescribing practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the practitioner's phone number as listed in the phone book or telephone directory and/or either good faith efforts to insure his identity; and

(4) Within seventy-two (72) hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Section 9.6 of these rules, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seventy-two (72) hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which has earlier been reduced to writing. The pharmacist shall notify the Board of Pharmacy if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

9.11. Refilling prescriptions.

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

9.12. Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

9.13. Labeling of substances.

The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the

name of the patient, the name of the prescribing practitioner and directions for use and cautionary statements, if any, contained in such prescription or required by law.

9.14. Filling of prescriptions.

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of this chapter.

9.15. Controlled substances listed in Schedules III and IV.

9.16. Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in Schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner and/or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 9.6 of these rules, except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to the provisions of Section 9.8 of these rules.

(c) An institutional practitioner, as described in Section 9.7 of these rules, may administer or dispense directly (but not prescribe) a controlled substance listed in Schedules III and IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 9.6 of these rules, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 9.8 of these rules.

9.17. Refilling of prescriptions.

No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five (5) times. Each refilling of a prescription shall be entered on the back of the prescription (or on another uniformly maintained appropriate record, such as medication records, which indicate prescription refills), initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in Section 9.16 of these rules, which shall be a new and separate prescription.

9.18. Labeling of substances.

The pharmacist filling a prescription for a controlled substance listed in Schedule III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

9.19. Filing prescriptions.

All prescriptions for controlled substances listed in Schedules III and IV shall be kept in accordance with Section 7.5 (d) of these rules.

9.20. Controlled substances listed in Schedule V.

9.21. Requirement of prescription.

(a) A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedules III and IV in Section 9.16 of these rules. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with Section 9.18 of these rules and file the prescription in accordance with Section 9.8 of these rules.

(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription, subject to Section 9.8 of these rules.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 9.6 of these rules, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 9.8 of these rules.

9.22. Dispensing without prescription.

A controlled substance listed in Schedule V may be dispensed by a pharmacist without a prescription to a purchaser at retail: **Provided,** That

(a) Such distribution is made only by a pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other controlled substance listed in Schedule V, may be distributed at retail to the same purchaser in any given forty eight (48) hour period;

(c) The purchaser is at least eighteen (18) years of age;

(d) The pharmacist requires every purchaser of a controlled substance listed in Schedule V not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances listed in Schedule V (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who distributed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of Section 7.5 of these rules); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law.

**§15-2-10. Miscellaneous.**

10.1. Exceptions for distribution and disposal. Report of theft.

10.2. Emergency distribution by a dispenser.

(a) In the event of an emergency, a dispenser may distribute (without being registered to distribute) a controlled substance to a second

dispenser in order for the second dispenser to dispense the substance: **Provided,** That

(1) The amount distributed does not exceed to the amount required by the second dispenser for immediate dispensing;

(2) The distribution is recorded as a dispensing by the first dispenser, and the receipt as a distribution received by the second dispenser, and each dispenser retains a signed receipt of the distribution;

(3) The second dispenser is registered under the Act to dispense the controlled substance to be distributed to him; and

(4) If the substance is listed in Schedule I or II, an order form is used as required in Part 1305-Order Forms-Code of Federal Regulations.

(b) For purposes of this section, an emergency shall mean a situation where a quantity of a controlled substance must be dispensed to a person who does not have an alternative source for such substance reasonably available to him and the dispenser cannot obtain such substance through normal distribution channels within the time required to meet the need of the person for such substance.

10.3. Distribution of aqueous of oleaginous solutions by a pharmacist.

A pharmacist who is registered to dispense or is covered by another person's registration to dispense may distribute (without being registered to distribute) to a registered practitioner, an aqueous or oleaginous solution, in a quantity not exceeding one (1) ounce at any one time, containing a narcotic controlled substance in a proportion not exceeding twenty percent (20%) of the complete solution, to be used by the practitioner in the course of his professional practice for administration to a patient: Provided, That a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address and registration number of the pharmacist (or other registered person), and the name, address and registration number of the practitioner. In the case of a controlled substance listed in Schedule I or II, an order form shall be used in the manner prescribed by federal laws and regulations.

10.4. Distribution to supplier.

A person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance: **Provided,** That a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I or II, an order form shall be used in the manner prescribed by federal laws and regulations.

10.5. Distribution upon discontinuance or transfer of business.

Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall notify the Board of Pharmacy immediately and on such notification shall submit a complete and detailed closing inventory of all controlled substances in the registrant's possession.

Furthermore, it shall be necessary that the requirements of Section 10.5 of the regulations implementing the Federal Controlled Substances Act be complied with.

10.6. Disposal of controlled substances.

Compliance with federal law and regulations shall be deemed in compliance with this section.

10.7. Reporting theft of drugs.

In the event of any controlled substances

being stolen, it shall be the duty of the registrant to submit a report of drug theft with the Board of Pharmacy.